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WELCOME LETTER FROM CONFERENCE PRESIDENT

Dear Colleagues,

Every 3 years, we gather to highlight the efforts that our psoriatic disease community has made to improve the lives of patients living with psoriatic disease. As Conference President and Chair of the SEC and on behalf of the organizing committee, I welcome you to the upcoming IFPA Conference with the theme “Uncovering the Broad Spectrum of Psoriatic Disease”.

Together, as a clinical and research community, we strive to advance the care for patients living with psoriatic diseases, which encompasses not only psoriasis and psoriatic arthritis, but also other comorbid conditions that impact our patients’ lives. At the upcoming IFPA conference in Stockholm, we will share our knowledge and have meaningful conversations about these advances. We will share significant achievements in the prevention, diagnosis, and treatment of psoriatic diseases. We will also discuss where we should focus future efforts across the spectrum of basic, translational, and clinical research to bring discoveries and novel therapies. The topics will be clinically relevant, globally collaborative, and patient centric.

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Ref.no Title

Biomarkers and imaging

P-001 Transcriptome profiling using tape strip RNA-seq in psoriasis patients treated with risankizumab
P-002 Deciphering proteomic signatures associated with disease severity in psoriasis and atopic dermatitis
P-003 Ultrasound Findings associated with clinical and radiological outcomes in psoriatic arthritis.
P-004 Joints mobility in psoriatic arthritis – value of disease activity and radiological changes
P-005 Nail psoriasis as a potential indicator of echocardiographic abnormalities in psoriatic arthritis patients
P-006 Echocardiographic abnormalities in psoriatic arthritis patients
P-007 Small dense low-density lipoprotein as a biomarker of subclinical atherosclerosis in psoriatic arthritis patients
P-008 Comparing the 2023 PREVENT and the 2013 American College of Cardiology/American Heart
P-009 Predicting IL-23 inhibitors primary failure, short and long-term efficacy using epitope structural biology
P-010 Axial disease activity in patients with psoriatic arthritis is greater in patients with carotid plaque.
P-011 Correlation between atherogenic index of plasma and cardiovascular risk algorithms in patients with psoriatic arthritis.
P-012 Efficacy of new cardiovascular risk scores in patients with psoriatic arthritis.
P-013 Nail activity in patients with psoriatic arthritis and ACPA/RF seropositivity.
P-014 Relationship between new serological markers of cardiovascular risk and the presence of carotid plaque in patients with psoriatic arthritis.
P-015 Calculating PASI with 3D total body imaging: a preliminary study in clinical practice
P-016 The importance of ultrasound examination in early diagnosis of psoriatic arthritis

Clinical phenotypes

P-017 Multi-failure psoriasis patients: characterization of the patients and response to biological therapy in a multicenter Italian cohort
P-018 Overlapping phenotype of atopic dermatitis and psoriasis exhibits intermediate histopathological features of both conditions: a single-center retrospective study
P-019 Work productivity and its relationship to clinical features of psoriatic arthritis

Comorbidities

P-020 Association between daily step count and incident NAFLD in patients with psoriasis: a prospective cohort study in the UK Biobank
P-021 Psoriasis and hidradenitis suppurativa resistant in adalimumab, what's the next step?
P-022 Cardiovascular risk factors and comorbidities: A cross-sectional study of 127 patients with psoriatic arthritis.
P-023 Impact of biologic disease-modifying anti-rheumatic drugs in lipid profile of psoriatic arthritis patients.
P-024 Fibrosis-4 index analysis of non-alcoholic fatty liver disease fibrosis in psoriatic arthritis: implications for cardiovascular health
P-025 Association between periodontal health indices and psoriasis risk among greek adults: a case-control study

Current and new therapeutic modalities

P-026 Deucravacitinib in plaque psoriasis: maintenance of response over 3 years in hispanic/latino patients in the phase 3 POETYK trials
P-027 Long-term efficacy and safety of risankizumab: a retrospective, multicenter, real-world study
P-028 Netakimab, an IL17 inhibitor, reduces extraarticular manifestations of psoriatic arthritis: 3-year results of the patera study
P-029 Netakimab, a novel IL17 inhibitor, provides sustained reduction of psoriatic arthritis activity: long-term results of the patera study
P-030 VISIBLE: efficacy of guselkumab at week 16 in moderate-to-severe scalp psoriasis participants with low body surface area involvement
P-031 Caveats in interpreting and comparing long-term efficacy in biologic studies for moderate-to-severe plaque psoriasis
P-032 Time to onset of action for biologics and targeted treatments in psoriasis: systematic targeted literature review and network meta-analysis
P-033 Drug survival of biologics in plaque psoriasis patients: a single center study
P-034 Safety in patients with latent tuberculosis who received concomitant anti-tuberculosis medications: analysis of 11 studies of guselkumab in psoriatic disease
P-035 Clinical predictors of IL-17 and IL-23 inhibitors dose spacing in adult psoriatic patients: a real-world pilot study
P-036 Comparison of the drug survival of interleukin (IL)-17 and IL-23 Inhibitors for the treatment of psoriasis: A two-center study
P-037 Effectiveness and safety of risankizumab dose optimization in adult patients with plaque psoriasis: an international multicenter retrospective cohort study
P-038 Real-world effectiveness and safety of risankizumab in adult patients with plaque psoriasis: a 16-week international multicenter retrospective cohort study
P-039 Real-world effectiveness and safety of risankizumab in adult patients with plaque psoriasis: a 1-year international multicenter retrospective cohort study
P-040 The efficacy and safety of switching between interleukin inhibitors in psoriasis therapy: a systematic review
P-041 How satisfied are psoriasis patients with their treatment? Results from a prospective observational study
P-042 Efficacy and safety of adding fumaric acid esters in psoriatic patients receiving TNF-alpha blockers who failed to reach PASI 75
P-043 Cardiovascular safety of ustekinumab versus etanercept in psoriasis: results from an observational post-authorization safety study based on swedish national registers
P-044 Biologics for palmoplantar psoriasis and palmoplantar pustulosis: a systematic review and network meta-analysis
P-045 Patient-reported well-being using tildrakizumab in a real-world setting: 52-week interim data of the phase IV POSITIVE study
P-046 Real-world efficacy of bimekizumab treatment in psoriasis: a case series of 49 patients
P-047 Data from Belgian psoriasis registry BePso predicts treatment response in specific patient groups.
P-048 Is super-response to anti-IL23 therapy in psoriasis a predictor of long-term response?
P-049 Evaluation of real-world effectiveness and safety of guselkumab in patients with plaque psoriasis: Data from a multicenter observational study
P-050 Effectiveness, persistence of use, and safety of guselkumab in real clinical practice: a case series of 27 patients.

P-051 Month 6 and Month 12 outcomes from the European cohort of the observational Psoriasis Study of Health Outcomes (PSoHO).
P-052 Real-world data on the efficacy and safety of Ixekizumab in patients with plaque psoriasis
P-053 Impact of patient psoriasis on partner well-being in a real-world setting: 52-week interim data of the phase IV POSITIVE study
P-054 Effectiveness of tildrakizumab for itch, pain, and fatigue in patients with moderate-to-severe psoriasis: 52-week results from the real-world POSITIVE study
P-055 Phase 2b, long-term extension, dose-ranging study of oral jnj-77242113 for the treatment of Moderate-to-Severe Plaque Psoriasis: FRONTIER-2
P-056 Effectiveness and safety of tildrakizumab in patients with moderate-to-severe psoriasis located in special areas: 52-week results from the POSITIVE study
P-057 Quality of life and treatment satisfaction with tildrakizumab in moderate-to-severe psoriasis patients: 52-week interim data of the real-world POSITIVE study
P-058 Influence of patient baseline characteristics on TAK-279 efficacy, a selective oral TYK2 inhibitor: Phase 2b trial in psoriatic arthritis
P-059 Bimekizumab simultaneous skin and nail clearance in patients with psoriasis: Assessing comparative efficacy in four phase 3/3b studies
P-060 Baseline characteristics in patients initiating ixekizumab in the psoriasis special areas (PSoSA) observational study - first interim results
P-061 Bimekizumab efficacy by body region in plaque psoriasis: Comparative analyses from four phase 3/3b studies
P-062 Real world effectiveness of initiating topical therapy compared with initiating apremilast early or late
P-063 Bimekizumab long-term efficacy in patients with plaque psoriasis from BE BRIGHT: Mean percentage improvement in clinical outcomes over 4 years
P-064 Early oligoarticular psa responds to treatment with apremilast: week 16 results from foremost – a phase 4 RCT
P-065 Efficacy and safety of TAK-279, a selective, oral TYK2 inhibitor, in a randomized, placebo-controlled phase 2b trial in psoriatic arthritis
P-066 Effectiveness and patient-reported well-being of tildrakizumab in patients with nail psoriasis: 52-week results from the phase IV POSITIVE study
P-067 Drug survival of secukinumab for moderate-to-severe psoriatic arthritis: a 7-year real life experience from three romanian referral centers
P-068 Modulation of disease-central cytokine pathways with TAK-279, a highly selective oral TYK2 inhibitor, defines clinical response in patients with psoriasis
P-069 Absolute PASI reductions in a phase 2b trial of the selective oral TYK2 inhibitor, TAK-279, in moderate-to-severe plaque psoriasis
P-070 TAK-279, a selective oral TYK2 inhibitor, reduces BSA involvement in a phase 2b trial in moderate-to-severe plaque psoriasis
P-071 Pregnancy outcomes in women exposed to guselkumab: review of cases reported to the manufacturer's global safety database
P-072 Bimekizumab treatment in psoriasis patients: A mechanistic understanding of the durable clinical response
P-073 Real-world safety profile of spesolimab in generalised pustular psoriasis (GPP): expanded access programmes in Japan and China
P-074 Bimekizumab efficacy and safety in patients with psoriatic arthritis and psoriasis: up to 2-year results from two phase 3 studies

Epidemiology

P-075 New-onset and exacerbation of psoriasis following COVID-19 vaccination: A Nationwide population-based cohort study in Korea
P-076 Risk of major adverse cardiovascular events and all-cause mortality among patients with psoriatic disease treated with TNF-α and IL-12/23 inhibitors
P-077 Risk of Incident inflammatory heart diseases and autoimmune neural diseases in patients with psoriatic disease
P-078 Comparison of efficacy and duration between Intra-class switching and Inter-class switching in biologics for psoriasis treatment
P-079 Systemic inflammation in psoriasis – the chicken or the egg?
P-080 Alcohol abuse and discretionary habits in psoriatic patients: impact on IL-17 and IL-23 inhibitors response
P-081 Safety of biologics for psoriasis patients with cancer: a single-center, retrospective study
P-082 Description of patients included in the psoriatic disease registry of the argentine society of rheumatology and the Argentine psoriasis society
P-083 Real world study regarding the use of a clinical decision-support digital app for the management of chronic inflammatory skin diseases
P-084 Environmental triggers of psoriasis: findings from the mySkin study
P-085 Belgian psoriasis registry "BePso": Objectives, methodology, first inclusion data and perspectives.
P-086 Prevalence of psoriasis in indigenous communities around the world: An overview

Genetics

P-087 Psoriasis and in situ or invasive non-melanoma skin cancer: A bidirectional Mendelian randomisation study
P-088 Genome-wide pleiotropy analysis reports LDL metabolism as a shared pathway between psoriasis and coronary artery disease

Interesting clinical cases

P-089 Active pulmonary tuberculosis in a patient with secukinumab treatment
P-090 A case report of generalized pustular psoriasis in a patient with plaque psoriasis undergoing biologics therapy
P-091 Striae-induced psoriasis: a rare demonstration of Koebner's phenomenon - case report and systematic review
P-092 Treating intractable pruritus associated with ILVEN and concomitant psoriasis: Achieving success with bimekizumab

Pathophysiology and immunobiology

P-093 Expression profiles of Th1 and Th17 inflammatory cytokines in the lesional skin in psoriasis vulgaris patients before and after treatment
P-094 Small intestinal inflammatory changes associated with eosinophil degranulation increase the severity of psoriatic skin inflammation
P-095 Deficiency of IL-1 receptor antagonist enhances IL-17 production by tissue-resident memory T cells in psoriasis
P-096 Unveiling the genetic foundations and pathways in plaque psoriasis: a comprehensive meta-analysis of transcriptomes

Patient organization projects/Patient research partners

P-097 Beyond the skin: comprehensive insights into psoriasis and its nexus with psoriatic arthritis
P-098 Patients' learning journey: An innovative, accessible digital tool about psoriatic disease

Psoriasis and Psoriatic Arthritis relationship

P-099 Deucravacitinib efficacy in special areas of scalp, fingernails, and palms/soles in plaque psoriasis: results from a Phase 3 Trial
P-100 Clinical characteristic of difficult-to-treat (D2T) psoriatic arthritis (PSA) patients. Data from real clinical practice
P-101 Dactylitis clinical domain of psoriatic arthritis: association with arthritis, enthesitis, skin and nail psoriasis severity
P-102 Hyperuricemia in axial Psoriatic arthritis. Data from real clinical practice
P-103 Comparison of clinical and imaging characteristics of psoriatic arthritis in men and women. Data from observational cohort
P-104 Association of nail psoriasis with significantly more severe disease status
P-105 Comparative characteristics of psoriatic arthritis with axial involvement and axial spondyloarthritis
P-106 Non-invasive transdermal delivery with biocompatible permeation enhancers for peptide inhibitors of IL23/IL-17 axis in psoriasis
P-107 Baseline musculoskeletal symptoms in psoriasis patients: a prospective observational study
P-108 Association between subclinical atherosclerosis and Psoriasis to Psoriatic Arthritis transition onset.
P-109 Relationship between nail psoriasis severity index in psoriatic arthritis population and six cardiovascular risk calculators.
P-110 Clinical outcomes and patients' perspectives of the multidisciplinary psoriasis management: A 5-year, retrospective study.
P-111 Bimekizumab reduced psoriatic arthritis impact in patients with psoriasis: up to 2-year results from two phase 3 studies
P-112 Efficacy of the oral, selective, allosteric tyrosine kinase 2 inhibitor, deucravacitinib, on psoriasis in patients with active psoriatic arthritis (PsA)
P-113 Effectiveness of ixekizumab at 12 weeks in b/tsDMARD treatment-naive and experienced patients with Psoriatic Arthritis (PsA): PRO-SPIRIT study data
P-114 Effectiveness of ixekizumab and secukinumab: 3-month interim descriptive analysis of the Psoriatic Arthritis Observation Study of Persistence of Treatment (PRO-SPIRIT)
P-115 The effectiveness of ixekizumab and other b/tsDMARDs at 12-weeks for patients with PsA in real-world settings: PRO-SPIRIT study results
P-116 Do real-world treatment patterns reflect PsA recommendations? Results from the PRO-SPIRIT study
P-117 Ixekizumab Demonstrates Rapid and Consistent Efficacy for Patients with Psoriatic Arthritis, Regardless of Psoriasis Severity
P-118 Achievement of NPF Treat-to-Target goals at week-12 for patients receiving commonly-used biologic treatment according to US labels in PSoHO

Quality of Life or Patient-related Outcome Measures (PROMs)

P-119 Quality of life and treatment options in patients with genital psoriasis: the Filipino experience
P-120 Assessment of quality of life in patients with psoriatic arthritis treated according to the treat to target strategy
P-121 Netakimab, an IL-17 inhibitor, improves patient-reported outcomes in psoriatic arthritis: 3-year results of the patera study
P-122 Patients reported outcomes (PROs) in psoriatic arthritis (PsA) with axial involvement
P-123 Who are more itchy and what works better for pruritus in patients with plaque psoriasis?
P-124 Development of the patient-reported impact of dermatological diseases (PRIDD) measure
P-125 Tackling stigma against persons with chronic skin disease among health and body care professionals
P-126 Determinants of quality of life in mexican patients with generalized pustular psoriasis
P-127 A thematic analysis of the Psoriasis Association (UK) Instagram, Facebook and website forums in discussing the dietary management of psoriasis.
P-128 Towards an international consensus on outcomes that matter to patients with psoriasis: a modified Delphi study
P-129 Relationship between early and late onset presentation in psoriatic arthritis and cardiovascular risk.
P-130 Associations between disease activity, cardiovascular risk, and diagnosis delay in psoriatic arthritis
P-131 Physical exercise and Mediterranean diet in psoriatic patients amid the pandemic COVID-19
P-132 Navigating mental health struggles among psoriatic patients during the COVID-19 pandemic
P-133 Bimekizumab efficacy in moderate to severe plaque psoriasis: Improvements in fatigue observed in two phase 3 studies
P-134 Real-world patient satisfaction and quality of life among ixekizumab treated patients with and without nail psoriasis
P-135 Designing a shared decision-making tool for adolescents with psoriasis using a modified Delphi method

SARS-CoV-2/Covid-19

P-136 The impact of psoriasis on COVID-19 susceptibility, severity, and vaccine effectiveness: a nationwide cohort study in South Korea

Late breakers

P-137 The sonelokimab Nanobody® in patients with psoriatic disease: Week 12 multidomain outcomes from the Phase 2 ARGO psoriatic arthritis trial
P-138 High disease control and state of remission with risankizumab in patients with moderate-to-severe psoriasis during the 6-year LIMMitless study
P-139 Aureobasidium pullulans produced Beta-1,3-1,6 glucans improving clinical parameters, ameliorating inflammation and skin lymphocyte infiltration in patients with psoriasis vulgaris
P-140 Demographics, disease characteristics and time to effective treatment of psoriasis patients in the Ghent PsoPlus Cohort of 2021
P-141 Efficacy of statins in the treatment of psoriasis: a systematic review and meta-analysis
P-142 Efficacy and Safety of roflumilast in the treatment of psoriasis: a systematic review and meta-analysis
P-143 Real-world effectiveness of risankizumab in the multi-country post-marketing VALUE study: 148-week interim analysis
P-144 Development and evaluation of a machine learning model for the early identification of psoriatic arthritis in the community
P-145 Genetics and functional studies of psoriatic arthritis mutilans
P-146 Anti-PD-1 exacerbates psoriatic inflammation by increasing IL-17A production from γδ T cells
P-147 Social characteristics of russian patients with psoriasis and arthropathic psoriasis
P-148 Psoriasis and nursing care – an educational project to help improve clinical development and quality of care
P-149 Inclusion of the patient voice in developing holistic treatment goals for rare skin diseases
P-150 Predicting psoriatic arthritis at onset of psoriasis: results from an inception cohort study

POSTERS

P-001

TRANSCRIPTOME PROFILING USING TAPE STRIP RNA-SEQ IN PSORIASIS PATIENTS TREATED WITH RISANKIZUMAB

No consent given to publish in scientific journal.

P-002

DECIPHERING PROTEOMIC SIGNATURES ASSOCIATED WITH DISEASE SEVERITY IN PSORIASIS AND ATOPIC DERMATITIS

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Introduction: Psoriasis and atopic dermatitis (AD) are both chronic T-cell mediated inflammatory diseases. There are growing efforts to discover biomarker proteins that aid in diagnosis and reflect disease severity.

Objectives: We aimed to investigate blood proteomic signatures of psoriasis and AD and find biomarkers associated with disease severity.

Methods: We assessed 276 inflammatory and cardiovascular-related proteins utilizing OLINK® high-throughput proteomics in patients with psoriasis ($n = 11$), patients with AD ($n = 13$), and healthy control participants ($n = 17$). Biomarker candidate proteins that were upregulated in psoriasis or AD and showed correlation with Psoriasis Area and Severity Index (PASI), and Eczema Area and Severity Index (EASI) were investigated.

Results: Among 276 proteins, 59 differentially expressed proteins were retrieved (fold change>1.3, false delivery rate<0.1). One-way analysis of variance and Scheffe's post hoc analysis revealed 16 potential biomarker candidates differentiating psoriasis versus AD. Serum levels of peptidase inhibitor 3 (PI3) were significantly upregulated in psoriasis and correlated with PASI, whereas CCL17 were increased in AD and correlated with EASI.

Conclusions: Serum protein biomarkers of peptidase inhibitor 3 in psoriasis and CCL17 in AD can reflect the severity of the respective diseases and can be useful in predicting treatment response.

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P-003

ULTRASOUND FINDINGS ASSOCIATED WITH CLINICAL AND RADIOLOGICAL OUTCOMES IN PSORIATIC ARTHRITIS

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Background: The Ultrasound (US) finding of proliferative synovitis (PS) [synovial hypertrophy (SH)>2+Power Doppler (PD)] in patients with Rheumatoid Arthritis is associated with ACPA+, erosive disease and change of therapy in the long-term [1]. There is no evidence of the presence of this US pattern in psoriatic arthritis (PsA).

Objectives: To characterize the US findings in PsA patients with active hand inflammation and investigate their associations with clinical and radiological outcomes.

Methods: Cross-sectional, multicenter study. Clinical and US variables were collected from patients with PsA manifesting active hand inflammation in the physical assessment. Recent onset PsA (<6 months) were excluded. SH and PD signal were evaluated in carpal, metacarpophalangeal, carpal extensor, and hand flexor tendons. US PS was defined as SH >2+PD. US total score was obtained as the sum of SH and PD (0-100).

Results: Eighty-eight patients were included: 53.4% were women with a mean age of 55.97 (SD+12.93) years and disease duration of 103.03 (SD+107.00) months. The mean of disease activity in PsA (DAPSA) score was 19.90 (SD+9.38). Mean BSA was 1.52 (SD+ 2.17) (half of them showed BSA=0%), 42% patients had dactylitis, 13.6% enthesitis, 31.8% onychopathy and 39.8% erosive disease. Treatment with conventional synthetic disease-modifying drugs (csDMARDs) was present in 31 patients (35.2%), biological therapy (bDMARDs) in 31 (35.2%) and glucocorticoids (<5mg/prednisone) in 24 (27.3%) patients. PS was observed in 35 (39.8%) patients. Among patients with US PS, 64.7% exhibited erosive disease, whereas only 24.5% without this US pattern showed erosive disease ($p < 0.001$). In the multivariable analysis, adjusting for age, sex, treatment and disease duration, only erosive disease was independently associated with PS (OR 6.01 [2.15-16.73], $p < 0.001$). Fourteen patients (15.9%) had exclusively tendon involvement without synovitis. Paratendonitis was present in 25 (28.4%) patients and was associated with radiographic joint ankylosis ($p < 0.001$). The mean US score was 10.84 (SD+12.91). Patients with erosive disease and those with PS pattern had higher US score (14.40 [SD+15.56], $p = 0.039$ and 16.77 [SD+ 18.15], $p < 0.001$, respectively). Additionally, patients taking bDMARDs had also higher US score (14.55 [16.02], $p < 0.046$). The US score showed a significant correlation with DAPSA (r= 0.403, $p < 0.001$), CRP (r=0.330, $p = 0.002$), ESR (r=0.283, $p = 0.011$), pain scale (r=0.246, $p = 0.021$), PtGA (r=0.28, $p = 0.015$) and PGA (r=0.296, $p = 0.005$). The ROC curve of the total US score showed an AUC of 0.691, and the cut-off of 6.5 demonstrated a sensitivity of 68.6% and specificity of 61% to discriminate erosive disease (Figure 1).

Conclusions: US proliferative synovitis is associated with erosive disease in patients with PsA, irrespective of disease activity.

Paratendonitis is associated with joint ankylosis. The US total score showed associations with clinical and radiological outcomes such as erosive disease, use of bDMARDs, pain assessment and disease activity indexes.

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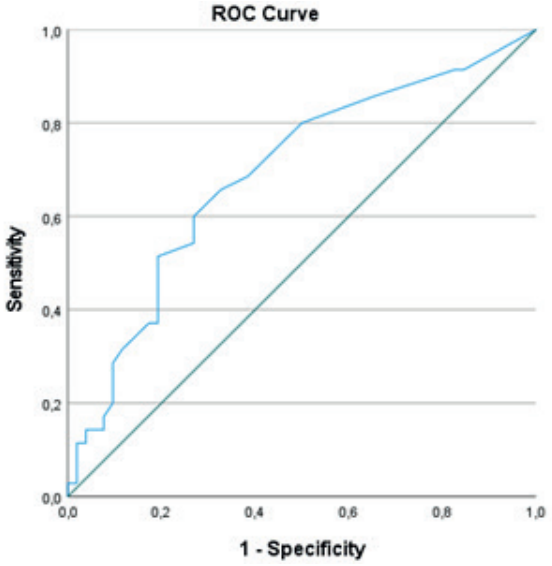

Figure 1. ROC curve for prediction of erosive disease based on ultrasound total score.

P-004

JOINTS MOBILITY IN PSORIATIC ARTHRITIS – VALUE OF DISEASE ACTIVITY AND RADIOLOGICAL CHANGES

No consent given to publish in scientific journal.

P-005

NAIL PSORIASIS AS A POTENTIAL INDICATOR OF ECHOCARDIOGRAPHIC ABNORMALITIES IN PSORIATIC ARTHRITIS PATIENTS

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Introduction: Psoriatic arthritis (PsA) is an autoimmune chronic disease, characterized by a systemic inflammatory state affecting joints, skin and nails. These patients have a higher risk of developing a cardiovascular event than the general population due to disease characteristics. Nail psoriasis has been associated with increased inflammatory burden, cardiovascular risk and higher prevalence of atherosclerosis (1). However, there is lack of information regarding the association of nail psoriasis and echocardiographic parameters in PsA patients.

Objectives: We aimed to compare echocardiographic parameters between PsA patients with and without nail psoriasis.

Methods: This was a cross-sectional study. We recruited PsA patients aged ≥ 18 years who fulfilled the 2006 CASPAR classification criteria for PsA. Patients with a previous cardiovascular event (myocardial infarction, stroke or periphery artery disease), another connective tissue disease or pregnancy were excluded. Patients were divided in two groups, those with nail involvement defined as a Nail Psoriasis Severity Index (NAPSI) > 0, and those without nail involvement defined as a NAPSI=0. A transthoracic echocardiogram was performed by two certified echocardiographers blinded to clinical information. Comparisons were done with Chi-square test for qualitative variables and Student's T-test or Mann-Whitney's U test for quantitative variables. Correlations between NAPSI and echocardiographic parameters were performed with Spearman's correlation coefficient (rs). A p-value < 0.05 was considered statistically significant.

Results: A total of 53 consecutive PsA patients were recruited, 19 patients with nail psoriasis and 34 patients without nail psoriasis. There were no significant differences in clinical and demographic characteristics between both groups. When comparing echocardiographic parameters, we found that PsA patients with nail psoriasis had lower TAPSE (20.47 ± 2.91 mm vs 22.70 ± 3.02 mm, $p = 0.012$) and higher incidence of eccentric hypertrophy (36.8% vs 2.9%, $p = 0.002$). We found a negative moderate correlation between NAPSI and TAPSE (rs=-0.350, $p = 0.010$) (Table 1 and Figure 1).

Conclusions: Our research reveals that PsA patients with nail involvement exhibit reduced TAPSE, a marker of right ventricular systolic function, along with a heightened incidence of eccentric left ventricular hypertrophy. These results imply an elevated risk of cardiovascular disease, including heart failure, in individuals with nail psoriasis. To our knowledge this is the first study to find an association of nail psoriasis and echocardiographic abnormalities in Hispanic PsA patients. The incorporation of transthoracic echocardiograms into the cardiovascular assessment of PsA patients should be considered, particularly in those with nail psoriasis.

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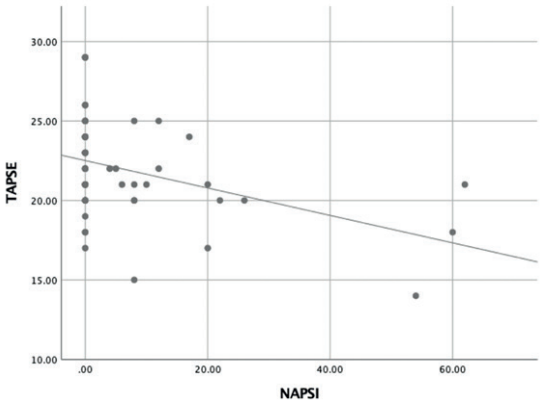
Table 1. Demographic and echocardiographic findings.

Characteristics	Patients with nail psoriasis (n=19)	Patients without nail psoriasis (n=34)	*p*-value
Women, n (%)	10 (52.6)	19 (55.9)	0.820
Age, years, mean ± SD	54.26 ± 10.81	54.08 ± 10.30	0.954
T2DM, n (%)	5 (23.3)	7 (20.6)	0.736
Hypertension, n (%)	4 (21.1)	13 (38.2)	0.199
Dyslipidemia, n (%)	8 (42.1)	17 (50.0)	0.581
Obesity, n (%)	7 (36.8)	12 (35.3)	0.910
Active smoking, n (%)	2 (10.5)	6 (17.6)	0.696
Disease duration, years, median (p25-p75)	9.0 (3.5-14.2)	4.5 (3.0-11.2)	0.221
MTX, n (%)	10 (52.6)	15 (44.1)	0.552
Glucocorticoids, n (%)	4 (21.1)	5 (14.7)	0.706
bDMARD, n (%)	9 (47.4)	13 (38.2)	0.518
NAPSI, median (p25-p75)	12.0 (8.0-22.0)	-	-
LVEF, %, mean ± SD	62.26 ± 6.99	61.76 ± 5.67	0.779
GLS, %, median (p25-p75)	-20.00 (-21.35 - - 15.50)	-19.00 (-20.00 - - 17.15)	0.803
LVMI, ml/m², median (p25-p75)	101.91 (64.44-135.95)	77.06 (62.81-87.77)	0.143
TAPSE, mm, mean ± SD	20.47 ± 2.91	22.70 ± 3.02	**0.012**
PASP, mmHg, mean ± SD	25.54 ± 5.91	24.91 ± 7.26	0.770
Eccentric hypertrophy, n (%)	7 (36.8)	1 (2.9)	**0.002**

PsA, psoriatic arthritis; T2DM, type 2 diabetes mellitus; MTX, methotrexate; bDMARD, biological disease modifying anti-rheumatic drugs; NAPSI, Nail Psoriasis Severity Index; LVEF, left ventricular ejection fraction; GLS, global longitudinal strain; LVMI, left ventricular mass index; TAPSE, tricuspid annular plane systolic excursion; PASP, pulmonary artery systolic pressure.

Figure 1. Scatter plot of association between NAPSI and TAPSE in PsA patients.



P-006
ECHOCARDIOGRAPHIC ABNORMALITIES IN PSORIATIC ARTHRITIS PATIENTS

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Introduction: Psoriatic arthritis (PsA) is a chronic, inflammatory, and autoimmune disease characterized by articular and skin involvement. Individuals with PsA face an elevated risk of cardiovascular events compared to the general population (1). This heightened risk is attributed to the increased prevalence of traditional cardiovascular risk factors and systemic inflammation, which contributes to endothelial damage and atherosclerosis progression (2).

Objectives: We aimed to compare echocardiographic parameters between PsA patients and matched controls.

Methods: This was a cross-sectional study. We recruited 53 PsA patients aged ≥ 18 years who fulfilled the 2006 CASPAR classification criteria for PsA, and 53 controls matched by age, gender, and traditional cardiovascular risk factors. Patients with a previous cardiovascular event, another connective tissue disease or pregnancy were excluded. A transthoracic echocardiogram was performed by two certified echocardiographers blinded to clinical information. Comparisons were done with Chi-square test for qualitative variables and Student's T-test or Mann-Whitney's U test for quantitative variables. A p-value<0.05 was considered statistically significant.

Results: Mean age of PsA patients and controls was 54.5 years, there were no significant differences in demographic characteristics and traditional cardiovascular risk factors between both groups, as shown in Table 1. When comparing echocardiographic parameters, we found that PsA patients had higher global longitudinal strain (GLS) (-18.94%±2.58 vs -20.40%±2.60, p = 0.017), lower tricuspid annular plane systolic excursion (TAPSE) [22.0 mm (20.0-24.0) vs 23.0 mm (21.0-25.0), p = 0.034] and higher prevalence of left ventricular eccentric hypertrophy (15.1% vs 0.0%, p = 0.006) (Table 2). A binary logistic regression was performed, including PsA diagnosis and traditional cardiovascular risk factors (type 2 diabetes mellitus, hypertension, dyslipidemia, obesity, and active smoking), and we found that PsA diagnosis was the only variable associated with left ventricular geometry abnormalities with an OR 3.38 (95% CI 1.46-7.77, p = 0.004).

Conclusions: Our study revealed that patients PsA exhibit poorer GLS, reflecting compromised left ventricular systolic function, diminished TAPSE, indicative of impaired right ventricular systolic function, and a higher incidence of eccentric hypertrophy compared to controls. These findings suggest a potential association between PsA and cardiovascular complications, including the risk of heart failure. A transthoracic echocardiogram should be considered as part of the cardiovascular evaluation of PsA patients.

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Table 1. Demographic and clinical characteristics.

Characteristics	PsA patients (n=53)	Controls (n=53)	*p*-value
Women, n (%)	29 (54.7)	29 (54.7)	1.000
Age, years, mean ± SD	54.15 ± 10.38	54.15 ± 7.12	1.000
T2DM, n (%)	12 (22.6)	11 (20.8)	0.814
Hypertension, n (%)	17 (32.1)	17 (32.1)	1.000
Dyslipidemia, n (%)	25 (47.2)	21 (39.6)	0.433
Obesity, n (%)	19 (35.8)	16 (30.2)	0.536
Active smoking, n (%)	8 (15.1)	8 (15.1)	1.000
Statin therapy, n (%)	16 (30.2)	7 (13.2)	0.034
Disease duration, years, median (p25-p75)	6.0 (3.0-12.0)	-	-
DAPSA, median (p25-p75)	14.0 (2.4-26.4)	-	-
PASI, median (p25-p75)	0.2 (0.0-1.1)	-	-
NAPSI, median (p25-p75)	0.0 (0.0-8.0)	-	-

PsA, psoriatic arthritis; T2DM, type 2 diabetes mellitus; DAPSA, Disease Activity for Psoriatic Arthritis; PASI, Psoriatic Area Severity Index; NAPSI, Nail Psoriasis Severity Index.

Table 2. Comparison of echocardiographic parameters.

Characteristics	PsA patients (n=53)	Controls (n=53)	*p*-value
LVEF, %, mean ± SD	61.94 ± 6.11	63.52 ± 6.79	0.210
GLS, %, mean ± SD	-18.94 ± 2.58	-20.40 ± 2.60	**0.017**
LVMI, ml/m², mean ± SD	92.31 ± 37.74	87.02 ± 31.14	0.448
TAPSE, mm, median (p25-p75)	22.00 (20.00-24.00)	23.00 (21.00-25.00)	**0.034**
Geometry abnormalities, n (%)			
Any	33 (62.3)	18 (34.0)	**0.004**
Concentric remodeling	19 (35.8)	16 (30.2)	0.536
Concentric hypertrophy	6 (11.3)	2 (3.8)	0.270
Eccentric hypertrophy	8 (15.1)	0 (0.0)	**0.006**

PsA, psoriatic arthritis; LVEF, left ventricular ejection fraction; GLS, global longitudinal strain; LVMI, left ventricular mass index; TAPSE, tricuspid annular plane systolic excursion.

P-007
SMALL DENSE LOW-DENSITY LIPOPROTEIN AS A BIOMARKER OF SUBCLINICAL ATHEROSCLEROSIS IN PSORIATIC ARTHRITIS PATIENTS

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Introduction: Psoriatic arthritis is a chronic inflammatory disease. These patients have increased risk of developing cardiovascular (CV) events due to disease characteristics. While reducing low-density lipoprotein cholesterol (LDL-C) remains a primary focus in CV disease prevention, it's important to consider LDL-C subfractions, such as small dense LDL (sdLDL). Even when overall LDL-C levels are within the normal range, sdLDL has been reported to be elevated in chronic inflammatory conditions. The association of CV disease with sdLDL is noteworthy, as these particles possess the capacity to penetrate the arterial wall, increasing susceptibility to oxidation (1). There is a lack of information regarding the association of sdLDL and atherosclerotic disease in PsA patients.

Objectives: We aimed to evaluate the association between sdLDL and subclinical atherosclerosis in PsA patients.

Methods: We recruited a total of 109 consecutive patients with PsA diagnosis according to 2006 CASPAR classification criteria, aged ≥18 years. A carotid ultrasound was performed to all patients. A blood sample was drawn to measure a lipid profile. We calculated sdLDL with the following formula: 0.580 [non–high density lipoprotein (HDL-C)] + 0.407 (direct LDL-C) – 0.719 (calculated LDL-C) – 12.05, where calculated LDL-C=Total cholesterol (TC) – HDL-C – (Triglycerides/5) (2). Patients were divided in two groups, with and without CP. Comparisons were done with Chi-square, Student's T test and Mann-Whitney's U test. Correlations between cIMT and lipid profile were performed with Spearman's correlation coefficient (rs). A p-value < 0.05 was considered statistically significant.

Results: Comparisons between both groups showed that PsA patients with CP were older (57.9 vs 50.8 years, p = 0.001), had higher prevalence of type 2 diabetes mellitus (34.1% vs 15.4%, p = 0.023), and had increased sdLDL (102.1 vs 96.7 mg/dl, p = 0.003). When comparing the rest of the lipid profile no significant differences

were found (Table 1). In the univariate analysis we identified a moderately positive correlation between sdLDL and cIMT (rs=0.305, $p = 0.001$), and a low positive correlation between TC and cIMT (rs=0.199, $p = 0.038$). Correlations with the rest of the lipid profile were not significant. Subsequently, a multivariate analysis, adjusted for age and TC, revealed that elevated sdLDL is independently associated with increased cIMT, with a β=0.007 (95% CI 0.002-0.012, $p = 0.012$). Finally, a ROC-curve analysis of sdLDL and CP showed an AUC 0.651 (95% CI 0.547-0.754, $p = 0.008$), with a cutoff point of 32.3, a sensibility of 63.6% and a specificity of 56.2% (Figure 1).

Conclusions: This study revealed a significant association between sdLDL and subclinical atherosclerosis in patients with PsA. Elevated sdLDL levels were observed in patients with CP, and these increased levels were independently linked to higher cIMT. Interestingly, the conventional lipid profile did not demonstrate a comparable association with atherosclerosis. Furthermore, sdLDL demonstrated a specific capability to identify PsA patients with CP. Given these findings, the measurement or calculation of sdLDL should be incorporated into the routine CV risk assessment for PsA patients.

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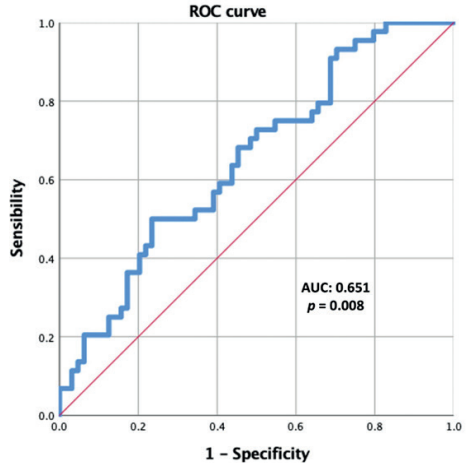
Table 1. Comparison of demographic and disease characteristics between PsA patients with and without CP.

Characteristics	PsA patients with CP (n=44)	PsA patients without CP (n=65)	p-value
Women, n (%)	23 (52.3)	38 (58.5)	0.523
Age, years, mean ± SD	57.9 ± 12.3	50.8 ± 9.1	**0.001**
T2DM, n (%)	15 (34.1)	10 (15.4)	0.023
Hypertension, n (%)	20 (45.5)	21 (32.3)	0.164
Dyslipidemia, n (%)	24 (54.5)	25 (38.5)	0.098
Obesity, n (%)	14 (31.8)	26 (40.0)	0.385
Active smoking, n (%)	7 (15.9)	14 (21.5)	0.528
Disease duration, years, median (p25-p75)	7 (3-12)	4 (2-8)	0.141
MTX, n (%)	28 (63.6)	35 (53.8)	0.310
Glucocorticoids, n (%)	6 (13.6)	11 (16.9)	0.643
bDMARD, n (%)	18 (40.9)	20 (30.8)	0.276
TGL, mg/dl, mean ± SD	176.6 ± 104.6	146.6 ± 68.9	0.073
TC, mg/dl, mean ± SD	186.8 ± 40.5	174.2 ± 34.2	0.082
HDL-C, mg/dl, mean ± SD	49.6 ± 17.1	48.7 ± 14.4	0.766
LDL-C, mg/dl, mean ± SD	102.1 ± 34.5	96.7 ± 29.4	0.378
sdLDL, mg/dl, mean ± SD	37.4 ± 12.1	30.3 ± 11.7	**0.003**

PsA, psoriatic arthritis; CP, carotid plaque; T2DM, type 2 diabetes mellitus; MTX, methotrexate; bDMARD, biological disease modifying anti-rheumatic drugs; TGL triglycerides; TC, total cholesterol; HDL, high density lipoprotein; LDL, low density lipoprotein; sdLDL, small dense LDL.

Figure 1. ROC-curve analysis between sdLDL and CP.



P-008

COMPARING THE 2023 PREVENT AND THE 2013 AMERICAN COLLEGE OF CARDIOLOGY/AMERICAN HEART ASSOCIATION ALGORITHMS FOR DETECTION OF CAROTID PLAQUE

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Introduction: Psoriatic arthritis (PsA) is a persistent inflammatory condition affecting both the skin and joints, and individuals with this condition face a heightened risk of cardiovascular disease, which remains a primary cause of mortality in this group. The increased cardiovascular risk has been associated with disease characteristics that induce a systemic inflammatory state resulting in atherosclerosis development and endothelial damage. Various cardiovascular risk assessment algorithms are employed to evaluate the risk in this population, with the 2013 American College of Cardiology/American Heart Association (ACC/AHA) algorithm being among the most widely used. Notably, in 2023, the AHA introduced the Predicting Risk of CV Disease EVENTs (PREVENT) algorithm as an updated tool for evaluating the 10-year risk of developing atherosclerotic cardiovascular disease.

Objectives: We aimed to assess the effectiveness of the 2013 ACC/AHA and the 2023 PREVENT algorithms to detect the presence of carotid plaque (CP) and to evaluate the cardiovascular risk reclassification with the carotid ultrasound in PsA patients.

Methods: This was a cross-sectional study. We recruited a total of 101 patients with PsA diagnosis, according to the 2006 CASPAR classification criteria, aged 40-75 years. Patients with a previous cardiovascular event were excluded. Cardiovascular risk was evaluated with the 2013 ACC/AHA and the 2023 PREVENT algorithms. A carotid ultrasound was performed to all study subjects by a certified radiologist blinded to clinical information. Distribution was evaluated with the Kolmogorov-Smirnov test. Correlations were performed with the Spearman-rho coefficient (rho). A ROC-curve analysis was performed for both algorithms. A p-value <0.05 was considered statistically significant.

Results: The presence of CP was detected in 37 (36.6%) patients. Demographic characteristics are shown in Table 1. There was a large positive correlation between the PREVENT and the ACC/AHA algorithms (rho=0.864, $p = <0.001$). Both algorithms showed significant discrimination for the presence of CP in PsA patients, the PREVENT algorithm had an AUC 0.691 (95% CI 0.579-0.804, $p = 0.002$), with a cutoff point of 3.55, sensibility of 61.1% and specificity of 58.1%. The ACC/AHA algorithm had an AUC 0.694 (95% CI 0.579-0.810, $p = 0.001$) with a cutoff point of 4.75, sensibility of 66.7% and specificity of 62.9% (Figure 1). Following carotid ultrasound, 34 patients (33.7%), initially categorized as low, borderline, or intermediate risk using the PREVENT, were subsequently reclassified to high cardiovascular risk due to the identification of CP. Furthermore, 25 (24.8%) patients, initially classified as low or intermediate risk with the ACC/AHA algorithm, were reclassified to high cardiovascular risk.

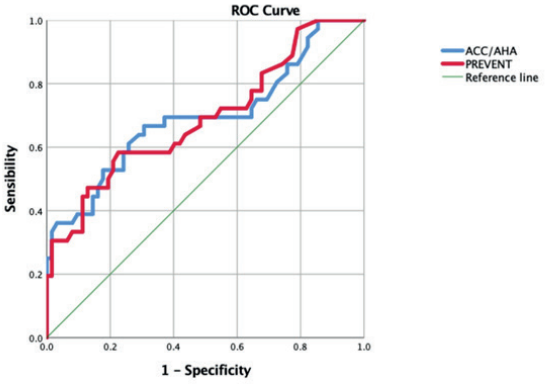
Conclusions: Our findings indicate that both algorithms exhibited significant discrimination for the presence of CP. Nevertheless, the identified cutoff points for CP, as determined by both algorithms, fall within the category of low cardiovascular risk. Notably, a substantial number of patients were reclassified to high cardiovascular risk following carotid ultrasound, particularly with the PREVENT algorithm. The incorporation of the carotid ultrasound as part of the cardiovascular assessment in PsA patients should be considered, as the algorithms appear to underestimate the actual cardiovascular risk in this population.

Table 1. Demographic characteristics of PsA patients.

Characteristics	PsA patients (n=101)
Age, years, mean ± SD	55.3 ± 9.4
Women, n (%)	55 (54.5)
T2DM, n (%)	22 (21.8)
Hypertension, n (%)	37 (36.6)
Dyslipidemia, n (%)	43 (42.6)
Obesity, n (%)	34 (33.7)
ACC/AHA algorithm, median (IQR)	4.4 (1.8-12.0)
PREVENT™ algorithm, median (IQR)	3.5 (1.6-6.6)
Carotid plaque, n (%)	37 (36.6)

PsA, psoriatic arthritis; T2DM, type 2 diabetes mellitus; WHO, world health organization; ACC/AHA, American College of Cardiology/American Heart Association; PREVENT™, Predicting Risk of CV Disease EVENTs.

Figure 1. ROC-curve analysis of ACC/AHA and PREVENT™ algorithms to detect CP.



P-009

PREDICTING IL-23 INHIBITORS PRIMARY FAILURE, SHORT AND LONG-TERM EFFICACY USING EPITOPE STRUCTURAL BIOLOGY

No consent given to publish in scientific journal.

P-010

AXIAL DISEASE ACTIVITY IN PATIENTS WITH PSORIATIC ARTHRITIS IS GREATER IN PATIENTS WITH CAROTID PLAQUE.

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Introduction: It was reported that psoriatic arthritis (PsA)-patients with axial involvement present a higher cardiovascular risk compared with those without axial disease. In addition, axial disease has been documented to be more common in patients with axial spondylarthritis and carotid plaques (CP).

Objective: To compare the Bath Ankylosing Spondylitis Metrology Index (BASMI) between PsA-patients with and without CP.

Methods: Cross-sectional and comparative study that included PsA patients aged 30 to 75 years old who fulfilled the 2006 CASPAR classification criteria for PsA. Patients with previous cardiovascular disease (myocardial infarction, stroke, or peripheral artery disease) were excluded. Carotid ultrasound was performed on all study participants. The presence of CP was defined as diffuse carotid intima-media thickness (cIMT) ≥1.2 mm or focal thickness ≥0.5 mm. Axial disease activity was measured using the BASMI in all patients. The distribution between groups was assessed with the Kolmogorov-Smirnov test. Comparisons with Chi-square and Student's t-test or Mann Whitney's U-test, accordingly. A p-value of £0.05 was considered statistically significant.

Results: A total of 70 patients with PsA were included, the mean age was 55 ± 11.47 years, the disease evolution of PsA was 7.95 ± 7.08 years, and the mean BASMI of all patients included was 3.09 ± 0.99. The prevalence of type 2 diabetes mellitus was higher in patients with PsA and CP (10.5% vs 40.6%, $p = 0.003$). There was no difference between the prevalence of obesity and other cardiovascular risk factors, including smoking, obesity, hypertension, and dyslipidemia. BASMI was higher in PsA patients with CP in comparison to those patients without CP (3.4 vs 2.8, $p = 0.016$). In a sub-analysis, the Youden Index between CP and BASMI was assessed to determine the best cut-off point to identify CP, which resulted in a cut-off point of a BASMI of 2.9 with a sensitivity of 68% and a specificity of 65.7% (95% CI, 0.541-0.826, $p = 0.012$) (Figure 1).

Conclusion: Patients with PsA and CP present higher axial disease activity compared to PsA patients without CP. BASMI could be an appropriate scale screening for detecting the risk of subclinical atherosclerosis.

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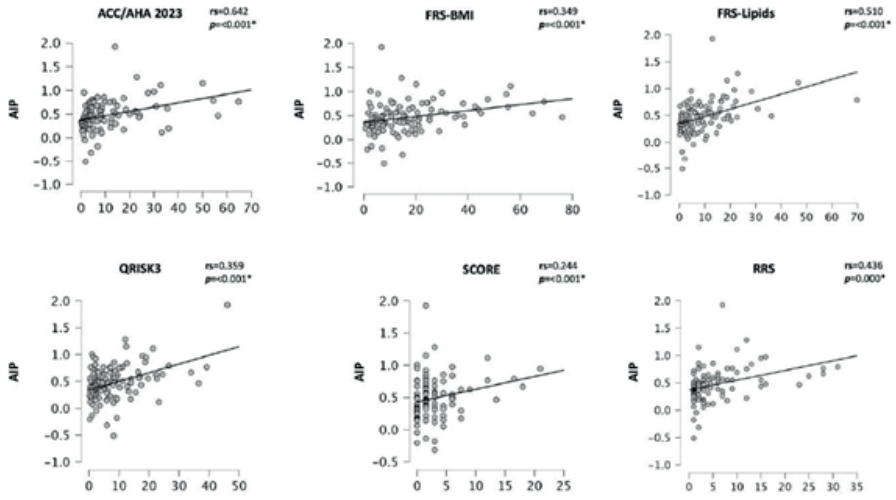
Table 1. Demographic characteristics.

Characteristics	PsA patients without CP (n=38)	PsA patients with CP (n=32)	*p*-value
Age, years, ± SD	52.3 ± 9.4	56.3 ± 12.2	**0.012**
Women, n (%)	20 (52.6)	17 (53.1)	NS
Diabetes, n (%)	4 (10.5)	13 (40.6)	**0.003**
Hypertension, n (%)	15 (39.5)	18 (56.3)	NS
Dyslipidemia, n (%)	15 (39.5)	17 (53.1)	NS
Obesity, n (%)	16 (42.1)	12 (37.5)	NS
Active smoking, n (%)	10 (26.3)	5 (16.1)	NS
Time of evolution, years, median (p25-p75)	5.5 (3.2-10.2)	6.0 (3.0-14.0)	NS
DAPSA, median (p25-p75)	13.0 (6.1-19.1)	10.3 (5.3-21.1)	NS
PASI, median (p25-p75)	0.75 (0.0-2.2)	0.20 (0.0-3.0)	NS
NAPSI, median (p25-p75)	0.0 (0.0-4.0)	0.0 (0.0-10.0)	NS
BASMI, median (p25-p75)	2.8 (2.4-3.4)	3.4 (2.4-4.2)	**0.016**

PsA, psoriatic arthritis; CP, carotid plaque; SD, standard deviation; NS, no significative; PASI, psoriasis area severity index; NAPSI, nail psoriasis severity index; DAPSA, disease activity in psoriatic arthritis; BASMI, Bath Ankylosing Spondylitis Metrology Index.

Figure 1. Scatterplots of the correlations between cardiovascular risk algorithms and AIP in patients with PsA.



P-011

CORRELATION BETWEEN ATHEROGENIC INDEX OF PLASMA AND CARDIOVASCULAR RISK ALGORITHMS IN PATIENTS WITH PSORIATIC ARTHRITIS.

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Introduction: The atherogenic index of plasma (AIP) predicts atherosclerosis and coronary heart disease, this has been described independently of traditional cardiovascular risk factors. The correlation between AIP and calculated cardiovascular risk has not been studied in psoriatic arthritis (PsA)-patients.

Objective: To evaluate the correlation between AIP and six cardiovascular risk algorithms in patients with PsA.

Methods: A cross-sectional study included patients with PsA aged 40 to 75 years who fulfilled the 2006 CASPAR classification criteria for PsA. Patients with previous cardiovascular disease (myocardial infarction, stroke, or peripheral artery disease) were excluded. AIP was defined by log (TG/HDL-C) mg/dL. Cardiovascular disease risk was evaluated using 6 algorithms: ACC/AHA 2013, FRS-Lipids, FRS-BMI, RRS, QRISK3, and SCORE2. Kolmogorov-Smirnov test was performed to evaluate the distribution of variables. Spearman's correlation coefficient assessed the correlation between the AIP and cardiovascular risk algorithms. A value of p£0.05 was considered statistically significant.

Results: A total of 133 patients with PsA were included, mostly women ($n = 74$, 55.6%), the mean age was 53 ± 11.7, the disease duration of PsA was 5.0 (2.0-10.0) years, and the median AIP of all patients included was 0.44 (0.29-0.62). The median of each algorithm was: FRS-BMI 12.2 (5.4-21.0), FRS-Lipids 5.2 (2.3-12.6), SCORE 1.5 (0.0-3.0), QRISK3 5.1 (2.0-10.2), RRS 3.0 (1.5-7.0) and ACC/AHA 2013 4.9 (1.9-13.3). Dyslipidemia was the most prevalent cardiovascular risk factor ($n = 57$, 42.8%). All cardiovascular risk algorithms presented a high positive correlation between AIP levels and cardiovascular risk. The calculator with the highest correlation was ACC/AHA 2013 (rs=0.642, $p = <0.001$). (Table 1 and Figure 1).

Conclusions: In patients with PsA, higher values of AIP are associated with increased cardiovascular risk irrespective of the algorithm used. High AIP values could identify patients who would benefit from a non-invasive evaluation for subclinical atherosclerosis. Despite this, a prospective study is needed to assess its performance as a predictor.

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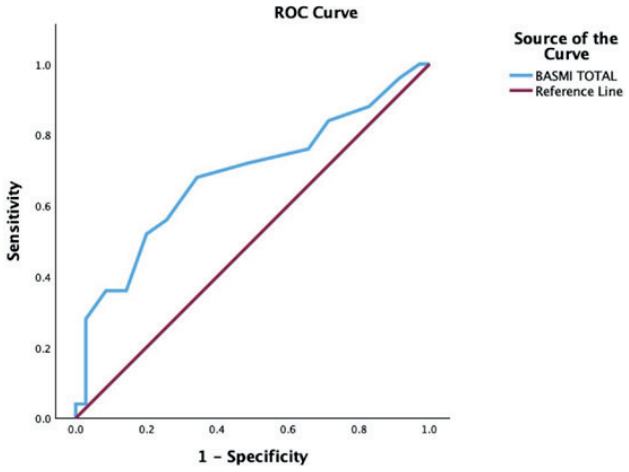
Table 1. Demographic characteristics in PsA patients.

Characteristics	PsA patients (n=133)
Age, years, ± SD	53.1 ± 11.7
Women, n (%)	74 (55.6)
Diabetes, n (%)	27 (20.3)
Hypertension, n (%)	44 (33.0)
Dyslipidemia, n (%)	57 (42.8)
Obesity, n (%)	48 (36.0)
Active smoking, n (%)	29 (21.8)
Time of evolution, years, median (p25-p75)	5.0 (2.0 – 10.0)
DAS28-CRP, median (p25-p75)	2.5 (1.5 – 3.7)
PASI, median (p25-p75)	0.7 (0.0 – 3.6)
NAPSI, median (p25-p75)	0.0 (0.0 – 14.0)
DAPSA, median (p25-p75)	15.0 (6.9 – 25.9)
AIP, median (p25-p75)	0.44 (0.29 – 0.62)
FRS-BMI, median (p25-p75)	12.2 (5.4-21.0)
FRS-Lipids, median (p25-p75)	5.2 (2.3-12.6)
SCORE2, median (p25-p75)	1.5 (0.0-3.0)
QRISK3, median (p25-p75)	5.1 (2.0-10.2)
RRS, median (p25-p75)	3.0 (1.5-7.0)
ACC/AHA 2013, median (p25-p75)	4.9 (1.9-13.3)

PsA, psoriatic arthritis; AIP, atherogenic plasma index; SD, standard deviation; DAS28-CRP, 28-joint Disease Activity Score based on C-reactive protein; PASI, psoriasis area severity index; NAPSI, nail psoriasis severity index; DAPSA, disease activity in psoriatic arthritis, FRS, Framingham risk score; BMI, body mass index; SCORE2, Systematic Coronary Risk Evaluation 2.; RRS, Reynolds Risk Score.

Figure 1. ROC analysis to evaluate the best cut-off point of BASMI to identify CP.



P-012

EFFICACY OF NEW CARDIOVASCULAR RISK SCORES IN PATIENTS WITH PSORIATIC ARTHRITIS.

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Introduction: Patients with psoriatic arthritis (PsA) face a 43% increased risk of developing cardiovascular disease (CVD) compared to the general population (1). Assessment with cardiovascular risk (CVR) algorithms are useful and economical tools for early detection of atherosclerotic cardiovascular disease (ASCVD). The new algorithm developed by the American College of Cardiology (ACC) and the American Heart Association (AHA) called, Predicting Risk of Cardiovascular Disease EVENTs (PREVENT), estimates the 10- and 30-year chances of both ASCVD and heart failure. Its efficacy in PsA has not been evaluated (2,3).

Objective: To compare CVR scores in PsA patients without clinical ASCVD and identify which algorithm has the best diagnostic accuracy that correlates with CP.

Methods: A cross-sectional and descriptive study that included PsA-patients aged 30 to 79 who fulfilled the 2006 CASPAR classification criteria for PsA. Patients with previous CVD (myocardial infarction, stroke, or peripheral artery disease) were excluded. CVR was calculated using five algorithms: Globorisk, HEARTS, QRISK3, SCORE2, and PREVENT. A carotid ultrasound was performed on all study participants, and the presence of CP defined as a diffuse carotid intima-media thickness (cIMT) ³ 1.2 mm or a focal thickness ³ 0.5 mm, was assessed. ROC curve analysis was performed to evaluate the different CVR algorithms' performance and the presence of CP. The Youden index was calculated to select the optimum sensitivity, specificity, negative and positive predictive values, and likelihood ratios. A value of p£0.05 was considered statistically significant.

Results: A total of 97 patients with PsA, mostly women ($n = 52$, 53.6%) with a mean age of 52.6 ± 11.7 years, and a median disease duration of 5.5 (2.0 – 10.7) years were included. Dyslipidemia was the most prevalent CVR factor ($n = 45$, 46.4%). Prevalence of subclinical CP was 38%. According to the ROC curves, the HEARTS and PREVENT algorithms showed a higher area under the curve (AUC) than the other algorithms (Figure 1).

Conclusions: In our study, all algorithms had significant discrimination for the presence of PC, except for the SCORE2 algorithm, which does not appear to work in our population. However, the CVR algorithms such as Globorisk, HEARTS, and QRISK3 presented the best diagnostic accuracy with the greatest sensitivity and specificity to detect CP in PsA-patients.

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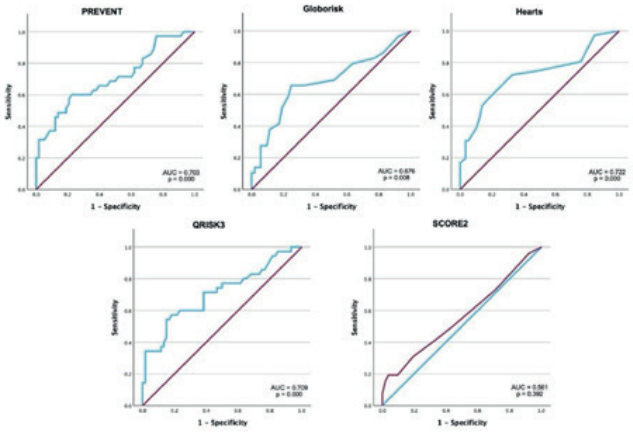
Table 1. Demographic and clinic characteristics of PsA-patients.

Characteristics	PsA-patients (n=97)
Age, years, ± SD	52.6 ± 11.7
Women, n (%)	52 (53.6)
Diabetes, n (%)	22 (22.7)
Hypertension, n (%)	35 (36.1)
Dyslipidemia, n (%)	45 (46.4)
Active smoking, n (%)	18 (18.6)
Disease duration, years, median (p25-p75)	5.5 (2.0 – 10.7)
DAPSA, median (p25-p75)	12.6 (4.0 – 26.0)
PASI, median (p25-p75)	0.4 (0.0 – 2.1)
NAPSI, median (p25-p75)	0.0 (0.0 – 10.2)
PREVENT, %, median (p25-p75)	3.5 (1.6 – 6.0)
Globorisk, %, median (p25-p75)	6.0 (4.0 – 10.0)
HEARTS, %, median (p25-p75)	4.0 (3.0 – 6.5)
QRISK3, %, median (p25-p75)	5.4 (2.4 – 10.4)
SCORE2, %, median (p25-p75)	3.0 (2.0 – 5.0)

PsA, psoriatic arthritis; SD, standard deviation; DAPSA, disease activity in psoriatic arthritis; PASI, psoriasis area severity index; NAPSI, nail psoriasis severity index; PREVENT, predicting risk of cardiovascular disease EVENTs; SCORE2, Systematic Coronary Risk Evaluation 2.

Figure 1. ROC curves of cardiovascular risk algorithms in patients with PsA.



P-013

NAIL ACTIVITY IN PATIENTS WITH PSORIATIC ARTHRITIS AND ACPA/RF SEROPOSITIVITY.

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Introduction: Autoantibodies such as rheumatoid factor (RF) and anti-citrullinated peptide antibodies (ACPA) are present in a minority of patients. Between 2 and 10% of patients with psoriatic arthritis (PsA) have RF, and up to 10% may have ACPA positive. The presence of these antibodies has been related to an increase in joint disease in patients; however, their association with nail disease has not been clarified (1,2).
Objective: To compare disease activity in patients with PsA according to their serology (ACPA and/or RF).
Methods: Cross-sectional study that included PsA-patients aged 40 to 75 years old who fulfilled the 2006 CASPAR classification criteria for PsA. Patients with previous cardiovascular disease (myocardial infarction, stroke, or peripheral artery disease) were excluded. Disease activity was assessed by various indices: psoriasis area severity index (PASI), nail psoriasis severity index (NAPSI), disease activity in psoriatic arthritis (DAPSA), and bath ankylosing spondylitis metrology index (BASMI). The groups were divided according to their reactivity in RF and ACPA serology. The distribution between groups was assessed with the Kolmogorov-Smirnov test. Comparisons with Chi-square or Fisher's exact test and Student's t-test or Mann Whitney's U-test, accordingly. A value of p£0.05 was considered statistically significant.
Results: A total of 98 patients with PsA were included, mostly women ($n = 52$, 63.0%), the mean age was 53.4 ± 11.6 years, and the median disease duration of PsA was 4.0 (2.0-10.0) years. The most prevalent cardiovascular risk factor was dyslipidemia ($n = 43$, 43.8%). Patients with positive serology for RF and/or ACPA had increased nail psoriasis activity compared to those who did not (3.5 vs 0.0, $p = 0.039$) (Table 1). No differences were found between groups in DAPSA (12.8 vs 14.0, $p = 0.876$), PASI (0.9 vs 0.0, $p = 0.130$), and BASMI (2.6 ± 1.3 vs 2.6 ± 1.0, $p = 0.992$).
Conclusions: Patients who presented seropositivity to ACPA and/or RF were associated with increased NAPSI in patients with PsA. This differs from previous literature, where most of the associations were in the rest of the scales. Prospective studies are needed to evaluate the relationship of titers of these antibodies on disease activity.

Table 1. Demographic characteristics.

Characteristics	Patients with PsA, ACPA and/or RF-positive (n=53)	Patients with PsA, anti-CCP and RF-negative (n=45)	*p*-value
Age, years, ± SD	53.9 ± 12.1	52.9 ± 11.1	0.684
Women, n (%)	27 (50.9)	25 (55.5)	0.648
Diabetes, n (%)	11 (20.7)	9 (20.0)	0.926
Hypertension, n (%)	20 (37.7)	15 (33.3)	0.650
Dyslipidemia, n (%)	21 (39.6)	22 (48.8)	0.357
Obesity, n (%)	17 (32.0)	19 (42.2)	0.299
Active smoking, n (%)	11 (20.7)	8 (17.7)	0.498
Time of evolution, years, median (p25-p75)	6.0 (1.7 – 11.0)	4.0 (2.0 – 7.0)	0.369
PASI, median (p25-p75)	0.9 (0.0 – 2.7)	0.0 (0.0 – 1.8)	0.130
NAPSI, median (p25-p75)	3.5 (0.0 – 18.5)	0.0 (0.0 – 4.7)	**0.039***
DAPSA, median (p25-p75)	12.8 (4.8 – 25.6)	14.0 (7.2 – 22.1)	0.876
BASMI, ± SD	2.6 ± 1.3	2.6 ± 1.0	0.992
Serology, n (%)	-	-	-
ACPA + RF	9 (16.9)	-	-
ACPA	2 (3.7)	-	-
RF	42 (79.2)	-	-

PsA, psoriatic arthritis; ACPA, anti-citrullinated protein antibodies; RF, rheumatoid factor; SD, standard deviation; PASI, psoriasis area severity index; NAPSI, nail psoriasis severity index; DAPSA, disease activity in psoriatic arthritis; BASMI, Bath Ankylosing Spondylitis Metrology Index.

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P-014

RELATIONSHIP BETWEEN NEW SEROLOGICAL MARKERS OF CARDIOVASCULAR RISK AND THE PRESENCE OF CAROTID PLAQUE IN PATIENTS WITH PSORIATIC ARTHRITIS.

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Introduction: Triglyceride-glucose index (TyG) allows the estimation of insulin resistance and is a surrogate marker positively correlated with atherosclerotic burden in patients with psoriatic arthritis (PsA). Atherosclerotic index of plasma (AIP) levels has not been evaluated in patients with subclinical atherosclerosis and PsA (1,2).
Objective: To compare levels of AIP and TyG between PsA-patients with and without carotid plaque (CP).
Methods: Cross-sectional study that included PsA-patients aged 40 to 75 years old who fulfilled the 2006 CASPAR classification criteria for PsA. Patients with previous cardiovascular disease (myocardial infarction, stroke, or peripheral artery disease) were excluded. Carotid ultrasound was performed on all study participants. The presence of carotid plaque (CP) was defined as diffuse carotid intima-media thickness (cIMT) ≥1.2 mm or focal thickness ≥0.5 mm. Cardiovascular disease risk was evaluated using the algorithm: Framingham (FRS)-Lipids. AIP was defined by Log (TG/HDL-C) mg/dL. TyG was defined by Log (Fasting triglyceride (mg/dl) x fasting glucose (mg/dl)/2. The distribution between groups was assessed with the Kolmogorov-Smirnov test. Comparisons with Chi-square or Fisher's exact test and Student's t-test or Mann Whitney's U-test, accordingly. The correlation between the AIP, TyG, cIMT, and FRS-Lipids was assessed by Spearman's correlation coefficient. A ROC curve analysis was performed, and each algorithm's cutoff points were determined using the Youden index. The area under the curve (AUC), sensitivity, specificity, and likelihood ratios (LR) were calculated. A value of p£0.05 was considered statistically significant.
Results: A total of 88 patients with PsA were included, mostly women ($n = 46$, 52.3%), the mean age was 53 ± 11.3, median disease duration of PsA was 5.0 (3.0-10.7) years. Median AIP was 0.44 (0.31-0.66) and TGI 3.8 (3.6-4.0) of all patients included. The most prevalent cardiovascular risk factor was dyslipidemia ($n = 36$, 41.4%). Patients with carotid plaque and PsA presented higher TyG compared to the group without carotid plaque ($p = 0.010$). (Table 1). In a sub-analysis, TyG showed a sensitivity and specificity of 70% and 47%, respectively, with an AUC of 0.687 95% CI 0.554-0.820, and a PPV of 49% to identify CP, similar to cardiovascular risk algorithms such as FRS-Lipids (sensitivity of 69%, specificity of 53%, AUC 0.675, 95% CI 0.528-0.812, PPV

51%). AIP did not identify CP in PsA-patients (AUC 0.615 95% CI 0.476-0.754, $p = 0.107$).

Conclusions: AIP is not elevated in patients with PsA and carotid plaque. TyG levels are increased in PsA-patients and CP, in addition, showed similar sensitivity and specificity to conventional CVR algorithms to identify PsA-patients with CP. This needs to be evaluated in a prospective study for a better comparison and detection of CP.

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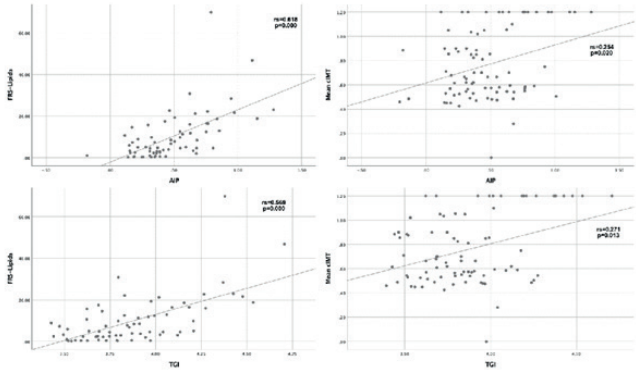
Table 1. Demographic characteristics.

Characteristics	PsA Patients with CP (n=36)	PsA patients without CP (n=52)	*p*-value
Age, years, ± SD	57.7 ± 9.8	54.9 ± 6.3	**0.006**
Women, n (%)	18 (50)	28 (53.8)	NS
Diabetes, n (%)	13 (37.1)	6 (11.5)	**0.005**
Hypertension, n (%)	17 (48.6)	17 (32.7)	NS
Dyslipidemia, n (%)	19 (54.3)	17 (32.7)	**0.045**
Obesity, n (%)	11 (31.4)	22 (42.3)	NS
Active smoking, n (%)	6 (17.6)	12 (23.1)	NS
Time of evolution, years, median (p25-p75)	7.5 (3.2-16.5)	6.0 (3.5-8.0)	NS
DAS28-CRP, ± SD	2.4 ± 1.3	2.4 ± 1.0	NS
PASI, median (p25-p75)	0.4 (0.0-4.0)	0.4 (0.0-1.9)	NS
NAPSI, median (p25-p75)	0.0 (0.0-17.0)	0.0 (0.0-4.5)	NS
DAPSA, median (p25-p75)	10.1 (4.6-24.8)	13.3 (5.3-22.4)	NS
AIP, median (p25-p75)	0.48 (0.35-0.78)	0.35 (0.21-0.54)	NS
TyG, median (p25-p75)	3.9 (3.7-4.3)	3.7 (3.6-3.8)	**0.010**
cIMT, mm, median (p25-p75)	1.0 (0.8-1.2)	0.5 (0.5-0.6)	**0.000**

PsA, psoriatic arthritis; CP, carotid plaque; SD, standard deviation; IQR, interquartile range; NS, no significative; DAS28-CRP, 28-joint Disease Activity Score based on C-reactive protein; PASI, psoriasis area severity index; NAPSI, nail psoriasis severity index; DAPSA, disease activity in psoriatic arthritis; AIP, atherogenic index of plasma; TyG, triglyceride-glucose index; cIMT, carotid intima-media thickness.

Figure 1. Scatterplots of the association between FRS-Lipids, cIMT, and indexes.



P-015

CALCULATING PASI WITH 3D TOTAL BODY IMAGING: A PRELIMINARY STUDY IN CLINICAL PRACTICE

No consent given to publish in scientific journal.

P-016

THE IMPORTANCE OF ULTRASOUND EXAMINATION IN EARLY DIAGNOSIS OF PSORIATIC ARTHRITIS

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Introduction: Psoriatic arthritis (PsA) is one of the most important diseases of great medical and social importance, due to its progressive and significant takeover, which can lead to early disability.

Objectives: Early establishment of arthritis in PsA based on clinical data and ultrasound examination.

Methods: The study was conducted between 2019-2023, in the rheumatology and arthrology departments of the Timofei Moşneaga Republican Clinical Hospital, or treated in outpatient. In order to meet the requirements of the study, 100 people were examined, including 70 patients with PsA.

Results: The most common changes were an increase in the amount of intra-articular fluid and the proliferation of the synovial membrane. The appearance of fluid in the joints occurred in the overwhelming number of patients (63.90%, $p = 0.0021$) and only in 10% ($n = 7$) of the observations there was no inflammatory liquid. In total, fluid was detected in 293 out of 3,232 joints (9.1%). Among the knee joints in which there was an increase in the amount of intraarticular fluid ($n = 79$; 100%, $p = 0.016$), in 48.8% ($n = 37$, $p = 0.033$) of the observations were joints with a small amount of fluid (gradation 1). In a smaller number, the amount of liquid corresponding to grade 2 ($n = 24$; 30.4%) and grade 3 ($n = 18$; 20.8%, $p = 0.041$) were observed. In the radiocarpal joints, the maximum thickness of the liquid in the joints was 6 mm, in the ankle joints – 8 mm. The maximum thickness of the fluid in small joints was 2 mm. In our study, homogeneous effusion into the joint cavity prevailed ($n = 201$; 68.6%, $p = 0.0037$). The heterogeneity of the structure ($n = 92$; 31,4%, $p = 0.022$) was due to the appearance of partitions, suspensions or hyperechogene solid inclusions against the background of anechogenic contents. Erosions were detected in 3 joints and localized in the condyles of the femoral and tibial bones and in the ends of the metatarsal bones II and III of all surfaces. The changes in cartilage consisted of its thinning and structural changes and were observed in 28.57% of cases ($n = 4$, $p = 0.042$). In one observation, fragmentation of cartilage occurred, in the other, changes in the type of cracking were revealed, falling into the manifestations of chondromalacia.

Conclusions: Ultrasound is a highly informative method in detecting a wide range of morphological changes in the joints of patients with PsA. The highest sensitivity markers occurred when inflammatory fluid, cartilage changes, osteophytes and tenosynovitis were detected. Less sensitivity markers were achieved in the detection of synovial membrane proliferation, enthesopathy, the slightest sensitivity was observed in the visualization of marginal bone erosions. In large joints, the proliferation of the synovial membrane was detected in a half of the joints and had predominantly high echogenicity, as well as accompanied by intraarticular overflow in all observations and may be considered an important marker for PsA. In small joints, synovial proliferation with predominantly low echogenicity occurred only in several numbers of the joints, due to their rarer lesion, and was combined with an increase in intraarticular fluid in majority of cases.

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P-017

MULTI-FAILURE PSORIASIS PATIENTS: CHARACTERIZATION OF THE PATIENTS AND RESPONSE TO BIOLOGICAL THERAPY IN A MULTICENTER ITALIAN COHORT

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Introduction: Patients with psoriasis who have failed multiple biologic drugs have been defined as "multi-failure," although there are no clear data on the characteristics, comorbidities, and best treatment strategies for this population. Nowadays, given the next generation and the number of biologics available, patients are considered multi-failure when ≥4 biologics fail to achieve a good response.
Methods: Demographic characteristics and efficacy of anti-interleukin drugs in multi-failure patients were compared to a cohort of general psoriatic patients treated with IL-23 or IL-17 inhibitors.
Results: In total 97 multi-failure patients (≥4 lines of biologics) were compared with 1,057 patients in the general cohort. The current drugs in the multi-failure group were risankizumab (34), ixekizumab (23), guselkumab (21), brodalumab (7), tildrakizumab (5), ustekinumab (4), secukinumab (2), and certolizumab pegol (1). A significant difference was found in the multi-failure cohort for age of psoriasis onset (mean 29.7 vs. 35.1, $p < 0.001$), concurrent psoriatic arthritis (45.4 vs. 26.9%, $p < 0.001$), diabetes mellitus (30.9 vs. 10.9%, $p < 0.001$), and cardiovascular comorbidity (54.6 vs. 39.8%, $p = 0.005$). In multi-failure patients, current biological therapy showed a good initial response (PASI 90 and 100 of 41.24 and 27.84%, respectively, at 16 weeks); the response tended to decline after 40 weeks. Anti-IL-17 agents showed clinical superiority over IL-23 agents in terms of achieving PASI90 at 28 weeks ($p < 0.001$) and 40 weeks ($p = 0.007$), after which they reached a plateau. In contrast, IL-23 agents showed a slower but progressive improvement that was maintained for up to 52 weeks. A similar trend was also seen for PASI100 (28 weeks $p = 0.032$; 40 weeks $p = 0.121$).
Conclusions: The multi-failure patient is characterized by many comorbidities and longstanding inflammatory disease that frequently precedes the introduction of systemic biologic therapy. Further studies are needed to identify more specific criteria that could be applied as a guideline by clinicians.
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P-018

OVERLAPPING PHENOTYPE OF ATOPIC DERMATITIS AND PSORIASIS EXHIBITS INTERMEDIATE HISTOPATHOLOGICAL FEATURES OF BOTH CONDITIONS: A SINGLE-CENTER RETROSPECTIVE STUDY

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Introduction: Atopic dermatitis (AD) and psoriasis (PsO) are common dermatological conditions characterized by inflammation. The clinical and histopathological features of AD and PsO often overlap, leading to occasional diagnostic challenges. In specific patient populations, such as children and Asian patients, there are reports of overexpression of the interleukin-17 pathway in AD, leading to clinical manifestations resembling PsO. Moreover, with the use of biological agents, reports have emerged of patients experiencing the paradoxical occurrence of one condition after treating the other without a clearly understood mechanism.
Objectives: This study aimed to investigate the clinical and histopathological characteristics of Korean patients concurrently diagnosed with both conditions of AD and PsO at our department, including association with treatment modalities, particularly biological agents. We hypothesized that patients with an overlapping phenotype would exhibit clinical and histopathologic features intermediate between classic PsO patients and classic AD patients.
Methods: The medical charts of patients eight patients who were concurrently diagnosed with AD and PsO or who had histologic findings suggestive of both eczema and PsO between 2004 and 2023 were retrospectively reviewed. Additionally, we enrolled 8 PsO patients and 8 atopic dermatitis patients diagnosed through skin biopsy as a control group. We analyzed laboratory, histopathological, and clinical features of enrolled patients. In analyzing histopathological findings, we calculated the Psoriasis Histopathologic Score for each patient. This involved grading histological features on a scale of up to 3 points, summing those indicative of PsO, and subtracting those suggestive of eczema to obtain the total score.
Results: Patients with concomitant AD and PsO were frequently men (75%) and currently had cyclosporine treatment (37.5%). (Table 1) The mean values are age 42 years, duration of illness 36 months, BMI 21.99, PASI 8.41, and EASI 12.55. The average IgE is 1440.50, and the average eosinophil percentage is 6.81. Only one patient exhibited symptoms related to the administration of biologics. Patients with overlapping phenotypes had a PHS of 3.58 ± 3.04, classic PsO patients scored 9.25 ± 2.04, and classic atopic dermatitis patients scored -0.5 ± 1.32. (Table 2)
Conclusions: This study offers information on the clinical and histopathological features of Asian patients exhibiting overlapping features of PsO and AD. Additionally, it demonstrates that patients showing overlapping features exhibit intermediate histopathological characteristics between AD and PsO. When we scored histopathological features and calculated their overall sums, significant differences were observed between groups.
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P-019

WORK PRODUCTIVITY AND ITS RELATIONSHIP TO CLINICAL FEATURES OF PSORIATIC ARTHRITIS

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Introduction: Psoriatic arthritis (PsA) is a chronic inflammatory condition affecting joints and skin, often causing significant reductions in work productivity. While biologics and Janus kinase (JAK) therapies show potential in slowing disease progression, their cost and limited use as first-line treatments require further evaluation of their impact on work impairment.
Objectives: This study aimed to investigate the relationship between work productivity and clinical features of PsA, and differences in patients treated with or without biologics and/or JAKs.
Methods: Between May and August 2023, PsA Clinic patients were invited to complete the Work Productivity and Activity Impairment (WPAI) questionnaire, assessing disease-related work and activity limitations. Clinical assessments of activity and damage, as well as X-rays (using the modified Steinbrocker method), were used to gauge disease severity. Kendall's correlation explored associations with WPAI outcomes. Logistic and linear regression analyses, adjusted by propensity scores, examined the relationship between biologics and/or JAKs usage and WPAI outcomes.
Results: Among the 113 participants, 60 (53%) were employed, and 66 (58%) were male, with an average age of 60.66 (± 11.72) years. Various PsA clinical features were significantly associated with WPAI outcomes [Table]. Notably, the percentage of work time missed due to PsA exhibited significant positive correlations with measures, including the Clinical Disease Activity Index for PsA (cDAPSA; $p = 0.007$), Health Assessment Questionnaire (HAQ; $p = 0.017$), Patient Pain Assessment ($p = 0.005$), Patient Skin and Joint Activity Assessment ($p = 0.006$), Physician Global Assessment ($p < 0.001$), Physician Joint Assessment ($p = 0.017$), and Physician Skin Joint Assessment ($p = 0.019$). The percent impairment while working due to PsA, percent overall work impairment, and percent activity impairment showed significant positive associations with the same measures ($p < 0.05$). However, the Physician Global Assessment was the sole physician-assessed score significantly correlated with the percent impairment while working due to PsA ($p = 0.044$) and overall work impairment ($p = 0.004$). Significant positive associations were observed between Tender Joint Count ($p = 0.032$), Swollen Joint Count ($p = 0.044$), Actively inflamed Joint Count ($p = 0.008$), and the percent activity impairment. Importantly, patients treated with biologics and/or JAKs experienced a statistically significant reduction in the percent impairment while working due to PsA compared to those without such treatments (β=-16.97, $p = 0.016$).
Conclusion: Clinical features of PsA, particularly disease activity, significantly correlated with decreased work productivity. PsA damage (clinical or radiological) showed no such association. This study highlights the effectiveness of biologics and/or JAKs therapies in improving work-related outcomes, particularly in reducing impairment while working. Future research should further investigate these treatments to enhance patients' work productivity and quality of life.

Table: Results of Kendall correlation between 4 WPAI outcomes and clinical features of PsA

	tau	p-value
Percent work time missed due to health for those who were currently employed		
cDAPSA	0.28	0.007**
HAQ	0.25	0.017*
Patient assessment of pain	0.30	0.005**
Patient assessment skin & joints	0.29	0.006**
Physician global	0.41	<0.001***
Physician assessment joints	0.27	0.017*
Physician assessment skin	0.26	0.019*
Percent impairment while working due to health for those who worked in the past seven days		
cDAPSA	0.48	<0.001***
HAQ	0.34	0.002**
Patient assessment of pain	0.53	<0.001***
Patient assessment skin & joints	0.45	<0.001***
Physician global	0.24	0.044*
cDAPSA	0.48	<0.001***
Percent overall work impairment due to health for those who were currently employed		
cDAPSA	0.40	<0.001***
HAQ	0.26	0.008**
Patient assessment of pain	0.45	<0.001***
Patient assessment skin & joints	0.40	<0.001***
Physician global	0.31	0.004**
Percent activity impairment due to health for all respondents		
Tender Joint Count	0.17	0.032*
Swollen Joint Count	0.16	0.044*
Actively inflamed Joint Count	0.20	0.008**
cDAPSA	0.47	<0.001***
HAQ	0.49	<0.001***
Patient assessment of pain	0.51	<0.001***
Patient assessment skin & joints	0.44	<0.001***
Physician global	0.32	<0.001***
Physician assessment joints	0.22	0.004**
Physician assessment skin	0.19	0.011*
Only variables significantly correlated with WPAI outcomes using Kendall's correlation are presented. Other variables, including Age, Psoriatic Arthritis duration, Damaged Joint Count, Psoriasis Area and Severity Index Score, Body Surface Area, Steinbrocker Score, Radiographically Damaged Joints, Erythrocyte Sedimentation Rate, did not show significance.		

P-020

ASSOCIATION BETWEEN DAILY STEP COUNT AND INCIDENT NAFLD IN PATIENTS WITH PSORIASIS: A PROSPECTIVE COHORT STUDY IN THE UK BIOBANK

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Introduction: Psoriasis is a heterogenous inflammatory condition characterised by scaly, erythematous plaques on the trunk, scalp and extensor surfaces. Psoriasis has been found to be associated with the development of non-alcoholic fatty liver disease (NAFLD).[1] Higher adiposity and chronic low-grade inflammation have been proposed as potential mechanisms.[1] There is emerging evidence highlighting possible benefits of physical activity in both the prevention and treatment of NAFLD.[2] However, there are no studies specifically investigating the association between physical activity and incident NAFLD in individuals with psoriasis.
Objectives: We aimed to examine the association between accelerometer-measured daily step count and incident NAFLD in UK Biobank participants with pre-existing psoriasis.
Methods: Physical activity was characterised as median daily step count over a seven-day period both as a continuous measurement and in tertiles of steps. Prevalent psoriasis at time of accelerometer wear was defined using self-report and record linkage. Incident NAFLD cases were identified via record linkage with hospital inpatient data and through abdominal magnetic resonance imaging (MRI), conducted as part of the UK Biobank study. NAFLD

was defined using a proton density fat fraction (PDFF) >5.5% on liver MRI. Individuals with prevalent NAFLD, other prevalent liver diseases or incomplete accelerometer data were excluded. Cox proportional hazards models were utilised to investigate the association between step count and incident NAFLD adjusting for sociodemographic and lifestyle factors. Separate mediation analyses including body mass index (BMI) by categories: <25, 25-29.9 and >30 kg/m2, methotrexate use and comorbid psoriatic arthritis (PsA) were conducted.

Results: Amongst 2822 participants with psoriasis aged 62.8 (SD 7.8) years, there were 36 incident cases of NAFLD on hospital records. Compared to individuals who took less than 5000 daily steps, those who took more than 10,000 daily steps in the top tertile had a 79% lower risk of NAFLD (HR 0.21, [95% confidence interval [CI] 0.10-0.47]) (Figure 1A). An increase of 1,000 steps per day was associated with a 14% (HR 0.86 [0.77-0.95]) lower hazard of NAFLD. Addition of BMI to the modelling led to partial mediation of the association (HR 0.89 [0.80-0.98]). Amongst 477 participants with prevalent psoriasis and valid accelerometer and MRI data, 24.7% (118/477) had a PDFF value consistent with a diagnosis of NAFLD. Individuals with psoriasis in the top tertile taking more than 10,000 steps had a 58% lower risk of MRI-defined NAFLD when compared to those in the bottom tertile taking <5000 steps (HR 0.42 [0.23, 0.76]) (Figure 1B). This association was attenuated with the addition of BMI to the models. Addition of either comorbid PsA or methotrexate usage into the primary models had little impact on the associations.

Conclusions: In this cohort study of UK Biobank participants with psoriasis, a higher daily step count was associated with a lower risk of developing NAFLD. This association was partially mediated through BMI. Although based on a relatively small number of incident NAFLD cases, these early findings lend support to existing evidence highlighting the potential benefits of physical activity in patients with psoriasis both at reducing disease severity and comorbidity burden.

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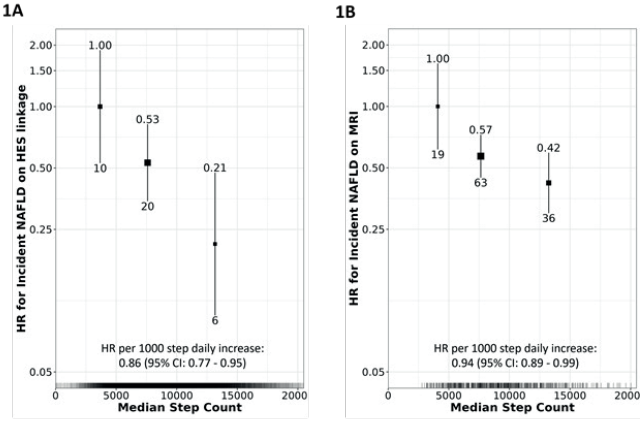

Figure 1: Association of accelerometer-measured median daily step count in tertiles of steps with risk of incident NAFLD as identified through A) hospital record linkage and B) liver MRI.

Adjusted for sex, Townsend deprivation index, alcohol consumption and smoking status

Step tertiles: Tertile 1: <5000 daily steps, tertile 2: 5001 – 10000 daily steps, tertile 3: >10000 daily steps.

Number below confidence interval (CI) = NAFLD events per step tertile; Number above CI = hazard ratio per tertile. 95% CI calculated using floating absolute risk method.

HES, hospital episode statistics; *MRI*, magnetic resonance imaging; *HR*, hazard ratio.

P-021

PSORIASIS AND HIDRADENITIS SUPPURATIVA RESISTANT IN ADALIMUMAB, WHAT'S THE NEXT STEP?

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Introduction: Psoriasis and hidradenitis suppurativa are chronic inflammatory skin diseases whose co-existence is increasingly being described the last years1. The negative impact in quality of life and the dissatisfaction with current treatments creates unmet needs for new therapeutic options such as interleukin A and F inhibitors2.

Objectives: The fundamental role of IL-17 isoforms (IL-17A, IL17F) has recently been recognized not only in the pathogenesis of psoriasis but also in hidradenitis suppurativa, making this dual inhibition an attractive therapeutic option in patients suffering from both diseases3. Based on this we used bimekizumab in 2 patients with both diseases,refractory to adalimumab therapy.

Methods: First patient, a 35 years old Caucasian woman presented with extensive psoriasis (PASI: 18) over a period of 14 years, not responded in apremilast treatment receiving it for 4 years, on the contrary under treatment developed hidradenitis suppurativa (IHS4 : 9). Patient switched therapy and received adalimumab for 2 years, due to loss of effectiveness, started treatment with bimekizumab (PASI:12, IHS4:8), in 320 mg (2 subcutaneous injections of 160 mg each) at week 0, 4, 8, 12, 16 and every 8 weeks thereafter.
Second patient, a 54 years old Caucasian woman presented with hidradenitis suppurativa (IHS4 : 10) over a period of 5 years treated with adalimumab. One year ago, due to the worsening of hidradenitis (IHS4: 13) but also the appearance of psoriasis (PASI:12) simultaneously, a change of treatment was made to bimekizumab, in psoriasis dosage, as first patient.

Results: In first patient, psoriasis was highly reduced in 4 weeks (PASI:3) and hidradenitis suppurativa also in 8 weeks (IHS4 : 4) respectively. In second, PASI reduced also in one month treatment impressively (PASI: 2) and hidradenitis suppurativa in 16 weeks (IHS4 : 6). Both, continued treatment 1 year after, under 3 months follow up with improvement not only clinically, but also physiologically.

Conclusions: Living with a dual diagnosis of psoriasis and hidradenitis suppurativa can be challenging and require common treatment approach. The expectation of rapid response in inflammatory lesions in both diseases, was confirmed as expected quickly and safely4. Binding to both IL-17A and IL-17F, double check point was achieved suppressing Th17 mediated inflammatory pathway selectively. Combing a treatment like bimekizumab in these patients with or without resistance in adalimumab could be the next step in clinical approach in psoriasis and hidradenitis suppurativa simultaneously or as separate pathological entities.

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P-022

CARDIOVASCULAR RISK FACTORS AND COMORBIDITIES: A CROSS-SECTIONAL STUDY OF 127 PATIENTS WITH PSORIATIC ARTHRITIS

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Introduction: Patients with psoriatic arthritis (PsA) are at an increased risk of cardiovascular morbidity and mortality, leading to a reduced life expectancy compared to the general population. A specialized evaluation in a cardio-rheumatology preventive clinic could help recognize and manage these risk factors, improving patient outcomes.

Objective: This study aimed to determine the prevalence of cardiovascular risk factors in a cohort of Mexican Mestizo patients with PsA evaluated in a cardio-rheumatology preventive clinic.

Methods: Observational and prospective study of the cohort of patients with PsA from the cardio-rheumatology preventive clinic in a teaching hospital. Patients aged 30 to 75 years old who fulfilled the 2006 CASPAR classification criteria for PsA from August 2014 to November 2023, were included. Patients with known cardiovascular disease (myocardial infarction, cerebrovascular event, or peripheral arterial disease) were excluded. The presence of type 2 diabetes, hypertension, and dyslipidemia were defined as a diagnosis included in the patient's medical record and treatment. Overweight and obesity were defined as a BMI of 25 to<30 kg/m2, and a BMI of ≥30 kg/m2, respectively. High blood pressure was outlined as blood pressure ≥140/90 mmHg. Hyperglycemia was defined as fasting glucose ≥100 mg/dl. Alterations of lipid profile was stated as total cholesterol (TC) >200 mg/dl, triglycerides (TGL) >150 mg/dl, high-density lipoprotein cholesterol (HDL-C)<40 mg/dl, and low-density lipoprotein cholesterol (LDL-C) >100 mg/dl. The distribution was evaluated with the Kolmogorov-Smirnov test. Normally distributed variables were described with mean and standard deviation (SD) and the 25th and 75th percentiles (p25-p75) were used to report variables without normal distribution.

Results: One hundred twenty-seven patients with PsA were included; the majority were women (55.9%). The mean age was 53 ± 11.6 years and the median disease activity, measured by DAPSA, was 15.0 (7.2-25.6). The most prevalent cardiovascular risk factor was dyslipidemia (n = 55, 43.3%), and overweight (n = 53, 41.7%). In patients with PsA without a previous diagnosis of type 2 diabetes, high blood pressure, and dyslipidemia, we documented hyperglycemia in a total of 34 (34.0%) patients, increased blood pressure in 22 (27.1%), and alterations in lipid profile, represented by CT, TGL, and LDL-C, were detected in 50 (73.5%) with high lipid levels, respectively. Full results are shown in table 1.

Conclusions: Dyslipidemia and overweight were the most prevalent cardiovascular risk factors in our cohort. More than half of the patients with PAs were detected with alterations of the lipids profile and dyslipidemia, without a previous diagnosis. These results reinforce the idea that systematic evaluation and screening for comorbidities and risk factors in patients with PsA may allow earlier detection, which may improve the outcomes of these patients.

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Table 1. Cardiovascular risk factors and comorbidities in PsA patients.

Characteristic	PsA patients (n = 127)
Age, years, ± SD	53.1 ± 11.6
Women, n (%)	71 (55.9)
Disease duration, years, (p25-p75)	5.0 (2.0 – 10.0)
PASI, (p25-p75)	0.6 (0.0 – 3.6)
NAPSI, (p25-p75)	0.0 (0.0 – 11.7)
DAPSA, (p25-p75)	15.0 (7.2 – 25.6)
Comorbidities, n (%)	
Hypertension	43 (33.8)
Dyslipidemia	55 (43.3)
Diabetes	27 (21.2)
Cardiovascular risk factors, n (%)	
Overweight[a]	53 (41.7)
Obesity[b]	45 (35.4)
Active smoking	26 (20.4)

PsA, psoriatic arthritis; SD, standard deviation; PASI, psoriasis area severity index; NAPSI, nail psoriasis severity index; DAPSA, disease activity in psoriatic arthritis; [a]BMI ≥25 kg/m2 and <30 kg/m2; [b]BMI ≥30 kg/m2.

Table 2. Alterations in clinical and laboratory values without diagnosis in PsA patients.

Characteristic	PsA patients
Hyperglycemia, n (%)	34/100 (34.0)
Glucose levels, mg/dL, ± SD	95.8 ± 10.6
High Blood Pressure[a], n (%)	22/81 (27.1)
SBP, mmHg, (p25-p75)	119.0 (110.0 – 132.2)
DBP, mmHg, (p25-p75)	78.5 (70.0 – 84.0)
High Lipid Values, n (%)	50/68 (73.5)
TC, mg/dL, ± SD	170.3 ± 34.0
TGL, mg/dL, (p25-p75)	111.2 (87.2 – 161.3)
HDL-C, mg/dL (p25-p75)	47.3 (40.3 – 54.2)
LDL-C, mg/dL, ± SD	94.4 ± 30.0

PsA, psoriatic arthritis; [a]Systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg; SBP, systolic blood pressure; DBP, diastolic blood pressure; TC, total cholesterol; TGL, triglycerides; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol.

P-023

IMPACT OF BIOLOGIC DISEASE-MODIFYING ANTI-RHEUMATIC DRUGS IN LIPID PROFILE OF PSORIATIC ARTHRITIS PATIENTS

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Background: Biologic therapy has been linked to lipid alterations without changes in cardiovascular disease outcomes. The effect of biologic therapy on lipid parameters among psoriatic arthritis (PsA) patients treated with biologic Disease-Modifying anti-rheumatic drugs (bDMARDs) has not been defined.

Objectives: To compare serum lipid levels, cardiovascular risk, the prevalence of carotid plaque (CP), and increased carotid intima-media thickness (cIMT) between PsA patients with and without biologic treatment.

Methods: We performed an observational, comparative, and transversal study in patients who fulfilled the 2006 Classification Criteria for Psoriatic Arthritis (CASPAR). Patients with a history of previous atherosclerotic cardiovascular disease and pregnancy were excluded. A clinical history and blood tests were performed. Disease activity was measured by the Disease Activity for Psoriatic Arthritis Score (DAPSA), Psoriasis Severity Index (PASI), and Nail Psoriasis Severity Index (NAPSI). Cardiovascular risk was estimated with ASCVD, QRISK3, and SCORE calculators. The results were multiplied by 1.5 according to the EULAR recommendations. Carotid B mode ultrasonography was used to measure cIMT and the presence of plaques. Increased cIMT was defined as a ≥ 0.9 mm. CP was defined as a focal narrowing ≥0.5 mm of the surrounding lumen or a cIMT ≥1.2 mm. Descriptive analysis was done with frequencies (%), mean (± SD), and median (p25-p75), and comparisons with Chi-square, Student s t, and Mann-Whitney U test. We considered $p < 0.05$ significant.

Results: We recruited 112 patients who fulfilled the criteria. The prevalence of bDMARDs use was 33.92%. The most frequent bDMARDs used were TNF inhibitors (84,84%). Patients in biologic therapy had a significantly lower NAPSI score than those with synthetic DMARDs [0.00 (0.00-50.00) vs. 2.00 (0.00-80.00), $p = 0.013$]. We found no significant differences in DAPSA, PASI, DAS28-CRP, or DAS28-ESR. Patients with biologic therapy had higher total cholesterol (TC) [188.23 ±38.53 vs. 171.09±33.51; $p = 0.017$] and Low-Density Lipoprotein cholesterol (LDL-c) [107.46±29.13 vs. 93.07 ±29.07; $p = 0.016$] than those without biologic therapy. No significant differences were found between biologic therapy and cardiovascular risk, CP prevalence, or between biologic therapy and prevalence of increased cIMT. (Table 1)
Conclusion: In this population, patients treated with bDMARDs had higher levels of CT and LDL-C, without significant differences detected in cardiovascular risk, prevalence of CP, or increased cIMT. However, prolonged exposure to increased levels of LDL-C and TC has been associated with a higher cardiovascular risk. Close monitoring and early intervention of lipid levels in patients treated with biological therapy is imperative.

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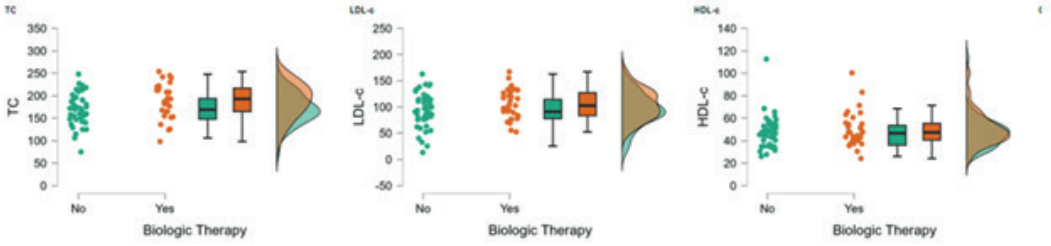
Table 1. Clinical and sociodemographic characteristics.

	Patients without biologic therapy n=74	Patients with biologic therapy n=38	*p*-value
Age, mean SD	53.85 ±12.89	51.89 ±9.01	NS
Gender			
- Woman, n (%)	42 (56.75)	22 (57.89)	NS
- Man, n (%)	32 (43.24)	16 (42.10)	NS
Biologic			
- TNF-inhibitor	-	28 (84.84)	
- Anti-IL17	-	3 (9.09)	
- Other	-	2 (6.06)	
DAPSA, mean SD	19.84 ±17.13	15.70 ±11.93	NS
NAPSI, median p25-p75	2.00 (0.00-80.00)	0.00 (0.00-50.00)	**0.013**
PASI, median p25-p75	1.40 (0.00 – 36.00)	0.60 (0.00-17.90)	NS
DAS28-CRP, mean SD	2.65 ±1.30	2.50 ±1.05	NS
DAS28-ESR, mean SD	4.04 ±1.59	3.71 ± 1.35	NS
ESR, median p25-p75	18.00 (1.00-103.00)	14.50 (3.00-43.00)	NS
CRP, median p25-p75	0.69 (0.01-6.80)	0.34 (0.00-3.46)	**<0.001**
ASCVD, median p25-p75	6.60 (0.30-56.30)	4.35 (0.40-64.70)	NS
QRISK3, median p25-p75	5.60 (0.30-46.10)	4.85 (0.30-39.20)	NS
SCORE, median p25-p75	1.00 (0.00-12.00)	1.00 (0.00-14.00)	NS
TC, mean SD	171.09 ± 33.51	188.23 ± 38.53	**0.017**
LDL-c, mean SD	93.07 ±29.07	107.46 ± 29.13	**0.016**
HDL-c, median p25-p75	46.65 (20.50-112.60)	47.4 (24.10-100.40)	NS
CP, n (%)	19 (25.67)	15 (39.47)	NS
Increased cIMT, n (%)	8 (10.81)	5 (13.15)	NS
Glucocorticoid use, n (%)	18 (24.32)	3 (7.89)	0.055

TNF-inhibitor, Tumor Necrosis Factor Inhibitor; Anti-Il17, Anti-Interleukin 17; DAPSA, Disease Activity in Psoriatic Arthritis; NAPSI, Nail Psoriasis Severity Index; PASI, Psoriasis Area Severity Index; DAS28-CRP, 28 joint Disease Activity Score- C reactive protein; DAS28-ESR, 28 joint Disease Activity Score - Erythrocyte Sedimentation Rate; ASCVD, Atherosclerotic Cardiovascular Disease risk algorithm; TC, total cholesterol; LDL-c, Low-density lipoprotein cholesterol; HDL-C, High Density Lipoprotein cholesterol; CP, carotid plaque; cIMT, carotid intima media thickness.

Figure 1: Comparative Raincloud Plots of Lipid Parameters.



P-024

FIBROSIS-4 INDEX ANALYSIS OF NON-ALCOHOLIC FATTY LIVER DISEASE FIBROSIS IN PSORIATIC ARTHRITIS: IMPLICATIONS FOR CARDIOVASCULAR HEALTH

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Background: Non-Alcoholic Fatty Liver Disease (NAFDL) is characterized by hepatic steatosis and subsequent fibrosis associated with metabolic abnormalities such as insulin resistance, dyslipidemia, obesity, hypertension and atherosclerosis. It is closely associated with an increased cardiovascular (CV) risk and other cardiac complications independent of traditional CV risk factors and metabolic syndrome features. Psoriatic arthritis (PsA) and NAFLD share similar underlying inflammatory pathways, cells, and pro-inflammatory cytokines which may be involved in the occurrence and development of NAFLD. The fibrosis-4 index (FIB-4) is an economical practical calculator to assess fibrosis in NAFLD. The effect of NAFDL fibrosis on cardiovascular risk in the context of psoriatic arthritis has not been reported.
Objectives: To compare disease activity, cardiovascular risk, prevalence of carotid plaque (CP), and prevalence of increased carotid intima-media thickness (cIMT) in patients with liver fibrosis stage 0-1 vs. fibrosis stage ≥2 measured by FIB-4.
Methods: We performed an observational, comparative, and transversal study on patients who fulfilled the 2006 Classification Criteria for Psoriatic Arthritis (CASPAR). Patients with a history of previous atherosclerotic cardiovascular disease and pregnancy were excluded. A clinical history and blood tests were performed. Disease activity was measured by Disease Activity for Psoriatic Arthritis Score (DAPSA), Psoriasis Severity Index (PASI), and Nail Psoriasis Severity Index (NAPSI). Cardiovascular risk was estimated with by QRISK3 calculator. FIB-4 score was calculated as (Age* x AST) / (Platelets x √(ALT). Carotid B-mode ultrasonography was used to measure cIMT and the presence of plaques. Increased cIMT was defined as a ≥0.9 mm. CP was defined as a focal narrowing ≥0.5 mm of the surrounding lumen or a cIMT ≥1.2 mm. Descriptive analysis was done with frequencies (%), mean (± SD), and median (p25-p75), and comparisons with Chi-square, Student´s t, and Mann Whitney U test. We considered $p < 0.05$ significant.
Results: We recruited 86 patients who fulfilled the criteria. The prevalence for NAFLD fibrosis stage ≥2 was 26.74%. We found

no significant difference between the groups in the disease activity criteria or statin use. Patients with a higher NAFDL stage were older [60.21 +/-9.45 vs. 53.61 +/-9.67; $p = 0.006$] and had a higher prevalence of hypertension [13 (56.52%) vs. 19 (30.15%); $p = 0.025$]. We found no other significant differences among the comorbidities between groups. Patients with a FIB-4 in stage ≥ 2 had higher CV risk [13.20 (1.7- 46.10) vs. 7.43 (0.3-36.50); $p = 0.010$]. There was no difference between groups in the prevalence of carotid plaque [7 (30.43%) vs. 19 (30.15%); $p =$ NS] or increased cIMT [1 (4.34% vs. 7 (11.11); $p =$ NS]. (Table 1).

Conclusion: NAFDL and liver fibrosis have been linked to an increased CV risk and atherosclerosis. In our population, patients with stage ≥2 NAFDL measured by FIB-4 had an increased CV risk, without significant differences in the prevalence of carotid plaque or increased cIMT.

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Table 1. Clinical and sociodemographic characteristics

	Patients with fibrosis stage 0-1 n= 63	Patients with fibrosis stage ≥ 2 n= 23	*p*-value
Age, Mean SD	53.61 +/-9.67	60.21 +/-9.45	**0.006**
Gender, n (%)			
- Woman, n (%)	35 (55.55)	14 (60.87)	NS
- Man, n (%)	28 (44.44)	9 (39.13)	NS
Comorbidities, n (%)			
- Diabetes Mellitus	11 (17.46)	7 (30.43)	NS
- Hypertension	19 (30.15)	13 (56.52)	**0.025**
- Dyslipidaemia	25 (39.68)	11 (47.82)	NS
- Obesity	23 (36.50)	8 (34.78)	NS
- Active smoking	13 (20.63)	6 (26.08)	NS
Statin use	11 (17.46)	7 (30.43)	NS
DAPSA, mean SD	17.75 +/- 16.89	19.10 +/-11.02	NS
NAPSI, median (q25-q75)	4.00 (0.0 - 80.0)	0.00 (0.0 -27.0)	NS
PASI, median (q25-q75)	0.40 (0.00-36.00)	2.65 (0.00-17.90)	NS
QRISK3, median (q25-q75)	7.43 (0.3-36.50)	13.20 (1.7- 46.10)	**0.010**
Carotid plaque, n (%)	19 (30.15)	7 (30.43)	NS
Increased cIMT, n (%)	7 (11.11)	1 (4.34)	NS

DAPSA, Disease Activity in Psoriatic Arthritis; NAPSI, Nail Psoriasis Severity Index; PASI, Psoriasis Activity Severity Index; c IMT, Carotid intima media thickness; NS, Non-Significant; SD, Standard Deviation.

P-025

ASSOCIATION BETWEEN PERIODONTAL HEALTH INDICES AND PSORIASIS RISK AMONG GREEK ADULTS: A CASE-CONTROL STUDY

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Introduction: The potential role of periodontal disease as a risk factor for developing psoriasis has not be widely explored and the possible link remains still unidentified.

Objectives: The aim of the current study was to investigate the possible relationship between periodontal status indices and the risk for psoriasis development in a Greek adult population.

Methods: The study sample comprised 337 psoriasis patients-cases and 337 healthy individuals-controls between 40 to 69 years of age who referred by three dermatology and one dental private practice. Cases and controls completed a health medical and dental questionnaire and underwent an examination of their periodontal status that included the following parameters: Probing Pocket Depth (PPD), Clinical Attachment Loss (CAL), frequency of a regular/irregular annual dental follow-up, and number of missing teeth. Odds ratios (OR's) and 95% Confidence Intervals (95% CI's) were assessed using logistic regression model adjusted for possible confounders.

Results: The multivariate regression analysis model showed that a higher BMI ($p = 0.009$, OR= 3.154, 95% CI= 1.532-4.028), alcohol over-consumption ($p = 0.012$, OR= 2.024, 95% CI=1.445-3.435), moderate /severe CAL ($p = 0.047$, 95% CI=2.112, 1.156-3.249), and a number of missing teeth more than four ($p = 0.027$, OR=2.817, 95% CI= 1.267-3.872 and $p = 0.016$, OR=3.510, 95% CI= 1.350-4.145) were statistically significantly associated with risk for psoriasis development.

Conclusion: Individuals with a higher BMI, excessive alcohol consumption, moderate/severe attachment loss and a number of missing teeth more than four were at significantly higher risk for developing psoriasis.

P-026

DEUCRAVACITINIB IN PLAQUE PSORIASIS: MAINTENANCE OF RESPONSE OVER 3 YEARS IN HISPANIC/LATINO PATIENTS IN THE PHASE 3 POETYK TRIALS

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Introduction: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was superior to placebo and apremilast in the global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751) parent trials and maintained long-term efficacy through 2 years with no new safety signals in the ongoing POETYK long-term extension (LTE) (NCT04036435) trial. [1 2 3]

Objectives: We report the clinical efficacy of deucravacitinib through 3 years (148 weeks; cutoff date, June 15, 2022) in a subset of patients who received continuous deucravacitinib treatment from Day 1 in the parent trials, achieved ≥75% reduction from baseline in Psoriasis Area and Severity Index (PASI 75) at Week 16 or Week 24, and entered the LTE in the overall population and in the subgroup of Hispanic/Latino patients from these trials.

Methods: PSO-1/PSO-2 randomized patients 1:2:1 to oral placebo, deucravacitinib 6 mg once daily (QD), or apremilast 30 mg twice daily. At Week 52, patients could enter the LTE and receive open-label deucravacitinib 6 mg QD. Efficacy was evaluated in the overall population and in the subgroup of patients who self-identified as ethnically Hispanic or Latino and received continuous deucravacitinib treatment from Day 1 of the parent trial, achieved PASI 75 at Week 16 (primary endpoint) or at Week 24 (peak response), and entered the LTE. Maintenance of response assessments for Week 16 PASI 75 and Week 24 PASI 75 responders included PASI 75, PASI 90, and sPGA 0/1 (static Physician Global Assessment of 0 [clear] or 1 [almost clear] with a ≥2-point improvement from baseline), which were reported using the modified nonresponder imputation method.

Results: Of the 513 patients who received continuous deucravacitinib treatment from Day 1, completed 52 weeks in the parent trials, and entered the LTE, 60 (11.7%) were Hispanic/Latino. Among Week 16 PASI 75 responders, clinical response rates were similar between the overall population ($n = 313$) and the Hispanic/Latino patient subgroup ($n = 28$) at Week 52 and were maintained at similar rates from Week 52 through Week 148 (Table). Among Week 24 PASI 75 responders, clinical response rates were comparable at Week 52 and maintained from Week 52 through Week 148 in the overall population ($n = 336$) and in the Hispanic/Latino patient subgroup ($n = 37$).

Conclusions: Clinical efficacy was comparable at Week 52 and maintained well overall through 3 years with continuous deucravacitinib treatment in Week 16 PASI 75 responders and Week 24 PASI 75 responders from the parent trials in the overall study

population and in the subgroup of Hispanic/Latino patients. These results further support the long-term effectiveness of once-daily oral deucravacitinib for patients with moderate to severe plaque psoriasis in the overall population as well as in Hispanic/Latino patients.

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Table. Outcomes at Week 52 and Week 148 (modified nonresponder imputation)

Endpoint: response rate, % of patients (95% CI)	Continuous deucravacitinib treatment			
	Week 16 PASI 75 responders		Week 24 PASI 75 responders	
	Overall population (n = 277)	Hispanic/Latino subgroup (n = 23)	Overall population (n = 305)	Hispanic/Latino subgroup (n = 33)
PASI 75				
Week 52	87.0 (82.5-90.7)	82.6 (61.2-95.0)	90.2 (86.3-93.3)	90.9 (75.7-98.1)
Week 148	84.5 (79.8-89.2)	95.0 (83.6-100)	86.0 (81.6-90.3)	89.7 (77.8-100)
PASI 90				
Week 52	60.6 (NE, NE)	65.2 (42.7-83.6)	61.6 (55.9-67.1)	66.7 (48.2-82.0)
Week 148	60.0 (53.9-66.1)	81.6 (64.1-99.0)	60.4 (54.6-66.3)	75.4 (59.5-91.3)
sPGA 0/1				
Week 52	70.8 (65.0-76.0)	73.9 (51.6-89.8)	74.1 (68.8-78.9)	81.8 (64.5-93.0)
Week 148	62.8 (56.7-68.9)	66.9 (45.9-87.8)	64.5 (58.7-70.3)	68.8 (51.7-85.8)

Patients pooled from POETYK PSO-1 and POETYK PSO-2 who were randomized to deucravacitinib in the parent trials, received continuous deucravacitinib from Day 1, and entered the POETYK long-term extension trial.
CI, confidence interval; NE, not estimable; PASI 75/90, ≥75%/≥90% reduction from baseline in Psoriasis Area and Severity Index; sPGA 0/1, static Physician Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline.

P-027

LONG-TERM EFFICACY AND SAFETY OF RISANKIZUMAB: A RETROSPECTIVE, MULTICENTER, REAL-WORLD STUDY

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Introduction: Risankizumab is a humanized monoclonal antibody that selectively blocks the p19 subunit of interleukin-23. While long-term data from clinical trials are available, long-term real-world evidence is still limited. Additionally, most data comes from North America or Europe, with relatively scarce information available from Asia.
Objectives: To investigate long-term efficacy and safety of risankizumab for moderate-to-severe psoriasis
Methods: We conducted a retrospective analysis of all patients undergoing risankizumab treatment for a minimum of 52 weeks within a major university healthcare system. Patients' demographic data, duration of psoriasis, prior treatment, presence of psoriatic arthritis, severity of psoriasis measured by psoriasis area and severity index (PASI) and body surface area (BSA) at defined timepoints (0, 16, 52, 104, 156 weeks), and recorded adverse events were collected.
Results: A total of 155 patients were included in the analysis. The mean PASI score significantly decreased from 10.3 ± 4.4 at baseline to 0.9 ± 0.9 at 52 weeks. Similar reduction was observed for BSA. By week 52, 91.0%, 55.6%, and 37.9% of patients achieved PASI≤2, PASI 90, and PASI 100, respectively. Prior biologic treatment failure correlated with a diminished response to risankizumab. Psoriasis improvement persisted over time, with PASI≤2, PASI 90, and PASI 100 responses increasing to 93.3%, 77.0% and 54.8%, respectively, at week 104. Among those completing 156 weeks of treatment, the treatment response was sustained. The majority of treatment-emergent adverse events were mild, primarily pruritus, injection site reactions, and COVID-19 infection, while all recorded serious adverse events were unrelated to risankizumab.
Conclusions: Risankizumab showed sustained long-term efficacy and favorable safety profile in real-life clinical setting.

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P-028

NETAKIMAB, AN IL17 INHIBITOR, REDUCES EXTRAARTICULAR MANIFESTATIONS OF PSORIATIC ARTHRITIS: 3-YEAR RESULTS OF THE PATERA STUDY

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Background: Extraarticular manifestations – skin and nail disease, enthesitis, dactylitis – are one of the key psoriatic arthritis (PsA) domains, highly prevalent in PsA. Netakimab (NTK) is a humanized anti-interleukin 17A antibody approved for the treatment of plaque psoriasis, ankylosing spondylitis, PsA. Previously, treatment with NTK was shown to result in significant improvement in skin manifestations, dactylitis, enthesitis and nail involvement1,2,3. To address NTK long-term efficacy results of the PATERA (NCT03598751) clinical trial were analyzed.
Objectives: To evaluate NTK efficacy on PsA skin and nail manifestations, enthesitis, dactylitis through the long-term period of treatment with NTK up to week 154 (3 years).
Methods: 194 eligible adult patients with PsA (CASPAR, 2006), with inadequate response to csDMARD or one TNFi, were randomly assigned (1:1) to receive NTK 120mg or placebo subcutaneously at week 0, 1, 2, 4, 6, 8, 10 and Q4W from week 14. 84 patients from placebo arm, failed to achieve ACR20 (20% improvement in American College of Rheumatology criteria) at week 16, were switched to NTK. After week 24 all patients received NTK 120mg. Endpoints included the proportion of patients achieved 75%, 90%, and 100% improvement in Psoriasis Area and Severity Index score (PASI75, PASI90, PASI100, respectively), proportion of patients achieved Leeds Enthesitis Index (LEI), Leeds Dactylitis Index (LDI) and Nail Psoriasis Severity Index (NAPSI) zero score. Treatment response was assessed in the overall population up to week 154 of treatment with NTK (week 154 for NTK arm, weeks 172 and 178 for nonresponders and responders in placebo arm). Proportions of responders were calculated based on available data: no imputation was used.
Results: Among 194 randomized patients 148 had baseline BSA≥3, 94 baseline LEI>0, 61 baseline LDI>0, 149 baseline NAPSI>0. Percentage of patients with PASI75/90/100 response rates was stable during 2nd and 3rd year (Figure 1). More than 50% of patient maintained PASI100. Percentage of patients with LEI0, LDI0, NAPSI0 also persisted (Figure 2). Almost compete resolution of dactylitis and enthesitis without worsening during long-term period was observed. About 60% of subjects maintained NAPSI0 improvement.
Conclusions: Long-term treatment with NTK at the dose of 120mg resulted in significant improvement in extraarticular manifestations

in PsA patients maintained up to 3 years: more than half of the patients with BSA≥3 or NAPSI>0 at baseline achieved complete skin or nail clearance. More than 90% of patients had maintained resolution of enthesitis or dactylitis.

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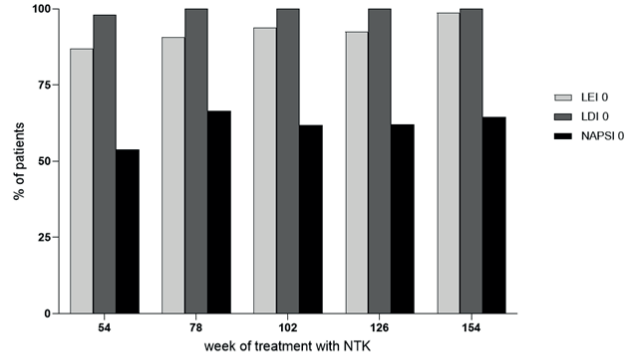
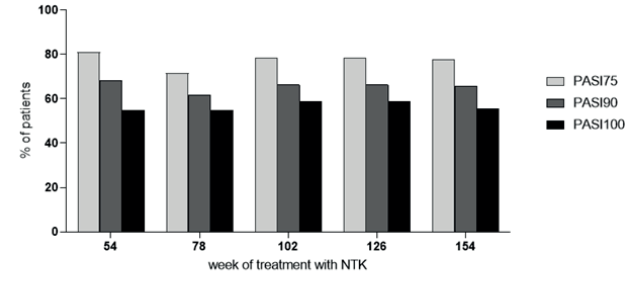


LEI 0	74 (87.1%)	69 (90.8%)	76 (93.8%)	75 (92.6%)	75 (98.8%)
LDI 0	53 (98.1%)	47 (100%)	50 (100%)	49 (100%)	48 (100%)
NAPSI 0	71 (53.8%)	79 (66.4%)	79 (61.7%)	77 (62.1%)	80 (64.5%)



PASI75	120 (81.1%)	106 (71.6%)	116 (78.4%)	116 (78.4%)	115 (77.7%)
PASI90	101 (68.2%)	91 (61.5%)	98 (66.2%)	98 (66.2%)	97 (65.5%)
PASI100	81 (54.7%)	81 (54.7%)	87 (58.8%)	87 (58.8%)	82 (55.4%)

P-029

NETAKIMAB, A NOVEL IL17 INHIBITOR, PROVIDES SUSTAINED REDUCTION OF PSORIATIC ARTHRITIS ACTIVITY: LONG-TERM RESULTS OF THE PATERA STUDY

Tatiana Korotaeva[1], V Mazurov[2], I Gaydukova[2,3], A Samtsov[4], V Khayrutdinov[4], A Bakulev[5], M Kokhan[6], E Kunder[7], N Soroka[8], A Eremeeva[9]

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Introduction: Netakimab (NTK) is an anti-interleukin-17A monoclonal antibody approved for psoriasis, ankylosing spondylitis, psoriatic arthritis (PsA). PATERA is a phase 3 international double-blind, placebo-controlled clinical study of netakimab (NTK) in PsA (NCT03598751). NTK lead to sustained decline in activity and other PsA symptoms during first year of PATERA trial 1,2,3.
Objectives: To assess the long-term impact of NTK on PsA activity by defining the percentage of patients with DAPSA remission and minimal disease activity (MDA) through the long-term period of treatment with NTK up to wk 154.
Methods: 194 eligible adult patients with PsA fulfilling the CASPAR criteria, with inadequate response to csDMARD or one TNFi, were randomly assigned in 1:1 ratio to receive NTK 120 mg or placebo at weeks (wk) 0, 1, 2, 4, 6, 8, 10 and Q4W starting from wk 14. 84 patients from placebo arm, failed to achieve ACR20 (20% improvement in American College of Rheumatology criteria) at wk 16, were switched to NTK. After wk 24 all patients received NTK 120 mg. The efficacy was assessed in the overall population up to wk 154 of treatment with NTK (wk 154 for NTK arm, wks 172 and 178 for nonresponders and responders in placebo arm).
Results: Of 194 randomized patients who received ≥1 dose of study drug, 166 (85.6%) completed 154 wks of treatment with NTK. The proportion of patients achieved DAPSA remission and MDA was consistent with those at wk 54 and was stable throughout the long-term period. No increase in proportion of patients with DAPSA moderate and high activity was detected (Figure 1, 2).
Conclusions: NTK 120 mg was effective in declining PsA activity over 154 wks.

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This study was sponsored by JSC BIOCAD.

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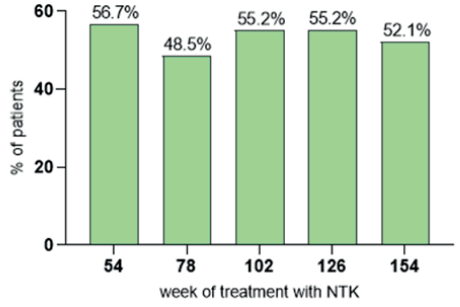
2. Ann Rheum Dis, volume 79, supplement 1, year 2020, page 763
3. Ann Rheum Dis, volume 79, supplement 1, year 2020, page 1690

Figure 1. DAPSA score throughout long-term period of the PATERA study in the overall population (N=194). Weeks of treatment with NTK are shown.
High activity: DAPSA>28, moderate activity: 15≤DAPSA≤28, low activity 5≤DAPSA<15, remission DAPSA<5.

Figure 2. Percentage of patients achieved MDA throughout long-term period of the PATERA study in the overall population (N=194). Weeks of treatment with NTK are shown.



P-030

VISIBLE: EFFICACY OF GUSELKUMAB AT WEEK 16 IN MODERATE-TO-SEVERE SCALP PSORIASIS PARTICIPANTS WITH LOW BODY SURFACE AREA INVOLVEMENT

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Introduction: VISIBLE is an ongoing, novel, prospective, Phase 3b, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of guselkumab in moderate-to-severe plaque psoriasis patients across all skin tones. Scalp is often the first and also one of the most commonly involved special sites among patients with moderate-to-severe plaque psoriasis.[1] However, moderate-to-severe scalp psoriasis patients with low total body surface area (BSA) involvement are not always considered for systemic therapy, despite the unique challenges of treating scalp psoriasis and the eligibility of these patients for systemic treatment.[2] Limited data exist on whether the efficacy of systemic therapies such as guselkumab differs in scalp psoriasis patients with low BSA involvement. Thus, Cohort B of VISIBLE recruited those with moderate-to-severe scalp psoriasis regardless of their total BSA.

Objectives: These post hoc analyses evaluate the efficacy of guselkumab in moderate-to-severe scalp psoriasis participants with low BSA involvement (baseline BSA of ≥2 to<10%) and baseline overall IGA of 3.

Methods: In VISIBLE Cohort B, 108 participants with Psoriasis Scalp Severity Index (PSSI) ≥12, Scalp Surface Area (SSA) ≥30%, and scalp-specific Investigator Global Assessment (ss-IGA) ≥3 were randomized 3:1 to receive guselkumab 100 mg or placebo at Weeks 0, 4, then every 8 weeks. Overall Cohort B includes efficacy analyses of 102 participants whereas low BSA refers to the 33 participants in Cohort B who met low BSA criteria.

Results: The low BSA subgroup had a mean baseline BSA of 6.1% and mean PASI of 7.1 (Table 1), as compared to the entirety of Cohort B which had mean BSA of 16.6% and mean PASI of 14.6 at baseline. Those in Cohort B with moderate-to-severe scalp psoriasis but low BSA had considerable scalp disease at baseline with a mean SSA of 53% and mean PSSI of 29.1, similar to the overall Cohort B where baseline mean SSA was 60% and mean PSSI was 34.3. At Week 16 (Table 2), guselkumab-treated participants with low BSA achieved greater mean percent improvement from baseline in PSSI (82.4%) and in SSA (85.3%) vs placebo (29.4% and 16.1%, respectively). These results are similar to those seen in the overall Cohort B, where mean percent improvement at Week 16 in PSSI was 87.6% vs 37.8% and in SSA was 86.6% vs 33.4% for guselkumab vs placebo groups, respectively. At Week 16 (Table 2), 69% of participants with low BSA receiving guselkumab achieved ss-IGA 0/1, whereas none receiving placebo did. In the overall Cohort B, 68% of the guselkumab group and 12% of the placebo group achieved ss-IGA 0/1.

Conclusion: After 3 doses of guselkumab, the majority of participants with moderate-to-severe scalp psoriasis but otherwise low total BSA involvement achieved similarly high levels of scalp clearance, as demonstrated by improvements in SSA, PSSI, and ss-IGA, as compared with the overall Cohort B (where the majority of participants had baseline BSA≥10%). These results show guselkumab to be an effective treatment for patients with moderate-to-severe scalp psoriasis regardless of the extent of overall body surface area involvement.

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Table 1. Baseline Demographics and Disease Characteristics of VISIBLE Cohort B Participants with Baseline BSA of ≥2 to <10 and Baseline IGA=3

	Placebo (n=7)	Guselkumab (n=26)	Total (n=33)
Age (years)	39.0 (11.73)	43.0 (14.98)	42.2 (14.28)
Gender Male, n (%)	4 (57.1%)	12 (46.2%)	16 (48.5%)
Race/ethnicity, n (%)			
Asian	6 (85.7%)	11 (42.3%)	17 (51.5%)
Hispanic or Latino	0	6 (23.1%)	6 (18.2%)
Black	0	3 (11.5%)	3 (9.1%)
Middle Eastern	0	3 (11.5%)	3 (9.1%)
American Indian or Alaska Native	0	1 (3.8%)	1 (3.0%)
Multi-racial	1 (14.3%)	1 (3.8%)	2 (6.1%)
Other	0	1 (3.8%)	1 (3.0%)
BMI (kg/m^2)	26.2 (4.95)	30.5 (7.46)	29.6 (7.16)
Psoriasis disease duration (years)	8.0 (8.18)	11.0 (10.04)	10.4 (9.63)
PASI Score (0-72)	8.4 (3.48)	6.7 (3.29)	7.1 (3.35)
BSA (%)	6.6 (1.51)	5.9 (1.74)	6.1 (1.69)
IGA score	3	3	3
PSSI score (0-72)	31.3 (12.82)	28.5 (9.10)	29.1 (9.84)
SSA (%)	55.4 (25.29)	52.5 (25.15)	53.1 (24.81)

Data are mean (SD) unless otherwise stated. BMI=Body Mass Index; BSA=Body Surface Area with disease; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PSSI= Psoriasis Scalp Severity Index; SD=standard deviation; SSA= Scalp Surface Area with disease

Table 2. Improvements in Scalp Psoriasis Measures at Week 16 with Guselkumab vs Placebo in VISIBLE Cohort B Participants with Baseline BSA of ≥2 to <10 and Baseline IGA=3

	Placebo	Guselkumab
n	7	25
PSSI % change from baseline, LS mean (95% CI)[a]	-29.39 (-53.28, -5.49)	-82.37 (-94.27, -70.47)***
n	6	25
SSA % change from baseline, LS mean (95% CI)[a]	-16.10 (-37.66, 5.46)	-85.26 (-96.10, -74.42)***
n	7	26
ss-IGA 0, n (%)[b]	0	13 (50.0%)*
ss-IGA 0/1, n (%)[b]	0	18 (69.2%)***

*Nominal P vs placebo<0.05; *** Nominal P vs placebo<0.001; BSA=Body Surface Area; CI=confidence interval; LS=least squares; PSSI=Psoriasis Scalp Severity Index; SSA=Scalp Surface Area with disease; ss-IGA=scalp-specific Investigator's Global Assessment, absence of disease (0) or very mild disease (1).
[a]LS means and P values determined using a Mixed-Effect Model Repeated Measures (MMRM) model.
[b]P values based on the Cochran-Mantel-Haenszel (CMH) test stratified by Fitzpatrick Skin Type (Type I-III/ Type IV-VI).[3]

P-031

CAVEATS IN INTERPRETING AND COMPARING LONG-TERM EFFICACY IN BIOLOGIC STUDIES FOR MODERATE-TO-SEVERE PLAQUE PSORIASIS

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Introduction: Comparisons of long-term efficacy of biologics in moderate-to-severe plaque psoriasis (PsO) clinical trials are confounded by inconsistent study designs and methods.

Objective: To examine study design features and the statistical methods used to handle missing data in long-term extension (LTE) studies.

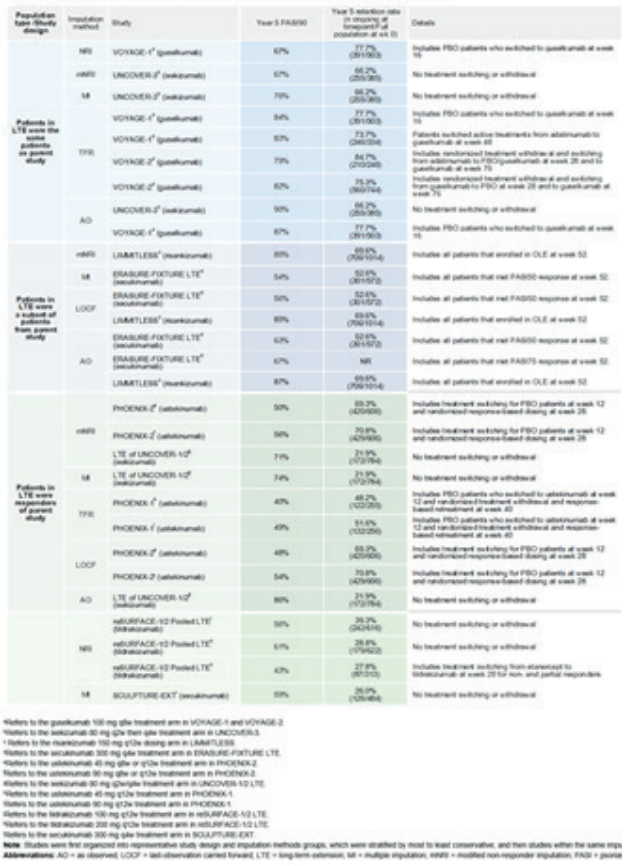
Methods: A systematic targeted literature review using Trialtrove© identified phase III clinical trials of biologics indicated for adults with PsO reporting efficacy outcomes >52 weeks published through 07/15/2022 for inclusion in a descriptive comparative analysis. After the search, additional reports published through 07/22/2023 were identified by a clinical expert review panel and added to the analysis.

Results: Across 23 LTE studies involving 11 biologic treatments, intention-to-treat (ITT) analysis (ie., continuous treatment with no responder-enrichment or LTE entry criteria) was used in 4 studies

and non-responder imputation (NRI) was used in 9 studies. For the 13 studies that reported 90% improvement in psoriasis area and severity index (PASI90) rates at 2 years with continuous treatment and approved dosing, 2 reported data with an ITT study design (UNCOVER 3, VOYAGE-1), 3 reported data with LTE entry criteria (ERASURE-FIXTURE LTE, LIMMITLESS), 4 reported data with responder enrichment (BE BRIGHT, PHOENIX-1, UNCOVER-1/2 LTE), and 4 reported data with both responder enrichment and LTE entry criteria (REVEAL OLE, SCULPTURE-EXT, reSURFACE 1/2 LTE). Few direct comparisons of long-term treatment efficacy were possible due to differences in reported imputation methods. For studies of any design with data through 5 years, 3 studies reported PASI90 data with NRI methods (VOYAGE-1, reSURFACE 1/2 LTE).

Conclusion: Substantial variability in study design and analytic methods were observed, limiting comparisons between studies. We suggest that standardization in future PsO LTE studies is necessary, to improve reporting and understanding of long-term outcomes.

Table 1. PASI90 data at five years across studies of all designs



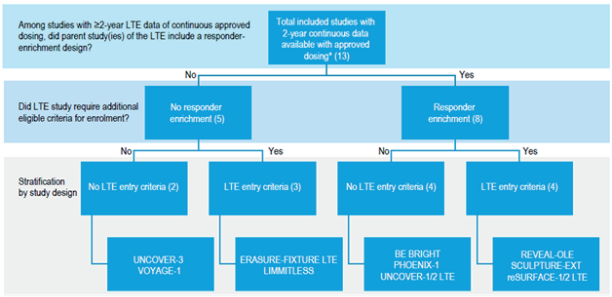


Figure 1. Flowchart of psoriasis study groupings for the descriptive comparative analysis of PASI90 rates among LTE studies with ≥2-years of continuous and approved dosing data

* 7 studies with 2-year data were excluded for lack of continuous data or unapproved dosing.
Abbreviations: AO = as-observed; LOCF = last observation carried forward; LTE = long-term extension; MI = multiple imputation; mNRI = modified non-responder imputation; NRI = non-responder imputation; PASI = psoriasis area and severity index; TFR = treatment failure rules.

P-032

TIME TO ONSET OF ACTION FOR BIOLOGICS AND TARGETED TREATMENTS IN PSORIASIS: SYSTEMATIC TARGETED LITERATURE REVIEW AND NETWORK META-ANALYSIS

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Introduction: Moderate to severe plaque psoriasis (PsO) is a chronic condition for which there is no "cure". For some patients, a rapid response (ie, short interval to time to onset of action [TOA]) is desirable.

Objectives: The primary objective was to determine time to achieve a PASI 90 response, on average (50% of patients), for individual biologics or targeted therapies. Secondary outcomes included the time to achieve a PASI 75 response, on average (50% of patients), as well as PASI 90 and PASI 75 responses over the first 16 weeks of therapy.

Methods: A systematic targeted literature review was conducted to identify phase III and IV randomized, double-blinded trials according to pre-specified eligibility criteria that investigated interleukin (IL)-12/23, IL-17, IL-23, Janus kinase (JAK), and phosphodiesterase (PDE) inhibitors. Proportions of patients achieving PASI 90 and PASI 75 responses at various timepoints up to 16 weeks from included trials were used to conduct network meta-analyses to estimate response over time. Response over time was presented in curves from week 0 through 16, and TOA was summarized as median time to reach the 50th percentile.

Results: Forty-five trials were included in the main analyses. IL-17 inhibitors were estimated to provide the earliest onset of PASI 90 response at approximately 6 to 8 weeks, followed by the IL-23 inhibitors risankizumab and guselkumab at approximately 9 to 10 weeks, and the IL-12/23 inhibitor ustekinumab at 11 to 12 weeks. Although, wide and overlapping credible intervals and similar point estimates were observed suggesting onset of action does not vary greatly across biologics in these classes, onset of PASI 90 response could not be estimated by the model for tildrakizumab, and JAK and PDE-4 inhibitors. Onset of PASI 75 response showed similar trends to PASI 90 response.

Conclusions: IL-17 inhibitors and IL-23 inhibitors have the most rapid time to onset of action among PsO biologics evaluated; any differences in onset of action between specific agents are not statistically or clinically significant. These analyses will allow clinicians to make more informed treatment decisions for their patients.

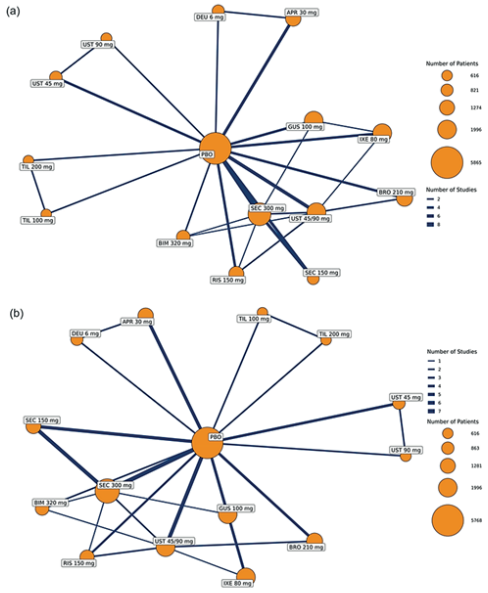

Figure 1: Evidence networks for (a) average time to achieve a PASI 90 response; (b) average time to achieve a PASI 75 response

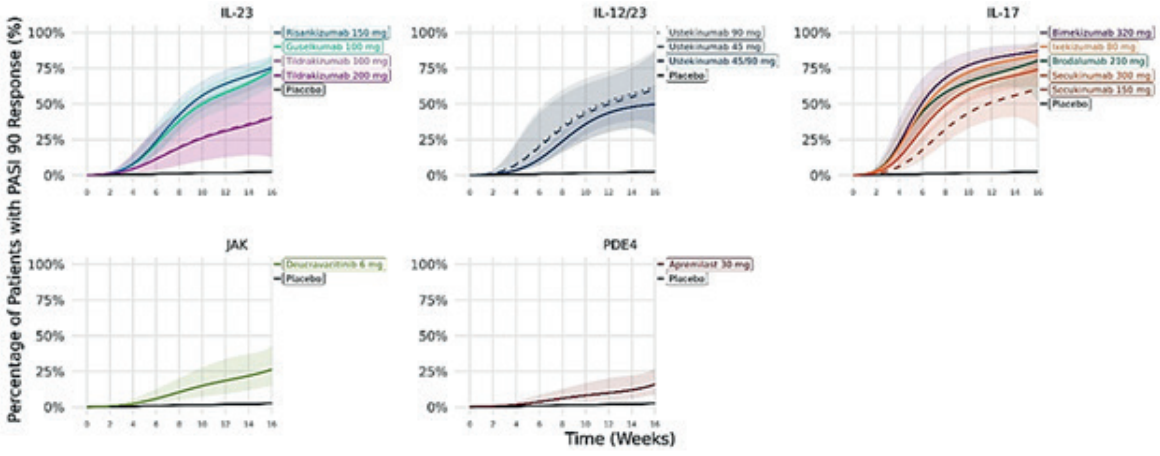

Figure 2: PASI 90 response curves over time up to week 16

P-033

DRUG SURVIVAL OF BIOLOGICS IN PLAQUE PSORIASIS PATIENTS: A SINGLE CENTER STUDY

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Background: Psoriasis is chronic immune-mediated inflammatory skin disease and biologics are currently being used to treat moderate-to-severe psoriasis. Many biologics have been developed and are in use, however comparative studies of these biologics are scarce and further research is needed.

Objective: To analyze the drug survival of biologics in the treatment of patients with plaque psoriasis.

Methods: This is a retrospective study that analyzed electronic medical records of 166 patients with plaque psoriasis who were treated with biologics at Chosun University Hospital between January 2013 and April 2023. Kaplan-Meier survival analysis was used for statistical analysis.

Results: The study included plaque psoriasis patients treated with biologics, specifically secukinumab ($n = 45$, 27.1%), adalimumab ($n = 3$, 1.8%), risankizumab ($n = 36$, 21.7%), ixekizumab ($n = 18$, 10.8%), ustekinumab ($n = 20$, 12.0%), and guselkumab ($n = 44$, 26.5%). Persistence rates for all biologics had declined, with persistence at year 3 being 93.2% for guselkumab, 91.7% for risankizumab, 66.7% for ixekizumab, 64.4% for secukinumab, 60% for ustekinumab, and 0% for adalimumab. Guselkumab and Risankizumab showed better results in drug survival for 3 years than Secukinumab and Ixekizamab. In some cases, biologics were discontinued or switched due to loss of response over time ($n = 22$) and the development of side effects ($n = 14$). This study has limitations, such as the varying launch dates of the biologics and the number of patients treated with biologics.

Conclusions: In this study, Guselkumab has demonstrated better drug survival results than other biologics. However, additional large-scale studies are required. The survival of all biologics declines over time, indicating the need for appropriate switching of biologics and development of new ones.

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P-034

SAFETY IN PATIENTS WITH LATENT TUBERCULOSIS WHO RECEIVED CONCOMITANT ANTI-TUBERCULOSIS MEDICATIONS: ANALYSIS OF 11 STUDIES OF GUSELKUMAB IN PSORIATIC DISEASE

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Introduction: Tuberculosis (TB) is a serious infection common in many regions worldwide.(1) Certain psoriatic disease treatments, including tumor necrosis factor-α inhibitors (TNFi), increase risk of latent TB infection (LTBI) activation.(2,3) Current psoriatic disease treatment guidelines recommend TB screening before initiating systemic therapy.(4,5)

Objectives: To report safety outcomes in LTBI+ patients with moderate-to-severe psoriasis (PsO) or active psoriatic arthritis (PsA) who received guselkumab treatment for up to 5 years.

Methods: Safety data were pooled from 11 phase 2/3 studies (7 PsO, 4 PsA). Guselkumab was generally administered as 100-mg subcutaneous injections at Week (W)0, W4, then q8w in PsO studies and W0, W4, then q4w or q8w in PsA studies. Patients randomized to placebo crossed over to guselkumab at W16 and W24 in the PsO and PsA studies, respectively. All patients were screened for TB at baseline. Patients with active TB were excluded. Patients with LTBI were eligible to participate if appropriate LTBI treatment was to be initiated prior to/with the first study drug administration or if appropriate treatment had been completed within 5 years. Safety was reported for the placebo-controlled period, year-by-year, and through the end of follow-up (PsO, up to 5 years; PsA, up to 2 years).

Results: Among all randomized patients, 10.0%(70/697) from Asia-Pacific, 7.3%(51/698) from Western Europe, 7.3%(179/2453) from Eastern Europe, and 5.3%(74/1407) from North America had LTBI. LTBI treatment initiation occurred prior to (88.2%[330/374]), with (6.1%[23/374]), or after (5.6%[21/374]) the first dose of study drug (median, -8.0 days; interquartile range, -20.0 to -2.0). LTBI treatments included isoniazid (82.1%), rifampicin (11.8%), and other medications (17.4%); 89.8% received monotherapy. No new-onset TB or LTBI activation was observed in any guselkumab-treated patient. During the placebo-controlled period, rates of adverse events (AEs) and serious AEs were similar for guselkumab- and placebo-treated patients in the LTBI+ and LTBI- groups (Table 1). Through the end of follow-up, guselkumab-treated LTBI+ and LTBI- patients had similar cumulative rates of AEs and serious AEs. Through Year 1, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) elevations were more common in the LTBI+ versus LTBI- group; ≤2% of LTBI+ patients had CTCAE Grade 3 elevations versus 0.5% of LTBI- patients (no LTBI+ patients had Grade 4 elevations) (Table 2). From Year 1-5 (after ~98% of LTBI+ patients completed prophylaxis [median (interquartile range) treatment duration $n = 185$ (124-274) days]), proportions of LTBI+ patients with elevated ALT/AST were generally similar to the LTBI- group.

Conclusions: No cases of new-onset TB or LTBI activation were observed in up to 5 years of treatment with guselkumab. Guselkumab safety was generally similar in LTBI+ and LTBI- patients. Consistent with the known safety of LTBI medications,(6) ALT/AST elevations were more common in LTBI+ versus LTBI- patients through Year 1; however, ≤2% of LTBI+ patients had Grade 3 elevations and 0 had Grade 4 elevations. Rates of ALT/AST elevation were generally similar in LTBI+ and LTBI- patients post-LTBI treatment. The absence of observed TB risk in guselkumab-treated patients suggests guselkumab may be a better treatment option than TNFi in high-risk patients, including those in TB-endemic regions.

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Table 1. Safety in Guselkumab-Treated LTBI+ and LTBI- Patients

	Placebo-Controlled Period				Through End of R
	Placebo		Guselkumab		All Gusel
	LTBI+	LTBI-	LTBI+	LTBI-	LTBI+
Treated patients, N	71	990	188	2069	313
Mean duration of follow-up, weeks	19.6	19.4	20.2	19.8	129.0
Mean exposure (no. of administrations)	6.8	7.4	7.0	7.2	24.9*
Patients with active TB, n	0	0	0	0	0
Patients with ≥1 AE, n (%)	33 (46.5%)	475 (48.0%)	90 (47.9%)	999 (48.3%)	227 (72.5%)
Patients with ≥1 serious AE	2 (2.8%)	23 (2.3%)	4 (2.1%)	42 (2.0%)	38 (12.1%)

*LTBI+, N=310; LTBI-, N=3909 (data not available for the PsO Phase 3 Japan registration study).

Table 2. Guselkumab-Treated Patients With Elevated ALT and AST by Year*

	Through Year 1		Year 1 Through Year 2		Year 2 Through Year 3		Year 3 Through Year 4		Year 4 Through Year 5	
	LTBI+	LTBI-	LTBI+	LTBI-	LTBI+	LTBI-	LTBI+	LTBI-	LTBI+	LTBI-
Patients with increased ALT, n (%)										
N	296	3846	238	3128	155	1798	93	1096	83	1048
CTCAE Grade 1	114 (38.5%)	1232 (32.0%)	53 (22.3%)	702 (22.4%)	29 (18.7%)	330 (18.4%)	18 (19.4%)	234 (21.4%)	20 (24.1%)	194 (18.5%)
CTCAE Grade 2	10 (3.4%)	74 (1.9%)	1 (0.4%)	31 (1.0%)	1 (0.6%)	16 (0.9%)	0	9 (0.8%)	2 (2.4%)	3 (0.3%)
CTCAE Grade 3	6 (2.0%)	20 (0.5%)	1 (0.4%)	8 (0.3%)	0	1 (0.1%)	1 (1.1%)	1 (0.1%)	0	3 (0.3%)
CTCAE Grade 4	0	0	0	0	0	0	0	0	0	0
Patients with increased AST, n (%)										
N	296	3846	237	3117	155	1792	93	1093	82	1046
CTCAE Grade 1	93 (31.4%)	849 (22.1%)	38 (16.0%)	412 (13.2%)	17 (11.0%)	189 (10.5%)	15 (16.1%)	120 (11.0%)	12 (14.6%)	95 (9.1%)
CTCAE Grade 2	9 (3.0%)	69 (1.8%)	0	24 (0.8%)	1 (0.6%)	7 (0.4%)	1 (1.1%)	3 (0.3%)	1 (1.2%)	3 (0.3%)
CTCAE Grade 3	5 (1.7%)	20 (0.5%)	1 (0.4%)	11 (0.4%)	2 (1.3%)	4 (0.2%)	0	3 (0.3%)	0	3 (0.3%)
CTCAE Grade 4	0	1 (<0.1%)	0	0	0	0	0	0	0	0

CTCAE, United States National Cancer Institute Common Terminology Criteria for Adverse Events.
*Results do not include data from the PsO Phase 2 X-PLORE study, which did not report CTCAE toxicity grading.

P-035

CLINICAL PREDICTORS OF IL-17 AND IL-23 INHIBITORS DOSE SPACING IN ADULT PSORIATIC PATIENTS: A REAL-WORLD PILOT STUDY

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Introduction & Objectives: De-escalation strategies of biologics in psoriasis treatment are widespread in clinical practice. Dose spacing (D-S) consists of de-escalating the time range between biological drug injections. This strategy could both reduce treatment costs and increase patients' compliance with therapy after an initial stable response.

Materials & Methods: A retrospective cohort study from January 2017 to December 2022 was conducted at the dermatologic clinic of the University of Turin.

All consecutive adult psoriatic patients undergoing D-S of IL-23 and IL-17 inhibitors were enrolled.

Major objectives were: to identify phenotypic characteristics related to the selection of patients candidable for therapeutic D-S; describe trends in mean PASI, PASI100, PASI90, and PASI<=1

from baseline to 12 months after D-S, and drug survival analysis of dose-spaced regimen.
Pre-post analysis between mean PASI at dose spacing and baseline, and time points following dose-spacing 3, 6, 9, and 12 months was also conducted.
Results: Of 1144 patients treated with IL-23 and IL-17 inhibitors 61 patients underwent D-S. They presented with less mean baseline Body Mass Index (BMI) ($p = 0.011$) and PASI (Psoriasis Area Severity Index) ($p = 0.044$) and were more frequently bio-experienced ($p = 0.033$).
After 12 months from dose-spacing 42.9%, 85.7%, and 92.9% of observed patients achieved PASI 100, 90, and ≤1.
There were no significant differences in mean PASI between D-S and subsequent time points. The D-S survival was 70% at 1 year.
Conclusion: Therapeutic modulation, such as D-S, is an effective strategy in most psoriasis patients showing a clear or almost clear response of the skin, maintained over time.
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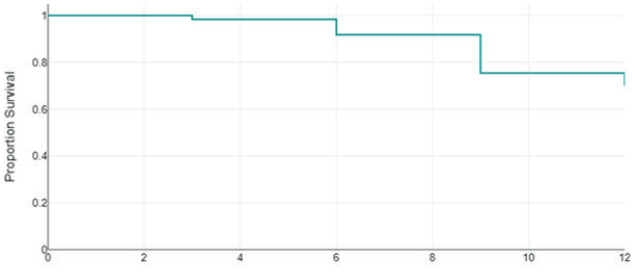

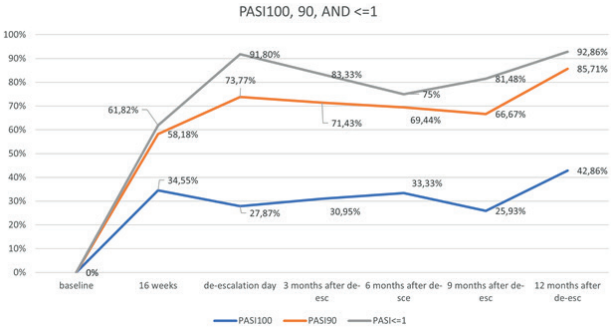

P-036

COMPARISON OF THE DRUG SURVIVAL OF INTERLEUKIN (IL)-17 AND IL-23 INHIBITORS FOR THE TREATMENT OF PSORIASIS: A TWO-CENTER STUDY

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Introduction: Recent years, biologics targeting IL-17 and IL-23 were prescribed as the latest and most effective treatment to manage moderate-to-severe chronic psoriasis. However, real world data comparing drug survival and efficacy of these agents in daily practice are lacking.
Objectives: This study aims to assess the drug survival, efficacy and safety between anti-IL23 and anti-IL17 biologics and each biologics (Guselkumab, Secukinumab, Ixekizumab, Risankizumab).
Methods: This is a retrospective cohort study involving patients with moderate to severe psoriasis who have treated with one of 4 biologics (Guselkumab, Secukinumab, Ixekizumab, Risankizumab) in Kyung Hee University Hospital and Kyung Hee University hospital at Gang-dong from 2018 to 2022. Drug survival was assessed with Kaplan–Meier survival analysis and Cox regression analysis.
Results: A total of 211 treatment courses (total patients: 176) were included in this analysis. The cumulative survival rate of anti-IL23 and anti-IL17 biologics at 18 months were 73.5%, 72.8%. The cumulative survival rate of each biologics at 18 months were 66.3% for guselkumab, 64.5% for secukimab, 85.6% for ixekizumab, 92.6% for risankizumab. There was no significant difference in drug survival between anti-IL23 and anti-IL17 biologics. Using secukinumab as reference, survival of risankizumab and ixekizumab was statistically significantly higher. Prior exposure to TNF-inhibitor significantly increased risk of drug discontinuation, while presence of psoriatic arthritis was protective.
Conclusion: In this two-center retrospective cohort study, every biologics' cumulative survival rate at 18 months were over 60%. Both anti-IL17 and anti-IL23 appeared to have same drug survival and efficacy. It is important to make a choice based on patient and provider preferences.
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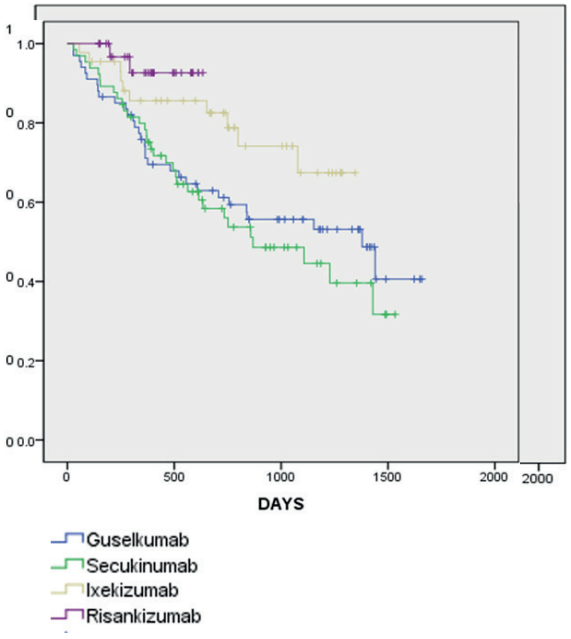

P-037

EFFECTIVENESS AND SAFETY OF RISANKIZUMAB DOSE OPTIMIZATION IN ADULT PATIENTS WITH PLAQUE PSORIASIS: AN INTERNATIONAL MULTICENTER RETROSPECTIVE COHORT STUDY

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Introduction: Psoriasis, a chronic autoimmune disease, poses significant physical and psychological challenges to those affected. Risankizumab, an interleukin-23 inhibitor, has shown marked effectiveness in controlled trials and has maintained its efficacy in real-world studies. However, existing studies primarily focus on risankizumab's performance under approved dosing schedules, leaving its potential in dose-optimized scenarios unexplored. This gap is particularly relevant as dose optimization becomes a focal point in psoriasis management, prompting the need for a comprehensive evaluation of risankizumab's effectiveness and safety in such contexts.

Methods: We conducted an international, multicentre retrospective study of patient charts from academic dermatology clinics in Canada and Portugal. Patients included in this study were adults aged ³18 years diagnosed with moderate-to-severe plaque psoriasis. All participants initially received risankizumab at standard dosing, with subsequent adjustments to dose frequency tailored to individual patient needs. Effectiveness was measured by achieving a Psoriasis Area and Severity Index (PASI) improvement of e90% (PASI90) or a Physician Global Assessment (PGA) of clear (0) or almost clear (1). Safety assessments included adverse event reports and discontinuation rates.

Results: The study involved 82 patients, predominantly male (63.4%), with a mean age of 51.4 years. Before risankizumab, patients were primarily treated with adalimumab, guselkumab, and ustekinumab. At the time of dose optimization, patients had an initial mean PASI score of 3.7, with the average time on risankizumab prior to dose optimization being 212.2 days. The majority of our patients were optimized to receive psoriasis every 8 weeks (72%, 59/82), and most patients were optimized due to lack of desired efficacy. A minor subset of our cohort preferentially chose to prolong their dosing schedule (4.8%, 4/82).

Conclusion: After dose optimization, 90.2% (74/82) of our patients achieved PASI90 or PGA 0/1. Additionally, 37.8% (31/82) of our patients achieved PASI100. Adverse events were uncommon, with only 3 patients reporting at least one adverse event, and only one case (alopecia) resulting in risankizumab's discontinuation. One adverse event was also reported as an isolated thrombosis event, which upon further work-up was found to be unrelated to risankizumab. Discontinuation was reported in 18.3% (15/82) of patients, with 73% (11/15) of them being due to lack of efficacy. Dose optimization has been documented in literature for other biologics in psoriasis treatment, which conclude that this is a safe approach to enhancing patients who are otherwise not achieving satisfactory outcomes. The outcomes of our current study reaffirm these previous findings, with the added novelty of investigating this approach with risankizumab. Additionally, both increasing and decreasing the dosing interval, beyond the standard dosing, yielded favourable outcomes. Despite limitations like patient heterogeneity and sample size, these findings advocate for further, more controlled research to validate dose optimization as a viable strategy in psoriasis therapy with risankizumab.

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P-038

REAL-WORLD EFFECTIVENESS AND SAFETY OF RISANKIZUMAB IN ADULT PATIENTS WITH PLAQUE PSORIASIS: A 16-WEEK INTERNATIONAL MULTI-CENTER RETROSPECTIVE COHORT STUDY

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Introduction: The UltIMMa-1 and UltIMMa-2 phase 3 trials established the efficacy of risankizumab in treating moderate-to-severe psoriasis, yet real-world data on its effectiveness and safety remain limited. This knowledge gap is particularly relevant considering the divergence in patient profiles between controlled trials and the real-world setting, where comorbidities and systemic medication use are more prevalent. This study presents the 16-week real-world outcomes of risankizumab in treating moderate-to-severe plaque psoriasis.

Methods: In this international, multi-centre retrospective study, moderate-to-severe psoriasis patients from academic dermatology clinics in Canada and Portugal were included. Included patients were aged ≥18 years and received risankizumab for at least 16 consecutive weeks of treatment. Effectiveness was assessed by

the achievement of a 90% improvement in the Psoriasis Area and Severity Index (PASI90) or a Physician Global Assessment (PGA) of clear (0) or almost clear (1) at 16 weeks. Safety was evaluated through reported adverse events and discontinuation rates.
Results: The cohort consisted of 388 patients with a mean age of 51.9, 60.8% (236/388) of whom were male. The baseline mean PASI score was 12.7, with methotrexate and adalimumab being the most common prior systemic and biologic treatments, respectively. Concomitant systemic therapy was present in 5.2% (20/388) of the cohort, with methotrexate being the most commonly used concomitant medication (35%, 7/20). Following 16 weeks of risankizumab, 75% (291/388) of our patients achieved a PASI90 or PGA 0/1 (287/388). Notably, PASI100 was achieved by 38.4% (149/388) of our patients. Adverse events were reported in 1.9% (7/388) of patients, leading to discontinuation in cases of dermatitis and diarrhea. Overall, 8 patients discontinued risankizumab, 5 due to loss of efficacy.
Conclusion: This study confirms risankizumab's efficacy in a real-world setting, even among patients with comorbidities and on concomitant medications, mirroring the success rates observed in clinical trials. It represents the first real-world risankizumab study with a multinational cohort of a size comparable to those of controlled trials. However, our study remains limited by the heterogeneity of our patient population and the absence of a comparator control group. Additional investigations with control populations are necessary.
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P-039

REAL-WORLD EFFECTIVENESS AND SAFETY OF RISANKIZUMAB IN ADULT PATIENTS WITH PLAQUE PSORIASIS: A 1-YEAR INTERNATIONAL MULTI-CENTER RETROSPECTIVE COHORT STUDY

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Introduction: Risankizumab has been established as clinically superior to ustekinumab and adalimumab through controlled trials, particularly in achieving a 90% improvement in the Psoriasis Area and Severity Index (PASI90) and a Physician's Global Assessment (PGA) of clear (0) or almost clear (1) for patients with moderate-to-severe psoriasis. However, these trials often do not fully encapsulate the comorbidities and treatment complexities frequently encountered in the real-world patient population. Consequently, there is a crucial need for real-world data to evaluate risankizumab's effectiveness and safety in a broader, more representative patient cohort. This study aims to address this gap by assessing the 1-year outcomes of risankizumab in treating moderate-to-severe psoriasis in a real-world context.
Methods: Our international multicenter retrospective analysis included adult patients (≥18 years) from tertiary academic clinics, in Canada and Portugal, diagnosed with moderate-to-severe psoriasis. Successful respondents were patients who achieved PASI90 or PGA 0/1 at the 1-year follow-up period, and safety was assessed via reported adverse events and discontinuation cases.
Results: This analysis included 291 patients, with the mean age being 50.7, and males composing 62.5% (182/291) of the cohort. Biologically-naïve patients represented 56.4% (164/291) of patients, and 6.5% (19/291) utilized concomitant systemic therapy in conjunction with risankizumab. At 1-year of follow-up 90.7% (264/291) of patients achieved PASI90 or PGA 0/1, and 56.4% (164/291) achieved PASI<1. Adverse events were rare, with only 4.5% (13/291) reporting at least one adverse event. Fatigue was reported as the most common adverse event (23%, 3/13), and none of the adverse events were severe. Furthermore, discontinuation events were also rare with 7.9% (23/291) discontinuing risankizumab, none of which were due to adverse events.
Conclusion: In summarizing our findings, risankizumab has demonstrated notable effectiveness and safety in a real-world cohort of patients with moderate-to-severe psoriasis over a 1-year period. These results contribute valuable perspectives on the drug's utility in managing a condition that presents with diverse clinical presentations and comorbidities, more reflective of everyday clinical scenarios than controlled trial environments. While our data suggest promising outcomes, it is essential to interpret these findings within the context of the study's limitations, including the heterogeneity of the patient population and the absence of a comparator group. Consequently, the pursuit of further studies, ideally incorporating control groups while maintaining a broad array of patient demographics, is imperative to validate and extend our understanding of risankizumab's real-world efficacy and safety.
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P-040

THE EFFICACY AND SAFETY OF SWITCHING BETWEEN INTERLEUKIN INHIBITORS IN PSORIASIS THERAPY: A SYSTEMATIC REVIEW

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Introduction: Biologic therapy has increasingly been adopted in dermatological practice, especially for managing moderate-to-severe psoriasis. While the literature endorses the practice of transitioning between different generations of biologics, the efficacy and safety of switching within the same class of biologics remains understudied. Interleukin (IL) inhibitors, a newer generation class of biologics used in psoriasis therapy, are at the forefront of this inquiry. This systematic review aims to address this knowledge gap by analyzing the efficacy and safety outcomes of switching between IL inhibitors in the treatment of psoriasis.
Methods: Following PRISMA guidelines, a search of OVID's MEDLINE and Embase databases was conducted. The evidence quality was appraised using the Oxford Centre for Evidence-Based Medicine Levels of Evidence. Thirteen articles were included after screening, involving 665 patients (mean age 53.9; 64.4% male) treated with IL-17 (596 patients) and IL-23 (69 patients) inhibitors. Efficacy was measured by the achievement of PASI90 or a Physician's Global Assessment (PGA) score of 0 or 1. Safety was evaluated based on reported adverse events.
Results: The analysis indicated that primary and secondary failures were the main reasons for switching within the IL-17 inhibitors group, with 61.4% (366/596) and 20% (119/596) of patients switching due to these reasons, respectively. For IL-23 inhibitors, primary and secondary failures were also the sole reasons for switching. Post-switch, 60.6% (361/596) of the IL-17 inhibitor group and 26% (18/69) of the IL-23 inhibitor group achieved PASI90. Additionally, 80% (329/411) of patients in the IL-17 group and 76% (10/13) in the IL-23 group reached a PGA score of 0 or 1. Adverse events were minimal, with injection site reactions reported in 1.8% (12/665) of patients.
Conclusion: This review demonstrates that switching between IL inhibitors is a viable option for patients unresponsive to their initial biologic treatment, with a favourable safety profile. The potential role of genetic polymorphisms in IL-17 and IL-23 receptor genes may explain the variability in treatment responses, although this area requires further investigation.
The study is limited by data heterogeneity and a small sample size, underscoring the need for larger, more controlled studies to solidify these findings. This systematic review confirms the practicality of intra-class biologic switching and highlights the importance of continued research to optimize treatment strategies for psoriasis.

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P-041

HOW SATISFIED ARE PSORIASIS PATIENTS WITH THEIR TREATMENT? RESULTS FROM A PROSPECTIVE OBSERVATIONAL STUDY

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Introduction: Treatment satisfaction is defined as the degree to which patients perceive that their treatment fulfils their health needs. It is a predictor of adherence and influences patient outcomes. In chronic diseases, such as psoriasis, treatment satisfaction is an essential driver of disease control. Despite the increasingly effective treatments, up to 40% of patients are non-adherent and treatment dissatisfaction is thought to contribute towards this.
Objectives: To describe the characteristics of the psoriasis participants, their treatment, and results from the Treatment Satisfaction Questionnaire for Medication-9 (TSQM-9) in the HIPPOCRATES Prospective Observational Study (HPOS).
Methods: HPOS is a prospective observational online study of adults with psoriasis, with the aim to identify patients at risk of developing psoriatic arthritis (PsA). Inclusion criteria includes presence of psoriasis, >18 years old and no diagnosis of PsA. It was launched in the United Kingdom and Ireland in 2023 and is being widely advertised via emails, newspaper articles, NHS app, social media, and radio.
Participants were asked to complete online questionnaires covering demographics, self-reported psoriasis activity and the Psoriasis Epidemiology Screening Tool (PEST). Those who were PEST negative (score<3) were asked to complete the Treatment Satisfaction Questionnaire for Medication-9 (TSQM-9). The questionnaires are repeated every 6 months for 3 years. Satisfaction across the different components of the TSQM-9 and the different treatment modalities were evaluated through a Student t-test.
Results: Of the 1224 psoriasis participants who enrolled in 2023, the majority were female (63%, 772/1224) and had mean age 51 years (standard deviation 14.7). Half (50%, 529/1049) reported having a family history of psoriasis. Table 1 summarises the pattern and severity of the psoriasis reported; the majority had mild to moderate psoriasis.
Of those participants who were PEST negative, 475 answered the TSQM-9. Table 2 summarises the different components of the TSQM-9 globally and across the different treatment modalities. Most participants (67%, 317/475) were on topical treatment, with only 5% ($n = 26$) on oral medications, 11% ($n = 51$) on biologic/ injectable medications, 15% ($n = 73$) were not on any treatment, and 2% ($n = 8$) did not report their treatment option. Convenience of treatment modality scored higher than global satisfaction and effectiveness, with biologic/ injectables scoring the highest in all the domains, followed by oral medications and then topical treatments ($p < 00.1$).
Conclusion: In the HPOS cohort, participants mainly had mild to moderate psoriasis and were mostly on topical treatments. In line with other studies [1, 2], we found that those who were taking biologic/ injectables had the highest satisfaction scores across all domains (convenience, global satisfaction and effectiveness. Optimising satisfaction with treatment is crucial to improve adherence; dissatisfaction may result in non-adherence, which in turn may be misinterpreted as treatment failure and lead to an otherwise effective treatment being discontinued [3].
Funding: HIPPOCRATES has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement no. 101007757. The JU receives support from the European Union's Horizon 2020 research and innovation program and EFPIA.

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Table 1: Description of psoriasis

	n (%)
Type of psoriasis	
Scalp	660 (54)
Plaque	598 (49)
Guttate	292 (24)
Inverse	163 (13)
Palmoplantar pustulosis	88 (7)
Psoriasis redness (n=953)	
0 (absent)	71 (7)
1 (mild)	334 (35)
2 (moderate)	223 (23)
3 (severe)	218 (23)
4 (very severe)	107 (11)
Psoriasis scaling (n=955)	
0 (absent)	41 (4)
1 (mild)	324 (34)
2 (moderate)	279 (29)
3 (severe)	243 (25)
4 (very severe)	68 (7)
Psoriasis thickness (n=952)	
0 (absent)	130 (14)
1 (mild)	450 (47)
2 (moderate)	258 (27)
3 (severe)	88 (9)
4 (very severe)	26 (3)
Psoriasis nail (n=1224)	
Psoriasis nail disease present	698 (57)
Nail pitting	345 (28)
Onycholysis	146 (12)

Table 2: Treatment Satisfaction Questionnaire for Medication-9 (TSQM-9)

Component	All treatments[2] (n=475) Mean (standard deviation)	No treatment (n=73) Mean (standard deviation)	Topicals (n=317) Mean (standard deviation)	Oral medications (n=26) Mean (standard deviation)	Biologic/ injectables (n=51) Mean (standard deviation)	P values[3]
Global satisfaction[1]	49.4 (23.1)	41.4 (21.6)	47.9 (22.0)	53.8 (19.9)	68.8 (22.9)	< 0.001
Effectiveness[1]	50.6 (22.6)	42.5 (22.8)	47.5 (19.2)	61.8 (21.7)	77.0 (21.9)	< 0.001
Convenience[1]	60.6 (22.1)	55.9 (20.6)	57.7 (21.4)	72.4 (16.8)	79.2 (20.1)	< 0.001

[1]TSQM-9 components ranges from 0 to 100, where 100 means maximum satisfaction. [2]From the 475 participants who replied the TSQM-9 questionnaire, 8 did not report their treatment option. [3]P values were calculated using a Student t-test comparison across different treatment options (i.e., no treatment, topicals, oral medications and biologic/ injectables, adjusting for multiple comparisons).

P-042

EFFICACY AND SAFETY OF ADDING FUMARIC ACID ESTERS IN PSORIATIC PATIENTS RECEIVING TNF-ALPHA BLOCKERS WHO FAILED TO REACH PASI 75

No consent given to publish in scientific journal.

P-043

CARDIOVASCULAR SAFETY OF USTEKINUMAB VERSUS ETANERCEPT IN PSORIASIS: RESULTS FROM AN OBSERVATIONAL POST-AUTHORIZATION SAFETY STUDY BASED ON SWEDISH NATIONAL REGISTERS

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Introduction: There is substantial epidemiologic evidence that psoriasis (PsO) and psoriatic arthritis (PsA) are associated with a higher prevalence of cardiovascular risk factors and an increased risk of cardiovascular disease. Evidence from real-world settings on the comparative cardiovascular safety of available biologic treatments for PsO and PsA remains limited, however.

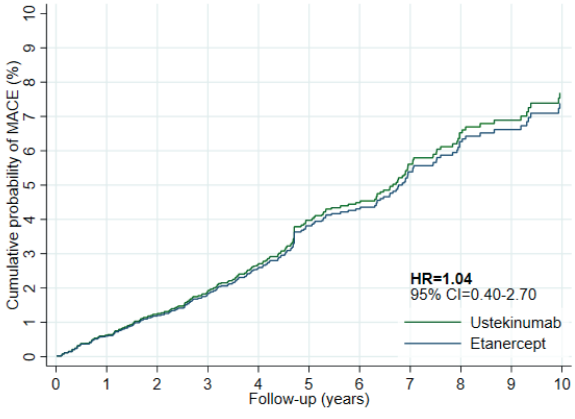
Objectives: The primary objective of this post-authorization safety study (EUPAS49873) was to estimate and compare the long-term risk of major adverse cardiovascular events (MACE) in PsO and PsA patients initiating treatment with ustekinumab relative to patients initiating treatment with etanercept in routine clinical practice.

Methods: This observational cohort study based on an active-comparator, new-user design, used patient-level data from Swedish population-based national registers. Biologic-naïve adult patients (≥18 years) diagnosed with PsO and/or PsA who initiated treatment with either ustekinumab or etanercept between July 2009 and 30 December 2021 were included, with patients allocated to mutually exclusive cohorts based on first drug initiated during the inclusion period. The primary outcome was incident MACE, defined as myocardial infarction, ischemic stroke, or cardiovascular-related death. Patients were followed from initiation of treatment until MACE, death, emigration, or end of study period, whichever came first. Adjusted hazard ratios (HR) were estimated using cause-specific Cox proportional hazards regression models with stabilized inverse probability of treatment weighting (IPTW) by propensity scores. A broad range of potential confounding factors were adjusted for, including e.g., age, sex, education level, marital status, presence of PsA, as well as cardiovascular risk factors such as obesity, diabetes, dyslipidemia, hypertension, and history of MACE. A robust variance estimator was used to account for the within-subject correlation introduced through the weighting. Standardized differences were used to assess balance of baseline characteristics achieved in the weighted population, with standardized differences<10% required for all variables. Several predefined sensitivity and subgroup analyses were performed to test the robustness of results and investigate potential effect modification.

Results: In total, 525 biologic-naïve ustekinumab and 4,888 biologic-naïve etanercept patients were eligible for inclusion. Mean (SD) age was 50.4 (15.6) years in the ustekinumab cohort and 50.5 (14.0) years in the etanercept cohort, 38.3% and 51.1% were female, respectively, and 23.8% and 72.5% of patients had a diagnosis of PsA, respectively. A total of 21 and 191 MACE events were observed in the ustekinumab and etanercept cohorts during a mean (SD) of 5.0 (3.1) and 5.4 (3.0) years of follow up, respectively, corresponding to crude incidence rates of 0.79 (95% CI: 0.52–1.22) and 0.72 (95% CI: 0.63–0.83) per 100 person years. The IPTW-adjusted HR of MACE comparing ustekinumab vs. etanercept was 1.04 (95% CI: 0.40–2.70; p-value: 0.93). Similarly, there were no significant differences in risk of MACE across any of the pre-specified sensitivity or subgroup analyses.

Conclusions: In this nationwide study of Swedish PsO and PsA patients treated with ustekinumab or etanercept spanning more than ten years, the overall risk of MACE was low and no significant difference in risk of MACE between the two treatments was observed.

Figure 1. IPTW-adjusted survival curves, HR with 95% CI; ustekinumab vs. etanercept



P-044

BIOLOGICS FOR PALMOPLANTAR PSORIASIS AND PALMOPLANTAR PUSTULOSIS: A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS

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Introduction: The comparative efficacy of biologics in treating palmoplantar psoriasis (PP) and palmoplantar pustulosis (PPP) remains ambiguous.

Objectives: This study aims to conduct a systematic review and network meta-analysis (NMA) to compare the efficacy of biologics for the treatment of PP and PPP.

Methods: This NMA was conducted and reported following the Preferred Reporting Items for Systematic Reviews and Meta-analyses Extension Statement for Network Meta-Analyses guidelines. MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials were systematically searched for relevant studies from inception up to January 22, 2023. Two authors independently screened titles, abstracts, and full-text articles to identify potential randomized controlled trials. Out of the initially identified studies, 1.4% met our inclusion criteria. Frequentist random-effects models NMA was performed with the surface under the cumulative ranking curve calculated for ranking. Our primary outcome was the proportion of patients achieving a clear/minimal Palmoplantar Psoriasis/Pustulosis Physician Global Assessment score (PPPGA 0/1 or PPPPGA 0/1) response at 12 to 16 weeks. The secondary outcome was the percentage of palmoplantar score improvement at 12 to 16 weeks.

Results: The study comprised a total of 24 randomized controlled trials (RCTs), involving 4,037 psoriasis patients with palmoplantar diseases. Regarding PP, 10 RCTs with 8 different treatments including adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, and ustekinumab were included for the analysis. In the NMA of PP, secukinumab 300 mg ranked highest (odds ratio [OR] 33.50, 95% confidence interval [CI] 4.37–256.86) in achieving PPPGA 0/1, followed by guselkumab 100 mg (OR 18.68, 95% CI 10.07–34.65). For PPP, a total of 7 RCTs with 5 treatments including etanercept, guselkumab, imsidolimab, spesolimab, and ustekinumab were included for the analysis. In the NMA of PPP, although no treatment demonstrated a significant difference compared to placebo in achieving PPPPGA 0/1, guselkumab 100 mg exhibited the most significant improvement in the palmoplantar score (weighted mean difference 31.73, 95% CI 19.89–43.57) as a secondary outcome.

Conclusions: Among all available biologics for PP, secukinumab 300 mg demonstrated the best clinical efficacy in the achievement of PPPGA 0/1 at 12 to 16 weeks. In the case of PPP, guselkumab 100 mg presented the greatest improvement of the palmoplantar score at 12 to 16 weeks.

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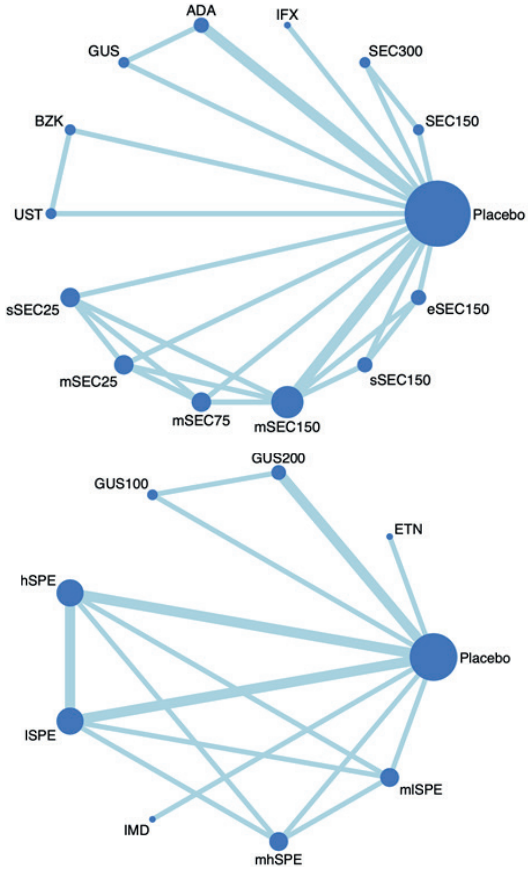

P-045

PATIENT-REPORTED WELL-BEING USING TILDRAKIZUMAB IN A REAL-WORLD SETTING: 52-WEEK INTERIM DATA OF THE PHASE IV POSITIVE STUDY

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Introduction: Psoriasis is a chronic inflammatory disease that profoundly impairs patients' social, emotional, functional, and physical condition as well as their families', impacting on their

overall well-being (1). An effective management and control of the disease can help maintaining long-term well-being. Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety (2,3).
Objectives: The objective of this analysis was to assess the effect of tildrakizumab on the overall well-being of patients with moderate-to-severe psoriasis treated with tildrakizumab in routine care.
Methods: POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis treated with tildrakizumab (4). Participant countries are Austria, Belgium, France, Germany, Italy, Spain, Switzerland, The Netherlands, and United Kingdom. Well-being was assessed through the 5-item WHO Well-being Index (WHO-5). The overall score ranges from 0 to 100, where 0=absence of well-being and 100=maximal well-being (5). As a reference, the mean WHO-5 score in the general population of the countries participating in the POSITIVE study was calculated to be 64.9 (6), and was 52.2 among women with breast cancer or 51.4 among patients with diabetes with distress (7, 8). The threshold for a clinically relevant change is considered to be 10 points (5). Here, we report 52-week interim data using an observed cases approach.
Results: A total of 400 patients were included (63.3% male, mean ± 95%CI age of 46.5 ± 1.5 years, mean body mass index of 28.4 ± 0.6 kg/m², 72.5% biologic-naïve patients). Mean ± 95%CI time since psoriasis diagnosis was 15.1 ± 1.3 years. Mean ± 95%CI WHO-5 score significantly increased from 53.8 ± 2.2 at baseline to 65.2 ± 2.2 at week 16 ($p < 0.0001$; mean change from baseline of 11.3), to 66.0 ± 2.3 at week 28 ($p < 0.0001$; mean change from baseline of 11.5), and to 65.7 ± 2.7 at week 52 ($p < 0.0001$; mean change from baseline of 11.1). The mean ± 95%CI individual WHO-5 item scores at baseline, week 16, and week 52 were 11.6 ± 0.5, 14.2 ± 0.5, and 14.3 ± 0.5 for "I have felt cheerful and in good spirits", 10.7 ± 0.5, 13.4 ± 0.5, and 13.4 ± 0.6 for "I have felt calmed and relaxed", 10.4 ± 0.6, 12.7 ± 0.5, and 12.6 ± 0.6 for "I have felt active and vigorous", 9.5 ± 0.6, 11.6 ± 0.6, and 12.0 ± 0.7 for "I woke up feeling fresh and rested", and 11.8 ± 0.5, 13.3 ± 0.5, and 13.3 ± 0.6 for "My daily life has been filled with things that interest me", respectively ($p < 0.0001$ for all comparisons with baseline).
Conclusions: Patients with moderate-to-severe plaque psoriasis showed an impaired well-being score, comparable to other impacting diseases, such as breast cancer or diabetes with distress, which highlights the unmet needs in the management of psoriatic patients. Tildrakizumab significantly improved patients' well-being in patients with moderate-to-severe plaque psoriasis, achieving a well-being status similar to the general population after 16 weeks, which was maintained up to week 52.
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P-046
REAL-WORLD EFFICACY OF BIMEKIZUMAB TREATMENT IN PSORIASIS: A CASE SERIES OF 49 PATIENTS

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Introduction: Psoriasis, a chronic inflammatory skin condition, affects a significant global population. Bimekizumab, an interleukin (IL)-17A and IL-17F targeting monoclonal antibody, has demonstrated promising results in clinical trials for psoriasis. However, real-world evidence is crucial to validate its effectiveness.
Objectives: The primary aim of this investigation is to assess the real-world efficacy of bimekizumab treatment in patients with moderate to severe psoriasis. Specifically, we aim to evaluate its impact on the Psoriasis Area and Severity Index (PASI) scores and the Dermatology Life Quality Index (DLQI) in a cohort of 49 patients.
Methods: We conducted a retrospective case series involving 49 adult patients with moderate to severe psoriasis who initiated bimekizumab treatment at our institution. Patients received subcutaneous injections of bimekizumab 320 mg at weeks 0, 4, and every 8 weeks thereafter. Effectiveness was evaluated using the Psoriasis Area and Severity Index (PASI) scores and the Dermatology Life Quality Index (DLQI) at baseline, week 4, and week 12.
Results: The average age of participants was 62 years, with a majority being female (59%). Among the patients, 11 (22.4%) were treatment-naive, 38 (77.6%) switched from other biologics, and 15 (30.6%) had prior experience with IL-17 inhibitors. Additionally, 13 patients (26.5%) had psoriatic arthritis, 13 (26.5%) had palmoplantar psoriasis, 10 (20.4%) had nail psoriasis, 11 (22.4%) had scalp psoriasis, and 4 (8.2%) had genital involvement. By week 4, the mean PASI score improved from 9.7 at baseline to 2.8, and by week 12, it was 1.3. The mean DLQI improved from 10.9 at baseline to 2.5 at week 4 and 1.6 at week 12. Furthermore, at week 4, 28 patients (57.1%) achieved PASI 90, and 7 (14.2%) achieved PASI 100. By week 12, 36 patients (78.2%) achieved PASI 90, and 22 patients (47.8%). 3 patients (6.1%) discontinued bimekizumab treatment, with 1 due to persistent middle ear candidiasis and 2 due to secondary failure.
Conclusion: Our case series involving 49 patients provides evidence supporting the efficacy of bimekizumab in improving psoriasis, even in those who have previously received multiple biological agents. Additionally, no serious adverse events were observed. These encouraging findings endorse the utilization of bimekizumab in real-world clinical settings. Nevertheless, larger-scale studies with longer follow-up periods are warranted to confirm and solidify these results.
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P-047
DATA FROM BELGIAN PSORIASIS REGISTRY BEPSO PREDICTS TREATMENT RESPONSE IN SPECIFIC PATIENT GROUPS

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Introduction: Psoriasis is a chronic autoimmune skin disorder, affecting 2% of the population worldwide (1). Psoriasis is associated with various comorbidities, especially arthritis (2). It is a multifactorial disease, with genetics interacting with environmental factors. As the number of the therapies increases, Belgium decided to establish its own registry. Analysis of the evolution of psoriasis through follow-up data may inform about clinically relevant subgroups and personalized treatments.
Objective: The main objective is to study the effect of treatments by analysing the evolution of the Psoriasis Area and Severity Index (PASI) score from the first inclusion to the follow-up and assess

patient characteristics responding favourably to certain treatments compared to others.

Material and Methods: We conducted a retrospective study, for patients having undergone a follow-up consultation but not responding to the follow-up questionnaire.

Collected data included socio-demographic and lifestyle change, psoriasis related characteristics, treatment change, as well as new associated diseases.

Results: We collected data from 104 patients. Among these patients, 36 (34.6%) had a follow-up between 10 to 20 weeks (short term), while 68 (65.4%) had their follow-up after 40 weeks (long-term). We assessed the response to treatment by change in their PASI score. Patients were classified as responders if their PASI score decreased by more than 75% between the initial visit and the follow-up. In this cohort, 52% of patients responded to their treatment. In the short term, from patients under biotherapies, systemic conventional therapies, and topicals/phototherapy, 54.4%, 40% and 30% responded to their treatment respectively.

At long-term follow-up, an increase in response was observed in patients receiving biotherapies (61.9%). However, patients undergoing systemic conventional therapy tend to respond better in the long term (66.7%). Patients receiving topicals/phototherapy also showed an increased response in the long term (41.2%). At short-term, the median age is 33 years [IQR: 24-61] for responders and 61 years [IQR: 38-68] for non-responders. Non-responders experienced significantly more triggers for their psoriasis flares, particularly with stress and cold weather (p-value 0.09 and 0.034 respectively). Additionally, non-responders in the short term have a significantly higher prevalence of large plaque phenotype compared to responders (p-value 0.032). Patients who receive treatment promptly after the onset of their first lesions have better responses (p-value<0.0001). Patients treated rapidly with biotherapy show significant short-term responses (p-value 0.012), while those under systemic conventional therapy have better long-term responses (p-value 0.049).

Conclusion: Patients having biotherapy tend to respond faster to treatments, while patients undergoing conventional therapy will eventually respond equally but may take longer to react. Topical treatments also tend to give a delayed response. Treating patients promptly leads to a significantly better and quicker response, especially for biotherapies. Large plaque phenotype is a characteristic found in short-term non-responders.

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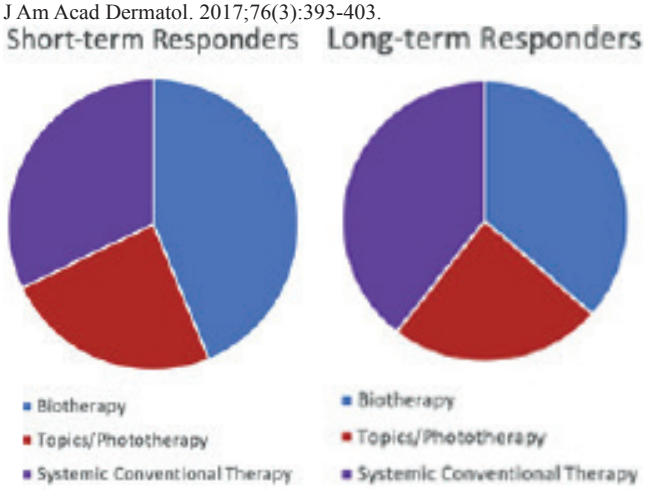

P-048

IS SUPER-RESPONSE TO ANTI-IL23 THERAPY IN PSORIASIS A PREDICTOR OF LONG-TERM RESPONSE?

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Introduction: Psoriasis patients that present a fast and complete improvement with treatment are called "super-responders" (SR) and the cause of their response is yet to be found. We have previously published a retrospective observational study of 86 patients treated with antiIL23 therapy to quantify and characterize those SR patients (1). We defined SR patients as those who achieved PASI 0 at week 16 and 24 of treatment. In multivariate analysis, only differences in response were found exclusively according to treatment administered. Patients treated with risankizumab had a significantly higher probability of having super-response than those treated with tildrakizumab.

Objectives: The present study aimed to determine if super-response is a predictor of good long-term response.

Methods: We performed a retrospective observational study to analyze the clinical outcome after 52 weeks of treatment under IL23 inhibitors of the previously described cohort of patients.

Results: While 73% of SR patients maintained PASI 0, only 27% of non-SR patients achieved PASI0 at 52 weeks. We found no significant clinical differences comparing SR and non-SR groups´ long term response.

Conclusions: Despite the interest of prospective studies with larger number of patients to find differences between the SR characteristics related with the different IL-23 inhibitors, our study highlights that a more powerful inhibition of IL23 may be related with a higher percentage of SR to this group of drugs. This early excellent response is related to a long term efficacy of the drug.

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P-049

EVALUATION OF REAL-WORLD EFFECTIVENESS AND SAFETY OF GUSELKUMAB IN PATIENTS WITH PLAQUE PSORIASIS: DATA FROM A MULTICENTER OBSERVATIONAL STUDY

No consent given to publish in scientific journal

P-050

EFFECTIVENESS, PERSISTENCE OF USE, AND SAFETY OF GUSELKUMAB IN REAL CLINICAL PRACTICE: A CASE SERIES OF 27 PATIENTS

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Introduction: Psoriasis is a chronic immune-mediated inflammatory skin disease with systemic involvement and negative impact on quality of life of patients. The IL-23/Th17 axis plays an important role in its pathogenesis. Guselkumab is a fully human monoclonal antibody that selectively inhibits the p19 subunit of interleukin-13 and is approved for both moderate-to-severe psoriasis and psoriatic arthritis.

Objectives: The main objectives of the study were to analyze the effectiveness, persistence, and safety of guselkumab in a real clinical practice setting in the University Hospital Joan XXIII of Tarragona and to compare these data with those observed in the Clinical Trials.

Methods: A total of 27 patients with moderate-to-severe psoriasis in treatment with guselkumab for at least 52 weeks of follow-up were included. Data from PASI, BSA, DLQI, VAS pruritus scores, persistence and gulsekumab safety were collected and analyzed up to 52 weeks of follow-up.
Results: Statistically significant improvement was achieved in all recollected scores (PASI, BSA, DLQI, VAS pruritus) as early as 4 weeks of treatment and continued improving up to 52 weeks. At 52 weeks of treatment, more than a half of the patients (53%) achieved PASI=9 and 73% achieved PASI ≤3 (with a mean PASI=0, BSA=0, DLQI=0 and VAS=0). The overall persistence of treatment with guselkumab was very high: suspension for all causes was 85% at 52 weeks while suspension exclusively for safety or efficacy criteria was 94,4%. No significant adverse effects were reported.
Conclusion: Several studies demonstrated that guselkumab was effective, safe, and well-tolerated (VOYAGE 1 and 2, ECLIPSE, NAVIGATE), both in plaque psoriasis and psoriatic arthritis. Its efficacy in patients with prior failure or adverse effects of other biological treatments has also been assessed (including anti-TNF, anti-IL17, anti-IL12/23) and in the treatment of difficult-to-treat body regions (scalp, palms, soles, and nails). The results of this study demonstrate that guselkumab is an effective treatment with high persistence during short and long-term use with a very favorable safety profile.

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P-051

MONTH 6 AND MONTH 12 OUTCOMES FROM THE EUROPEAN COHORT OF THE OBSERVATIONAL PSORIASIS STUDY OF HEALTH OUTCOMES (PSOHO)

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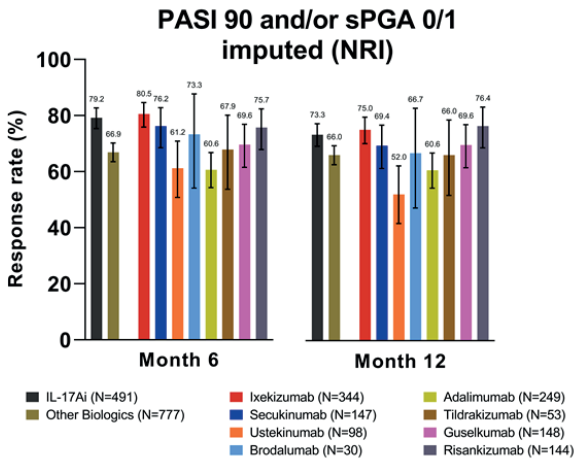
Introduction: European data regarding the effectiveness of biologics in real-world treatment of psoriasis are limited. We have previously reported the baseline demographics and Week 12 (W12) effectiveness endpoints observed among the European cohort of the large-scale observational Psoriasis Study of Health Outcomes (PSoHO), a prospective, non-interventional study of adult patients receiving biologics for moderate-to-severe plaque psoriasis.
Objectives: The primary objective is to compare the proportion of patients treated with anti-IL-17A biologics versus other biologics who achieve at least a 90% improvement in the psoriasis area and severity index score (PASI 90) and/or a static Physician Global Assessment score (sPGA) of 0/1 (collectively, the primary endpoint) by W12 following the initiation or switch of a biologic therapy. This analysis extends the W12 findings to Month 6 (M6) and Month 12 (M12).
Methods: This descriptive subgroup analysis of key effectiveness outcomes included 1,268 patients from 12 European countries. Categorical variables [unadjusted response rates for the primary endpoint, PASI 90, and PASI 100 (total skin clearance), and the proportion of participants with absolute PASI scores ≤1, ≤2, and ≤3] are reported using percentages, while continuous variables [change from baseline (CFB) in absolute PASI score] are reported using mean and standard deviation (SD). Nonresponder imputation (NRI) was used for imputing missing values.
Results: At M6, achievement of PASI90 and/or sPGA 0/1 was 79.2% in the anti-IL-17A (N = 491) cohort [80.5% for ixekizumab (N = 344), 76.2% for secukinumab (N = 147)], which was higher than the 66.9% observed in the other biologics (anti IL-17 receptor A, anti-IL-12/23, anti-IL-23, and anti-TNFα; N = 777) cohort. PASI 90 and 100 response rates were 68.2% and 51.5% in the anti-IL-17A cohort, and 51.0% and 33.2% in the other biologics cohort. Likewise, the proportions of patients attaining low absolute PASI scores (specifically, ≤1, ≤2, and ≤3) at M6 were higher following anti-IL-17A treatment (67.0%, 76.8%, and 80.7%, respectively) than with other biologics (47.9%, 60.9%, and 67.6%). The overall highest response rates were seen among patients who had initiated treatment with ixekizumab (69.2%, 79.4%, and 82.0%), brodalumab (N = 30) (66.7%, 66.7%, and 70.0%), and secukinumab (61.9%, 70.7%, and 77.6%). The mean CFB in PASI score at M6 was -13.6 (8.7) for the anti-IL-17A cohort and -11.8 (8.5) for other biologics.
M6 patterns persisted into M12. Achievement of the primary endpoint remained more frequent in the anti-IL-17A cohort at 73.3% (75.0% for ixekizumab, 69.4% for secukinumab) than in the other biologics cohort (66.0%). PASI 90 and 100 response rates likewise remained higher in those receiving anti-IL-17A treatment (61.1%, 48.5%) than those receiving other biologics (51.2%, 39.8%). Accordingly, the proportions of patients with absolute PASI scores of ≤1, ≤2, and ≤3 also remained higher at M12 in the anti-IL-17A cohort (60.5%, 70.1%, and 73.3%) than with other biologics (50.2%, 61.8%, and 67.3%). The M12 CFB in PASI scores remained -13.6 (8.5) for anti-IL-17A treatments, while other biologics increased slightly to -12.5 (8.0).
Conclusions: This subgroup analysis of European patients with plaque psoriasis highlights the sustained high effectiveness of anti-IL-17A biologics at M6 and M12 in a real-world treatment setting.



Abbreviations: IL, interleukin; N, number; NRI, nonresponder imputation; PASI 90, 90% improvement in Psoriasis Area and Severity Index score; sPGA 0/1, score of 0 or 1 on static Physician Global Assessment.

P-052

REAL-WORLD DATA ON THE EFFICACY AND SAFETY OF IXEKIZUMAB IN PATIENTS WITH PLAQUE PSORIASIS

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Introduction: Psoriasis is a common, systemic, inflammatory disease with prominent skin and joint manifestations1. Interleukin 17A (IL-17A) has been identified as a key effector cytokine that mediates immunopathogenesis of psoriasis2,3. Ixekizumab, a humanized monoclonal antibody that targets IL-17A, has been approved for treatment of moderate-to-severe plaque psoriasis and has been associated with high clinical response and an established safety profile 4,5.

Objectives: The aim of this study was to evaluate the long-term efficacy and safety of ixekizumab, in patients with moderate-to-severe plaque psoriasis in Andreas Syggros Hospital, Athens, Greece.

Methods: We performed a retrospective review of medical records of patients with moderate-to-severe plaque psoriasis who received Ixekizumab from January 2021 to December 2023. Eligible patients were 18 years or older, who had received at least one dose of Ixekizumab. Clinical data, including demographics, medical history, previous therapies, psoriatic manifestations, adverse events, and outcomes were obtained from the patients' medical records. Descriptive statistics and logistic regression analysis were performed to evaluate possible relationship between patient characteristics and clinical response to Ixekizumab.

Results: Overall, 72 patients were enrolled, 44 (61.1%) males, with a median age of 55 ± 13.4 years. Median BMI was 29,2 ± 6.4 kg/m2. Baseline disease severity was determined to be moderate to severe by PASI score (10.3 ± 8.0). Psoriatic arthritis was present in 36 (50%) patients. 47 patients (65.3%) were bio-experienced, 25 (34.7%) were bio-naïve, and among them 10 patients (13.9%) had not received any systemic treatment in the past. 61.1% of patients had at least one comorbidity, with metabolic syndrome reported in 40.3% of patients. 59/72 and 47/72 patients were treated for at least 24 and 52 weeks, respectively. A significant reduction of mean PASI score was observed at 4 weeks of ixekizumab therapy (2.6 ± 3.5), with further improvement recorded at weeks 24 (0.79 ± 1.4), and 52 (1.06 ± 2.2). Patients were considered as good responders if they achieved an absolute PASI score<2, according to the recommendations of the European Dermatology Forum6. 78.5% and 61.5% of patients were recorded as good responders at week 24 and 52 respectively. Age, gender, BMI, comorbidities, psoriatic arthritis, prior biologic therapy, and previous systemic treatment were not found to be significantly associated with response. Metabolic syndrome was found to be significantly associated with lack of response at week 52 ($p < 0.05$). No emerging safety issues were identified.

Conclusion: This study demonstrates the first cohort of real-world data of Ixekizumab use in patients with plaque psoriasis in Greece. Our findings are in line with literature in terms of efficacy and safety, confirming Ixekizumab usefulness in treating patients with plaque psoriasis and psoriatic arthritis. Real-world evidence in larger populations is needed to establish patients' factors that predict treatment outcome.

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P-053

IMPACT OF PATIENT PSORIASIS ON PARTNER WELL-BEING IN A REAL-WORLD SETTING: 52-WEEK INTERIM DATA OF THE PHASE IV POSITIVE STUDY

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Introduction: Psoriasis is a chronic inflammatory disease that profoundly impairs patients' social, emotional, functional, and physical condition as well as their families'. However, evaluation of the impact of psoriasis on patients' families, particularly partners, in a robust prospective study is missing. In addition, an effective control of the disease can help maintaining patients' and partners' well-being in long-term. Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety (1,2).

Objectives: The objective of this analysis was to investigate the impact of psoriasis on the well-being of partners of patients included in the POSITIVE study.
Methods: POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis designed to investigate patient-reported well-being using tildrakizumab in a real-world setting (3). Partner's well-being was assessed through the FamilyPso questionnaire, which is a partner self-administrated questionnaire, in absence of the patient, to assess the burden on partners of patients with psoriasis (4). The questionnaire has 15 items divided into five factors: (1) perceived strain by social reactions to the partner's psoriasis; (2) strain caused by cleaning; (3) acute emotional strain attributed directly to the psoriasis; (4) restrictions of social life; and (5) general emotional strain. The items are scaled in a 5-point Likert format (range 0-4; 0=not true, 4=very true). FamilyPso total scores below 1.27 indicate normal-to-moderate strain (4). Here, we report 52-week interim data using an observed cases approach.
Results: The cohort comprised 400 patients, of whom 248 (62.0%) were married or living in marital union. Mean±95%CI age of patients was 46.5±1.5 years (19.5% ≥60 years), and 63.3% of them were male. Mean±95%CI time since psoriasis diagnosis was 15.1±1.3 years. Mean±95%CI total FamilyPso score decreased from 1.3±0.1 at baseline to 0.9±0.1 at week 16 ($p<0.0001$), with a mean change from baseline of -0.5, to 0.8±0.2 at week 28 ($p<0.0001$), with a mean change from baseline of -0.6, and to 0.7±0.2 at week 52 ($p<0.0001$), with a mean change from baseline of -0.7. The mean±95%CI FamilyPso scores by factor at baseline, week 16, and week 52 were 1.1±0.2, 0.8±0.2, and 0.7±0.2 for "perceived strain by social reactions to the partner's psoriasis", 1.4±0.2, 0.8±0.2, and 0.7±0.2 for "strain caused by cleaning", 1.2±0.2, 0.7±0.2, and 0.5±0.2 for "acute emotional strain attributed directly to the psoriasis", 0.9±0.2, 0.5±0.2, and 0.4±0.1 for "restrictions of social life", and 1.9±0.2, 1.4±0.2, and 1.2±0.2 for "general emotional strain", respectively ($p<0.001$ for all comparisons with baseline).
Conclusions: There is an impact of patient's psoriasis on social and emotional well-being of their partners, which highlights the unmet needs not only in the management of psoriatic patients but also their families. Tildrakizumab significantly improved partners' well-being after 16 weeks and continued to improve through 52 weeks.

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P-054

EFFECTIVENESS OF TILDRAKIZUMAB FOR ITCH, PAIN, AND FATIGUE IN PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS: 52-WEEK RESULTS FROM THE REAL-WORLD POSITIVE STUDY

Ulrich Mrowietz[1], Matthias Augustin[2], Ziad Reguiai[3], Sascha Gerdes[4], Esteban Daudén[5], Wolfgang Weger[6], Julia-Tatjana Maul[7,8], Philip Laws[9], Luigi Naldi[10], Pierre-Dominique Ghislain[11], Elke de Jong[12], Sicily Mburu[13], Volker Koscielny[14], Eric Massana[14], Ismail Kasujee[14], Raquel Sommer[2]

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Introduction: Psoriasis is a chronic inflammatory disease that profoundly impairs patients' social, emotional, functional, and physical condition, impacting on their overall well-being (1). Itch and skin pain can be two of the most burdensome symptoms associated with psoriasis (2). Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety (3,4).
Objectives: The objectives of this analysis were to assess the effectiveness of tildrakizumab on burdensome symptoms in patients with moderate-to-severe psoriasis in routine care.
Methods: POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis treated with tildrakizumab designed to investigate patient-reported well-being using tildrakizumab in a real-world setting (5). Patient-reported outcomes in this analysis included 11-point Itch-, Pain-, Joint Pain- and Fatigue-Numeric Rating Scale (NRS), ranging from 0 to 10 (10=worse symptoms) (6). The percentage of patients with a reduction in NRS scores from baseline ≥4 points was calculated for patients with a baseline NRS scores ≥4. Here, we report 52-week interim data using an observed cases approach.
Results: A total of 400 patients were included (63.3% male, mean±95%CI age of 46.5±1.5 years). The mean±95%CI Itch-NRS improved from 5.7±0.3 at baseline to 2.2±0.3 at week 16, to 2.1±0.3 at week 28, and to 2.4±0.4 at week 52 ($p<0.0001$, all). The mean±95%CI Pain-NRS improved from 4.1±0.3 at baseline to 1.5±0.3 at week 16, to 1.4±0.3 at week 28, and to 1.2±0.3 at week 52 ($p<0.0001$, all). The mean±95%CI Joint Pain-NRS improved from 2.5±0.3 at baseline to 1.6±0.3 at week 16, to 1.5±0.3 at week 28, and to 1.4±0.3 at week 52 ($p<0.0001$, all). The mean±95%CI Fatigue-NRS improved from 3.8±0.3 at baseline to 1.9±0.3 at week 16, to 1.8±0.3 at week 28, and to 1.9±0.3 at week 52 ($p<0.0001$, all). At week 28 and week 52, respectively, 69.3%/74.0%/52.1%/65.6% and 64.1%/83.1%/56.0%/60.0% of patients with a baseline Itch-/Pain-/Joint Pain-/Fatigue-NRS score ≥4 achieved a ≥4-point reduction in Itch-/Pain-/Joint Pain-/Fatigue-NRS.
Conclusions: Patients treated with tildrakizumab in a real-world setting achieved rapid and significant reductions in burdensome symptoms of psoriasis (itch, skin pain, joint pain, and fatigue) after 16 weeks, which were maintained through week 52.

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P-055

PHASE 2B, LONG-TERM EXTENSION, DOSE-RANGING STUDY OF ORAL JNJ-77242113 FOR THE TREATMENT OF MODERATE-TO-SEVERE PLAQUE PSORIASIS: FRONTIER-2

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Introduction: JNJ-77242113, a targeted oral peptide, inhibits IL-23 signaling by binding the interleukin-23 (IL-23) receptor. At all doses, JNJ-77242113 showed superior efficacy at Week 16 versus placebo (PBO) in moderate-to-severe psoriasis in FRONTIER-1.[1]

Objective: FRONTIER-2 was a multicenter, long-term extension, double-blind, dose-ranging, phase 2b study evaluating efficacy and safety of JNJ-77242113 in adults with moderate-to-severe plaque psoriasis who were candidates for systemic treatment or phototherapy.

Methods: FRONTIER-1 randomized patients 1:1:1:1:1:1 to JNJ-77242113 25mg daily (QD), 25mg twice daily (BID), 50mg QD, 100mg QD, 100mg BID, or PBO through Week 16. In FRONTIER-2, patients completing FRONTIER-1 (at Week 16) continued their assigned dose through Week 52; those randomized to PBO crossed over to 100mg QD (PBO→100mg QD). The primary endpoint was the proportion of patients achieving ≥75% improvement in Psoriasis Area and Severity Index (PASI75) at Week 52. Response rates were estimated using non-responder imputation and FRONTIER-1 baseline data.

Results: Response rates among JNJ-77242113–treated patients from FRONTIER-1 were maintained, across dose groups, through Week 52 (Figure 1). Patients who crossed over to JNJ-77242113 from PBO at Week 16 (PBO→100mg QD) had substantially higher response rates at Week 52 (Figure 1). At Week 52, proportions of patients achieving PASI75 were JNJ-77242113: 25mg QD 48.8%, 25mg BID 58.5%, 50mg QD 69.8%, 100mg QD 65.1%, 100mg BID 76.2%, and PBO→100mg QD 65.7%; respective rates for PASI90/PASI100 were 27.9%/14.0%, 36.6%/17.1%, 41.9%/20.9%, 51.2%/25.6%, 64.3%/40.5%, and 57.1%/34.3%. Proportions of patients achieving an Investigator's Global Assessment (IGA) score of 0/1 or 0 were JNJ-77242113 at Week 52 were: 25mg QD 37.2%/14.0%, 25mg BID 46.3%/19.5%, 50mg QD 60.5%/23.3%, 100mg QD 60.5%/30.2%, 100mg BID 73.8%/42.9%, and PBO→100mg QD 65.7%/31.4%. Approximately 90% of patients receiving JNJ-77242113 100mg BID who had achieved a PASI75, PASI90, or IGA 0/1 response at Week 16 maintained the response at Week 52 (Figure 2). Across dose groups, 58.6% of patients experienced adverse events (AEs), with no evidence of a dose-dependent increase in AEs, including gastrointestinal disorders. The proportion of patients with serious AEs through Week 52 was 4% and all serious AEs were considered unrelated to study treatment.

Conclusions: In psoriasis patients receiving JNJ-77242113, the first targeted oral peptide to selectively block IL-23 pathway signaling, rates of near-complete/complete skin clearance from FRONTIER-1[1] were maintained through Week 52; the highest response rates were seen in patients randomized to JNJ-77242113 100mg BID. Among patients who had achieved a PASI or IGA response at Week 16, responses were maintained in substantial proportions of patients at Week 52. Consistent with prior studies, no safety signals were identified.

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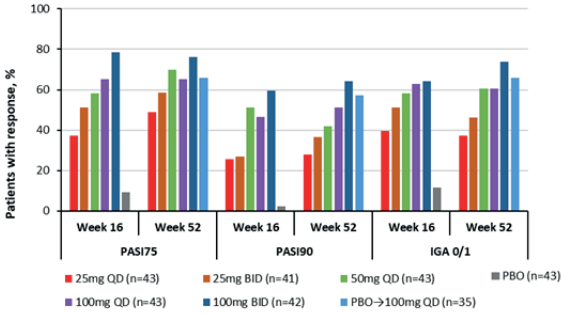
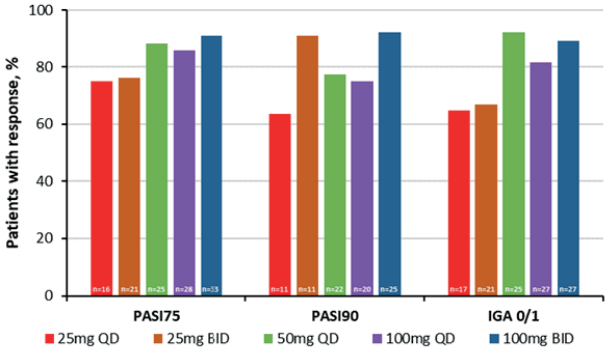
Figure 1. Response rates achieved at Week 16 and Week 52 across treatment groups



BID=twice daily; IGA=Investigator's Global Assessment; PASI= Psoriasis Area and Severity Index; PBO=placebo; QD=daily.
Gray bars show data on patients who were randomized to PBO and, at Week 16, had not yet received JNJ-77242113 100mg QD.

Figure 2. Maintenance of response at Week 52 among patients with a response at Week 16



BID=twice daily; IGA=Investigator's Global Assessment; PASI= Psoriasis Area and Severity Index; QD=daily.

P-056

EFFECTIVENESS AND SAFETY OF TILDRAKIZUMAB IN PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS LOCATED IN SPECIAL AREAS: 52-WEEK RESULTS FROM THE POSITIVE STUDY

Matthias Augustin[1], Rachel Sommer[1], Ziad Reguiai[2], Sascha Gerdes[3], Esteban Daudén[4], Wolfgang Weger[5], Julia-Tatjana Maul[6,7], Philip Laws[8], Luigi Naldi[9], Pierre-Dominique Ghislain[10], Elke de Jong[11], Sicily Mburu[12], Volker Koscielny[13], Eric Massana[13], Ismail Kasujee[13], Ulrich Mrowietz[14]

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Introduction: Psoriasis is a chronic immune-mediated disease that profoundly impairs patients' social, emotional, functional, and phy-

sical condition, impacting on their overall well-being (1). Psoriasis commonly affects special areas, such as the scalp, palms or soles, or nails. The burden of disease, particularly when special areas are affected, is very high (2). Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety (3,4).
Objectives: The objectives of this analysis were to assess the effectiveness (overall and in special locations) and safety of tildrakizumab in patients with moderate-to-severe psoriasis in routine care.
Methods: POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis treated with tildrakizumab designed to investigate patient-reported well-being using tildrakizumab in a real-world setting (5). Effectiveness assessments in this analysis included Psoriasis Area and Severity Index (PASI) and five-point Physician Global Assessment (PGA). In addition, scalp-PGA, palmoplantar-PGA, and nail-PGA were used to assess tildrakizumab effectiveness in special areas (6). Safety assessments were based on reports of adverse events (AEs). Here, we report 52-week interim data using an observed cases approach.
Results: A total of 400 patients were included (63.3% male, mean ± 95%CI age of 46.5 ± 1.5 years). Mean ± 95%CI Psoriasis Area and Severity Index (PASI) decreased from 13.1 ± 0.8 at baseline to 1.7 ± 0.3 at week 28 ($p < 0.0001$), with a mean change from baseline of -11.3, and to 1.5 ± 0.3 at week 52 ($p < 0.0001$), with a mean change from baseline of -11.7. At week 28 and week 52, respectively, 85.8%/54.8% and 88.4%/56.8% of patients achieved PASI ≤3/≤1. The mean ± 95%CI PGA improved from 2.9 ± 0.1 at baseline to 0.9 ± 0.1 at week 28, and to 0.8 ± 0.1 at week 52. At week 28 and week 52, 84.4% and 83.4% of patients with a PGA score >1 at baseline achieved a PGA score of 0 or 1. At baseline, 71.2% of patients had scalp psoriasis (scalp-PGA>0), 25.5% of patients had palmoplantar psoriasis (palmoplantar-PGA>0), and 39.9% of patients had nail psoriasis (nail-PGA>0). At week 28 and week 52, respectively, 87.0%/90.5%/77.9% and 88.5%/94.5%/85.7% of patients with a scalp-PGA/palmoplantar-PGA/nail-PGA score >1 at baseline achieved a scalp-PGA/palmoplantar-PGA/nail-PGA score of 0 or 1. At the point of this analysis, 23.3% of patients had ≥1 AE, being COVID-19 and nasopharyngitis the most frequent AEs, and 3.8% had ≥1 related AE. Only 2 patients discontinued due to related AEs (urinary tract infection and angioedema).
Conclusions: In a real-world setting, tildrakizumab significantly improved skin symptoms in patients with moderate-to-severe plaque psoriasis after 28 weeks, and this improvement was maintained through week 52. In addition, tildrakizumab showed marked and sustained improvement in areas of special burden such as the scalp, palms or soles, and nails. Tildrakizumab maintained a favourable safety profile, consistent with previous studies (3,4).
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P-057
QUALITY OF LIFE AND TREATMENT SATISFACTION WITH TILDRAKIZUMAB IN MODERATE-TO-SEVERE PSORIASIS PATIENTS: 52-WEEK INTERIM DATA OF THE REAL-WORLD POSITIVE STUDY

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Introduction: Psoriasis is a chronic immune-mediated disease that profoundly impairs patients' social, emotional, functional, and physical condition as well as their families', impacting on their overall well-being (1). Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety (2,3).
Objectives: The objectives of this analysis were to assess the effect of tildrakizumab on health-related quality of life (HRQoL), and treatment satisfaction and patient-relevant benefits with tildrakizumab in patients with moderate-to-severe psoriasis in routine care.
Methods: POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis treated with tildrakizumab designed to investigate patient-reported well-being using tildrakizumab in a real-world setting (4). The HRQoL instrument was Dermatology Life Quality Index-Relevant (DLQI-R; range 0-30, where a higher score represents a greater impairment in HRQoL; 0-1.99=no effect on patient's life) (5). Treatment satisfaction was assessed through the Treatment Satisfaction Questionnaire for Medication (TSQM-9: 3 domains ranging 0-100 with higher scores representing higher satisfaction on that domain) (6). The Patient Benefit Index (PBI) evaluates patient-relevant treatment needs (with the Patient Needs Questionnaire [PNQ] at baseline) and benefits (with the Patient Benefit Questionnaire at follow-up visits). The PBI score ranges 0-4 (4=maximal benefit; PBI ≥1=relevant benefit) (7). Here, we report 52-week interim data using an observed cases approach.
Results: A total of 400 patients were included (63.3% male, mean ± 95%CI age of 46.5 ± 1.5 years). Mean ± 95%CI DLQI-R score decreased from 12.6 ± 0.8 at baseline to 3.3 ± 0.6 at week 28 ($p < 0.0001$), with a mean change from baseline of -8.9, and to 3.1 ± 0.6 at week 52 ($p < 0.0001$), with a mean change from baseline of -9.2. At week 28 and week 52, respectively, 46.5% and 47.3% of patients with DLQI-R >1.99 at baseline had a DLQI-R score between 0 and 1.99. At week 28 and week 52, the mean ± 95%CI scores on TSQM-9 domains were 75.4 ± 2.9 and 77.4 ± 3.2 for effectiveness, 82.2 ± 2.1 and 81.5 ± 2.6 for convenience, and 77.3 ± 2.6 and 81.1 ± 2.6 for global satisfaction. Regarding treatment goals (PNQ), "to be healed of all skin defects" and "to regain control of the disease" were rated as "very much" important by 82.1% and 81.2% of patients at baseline, respectively. At week 28 and week 52, 93.6% and 97.2% of patients achieved a PBI score ≥1, respectively.
Conclusions: In a real-world setting, tildrakizumab demonstrated improvements in HRQoL with high rates of treatment satisfaction in patients with moderate-to-severe plaque psoriasis after 28 weeks, which were maintained through week 52. Most desired treatment goals were reached in a high proportion of patients.
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P-058

INFLUENCE OF PATIENT BASELINE CHARACTERISTICS ON TAK-279 EFFICACY, A SELECTIVE ORAL TYK2 INHIBITOR: PHASE 2B TRIAL IN PSORIATIC ARTHRITIS

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Introduction: TAK-279 (previously NDI-034858) is a highly potent, selective allosteric tyrosine kinase 2 (TYK2) inhibitor computationally designed to bind the Janus homology 2 domain of TYK2 but not that of other Janus kinases. In a recent phase 2b trial in active psoriatic arthritis (PsA) (NCT05153148), TAK-279 achieved a greater American College of Rheumatology 20 (ACR20) response at 15 and 30 mg doses versus placebo (53.3% and 54.2%, respectively, versus 29.2%, each $p = 0.002$) at Week 12 (primary endpoint).[1] TAK-279 was well tolerated in this patient population. Here, we evaluate the impact of body weight, sex and prior biologic use on the efficacy of TAK-279 at the 15 and 30 mg doses.

Objectives: To determine differences in the ACR20 response of TAK-279 versus placebo across clinically relevant patient subgroups.

Methods: This was a randomized, multicentre, double-blind, placebo-controlled, dose-ranging trial. Eligible patients were aged ≥18 years with PsA (fulfilling the Classification Criteria for Psoriatic Arthritis), had symptoms for ≥6 months before screening, and ≥3 tender and ≥3 swollen joints at enrolment despite previous use of non-steroidal anti-inflammatory drugs or conventional or biological disease-modifying antirheumatic drugs. Patients with diseases that may confound the effects of TAK-279 or those with a previous lack of response to therapeutic agents targeting interleukin (IL)-12, IL-17 and/or IL-23 were excluded. Patients were randomized 1:1:1:1 to receive placebo or TAK-279 (5, 15 or 30 mg) orally once daily for 12 weeks. Subgroup analyses (pooled analysis and group-level data) were performed on ACR20 response at Week 12 according to body weight (<90 kg and ≥90 kg), sex and prior biologic use. Patients with missing ACR20 data at Week 12 were imputed as non-responders. Treatment difference in ACR20 responder rate between TAK-279 and placebo groups was obtained using Mantel–Haenszel tests adjusting for randomization stratification factors. Odds ratios (ORs) were obtained using a logistic regression model with treatment as the independent variable. Subgroup analyses were pre-specified except for body weight (post hoc).

Results: Overall, 290 patients were randomized and treated, of whom 245 completed 12 weeks of treatment. Baseline characteristics were generally comparable across treatment groups; however, the proportion of female patients was higher in TAK-279 15 and 30 mg groups versus placebo (61.3% and 59.7%, respectively, versus 51.4%). Pooled analysis of the TAK-279 15 and 30 mg groups ($n = 147$) showed that these patients were more likely to achieve ACR20 across subgroups defined by body weight, sex or prior biologic use than placebo (OR [95% confidence interval; CI]):<90 kg 3.2 [1.5–7.0], ≥90 kg 2.3 [0.9–6.0]; males 1.4 [0.6–3.2], females 5.3 [2.2–13.0]; prior biologics 3.7 [1.3–11.0], no prior biologics 2.5 [1.2–5.1]), although body weight ≥90 kg and male subgroups had 95% CIs that included 1. Similar trends for these variables were observed when the two treatment groups were considered separately (Figure).

Conclusions: In patients with active PsA, ACR20 response was higher in those treated with 15 or 30 mg doses of TAK-279 than placebo regardless of body weight, sex or prior exposure to biologics.

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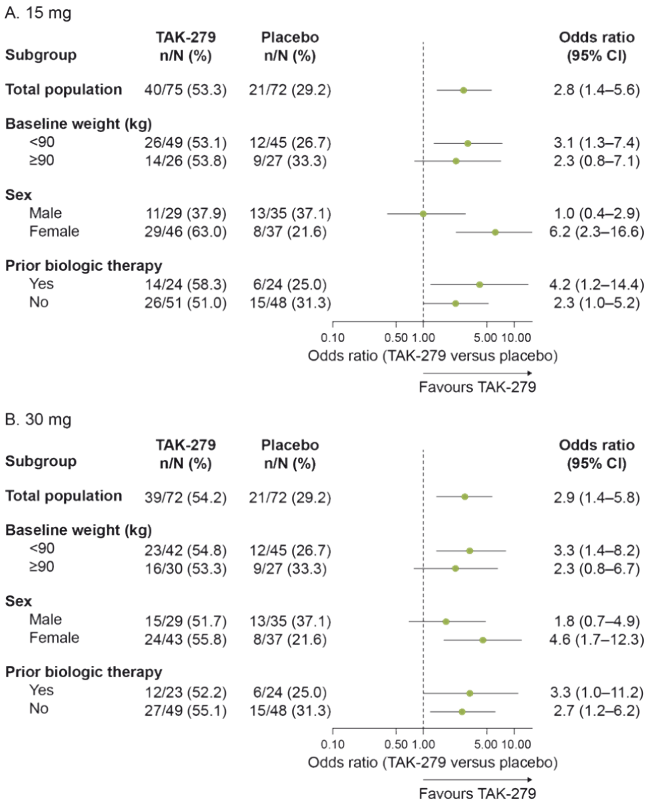
Figure. ACR20 responder rates at Week 12 by patient subgroup (TAK-279 vs placebo).



n represents the number of responders in each subgroup. For the total population, odds ratios were calculated using logistic regression with ACR20 as the dependent variable and treatment as the independent variable. Owing to the small number of patients in some subgroups, data comparisons should be interpreted with caution in some instances.
ACR20, American College of Rheumatology 20% response criteria; CI, confidence interval.

P-059

BIMEKIZUMAB SIMULTANEOUS SKIN AND NAIL CLEARANCE IN PATIENTS WITH PSORIASIS: ASSESSING COMPARATIVE EFFICACY IN FOUR PHASE 3/3B STUDIES

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Introduction: Nail psoriasis has been identified as a predictor of psoriatic arthritis (PsA), with nail involvement impacting 40–60% of patients with psoriasis.[1] Due to their structure and growth rate, nails are often more difficult to treat than skin.[2] Psoriasis of the nails disproportionately impacts physical and emotional well-being,[2–6] and clearance of nails could improve patient health-related quality of life.[3,4] Complete skin clearance (100% improvement from baseline in Psoriasis Area and Severity Index [PASI 100]) is becoming an achievable treatment goal with new biologics;[7–10] however, the PASI does not include assessment of nail clearance. Complete clearance of nail psoriasis in addition to skin may result in lower rates of progression to PsA.[3] With complete clearance of multiple domains of psoriatic disease becoming an increasingly important and achievable treatment goal,[4] it is essential to evaluate clearance of nail psoriasis alongside skin.
Objectives: To evaluate simultaneous complete skin and nail clearance in patients with moderate to severe plaque psoriasis treated with bimekizumab (BKZ) or active comparators.
Methods: Data were analysed from patients receiving BKZ 320 mg every 4 weeks (Q4W) or Q8W vs active comparators in the comparator-controlled periods of four phase 3/3b trials: pooled BE VIVID/BE READY (BKZ Q4W vs placebo [PBO] to Week 16),[7,8] BE SURE (BKZ Total vs adalimumab [ADA] to Week 24),[9] BE RADIANT (BKZ Total vs secukinumab [SEC] to Week 48),[10] and BE VIVID (BKZ Q4W vs ustekinumab [UST] to Week 52).[7] BKZ Total represents BKZ Q4W and Q8W dose groups combined. Patients included in these analyses had fingernail involvement at baseline, defined as a modified Nail Psoriasis Severity Index (mNAPSI) >0.
Proportions of patients who achieved simultaneous complete clearance of skin (PASI 100) and complete clearance of nails (mNAPSI 0) are reported. Data are reported primarily using non-responder imputation (NRI); observed case (OC) data are only presented in the Table.
Results: Across BE VIVID/BE READY, 404/670 (60.3%) BKZ- and 101/169 (59.8%) PBO-randomised patients had mNAPSI >0 at baseline; 181/319 (56.7%) BKZ- and 95/159 (59.7%) ADA-randomised patients in BE SURE, 204/373 (54.7%) BKZ- and 179/370 (48.4%) SEC-randomised patients in BE RADIANT, and 194/321 (60.4%) BKZ- and 109/163 (66.9%) UST-randomised patients in BE VIVID had mNAPSI >0 at baseline.
At Week 16, 21.3% BKZ vs 0.0% PBO patients (BE VIVID/BE READY), 20.4% BKZ vs 6.3% ADA patients (BE SURE), 28.4% BKZ vs 26.8% SEC patients (BE RADIANT), and 16.5% BKZ vs 4.6% UST patients (BE VIVID) achieved PASI 100 and mNAPSI 0 simultaneously (Table).
At the end of comparator-controlled periods, 39.2% BKZ vs 16.8% ADA patients (BE SURE Week 24), 56.9% BKZ vs 33.0% SEC patients (BE RADIANT Week 48), and 44.8% BKZ vs 22.0% UST patients (BE VIVID Week 52) achieved PASI 100 and mNAPSI 0 simultaneously (Table).
Conclusions: Simultaneous complete clearance of skin and nail psoriasis was achieved in higher proportions of BKZ-treated patients vs active comparators in controlled study periods from four phase 3/3b trials. Rates of simultaneous complete skin and nail clearance increased over comparator-controlled periods.
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Table. Simultaneous achievement of PASI 100 and mNAPSI 0 during comparator-controlled study periods (NRI, OC)

	Simultaneous achievement of PASI 100 and mNAPSI 0			
	BKZ		Comparator	
	NRI, n (%)	OC, n/N_{obs} (%)	NRI, n (%)	OC, n/N_{obs} (%)
Pooled BE VIVID and BE READY (Week 16)				
	BKZ Q4W (N=404)		PBO (N=101)	
Week 16	86 (21.3%)	86/388 (22.2%)	0 (0.0)	0/97 (0.0)
BE SURE (Week 16 and 24)				
	BKZ Total (N=181)		ADA (N=95)	
Week 16	37 (20.4%)	37/169 (21.9%)	6 (6.3%)	6/89 (6.7%)
Week 24	71 (39.2%)	71/164 (43.3%)	16 (16.8%)	16/89 (18.0%)
BE RADIANT (Week 16 and 48)				
	BKZ Total (N=204)		SEC (N=179)	
Week 16	58 (28.4%)	58/194 (29.9%)	48 (26.8%)	48/173 (27.7%)
Week 48	116 (56.9%)	116/183 (63.4%)	59 (33.0%)	59/156 (37.8%)
BE VIVID (Week 16 and 52)				
	BKZ Q4W (N=194)		UST (N=109)	
Week 16	32 (16.5%)	32/185 (17.3%)	5 (4.6%)	5/104 (4.8%)
Week 52	87 (44.8%)	87/169 (51.5%)	24 (22.0%)	24/93 (25.8%)

All patients randomised to each treatment regimen, with mNAPSI >0 at baseline, are included. BKZ Total represents BKZ 320 mg Q4W and Q8W dose groups combined. ADA: adalimumab; BKZ: bimekizumab; mNAPSI: modified Nail Psoriasis Severity Index; N_{obs}: N observed; NRI: non-responder imputation; OC: observed case; PASI 100: 100% improvement from baseline in Psoriasis Area and Severity Index; PBO: placebo; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab; UST: ustekinumab.

P-060
BASELINE CHARACTERISTICS IN PATIENTS INITIATING IXEKIZUMAB IN THE PSORIASIS SPECIAL AREAS (PSOSA) OBSERVATIONAL STUDY - FIRST INTERIM RESULTS

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Introduction: Ixekizumab (IXE) is a treatment for moderate to severe plaque psoriasis[1]. The efficacy of IXE in challenging body areas has been established in clinical trials[2],[3]. However, there is a lack of information on the extent/trajectory of improvements and rate of complete resolution in patients with nail and scalp psoriasis in real-world settings.
Methods: PSoSA (PSOriasis Special Areas) is a US-based, single-arm, prospective, multicenter, observational study of nail and scalp psoriasis improvement in patients initiating IXE. The PSoSA study included adult patients with a confirmed diagnosis of moderate to severe plaque psoriasis and nail involvement, with/without scalp involvement, whose dermatologist has prescribed IXE.
Objective: The primary objective of the PSoSA study is to assess improvements and complete clearance in nail and scalp psoriasis at week 52, with key secondary assessments at weeks 4, 12, and 24. Baseline patient characteristics from the first interim analysis are presented.
Results: At the time of first interim data cut (May 15, 2023), 92 patients entered the PSoSA study. At baseline, the interim patient

population included 38.0% females, had a mean ± SD age of 49.3 ± 15.7 years, body mass index of 29.5 ± 7.1, Psoriasis Area and Severity Index (PASI) of 11.5 ± 12.8, body surface area of 17.5% ± 18.4, modified Nail Psoriasis Severity Index (mNAPSI) of 23.7 ± 22.8, and Psoriasis Scalp Severity Index (PSSI) of 16.2 ± 15.3. At the time of enrolment, patient disease duration mean ± SD for psoriasis was 12.9 ± 14.6 years, nail psoriasis was 7.2 ± 11.1 years, and scalp psoriasis was 11.1 ± 14.2 years. Most patients (67.4%) had at least one pre-specified medical history and comorbidity. Specifically, 39.1% of patients were overweight and 28.3% were obese (both designations were determined by the healthcare professional), 26.1% had hypertension, 21.7% had psoriatic arthritis, 10.9% had diabetes mellitus, 10.9% had dyslipidemia, and 19.6% had other conditions. Approximately one fourth of the patients (n/*N* = 25/92) discontinued systemic treatment within 12-month prior to enrolment. Of these patients, 64.0% vs. 36.0% discontinued biologic vs. non-biologic systemic agents. Main discontinuation reasons were loss of response (36.0%), lack of efficacy (32.0%), and inability to afford medication (16.0%). Proportion of patients using at least one concomitant psoriasis therapy other than IXE was 17.4%, with topical therapies being used by 16.3% of patients.

Conclusion: At baseline, the interim patient population entering the PSoSA study had a mean ± SD PASI of 11.5 ± 12.8, mNAPSI of 23.7 ± 22.8, PSSI of 16.2 ± 15.3, concomitant psoriatic arthritis was reported in 21.7% of patients, and among patients who discontinued a prior systemic treatment in the past 12 months, 64.0% had used a prior biologic agent.

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P-061

BIMEKIZUMAB EFFICACY BY BODY REGION IN PLAQUE PSORIASIS: COMPARATIVE ANALYSES FROM FOUR PHASE 3/3B STUDIES

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Introduction: Plaque psoriasis can negatively affect patients' quality of life differently, depending on the body region involved.[1] Psoriasis severity and treatment responsiveness can also vary by body region.[1] Therefore, patients may benefit from reassurance that new therapies provide uniform improvement.

Bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A,[2] has demonstrated rapid and superior efficacy in treatment of moderate to severe psoriasis in head-to-head studies vs adalimumab (ADA), secukinumab (SEC), and ustekinumab (UST), with established long-term response durability.[3–7] The Psoriasis Area and Severity Index (PASI) assesses the size and severity of psoriatic lesions in four body regions: head and neck, trunk, arms, and legs.

Objectives: To compare achievement of 100% improvement in PASI (PASI 100) and ≥90% improvement in PASI (PASI 90) in each PASI body region for BKZ vs comparators over the placebo- (PBO-) and active comparator-controlled periods of four studies.

Methods: Data were included from four phase 3/3b studies, three of which assessed patients who received BKZ 320 mg every 4 weeks (Q4W) or Q8W vs active comparators: BE SURE (BKZ Total vs ADA to Week 24),[3] BE RADIANT (BKZ Total vs SEC to Week 48),[4] and BE VIVID (BKZ Q4W vs UST to Week 52).[5] Pooled Week 16 data from BE VIVID and BE READY (BE VIVID/BE READY) comparing BKZ Q4W vs PBO were also analysed.[6] BKZ Total represents pooled BKZ Q4W and Q8W dose groups.

PASI 100 and PASI 90 responses for each PASI body region are reported using non-responder imputation (NRI). Analysis was restricted to patients with baseline PASI >0 in the relevant body region.

Results: In BE SURE, 319 patients were randomised to BKZ, and 159 to ADA. In BE RADIANT, 373 patients were randomised to BKZ, and 370 to SEC. In BE VIVID, 321 patients were randomised to BKZ, and 163 to UST. Across BE VIVID/BE READY, 670 patients were randomised to BKZ, and 169 to PBO.

In each study, greater proportions of BKZ-randomised patients achieved PASI 100 (Table 1) and PASI 90 (Table 2) across all PASI body regions vs their respective comparator. Rates of achievement were largely consistent across body regions for both outcomes.

Across studies, 72.0–80.2% of BKZ-randomised patients achieved PASI 100 in the head and neck. PASI 100 in the trunk, arms, and legs was achieved by 83.5–86.0%, 78.4–81.4%, and 75.2–79.9% of BKZ-randomised patients, respectively. PASI 90 rates were also high among BKZ-randomised patients.

The greatest differences in treatment effect for BKZ vs an active comparator for PASI 100 and PASI 90 were observed in BE SURE; 20.1–36.2% more BKZ-randomised patients achieved these PASI outcomes than ADA-randomised patients. BKZ vs SEC/UST showed a difference of 6.8–19.4% and 10.2–30.3%, respectively.

Conclusions: BKZ-randomised patients achieved greater clinical responses in all PASI body regions vs comparators during PBO- and active comparator-controlled study periods.

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Table 1. PASI 100 achievement in the PASI body regions with BKZ vs comparators (NRI)

	BE VIVID/BE READY Week 16		BE SURE Week 24		BE RADIANT Week 48		BE VIVID Week 52	
Body region, %	BKZ 320 mg Q4W N=670	PBO N=169	BKZ Total N=319	ADA N=159	BKZ Total N=373	SEC N=370	BKZ 320 mg Q4W N=321	UST N=163
Head and neck	80.2 (n=631)	6.3 (n=158)	79.4 (n=306)	57.5 (n=146)	78.5 (n=358)	69.6 (n=352)	72.0 (n=307)	59.6 (n=156)
Trunk	86.0 (n=656)	3.6 (n=167)	85.7 (n=314)	59.6 (n=156)	84.3 (n=364)	76.4 (n=356)	83.5 (n=315)	62.5 (n=160)
Arms	80.4 (n=667)	3.0 (n=168)	81.4 (n=317)	46.2 (n=158)	80.9 (n=372)	65.5 (n=368)	78.4 (n=320)	57.8 (n=161)
Legs	75.2 (n=670)	1.2 (n=169)	78.6 (n=318)	43.4 (n=159)	79.9 (n=373)	60.5 (n=367)	79.1 (n=321)	48.8 (n=162)

Only patients with a PASI of >0 for each given body region at baseline are included. n represents the number of patients with a PASI of >0 for each given body region at baseline. PASI 100 response achievement reported relative to baseline. BKZ Total represents pooled BKZ 320 mg Q4W and Q8W dose groups. ADA: adalimumab; BKZ: bimekizumab; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; PASI 100: 100% improvement from baseline in PASI; PBO: placebo; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab; UST: ustekinumab.

Table 2. PASI 90 achievement in the PASI body regions with BKZ vs comparators (NRI)

	BE VIVID/BE READY Week 16		BE SURE Week 24		BE RADIANT Week 48		BE VIVID Week 52	
Body region, %	BKZ 320 mg Q4W N=670	PBO N=169	BKZ Total N=319	ADA N=159	BKZ Total N=373	SEC N=370	BKZ 320 mg Q4W N=321	UST N=163
Head and neck	84.8 (n=631)	7.6 (n=158)	82.4 (n=306)	62.3 (n=146)	81.6 (n=358)	72.2 (n=352)	74.9 (n=307)	64.7 (n=156)
Trunk	90.7 (n=656)	4.8 (n=167)	88.9 (n=314)	62.8 (n=156)	86.0 (n=364)	79.2 (n=356)	84.8 (n=315)	64.4 (n=160)
Arms	86.7 (n=667)	3.6 (n=168)	85.2 (n=317)	53.2 (n=158)	82.3 (n=372)	66.8 (n=368)	80.0 (n=320)	60.9 (n=161)
Legs	85.8 (n=670)	1.8 (n=169)	84.0 (n=318)	47.8 (n=159)	82.0 (n=373)	64.3 (n=367)	82.2 (n=321)	51.9 (n=162)

Only patients with a PASI of >0 for each given body region at baseline are included. n represents the number of patients with a PASI of >0 for each given body region at baseline. PASI 90 achievement reported relative to baseline. BKZ Total represents pooled BKZ 320 mg Q4W and Q8W dose groups. ADA: adalimumab; BKZ: bimekizumab; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; PASI 90: ≥90% improvement from baseline in PASI; PBO: placebo; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab; UST: ustekinumab.

P-062

REAL WORLD EFFECTIVENESS OF INITIATING TOPICAL THERAPY COMPARED WITH INITIATING APREMILAST EARLY OR LATE

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Introduction: The International Psoriasis Council recommends considering systemic therapy based on special area involvement, topical treatment failure, or body surface area (BSA).[1] This approach enables patients with significant disease impact to be identified earlier and advance to appropriate therapy.
Objectives: Assess real world effectiveness of topical initiators (TI) compared with early or late apremilast initiators (EAI or LAI), measured by change in BSA and achievement of treatment targets, from pre-initiation to 6 and 12 months post-initiation.
Methods: A retrospective observational study was conducted in the OM1 database, including electronic medical records and claims data. Patients included systemic-naive adults with a psoriasis diagnosis, a first observed BSA value between 1% and ≤10% (index date), no prior evidence of psoriatic arthritis, and ≥365 days of baseline data, and had either initiated apremilast or a topical prescription of a second type between 2014 and 2022 after index date. EAI and LAI were defined as patients with initiation ≤6 and >6 months after index date, respectively. Outcomes included mean BSA, achievement of BSA ≤1% (in patients with a baseline BSA >1%), and ≥75% improvement in BSA (BSA-75) after 6 and 12 months of apremilast or index topical initiation. Relative risks (RR) for achieved outcomes were estimated using a Poisson model for a three-way comparison between EAI, LAI, and TI. Adjustments were made based on the index BSA value; potential confounding and differential censoring were addressed using inverse probability of treatment and missingness weights (to account for missing BSA outcomes) for the study population.
Results: The study included 9,777 TI, 2,073 EAI, and 1,516 LAI. Baseline characteristics are shown in Table 1; mean age and sex were balanced across the groups. Mean index BSAs were 4.6%, 6.0%, and 4.9% for TI, EAI, and LAI, respectively. The median number of days between index BSA and treatment initiation were 0, 16, and 485, for TI, EAI, and LAI, respectively. At treatment initiation, BSA was 4.8%, 6.1%, and 7.3% for TI, EAI, and LAI, respectively (Table 2). For TI, mean BSA at 6 and 12 months post-initiation was 5.5% and 5.3%. At 6 months, the proportion of patients achieving BSA ≤1% (RR [95% CI]) was significantly higher for EAI (1.54 [1.27, 1.87]) and LAI (1.56 [1.25, 1.95]) versus TI; additionally, the proportion of patients achieving a BSA-75 was significantly higher for EAI (1.52 [1.21, 1.89]) and LAI (1.59 [1.24, 2.03]) versus TI. At 12 months, the proportion of patients achieving BSA ≤1% was significantly higher for EAI versus TI, and BSA-75 was significantly higher for EAI and LAI versus TI.
Conclusions: Topical cycling is a recognized treatment pattern in clinical care.[2] We investigated effectiveness of this approach versus early and delayed systemic therapy. We found EAI were 54% and 52% more likely to achieve BSA ≤1% and BSA-75 goals, respectively, at 6 months compared to those who received topical therapy alone. The BSA among TI remained similar out to 12 months. Earlier initiation of apremilast could attenuate patient life course impairment related to topical cycling in mild-to-moderate psoriasis.[2,3]

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Table 1. Baseline characteristics for topical initiators, early apremilast initiators, and late apremilast initiators

Characteristics	Topical Initiators N=9777	Early Apremilast Initiators N=2073	Late Apremilast Initiators N=1516	Overall Apremilast Initiators N=3589
Age, mean (SD)	53.2 (16.0)	51.6 (15.4)	52.4 (15.0)	51.9 (15.2)
Female, n (%)	5583 (57.1)	1238 (59.7)	884 (58.3)	2122 (59.1)
Days from first PsO diagnosis to index date				
Mean (SD)	622.6 (725.8)	341.5 (593.7)	398.8 (570.7)	365.7 (584.7)
Median (IQR)	329.0 (34.0, 1030.0)	29.0 (0, 390.0)	91.5 (0, 641.5)	45.0 (0, 500.0)
Days from index date to treatment initiation				
Mean	49.7	41.0	649.9	298.2
Median	0	16	485	108
BSA%				
Mean (SD)	4.6 (3.1)	6.0 (3.2)	4.9 (3.2)	5.5 (3.2)
Median (IQR)	4.0 (2.0, 7.0)	5.0 (3.0, 10.0)	5.0 (2.0, 7.0)	5.0 (3.0, 10.0)
1–3%, n (%)	3250 (33.2)	338 (16.3)	440 (29.0)	778 (21.7)
3–10%, n (%)	6527 (66.8)	1735 (83.7)	1076 (71.0)	2811 (78.3)
Comorbidities, n (%)				
Anxiety	676 (6.9)	141 (6.8)	89 (5.9)	230 (6.4)
Malignancies*	406 (4.2)	31 (1.5)	23 (1.5)	54 (1.5)
Depression	589 (6.0)	142 (6.8)	82 (5.4)	224 (6.2)
Dyslipidemia	1538 (15.7)	307 (14.8)	243 (16.0)	550 (15.3)
Hypertension	1836 (18.8)	387 (18.7)	272 (17.9)	659 (18.4)
Renal dysfunction/CKD	1108 (11.3)	247 (11.9)	175 (11.5)	422 (11.8)
Obesity	1013 (10.4)	221 (10.7)	148 (9.8)	369 (10.3)
Type 2 diabetes mellitus	721 (7.4)	171 (8.2)	118 (7.8)	289 (8.1)
Prior treatments, n (%)				
Topicals, any	9777 (100.0)	1728 (83.4)	1274 (84.0)	3002 (83.6)
1 topical	1008 (10.3)	522 (25.2)	335 (22.1)	857 (23.9)
2 topicals	2918 (29.8)	508 (24.5)	383 (25.3)	891 (24.8)
≥3 topicals	5843 (59.8)	698 (33.7)	556 (36.7)	1254 (34.9)

*Excluding nonmetastatic skin cancer.
BSA=body surface area; CKD=chronic kidney disease; IQR=interquartile range; PsO=psoriasis; SD=standard deviation.

Table 2. Mean BSA and achieved treatment targets of topical initiators, early apremilast initiators, and late apremilast initiators at treatment initiation, and 6 and 12 months post-initiation

		Topical Initiators N=9777	Early Apremilast Initiators N=2073	Late Apremilast Initiators N=1516
Initiation				
BSA	N	8065	1908	759
	Mean (SD)	4.8 (2.2)	6.1 (3.9)	7.3 (8.0)
6 months				
BSA	N	2954	802	450
	Mean (SD)	5.5 (7.1)	4.9 (5.1)	5.2 (6.6)
BSA ≤1%*	N	380	166	98
	RR (95% CI)	Ref	1.54 (1.27, 1.87)†	1.56 (1.25, 1.95)†
BSA-75‡	N	289	151	85
	RR (95% CI)	Ref	1.52 (1.21, 1.89)†	1.59 (1.24, 2.03)†
12 months				
BSA	N	2419	541	354
	Mean (SD)	5.3 (7.5)	4.6 (6.4)	5.1 (7.0)
BSA ≤1%*	N	393	161	84
	RR (95% CI)	Ref	1.49 (1.23, 1.80)†	1.22 (0.96, 1.54)
BSA-75‡	N	313	152	78
	RR (95% CI)	Ref	1.50 (1.22, 1.85)†	1.33 (1.03, 1.71)†

The comparative analysis was adjusted for the index BSA value.
*Excluded patients with index BSA=1%.
†Statistically significant difference from topical initiators.
‡BSA-75= ≥75% improvement in BSA.
BSA=body surface area; CI=confidence interval; Ref=referent category; RR=relative risk; SD=standard deviation.

P-063

BIMEKIZUMAB LONG-TERM EFFICACY IN PATIENTS WITH PLAQUE PSORIASIS FROM BE BRIGHT: MEAN PERCENTAGE IMPROVEMENT IN CLINICAL OUTCOMES OVER 4 YEARS

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Introduction: Bimekizumab (BKZ) has demonstrated rapid and superior efficacy in the treatment of moderate to severe plaque psoriasis vs ustekinumab, adalimumab, and secukinumab, with established long-term durability of response.[1–5]

Assessments of mean percentage improvements in clinical outcomes, alongside rates of achievement of standard improvement thresholds, such as PASI 90 (≥90% improvement from baseline in Psoriasis Area and Severity Index), can be used by clinicians to better understand skin responses. Marked mean percentage improvements (>40%) in PASI in patients receiving BKZ treatment have previously been reported as early as Week 1.[6]

Objectives: To evaluate mean percentage improvements from baseline in commonly used clinical outcomes through 4 years of BKZ treatment.

Methods: Data were pooled from the 52-week BE VIVID, the 56-week BE READY and BE SURE phase 3 trials, and their open-label extension (OLE), BE BRIGHT. Included patients received BKZ 320 mg every 4 weeks (Q4W) to Week 16 then BKZ Q4W or every 8 weeks (Q8W) into the OLE. From OLE Week 48, or the next clinic visit, all patients received BKZ Q8W dosing.[2–5] Mean percentage improvement from baseline in PASI (scored 0–72), Investigator's Global Assessment (IGA; scored 0–4), body surface area affected by psoriasis (BSA; scored 0–100%), and Dermatology Life Quality Index (DLQI; scored 0–30) are reported to Year 4 (OLE Week 144). Data are reported for patients who received continuous BKZ treatment, regardless of dosing regimen (BKZ Total), and for the subset who received BKZ Q4W to Week 16 then Q8W continuously into the OLE (Q4W/Q8W), the approved dosing regimen for the majority of patients.[7,8]

Missing data and any data following discontinuation of treatment due to lack of efficacy or treatment-related adverse events were imputed using a multiple imputation (MI) model. Observed case (OC) data are presented in the Table only.

Results: Of the 771 patients who received BKZ continuously throughout the feeder studies and entered the OLE, 197 received BKZ Q4W/Q8W. Mean baseline scores were: PASI 21.1; IGA 3.3; BSA 27.0%; and DLQI 10.5. Scores in the subset receiving BKZ Q4W/Q8W were similar (PASI: 20.4; IGA: 3.3; BSA: 24.5%; and DLQI: 10.8). Mean percentage improvements in PASI, IGA, BSA, and DLQI were high by Week 16 and were durable in the long term (Table). At Year 4, mean percentage improvements were 96.3%, 86.3%, 95.0%, and 87.9%, respectively (Year 4 absolute means: PASI 0.7; IGA 0.5; BSA 1.2%; and DLQI 0.9).

Similar results were reported in the subset who received BKZ Q4W/Q8W (Table); mean percentage improvements in PASI, IGA, BSA, and DLQI at Year 4 were 96.7%, 91.6%, 94.8%, and 90.4%, respectively (absolute means: PASI 0.6; IGA 0.3; BSA 1.2%; and DLQI 0.7).

Conclusions: Building on previous reports of marked mean percentage improvements in PASI as early as Week 1,[6] here, mean percentage improvements in PASI, IGA, BSA, and DLQI were high by Week 16 of BKZ treatment and durable through 4 years, including in the subset who received BKZ Q4W/Q8W.

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Table. Mean percentage improvement from baseline in clinical outcomes through 4 years of bimekizumab treatment (MI, OC)

	BKZ Total (N=771)		BKZ Q4W/Q8W (N=197)	
	MI[a]	OC[b]	MI[a]	OC[b]
	Mean Percentage CfB	Mean Percentage CfB [N_{obs}][c]	Mean Percentage CfB	Mean Percentage CfB [N_{obs}][c]
PASI				
Week 16	96.8%	96.8% [764]	98.3%	98.4% [194]
Year 1[d]	98.1%	98.6% [727]	99.1%	99.1% [195]
Year 2[e]	98.3%	98.5% [712]	98.9%	99.0% [183]
Year 3[f]	97.6%	98.2% [675]	98.4%	98.8% [172]
Year 4[g]	96.3%	97.3% [623]	96.7%	97.7% [157]
IGA				
Week 16	86.7%	86.8% [764]	90.2%	90.5% [194]
Year 1	91.0%	92.2% [727]	95.2%	95.3% [195]
Year 2	91.2%	91.8% [712]	94.3%	94.7% [183]
Year 3	89.2%	90.7% [675]	93.3%	94.4% [172]
Year 4	86.3%	87.9% [621]	91.6%	92.5% [157]
BSA				
Week 16	94.0%	94.1% [763]	97.2%	97.2% [194]
Year 1	97.3%	97.9% [727]	98.9%	98.9% [195]
Year 2	97.7%	98.1% [712]	98.7%	98.8% [183]
Year 3	97.1%	97.6% [675]	98.2%	98.5% [172]
Year 4	95.0%	96.5% [623]	94.8%	97.3% [157]
DLQI				
Week 16	85.0%	85.0% [759]	86.0%	85.8% [192]
Year 1[h]	90.8%	91.8% [721]	93.5%	93.5% [193]
Year 2	91.8%	92.4% [710]	93.9%	94.6% [181]
Year 3	89.9%	90.9% [668]	95.1%	95.9% [170]
Year 4	87.9%	89.4% [620]	90.4%	92.6% [156]

Data are reported for patients who entered the OLE only. Percentage change from baseline indicates improvement (reduction of score) for all outcomes. [a] For MI, patients who entered the BE READY escape arm were considered non-responders from the date of escape until the end of BE READY, after which they were considered in the same way as all other non-escape patients during the BE BRIGHT OLE; [b] For OC, data from patients who entered the BE READY escape arm were considered missing from the date of escape until the end of BE READY, after which their data are presented as observed; [c] N_{obs} represents the number of patients with observed data at a given timepoint; [d] BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 52 was considered as the last common timepoint before OLE entry (Year 1); [e] Week 100/104; [f] Week 148/152; [g] Week 196/200; [h] Due to lack of common timepoints at which the DLQI was assessed, Week 48 (BE SURE and BE READY)/52 (BE VIVID) was used as a composite last timepoint before OLE entry (Year 1) when pooling the studies. BKZ: bimekizumab; BSA: body surface area; CfB: change from baseline; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; MI: multiple imputation; N_{obs}: N observed; OC: observed case; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks.

P-064

EARLY OLIGOARTICULAR PSA RESPONDS TO TREATMENT WITH APREMILAST: WEEK 16 RESULTS FROM FOREMOST – A PHASE 4 RCT

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Introduction: Psoriatic arthritis (PsA) is underdiagnosed in dermatology practice, typically presenting 10 years after skin symptoms. Dermatologists may encounter early PsA (up to 30% of patients with psoriasis have PsA). Oligoarticular PsA affects ≤4 joints, is very common, and is underrepresented in clinical trials (most pivotal studies exclude patients with<3 swollen and tender joints).

Objectives: Report the efficacy and safety of apremilast vs placebo for treatment of early oligoarticular PsA.

Methods: FOREMOST (NCT03747939), a randomized controlled trial, compared apremilast 30 mg BID + standard of care (SOC) vs placebo+SOC in patients with oligoarticular PsA (>1 but ≤4 tender joint count [TJC] and ≤4 swollen joint count [SJC], of 66-68 joints assessed) and early disease (≤5 years). A stable dose of oral glucocorticosteroids, NSAIDs, or 1 csDMARD (MTX or SSZ) was allowed. Patients were randomized 2:1 apremilast:placebo for 24 weeks, stratified on concomitant medication use, with early escape at Week 16. The primary endpoint was proportion of patients at Week 16 who achieved modified Minimal Disease Activity (MDA-Joints1), a composite of TJC ≤1 and SJC ≤1 plus 3 of the following: psoriasis Body Surface Area (BSA) ≤3%, patient pain visual analog scale (100-mm scale) ≤15, Patient Global Assessment (PtGA; 100-mm scale) ≤20, physical function (HAQ-DI) ≤0.5, and enthesitis count ≤1 (Leeds Enthesitis Index). Secondary endpoints, Clinical Disease Activity in PsA (cDAPSA) remission (REM ≤4) or low disease activity (LDA >4 to ≤13) score, Patient Assessment of Pain, PtGA, PsA Impact of Disease (PsAID-12), PsA Disease Activity Score (PASDAS), safety, and exploratory endpoints (nail evaluation, BSA 0%) were assessed. Primary and secondary analyses were based on sentinel joints (those affected at baseline); exploratory analyses performed for all joints. Patients who discontinued before week 16 due to AEs or lack of efficacy were imputed as non-responders; remaining missing values at week 16 were imputed by multiple imputation.

Results: Of 308 patients randomized (apremilast: $n = 203$; placebo: $n = 105$), mean PsA duration was 9.9 (SD 10.2) months, mean age 50.9 (SD 12.5) years, and 39.9% were using csDMARD (Table 1). MDA-Joints response was achieved in 33.9% vs 16.0% for apremilast vs placebo (primary endpoint, $p = 0.0008$; Table 2). At Week 16, a greater proportion of patients treated with apremilast achieved cDAPSA REM/LDA (70.2% vs placebo 51.8%, $p = 0.0017$, Table 2) and good/moderate response in PASDAS score (61.0% vs placebo 41.8%). Consistently higher MDA-joints, cDAPSA REM/LDA, TJC ≤1, and PASDAS responses were observed with apremilast vs placebo when evaluated by sentinel vs all joints impacted (Table 2). Patients treated with apremilast achieved greater improvements in nail psoriasis score and quality-of-life measures (Pt Pain, PsAID-12, and PtGA) compared to placebo (Table 2). No new safety signals were identified.

Conclusion: FOREMOST is the first global randomized controlled trial exclusively studying early oligoarticular PsA. Results from FOREMOST, including primary outcome, indicate better disease control with apremilast+SOC, with twice the MDA-Joint response compared to placebo+SOC at 16 weeks. Apremilast treatment of early oligoarticular PsA improves clinical and quality-of-life outcomes and may inform optimal management of these patients.

References

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Table 1. FOREMOST Baseline Characteristics

Characteristic	PBO N=105	APR N=203	Total (N=308)
Age, years	50.2 (13.0)	51.3 (12.3)	50.9 (12.5)
Female, n (%)	51 (48.6)	118 (58.1)	169 (54.9)
BMI, kg/m^2	31.4 (7.5)	30.2 (6.8)	30.6 (7.1)
PsA duration, months	10.0 (10.6)	9.8 (10.0)	9.9 (10.2)
SJC[a]	2.6 (0.7)	2.7 (0.7)	2.6 (0.7)
TJC[a]	3.2 (0.8)	3.2 (0.8)	3.2 (0.8)
BSA (%)	6.3 (10.9)	6.9 (12.3)	6.7 (11.8)
≤3%	63 (60.0)	120 (59.1)	183 (59.4)
Pt pain VAS (0-100 mm)[b]	51.1 (22.7)	52.3 (22.0)	51.9 (22.2)
PtGA VAS (0-100 mm) [b]	50.5 (20.7)	51.6 (22.0)	51.3 (21.5)
HAQ-DI[b]	1.1 (0.6)	1.0 (0.6)	1.0 (0.6)
PsAID-12[b]	4.8 (2.2)	4.7 (2.0)	4.7 (2.1)
cDAPSA[b]	15.9 (4.5)	16.3 (4.3)	16.2 (4.4)
cDAPSA, n (%)			
REM	0 (0.0)	0 (0.0)	0 (0.0)
LDA	30 (28.6)	45 (22.2)	75 (24.4)

Data are presented as mean (SD), unless otherwise specified.
[a] Sentinel joints are defined as joints affected at baseline. [b] Higher scores indicate greater burden/worse status.
APR, apremilast; BMI, body mass index; BSA, body surface area; cDAPSA, Clinical Disease Activity in Psoriatic Arthritis; HAQ-DI, Health Assessment Questionnaire Disability Index; LDA, low disease activity (cDAPSA >4–≤13); PBO, placebo; PsA, psoriatic arthritis; PsAID-12 (0–10), Psoriatic Arthritis Impact of Disease; Pt, patient; PtGA, Patient Global Assessment of Disease Activity; REM, remission (cDAPSA ≤4); SD, standard deviation; SJC, swollen joint count; TJC, tender joint count; VAS, visual analog scale.

Table 2. FOREMOST Week 16 Results

Endpoints	Sentinel* Joints			All Joints		
	PBO N=105 n (%)	APR N=203 n (%)	Difference (95% CI)	PBO N=105 n (%)	APR N=203 n (%)	Difference (95% CI)
Primary Endpoint						
MDA-Joints	16.8 (16.0)	68.8 (33.9)	18.5% (8.9, 28.1) p=0.0008	8.3 (7.9)	43.2 (21.3)	13.6% (5.9, 21.4) p=0.0028
Secondary Endpoints						
cDAPSA REM/LDA	54.4 (51.8)	142.6 (70.2)	18.6% (7.0, 30.2) p=0.0017	40.0 (38.0)	122.5 (60.3)	22.5% (10.7, 34.3) p=0.0004†
SJC ≤1‡	72.4 (69.0)	150.2 (74.0)	5.1% (-5.8, 16.0) p=0.3539†	43.5 (41.5)	117.5 (57.9)	16.4% (4.7, 28.0) p=0.0068†
TJC ≤1‡	46.7 (44.4)	134.4 (66.2)	22.1% (10.4, 33.7) p=0.0003†	17.5 (16.7)	77.2 (38.0)	21.4% (11.6, 31.2) p=0.0002†
PtGA VAS ≤20‡	–	–	–	20.1 (19.1)	61.7 (30.4)	11.8% (1.7, 22.0) p=0.0286†
Pt Pain VAS ≤15‡	–	–	–	13.8 (13.1)	59.6 (29.4)	16.3% (6.9, 25.8) p=0.0022†
PsAID-12, LS Mean (SE) Change From Baseline‡	–	–	–	-0.42 (0.216)	-1.45 (0.178)	-1.03 (-1.48, -0.59) p<0.0001†
PASDAS Good/ Moderate Response‡	43.9 (41.8)	123.8 (61.0)	19.7% (7.7, 31.8) p=0.0016†	42.8 (40.8)	120.3 (59.3)	19.0% (7.0, 31.1) p=0.0023†
Exploratory Endpoints				**PBO N=69**	**APR N=143**	**Difference (95% CI)**
Nail Psoriasis Score, LS Mean (SE) Change From Baseline	–	–	–	-6.8 (2.6)	-13.9 (2.1)	-7.1 (-12.4, -1.8) p=0.0094†
BSA 0%, n (%)¥	–	–	–	17.7 (16.9)	63.3 (31.2)	14.4 (4.6, 24.2) p=0.0073†

Non-responder and multiple imputation methods were used for handling missing data. All the secondary endpoints were tested sequentially in the pre-specified order as presented in the table.
For binary outcomes (MDA-Joints, cDAPSA REM/LDA, SJC ≤1, TJC ≤, Pt Pain ≤15, PtGA ≤20, PASDAS response, and BSA 0%), the adjusted difference in proportions was the weighted average of the treatment differences across strata formed by two stratification factors, prior/concomitant use of csDMARD, and baseline glucocorticoid use per IWRS data, using CMH weights. Two-sided 95% CI was based on a normal approximation to the weighted average. P-value was based on the CMH test, adjusting for prior/concomitant use of csDMARD and baseline glucocorticoid use that was normalized via the Wilson-Hilferty transformation.
For continuous outcomes (Nail Psoriasis Score and PsAID-12), the LS mean treatment difference and p-value were based on MMRM model including treatment group, time, treatment group by time interaction, prior/concomitant use of csDMARD, and baseline glucocorticoids use per IWRS data as factors, and baseline value of the measure as a covariate.
*Sentinel joints are defined as joints affected at baseline. †Nominal p-value. ‡The following secondary endpoints did not achieve statistical significance according to the pre-specified sequential testing for the purpose of multiplicity adjustment, however, the p-values are all less than 0.05and numerical improvement was observed. ¥Proportion of pts with pre-existing skin involvement (BSA >3%) whose BSA improves to 0%.
APR, apremilast; BSA, body surface area; cDAPSA, Clinical Disease Activity in Psoriatic Arthritis; CI, confidence interval; CMH, Cochran-Mantel-Haenszel; csDMARD, conventional synthetic disease-modifying antirheumatic drug; IWRS, Interactive Web Response System; LDA, low disease activity (cDAPSA >4–≤13); LS, least- squares; MDA, Minimal Disease Activity; MMRM, mixed-effects model for repeated measures; PASDAS, Psoriatic Arthritis Disease Activity Score; PBO, placebo; PsAID-12 (0–10), Psoriatic Arthritis Impact of Disease; PtGA, Patient Global Assessment of Disease Activity; REM, remission (cDAPSA ≤4); SE, standard error; SJC, swollen joint count; TJC, tender joint count; VAS, visual analog scale.

P-065

EFFICACY AND SAFETY OF TAK-279, A SELECTIVE, ORAL TYK2 INHIBITOR, IN A RANDOMIZED, PLACEBO-CONTROLLED PHASE 2B TRIAL IN PSORIATIC ARTHRITIS

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Introduction: TYK2 mediates signaling by key cytokines involved in the pathogenesis of immune-mediated inflammatory diseases such as psoriatic arthritis (PsA) and psoriasis. TAK-279 is a highly potent, selective, oral, allosteric TYK2 inhibitor shown to be clinically effective with an acceptable safety profile in a phase 2b trial in patients with moderate-to-severe psoriasis.[1]

Objectives: To evaluate efficacy and safety of TAK-279 in patients with active PsA treated over 12 weeks.

Methods: In this phase 2b, randomized, double-blind, placebo-controlled, dose-ranging study (NCT05153148), eligible patients were aged ≥18 years, with PsA symptoms for ≥6 months prior to screening, met CASPAR criteria, and had ≥3 tender and ≥3 swollen

joint counts (TJC/SJC) at enrolment despite prior non-steroidal anti-inflammatory drugs, disease-modifying antirheumatic drugs or biologic treatment. Patients were randomized 1:1:1:1 to receive oral TAK-279 5 mg, 15 mg, 30 mg, or placebo, once daily for 12 weeks. Primary endpoint: ACR20 response at Week 12. Secondary endpoints at Week 12 included: ACR50, ACR70, PASI75 responses (in patients with ≥3% BSA), change from baseline in TJC/SJC, physician global assessment (PhGA) of PsA, and safety.
Results: In total, 290 patients were randomized and treated; 245 completed 12 weeks' treatment. Baseline characteristics were generally comparable across groups (except for a lower mean TJC in the 30 mg group); 58.6% had BSA ≥3% (of which mean baseline PASI score was 6.2), and 32.1% had prior biologic use (20.7% tumour necrosis factor inhibitors). Mean baseline high-sensitivity C-reactive protein (hsCRP) was 7.0 mg/L; 45.9% had hsCRP ≥3 mg/L. The primary endpoint was met with a significantly greater proportion of patients achieving ACR20 with TAK-279 15 mg and 30 mg vs placebo (53.3% and 54.2% vs 29.2%, both $p = 0.002$; Figure 1A). ACR50 response rates were also higher in the TAK-279 15 mg and 30 mg groups vs placebo ($p = 0.005$ and $p = 0.009$, respectively; Figure 1B). PASI75 response was highest in the 30 mg group vs other doses and placebo (45.7% [30 mg] and 28.3% [15 mg] vs 15.4% [placebo]; $p = 0.002$ and $p = 0.101$, respectively). A numerically higher proportion of patients treated with TAK-279 15 mg and 30 mg achieved ACR70 than with placebo (Figure 1B). Numerical reductions were observed in mean change from baseline in the TJC/SJC in all groups, with higher reductions with the 15 mg and 30 mg doses vs placebo and 5 mg TAK-279. Improvements from baseline were seen in PhGA of PsA in all TAK-279 groups vs placebo (5 mg [$p = 0.016$]; 15 mg [$p = 0.004$]; 30 mg [$p = 0.003$]). Safety outcomes are summarized in Table 1. No opportunistic infections, major adverse cardiovascular events or differences in mean laboratory parameters of interest were observed, compared with placebo. Serious and Grade 3 or higher treatment-emergent adverse events occurred infrequently and at a similar rate in the TAK-279 and placebo groups.
Conclusions: TAK-279 was well tolerated and demonstrated superior dose-dependent efficacy to placebo over 12 weeks of treatment in patients with active PsA.

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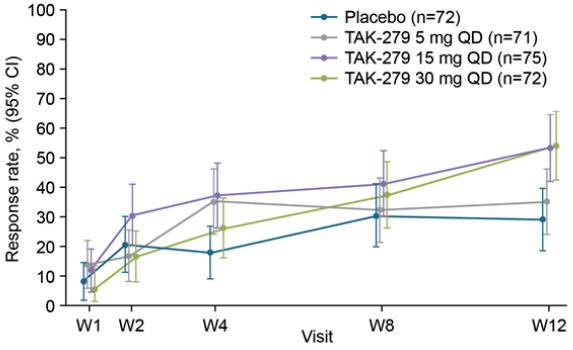
Table 1. Safety overview.

	Placebo (n=72)	TAK-279 5 mg QD (n=71)	TAK-279 15 mg QD (n=75)	TAK-279 30 mg QD (n=72)
Any TEAE, n (%)	39 (54.2)	42 (59.2)	45 (60.0)	56 (77.8)
Drug-related TEAEs, n (%)	11 (15.3)	15 (21.1)	20 (26.7)	29 (40.3)
TEAEs leading to study discontinuation, n (%)	1 (1.4)	0	3 (4.0)	5 (6.9)
Serious TEAEs, n (%)	4 (5.6)	4 (5.6)	3 (4.0)	2 (2.8)
At least one Grade 3 or higher TEAE	7 (9.7)	6 (8.5)	7 (9.3)	3 (4.2)
TEAEs leading to death, n	0	0	0	0
Most frequent TEAEs,* n (%)				
Nasopharyngitis	3 (4.2)	6 (8.5)	7 (9.3)	7 (9.7)
URTIs	2 (2.8)	8 (11.3)	3 (4.0)	7 (9.7)
Headache	3 (4.2)	2 (2.8)	6 (8.0)	4 (5.6)
Rash	0	3 (4.2)	6 (8.0)	4 (5.6)
Blood CPK increased	3 (4.2)	2 (2.8)	4 (5.3)	1 (1.4)
Dermatitis acneiform	0	0	2 (2.7)	6 (8.3)
Psoriatic arthropathy	5 (6.9)	0	2 (2.7)	1 (1.4)
Rash papular	0	1 (1.4)	3 (4.0)	4 (5.6)
Aphthous ulcer	0	0	1 (1.3)	6 (8.3)
Dermatitis allergic	0	1 (1.4)	1 (1.3)	4 (5.6)
Rash maculo-papular	0	0	2 (2.7)	4 (5.6)

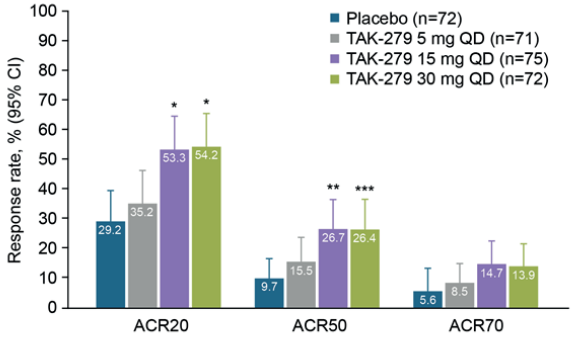
*TEAEs occurring at ≥5% by preferred term in any treatment arm.
CPK, creatine phosphokinase; QD, once daily; TEAE, treatment-emergent adverse event; URTI, upper respiratory tract infection.

Figure 1. ACR responses.

A. ACR20 response over time.



B. ACR20/50/70 responses at Week 12.



ACR20/50/70 are composite measures defined as both improvements of 20%/50%/70% in the number of tender joint counts and swollen joint counts, and a 20%/50%/70% improvement in three of the following five criteria: Patient Global Assessment of PsA, Physician Global Assessment of PsA, Patient Global Assessment of PsA pain, Health Assessment Questionnaire – Disability Index and high-sensitivity C-reactive protein.
*ACR20: p=0.002 versus placebo.
p values for ACR50 are nominal: **p=0.005, ***p=0.009 versus placebo.
ACR, American College of Rheumatology; CI, confidence interval; PsA, psoriatic arthritis; QD, once daily; W, Week.

P-066

EFFECTIVENESS AND PATIENT-REPORTED WELL-BEING OF TILDRAKIZUMAB IN PATIENTS WITH NAIL PSORIASIS: 52-WEEK RESULTS FROM THE PHASE IV POSITIVE STUDY

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Introduction: Psoriasis is a chronic inflammatory disease that profoundly impairs patients' social, emotional, functional, and physical condition, impacting on their overall well-being (1). Nail psoriasis is a difficult-to-treat manifestation of psoriatic disease affecting 40-60% of patients with plaque psoriasis and often causing significant impairments in health-related quality of life (HRQoL) (2,3). Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety (4,5).
Objectives: The objectives of this analysis were to assess the effectiveness and patient reported well-being of tildrakizumab in Austrian patients with nail psoriasis in routine care.
Methods: POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-

severe plaque psoriasis treated with tildrakizumab designed to investigate patient-reported well-being using tildrakizumab in a real-world setting (6). The well-being was assessed through the 5-item WHO Well-being Index (WHO-5; range 0-100, 100=maximal well-being) (7). As a reference, the mean WHO-5 score in the general Austrian population is 66.3 (8). The HRQoL instrument was Dermatology Life Quality Index-Relevant (DLQI-R). Effectiveness assessments in this analysis included Psoriasis Area and Severity Index (PASI) for skin symptoms and Nail Psoriasis Severity Index (NAPSI) score for the nail assessment. Here, we report 52-week interim data of Austrian patients with nail psoriasis using an observed cases approach.

Results: A total of 42 patients were included (81.0% male, mean [95%CI] age of 48.2 [43.8, 52.6] years, mean body mass index of 29.4 [27.7, 31.1] kg/m², 47.6% current smokers). Mean (95%CI) time since psoriasis diagnosis was 14.0 (10.0, 18.0) years. Mean (95%CI) WHO-5 score significantly increased from 55.6 (48.7, 62.5) at baseline to 68.7 (61.0, 76.4) at week 28 ($p < 0.001$), and to 70.6 (63.8, 77.4) at week 52 ($p < 0.001$). Mean (95%CI) DLQI-R score decreased from 13.0 (10.3, 15.7) at baseline to 3.3 (1.3, 5.3) at week 52 ($p < 0.001$). Mean (95%CI) PASI decreased from 11.6 (8.8, 14.4) at baseline to 1.1 (0.6, 1.6) at week 28 ($p < 0.001$), with a mean change from baseline of -10.7, and 0.8 (0.5, 1.1) at week 52 ($p < 0.001$), with a mean change from baseline of -11.6. At week 28 and week 52, respectively, 80.0%/47.5% and 82.9%/60.0% of patients achieved PASI ≤3/≤1. Mean (95%CI) NAPSI decreased from 44.4 (34.9, 53.9) at baseline to 21.9 (14.5, 29.3) at week 28 ($p < 0.001$), with a mean change from baseline of -22.1, and 15.7 (9.5, 21.9) at week 52 ($p < 0.001$), with a mean change from baseline of -32.1. At the point of this analysis one patient had a treatment related adverse event (AE) (mild nausea). No patients discontinued due to AEs.

Conclusions: In a real-world setting, tildrakizumab significantly improved nail psoriasis patients' well-being as well as skin symptoms and HRQoL without safety concerns, and this improvement was maintained through week 52. In addition, tildrakizumab showed marked and sustained improvement in a difficult to treat area such as nails.

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P-067

DRUG SURVIVAL OF SECUKINUMAB FOR MODERATE-TO-SEVERE PSORIATIC ARTHRITIS: A 7-YEAR REAL LIFE EXPERIENCE FROM THREE ROMANIAN REFERRAL CENTERS

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Introduction: secukinumab is a fully human immunoglobulin G1kappa monoclonal anti-IL17 A antibody, with high efficacy and a good safety profile for patients with moderate to active spondyloarthropathies in different clinical settings.

Objective: to explore the treatment effectiveness, safety and drug survival of secukinumab (SEC) in a real-life cohort of patients with moderate-to-severe psoriatic arthritis (PsA) and to identify predictors of discontinuation.

Methods: multicentric retrospective analysis of consecutive PsA patients receiving either 150 or 300 mg SEC once monthly (after the standard loading dose) followed-up from October 2017 to January 2024, according to local standards of care for patients under biologics in three academic rheumatology departments in North-East Romania. A series of variables were collected at baseline and every six-months including rheumatic and dermatologic data/parameters such as activity scores and responder status, typical and non-typical psoriasis variant, comorbidities that may impact the choice of biologics. Drug survival and the risk of discontinuation were assessed in subgroup (bio-naive versus previous anti-TNFα use) analysis (logistic regression, Kaplan-Meier curves; SPSS-21, $p < 0.05$).

Results: about half (43 cases) of all PsA under biologics in our database (98 cases) received secukinumab for their active disease, 34.88% (15 cases) as first line, 65.12% (34 cases) as switch in TNF non-responder patients. 48.83% patients received secukinumab overall, the retention rates at 6, 12, 24, 36, 48 and 52 months were 100%, 90.16%, 78.13%; 56.27%, 36.35% and 25%, respectively. Surprisingly, there was no statistic significant difference between drug survival in biologic-naïve patients versus those with previous exposure to TNF inhibitors in the whole population ($p > 0.05$); though, the response was more rapid and sustained in PsA failing to only one anti-TNF drug compared to those with two or more ($p < 0.05$). The multivariate COX regression showed factors associated with the risk of discontinuation: obese patients had significant higher chance to fail secukinumab, while naïve super-responder for Pso (PASI) significantly associated with lower rate of discontinuation 22 patients discontinued, the majority due to loss of efficacy.

Injection-site reactions were the most commonly reported adverse event; only one patient presented with exacerbation of inflammatory bowel disease, while one patient had a significant flare of skin psoriasis after a dramatic PASI response – as the articular disease was in remission, this case undergone swap on rixankizumab.

Conclusions: secukinumab showed high effectiveness and safety in routine clinical practice for up to 5 years in active PsA regardless the history of previous biological therapy.

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P-068

MODULATION OF DISEASE-CENTRAL CYTOKINE PATHWAYS WITH TAK-279, A HIGHLY SELECTIVE ORAL TYK2 INHIBITOR, DEFINES CLINICAL RESPONSE IN PATIENTS WITH PSORIASIS

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Introduction: A phase 2b study (NCT04999839) demonstrated promising efficacy and acceptable safety of TAK-279 in patients with moderate-to-severe psoriasis.[1] This study also investigated associations between TAK-279 treatment, psoriasis/TYK2 biomarkers and clinical/histologic response.

Objectives: To report disease biomarker changes and associations with clinical or histologic response using serum samples and lesional and non-lesional skin biopsies from patients in the study.
Methods: Lesion and non-lesion skin biopsies and serum samples were obtained at Day 1 (pre-dose) and Weeks 4 and 12 from patients receiving TAK-279 (2 mg, 5 mg, 15 mg, 30 mg) or placebo orally once daily. RT-qPCR, RNA-Seq, and immunohistochemistry were used to assess changes in lesion keratinocyte proliferation (KRT16 expression), psoriasis/TYK2 biomarkers, lesion gene signatures and plaque resolution (histological), and their associations with response (clinical [PASI-75] and histologic[2]).
Results: Biopsies from 63 consenting patients and serum from 252 patients were analyzed. At Week 12, most clinical responders ($n = 21/24$, 88%) had reductions in KRT16 expression of >87% versus baseline lesion levels. Pooled analysis showed that in most histologic responders (18/25, 72%), IL-17A and IL-17F expression reduced by >80% versus baseline lesion levels. Reductions in lesional type I IFN, IL-12, and IL-23 pathway gene expression occurred at 15 mg and 30 mg doses compared with baseline levels ($p < 0.05$). Dose- and time-dependent reductions in serum IL-17A, IL-17C, and IL-17F were observed in all TAK-279 groups versus placebo. In the 15 mg and 30 mg groups ($n = 23$), expression of key psoriasis/TYK2 biomarkers (e.g. DEFB4A, IL-36G, IL-19, IL-23A) reverted to non-lesion levels; of PASI90 responders at Week 12 ($n = 12$), 48/50 top upregulated genes in lesions reverted to non-lesion expression levels. Laboratory parameters were similar between groups. In all dose groups, patients had reduced lesion epidermal thickness, CD3+ T-cell and CD11c+ myeloid dendritic cell counts with TAK-279 versus baseline and placebo.
Conclusions: TAK-279 modulated psoriasis/TYK2 biomarkers, which was associated with clinical and histologic response in patients with moderate-to-severe psoriasis.

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P-069

ABSOLUTE PASI REDUCTIONS IN A PHASE 2B TRIAL OF THE SELECTIVE ORAL TYK2 INHIBITOR, TAK-279, IN MODERATE-TO-SEVERE PLAQUE PSORIASIS

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Introduction: TAK-279 (previously NDI-034858) is a highly selective, allosteric, oral inhibitor of tyrosine kinase 2 (TYK2), computationally designed to bind to the Janus homology 2 pseudokinase domain of TYK2.[1] In a recent phase 2b trial in patients with moderate-to-severe psoriasis (NCT04999839), TAK-279 was well tolerated and demonstrated safety and efficacy versus placebo at doses ≥5 mg once daily, with the 15 mg and 30 mg once daily doses achieving the highest levels of skin clearance at Week 12, as shown by PASI (Psoriasis Area and Severity Index) 75 (primary endpoint). Secondary efficacy endpoints (PASI90 and PASI100) were in accordance with the primary efficacy endpoint, with 33.0% of patients achieving PASI100 at the highest TAK-279 dose (30 mg).[2]
Objectives: This analysis further evaluated the efficacy of the 15 mg and 30 mg doses of TAK-279 using a range of PASI measures in patients with moderate-to-severe plaque psoriasis.
Methods: In this randomized, multicentre, double-blind, placebo-controlled trial, patients were randomized 1:1:1:1:1 to receive oral TAK-279 (2 mg, 5 mg, 15 mg or 30 mg) or placebo, once daily for 12 weeks. Mean PASI, mean change and mean percent change in PASI from baseline, and proportions of patients achieving PASI thresholds (≤2 and ≤1) were determined at Week 12. All analyses were pre-specified except for PASI thresholds (post hoc).
Results: At baseline, mean (standard deviation [SD]) PASI scores were similar across TAK-279 15 mg ($n = 53$; 15.5 [4.5]), TAK-279 30 mg ($n = 52$; 17.6 [6.2]) and placebo ($n = 52$; 18.3 [8.1]) groups. Mean PASI scores decreased as early as Week 2 and continued to decline throughout follow-up in the TAK-279 treatment groups, while scores decreased slightly in the placebo group. At Week 12, mean (SD) PASI scores were 2.5 (3.0) (least-squares [LS] mean change: −13.7; LS mean percentage change: −82.5%) in the 15 mg group, 3.5 (5.0) (LS mean change: −14.1; LS mean percentage change: −77.8%) in the 30 mg group and 13.4 (8.2) (LS mean change: −5.0; LS mean percentage change: −27.7%) in the placebo group ($p < 0.001$ for both doses versus placebo) (Figure 1). At Week 12, higher proportions of patients treated with TAK-279 15 mg and 30 mg achieved a PASI threshold of ≤2 (56.6% and 55.8%, respectively) compared with no patients in the placebo group (Figure 2). A similar pattern was observed for a PASI threshold of ≤1 (32.1% and 32.7% for 15 mg and 30 mg, respectively, versus 0% for placebo) (Figure 2).
Conclusions: TAK-279 was more effective at reducing absolute PASI scores at the 15 mg and 30 mg doses compared with placebo in patients with moderate-to-severe plaque psoriasis over 12 weeks. Further investigations of efficacy and safety of TAK-279 in phase 3 studies are ongoing.

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1. Leit S et al. J Med Chem 2023;66:10473–96.
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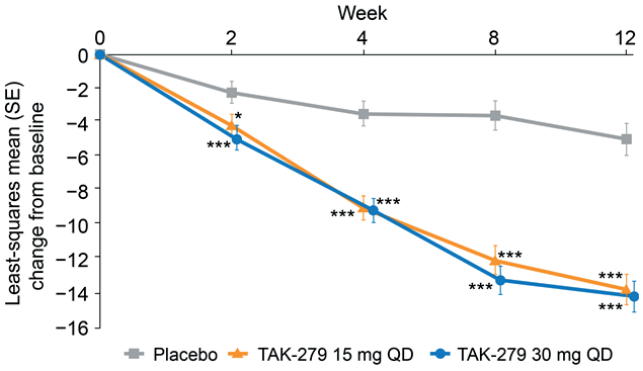
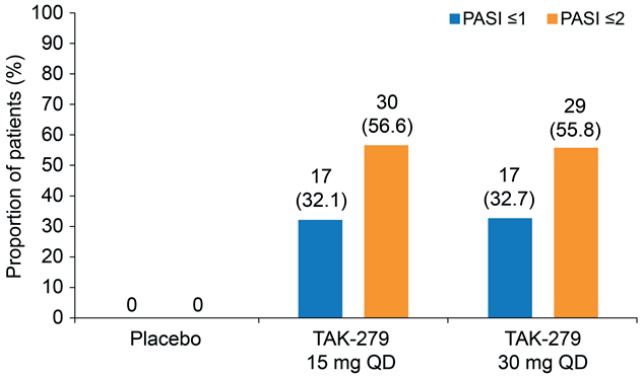
Figure 1. Least-squares mean change from baseline in PASI over 12 weeks (mITT analysis set).



Least-squares means were derived from a mixed model for repeated measurements on the change from baseline in PASI.
The model includes treatment, visit (Weeks 2, 4, 8 and 12), treatment-by-visit interaction and previous treatment with biologics as fixed effects, and baseline score as a covariate. Baseline was defined as the last non-missing assessment before or on the day of first study treatment dosing.
*p<0.05, **p<0.01, ***p≤0.001, relative to placebo.
mITT, modified intent-to-treat; PASI, Psoriasis Area and Severity Index; QD, once daily; SE, standard error.

Figure 2. Proportions of patients achieving PASI thresholds ≤1 and ≤2 at Week 12 (mITT analysis set).



Data above bars represent n (%).
mITT, modified intent-to-treat; PASI, Psoriasis Area and Severity Index; QD, once daily.

P-070

TAK-279, A SELECTIVE ORAL TYK2 INHIBITOR, REDUCES BSA INVOLVEMENT IN A PHASE 2B TRIAL IN MODERATE-TO-SEVERE PLAQUE PSORIASIS

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Introduction: TAK-279 (previously NDI-034858) is a highly selective, allosteric, oral inhibitor of tyrosine kinase 2 (TYK2). TYK2 mediates signalling from cytokines involved in the pathogenesis of psoriasis and other immune-mediated diseases.[1,2] In a recent phase 2b trial in patients with moderate-to-severe psoriasis (NCT04999839), TAK-279 was well tolerated and demonstrated safety and efficacy with greater skin clearance at doses ≥5 mg compared with placebo, with the two highest doses (15 mg and 30 mg) showing the strongest responses at Week 12.[3]

Objectives: This analysis further evaluated the efficacy of the 15 mg and 30 mg doses of TAK-279 using measures of body surface area (BSA) involvement in patients with moderate-to severe plaque psoriasis.

Methods: In this randomized, multicentre, double-blind, placebo-controlled trial, patients were randomized 1:1:1:1:1 to receive oral TAK-279 (2 mg, 5 mg, 15 mg or 30 mg) or placebo, once daily for 12 weeks. BSA outcome measures assessed at Week 12 were mean change in BSA from baseline, mean percentage change in BSA from baseline and the proportion of patients achieving a BSA threshold of ≤1% by visit. All analyses were pre-specified except for mean percentage change in BSA and achievement of BSA ≤1% threshold (post hoc).

Results: Baseline mean (standard deviation [SD]) absolute percentage BSA was generally consistent across TAK-279 15 mg ($n = 53$; 18.3 [10.3]), TAK-279 30 mg ($n = 52$; 22.2 [14.3]) and placebo ($n = 52$; 21.3 [13.6]) groups. Mean percentage BSA decreased as early as Week 2 and continued to decrease throughout follow-up in the TAK-279 groups, whereas scores slightly decreased in the placebo group. At Week 12, mean (SD) percentage BSA was 4.4 (5.3) (least-squares [LS] mean change: −14.7; LS mean percentage change: −72.9%) in the 15 mg group, 6.5 (12.5) (LS mean change: −15.7; LS mean percentage change: −73.1%) in the 30 mg group and 18.2 (13.6) (LS mean change: −4.0; LS mean percentage change: −19.3%) in the placebo group ($p < 0.001$ for both doses versus placebo) (Figure 1). A higher proportion of patients achieved a BSA threshold of ≤1% in the TAK-279 15 mg and 30 mg groups compared with the placebo group (35.8% and 44.2% versus 0%, respectively), and this was observed from Week 8 onwards (Figure 2).

Conclusions: Patients with moderate-to-severe plaque psoriasis who received the two highest doses of TAK-279 (15 mg and 30 mg) achieved greater reductions in BSA than patients who received placebo over 12 weeks. Further investigation of the efficacy and safety of TAK-279 in phase 3 studies is ongoing.

References
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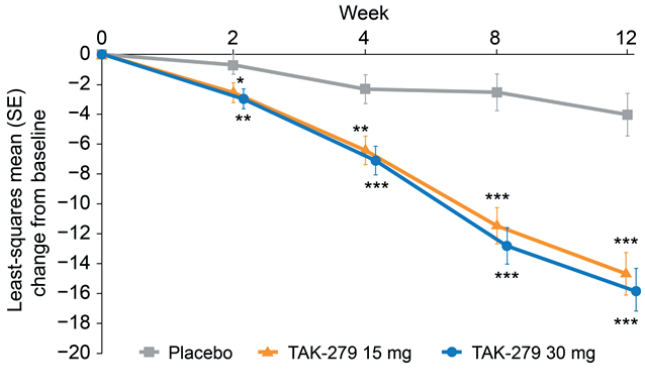
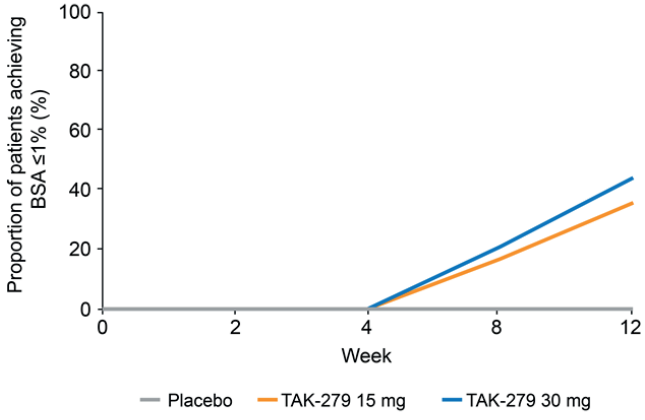
3. Armstrong A et al. Oral presentation presented at the Annual Meeting of the American Academy of Dermatology, March 17–21, 2023, New Orleans, LA, USA.

Figure 1. Least-squares mean change from baseline in BSA (%) over 12 weeks (mITT analysis set).



Least-squares means were derived from a mixed model for repeated measurements on the change from baseline in BSA.
The model includes treatment, visit (Weeks 2, 4, 8 and 12), treatment-by-visit interaction and previous treatment with biologics as fixed effects, and baseline score as a covariate. Baseline was defined as the last non-missing assessment before or on the day of first study treatment dosing.
*p<0.05, **p<0.01, ***p<0.001, relative to placebo.
BSA, body surface area; mITT, modified intent-to-treat; SE, standard error.

Figure 2. Proportion of patients achieving BSA ≤1% by visit (mITT analysis set).



BSA, body surface area; mITT, modified intent-to-treat.

P-071

PREGNANCY OUTCOMES IN WOMEN EXPOSED TO GUSELKUMAB: REVIEW OF CASES REPORTED TO THE MANUFACTURER'S GLOBAL SAFETY DATABASE

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Introduction: While biologics approved to treat a range of immunologic diseases have well established benefit-risk profiles in the overall target patient populations, data are limited on their use during pregnancy.(1,2) Guselkumab is a human immunoglobulin G1λ (IgG1λ) monoclonal antibody approved for the treatment of moderate-to-severe psoriasis (PsO) and active psoriatic arthritis (PsA) and currently in clinical development for the treatment of inflammatory bowel disease (IBD).(3,4) IgG1λ antibodies are known to cross the placental barrier and have the potential to affect pregnancy outcomes.(1-3,5)

Objectives: To assess pregnancy outcomes in pregnant women exposed to guselkumab.

Methods: Cumulative data from the Janssen Global Safety Database reported through 12 July 2023 are summarized descriptively for medically confirmed pregnancies with maternal exposure to guselkumab before conception (within 3 months prior to confirmed pregnancy), during the first trimester (T1), after the first trimester (T2, T3), or any time during confirmed pregnancy. Pregnancy reports may have been prospective or retrospective. Pregnancy outcomes were classified as live births with or without congenital anomalies; spontaneous abortions; elective terminations, stillbirths, or unspecified abortions with or without fetal defects; fetal deaths; ectopic pregnancies; induced/missed abortions; or pregnancies that are ongoing or that have no reported outcome.

Results: Through 12 July 2023, 590 pregnancy events (including twins [2]; triplets [1]) in 586 women exposed to guselkumab have been reported prospectively ($N = 505$) or retrospectively ($N = 85$) (Table 1). In cases in which the guselkumab therapeutic indication was reported, most were PsO (90.0% [371/412]); others included PsA (2.2% [9/412]), both PsO and PsA (3.4% [14/412]), and IBD (1.5% [6/412]). In cases with data allowing for calculation of the timing of guselkumab exposure, exposure was before conception (14.3% [27/189]), during T1 (77.8% [147/189]), during T2 or T3 (5.3% [10/189]), or any time during pregnancy (2.6% [5/189]). Mean duration of guselkumab exposure prior to pregnancy in known cases ($N = 158$) was 385 days (median, 238; range=0 to 1717 days). Mean maternal age in those with reported data ($N = 349$) was 32.0 years (median, 32 years; range=19 to 56 years). Outcomes have been reported for 30.2% (178/590) of pregnancy events and included live birth (63.5% [113/178]), spontaneous abortion (22.5% [40/178]), elective termination (no fetal defects or unknown) (6.7% [12/178]), ectopic pregnancy (3.4% [6/178]), induced abortion (1.1% [2/178]), fetal death (1.1% [2/178]), and 1 event each (0.6%) of elective termination with a fetal defect, missed abortion, and unspecified abortion with fetal defects.

Conclusions: In pregnancy cases with known outcomes, rates of live births, spontaneous and elective/induced abortions, and congenital anomalies in women exposed to guselkumab ≤3 months before or during pregnancy are consistent with rates reported for the United States general population,(6,7) suggesting no apparent impact of guselkumab on pregnancy outcomes. These results are limited by missing data on pregnancy outcomes, maternal age statistics, concomitant medication use, other risk factors, and duration of guselkumab exposure. However, these findings represent the most robust analysis of maternal guselkumab-exposed pregnancy outcomes to date. Additional evidence is needed to increase our understanding of the effects of guselkumab exposure on pregnancy outcomes across disease indications.

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Table. Pregnancy Outcomes for Prospective and Retrospective Cases by Trimester of Exposure Reported With Maternal Guselkumab Exposure (N=586)

	Number of Prospective Cases						Number of Retrospective Cases						Overall
	Timing of Exposure During Pregnancy						Timing of Exposure During Pregnancy						
Pregnancy outcome	Before conception[a]	First trimester[a]	After first trimester[a]	During all pregnancy	NR	Total	Before conception[a]	First trimester[a]	After first trimester[a]	During all pregnancy	NR	Total	Total
Live birth w/o congenital anomaly	9[b]	31[b]	0	2	24[f]	66	1	13[b]	3[b]	1	29[f]	47	113
Live birth w/ congenital anomaly	0	0	0	0	0	0	0	0	0	0	0	0	0
Spontaneous abortion	1	8	0	0	7	16	1	8	0	0	15	24	40
Elective termination (no fetal defects or unknown)	1	3	1	0	1	6	0	3	0	0	3	6	12
Elective termination (fetal defects)	0	1[c]	0	0	0	1	0	0	0	0	0	0	1
Ectopic pregnancy	0	0	0	0	1	1	0	1	0	0	4	5	6
Fetal death	0	2	0	0	0	2	0	0	0	0	0	0	2
Induced abortion[h]	0	0	0	0	0	0	0	1	0	0	1	2	2
Missed abortion[i]	0	1[e]	0	0	0	1	0	0	0	0	0	0	1
Abortion unspecified (fetal defects)	0	0	0	0	0	0	0	1[j]	0	0	0	1	1
Abortion unspecified (no fetal defects or unknown)	0	0	0	0	0	0	0	0	0	0	0	0	0
Stillbirth w/ fetal defects	0	0	0	0	0	0	0	0	0	0	0	0	0
Stillbirth w/o fetal defects	0	0	0	0	0	0	0	0	0	0	0	0	0
NR/ongoing	14	74[d]	6	2	316	412	0	0	0	0	0	0	412
Total	25	120	7	4	349	505	2	27	3	1	52	85	590

AE, adverse event; NR, not reported.
[a]Cases with reported exposure to guselkumab in all 3 trimesters are counted only once in the 'During all pregnancy' category.
[b]Includes 1 case of premature birth.
[c]Includes 1 case of premature birth; 1 twin pregnancy; 1 AE of baby's heart rate decreasing; 1 AE of jaundice; 4 cases of reported guselkumab exposure in the first and second trimesters; and 1 case of reported guselkumab exposure in the first and third trimesters.
[d]Includes 2 cases of premature birth and 1 AE of fetal heart rate decreased.
[e]Includes 1 case of reported guselkumab exposure in the first and second trimesters.
[f]Includes 1 AE of abnormal fetal heart rate.
[g]Reported AE of fetal disorder.
[h]Defined as deliberate surgical or medical termination of pregnancy that has no reached viability; includes both safe and unsafe abortions.
[i]Defined as vaginal bleeding, perhaps with some passage of tissue or products of conception.
[j]Congenital anomaly of fetal malformation.
[k]Includes 4 cases of reported guselkumab exposure in the first and second trimesters and 2 cases with reported guselkumab exposure in the first and third trimesters.
[l]Includes 1 twin pregnancy and 1 triplet pregnancy.

P-072

BIMEKIZUMAB TREATMENT IN PSORIASIS PATIENTS: A MECHANISTIC UNDERSTANDING OF THE DURABLE CLINICAL RESPONSE

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Introduction: Dual inhibition of interleukin (IL)-17F in addition to IL-17A with bimekizumab (BKZ) has been associated with long-term skin clearance in psoriasis patients, with >80% maintaining complete skin clearance from Week 16 through 3 years.[1] While IL-17A and IL-17F have overlapping biology, their production from IL-17-secreting cells is regulated differently. Chronic stimulation causes preferential IL-17F production, consistent with the greater abundance of IL-17F-secreting cells in psoriatic lesional tissue.[2–4] Resident memory T cells (Trm) have been implicated in disease recurrence at the same location following treatment withdrawal and in disease perpetuation during treatment.[5]

Objectives: To understand the molecular mechanisms that lead to the durable and continuous complete skin clearance observed in BKZ treated patients with psoriasis over 3 years.

Methods: Several transcriptomics datasets were analysed, including single-cell RNA sequencing (RNA-seq) datasets from lesional psoriasis biopsies (reported elsewhere),[4,6,7] alongside pre- and post-treatment bulk RNA-seq data from a phase 2a trial of BKZ in psoriasis (NCT03025542, study design previously described; biopsies collected: Weeks 0/8 [lesional/non-lesional skin] and Weeks 16/28 [lesional only]).[8]

Results: Analysis of the 3 independent psoriasis single-cell datasets consistently highlighted that IL17A- and IL17F-secreting cells have highly similar transcriptomes. IL7R was highly expressed on both IL17A- and, particularly, IL17F-secreting cells, and the IL7 pathway is associated with cell survival. Presence of IL17A- and IL17F-expressing Trm cells in psoriatic lesional tissue was

also indicated, alongside expression of several T cell pro-survival factors. Bulk transcriptomic analysis showed normalisation of a Trm gene signature after only 2 doses of BKZ (median percentage improvement: 78.1% at Week 8, which increased to 87.7% at Week 28, following 3 doses; Figure). Additionally, elevated expression of the pro-survival factors IL7R and IL32 was reversed alongside normalisation of an anti-apoptotic gene signature.

Conclusions: These mechanistic data from patient samples highlight the importance of IL-17F and IL-17A dual neutralisation in normalising both Trm biology and pro-survival factors. These observations have implications for disease modification and are important for the maintenance and durability of complete skin clearance in psoriasis.

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Previously presented at the Inflammatory Skin Disease Summit (ISDS) 2023; abstract subsequently published in the Journal of Investigative Dermatology (2023).

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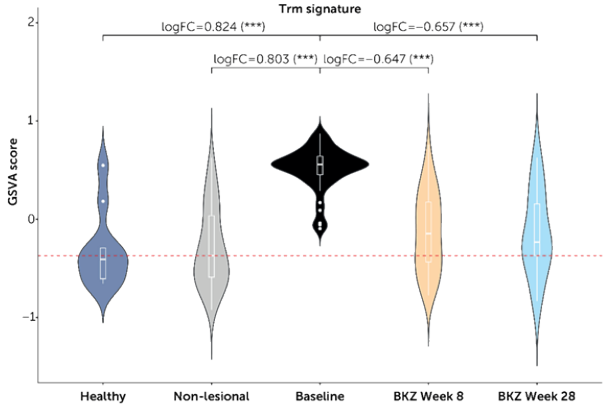
Figure. Normalisation of Trm signature (CD103, CD69, CD44) in treated lesional tissue at Weeks 8/28 versus baseline healthy, non-lesional and lesional tissue



Gene Set Variation Analysis (GSVA)[9] was used to estimate gene set level of expression. The red horizontal line corresponds to the median baseline expression in non-lesional tissue. LogFC and FDR-adjusted p-values were calculated using the limma moderated t-test. ***FDR<0.001. BKZ: bimekizumab; FC: fold change; FDR: false discovery rate; GSVA: Gene Set Variation Analysis; Trm: tissue-resident memory T cells.

P-073

REAL-WORLD SAFETY PROFILE OF SPESOLIMAB IN GENERALISED PUSTULAR PSORIASIS (GPP): EXPANDED ACCESS PROGRAMMES IN JAPAN AND CHINA

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Introduction: Generalised pustular psoriasis (GPP) is a rare inflammatory disease that causes chronic skin symptoms and recurring, unpredictable and sometimes life-threatening flares. Both chronic and flare-related symptoms negatively impact quality of life for patients [1,2] Spesolimab is an antibody-based therapy approved for the treatment of GPP flares [3].

Objectives: Expanded access programmes (EAPs) were implemented in Japan and China to provide early access to spesolimab for patients with GPP who were not eligible for clinical trials and had no other treatment options.

Methods: Patients 18–75 years old received a 900 mg dose of intravenous spesolimab for treatment of a GPP flare, with an optional second dose after 1 week for persistent flare symptoms. Adverse events (AEs), serious AEs (SAEs) and AEs of special interest (AESIs) were recorded for up to 16 weeks after the last spesolimab infusion.

Results: Fifty patients (Japan, $n=11$; China, $n=39$) with GPP received spesolimab ($n=29$ female; 58%). Study duration was ~1 year, with a mean (±SD) follow-up of 3.8 (0.4) months. Time since GPP diagnosis was ≤1 year ($n=10$), >1 and ≤5 years ($n=12$), >5 and ≤10 years ($n=8$), >10 years ($n=19$), and missing ($n=1$). Mean (±SD) age was 41.7 (14.8) years, with 96% of patients ($n=48$) below 65 years old. Overall, 49 patients had 1 flare and 1 patient had 2 flares. The cause of flares was unknown in approximately half of patients ($n=29/51$ flare events; 57%); reported flare triggers were treatment withdrawal ($n=6$; 12%), pregnancy ($n=2$; 4%), stress ($n=3$; 6%), infection ($n=1$; 2%) and other reasons such as vaccinations (COVID-19 and other), and lack of medication efficacy ($n=10$; 20%). Most patients ($n=46$; 92%) had co-existing medical conditions, with the most common (>10% of patients) being plaque psoriasis ($n=17$; 34%), pyrexia/fever ($n=10$; 20%), hypertension ($n=8$; 16%), psoriatic arthropathy and anaemia ($n=6$; 12% each).

Most patients ($n=47$; 94%) were also taking other medications, which included immunosuppressants, corticosteroids, topicals and biologic therapy. Use of ≥1 biologic in addition to spesolimab was reported in 30% of patients ($n=15$: IL-17 inhibitor [$n=14$], IL-23 inhibitor [$n=1$] and/or TNF-alpha inhibitor [$n=1$]). Of 27 patients with ongoing chronic plaque psoriasis (CPP), 89% ($n=24$) were receiving treatment for CPP. AEs occurred in 37 patients (74%) and were mostly mild or moderate (92%). The most common AEs were COVID-19 ($n=10$; 20%), pyrexia/fever ($n=6$; 12%), upper respiratory infection, low blood protein and pruritus/itching ($n=4$; 8% for all). Potential hypersensitivity events were mild or moderate. There were 3 patients with SAEs (pneumonia [$n=2$], COVID-19, respiratory failure and pustular psoriasis [$n=1$ for all]), 2 AESIs (COVID−19, pneumonia) and 14 investigator-defined drug-related AEs. No AE led to discontinuation or death.

Conclusions: EAPs can provide valuable information for patients and physicians about the natural history of a disease, as well as safety and tolerability of a treatment in a real-life patient population. Spesolimab was safe and well tolerated in patients with GPP,

including patients with co-existing medical conditions and those taking other medications. Findings were consistent with a previous clinical trial in patients with GPP flares (EFFISAYIL® 1) [3-5].

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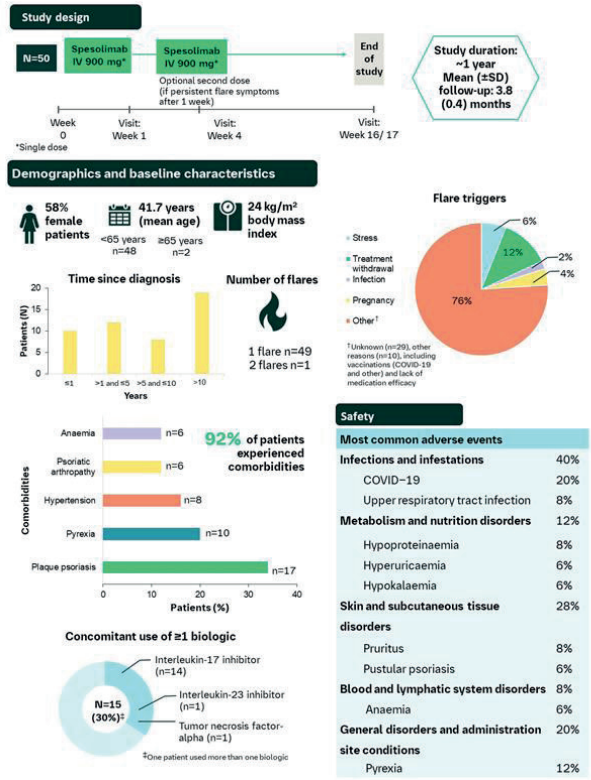

P-074

BIMEKIZUMAB EFFICACY AND SAFETY IN PATIENTS WITH PSORIATIC ARTHRITIS AND PSORIASIS: UP TO 2-YEAR RESULTS FROM TWO PHASE 3 STUDIES

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Introduction: Bimekizumab (BKZ), a humanised monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated efficacy and tolerability to 1 year in patients with psoriatic arthritis (PsA).[1,2] PsA develops in up to 30% of patients with psoriasis;[3] efficacy and safety of treatments in patients with PsA and skin involvement is therefore clinically important.

Objectives: To assess up to 2-year efficacy and safety of BKZ in patients with PsA and psoriasis who were biologic disease-modifying antirheumatic drug (bDMARD)-naïve or had prior inadequate response/intolerance to tumour necrosis factor inhibitors (TNFi-IR).

Methods: BE OPTIMAL (NCT03895203; bDMARD-naïve) and BE COMPLETE (NCT03896581; TNFi-IR), both placebo (PBO)-controlled to Week (Wk)16, assessed subcutaneous BKZ 160 mg every 4 wks (Q4W) in patients with PsA. PBO patients switched to BKZ (PBO/BKZ) at Wk16. BE OPTIMAL included a reference arm (adalimumab [ADA] 40 mg Q2W); these patients switched to BKZ at Wk52 (ADA/BKZ) with no washout between treatments. BE OPTIMAL Wk52 and BE COMPLETE Wk16 completers were eligible to enrol in the open-label extension BE VITAL (NCT04009499).

Post hoc data are reported for patients with psoriasis affecting ≥3% body surface area (BSA) at baseline; analyses also conducted for psoriasis ≥3%–≤10% and >10% BSA subgroups. Interim data cut reported; efficacy outcomes reported to Wk104 from BE OPTIMAL and Wk88 from BE COMPLETE. Missing data imputed using non-responder (binary), multiple (continuous), or worst category (categorical) imputation. Safety data are reported for patients treated with BKZ.

Results: 425/852 (49.9%) bDMARD-naïve (217/431 BKZ; 140/281 PBO; 68/140 ADA) and 264/400 (66.0%) TNFi-IR patients (176/267 BKZ; 88/133 PBO) had baseline psoriasis ≥3% BSA; 365/425 (85.9%) bDMARD-naïve and 221/264 (83.7%) TNFi-IR patients completed Wk104/88.

Efficacy responses seen at Wk52 with BKZ were sustained to Wk104/88, with high proportions of bDMARD-naïve and TNFi-IR patients achieving American College of Rheumatology (ACR)50, Psoriasis Area and Severity Index (PASI)100, and minimal disease activity responses (Figure). Trends were consistent for additional efficacy outcomes (Table). Results were generally similar across the ≥3%–≤10% and >10% BSA subgroups.

For bDMARD-naïve and TNFi-IR patients on BKZ, the exposure-adjusted incidence rates per 100 patient-years (EAIR/100 PY) for ≥1 treatment emergent adverse event (TEAE) were 157.2 and 84.7, respectively. Incidence rates (EAIR/100 PY) of serious TEAEs were 5.3 (bDMARD-naïve) and 4.7 (TNFi-IR). Over 2 years, 3 deaths occurred (bDMARD-naïve: 2 [1 before and 1 after Wk52], TNFi-IR: 1 [before Wk52]), all deemed unrelated to treatment. The most frequent TEAEs were nasopharyngitis, SARS-CoV-2 infection, and upper respiratory tract infection for bDMARD-naïve patients, and SARS-CoV-2 infection, nasopharyngitis, and urinary tract infection for TNFi-IR patients. Of reported Candida infections (EAIR/100 PY bDMARD-naïve: 5.8, TNFi-IR: 2.5), none were serious or systemic; 3 infections led to study discontinuation (bDMARD-naïve: 2, TNFi-IR: 1).

Conclusions: BKZ treatment resulted in sustained clinical efficacy up to 2 years; improvements were generally similar in bDMARD-naïve and TNFi-IR patients with PsA and psoriasis. BKZ was well tolerated; no new safety signals were observed.[1,2]

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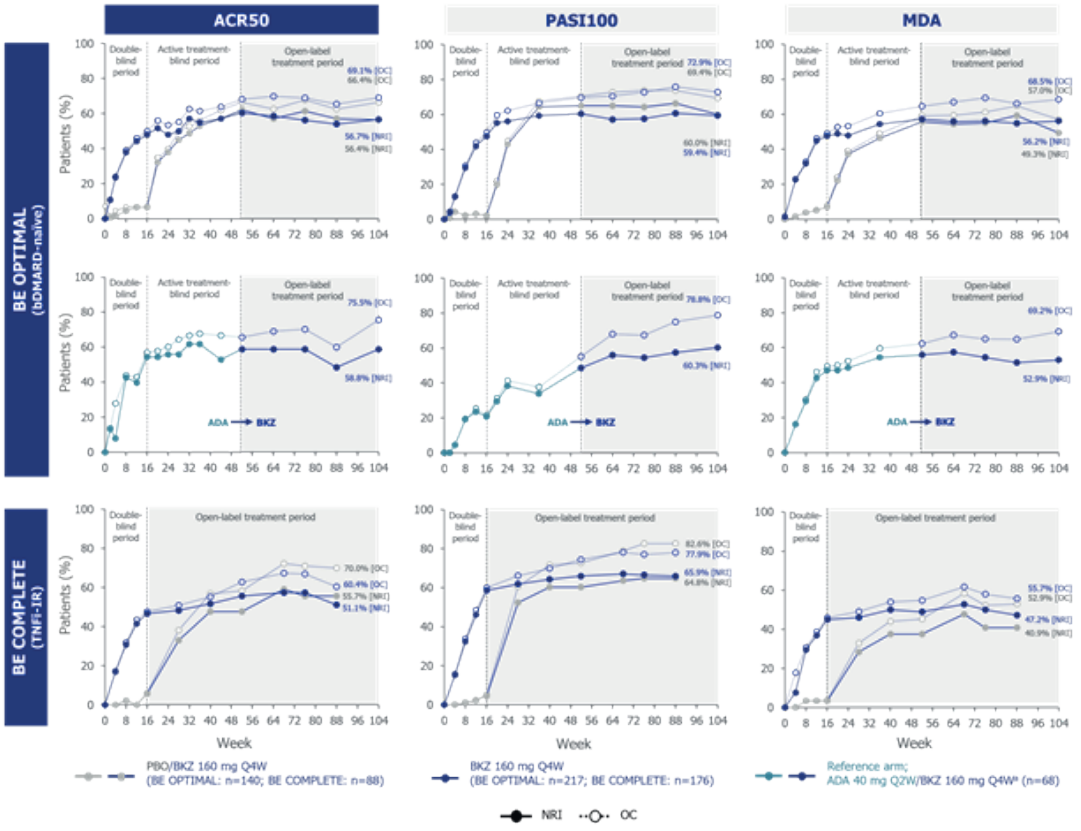
Figure. Proportion of patients with baseline psoriasis ≥3% BSA achieving ACR50, PASI100 and MDA over time to Week 104/88 (NRI, OC)



Randomised set, in patients with psoriasis affecting ≥3% BSA at baseline. In BE OPTIMAL patients were randomised 3:2:1 to BKZ 160 mg Q4W:PBO:reference arm (ADA 40 mg Q2W), in BE COMPLETE patients were randomised 2:1 to BKZ 160 mg Q4W:PBO. In both studies, patients on PBO switched to BKZ 160 mg Q4W at Week 16. In BE OPTIMAL, patients on ADA switched to BKZ 160 mg Q4W at Week 52. [a] Reference arm; study not powered for statistical comparisons of ADA to BKZ or PBO. ACR50: ≥50% improvement in American College of Rheumatology response criteria; ADA: adalimumab; bDMARD: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; BSA: body surface area; MDA: minimal disease activity; NRI: non-responder imputation; OC: observed case; PASI100: 100% improvement in Psoriasis Area and Severity Index; PBO: placebo; Q2W: every two weeks; Q4W: every four weeks; TNFi-IR: prior inadequate response or intolerance to tumour necrosis factor inhibitors.

Table. Additional efficacy outcomes for patients with baseline psoriasis ≥3% BSA at Week 104/88 (MI, NRI, WCI)

	BE OPTIMAL (bDMARD-naïve) Week 104			BE COMPLETE (TNFi-IR) Week 88	
	PBO/BKZ 160 mg Q4W n=140	BKZ 160 mg Q4W n=217	ADA 20 mg Q2W/ BKZ 160 mg Q4W[a] n=68	PBO/BKZ 160 mg Q4W n=88	BKZ 160 mg Q4W n=176
ACR20 responders, n (%)	98 (70.0)	151 (69.6)	45 (66.2)	61 (69.3)	119 (67.6)
ACR70 responders, n (%)	54 (38.6)	90 (41.5)	30 (44.1)	28 (31.8)	64 (36.4)
PASI75 responders, n (%)	112 (80.0)	162 (74.7)	49 (72.1)	66 (75.0)	143 (81.3)
PASI90 responders, n (%)	102 (72.9)	153 (70.5)	47 (69.1)	62 (70.5)	127 (72.2)
ACR50 + PASI100 responders, n (%)	60 (42.9)	93 (42.9)	33 (48.5)	43 (48.9)	71 (40.3)
VLDA responders, n (%)	39 (27.9)	71 (32.7)	24 (35.3)	16 (18.2)	45 (25.6)
DAPSA disease state [WCI], n (%)					
LDA+REM	71 (50.7)	122 (56.2)	36 (52.9)	49 (55.7)	85 (48.3)
REM	28 (20.0)	54 (24.9)	23 (33.8)	13 (14.8)	33 (18.8)
TJC=0 (of 68 joints), n (%)	46 (32.9)	77 (35.5)	25 (36.8)	19 (21.6)	52 (29.5)
SJC=0 (of 66 joints), n (%)	89 (63.6)	145 (66.8)	39 (57.4)	53 (60.2)	108 (61.4)
Enthesitis resolution,[b] n/N (%)	26/34 (76.5)	41/61 (67.2)	9/15 (60.0)	10/20 (50.0)	35/63 (55.6)
Dactylitis resolution,[c] n/N (%)	10/10 (100.0)	21/27 (77.8)	5/8 (62.5)	5/7 (71.4)	17/21 (81.0)
Nail psoriasis resolution,[d] n/N (%)	63/88 (71.6)	91/133 (68.4)	32/42 (76.2)	32/54 (59.3)	74/105 (70.5)
HAQ-DI CfB [MI], mean (SE)	−0.42 (0.05)	−0.39 (0.04)	−0.50 (0.08)	−0.50 (0.07)	−0.48 (0.04)
SF-36 PCS CfB [MI], mean (SE)	9.8 (0.8)	9.2 (0.7)	11.3 (1.4)	8.9 (1.3)	9.8 (0.8)

Randomised set, in patients with psoriasis affecting ≥3% BSA at baseline. Data are NRI unless otherwise stated. In BE OPTIMAL patients were randomised 3:2:1 to BKZ 160 mg Q4W:PBO:reference arm (ADA 40 mg Q2W), in BE COMPLETE patients were randomised 2:1 to BKZ 160 mg Q4W:PBO. In both studies, patients on PBO switched to BKZ 160 mg Q4W at Week 16. In BE OPTIMAL, patients on ADA switched to BKZ 160 mg Q4W at Week 52. [a] Reference arm; study not powered for statistical comparisons of ADA to BKZ or PBO; [b] In patients with baseline enthesitis (LEI >0); [c] In patients with baseline dactylitis (LDI >0); [d] In patients with baseline nail psoriasis (mNAPSI >0). ACR20/50/70: ≥20/50/70% improvement in American College of Rheumatology response criteria; ADA: adalimumab; bDMARD: biologic disease-modifying antirheumatic drug; BSA: body surface area; BKZ: bimekizumab; CfB: change from baseline; DAPSA: Disease Activity Index for Psoriatic Arthritis; HAQ-DI: Health Assessment Questionnaire-Disability Index; LDA: low disease activity; LDI: Leeds Dactylitis Index; LEI: Leeds Ent hesitis Index; MI: multiple imputation; mNAPSI: modified Nail Psoriasis Severity Index; NRI: non-responder imputation; PASI75/90/100: ≥75/90/100% improvement in Psoriasis Area and Severity Index; PBO: placebo; Q2W: every two weeks; Q4W: every four weeks; REM: remission; SE: standard error; SF-36 PCS: Short-Form 36-item Health Survey Physical Component Summary; SJC: swollen joint count; TJC: tender jo int count; TNFi-IR: prior inadequate response or intolerance to tumour necrosis factor inhibitors; VLDA: very low disease activity; WCI: worst-category imputation.

P-075

NEW-ONSET AND EXACERBATION OF PSORIASIS FOLLOWING COVID-19 VACCINATION: A NATION-WIDE POPULATION-BASED COHORT STUDY IN KOREA

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Introduction: Despite the World Health Organization (WHO) lifting the public health emergency of international concern (PHEIC) for COVID-19 on May 2023, the impact of mass SARS-CoV-2 vaccination persists, and concerns about the emergence of autoimmune or inflammatory disorders triggered by vaccination have been raised.1 SARS-CoV-2 vaccines have been associated with various cutaneous manifestations and flaring of certain dermatological diseases such as psoriasis.2 As cases of new-onset or exacerbation of psoriasis after vaccination have been reported globally, 3-5 a convincing large-scale investigation is required to estimate the association.

Objectives: Our study sought to investigate the association between SARS-CoV-2 vaccination and the new-onset (Study 1) or exacerbation (Study 2) of psoriasis.

Methods: Using the National Health Insurance Service claims database in South Korea, individuals who received the SARS-CoV-2 vaccinations from February 26, 2021 to July 31, 2021 were recruited (Figure 1). Patients diagnosed with psoriasis before vaccination were excluded from Study 1, whereas patients previously diagnosed with psoriasis but not having undergone treatment within the four preceding years were included in Study 2. Unvaccinated controls were selected by 1:1 propensity score matching with vaccinated individuals in Studies 1 and 2. Each individual was monitored for five months. The primary endpoint was the presence of psoriasis. The hazard ratio (HR) for psoriasis was calculated using a multivariate Cox proportional hazard model.

Results: In Study 1, we analysed the incidence of new-onset psoriasis in 673,048 vaccinated individuals and 673,048 unvaccinated controls. Study 1 revealed a 1.36-fold increased risk of developing psoriasis in the vaccinated group than in the non-vaccinated group (HR: 1.36, 95%CI 1.23-1.51, $p < 0.001$) (Figure 2). In Study 2, the study and control groups included 4,211 vaccinated and 4,211 unvaccinated patients with psoriasis who had not received any treatment during the past four years, respectively. We defined an exacerbation of psoriasis as psoriasis that was diagnosed again during the five-month follow-up in these groups. In Study 2, vaccinated patients showed a 1.83-fold higher incidence of psoriasis exacerbation than non-vaccinated patients (HR 1.83, 95%CI 1.15-2.93, $p < 0.001$). Additionally, sensitivity analyses showed that the significantly increased risk of new-onset (HR 1.32, 95%CI 1.19-1.47) or an exacerbation (HR 2.03, 95%CI 1.25-3.31) of psoriasis in the vaccination group did not change when patients with COVID-19 infection were excluded. Considering the type of vaccine, the HR for newly diagnosed psoriasis was 1.34, 1.31, and 1.47, and the HR for exacerbated psoriasis was 2.11, 1.52 and 2.58 with the mRNA, non-mRNA and mixed vaccinations, respectively.

Conclusion: This study demonstrated a significantly increased risk of new-onset or exacerbation of psoriasis in patients who received SARS-CoV-2 vaccination in South Korea. Although additional studies in other countries or over extended periods are needed, these findings suggest a possible connection between vaccination-related immunological changes and psoriasis pathogenesis, which may have implications for vaccination strategies for susceptible individuals. In the era of emerging new viruses, it is crucial to proactively prepare for the potential impact of vaccinations on existing skin diseases. Further prospective studies are necessary to uncover the precise mechanisms involved.

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P-076

RISK OF MAJOR ADVERSE CARDIOVASCULAR EVENTS AND ALL-CAUSE MORTALITY AMONG PATIENTS WITH PSORIATIC DISEASE TREATED WITH TNF-A AND IL-12/23 INHIBITORS

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Introduction: Few studies have investigated the impact of biologics on the risk of major adverse cardiovascular events (MACEs) among Korean patients with psoriatic diseases.

Objectives: To compare the risk of MACEs and all-cause mortality among patients with psoriatic disease treated with tumor necrosis factor (TNF)-α and interleukin (IL)-12/23 inhibitors in Korea.

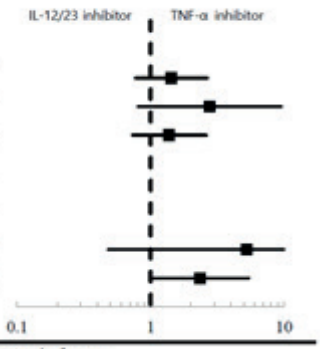
Methods: Patients with psoriatic disease prescribed with TNF-α and IL-12/23 inhibitors since 2016 were selected from the Korean National Health Insurance Service Database. Follow-up data for MACEs and all-cause mortality between 2016 and 2020 were collected. The risk of MACEs and all-cause mortality was compared between the two groups.

Results: A total of 2,886 individuals were included, including 1,987 IL-12/23 inhibitor users and 899 TNF-α inhibitor users. Compared with IL-12/23 inhibitor users, TNF-α inhibitor users had a higher prevalence of dyslipidemia (51.06% vs. 42.48%, $p < 0.001$) and a significantly higher risk of all-cause mortality (adjusted hazard ratio [aHR], 2.36; 95% confidence interval [CI], 1.02–5.49) but not MACE (aHR, 1.43; 95% CI, 0.77–2.67) (Figure). After controlling for age, female TNF-α inhibitor users had a significantly increased risk of all-cause mortality (aHR, 5.29; 95% CI, 1.32–21.28). Meanwhile, after controlling for sex, TNF-α inhibitor users aged 60 years or older demonstrated a significantly elevated risk of all-cause mortality (aHR, 5.81; 95% CI, 1.74–19.23).

Conclusions: No statistically significant difference in MACE risk was observed between patients who used TNF-α and IL-12/23 inhibitors. Nevertheless, the use of IL-12/23 inhibitors, especially among older and female patients, resulted in a lower overall mortality.

Figure. Risk of MACEs and all-cause mortality among TNF-α inhibitor users compared with IL-12/23 inhibitor users.

	TNF-α inhibitor user (n=899)			IL-12/23 inhibitor user (n=1,987)				
	No. of events	Sum of person-years	Incidence rate per 1,000 person-years (95% CI)	No. of events	Sum of person-years	Incidence rate per 1,000 person-years (95% CI)	Adjusted hazard ratio (95% CI)†	p-value
MACE	15	2235.8	6.71 (3.75 - 11.07)	30	6245.6	4.80 (3.24 - 6.86)	1.43 (0.77 - 2.67)	0.256
Acute myocardial infarction	5	2248.7	2.22 (0.72 - 5.19)	5	6291.5	0.79 (0.26 - 1.85)	2.78 (0.80 - 9.56)	0.108
Coronary revascularization	14	2235.8	6.26 (3.42 - 10.51)	29	6245.6	4.64 (3.11 - 6.67)	1.38 (0.73 - 2.63)	0.321
Heart failure	0	2257.1	0.00	5	6287.9	0.80 (0.26 - 1.86)	NE	NE
Ischemic stroke	0	2257.1	0.00	0	6298.1	0.00	NE	NE
Hemorrhagic stroke	0	2257.1	0.00	0	6298.1	0.00	NE	NE
Cardiovascular death	2	2257.1	0.89 (0.11 - 3.20)	1	6298.1	0.16 (0.004 - 0.88)	5.27 (0.48 - 58.46)	0.176
All-cause death	10	2257.1	4.43 (2.12 - 8.15)	12	6298.1	1.91 (0.98 - 3.33)	2.36 (1.02 - 5.49)	0.046



CI, confidence interval; IL, interleukin; MACEs, major adverse cardiovascular events; NE, not estimated; TNF, tumor necrosis factor.
†Adjusted for age, sex, and dyslipidemia.

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P-077

RISK OF INCIDENT INFLAMMATORY HEART DISEASES AND AUTOIMMUNE NEURAL DISEASES IN PATIENTS WITH PSORIATIC DISEASE

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Background: While various inflammatory and autoimmune diseases are reported to be comorbidities of psoriasis, the risk of incident inflammatory heart diseases (IHD) and autoimmune neural diseases in patients with psoriatic disease are lacking in literature.
Objectives: This study aimed to identify the risk of incident IHD and autoimmune neural diseases in patients newly diagnosed with psoriatic disease in Korean population.
Methods: Patients newly diagnosed with psoriatic disease between 2007 and 2019 in the Korean National Health Insurance Service database were included with two-year washout period along with their 1:1 age-, sex- matched comparators who were never diagnosed with psoriatic disease. The data on incident IHD and autoimmune neural diseases were identified during follow-up period from 2007 to 2020. Multivariable Cox regression models were used to evaluate the risk of each comorbidity in psoriatic disease group compared with the comparator group.
Results: A total of 358,899 and 359,548 patients with psoriatic disease were retrieved from the database to determine the risk of IHD and autoimmune neural diseases respectively in this study. After adjusting for insurance type and comorbidities, the risk of IHD in total (adjusted hazard ratio [95% confidence interval], 1.12 [1.01 -1.24]) and acute myocarditis (1.55 [1.01 - 2.39]) was significantly higher in psoriatic disease group compared with the matched comparators (Figure 1). After adjusting for insurance type and comorbidities, patients with psoriatic disease had higher risk of autoimmune diseases of the peripheral nervous system (PNS) in total (1.51 [1.21 - 1.88]), inflammatory myositis (2.53 [1.61 – 3.98]), and autoimmune diseases of the central nervous system (CNS) in total (1.69 [1.12 – 2.56]) compared with the matched comparators (Figure 2). The risk of IHD and autoimmune neural diseases were not associated with the severity of psoriatic disease.
Conclusions: Patients with psoriatic disease have a significantly increased risk of IHD, especially acute myocarditis, and autoimmune neural diseases including both those affecting PNS and CNS.

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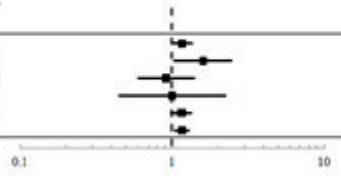
Figure 1. Risk of inflammatory heart diseases among patients with newly-diagnosed psoriatic disease compared with the matched comparators.

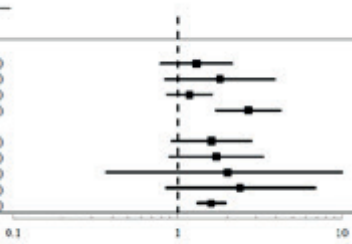
Inflammatory heart disease	Incidence rate* (No. of events/person-years) Matched comparator cohort (1:1)		Patients with newly-diagnosed psoriasis		Crude HR	(95% CI)	P value
Pericarditis	11.6	(302 / 2593238.68)	13.5	(349 / 2583073.48)	1.16	(0.995 - 1.35)	0.0585
Acute myocarditis	1.3	(34 / 2594176.14)	2.1	(54 / 2584129.32)	1.60	(1.04 - 2.45)	0.033 *
Endocarditis, valve unspecified	1.7	(44 / 2594109.04)	1.5	(40 / 2584190.42)	0.91	(0.60 - 1.40)	0.6764
Acute and subacute endocarditis	0.5	(12 / 2594275.88)	0.5	(12 / 2584308.24)	1.00	(0.45 - 2.24)	0.9917
Cardiomyopathy	11.2	(290 / 2593105.69)	12.8	(331 / 2582977.58)	1.15	(0.98 - 1.34)	0.0898
Total	25.9	(670 / 2591670.77)	30.0	(775 / 2581284.7)	1.16	(1.047 - 1.29)	0.0045 *



CI, confidence interval; HR, hazard ratio.

Figure 2. Risk of autoimmune neural diseases among patients with newly-diagnosed psoriatic disease compared with the matched comparators.

Autoimmune neural disease	Incidence rate* (No. of events/person-years) Matched comparator cohort (1:1)		Patients with newly-diagnosed psoriasis		Crude HR	(95% CI)	P value
Autoimmune diseases of the PNS							
Guillain-Barre syndrome	1.04	(27 / 2597949.78)	1.35	(35 / 2587918.03)	1.30	(0.79 - 2.15)	0.304
CIDP	0.38	(10 / 2598049.28)	0.70	(18 / 2587987.03)	1.81	(0.84 - 3.92)	0.133
MG	2.66	(69 / 2597817.11)	3.13	(81 / 2587748.68)	1.18	(0.86 - 1.63)	0.315
Inflammatory myositis	1.00	(26 / 2597959.04)	2.71	(70 / 2587761.18)	2.70	(1.72 - 4.23)	<0.001 *
CNS autoimmune diseases							
MS	0.77	(20 / 2597990.7)	1.24	(32 / 2587877.74)	1.61	(0.92 - 2.81)	0.096
NMOSD, MOGAD	0.54	(14 / 2598034.97)	0.93	(24 / 2587958.92)	1.72	(0.89 - 3.33)	0.106
ADEM	0.08	(2 / 2598077.94)	0.15	(4 / 2588049.43)	2.01	(0.37 - 10.93)	0.421
Autoimmune encephalitis	0.19	(5 / 2598073.31)	0.46	(12 / 2588024.67)	2.41	(0.85 - 6.85)	0.098
Total	6.35	(165 / 2591670.77)	10.2	(263 / 2586982.73)	1.60	(1.32 - 1.95)	<0.001 *



ADEM, acute disseminated encephalomyelitis; MG, myasthenia gravis; MS, multiple sclerosis; NMOSD, neuromyelitis optica spectrum disorder; MOGAD, Myelin oligodendrocyte glycoprotein antibody-associated disease; CI, confidence interval; CIDP, chronic inflammatory demyelinating polyradiculopathy; HR, hazard ratio.

P-078

COMPARISON OF EFFICACY AND DURATION BETWEEN INTRA-CLASS SWITCHING AND INTER-CLASS SWITCHING IN BIOLOGICS FOR PSORIASIS TREATMENT

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Background: In psoriasis treatment, inter-class switching is usually done when changing biologics, but intra-class switching is sometimes attempted in case of refractory cases.
Objective: This study aims to compare therapeutic efficacy and treatment duration of intraclass-switching and interclass-swtiching of biologics among psorasis patients.
Methods: We analyzed and compared the intra-class switching that occurred between secukinumab and ixekizumab which target IL-17, and risankizumab and guselkumab, which target IL-23 with inter-class switching with inter-class switching(among adalimumab, ustekinumab, secukinumab, ixekizumab, risankizumab, guselkumab). Efficacy was evaluated 12 weeks in IL-17 group and 16 weeks in IL-23 group initially.
Results: In the intra-class switching group that included both IL-17 and IL-23, during the initial evaluation period, 95%(19/20) achieved PASI75, and 65%(13/20) reached PASI90. In the IL-17 targeted class, after primary or secondary failure of first biologics, the percentage of patients initially meeting PASI75 and PASI90 in 12 weeks was 93.8%(15/16) and 62.5% (10/16) respectively after intra-class switching. While in the IL-23 targeted class, after primary or secondary failure of first biologics, the percentage of patients initially meeting PASI75 and PASI90 after intra-class switching was 100%(4/4) and 75%(3/4). In the inter-class swtiching group, after primary or secondary failure of first biologics, patients achieved PASI75 and PASI90 96.1% (170/177) and 60.5%(107/177) after inter-class switching.
Conclusion: Although the sample size for intra-class switching is small, the efficacy of intra-class switching showed clinically interesting results compared to conventional inter-class switching. Further research with larger sample sizeds is necessary to validate our findings.
Keywords: Psoriasis, Inter-class switching, Biologics, Intra-class switching

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P-079

SYSTEMIC INFLAMMATION IN PSORIASIS – THE CHICKEN OR THE EGG?

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Introduction: Psoriasis is a chronic immune-mediated disease with characteristic inflamed skin lesions [1]. Since the recognition of many co-existing diseases in patients with psoriasis [2], the underlying mechanism for these associations has been widely discussed [3,4]. Several different biomarkers of low-grade systemic inflammation are higher in patients with psoriasis compared to healthy controls [5-8]. However, it is unknown if this low-grade systemic inflammation is the cause or a consequence of psoriasis. We hypothesize that low-grade systemic inflammation is present in patients with psoriasis before the appearance of skin symptoms and may constitute a potential risk factor for the development of psoriasis.
Objectives: To investigate whether low-grade systemic inflammation, measured by the neutrophil-to-lymphocyte ratio (NLR), systemic immune-inflammation index (SII), and high-sensitivity C-reactive protein (hsCRP), is an independent risk factor for the development of psoriasis.

Methods: We used data from the Copenhagen General Population Study [9], a prospective cohort study of the Danish general population where individuals aged 20-100 were enrolled between 2003 and 2015. Response-rate was 43%. Upon enrolment in the study, all individuals underwent a physical examination, completed an extensive self-reported questionnaire regarding lifestyle factors, and provided blood samples. NLR and SII were calculated using the following formulas: NLR=neutrophils/lymphocytes; SII=(platelets x neutrophils)/lymphocytes.
Psoriasis was identified by individual-linkage to the Danish National Patient Registry, which contains ICD-10 diagnoses for all patients attending Danish hospitals. Associations between NLR, SII, and hsCRP and psoriasis were estimated using hazard ratios (HRs) from Cox proportional hazard regression models. Analyses were adjusted for potential confounders including sex, age, smoking, alcohol consumption, physical activity, educational level, hypertension, dyslipidaemia, and obesity.
Results: We included 108,224 individuals from the Copenhagen General Population Study, with a median follow-up of 9 years. Baseline characteristics of the study population are reported in Table 1. The baseline values of NLR, SII, and hs-CRP were categorised into percentiles (<50, 50-90, and >90), and individuals in the lowest percentile (<50 percentile) were used as reference. The risk of incident psoriasis increased in a stepwise manner with increasing levels of NLR, SII, and hsCRP (P for trend<0.0001) (Figure 1). The multivariable adjusted hazard ratio of incident psoriasis was 1.71 (95% confidence interval 1.36-2.14), 1.57 (1.24-2.01), and 2.31 (1.84-2.89) in individuals with the highest levels (>90 percentile) of SII, NLR, and hsCRP, respectively. We found similar results in sensitivity analyses excluding individuals who developed psoriasis within the first year of follow-up.
Conclusions: We found low-grade systemic inflammation to be an independent risk factor for the development of psoriasis. These results suggest that an underlying low-grade systemic inflammation might contribute to the pathogenesis of psoriasis rather than solely being a consequence of the disease. The psoriatic skin inflammation is known to be driven by T helper17 cells and the interleukin 23/17 pathway; however, what triggers this inflammatory cascade in the skin is not completely understood [1]. Our findings could support the hypothesis that low-grade systemic inflammation contributes to the initiation of this skin inflammation cascade; however, more studies are warranted.

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Figure 1. Risk of incident psoriasis according to categories of percentiles of systemic immune-inflammation index (SII), neutrophil-to-lymphocyte ratio, and high-sensitivity C-reative protein (hsCRP)

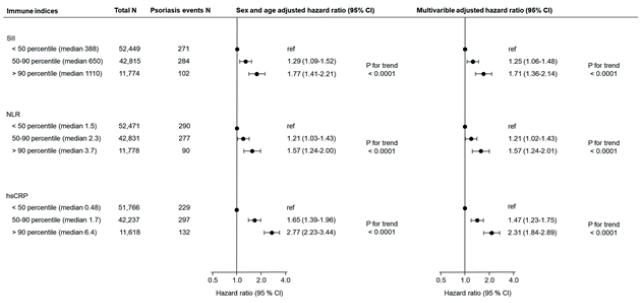

Table 1: Baseline characteristics at the day of enrolment in Copenhagen General Population Study (CGPS)

Variables	Individuals in CGPS N = 108,224
Age in years, median (IQR)	58 (48-67)
Women, *n* (%)	59,591 (55%)
Smoking	
Never smokers, *n* (%)	45,239 (42%)
Previous smokers, *n* (%)	43,969 (41%)
Current smokers, *n* (%)	18,398 (17%)
Pack-years in ever smokers, median (IQR)	15 (6-30)
Alcohol consumption	
None, *n* (%)	8,286 (8%)
Low, *n* (%)	52,744 (49%)
Moderate, *n* (%)	23,588 (22%)
Excessive, *n* (%)	18,609 (17%)
Alcohol consumption in drinkers in g/week, median (IQR)	108 (60-192)
Social status	
Low income, *n* (%)	38,421 (36%)
Low education, *n* (%)	58,481 (54%)
High psychosocial stress, *n* (%)	25,759 (24%)
Metabolic	
Total cholesterol, mmol/L, median (IQR)	5.5 (4.8-6.3)
LDL cholesterol, mmol/L, median (IQR)	3.2 (2.6-3.8)
HDL cholesterol mmol/L, median (IQR)	1.6 (1.2-1.9)
Statins, *n* (%)	12,972 (12%)
Systolic blood pressure, mmHg, median (IQR)	135 (122-150)
Diastolic blood pressure, mmHg, median (IQR)	80 (71-88)
Antihypertensive medication, *n* (%)	21,596 (20%)
Body mass index, median (IQR)	26 (23-28)
Abdominal obesity, *n* (%)	32,452 (30%)
Low physical activity, *n* (%)	6,648 (6.1%)
Diabetes mellitus (type 1 or 2), *n* (%)	4,574 (4.2%)

Continuous variables presented as medians (interquartile range) and categorical variable
Abbreviations: *n*, number; IQR, interquartile range

P-080

ALCOHOL ABUSE AND DISCRETIONARY HABITS IN PSORIATIC PATIENTS: IMPACT ON IL-17 AND IL-23 INHIBITORS RESPONSE

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Background: Alcohol abuse is known to be correlated with the onset and worsening of psoriasis, but its effects, as for smoking, on biological therapies are still poorly investigated.
Materials and Methods: The objective of this study is to identify the alcohol misuse prevalence in patients affected by psoriasis. The second is to investigate the impact on response to biological therapy.
To identify alcohol dependence, the CAGE questionnaire was administered to patients followed at our clinic.
Results: The study comprised a total of 305 patients, and 18% had a high risk of alcohol abuse. Clinically, guttate psoriasis and

psoriatic arthritis were more frequently found in patients with a higher risk of alcohol misuse. Furthermore, patients who started biological therapy and had an alcohol issue reported a higher PASI than those who drank less.
None of the variables considered appeared to correlate with drug discontinuation or less achievement of the outcomes (PASI100, PASI90, and PASI≤3).
Most patients undergoing conventional therapy had a stronger connection with alcohol dependence than patients receiving a biological agent.
Conclusion: The efficacy of biological therapy did not seem to be impacted by alcohol consumption, smoking, or sedentary lifestyle

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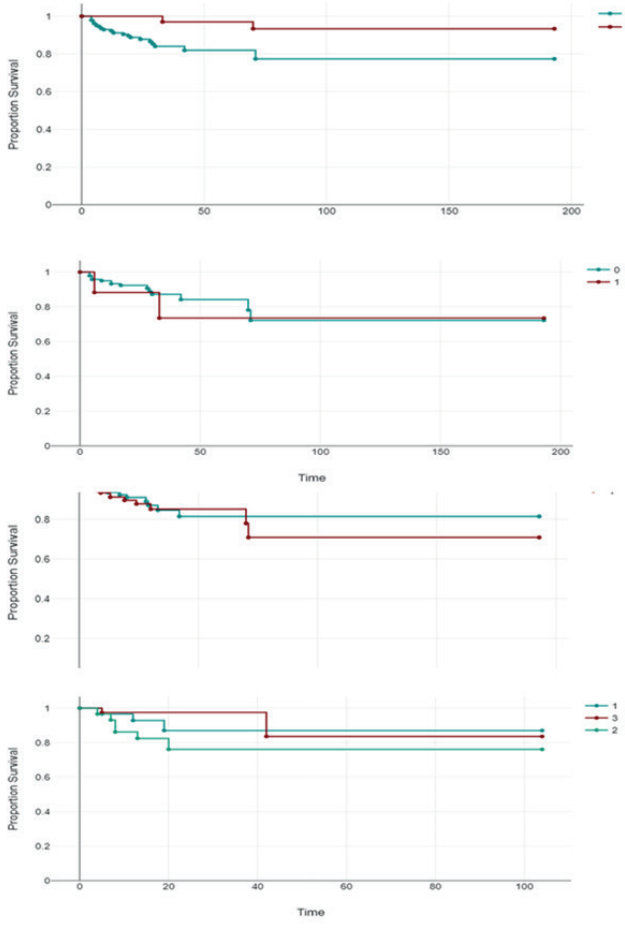

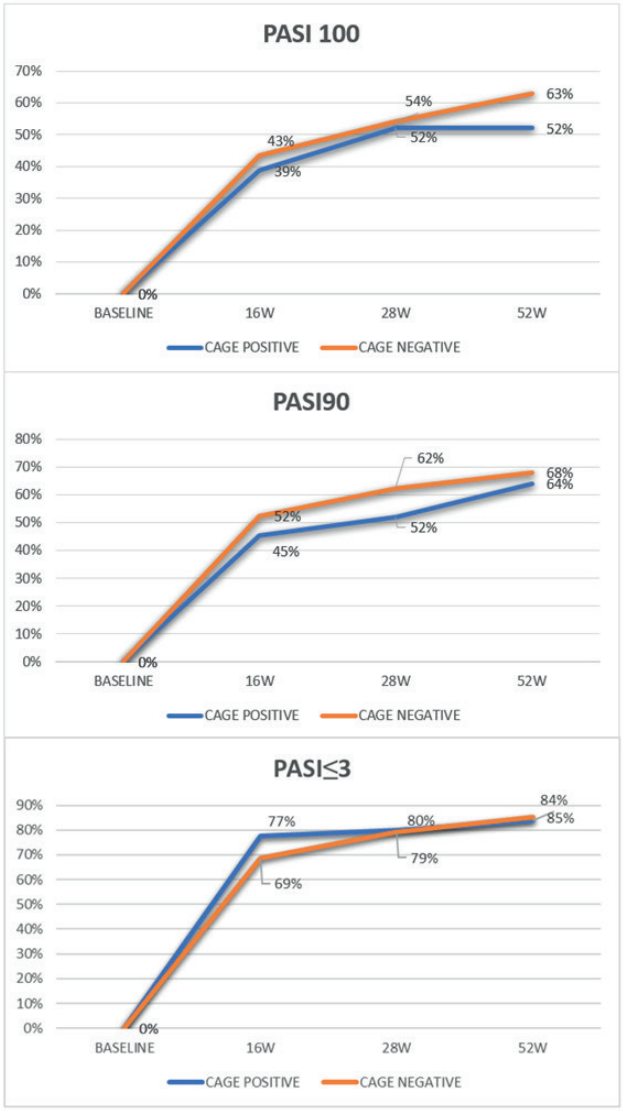

P-081

SAFETY OF BIOLOGICS FOR PSORIASIS PATIENTS WITH CANCER : A SINGLE-CENTER, RETROSPECTIVE STUDY

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Background: The causality and guideline of use regarding the pre, post application of biologics in psoriasis and cancer remain unestablished.
Objective: This study, we aim to share our experience of patients who had previous, new or recurrent maligancies to characterize the safety of biologics in psoriasis patients.
Methods: Between January 2009 and January 2024, data were extracted from electronic medical records (EMRs) for patients with severe psoriasis receiving treatment with a Psoriasis Area and Severity Index (PASI) score of 10 or higher, who also had cancer codes present in their EMRs.
Results: We had 9 patients who had previously been diagnosed with malignant neoplasm and were later treated with biologics for psoriasis, and vice versa, 6 patients receiving treatment for psoriasis who were subsequently found to have cancer. Six new malignancies occurred in patients who didn't have previous cancer history, and there was no recurrent malignancy in patients with previous cancer history. Our biologics include adalimuab for TNF-a, ixekizumab and secukinuman for IL-17, guselkumab

and risankizumab for IL-23 and there was no significant stastical difference between them.

Conclusion: There is a pressing need for research into the impact of biologic therapy on individuals with previous or concurrent cancer to optimally inform clinical guidelines. Based on our observations, the biological therapies administered to this specific group have proven to be efficacious without eliciting significant safety concerns.

Keywords: Biologics, Cancer

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P-082

DESCRIPTION OF PATIENTS INCLUDED IN THE PSORIATIC DISEASE REGISTRY OF THE ARGENTINE SOCIETY OF RHEUMATOLOGY AND THE ARGENTINE PSORIASIS SOCIETY

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Introduction: Psoriatic Disease (PD) is a term currently used to describe a spectrum of manifestations affecting patients with psoriasis (PsO). Articular involvement (PsA) can affect up to 30% of patients with PD.

Objectives: To describe the sociodemographic, clinical, treatment, and comorbidity characteristics of patients with PD in their baseline visit.

Material and Methods: A longitudinal, multicenter cohort study including patients aged ≥18 years with a diagnosis of PsO and/or PsA. The diagnosis of PsO had to be made by a dermatologist and PsA by a rheumatologist. Recorded variables included sociodemographic information, clinical data, treatments, affected domains, and comorbidities.

Results: A total of 382 patients were included, most of them were from 6 provinces (60% Buenos Aires, 16.2% Córdoba, 12.8 % Santa Fe, 3.14 % Santiago del Estero, 2.09% Tierra del Fuego and 1.83% Tucumán). Of the participants, 50.8% were female, with a mean age of 51.5 ±14.5 years. 46.3 % had a medium socioeconomic level; 52.07% had health insurance, 31.2% private insurance, and 13.1% relied on public healthcare. About 70.4% of patients had either part-time or full-time employment. At baseline, 34.4% of patients had a family history of PD. The average time to specialized care was 5 months [IQR 2-12]. Comorbidities were present in 66.2% of cases, including hypertension (55.8%), diabetes (26.4%), metabolic syndrome (32.7%), dyslipidemia (44.7%), hypothyroidism (23.3%), osteoporosis (8.06%), obesity (47.3%), cardiovascular disease (13.0%), depression (9.38%), anxiety (17.4%), fibromyalgia (6.25%), cancer (5.63%), renal lithiasis (1.86%), and hepatic steatosis (14.3%). Smoking prevalence was 35.6%, sedentary lifestyle 50.5%, and alcoholism 11.2%. At the time of diagnosis, 85.6% presented plaque or vulgar PsO, 5.61% guttate, 4.56% erythrodermic, 1.06 % generalized pustular psoriasis, 6.67% palmoplantar, 2.81% inverse, 22.5% nail involvement. PsA was present in 49.8% of patients, with 14.7% polyarticular, 12.3% oligoarticular, 9.47% distal interphalangeal, 25.7% axial, 49.5% enthesitis, and 32.7% dactylitis. Only one patient had mutilating arthritis. Additionally, seven patients had uveitis, and 2 had inflammatory bowel disease. Regarding treatment, 61.3% received topical therapy, 10.8% phototherapy, and 65.8% systemic treatment, with 49.5% on methotrexate, 2.81% on leflunomide and 2.11% on acitretin. Biological therapy was administered to 50.8% of patients, including adalimumab (14.4%), certolizumab (1.75%), etanercept (2.11%), secukinumab (14.7%), ixekizumab (3.16%), guselkumab (5.96%), risankizumab (7,72%) and ustekinumab (1.88%). Small molecule treatments included upadacitinib (1.75%). Tofacitinib and apremilast in one patient, with no patients on baricitinib. Five individuals were receiving investigational drugs.

Conclusions: This study presents the first report on the baseline characteristics of patients with PD in Argentina. We emphasize the importance of collaborative efforts between dermatologists and rheumatologists to gather and report sociodemographic, disease, and treatment characteristics nationwide

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P-083

REAL WORLD STUDY REGARDING THE USE OF A CLINICAL DECISION-SUPPORT DIGITAL APP FOR THE MANAGEMENT OF CHRONIC INFLAMMATORY SKIN DISEASES

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Introduction: Inmunoskin is a mobile app developed to aid physicians in managing Chronic Inflammatory Skin Conditions (CISC) such as psoriasis (PSO), hidradenitis suppurativa (HS), and atopic dermatitis (AD).

Objective: This study aims to describe the usage patterns of the Inmunoskin app among physicians in Argentina.

Materials and **Methods:** The Inmunoskin app was developed by the Argentinean Society of Psoriasis (SOARPSO) and includes various decision-support tools. These tools assist physicians in: a) selecting treatments based on patient characteristics and comorbidities, b) dispensing medications, c) administering treatments, and d) indicating vaccinations based on the patient's CISC treatment. Consultations from December 25th, 2021, to February 12nd, 2024, were analyzed. User demographics and consultation characteristics were retrieved. A comparison of tool usage between CISC specialists and non-specialists was conducted using the Chi-Square test, with statistical significance set at $p < 0.05$.

Results: A total of 1831 active users were registered, with 15,870 queries during the study period. The mean number of queries per app user was 12.1. Regarding user characteristics, the majority were women (80.99%) with a mean age of 40.4 years. The most common specialty among users was dermatology (85.91%), fol-

lowed by rheumatology (9.56%) and immunology (2.40%), with 48.06% being CISC specialists. Most queries were related to PSO (50.7%). The decision-support tool for treatment assessment was the most frequently used (34.04%), while the immunization assistant was the least used (6.33%). CISC non-specialists utilized the treatment indication tool according to patient comorbidities [$p = 0.0216$, OR 1.52 (1.28-1.80)] and vaccination tool [$p = 0.0185$, OR 1.88 (1.50-2.36)] significantly more often compared to specialists. No other significant differences in tool usage were found between CISC specialists and non-specialists.
Conclusion: Inmunoskin has been consistently utilized by physicians in Argentina by CISC specialists and non-specialists. Non-specialists in CISC tended to use tools for selecting therapies based on patient comorbidities and vaccination more frequently

P-084

ENVIRONMENTAL TRIGGERS OF PSORIASIS: FINDINGS FROM THE MYSKIN STUDY

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Background: Psoriasis is a common, debilitating inflammatory skin condition with an established genetic basis and rising incidence. Psoriasis has a heterogenous disease course and is associated with a substantial physical and emotional impact. Despite a wealth of genetic research on psoriasis susceptibility, epidemiological studies characterising environmental triggers of disease onset are limited.
Objectives: To identify self-reported triggers of psoriasis onset and the relationship between triggers and subsequent disease severity.
Methods: Self-reported data from people with a clinician-confirmed diagnosis of psoriasis were collected through the online mySkin survey (myskin.org). mySkin was launched UK-wide in June 2023 and all baseline surveys completed by 6th December 2023 were analysed. Measures of disease severity at the time of survey completion included patient global assessment (PtGA) and dermatology life quality index (DLQI). The association between triggers of psoriasis onset and disease severity was analysed using one-way ANOVA tests.
Results: Of 529 individuals with psoriasis who completed the mySkin survey, 93.4% were of white ethnicity and 64.8% were female. The average age of participants was 51.1 years, and their mean psoriasis duration was 29.2 years (standard deviation 16.9 years). A family history of psoriasis was reported by 49.9% of participants, and 55% ($n = 289$) reported at least 1 trigger of psoriasis onset. The most commonly reported trigger was stress ($n = 167$ [57.8%]), followed by infection ($n = 85$ [29.4%]) and skin injury ($n = 37$ [12.8%]). Of those who selected multiple triggers, there was considerable co-selection of stress, low mood, climate (pollution, weather) and lifestyle (weight gain, alcohol, smoking) factors. A greater proportion of participants with a family history of psoriasis reported climate and hormonal (pregnancy, childbirth, menopause) triggers of psoriasis onset, compared to those without a family history ($n = 11$ [73%] vs $n = 4$ [26%] and $n = 9$ [69%] vs $n = 4$ [31%], respectively). There was no significant association between triggers of psoriasis onset and disease severity (PtGA $p = 0.76$, DLQI $p = 0.41$).
Conclusion: These self-report data highlights the importance of stress in psoriasis onset. The co-occurrence of different triggers, including in those with vs without a family history of psoriasis, underscores the complex aetiology of psoriasis. Characterisation of gene-environment interactions is warranted.

P-085

BELGIAN PSORIASIS REGISTRY "BEPSO": OBJECTIVES, METHODOLOGY, FIRST INCLUSION DATA AND PERSPECTIVES.

No consent given to publish in scientific journal.

P-086

PREVALENCE OF PSORIASIS IN INDIGENOUS COMMUNITIES AROUND THE WORLD: AN OVERVIEW

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Introduction: The epidemiology of psoriasis remains ambiguous, with global prevalence figures ranging from 0.09 to 8.5%. The lack of data and understanding for the distribution of this disease is especially pertinent for indigenous populations around the world. Current literature demonstrates that various indigenous communities have significantly lower prevalence of psoriasis. There is a need to research further on the environmental, genetic, geographical and socioeconomic factors that result in the reduced cases of psoriasis and to provide improved dermatological services for indigenous people around the world.
Objective: Information on the epidemiology of psoriasis remains limited, especially for indigenous populations around the world. This review aims to collate data that highlights the burden of psoriasis upon indigenous groups worldwide, and discuss the genetic, environmental and historical factors that have contributed to the unique prevalence of the disease in these communities.
Methods: Out of 30 publications which observed the prevalence and incidence of psoriasis within indigenous communities, or the geographic distribution of psoriasis worldwide, 18 were selected for systematic review. Data is based on eight systematic reviews, four cross-sectional studies, three original articles, one case study and one letter to the editor.
Results: There were a total of 9 indigenous populations that were covered by these articles, with prevalence ranging from 0% to 1.4%, and number of participants from each study ranging from 380 to 3000 people. In Greenland Inuit and Taiwan Ami people, psoriasis was estimated to be 'rare' with no reported cases. In American Samoan people, 555 indigenous people in the Auaris region of Brazil and 3000 indigenous Australian people, psoriasis prevalence was 0%, except two half Aboriginal people in Australia who were later diagnosed in a separate study. Out of 380 Chilean Mapuche people, psoriasis prevalence was 0.26%. Within 1602 Aboriginal people of the Peruvian Andean regions, prevalence was 1.6%. The Sami people of Norway were estimated to have a prevalence of 0.6% to 1.4%. The indigenous people of Tigray, Ethiopia saw an incidence of 183 people per year.
Conclusion: Most indigenous populations were found to have lower prevalence rates of psoriasis when compared to urban communities of the same country. Interestingly, the low prevalence appears to result from four main factors: a) sunlight due to geographical distance from the equator, b) the environmental influences and cultural beliefs of the people, c) their genetic susceptibility to psoriasis paired with the introduction of infections and conditions through colonisation, and d) reduced access to specialised dermatological services for appropriate diagnosis and treatment. There must be more efforts made to produce better quality dermatological data and include a wider variety of groups in studies, in order to better cater for the healthcare of indigenous people worldwide.

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P-087

PSORIASIS AND IN SITU OR INVASIVE NON-MELANOMA SKIN CANCER: A BIDIRECTIONAL MENDELIAN RANDOMISATION STUDY

No consent given to publish in scientific journal.

P-088

GENOME-WIDE PLEIOTROPY ANALYSIS REPORTS LDL METABOLISM AS A SHARED PATHWAY BETWEEN PSORIASIS AND CORONARY ARTERY DISEASE

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Background/Objectives: Comorbidities and underlying correlations between psoriasis and coronary artery disease (CAD) have been widely reported, however the degree of shared genetic background is yet to be elucidated. Here, we performed a genome-wide pleiotropy scan to investigate the shared heritable etiology between both traits and identify relevant pathways.

Methods: We leveraged genome-wide association (GWAS) summary statistics from large-scale meta-analyses in psoriasis ($n = 44164$) and CAD ($n = 184305$) patients of European ancestry. We explored the global and local genetic correlation between psoriasis and CAD in 2375 independent genetic loci. Pleiotropy analysis was conducted under the composite null hypothesis, using shared bi-allelic variants with minor allele frequency (MAF)>0.01 in non-major histocompatibility complex (MHC) loci. We next employed gene-level and colocalization analyses to explore the biological implications of pleiotropic loci. Finally, drug-based mendelian randomization (MR) was used to investigate the causal relationship between lipid-lowering drugs and psoriasis risk, using the latest GWAS for low density lipoprotein (LDL) measurement in participants of European ancestry.

Results: Psoriasis and CAD show a modest, nevertheless positive genome-wide correlation (rg=0.1487, $P = 3.58\times10\text{-}6$), with a single region in chromosome 19 being correlated with both diseases ($P = 1.63\times10\text{-}9$). Out of the 7756803 shared variants between psoriasis and CAD GWASs, 1431 variants in 28 non-MHC, independent risk loci reported significant pleiotropic effects at a P-value threshold$<5\times10\text{-}8$. Gene-based analyses documented 73 genes enriched in LDL metabolism and T helper 17 related pathways, while 5 loci were reported as causal under the single causal variant assumption. Remarkably, genetically proxied inhibition of PCSK9 was associated with lower psoriasis risk, while exclusion of previously identified pleiotropic variants retained the causal associations (β=-0.2302, $P = 0.001$). Significant genetically proxied inhibition of LDLR in reducing psoriasis risk (β=-0.449, $P = 1.31\times10\text{-}8$) confirmed the implication of the LDL receptor-mediated pathway in psoriasis risk.

Conclusions: Here, we characterized the genetic architecture that governs the co-occurrence between psoriasis and CAD by employing a genome-wide pleiotropy scan, while drug-target MR approaches confirmed the causal role of LDL metabolism in psoriasis. Our findings provide strong genetic evidence for the underlying comorbid mechanisms, facilitating the development of therapeutic strategies.

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P-089

ACTIVE PULMONARY TUBERCULOSIS IN A PATIENT WITH SECUKINUMAB TREATMENT

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Various immunomodulators have been used in the treatment of skin diseases, leading to numerous studies on infections, especially tuberculosis (TB) infection or reactivation. While biologics

prescribed for psoriasis are generally considered safe, South Korea mandates latent TB infection testing before administering them due to the high prevalence of TB. Positive results necessitate the administration of TB medication. A 54-year-old man presented at the hospital with severe psoriasis. Cyclosporin administration resulted in increased blood pressure, prompting a switch to biologics given the patient's concurrent alcoholic hepatitis. Additionally, the patient was referred to an orthopedic physician for accompanying back pain. A spine x-ray revealed a "Bamboo spine," and he was identified as positive for HLA-B27, prompting an investigation for ankylosing spondylitis. Thus, a TNF-α inhibitor was initially intended for psoriasis treatment. However, Ustekinumab, with long intervals between doses, was administered due to the poor compliance of the patient. Pre-administration evaluations by IGRA and radiography detected no TB. However, after approximately 2.5 years, the psoriasis worsened, and arthritis started developing in the fingers, leading to the switch to secukinumab. Consequently, both the skin and joints showed improvements. However, the patient tested positive for TB in the IGRA blood test performed during a routine follow-up after one year. Thus, he was referred to the pulmonologist. Finally, the patient was confirmed to have active TB and started receiving treatment. Considerably, previously administered drugs like cyclosporin, methotrexate, and TNF-α inhibitors may have been associated with increased TB incidence, whereas biologics were considered to pose lower risks. In a study including over 12,000 patients receiving secukinumab, Boni et al. reported no active TB cases and only 0.1% of patients with latent TB. Thus, biologics, including secukinumab, appear to have limited association with new active TB or latent TB reactivation. In South Korea, a country with high TB prevalence, patients with underlying diseases such as alcoholism require periodic TB tests to monitor the development of TB, despite the absence of TB in the initial test.

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P-090

A CASE REPORT OF GENERALIZED PUSTULAR PSORIASIS IN A PATIENT WITH PLAQUE PSORIASIS UNDERGOING BIOLOGICS THERAPY

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Psoriasis has different clinical phenotypes depending on the subtype, including plaque, teardrop, pustular, and erythematous psoriasis. Generalized pustular psoriasis (GPP) is a rare form of psoriasis characterized by erythematous skin with aseptic pustules. Etiological factors include medications, infections, pregnancy, and stress. The authors discuss the factors and pathogenesis associated with a case of GPP in a patient with plaque psoriasis that occurred as an exacerbation of psoriasis during biologic therapy. A 62-year-old man diagnosed with plaque psoriasis was undergoing treated with nine times of subcutaneous injections of guselkumab, and achieved a Psoriasis Area and Severity Index (PASI) of 90. However, due to the worsening of skin lesions with PASI 12, we switched from guselkumab to ixekizumab. After 2 treatment cycles, the patient developed new erythematous plaque and pustular lesions with fever, pruritus, and oozing. The physical examination showed a fever of 37.5°C and elevated C-reactive protein (CRP) of 1.20 mg/dL (reference value: 0-0.3 mg/dL). Histological examination of the right buttock revealed neutrophilic infiltration and spongiform pustules in the lower stratum corneum. These findings led to a diagnosis of GPP based on clinical and histological evidence. Therefore, the patient received a combination of oral acitretin (20 mg/day) and topical calcipotriol/betamethasone for 5 weeks, along with ixekizumab. The skin lesions have gradually improved, and he is now being followed up on outpatient treatment with ixekizumab alone. GPP is a rare form of pustular psoriasis with a distinct pathogenesis from plaque psoriasis. Interleukin-17 (IL-17) inhibitors have been reported as an effective treatment for GPP. However, we experienced a rare case of GPP worsening during treatment with IL-17 inhibitors and report it with a literature review.

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P-091

STRIAE-INDUCED PSORIASIS: A RARE DEMONSTRATION OF KOEBNER'S PHENOMENON - CASE REPORT AND SYSTEMATIC REVIEW

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Introduction: Psoriasis is a common inflammatory skin disorder, with physical trauma being one of the most significant triggers, explaining various clinical findings, including Koebner's Phenomenon (KP).1, 2 Striae are a common cutaneous condition whose development is associated with mechanical damage to the skin; however, they are rarely linked to psoriatic lesions.
Objective: To present a case and conduct a comprehensive literature review to elucidate this infrequent association.
Methods: PubMed and Embase were systematically reviewed from database inception through January 2024 combining the term 'striae' with 'psoriasis'; and 'Koebner' with 'striae'. A case is also reported.
Results: An 11-year-old boy presented with striae on the axillary and trunk regions with erythema and scaling that appeared three years prior (Figures 1a-c). Biopsy of the left axilla revealed psoriasiform dermatitis with parakeratosis and intracorneal neutrophils, compatible with psoriasis (Figure 1d).
Discussion: KP or isomorphic response was initially described as the development of psoriatic lesions following trauma.3 Vitiligo, lichen planus, and psoriasis exhibit the true form of this event, with psoriasis incidence ranging from 11 to 75%.4 It can be triggered by physical traumas like stretching, friction, compression, and vibrations.3-5
Mechanical trauma to the epidermis activates keratinocytes, releasing chemokines, and recruiting CCR6+ Th17 positive cells and neutrophils. Additionally, stressed keratinocytes release nucleic acids and antimicrobial peptides, like LL37, activating dermal dendritic cells, crucial in adaptive immune system activation. These cells express mediators such as TNF-α and IL-23, intensifying the autoimmune response involving Th1 and Th17 cells, pivotal in psoriasis plaque development.1,2
KP correlates with the HLA-Cw6 allele, which increases the risk of developing psoriatic lesions after minimal traumas, as

observed in striae. HLA-Cw6 is also associated with an earlier onset of psoriasis.1

Striae function as a form of physical trauma. Local skin modifications leading to their formation involve extracellular matrix components (fibrillin, elastin, and collagen) with flattening of the epidermis. The mechanisms involved in their pathophysiology include mast cell involvement, tryptase, IL-6, IL-8, IL-17, and vascular endothelial growth factor (VEGF).1,2

Verma proposed a mechanism considering striae as an example of contused trauma, postulating that imperceptible microscopic traumas during striae formation, combined with dermal vascularization changes, mast cell participation and activation of CD4+ and memory cells, induce psoriatic lesions.3

However, despite this plausible explanation and the high prevalence of both conditions, KP in striae is rare. We identified six cases with these associations (Table 1).

The intensity and depth of trauma are crucial for psoriasis induction in KP. It did not occur with mere scraping of the stratum corneum, and lesions rarely occurred in those reaching the stratum spinosum. Additionally, a 2mm epidermal cut produced less psoriasis lesion than a 8mm one.6

Thus, it is observed that a certain level of mechanical stress is necessary for KP development. We believe that the mechanical stress achieved during striae formation may not reach this threshold, explaining the rarity of this association. Our patient had lesions primarily restricted to striae, which could be influenced by obesity and a possible presence of HLA-Cw6, two important risk factors for psoriasis.

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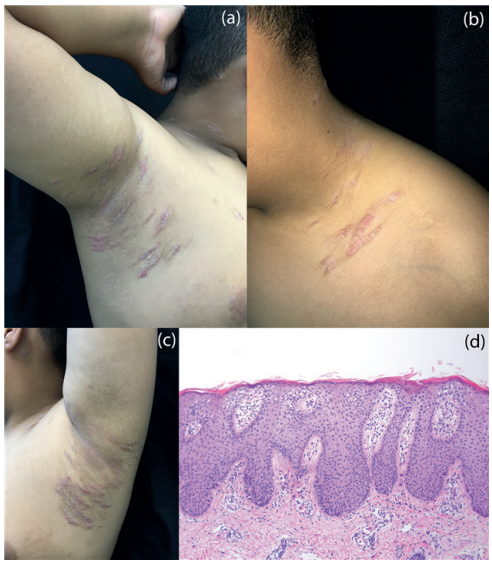
Table 1. Evidence supporting the onset of striae as a predisposing factor for psoriasis due to the triggering of Koebner's phenomenon

Patients (N)	Gender and age	Psoriasis onset (After or Before the Striae)	Other areas affected by psoriasis	Etiology of striae	Author(s), publication year
2	M, 22 F, 17	A ND	No NE	Weight variation Height variation	Verma (2009)
1	F, 27	A	Yes	Weight variation and topical corticotherapy	Morais (2013)
1	M, 23	D	Yes	Systemic corticotherapy	Balasubramanian (2016)
1	M, 40	A	Yes	Topical corticotherapy	Cuenca-Barrales (2022)
1	M, 39	A	Yes	Topical corticotherapy	Monteagudo, B. (2015)
1	M, 11	A	Yes	Weight variation	Our case

* ND = Not Described
* NE = Not Evaluated



P-092

TREATING INTRACTABLE PRURITUS ASSOCIATED WITH ILVEN AND CONCOMITANT PSORIASIS: ACHIEVING SUCCESS WITH BIMEKIZUMAB

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Introduction: Inflammatory linear verrucous epidermal naevus (ILVEN) is a rare and chronic skin disorder. It is characterized by linear, hyperkeratotic and hyperpigmented papules that frequently coalesce into plaques, generally following the lines of Blaschko. It typically presents in early childhood and persists into adulthood, leaving those who are affected with significant psychosocial and physical morbidity (1). Psoriasis is a chronic immune-mediated inflammatory skin disorder, characterized by well-demarcated erythematous plaques with overlying silvery scales, with an estimated prevalence of 3% (2).

Objectives: To present a case report of a patient with intractable pruritus associated with ILVEN and concomitant psoriasis.

Methods: We present the clinical manifestations, diagnostic approach and the different treatments employed in this challenging case.

Results: A 31-year-old male was referred to the dermatology clinic for extensive skin lesions associated with severe pruritus and pain since childhood. He had been using medium- to high-potency topical corticosteroids along with anti-histamines for years providing only temporary relief. On examination, the patient presents scaly and erythematous papules coalescing into plaques exclusively on the right side of his body: thorax, abdomen, arm and thigh. Some tend to follow a linear pattern. There was evidence of excoriation on his back and warty hyperpigmented lesions on the right side of his face. The patient also suffers from joint pain and has family members with psoriasis. A skin biopsy was performed. There was a classic alternation of hypergranulosis with orthokeratosis and hypogranulosis under the parakeratosis of the linear verrucous epidermal naevus. A significant inflammatory reaction rich in neutrophils with layers of Munro's abscesses and evidence of psoriatic hyperplasia were also observed. Psoriasis with concomitant ILVEN could be compatible with this presentation. Methotrexate 15 mg per week was prescribed but was stopped after 6 weeks, despite an improvement of more than 50% in symptoms, due to the patient feeling tired, suffering from insomnia, and elevated liver enzymes. Acitretin was contraindicated. The patient was then treated with subcutaneous injections of bimekizumab 320 mg (given as 2 subcutaneous injections of 160 mg each) for a

PASI 25.2 and BSA 15 %. The patient noted a 90% improvement in terms of pruritus, despite feeling a bit more tired, which was addressed by changing his antidepressant medication. To this day, he is continuing bimekizumab and has received a total of 5 doses (at week 0, 4, 8, 12, 16). He is very satisfied with the resolution of the psoriasis plaques and the thinning of some hypertrophic plaques of his inflammatory naevus (Figure 1).

Conclusion: We present the case of a patient suffering from intractable pruritus associated with ILVEN and concomitant psoriasis and discuss the therapeutic role of bimekizumab, which showed a notable improvement in our instance in both psoriasis plaques and ILVEN.

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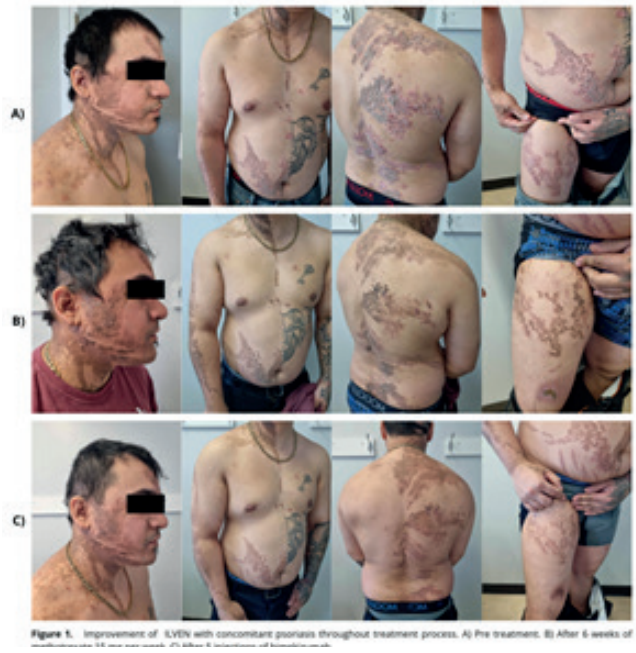

Figure 1. Improvement of ILVEN with concomitant psoriasis throughout treatment process. A) Pre treatment. B) After 6 weeks of

P-093

EXPRESSION PROFILES OF TH1 AND TH17 INFLAMMATORY CYTOKINES IN THE LESIONAL SKIN IN PSORIASIS VULGARIS PATIENTS BEFORE AND AFTER TREATMENT

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Introduction: Treatment of psoriasis can result in a dynamic changes in the T cells and their cytokine production. However, studies on the expression of Th1 and Th17 inflammatory cytokines after various treatments in psoriasis patients have reported inconsistent results.

Objectives: To investigate the alterations in inflammatory cytokine expression in psoriasis skin lesions before and after psoriasis treatment.

Methods: We included five patients with psoriasis vulgaris who showed improvement in their skin lesions after receiving treatment (phototherapy, systemic therapy, biologic agents etc.) for about two years. The median psoriasis area and severity index (PASI) before and after treatment were 12.0 and 0.6, respectively. The tissue mRNA and protein levels of interleukin (IL)-12, IL-2, interferon (IFN)-γ, IL-23, IL-17A, and IL-22 in psoriatic skin lesions before and after psoriasis treatment were detected using real-time polymerase chain reaction and immunohistochemical staining, respectively.

Results: The tissue mRNA expression levels of IL-12 and IL-23 and protein expression levels of IL-2 and IL-17A protein levels in psoriasis skin lesions were decreased after the treatment. Both mRNA and protein levels of IFN-γ in psoriatic skin lesions increased after the treatment. However, the tissue mRNA and protein levels of IFN-γ increased after psoriasis treatment.

Conclusions: The mRNA levels of tissue inflammatory cytokines (IL-12 and IL-23) and the protein levels of tissue inflammatory cytokines (IL-2 and IL-17A) significantly decreased after psoriasis treatment. Our study results may indicate that the expression of Th1 and Th17 inflammatory cytokines was decreased in skin lesions of plaque psoriasis patients after treatment.

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P-094

SMALL INTESTINAL INFLAMMATORY CHANGES ASSOCIATED WITH EOSINOPHIL DEGRANULATION INCREASE THE SEVERITY OF PSORIATIC SKIN INFLAMMATION

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Introduction: Patients with psoriasis often display elevated incidence of inflammatory bowel disease, indicating a link between the skin and gut immune responses. Increased intestinal permeability can exacerbate psoriasis and systemic inflammatory disease with complex pathogenesis.

Objectives: We investigated the link between inflammatory responses in the skin and small intestine associated with eosinophil degranulation which led to impaired intestinal barrier integrity using imiquimod (IMQ) induced mice model.

Methods: Seventeen patients (mean age 40.00 ± 14.16 years) diagnosed with psoriasis were included in the study. Control serum was collected from 10 healthy volunteers (mean age 38.30 ± 7.60 years). Serum level of CD14, zonulin were measured using ELISA. BALB/c mice received a topical dose of 62.5 mg/d IMQ cream (5%) or vehicle cream on the shaved back for 5-7 days. To assess the intestinal barrier integrity, mice treated with IMQ and administered FITC-dextran by oral gavage and checked serum level of FITC-dextran. We compared the transcriptomes in the psoriatic mice skin with those in the small intestine. Gene set enrichment analysis (GSEA) was performed. Genomic DNA was extracted from frozen stool samples. To validate the exacerbating effect of eosinophil degranulation-induced small intestinal damage on

psoriatic inflammation, we evaluated the development of psoriatic dermatitis in ΔdblGATA (ΔEO) mice, which lack eosinophils. To verify that granules derived from eosinophils induced damage to intestinal epithelial cells, we cultured Caco-2, human colon epithelial cells with culture supernatants from untreated or IMQ-stimulated AML14.3D10 cells, human eosinophil cell line. Differences among groups were examined for statistical significance using one-way analysis of variance (ANOVA).

Results: Compared with healthy individuals, patients with psoriasis showed increased serum levels of soluble CD14 (sCD14), calprotectin and upregulation of zonulin which are markers of increased intestinal permeability and inflammation.

In IMQ-treated mice also demonstrated increased serum levels of sCD14 and calprotectin. Mice treated with IMQ and administered FITC-dextran by oral gavage displayed elevated serum levels of FITC-dextran, which suggest increased intestinal permeability in mice with psoriatic skin inflammation. Most of the significant gene ontology terms in the mice lesion skin were related with upregulation of genes, such as Cxcl5, Il23r, Cd3, and Zap70, implicated in neutrophil recruitment and Th17 differentiation. Tlr8, Tlr9, C1qb, C1qc, and Tnf were among the most highly upregulated IMQ-induced genes related to leukocyte-mediated immunity in the small intestine. Mice with psoriatic inflammation showed increased intestinal levels of eosinophil granule-derived proteins, as demonstrated by increased EPX levels in stool. Caco-2 intestinal epithelial cells treated with media containing eosinophil granule proteins exhibited signs of inflammation and damage. IMQ-induced skin and intestinal inflammatory changes were attenuated in eosinophil-deficient mice, and this attenuation was counteracted by eosinophil transfer. TLR7-deficient mice did not show intestinal eosinophil degranulation and exhibited attenuated skin and small-intestinal inflammation following IMQ application.

Conclusions: Our findings strongly suggest that TLR7-dependent bidirectional skin-to-gut communication in psoriatic inflammation, and that intestinal inflammatory changes can accelerate psoriasis.

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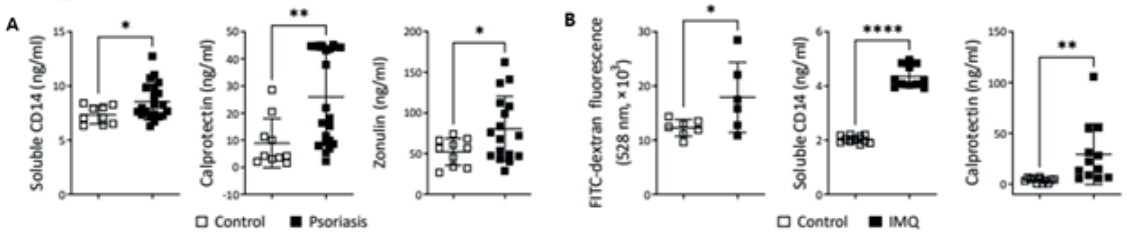

Fig. 1. A) Serum concentrations of soluble CD14, calprotectin, and zonulin in healthy humans and patients with psoriasis. B) Serum fluorescence of fluorescein isothiocyanate (FITC)-dextran and concentrations of soluble CD14 and calprotectin in mice.

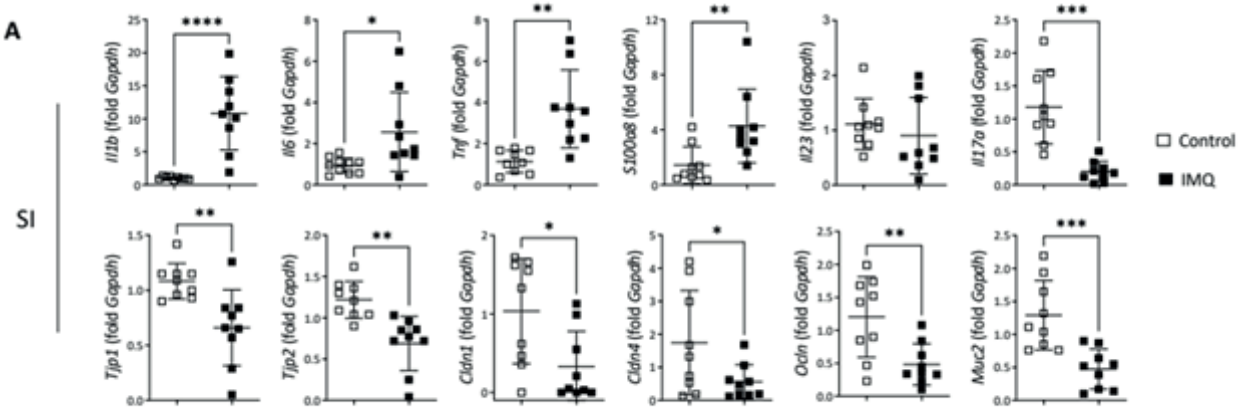

Fig. 3. Psoriatic skin inflammation induces inflammatory changes and reduces the number of eosinophils in the small intestine. A) Quantitative PCR analysis. SI=small intestine.

P-095

DEFICIENCY OF IL-1 RECEPTOR ANTAGONIST ENHANCES IL-17 PRODUCTION BY TISSUE-RESIDENT MEMORY T CELLS IN PSORIASIS

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Background: IL-1R signaling appears to correlate with psoriasis disease progression and treatment response. However, the exact cellular and molecular mechanisms are not fully understood.
Objectives: To investigate the effects of IL-1Ra on the development and progression of psoriasis and to elucidate possible mechanisms.
Methods: An interleukin-1 receptor antagonist-knockout (IL-1Ra-KO) mouse model was used. Fluorescence activated cell sorting (FACS) and confocal microscopy was used for immune cell subtyping in spleen and skin tissue.
Results: A more severe psoriasis phenotype, including redness, scaling, and thickness scores, was observed on the dorsal skin of IL-1RaKO mice compared to chronic psoriasis on normal balb/c. A dramatic increase in IL-17-positive CD4/CD8 T cells was found. In the spleen, T regulatory cells expressing Foxp3 decreased, while the proportion of tissue-resident memory CD4/CD8 T cells producing IL-17 increased. In conclusion, IL-1Ra appears to significantly inhibit IL-17-producing CD4 and CD8 T cells and IL-17-induced keratinocyte inflammation in psoriasis-derived cells.
Conclusion: The balance between IL-1 and IL-1Ra in skin tissue may plays an important role in the susceptibility and severity of psoriasis. When IL-17 induced by IL-1Ra deficiency generates CD8 TRM, it can act as a decisive aggressor in severe psoriasis and high relapse rates.

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P-096

UNVEILING THE GENETIC FOUNDATIONS AND PATHWAYS IN PLAQUE PSORIASIS: A COMPREHENSIVE META-ANALYSIS OF TRANSCRIPTOMES

No consent given to publish in scientific journal.

P-097

BEYOND THE SKIN: COMPREHENSIVE INSIGHTS INTO PSORIASIS AND ITS NEXUS WITH PSORIATIC ARTHRITIS

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Introduction: Psoriasis, a chronic inflammatory dermatological disease, significantly impacts global populations. The study aimed to investigate the profile of patients with psoriasis, focusing on disease duration and the onset of psoriatic arthritis symptoms.
Methods: A cross-sectional survey was conducted in Argentina involving 403 patients with confirmed psoriasis. The survey assessed disease evolution, duration, joint symptoms onset, comorbidities, and treatment modalities. Data analysis utilized R and PowerBi for Windows.
Results: Out of 500 distributed surveys, 403 (78.1%) were completed. Most participants (78%) were from Buenos Aires, Mendoza, Córdoba, San Juan, and Ciudad Autónoma de Buenos Aires. Notably, 38% lacked formal health coverage, relying on public systems. Demographically, the majority were females (59%), median age 45.9 years. Severity distribution (mild, moderate, severe) varied across age groups, with the majority experiencing moderate to severe psoriasis. Comorbidities were prevalent, with 58% having at least one. Obesity, hypertension, and dyslipidemia predominated, with 40% having obesity as the most common comorbidity. The study revealed 160 patients (40%) with obesity, primarily classified as type I or II.
Conclusion: A low level of confirmed prior psoriatic arthritis diagnosis was observed, even in patients with prolonged disease duration. Patients with more severe disease tended to have a higher prevalence of comorbidities. Limited pharmacological treatment was noted, particularly in severe cases and high-cost therapies. Actions: Increase public awareness of psoriasis and psoriatic arthritis. Educate healthcare professionals on the importance of accurate diagnosis and treatment. Emphasize psoriasis as a systemic disease affecting physical and emotional aspects. This study sheds light on the need for improved diagnosis, awareness, and comprehensive care for psoriasis patients, urging a more proactive approach in managing this complex and impactful condition.

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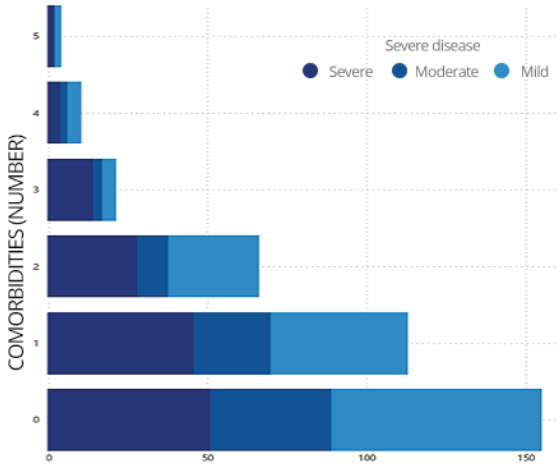

Age Rate	Mild	Moderate	Severe
under 17	1	1	2
17 to 25	3	5	9
26 to 35	11	24	29
36 to 45	18	45	40
45 to 55	21	36	29
55 to 65	22	24	29
65 to 75	1	8	7
More than 75		3	
Total	77	147	145

P-098

PATIENTS' LEARNING JOURNEY: AN INNOVATIVE, ACCESSIBLE DIGITAL TOOL ABOUT PSORIATIC DISEASE

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Introduction: As a patient support organization we have identified the deep need for patients (and their families) to better understand their chronic condition and how to manage it. Consultations with Doctors tend to be short and often leave patients with many unanswered questions about their disease and coping with their daily activities, as indicated in The Understanding Psoriatic Disease Leveraging Insights for Treatment (UPLIFT) survey (Lebwohl, Langley, Paul et al., 2022) conducted in North America, Europe and Japan. These insights are also relevant for Africa where even more challenges exist. For example, many patients are unable to even consult a clinician, as well as find one who is knowledgeable about psoriatic disease.

While search engines such as Google can be very helpful, as well as social media sharing, there is such an abundance of misinformation. The vast array of treatment options with different perspectives frequently leave patients feeling overwhelmed and lost. They struggle to recognize what information is useful, sometimes finding themselves buying costly remedies that have not been helpful.

Objectives: We aimed to develop a credible resource to offer valuable insights into psoriatic disease with links to more resources globally, and to expose some of the challenges of living with psoriatic disease alongside practical management guidelines to facilitate improved quality of daily living.

Methods: Together with a software developer, we put together an interactive eLearning resource using Articulate Rise on the Moodle Platform. The tool is available from any web-based browser. It is responsive and easy to navigate. It comprises four modules namely: An introduction to psoriatic disease; Living with psoriatic disease; Psoriatic arthritis; My support network

This accessible online tool is in a user-friendly format with interactive responsive modules that can support users to gain credible information about psoriatic disease as well as practical advice. The English text is purposefully written to clarify information provided in an understandable way rather than using medical discourse that often confuses patients. Patients' voices and experiences are also present through videos and quotes. Creative visuals add to the appeal of the learning tool.

Results: The modules were published in February 2024. Data collection will measure the uptake of each module. In time we hope to expand this resource in terms of translating it into different languages and adding to the information available on the platform.

Conclusions: There is acknowledgement that it is difficult for patients to navigate the complexity of their chronic disease and their health care. Education is key to health literacy. As a response, the new online tool provides validated information about psoriatic disease. So far it has received very positive feedback from both patients and healthcare providers. Patients feel this resource offers a sound foundation for themselves and others to learn more about their condition. Dermatologists have expressed appreciation for the tool as it empowers patients as well as helping the specialists to engage with a more informed patient. Data collection and analysis after 6 months from launch will bring new insights.

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P-099

DEUCRAVACITINIB EFFICACY IN SPECIAL AREAS OF SCALP, FINGERNAILS, AND PALMS/SOLES IN PLAQUE PSORIASIS: RESULTS FROM A PHASE 3 TRIAL

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Introduction: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was significantly more efficacious than placebo and apremilast in two global, 52-week, phase 3 trials, and maintained long-term

efficacy through 2 years with no new safety signals in an ongoing long-term extension (LTE) trial. [1 2 3]

Objectives: To evaluate the efficacy of deucravacitinib 6 mg once daily through Week 52 in patients with scalp, fingernail, and palmoplantar involvement at baseline of any severity, including limited involvement, at baseline in the phase 3 POETYK PSO-1 trial (NCT03624127) in patients with moderate to severe plaque psoriasis.

Methods: The analysis included patients from this trial who either (1) received continuous deucravacitinib from Day 1 through Week 52 or (2) were randomized to placebo at Day 1 and crossed over to deucravacitinib at Week 16. [1] Efficacy outcomes for scalp (Psoriasis Scalp Severity Index [PSSI]), fingernail (modified Nail Psoriasis Severity Index [mNAPSI]), and palmoplantar (palmoplantar Psoriasis Area and Severity Index [pp-PASI]) areas were performed separately by Physician Global Assessment scores of 1 or 2 (limited involvement) or ≥1 (1-4) in the respective body areas at baseline. The Clopper-Pearson method was used to calculate 95% confidence intervals. Nonresponder imputation was used to impute missing data.

Results: Baseline patient demographics and clinical characteristics were generally similar between the limited versus any involvement subgroups in scalp ($n = 110$ vs $n = 440$, respectively), fingernail ($n = 117$ vs $n = 194$), and palmoplantar ($n = 35$ vs $n = 61$) areas. Response rates at Week 16 in scalp, fingernail, and palmoplantar areas of involvement were greater in patients receiving deucravacitinib treatment than in patients receiving placebo through Week 16, regardless of extent of baseline involvement in the respective special areas (Table). Response rates at Week 52 were maintained with deucravacitinib in patients who received continuous deucravacitinib treatment and were improved in patients who crossed over from placebo to deucravacitinib at Week 16 in both subgroups (Table). At Week 52, patients who crossed over from placebo to deucravacitinib achieved response rates similar to those who received continuous deucravacitinib treatment, regardless of extent of baseline involvement.

Conclusions: Deucravacitinib maintained clinical efficacy through 52 weeks in patients with scalp, fingernail, and palmoplantar psoriasis, regardless of extent of involvement at baseline. These findings further support the use of deucravacitinib for treatment of the hard-to-treat special areas, specifically the scalp, fingernail, and palmoplantar areas, in patients with plaque psoriasis.

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Table. Efficacy outcomes at Week 16 and Week 52 (NRI)

Response rate, % of patients[a] (95% CI)	Continuous deucravacitinib		Placebo to deucravacitinib	
	Baseline score 1 or 2	Baseline score ≥1	Baseline score 1 or 2	Baseline score ≥1
Scalp	(n=79)	(n=288)	(n=31)	(n=152)
PSSI 75				
Week 16	60.8 (49.1-71.6)	67.7 (62.0-73.1)	*22.6 (9.6-41.1)*[b]	*19.7 (13.7-27.0)*[b]
Week 52	65.8 (54.3-76.1)	68.1 (62.3-73.4)	**67.7 (48.6-83.3)**[c]	**70.4 (62.5-77.5)**[c]
PSSI 90				
Week 16	55.7 (44.1-66.9)	57.3 (51.4-63.1)	*19.4 (7.5-37.5)*[b]	*13.2 (8.2-19.6)*[b]
Week 52	60.8 (49.1-71.6)	59.4 (53.5-65.1)	**61.3 (42.2-78.2)**[c]	**58.6 (50.3-66.5)**[c]
Fingernail	(n=82)	(n=125)	(n=35)	(n=69)
mNAPSI 75				
Week 16	18.3 (10.6-28.4)	18.4 (12.0-26.3)	*8.6 (1.8-23.1)*[b]	*8.7 (3.3-18.0)*[b]
Week 52	40.2 (29.6-51.7)	37.6 (29.1-46.7)	**34.3 (19.1-52.2)**[c]	**31.9 (21.2-44.2)**[c]
Palmoplantar	(n=22)	(n=40)	(n=13)	(n=21)
pp-PASI 75				
Week 16	63.6 (40.7-82.8)	62.5 (45.8-77.3)	*7.7 (0.2-36.0)*[b]	*14.3 (3.0-36.3)*[b]
Week 52	72.7 (49.8-89.3)	70.0 (53.5-83.4)	**46.2 (19.2-74.9)**[c]	**52.4 (29.8–74.3)**[c]

[a]Patients from POETYK PSO-1 who were randomized to and received continuous deucravacitinib treatment from Day 1 or who were randomized to placebo and crossed over from placebo to deucravacitinib at Week 16. [b]Response rate in placebo-randomized patients at Week 16 prior to crossing over to deucravacitinib treatment. [c]Response rate after crossover to deucravacitinib treatment at Week 16. CI, confidence interval; PSSI 75/90, ≥75%/≥90% reduction from baseline in Psoriasis Scalp Severity Index; mNAPSI 75, ≥75% reduction from baseline in modified Nail Psoriasis Severity Index; NRI, nonresponder imputation; pp-PASI 75, ≥75% reduction from baseline in palmoplantar Psoriasis Area and Severity Index.

P-100

CLINICAL CHARACTERISTIC OF DIFFICULT-TO-TREAT (D2T) PSORIATIC ARTHRITIS (PSA) PATIENTS. DATA FROM REAL CLINICAL PRACTICE

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Introduction: PsA is a multifaceted disease in which only 40% - 18% patients (pts) achieve a state of minimal disease activity (MDA) or remission despite of treatment. The ''Difficult-to-treat'' (D2T) concept of PsA with refractory-treatment PsA has been proposed recently [1, 2]. There is a lack of data concerning clinical characteristic of D2T PsA pts in real clinical practice.

Objectives: to identify clinical characteristics of D2T PsA pts in real clinical practice.

Methods: A retrospective study was performed in 6 rheumatology clinics. 263 pts (M/F=135/128) mean age 46.1 ± 12.5 years (yrs) with PsA according to CASPAR criteria treated by biologic or target synthetic (b/ts) DMARDs within 2 yrs were included. PsA activity by DAPSA, enthesitis by LEI, dactylitis, BSA (%), HAQ, BMI and comorbidity were evaluated. DAPSA>14 were considered as high/ moderate disease activity (HDA/MoDA), DAPSA<15 – as remission/low disease activity (LDA), BSA>10% - high psoriasis activity, HAQ>0.5 – high/moderate functional joints impairment. D2T PsA was defined as failure of ≥2 b/tsDMARDs with different mechanism of action among TNF inhibitors, anti-IL 17, anti-IL 12/23, anti-IL13 and JAK inhibitors within 2 years of follow-up. D2T PsA pts's characteristics were compared with non-D2T pts using the Fisher, Mann-Whitney and Wilcoxon tests. M ± SD, Me [Q25; Q75], Min-Max, % were performed. All $p < 0.05$, were considered to indicate statistical significance.

Results: 152 (57,8%) pts treated with 1 b/tsDMARDs within 2 yrs reached remission/LDA by DAPSA were considered Non-D2T. 111 pts (42,2%) changed ≥2 b/tsDMARDs within 2 yrs, 71 (27%) of them achieved remission/LDA, but 40 pts (15,2%) of them maintained HAD/MoDA and fulfil D2T criteria. A comparative analysis performed of 40 (M/F=20/20) D2T PsA pts and 152 (M/F=78/74) non-D2T PsA pts showed that D2T pts had a significantly longer PsA duration ($p = 0.017$), more often polyarthritis ($p = 0.014$), dactylitis ($p = 0.004$), enthesitis ($p = 0.001$), BSA>10% ($p = 0.008$) and presence onycholysis ($p = 0.001$), HAQ>0.5 ($p = 0.039$), depression ($p = 0.007$) and higher uric acid blood level ($p = 0.023$). A comparison of the main clinical parameters of 2 gr of pts is presented in Table 1.

Conclusions: D2T PsA occur in 15% cases in real clinical practice. D2T PsA pts compared with non-D2T are characterized by a longer PsA duration, more severe skin/nail psoriasis, presence of polyarthritis, dactylitis, enthesitis and functional disorders at the time of administration of bDMARDs, as well as the presence of concomitant diseases, in particular depression and hyperuricemia.

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Study name	Non-D2T (n=152)		D2T (n=40)		p
BMI, kg/m², Me [Q25; Q75]	27,1 [23,9; 29,9]		26,5 [22,8; 30,9]		> 0,05
PsO duration (months), Me [Q25; Q75]	214 [130; 318]		256 [187; 348]		> 0,05
PsA duration (months), Me [Q25; Q75]	118,0 [83,5; 185,5]		157,0 [102,5; 199,5]		**0,017**
DAPSA, Me [Q25; Q75]	22,3 [12,8; 37,7]		23,7 [17,1; 44,2]		> 0,05
Peripheral polyarthritis, n (%)	29	19,1%	15	37,5%	**0,014**
Dactylitis, n (%)	13	8,6%	10	25%	**0,004**
Enthesitis, n (%)	9	5,9%	12	30%	**0,001**
BSA >10, n (%)	24	16%	14	35%	**0,008**
Onycholysis, n (%)	7	4,7%	11	27,5%	**0,001**
Depression, n (%)	1	0,7%	3	7,5%	**0,007**
Moderate impairment of function HAQ>0.5, n (%)	52	34,7%	21	52,5%	**0,039**
Increased uric acid levels, n (%)	14	9,3%	9	22,5%	**0,023**
Metabolic syndrome, n (%)	7	4,7%	4	10%	> 0,05
Non-alcoholic liver damage (hepatosis), n%)	9	6%	4	10%	> 0,05

Table 1. Comparative characteristics of patients with Non-D2T and D2T PsA, n=192

P-101

DACTYLITIS CLINICAL DOMAIN OF PSORIATIC ARTHRITIS: ASSOCIATION WITH ARTHRITIS, ENTHESITIS, SKIN AND NAIL PSORIASIS SEVERITY

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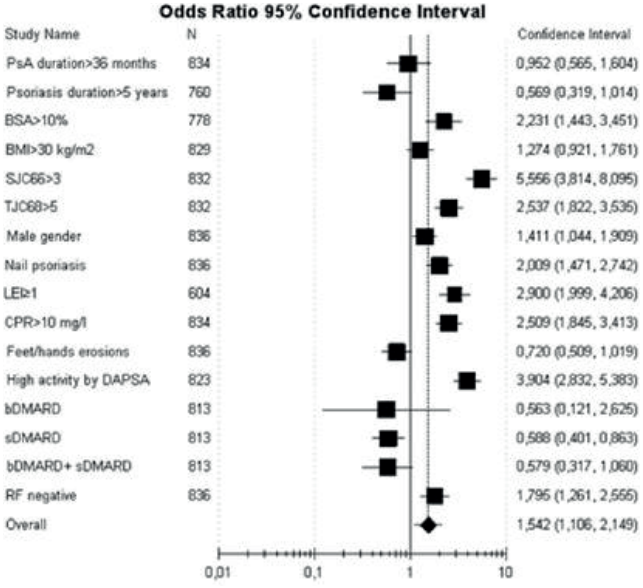
Introduction: Dactylitis is an important clinical domain of psoriatic arthritis (PsA) which has significant impact on disease severity and choice of treatment. There are limited real-world studies on the dactylitis clinical phenotype of PsA.
Objective: to identify clinical characteristics of PsA patients with dactylitis in real clinical practice.
Methods: 836 patients (M/F=386/450) with PsA according to CASPAR criteria were examined. Data was collected from 6 rheumatology clinics. Patients' mean age 46.4 ± 13.1 years, PsA duration 9.9 ± 7.8 years, psoriasis duration 20.2 ± 13.2 years. Median DAPSA 25.5 [15.2; 41.8]. At baseline PsA activity by tender/swelling joint count (TJC)/68, (SJC)/66, enthesitis by LEI, BSA (%), nail psoriasis, DAPSA were evaluated. BSA>10% - indicate high psoriasis activity, DAPSA>28 indicate high PsA activity. The patients were split into two groups: with and without dactylitis. The one-factor model of logistic regression was used to identify a group of features that are associated with presence of dactylitis. M ± SD, Me [Q25; Q75], Min-Max, %, t-test, Pearson-χ2, Manna-Whitney tests, ORs with 95% CI were performed. All $p < 0.05$, were considered to indicate statistical significance.
Results: Dactylitis was found in 237 out of 836 patients (28.4%). Comparative analysis in both groups with and without dactylitis (table) and one-factor model of logistic regression showed the following features at baseline were associated with dactylitis: BSA>10% ($p = 0.001$), nail psoriasis ($p = 0.001$), TJC>5 ($p = 0.001$), SJC>3 ($p = 0.001$), enthesitis by LEI ≥1 ($p = 0.001$), high disease activity by DAPSA ($p = 0.001$), CRP>10 mg/l ($p = 0.001$), male gender ($p = 0.025$). OR analysis with CI 95% for all parameters are shown on Figure.
Conclusion: In real clinical practice dactylitis are associated with more severe skin and nail psoriasis, peripheral polyarthritis, enthesitis, higher PsA activity by DAPSA, male gender. These findings may have a positive impact on the selection of the best therapeutic strategy.



P-102

HYPERURICEMIA IN AXIAL PSORIATIC ARTHRITIS. DATA FROM REAL CLINICAL PRACTICE

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Background: Psoriatic arthritis (PsA) is characterized by a high prevalence of concomitant cardiometabolic diseases such as obesity, hyperlipidemia, diabetes mellitus, hypertension and hyperuricemia (HU) [1, 2].
Objective: To study the prevalence of HU in patients with axial PsA (axPsA), to highlight the clinical features of axPsA with HU
Methods: 71 patients with PsA (M/F=59 (83%)/12 (17%), according to CASPAR criteria were examined. Patients had clinical and imaging signs of spondylitis and/or sacroiliitis. Patients' age 45.7 ± 11.3 years, PsA duration 209.3 ± 163.4 months, psoriasis duration 209.3 ± 163.4 months. Patients underwent standard clinical examination of PsA: LEI, BASMI, DAPSA, BASDAI, ASDAS-CRP, BSA, PASI were evaluated. PROs: Patient Global Assessment (PtGA), Pain, Nocturnal spinal pain, General spinal pain (VAS, mm), BASFI, PsAID-12, FACIT-F, FiRST. X-ray of sacroiliac joints, hands, feet, cervical, lumbar spine, CRP (mg/l), uric acid (UA), lipids were evaluated. The presence of HU was established at UA level ≥360 mmol/l. All patients were divided into 2 groups: 1st - "PsA with HU" (24 patients) and 2nd - "PsA without HU" (47 patients). M ± SD, Me [25; 75], %, Mann-Whitney U test, Kolmogorov-Smirnov two-sample test were performed. All $p < 0.05$ were considered to indicate statistical significance.
Results: The mean UA level was 329.9 ± 80.2 mmol/l. HU was detected in 24 of 71 (33.8%) patients with axPsA. Mean DAPSA 30.7 ± 17.1, BASDAI 5.3 ± 1.9, ASDAS-CRP 2.4 ± 0.8, BSA 5.4 ± 7.9, PASI 6.5 ± 11.2.
The following differences were found between 2 groups: in the 1st group Nocturnal pain in the spine ($p = 0.04$), Sleep disturbance ($p = 0.04$), the triglyceride level ($p = 0.03$) were higher, hypertriglyceridemia and steatohepatosis were more common ($p < 0.05$). No differences between the groups were found in the age of patients, in psoriasis and PsA duration, in other parameters (Table 1).
Conclusion: It is for the first time, that we studied the prevalence of HU in patients with axPsA. HU was detected in 33.8% of patients. In axPsA patients with HU the intensity of nocturnal pain in the spine was higher, sleep disturbance was more common, triglyceride level was higher, hypertriglyceridemia and liver steatosis were more common.

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Table 1

Comparative analysis of axial PsA patients with hyperuricemia and without hyperuricemia (M±SD, Me [25; 75])

Parameters	1st group axPsA with HU	2nd group axPsA without HU	p
Age	45.2±11.7	46.5±10.7	0.62
PsA duration, mo	42.9±40.1	57.5±46.1	0.11
Ps duration, mo	199.6±152.0	213.9±170.0	0.79
Tender Joint Count (68)	11.3±7.76	12.5±9.28	0.67
Swelling Joint Count (66)	3.82±3.56	6.85±6.59	0.06
LEI	1.28±1.2	1.41±0.93	0.18
BASMI	2.7±1.5	3.0±1.9	0.93
DAPSA	32.1±18.2	27.9±14.6	0.35
BASDAI	5.8±2.1	5.1±1.8	1.14
ASDAS-CRP	2.5±0.9	2.4±1.0	0.96
BSA	2.5 [1.0; 6.5]	1.8 [1.0;6.0]	0.78
PASI	2.2 [0.0; 10.0]	1.1 [0.0; 7.8]	0.72
Pain (VAS, mm)	57.1±22.3	50.8±19.9	0.17
PtGA (VAS, mm)	53.4±23.9	59.1±19.8	0.48
Nocturnal spinal pain (VAS, mm)	5.0±2.7	3.6±2.8	**0.04**
General spinal pain (VAS, mm)	4.95±2.7	4.0±2.5	0.2
BASFI	4.0±2.9	3.5±2.7	0.53
PsAID-12	5.1±2.0	4.6±2.3	0.42
Sleep disturbance (Q7 PsAID-12)	10.3±5.2	7.6±5.9	**0.04**
FACIT-F	28.7±8.9	31.4±9.8	0.28
FiRST, n(%)	6 (16,6)	4 (13,7)	0,72
Hypertriglyceridemia, n(%)	2 (8.3)	0	**0.04**
Triglycerides	0.9 [0; 1.7]	0.3 [0; 0.6]	**0.03**
Steatohepatosis	7 (29.1)	5 (10.6)	**0.04**

P-103

COMPARISON OF CLINICAL AND IMAGING CHARACTERISTICS OF PSORIATIC ARTHRITIS IN MEN AND WOMEN. DATA FROM OBSERVATIONAL COHORT

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Background: Gender is an important factor in rheumatic diseases and affects their course and prognosis. Data of gender differences in psoriatic arthritis (PsA) are currently accumulating.

Objective: To compare clinical and imaging features of PsA in men and women.

Material and **Methods:** 956 patients with PsA (M/F=411 (43%)/545 (57%), according to CASPAR criteria were examined. Patients' mean age M/F was 48.4±12.56/53.3±12.70 years ($p<0.001$), PsA duration 9.9±6.4/10.3±7.6 years (p>0.05), Psoriasis duration 18.2±11.1/22.4±14.5 years ($p<0.001$), PsA onset age was 37.1±12.30/41.8±13.5 ($p<0.001$). Pts underwent standard clinical examination of PsA, LEI, DAPSA, BASDAI, BSA, BMI (kg/m2), comorbidities (ICD-10) were evaluated. PROs: HAQ-DI, Patient Global Assessment (PtGA), Pain (VAS, mm). X-ray of sacroiliac joints (SIJs), hands and feet was performed. M±SD, %, t-test, $\chi 2$ Pearson were determined was performed. All $p<0.05$ were considered to indicate statistical significance.

Results: Comparative analysis in both groups of Male and Female (M/F) showed the following features: radiographic sacroiliitis was found in 175(42.6%) / 153(28.1%) ($p<0.001$); bone erosions in the hands and feet in 138(33.6%) / 170(31.2%) ($p=0.435$); BSA>10% in 54(13.1%) / 102(18.7%) ($p=0.021$); (LEI≥3) in 78(20.9%) / 34(11.4%) / ($p=0.001$); mean Pain – 48.5±22.60 / 51.5±22.80 mm VAS ($p=0.043$); mean PtGA – 50.2±23.07 / 54.0±21.91 mm VAS ($p=0.010$); mean DAPSA – 26.4±16.8 / 31.9±22.58 ($p<0.001$); DAPSA>28 in 152(37%) / 249(45,7%) ($p=0.007$), mean BASDAI: 2.7±2.83 / 1.8±2.78 ($p<0.001$); 1.1≤HAQ-DI≤2.0 in 112(28.5%) / 202(38.5%) ($p=0.002$), 2.1≤HAQ-DI≤3.0 in 8(2.0%) / 36(6.9%) ($p<0.001$), mean BMI: 27,0±4,68 / 28,5±6,28 kg/m2 ($p<0,001$); the presence of comorbidities in 154(37%) / 277(51%) ($p<0.001$).

Conclusion: In our observational cohort of patients with PsA pts female gender was associated with higher disease activity (DAPSA), Pain, Patient Global Assessment, BMI, worse quality of life. Women had multiple enthesitis, severe psoriasis, comorbitities more often compared to the male. Female gender was associated with later onset of PsA. Male gender was associated with axial disease, higher activity of spondylitis (BASDAI). No significant differences were found between bone erosions.

P-104

ASSOCIATION OF NAIL PSORIASIS WITH SIGNIFICANTLY MORE SEVERE DISEASE STATUS

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Introduction: The latest data show that nail involvement in psoriatic arthritis (PsA) patients is associated with significantly more severe disease status.

Objectives: To analyze, in clinical practice, the association of nail psoriasis with disease activity, quality of life, and work productivity in PsA patients.

Methods: 588 patients (M/F–277 /311) with PsA according to CASPAR criteria were included in the study. Patients' age 49.6±0.5 years, disease duration 7.2±0.3 years. Patients underwent standard clinical examination of PsA activity. Patients were split into two groups: those with nail psoriasis – group 1, and those without it – group 2. Demographics, disease activity, quality of life, and work productivity were compared between patients with and without nail psoriasis using Pearson's chi-square test and Mann–Whitney U test.

Results: Group 1 includes 312 (53.1%) cases, group 2 – 276 (46.9%) cases. More patients in group 1 were males (51.9% vs 44.1%, $p=0.013$), disabled at work (37.20% vs 26.40%, $p=0.000$), chronic smokers (18.9% vs 8.7%, $p=0.000$) and with axial PsA disease signs according to physician (35.0% vs 26.4%, $p=0.025$) compared to patients in group 2. Patients in group 1 had worse skin psoriasis measured by Psoriasis Area Severity Index – 6 [2-14] vs 3 [1-6] ($p=0.000$). Group 1 patients had higher tender and swollen joint counts: 8 [4-15] vs 5 [2-12] ($p=0.002$) and 5 [1-9] vs 2 [0-7] ($p=0.003$) respectively, higher frequency of erosive radiographic arthritis of feet (45.0% vs 31.2% $p=0.003$) compared to group 2 patients. Group 1 patients had higher frequency of dactylitis (24.4% vs 16.7% $p=0.022$) and heel enthesitis (17.0% vs 10.1% $p=0.016$) respectively, and higher disease activity measured by DAPSA 25 [15-39] vs 20 [12-33] ($p=0.001$). Less patients in group 1 than in group 2 (27.0% vs 52.0% $p=0.004$) achieved minimal disease activity (MDA). Patient-reported outcomes (PROs) in group 1 were worse than in group 2 in regard to reduced health-related quality of life according to PsAID (4.9±2.3 vs 4.0±2.3, $p=0.040$) and to EQ-5D (0.56±0.19 vs 0.64 ±0.21, $p=0.024$) questionnaires, overall work impairment (0.0 [0.0-0.3] vs 0.0 [0.0-0.2], $p=0.034$) and overall activity impairment (0.4 [0.1-0.7] vs 0.3 [0.0-0.5], $p=0.006$) according to WPAI.

Conclusion: Nail involvement in PsA patients is associated with male gender and axial disease. PsA patients with nail involvement are more often disabled, more often are chronic smokers, have significantly worse disease status as measured by disease activity; they are more likely to have more severe (erosive) peripheral arthritis of feet, higher frequency of heel enthesitis and dactylitis, higher psoriasis disease severity, lower frequency of MDA achievement, and worse quality of life and work productivity according to PROs. Detection of nail involvement is critical for choice of treatment approach and better outcomes.

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P-105

COMPARATIVE CHARACTERISTICS OF PSORIATIC ARTHRITIS WITH AXIAL INVOLVEMENT AND AXIAL SPONDYLOARTHRITIS

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Introduction: It has been detected that psoriatic arthritis (PsA) patients with axial involvement [axial PsA (axPsA)] and axial spondyloarthritis (axSpA) patients may have clinical, radiographic and genetic differences.
Objectives: To identify the differences between axPsA and axSpA cohorts.
Methods: 100 patients were examined: 55 with axPsA (group 1) and 45 with axSpA (group 2). Group 1 patients were included according to CASPAR criteria, provided they also had axial involvement. Axial involvement was detected in case of radiographic sacroiliitis[(rSI) bilateral grade ≥ 2 or unilateral grade ≥ 3] or active MRI SI (MRI-SI), or ≥1 syndesmophyte(s) of the cervical and/or lumbar spine. Group 2 patients were included according to ASAS criteria for axSpA. Patients were evaluated for presence of inflammatory back pain (IBP) by ASAS criteria. HLA-B27 antigen status was observed. Patients underwent pelvic radiographs, cervical and lumbar spine, hands and feet X-ray. Patients without rSI underwent sacroiliac joints MRI on Philips Multiva 1.5 T scanner. MRI-SI was categorized using ASAS 2016 criteria. All visualization results were interpreted by two musculoskeletal radiologists. Me [Q25; Q75], Pierson-χ^2 tests were performed. All $p < 0.05$ were considered to indicate statistical significance.
Results: Patients of group 2 were younger (34.9 ± 11.0 vs 45.5 ± 11.4 years old; $p < 0.001$), more often HLA-B27 positive (88.9% vs 28.0%; $p < 0.001$) and more often had IBP (93.3% vs 67.3%; $p = 0.001$). More patients of group 1 had older age (> 40 years) at back pain onset (32.7% vs 2.2%; $p < 0.001$). Group 1 patients had more often peripheral arthritis (100% vs 87.5%; $p < 0.001$), dactylitis (36.4% vs 4.4%; $p = 0.004$), and skin psoriasis (88.7% vs 6.7%; $p < 0.001$). Nail psoriasis was found only in group 1 patients (65.5%; $p < 0.001$). Group 2 patients had more often heel enthesitis (77.8% vs 50.9%; $p = 0.005$). Group 1 patients had worse axial disease activity scores: BASDAI (5.0 vs 3.0; $p = 0.006$), mBASDAI (5.2 vs 4.0; $p = 0.030$) and ASDAS-CRP (2.46 vs 1.76; $p < 0.001$); and worse patient reported outcomes: BASFI (3.7 vs 1.1; $p = 0.004$), patients' pain (6.0 vs 4.0; $p = 0.005$) and patients' global assessments (6.0 vs 5.0; $p = 0.036$). More patients of group 1 had syndesmophytes of the lumbar (50.9% vs 25.0%; $p = 0.009$) and cervical (55.8% vs 28.9%; $p = 0.007$) spine. Only in group 1 patients, chunky "non-marginal" syndesmophytes were found (in 32.1% of cases), as well as spinal lesions without rSI or MRI-SI (in 20.0% of cases). More patients of group 1 had joint erosions (47.1% vs 10.5%; $p = 0.001$), osteolysis (23.5% vs 5.0%; $p = 0.015$) and juxta-articular bone formation (53.1% vs 10.0%; $p < 0.001$). Joint ankyloses was found only in group 1 patients (in 11.8% of cases $p = 0.02$). All patients of group 2 and only 80.0% of group 1 ($p = 0.003$) met ASAS criteria for axSpA.
Conclusion: axPsA and axSpA seem to be two different diseases. In our cohort of patients, axPsA patients had worse disease status compared to axSpA patients.

P-106

NON-INVASIVE TRANSDERMAL DELIVERY WITH BIOCOMPATIBLE PERMEATION ENHANCERS FOR PEPTIDE INHIBITORS OF IL23/IL-17 AXIS IN PSORIASIS

No consent given to publish in scientific journal.

P-107

BASELINE MUSCULOSKELETAL SYMPTOMS IN PSORIASIS PATIENTS: A PROSPECTIVE OBSERVATIONAL STUDY

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Introduction: Up to one-third of people with psoriasis develop psoriatic arthritis (PsA). However, it is often diagnosed late; such delays contribute to the development of joint erosions and worse long-term physical function [1]. Studies have shown that a preclinical phase exists in patients with PsA prior to the diagnosis of the disease. This phase is characterized by the presence of nonspecific musculoskeletal symptoms, including joint pain, fatigue, and stiffness [3].
Objectives: To describe the baseline musculoskeletal symptoms reported by the participants with psoriasis in the HIPPOCRATES Prospective Observational Study (HPOS).
Methods: HPOS is a prospective observational online study of adults with psoriasis, with the aim to identify patients at risk of developing PsA. Inclusion criteria include presence of psoriasis, >18 years old and no diagnosis of PsA. It is a predominantly online study which was launched in the United Kingdom and Ireland in 2023; additional European countries will launch in 2024. HPOS is being widely advertised via emails, newspaper articles, GPs, NHS app, social media, websites, and radio.
Participants were asked to complete online questionnaires on demographics, the Psoriasis Epidemiology Screening Tool (PEST, with a score of 3 or more being positive and indicating a referral to Rheumatology to be considered to assess for PsA), and the Psoriatic Arthritis Impact of Disease (PsAID, the result of which ranges from 0-10, where higher figures indicate worse status). These questionnaires are repeated every 6 months for 3 years. Participants who answered both questionnaires, PEST and PsAID, were included in a Kruskal Wallis test to evaluate whether there were differences on the PsAID score between those who tested positive and those who tested negative on the PEST questionnaire. Data analysis was performed on R, version 4.1.0.
Results: 1224 psoriasis participants were enrolled in 2023. The demographics are summarised in Table 1. The most reported current co-morbidities included anxiety (35%, 331/953), depression (22%, 210/953), high cholesterol (20%, 194/953) and high blood pressure (20%, 191/953). Only a minority (13%, 139/1049) reported having a family history of arthritis.
A total of 985 participants answered both the PEST and PsAID questionnaires. Those who tested positive on PEST ($n = 407$ (41%)) had a higher PsAID score (median [interquartile range, IQR] 4.25 (1.98-6.33)) than those who tested negative on PEST (PsAID score median [IQR]: 1.50 (0.60-3.35)), which was statistically significant (<0.001). These results are summarised in Table 2.
Conclusion: In the HPOS cohort of psoriasis patients, it is apparent that that those who reported being PEST positive, had higher PsAID scores. This observation may increase our understanding of how to better define the early phases of PsA and thereby help to identify patients at risk of developing PsA and those who might be suitable for early interventions.
Funding: HIPPOCRATES has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement no.101007757. The JU receives support from the European Union's Horizon 2020 research and innovation program and EFPIA.
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Table 1: Demographics of the psoriasis participants

Variable	n	Percent	Mean	SD
Age (years)	1224	100	51	14.7
Gender	1224	100	-	-
- Female	772	63	-	-
- Male	452	37	-	-
Ethnicity	1048	86	-	-
- British	685	65	-	-
- Irish	283	27	-	-
- Any other white background	51	5	-	-
- All other backgrounds	29	3	-	-
Smoking	969	79	-	-
- Never	464	48	-	-
- Stopped	422	44	-	-
- Current	83	9	-	-

Table 2: Comparison of Psoriatic Arthritis Impact of Disease (PsAID) questionnaire scores in those who were Psoriasis Epidemiology Screening Tool (PEST) positive vs negative

Questionnaire	PEST positive (median, IQR[1])	PEST negative (median, IQR[1])
Psoriatic Arthritis Impact of Disease (PsAID)	4.25 (1.98- 6.33)	1.50 (0.60-3.35)

P-108

ASSOCIATION BETWEEN SUBCLINICAL ATHEROSCLEROSIS AND PSORIASIS TO PSORIATIC ARTHRITIS TRANSITION ONSET

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Background: Psoriatic arthritis (PsA) is a heterogeneous disease which may precede concurrently or after the development of psoriasis (PsO). The time to transition from PsO to PsA is not fully explained by genetic factors alone. Therefore, clinical, environmental, and immunological changes might play important roles. Previous studies have reported the important role of PsO and PsA in cardiovascular disease, this being the first cause of mortality in both populations.
Objective: To determine the association between subclinical atherosclerosis the transition onset from psoriasis to psoriatic arthritis.
Methods: Cross-sectional, observational, and comparative study of patients with PsA who met the 2006 Classification Criteria for Psoriatic Arthritis (CASPAR), aged 18 years or older. Patients with a diagnosis of overlapping syndromes, history of major cardiovascular events (myocardial infarction, stroke and heart failure) and pregnant individuals were excluded. The age of onset was defined through clinical history and the patients were paired by age and divided, accordingly, into two groups: patients with concurrent psoriasis and PsA (≤1 year) and patients with psoriasis before PsA (>1 year). A carotid ultrasound in B-mode was performed on all patients by a certified radiologist blinded to clinical information. Subclinical atherosclerosis was defined as the presence of carotid plaque (CP), defined as carotid intima-media thickness (cIMT) ≥1.2 mm or focal narrowing ≥0.5 mm of the surrounding lumen, or the presence of increased cIMT (≥0.8 mm). Group distribution was assessed using the Kolmogorov-Smirnov test. The comparisons were made using the chi-square test, the Kruskal-Wallis test, T-Student's test and U- Mann Whitney Test, accordingly. A p-value of ≤ 0.05 was considered statistically significant.
Results: Fifty-two patients with PsA were included, mostly women (55.7%), with a mean age of 55.5 ± 12.2 years. The mean interval of years transition between PsO and PsA was 5.3 ± 7.9 years. The most prevalent cardiovascular comorbidity was dyslipidemia (44.2%) in both of our groups. There was no difference between groups in the prevalence of traditional cardiovascular risk factors (diabetes, hypertension, dyslipidemia, active smoking and obesity). A significant difference was found in the presence of subclinical atherosclerosis between the groups, with a higher prevalence of carotid plaque reported in the concurrent PsO and PsA group (50% vs 23%, $p = 0.007$) (Table 1).
Conclusions: Concurrent PsO and PsA patients exhibit different clinical characteristics and a higher cardiovascular risk compared to PsO before PsA patients. There are few studies comparing the transition onset of this diseases. This categorization could carry significant implications for epidemiological research on the prognosis of psoriatic disease. This approach might offer potential focal points for the prevention of PsA and its cardiovascular implications.

Table 1. Demographic characteristics.

Characteristics	Concurrent PsO and PsA (n=26)	PsO before PsA (n=26)	*P value*
Age, years, mean ± SD	57.1 ± 12.6	53.8 ± 11.8	NS
Age during transition, mean ± SD	45.4 ± 12.3	45.41 ± 11.7	NS
Interval of transition, years median (IQR)	0 (0-0)	7.5 (4.1-14.5)	***<0.001***
PsO disease duration, median (IQR)	10 (4.6-11)	14 (8.5-22.7)	***0.016***
PsA disease duration, years, median (IQR)	10 (5-12)	6.5 (2-10.7)	NS
Women, n (%)	14 (53.8)	15 (57.6)	NS
Diabetes, n (%)	6 (23.0)	5 (19.2)	NS
Hypertension, n (%)	13 (50)	7 (26.9)	NS
Dyslipidemia, n (%)	11 (42.3)	12 (46.1)	NS
Active smoking, n (%)	4 (15.3)	3 (11.5)	NS
Obesity, n (%)	9 (34.6)	8 (30.7)	NS
DAS28CRP, mean ± SD	2.41 ± 1.43	2.96 ± 1.69	NS
DAPSA, mean ± SD	14.1 ± 17.5	16.1 ± 19.7	NS
Tender joints, median (IQR)	1 (0.0-4.7)	2 (0.0-8.7)	NS
Swollen joints, median (IQR)	0.5 (0.0-5.0)	0 (0.0-1.0)	NS
Carotid plaque, n (%)	13 (50)	6 (23.0)	***0.044***
Increased cIMT, n (%)	5 (19.2)	3 (11.5)	NS

PsO, psoriasis; PsA, psoriatic arthritis; DAS28CRP, disease activity score 28-c reactive protein; DAPSA, disease activity index for psoriatic arthritis; cIMT, carotid intima-media thickness; IQR, interquartile range; NS, not significant; SD, standard deviation.

P-109

RELATIONSHIP BETWEEN NAIL PSORIASIS SEVERITY INDEX IN PSORIATIC ARTHRITIS POPULATION AND SIX CARDIOVASCULAR RISK CALCULATORS

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Background: Psoriatic arthritis (PsA) is a chronic, inflammatory and immune-mediated disease that affects up to 30% of psoriasis (PsO) patients. Nail involvement affects 80% of PsA patients and 30%–50% of PsO patients. Nail involvement in PsO patients has been associated to a higher prevalence of metabolic syndrome, higher risk of heart failure and higher cardiovascular risk overall.
Objective: To determine the relationship between and Nail Psoriasis Severity Index (NAPSI) and cardiovascular risk assed by

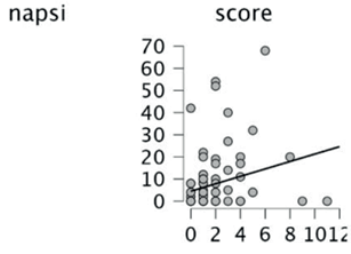
six cardiovascular risk calculators.
Methods: Cross-sectional, observational, and comparative study of patients with PsA who met the CASPAR 2006 classification criteria, aged 18 years or older. Patients with a diagnosis of overlapping syndromes, history of major cardiovascular events (myocardial infarction, stroke and heart failure) and pregnant individuals were excluded. The NAPSI was obtain through physical examination. The CVR of each patient was assessed by six different CVR algorithms, including: Framingham Risk Score (FRS)-lipids, FRS-body mass index (FRS-BMI), American College of Cardiology and American Heart Association (ACC/AHA) Risk Algorithm, Systematic Coronary Risk Evaluation (SCORE), QRISK3 and Reynolds Risk Score (RRS). Group distribution was assessed using the Kolmogorov- Smirnov test. The comparisons were made using the chi-square test, T-Student test and Kruskal Wallis test, accordingly. The correlation was performed through Spearman's rho. A p-value of ≤ 0.05 was considered statistically significant.
Results: Eighty-five patients with PsA were included, mostly women (55.2%), with a mean age of 55.9 ± 8.14 years. The most prevalent cardiovascular comorbidity was dyslipidemia (44.7%) There was a statistically significant difference in the DAS28PCR between the groups (2.33 ± 1.0 vs 2.99 ± 1.5, $p = 0.021$), DAPSA ($p = 0.016$), PASI ($p = 0.013$) and SCORE value (1.0 (0.0-2.0) vs 1.5 (1-3), $p = 0.023$) (Table 1). A positive correlation was found between NAPSI and age (Pearson's r=0.213, $p = 0.025$) and SCORE (Spearman's rho=0.321, $p = 0.001$) (Figure 1).
Conclusions: Nail involvement in PsA is a clinical sign often underrated by physicians. Clinicians need to pay attention to nail changes as early as possible, due to them being an important helper to determine our patients' disease status and cardiovascular health.

Table 1. Demographic characteristics.

Characteristics	NAPSI <1 (n=45)	NAPSI >1 (n=40)	*P value*
Age, years, mean ± SD	54.6 ± 8.7	57.2 ± 7.2	NS
Women, n (%)	26 (57.7)	21 (52.5)	NS
Diabetes, n (%)	8 (17.7)	12 (30.0)	NS
Hypertension, n (%)	20 (44.4)	13 (32.5)	NS
Dyslipidemia, n (%)	21 (46.6)	17 (42.5)	NS
Active smoking, n (%)	7 (15.5)	7 (17.5)	NS
Obesity, n (%)	16 (35.5)	17 (42.5)	NS
DAS28CPR, mean ± SD	2.33 ± 1.0	2.99 ± 1.5	***0.021***
Disease duration, months mean ± SD	9.9 ± 8.1	13.4 ± 9.8	NS
NAPSI, mean ± SD	0 ± 0	15.7 ± 15.6	-
DAPSA, mean ± SD	12.8 ± 12.9	21.0 ± 17.6	***0.016***
PASI, median (IQR)	0.0 (0.0-1.5)	1.1 (0.1-3.2)	***0.013***
FRS lipids, mean ± SD	10.0 ± 12.0	10.4 ± 9.23	NS
FRS BMI, mean ± SD	17.7± 15.5	19.5 ± 12.6	NS
ACC/AHA, mean ± SD	9.5 ± 12.6	9.6 ± 10.4	NS
RRS, median (IQR)	3 (1.0-5.0)	2.5 (2.0-7.2)	NS
QRISK3, mean ± SD	8.2 ± 9.4	8.4 ± 5.4	NS
SCORE, median (IQR)	1.0 (0.0-2.0)	1.5 (1-3)	***0.023***

NAPSI, Nail Psoriasis Severity Index; DAS28CRP, Disease Activity Score 28 c-reactive protein; DAPSA, Disease Activity Psoriatic Arthritis; PASI, Psoriasis Area Severity Index; F RS lipids, Framingham Risk Score lipids; FRS BMI, Framingham Risk Score body mass index; ACC/AHA, American College of Cardiology and American Heart Association; RRS, Reynolds Risk Score; SCORE, Systematic Coronary Risk Evaluation, interquartile range; NS, not significant.

Figure 1. Positive correlation between NAPSI and SCORE.



P-110

CLINICAL OUTCOMES AND PATIENTS' PERSPECTIVES OF THE MULTIDISCIPLINARY PSORIASIS MANAGEMENT: A 5-YEAR, RETROSPECTIVE STUDY.

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Introduction: A coordinated, multidisciplinary approach is highly recommended by dermatology societies and desired by patients worldwide to manage psoriasis (Pso) and its comorbidities
Objectives: To explore the benefits of a multidisciplinary care model in patients with PsO regarding treatment efficacy, and early detection of comorbidities, particularly psoriatic arthritis (PsA), patients' quality of life, and patient satisfaction
Methods: We recruited all patients attending the Pso combined clinic from June 2018 to June 2023. In 2018, a parallel multidisciplinary care model was developed in the Psoriasis Outpatient Clinic of our dermatology department, incorporating health services between dermatologists, rheumatologists, psychiatrists, and dietitians. Screening for potential PsA in patients with existing PsO was performed through the self-administered five-item Psoriasis Epidemiology Screening Tool (PEST) and/or psoriatic onychia. A PEST value ≥ 3 indicated referral to a rheumatologist
Demographics, clinical features and clinometric [Psoriasis Area Severity Index (PASI), Nail Area Psoriasis Severity Index (NAPSI), Dermatology Life Quality Index (DLQI), axial/peripheral involvement, Disease Activity Index for Psoriatic Arthritis (DAPSA) disease activity], history of PsO or PsA, body mass index (BMI), comorbidities, and previous and present treatments including conventional systemic or biologic PsO regimens, conventional synthetic disease-modifying antirheumatic drugs (csDMARDS) and/or biological disease-modifying antirheumatic drugs (bDMARDs) were recorded at baseline and the follow-up visits, as required.
Patients who attended the combined clinic were asked to rate their experience by completing a questionnaire at baseline and regularly at follow-up visits regarding their satisfaction. A 5-point Likert scale was used (1: the worst possible – 5: the best possible). At the end of the questionnaire were also available free-text boxes.
Results: Over the 5 years, 721 patients were managed in the Pso combined clinic. Demographics and detailed results are presented in Table 1. The utilization rate of the multidisciplinary unit was 48.0% (721/1503). The mean follow-up visits per patient per year were 4 ±2.8 for the rheumatologic re-evaluation, 6 ±3.1 for the dietitian re-evaluation, and 7 ±5.2 for the psychiatric re-assessment.
Early detection of PsA in PsO patients was 79.47% (418/526). Treatment modifications were reported for 63.88% (336/526) of Pso-PsA patients: 72.92% (245/336) were newly initiated bDMARDs, while 27.08% (91/336) were initiation or up-titration of csDMARDs. Among patients referred for a psychiatry visit, therapeutic adjustments were needed in 22.22% (8/36). All patients (209/721; 28.99%) referred to dietitians followed a weight-loss program, of which 35.89% (75/209) achieved a clinically meaningful ≥5% BMI reduction.
Most patients (97.92%; 706/721) rated the experience of the combined clinic as excellent (Figure 1). Positive free-text remarks included time efficiency, thorough evaluation, a sense of security, and better disease awareness; negative comments were too many people in the room and lack of privacy.
Conclusions: The diagnosis of PsA, because of consistent PEST evaluation and psoriatic onychia screening during the follow-up visits by dermatologists, was substantially high among patients with psoriasis. Moreover, the evident reduction of DAPSA and PASI scores simultaneously, suggests that holistic management

of a patient from the diagnosis to timely treatment is beneficial in significant aspects of psoriatic disease, namely the skin and joints.

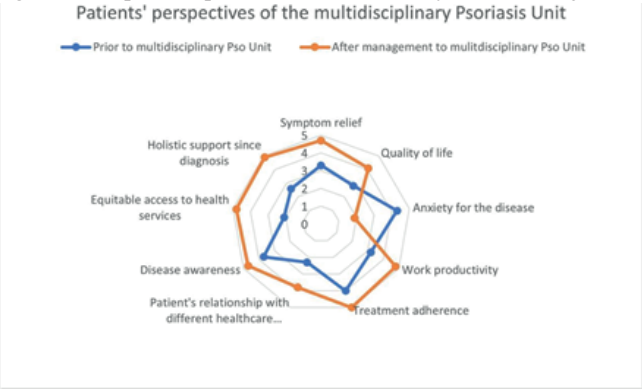

Figure 1. Differences regarding patients' outlook in certain areas before and after the multidisciplinary approach.

Demographics		
Age (Mean; ±SD in years)	53 (±17)	
Male	41.89% (302/721)	
Pso duration (Mean; ±SD in years)	16 (±14)	
PsA duration (Mean; ±SD in years)	1 (±2)	
BMI (Mean; ±SD)	24.8 (±12.5)	
Timely interventions between 2018-2023		
Newly diagnosed PsA	79.47% (418/526)	
Psychiatric medical intervention	22.22% (8/36)	
Weight-loss diet program initiation	100% (209/209)	
• *≥5% BMI reduction*	35.89% (75/209)	
Changes in systemic treatments between 2018-2023		
Without changes	52.98% (382/721)	
Molecule change	47.02% (339/721)	
• Due to PsA • Due to Major Depression diagnosis	99.12% (336/339) 0.88% (3/339)	
Newly initiated biologic DMARDs	72.92% (245/336)	
Newly initiated or up-titration of conventional DMARDs	27.08% (91/336)	
Clinimetrics		
	Baseline	**52 weeks after combined management**
≥5% BMI reduction	n/a	35.89% (75/209)
PASI (Mean; ±SD)	9.2 (±2.8)	2.1 (±1.3)
tNAPSI	8.9 (±5.3)	1.4 (±0.8)
DAPSA (Mean; ±SD)	12.8 (±5.0)	3.3 (±6.0)
DLQI (Mean; ±SD)	11 (±7.0)	1 (±3.0)

Table 1. Characteristics of patients and clinical outcomes after the multidisciplinary psoriasis disease management between 2018-2023. *Abbreviations: BMI: Body Mass Index; DAPSA: Disease Activity Index for Psoriatic Arthritis; DMARDs: disease-modifying antirheumatic drugs; DLQI: Dermatology Life Quality Index; PASI: Psoriasis Area Severity Index; PsA: Psoriatic Arthritis; Pso: Psoriasis; SD: Standard Deviation; tNAPSI: target Nail Psoriasis Severity Index.*

P-111

BIMEKIZUMAB REDUCED PSORIATIC ARTHRITIS IMPACT IN PATIENTS WITH PSORIASIS: UP TO 2-YEAR RESULTS FROM TWO PHASE 3 STUDIES

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Introduction: Bimekizumab (BKZ), a humanised monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated reduction in disease impact to 1 year in patients with psoriatic arthritis (PsA).[1,2] PsA negatively impacts health-related quality of life; patients with concomitant psoriasis may be impacted in different ways to those without skin symptoms.[3] The patient-reported PsA Impact of Disease-12 (PsAID-12), assesses the physical, social, and psychological impact of PsA.[4]

Objectives: To assess the effect of BKZ treatment on disease impact up to 2 years, using PsAID-12, in patients with PsA and psoriasis affecting ≥3%–≤10% and >10% body surface area (BSA).

Methods: Post hoc analysis of BE OPTIMAL (NCT03895203; biologic disease-modifying antirheumatic drug [bDMARD]-naïve) and BE COMPLETE (NCT03896581; inadequate response/intolerance to tumour necrosis factor inhibitors [TNFi-IR]); both studies were placebo (PBO)-controlled to Week (Wk)16, and assessed subcutaneous BKZ 160 mg every 4 wks (Q4W) in patients with PsA.[1,2] PBO patients switched to BKZ (PBO/BKZ) at Wk16. BE OPTIMAL included a reference arm (subcutaneous adalimumab [ADA] 40 mg Q2W); these patients switched to BKZ at Wk52 (ADA/BKZ) with no washout between treatments. BE OPTIMAL Wk52 and BE COMPLETE Wk16 completers were eligible to enrol in the open-label extension, BE VITAL (NCT04009499).
PsAID-12 total and single item domain scores range from 0–10; higher scores indicate worse status.[4] Change from baseline (CfB) and clinically meaningful improvement (≥3 point decrease from baseline when respective baseline score ≥3) are reported to Wk104 (BE OPTIMAL) and Wk88 (BE COMPLETE) for patients with baseline psoriasis affecting ≥3%–≤10% and >10% BSA. Missing data imputed using non-responder (binary) or multiple (continuous) imputation.

Results: 425 bDMARD-naïve (217 BKZ; 140 PBO; 68 ADA) and 264 TNFi-IR patients (176 BKZ; 88 PBO) had baseline psoriasis BSA ≥3%. 365/425 (85.9%) bDMARD-naive and 221/264 (83.7%) TNFi-IR patients completed Wk104/88.
For PBO/BKZ and BKZ patients with baseline psoriasis BSA ≥3%–≤10%, mean CfB (standard error) in PsAID-12 total score at Wk52/40 was sustained to Wk104/88 (bDMARD-naïve: –2.3 [0.2] PBO/BKZ, –2.4 [0.2] BKZ; TNFi-IR: –2.3 [0.3], –2.7 [0.2]). Additionally, clinically meaningful improvement response rate in PsAID-12 total score was generally sustained to Wk104/88 in bDMARD-naïve and TNFi-IR patients with baseline psoriasis BSA ≥3%–≤10% (Figure). In the >10% BSA subgroup, Wk52/40 mean CfB and clinically meaningful improvement response rate in PsAID-12 total score were also generally sustained to Wk104/88 in bDMARD-naïve and TNFi-IR patients. For ADA/BKZ patients, Wk52 outcomes in both subgroups were sustained following the switch to BKZ.
In both studies, improvements in all PsAID-12 domain scores were observed at Wk104/88 on BKZ and were generally similar across the ≥3%–≤10% and >10% BSA subgroups (Table). Greatest improvements from baseline were observed in domains with highest impact at baseline: skin problems, pain, functional capacity, and fatigue.

Conclusions: BKZ treatment resulted in clinically meaningful improvements in patient-reported disease impact that were sustai-

ned up to 2 years in patients with PsA and psoriasis. Results were consistent between BSA subgroups and across bDMARD-naïve and TNFi-IR patients.

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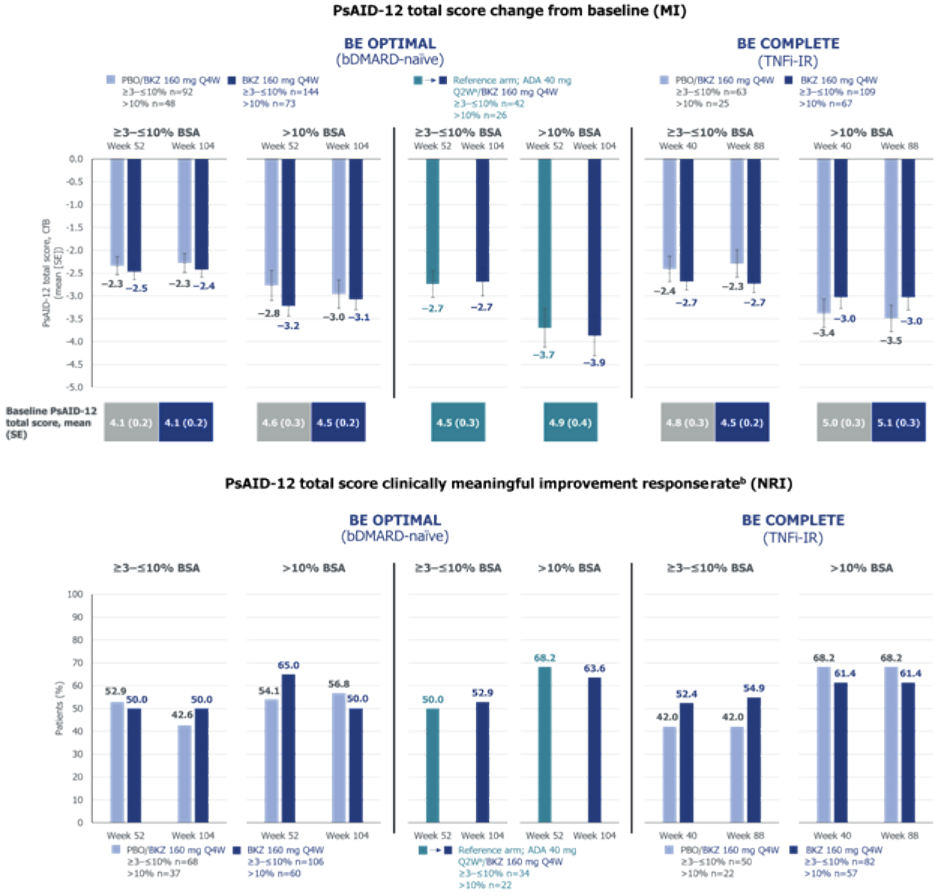
Table. PsAID-12 single-item domain scores CfB at Week 104/88 in patients with baseline psoriasis ≥3%–≤10% and >10% BSA (MI)

	BE OPTIMAL (bDMARD-naïve) Week 104				BE COMPLETE (TNFi-IR) Week 88			
CfB in PsAID-12 domain scores, mean (SE)	PBO/BKZ 160 mg Q4W		BKZ 160 mg Q4W		PBO/BKZ 160 mg Q4W		BKZ 160 mg Q4W	
BSA	**≥3–≤10% (n=92)**	**>10% (n=48)**	**≥3–≤10% (n=144)**	**>10% (n=73)**	**≥3–≤10% (n=63)**	**>10% (n=25)**	**≥3–≤10% (n=109)**	**>10% (n=67)**
Pain	−3.1 (0.3)	−3.2 (0.4)	−3.0 (0.2)	−3.4 (0.3)	−3.0 (0.4)	−4.0 (0.5)	−3.2 (0.3)	−3.3 (0.4)
Fatigue	−2.3 (0.3)	−2.6 (0.4)	−2.6 (0.2)	−2.7 (0.3)	−2.0 (0.4)	−2.7 (0.5)	−2.8 (0.3)	−2.7 (0.3)
Skin Problems	−3.3 (0.3)	−4.9 (0.4)	−3.7 (0.2)	−5.2 (0.3)	−3.6 (0.4)	−6.3 (0.5)	−3.9 (0.3)	−5.0 (0.3)
Work and/or Leisure Activities	−2.4 (0.3)	−3.1 (0.4)	−2.8 (0.2)	−3.2 (0.3)	−2.3 (0.4)	−3.5 (0.5)	−3.0 (0.3)	−3.3 (0.4)
Functional Capacity	−2.5 (0.3)	−3.1 (0.4)	−2.9 (0.2)	−3.2 (0.3)	−2.7 (0.4)	−3.8 (0.4)	−3.0 (0.3)	−3.2 (0.4)
Discomfort	−2.5 (0.3)	−2.7 (0.4)	−2.8 (0.2)	−3.3 (0.3)	−2.6 (0.4)	−3.6 (0.4)	−3.0 (0.3)	−3.3 (0.4)
Sleep Disturbance	−1.9 (0.3)	−2.4 (0.5)	−1.6 (0.2)	−2.3 (0.4)	−2.0 (0.4)	−2.7 (0.7)	−2.3 (0.3)	−2.3 (0.4)
Coping	−2.2 (0.3)	−3.1 (0.4)	−2.0 (0.2)	−3.1 (0.3)	−2.7 (0.4)	−3.8 (0.4)	−2.4 (0.3)	−2.6 (0.3)
Anxiety, Fear and Uncertainty	−0.9 (0.3)	−1.6 (0.4)	−1.0 (0.2)	−1.4 (0.3)	−0.9 (0.3)	−0.7 (0.3)	−1.5 (0.2)	−1.8 (0.4)
Embarrassment and/or Shame	−1.4 (0.3)	−3.3 (0.5)	−1.8 (0.2)	−3.4 (0.3)	−2.1 (0.4)	−3.2 (0.7)	−2.2 (0.3)	−2.9 (0.4)
Social Participation	−1.6 (0.3)	−2.3 (0.4)	−1.8 (0.2)	−2.3 (0.3)	−1.8 (0.4)	−2.8 (0.6)	−2.0 (0.2)	−2.5 (0.4)
Depression	−0.6 (0.2)	−1.5 (0.4)	−0.3 (0.2)	−1.0 (0.2)	−0.9 (0.3)	−1.5 (0.5)	−1.3 (0.2)	−1.4 (0.4)

Randomised set, in patients with psoriasis involving ≥3%–≤10% and >10% BSA at baseline. In BE OPTIMAL, patients were randomised 3:2:1 to BKZ 160 mg Q4W:PBO:reference arm (ADA 40 mg Q2W; data not reported in table). In BE COMPLETE, patients were randomised 2:1 to BKZ 160 mg Q4W:PBO. In both studies, patients on PBO switched to BKZ 160 mg Q4W at Week 16. PsAID-12 scores range from 0–10; higher scores indicate worse status.[4] bDMARD: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; BSA: body surface area; CfB: change from baseline; MI: multiple imputation; PBO: placebo; PsAID-12: Psoriatic Arthritis Impact of Disease-12; Q2W: every 2 weeks; Q4W: every 4 weeks; SE: standard error; TNFi-IR: prior inadequate response or intolerance to tumour necrosis factor inhibitors.

Figure. PsAID-12 total score CfB and clinically meaningful improvement response rate at Week 52/40 and Week 104/88 in patients with baseline psoriasis ≥3%–≤10% and >10% BSA (MI, NRI)



Randomised set, in patients with psoriasis involving ≥3%–≤10% and >10% BSA at baseline. In BE OPTIMAL, patients were randomised 3:2:1 to BKZ 160 mg Q4W:PBO:reference arm (ADA 40 mg Q2W). In BE COMPLETE, patients were randomised 2:1 to BKZ 160 mg Q4W:PBO. In both studies, patients on PBO switched to BKZ 160 mg Q4W at Week 16. In BE OPTIMAL, patients on ADA 40 mg Q2W switched to BKZ 160 mg Q4W at Week 52. PsAID-12 scores range from 0–10; higher scores indicate worse status.[4] [a] Reference arm; study not powered for statistical comparisons of ADA to BKZ or PBO; [b] Clinically meaningful improvement response: ≥3 point decrease from baseline when respective baseline score ≥3. ADA: adalimumab; bDMARD: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; BSA: body surface area; CfB: change from baseline; MI: multiple imputation; NRI: non-responder imputation; PBO: placebo; PsAID-12: Psoriatic Arthritis Impact of Disease-12; Q2W: every 2 weeks; Q4W: every 4 weeks; SE: standard error; TNFi-IR: prior inadequate response or intolerance to tumour necrosis factor inhibitors.

P-112

EFFICACY OF THE ORAL, SELECTIVE, ALLOSTERIC TYROSINE KINASE 2 INHIBITOR, DEUCRAVACITINIB, ON PSORIASIS IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS (PSA)

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Introduction: Tyrosine kinase 2 (TYK2) mediates signaling of key cytokines involved in plaque psoriasis (PsO) and PsA pathophysiology. Deucravacitinib is a first-in-class, oral, selective, allosteric TYK2 inhibitor approved in multiple countries for the treatment of adults with moderate to severe PsO. Deucravacitinib demonstrated superiority over apremilast and placebo (PBO), as determined by various outcome measures in 4 phase 3 trials (NCT03611751; NCT03624127), including trials in China (NCT04167462) and Japan (NCT03924427) in patients with moderate to severe plaque PsO.1,2 Deucravacitinib also improved multiple measures of disease activity, including arthritis and skin lesions of PsO, vs PBO in a phase 2 trial (NCT03881059) in patients with active PsA.3

Objectives: This analysis from the phase 2 trial in PsA further evaluated the efficacy of deucravacitinib on patients with PsA and baseline characteristics suggestive of PsO.

Methods: The phase 2, double-blind trial in PsA randomized patients ($N = 203$) 1:1:1 to PBO, deucravacitinib 6 mg once daily (QD) or 12 mg QD. After week 16 (part A), patients receiving deucravacitinib who achieved minimal disease activity could continue treatment in a blinded manner until week 52 (part B). Exploratory PsO disease activity measures, including mean body surface area (BSA), mean Psoriasis Area and Severity Index (PASI) score, achievement of different treat-to-target PASI and BSA thresholds, and comparison of responses according to conventional synthetic disease-modifying antirheumatic drugs (csDMARDs), were assessed at week 16 in part A. All reported p-values are nominal.

Results: At baseline (BL), PsO characteristics were comparable across treatment arms and were mild to moderate (PASI<12; BSA<10) in the majority of patients (≥ 74%). At week 16, mean PASI scores significantly improved in both deucravacitinib arms versus placebo across all BL PsO severities, including patients with mild to moderate involvement and moderate to severe involvement (BSA > 10%; PASI > 10%) (Figure 1). Deucravacitinib 6 and 12 mg QD decreased PASI scores from BL vs PBO in patients on background csDMARDs; −4.0 and −4.9 vs −2.3; $P < 0.05$ for both) and those without csDMARD use (−3.7 and −4.0 vs 2.5; $P < 0.001$ for both), respectively. At week 16, a greater proportion of patients with PsO treated with deucravacitinib at either dose achieved a treat-to-target PASI score of ≤ 1 than those receiving PBO. Decreases in mean change from BL at week 16 in key components of PASI, including induration and desquamation, were observed in patients receiving deucravacitinib 6 or 12 mg QD vs those receiving placebo (Figure 2).

Conclusions: Deucravacitinib treatment improved PASI scores in patients with PsA, along with improvements in induration and desquamation on PsO lesions, regardless of BL PsO severity and background csDMARD use. Improvements in patients with moderate to severe PsO were comparable to that observed in the phase 3 POETYK PSO-1 trial in patients with moderate to severe PsO.1

References

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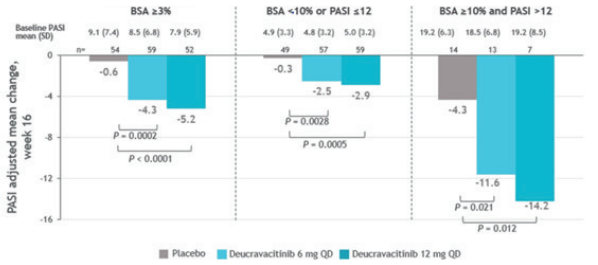
3. Mease PJ, et al. Ann Rheum Dis 2022;81:815–822.

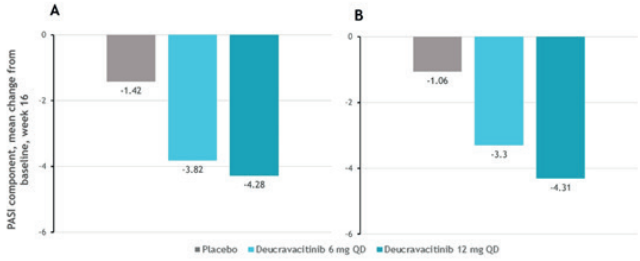
Figure 1. Mean change from baseline in PASI score at week 16 by psoriasis severity at baseline



Modified baseline observation carried forward method was used to handle missing data. Adjusted means and nominal *P* values were derived from an analysis of covariance model; factors for body weight and TNFi use are included, and the baseline value is used as a covariate.

BSA, body surface area; PASI, Psoriasis Area and Severity Index; QD, once daily; SD, standard deviation; TNFi, tumor necrosis factor inhibitor.

Figure 2. Mean change from baseline in PASI components (A) induration and (B) desquamation at week 16



PASI, Psoriasis Area and Severity Index; QD, once daily.

P-113

EFFECTIVENESS OF IXEKIZUMAB AT 12 WEEKS IN B/TSDMARD TREATMENT-NAIVE AND EXPERIENCED PATIENTS WITH PSORIATIC ARTHRITIS (PSA): PRO-SPIRIT STUDY DATA

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Background: Treatment guidelines for PsA recommend biologic disease-modifying antirheumatic drugs (bDMARDs) such as tumour necrosis factor inhibitors (TNFi), interleukin (IL)-12/23 and IL-23, or IL-17 after conventional disease-modifying antirheumatic (csDMARD) failure. However, there is limited evidence for treating patients (pts) with PsA after bDMARD failure. Pts with inadequate response to TNFis often have lower responses to subsequent therapies compared to bDMARD-naïve pts. Ixekizumab (IXE) has shown efficacy in pts with PsA who were bDMARD-naïve (SPIRIT-P1) and TNFi-experienced (SPIRIT-P2) but real-world data is still limited. PRO-SPIRIT is a multinational 2-year observational study aiming to investigate the real-world use of targeted synthetic DMARDs (ts/bDMARDs) including IXE in the treatment of PsA.

Objectives: To assess effectiveness of IXE in b/tsDMARD-naïve and -experienced pts at 12 weeks for pts with PsA in real-world setting.

Methods: This study was conducted in 6 countries, and enrolled

1192 adults with PsA (≥6 months) who initiated or switched to a new b/tsDMARD, locally approved for PsA. Patient characteristics, disease activity and pt reported outcomes were collected at baseline (BL) and after 12 weeks for both b/tsDMARD-naïve and -experienced pts. Results are presented descriptively. Missing values were imputed.
Results: Among the 341 pts on IXE, 70.4 % had prior b/tsDMARD treatment. At BL, 63.4 % of b/tsDMARD naïve and 65.4 % of those who had prior b/tsDMARD were female. Mean pt age was 52.9 and 54.1 year for b/tsDMARD-naïve and -experienced pts respectively. Disease activity measured by Tender and Swollen joint counts (TJC and SJC) and Clinical Disease Activity in Psoriatic Arthritis (cDAPSA) as well as physician and patient global assessment (PGA and PtGA respectively) were balanced in b/tsDMARD-naïve and -experienced subgroups (and subsequently reported in that order, herein); furthermore, both groups had a high burden of disease at BL. At 12 weeks, SJC showed an improvement of -3.1 and -2.4 points, whereas TJC improved by -4.5 and - 4.1 points in the respective groups. At 12 weeks, mean change from BL (CFB) in cDAPSA was -11.9 and -10.4. Pts in Minimal disease activity (MDA) increased to 27.5 % and 23.8 %. PGA also improved with a respective mean CFB of -28.8 and -25.0. Finally, PtGA improvement of -22.2 and -19.8 was observed at 12 weeks.
Conclusion: At week 12, IXE 80 mg demonstrated effectiveness in TJC, SJC, PGA, and PtGA in b/tsDMARD-naïve and -experienced pts. Similar observations were made on composite scores such as cDAPSA and MDA. This real-world analysis supports observations in clinical trials SPIRIT-P1 and SPIRIT-P2 conducted in b/tsDMARD-naïve and -experienced populations respectively.

P-114

EFFECTIVENESS OF IXEKIZUMAB AND SECUKINUMAB: 3-MONTH INTERIM DESCRIPTIVE ANALYSIS OF THE PSORIATIC ARTHRITIS OBSERVATION STUDY OF PERSISTENCE OF TREATMENT (PRO-SPIRIT)

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Background: IXE and SECU are IgG4 and IgG1 monoclonal antibodies inhibiting interleukin-17A and approved for multiple indications including PsA, Axial spondyloarthritis and psoriasis (PsO). Real-world data exist on the effectiveness of IL17A inhibitors on PsO but is scarce for the management of PsA domains. PRO-SPIRIT is one of the largest multinational observational prospective studies with the goal to investigate the real-world effectiveness of bDMARDs and tsDMARDs in the treatment of PSA.
Objectives: This analysis describes the effectiveness of IXE and SECU in the treatment of PsA at 12 weeks for patients (pts) within the PRO-SPIRIT study.
Methods: PRO-SPIRIT study describes the persistence at 24 months among pts diagnosed with PsA (≥6 months) who initiated or switched to a new locally approved bDMARD or tsDMARD in 6 countries. This analysis focuses on patient receiving either IXE* or SECU**. Pt characteristics were collected at baseline (BL) while clinical measures and patient related outcomes were collected at BL and 3, 6, 12, 18, and 24 months. Week 12 results are presented descriptively. Missing values were imputed.
Results: This analysis included 507 pts, 341 on IXE 80 mg, 87 on SECU 150 mg, and 79 on SECU 300 mg. Prior b/tsDMARD failure was reported in 70.4 %, 54 % and 79.7 % of pts on IXE 80 mg, SECU 150 mg, and SECU 300 mg, respectively (and subsequently reported in that order, herein). At week 12, 24.9 %, 28.0 %, and 18.2 % pts achieved Minimal disease activity (MDA). For pts with body surface area (BSA)<3, change from baseline (CFB) in MDA was 18.4 %, 15.7 %, and 6.3 %. For pts with BSA ≥ 3, CFB in MDA was 22.8 %, 32.8 %, and 21. 4 %. CFB in Clinical Disease Activity Index for Psoriatic Arthritis (cDAPSA) was -10.9 -10.0, and -9.3. At BL, high disease activity (cDAPSA>27) was observed in 39.9 % of pts on IXE, 34.5 % of pts on SECU 150 and 46.8 % of pts on SECU 300 mg. After 12 weeks, 12.6 %, 12.8, and 25.7 % of pts remained on cDAPSA >27.
Conclusion: At BL, IXE and SECU 300 mg pts had more previous treatment failures than SECU 150 mg treated pts. At week 12, overall MDA responses were similar across all groups. For pts with BSA<3, MDA was higher in the IXE group and numerically the lowest for SECU 300 mg. Furthermore, more pts remained on high cDAPSA with SECU 300 mg than IXE. IXE shows efficacy in pts with PsA with and without active skin involvement and all degrees of joint severity.

P-115

THE EFFECTIVENESS OF IXEKIZUMAB AND OTHER B/TSDMARDS AT 12-WEEKS FOR PATIENTS WITH PSA IN REAL-WORLD SETTINGS: PRO-SPIRIT STUDY RESULTS

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Background: Ixekizumab (IXE) is a humanised IgG4 antibody that selectively binds Interleukin-17 (IL-17A). PRO-SPIRIT is the first large-sample multi-national prospective observational PsA study including IXE.
Objectives: To report the effectiveness of IXE and other b/tsDAMRDs for patients (pts) with PsA at 12-weeks based on real-world evidence from PRO-SPIRIT.
Methods: Adults with PsA who initiated or switched to new biologic or targeted synthetic disease-modifying anti-rheumatic drugs (b/tsDMARD) from 2019 to 2022 were evaluated across France, Spain, Italy, Germany, the United Kingdom, and Canada. This analysis focuses on IXE versus (v) tumour necrosis factor inhibitor (i) (TNFi), IL-12/23i, IL-23i, Janus kinase (JAKi), and phosphodiesterase-4 (PDE4i). Pt demographic, disease activity, therapy characteristics, clinical and pt-reported outcome measures were collected at baseline (BL) and 12-weeks focusing on swollen-joint count (SJC) and tender-joint count (TJC) change from baseline (CFB), proportion of pts achieving body surface area (BSA)<3%, clinical DAPSA (cDAPSA) LDA and REM, and MDA. Descriptive results are presented. Missing values were imputed.
Results: Analysis includes 1,024 pts out of 1,192 in PRO-SPIRIT. At BL, IXE pts had longer disease duration, were more frequently treated on monotherapy, had higher prior b/tsDMARDs failures and ≥3% BSA involvement v TNFi group. Response rates at 12-weeks for SJC (-2.6), TJC (-4.2), BSA<3% (23.2 %), LDA (30.2 %), REM (12.3 %) and MDA (24.9 %) were comparable to the TNFi group (SJC -2.7, TJC -4.3, BSA<3% 14.2 %, LDA 28.7 %, REM 13.5 %, MDA 25.7 %).
BL characteristics of IL-12/23i and IL-23i pts were similar to IXE. At 12-weeks, IL-12/23i pts reported lower responses for SJC (-0.8), TJC (-0.9), BSA<3% (11.4 %), LDA (18.2 %), REM (15.2 %) and slightly lower MDA (22.4 %). IL-23i pts had similar results for BSA<3% (25.0 %) but less improvement in SJC (-1.1), TJC (-3.9), LDA (24.1 %), REM (7.4 %), and MDA (17.7 %).

Pts receiving JAKi had similar BL characteristics to IXE, except less pts received monotherapy or had BSA ≥3%. JAKi effectiveness was similar to IXE for joint and composite outcomes: SJC (-3.1), TJC (-5.1), LDA (31.9 %), REM (13.4 %), and MDA (24.2 %). For pts with BSA ≥3% IXE reported greater improvements in MDA (27.8 %) v JAKi (10.2 %).
Total pts receiving PDE4i was low, and the population was different to other groups with less skin and joint involvement.
Conclusion: Aside from longer disease duration, more prior b/tsDMARDs, and greater skin involvement, at 12-weeks IXE showed similar efficacy for joints as TNFi, numerically better than IL-12/23i and Il-23i, and greater improvements on skin than TNFi and JAKi, mainly for those with BSA ≥3%. IXE reported holistically better control across joints and skin domains than IL-12/23i. PRO-SPIRIT real-world evidence confirms IXE as an effective tx for PsA across domains.

P-116
DO REAL-WORLD TREATMENT PATTERNS REFLECT PSA RECOMMENDATIONS? RESULTS FROM THE PRO-SPIRIT STUDY

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Background: The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) and the European Alliance of Associations for Rheumatology (EULAR) developed recommendation sets for psoriatic arthritis (PsA) treatment based on current evidence. All biologic disease-modifying anti-rheumatic drugs (bDMARDs) are equally recommended for peripheral arthritis. Different treatments exist for relevant skin and axial involvement. Interleukin 17 (IL-17) inhibitors (i) and IL-12/23i are recommended over tumour necrosis factor inhibitors (TNFi) for PsA with significant skin involvement. IL-12/23i are not recommended with axial manifestations. PRO-SPIRIT is the first large sample prospective multi-national observational PsA study.
Objectives: To report on real-world treatment patterns reflecting PsA recommendations using results from the PRO-SPIRIT study.
Methods: PRO-SPIRIT enrolled adults with PsA from 2019 to 2022 who initiated or switched to approved biologic or targeted synthetic disease-modifying anti-rheumatic drugs (b/tsDMARD). Treatment groups included TNFi, IL-17Ai, IL-12/23i, IL-23i, Janus kinase (JAKi), and phosphodiesterase-4 (PDE4i). Mode of action (MoA) was at the discretion of the treating physician. Patient demographic, disease activity, treatment characteristics, and clinical and patient-reported outcomes were collected at baseline (BL). Descriptive results are presented. Missing BL values were imputed.
Results: Analysis includes 1,192 patients with PsA treated by different MoA. Patients with arthritis (defined by swollen joint count (SJC) and tender joint count (TJC) ≥5) were equally distributed across treatment classes except for a lower percentage in PDE4i. Patients receiving IL-17Ai commonly presented with joint, skin, and nail involvement. Patients with higher skin (body surface area (BSA) ≥3%) and nail involvement were more commonly treated by IL-17Ai and IL-23i, less so with JAKi. Patients receiving JAKi presented with more joint and axial, and less skin involvement. After IL-23i, PDE4i had the second highest proportion of patients with nail involvement. PDE4i patients were low and reported less active domain affectation in general. Line of therapy results showed more patients treated with IL-12/23i, JAKi, and IL-17Ai after prior b/tsDMARDs treatment.
Conclusion: In general, patients had polyarticular disease at BL. Pts with skin and nail involvement were more commonly treated with IL-17Ai and IL-23i over TNFi and JAKi. Patients with axial manifestations were more commonly treated with IL-17Ai and JAKi over IL-12/23i and IL-23i. Findings add to the evidence on real-world PsA treatment patterns and recommendations sets for guiding individualised PsA treatment.

P-117
IXEKIZUMAB DEMONSTRATES RAPID AND CONSISTENT EFFICACY FOR PATIENTS WITH PSORIATIC ARTHRITIS, REGARDLESS OF PSORIASIS SEVERITY

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Introduction: Skin involvement in psoriatic arthritis (PsA) worsens the severity and burden of disease.[1] The IL-17A antagonist ixekizumab (IXE) is approved to treat moderate-to-severe plaque psoriasis, active PsA, and axial spondyloarthritis.
Objectives: This analysis evaluates the efficacy of IXE in patients with PsA who had mild, moderate, or severe psoriasis from two Phase 3 trials.
Methods: This post-hoc analysis integrated patients from the SPIRIT-P1 (NCT01695239) and SPIRIT-P2 (NCT02349295) trials which evaluated the efficacy and safety of IXE compared to placebo (PBO) in adults with active PsA. Patients were randomly assigned to PBO or IXE 80mg every 4 weeks (Q4W) or every 2 weeks (Q2W). Efficacy outcomes were analyzed through Week 24 by baseline psoriasis severity, defined by the percentage of body surface area (BSA) affected; mild=BSA<3%, moderate=3%≤BSA≤10%, severe=BSA>10%. Musculoskeletal outcomes were measured by American College of Rheumatology (ACR) 20, 50, and 70 responses. Disease activity was measured by Minimum Disease Activity-Psoriasis Area Severity Index (MDA-PASI) and Disease Activity in Psoriatic Arthritis Low Disease Activity (DAPSA-LDA). Skin involvement was measured by PASI100 response. Proportions of patients achieving response were calculated with 95% confidence intervals for each outcome measure. Adjusted comparisons among baseline psoriasis severity categories were performed using logistic regression. Non-response imputation was used to handle missing data.
Results: For all outcome measures, response rates over time were greater with IXE versus PBO, and similar with both IXEQ4W and IXEQ2W, regardless of psoriasis severity. At Week 4, proportions of IXEQ4W-treated patients achieving ACR20 were 39%, 49%, and 47% for mild, moderate, and severe psoriasis. At Week 24, proportions of IXEQ4W-treated patients achieving ACR20/ACR50/ACR70 were 55/36/21% for mild psoriasis, 52/37/25% for moderate psoriasis, and 57/41/23% for severe psoriasis. Proportions of IXEQ4W-treated patients with mild, moderate, and severe psoriasis who achieved MDA-PASI were, respectively, 13%, 12%, and 7% at Week 4, and 26%, 30%, and 30% at Week 24. Proportions of IXEQ4W-treated patients with mild, moderate, and severe psoriasis who achieved DAPSA-LDA were, respectively, 21%, 30%, and 20% at Week 4, and 46%, 40%, and 46% at Week 24. There were no significant differences at Week 4 or Week 24 in ACR, MDA-PASI or DAPSA-LDA responses according to baseline psoriasis severity. Proportions of IXEQ4W-treated patients with mild, moderate, and severe psoriasis who achieved PASI100 were 23%, 15%, and 5% at Week 4, and 30%, 46%, and 32% at Week 24.

Conclusion: IXE demonstrates rapid and consistent efficacy for patients with PsA, regardless of baseline psoriasis severity.
Disclosure: This study was funded by Eli Lilly and Company. Previously presented at Winter Clinical Dermatology Conference - Hawaii 21st Annual
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P-118
ACHIEVEMENT OF NPF TREAT-TO-TARGET GOALS AT WEEK-12 FOR PATIENTS RECEIVING COMMONLY-USED BIOLOGIC TREATMENT ACCORDING TO US LABELS IN PSOHO

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Introduction: The Psoriasis Study of Health Outcomes (PSoHO) is an ongoing 3-year, international, prospective, observational study comparing the effectiveness of anti-interleukin (IL)-17A biologics (ixekizumab, secukinumab) to other biologics approved for the treatment of moderate-to-severe psoriasis (PsO) in the participating countries.
Objectives: This analysis compares the treatment response using the National Psoriasis Foundation (NPF)-defined treatment goals at week 12 for 1773 patients receiving US FDA-approved dosing, as well as in biologic-naïve and -experienced subpopulations.
Methods: The anti-IL-17A biologic cohort was compared to a cohort of other biologics targeting IL-17 receptor (R)A, tumor necrosis factor (TNF)-α, IL-12/23 and IL-23. Outcomes were evaluated at week 12 for the two cohorts, as well as for each individual treatment. According to the NPF, an acceptable response corresponds to an affected body surface area (BSA) of 3% or less or a BSA improvement of 75% or higher after 3 months. An NPF-defined target response corresponds to a BSA of 1% or less. The acceptable response analysis included 1635 (92%) patients who had greater than 3% BSA baseline involvement. The target response analysis included 1697 (96%) patients who had greater than 1% BSA baseline involvement. Patients with missing outcomes were imputed as non-responder imputation (NRI). Adjusted comparative analyses, reported as odds ratio (OR; 95% confidence intervals), were performed using Frequentist Model Averaging (FMA).
Results: For the 1773 patients who received FDA-approved dosing, the mean (standard deviation) BSA involvement at baseline was 21.6% (17.9). Compared to the other biologics cohort, patients in the anti-IL-17A cohort had approximately 2-times greater odds of achieving a target response (OR 1.8; CI 1.5, 2.2) and an acceptable response (OR 2.0; CI 1.6, 2.3) at week 12. Relative to other individual biologics, ixekizumab had the highest proportion of patients achieving the target (54%) and acceptable (77%) response at week 12. Adjusted comparative analyses also showed that patients had significantly higher odds of achieving either a target or acceptable response when treated with ixekizumab compared to all other biologics.
Conclusion: In PSoHO, patients with moderate-to-severe PsO had significantly higher odds of achieving NPF-defined target or acceptable responses at week 12 with anti-IL-17A biologics compared with other biologics (IL-17RA, TNF-α, IL-12/23 and IL-23). Moreover, patients treated with ixekizumab, an anti-IL-17A biologic, had the highest response rates and significantly higher odds of achieving the NPF-defined target or acceptable response at week 12 compared with other biologics in a real-world setting.
Disclosure: This study was funded by Eli Lilly and Company. Previously presented at Fall Clinical Dermatology Conference - 42nd Anniversary

P-119
QUALITY OF LIFE AND TREATMENT OPTIONS IN PATIENTS WITH GENITAL PSORIASIS: THE FILIPINO EXPERIENCE

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Background: Genital psoriasis (GenP) is often overlooked by both physicians and patients given the sensitive nature of the topic. It causes significant impairment on quality of life (QoL) despite available treatment.
Objectives: The study determined the impact of GenP on the QoL among Filipino adult patients. Specifically, baseline demographics, prevalence, treatment options, DLQI scores, and doctors' behavior in attending to GenP were determined.
Methods: A self-administered questionnaire were filled-up by PsorPhil members and patients seen at a tertiary hospital's outpatient clinic.
Results: Data of 461 Filipino psoriasis patients were analyzed. 67% had current genital involvement while 86% had current and/or previous history of GenP. Mean age at onset of GenP was 29.2 years. Topical steroids (66%) was the treatment choice. GenP patients reported significantly worse QoL than patients without genital involvement ($P < .0001$). Less than 50% did not discuss the presence of GenP with their physicians, 49% reported that their physicians probed about genital involvement, 36% examined the genitalia and 56% wished for more questioning for possible GenP.
Conclusion: GenP is extremely common in the Philippines. This study highlights the need for physicians to pay attention to the detrimental impact of GenP on the QoL when treating psoriasis patients.
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Table 1. Dermatology Life Quality Index (DLQI) scores of the two study groups

	With genital psoriasis n = 311			Without genital psoriasis n = 150			p-value
	Median	*IQR*	*Mean-rank*	*Median*	*IQR*	*Mean-rank*	
Total DLQI	13	12	249.96	11	10	191.68	<0.0001
Personal relations	1	3	244.33	1	2	203.36	0.0014
Symptoms and feelings	3	2	247.83	2	2	196.10	0.0001
Daily activities	3	3	246.06	2	3	199.78	0.0004
Leisure	2	3	246.85	2	3	198.14	0.0002
Work and school	0	3	239.59	0	3	213.19	0.0179
Treatment	1	1	250.09	1	2	191.42	<0.0001

Table 2. Treatment received by the patients (n=461)

	Frequency	%
Topical medications	306	66.38%
Steroids	267	57.92%
Vitamin D analogues	89	19.31%
Moisturizers	66	14.32%
Coal tar	55	11.93%
Calcineurin inhibitors	10	2.17%
Others	62	13.45%
Phototherapy	43	9.33%
UVB	36	7.81%
UVA	7	1.52%
Systemic chemotherapy	148	32.10%
Methotrexate	142	30.80%
Acitretin	11	2.39%
Hydroxyurea	2	0.43%
Cyclosporin	3	0.65%
Biologics	22	4.77%
Secukinumab	13	2.82%
Ustekinumab	3	0.65%
Etanercept	3	0.65%
Infliximab	3	0.65%
Guselkumab	2	0.43%
Ixekixumab	1	0.22%

P-120

ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH PSORIATIC ARTHRITIS TREATED ACCORDING TO THE TREAT TO TARGET STRATEGY

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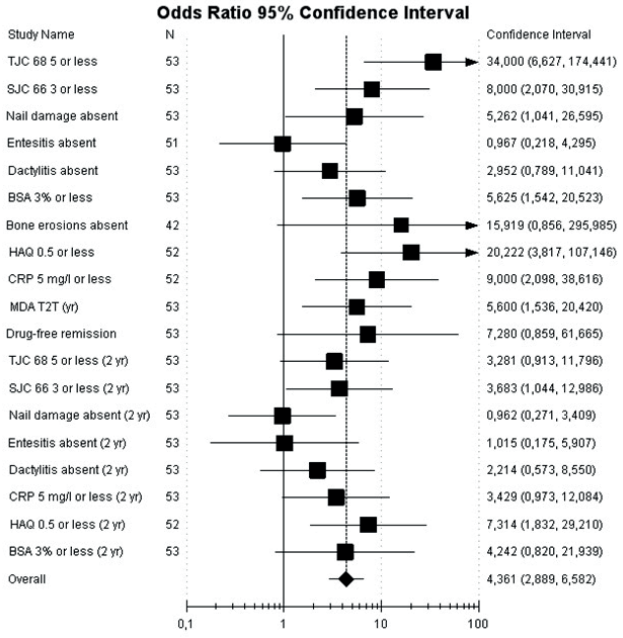
Background/purpose: To evaluate the factors associated with achieving a good quality of life (QoL) in patients (pts) with psoriatic arthritis (PsA) treated according to the treat-to-target (T2T) strategy after 5 years follow up.

Methods: 53 (M/F–25/28) PsA pts fulfilling CASPAR criteria, who were treated according to T2T at the early stage within 24 mos were analyzed. Mean age 45 ± 12.1 yrs, median (Me) PsA duration 90 [72;99] month (mos), Me follow-up 81 [61;91] mos. When T2T study was stopped all pts were treated according to the standard care. PsA activity was calculated by DAPSA. The number of pts (in %) who achieved minimal disease activity (MDA) were analyzed. At 5 years follow-up all pts underwent standard clinical examination (tender joint count (TJC), swollen joint count (SJC), CRP (mg/l), skin psoriasis by BSA (%), presence of nail psoriasis, DAPSA) and completed PsAID-12. The QoL of pts was assessed using a PsAID-12 questionnaire. A total PsAID score below 4 out of 10 is considered a 'patient-acceptable state' (PASS). M ± SD, Spearman's correlation, Mann-Whitney test were performed. All $p<0.05$ were considered to indicate statistical significance.

Results: After 5 years of follow-up in pts treated at an early stage with T2T strategy PASS was detected in 38 of 53 (71.7%) pts. Me PsAID-12 - 2.1 [0.95; 4.6]. Achieving a PASS associated with: TJC<5 (OR 34; 95% CI 6,6-174,4), SJC<3 (OR 8; 95% CI 2-30,9), absence of nail psoriasis (OR 5,262; 95% CI 1,041-26,595), mild severity of the skin psoriasis (BSA<3%) (OR 5,625; 95% CI 1,542-20,523), low level of CRP (<5 mg/l) (OR 9,000; 95% CI 2,098-38,616), low level of HAQ (OR 20,222; 95% CI 3,817-107,146). The achievement of MDA in the first 12 mos of PsA treatment is also associated with the achievement of PASS at 5 yrs follow-up (OR 5,600; 95% CI 1,536-20,420) (Table1).

Conclusion: After 5 yrs PsA follow-up, more than 70% of pts treated at an early stage of the disease with T2T reached PASS. Low TJC, SJC, CRP, HAQ, mild severity of skin psoriasis, achievement of minimal PsA activity during the first year of therapy are associated with a good quality of life in PsA pts.



P-121

NETAKIMAB, AN IL-17 INHIBITOR, IMPROVES PATIENT-REPORTED OUTCOMES IN PSORIATIC ARTHRITIS: 3-YEAR RESULTS OF THE PATERA STUDY

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Background: Psoriatic arthritis (PsA) is associated with multiple manifestations, resulting in reduced health-related quality of life (HR-QoL) and deterioration in other patient-reported outcomes (PROs). Netakimab (NTK) is a humanized anti-IL17A antibody approved for the treatment of moderate-to-severe plaque psoriasis, ankylosing spondylitis, psoriatic arthritis (PsA). Previously NTK demonstrated significant impact on key PsA symptoms irrespectively of baseline characteristics and previous treatment1,2,3,4.

Objectives: To assess the impact of NTK on HR-QoL and PROs in patients with active PsA, based on of 3-year data from the PATERA study (NCT03598751).

Methods: 194 adult patients with PsA (CASPAR criteria, 2006) with inadequate response to csDMARD or one TNFi, were randomly assigned to receive NTK 120 mg or placebo at weeks (week) 0, 1, 2, 4, 6, 8, 10 and Q4W starting from week 14. 84 patients from placebo arm, failed to achieve ACR20 (20% improvement in American College of Rheumatology criteria) at week 16, were switched to NTK. After week 24 all patients received NTK 120 mg. Treatment response was assessed in the overall population up to week 154 of treatment with NTK (week 154 for NTK arm, weeks 172 and 178 for nonresponders and responders in placebo arm). Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), BASDAI50, spinal and nocturnal pain were assessed in patients with inflammatory back pain at baseline (N=94), Dermatology Quality of Life Index (DLQI) was assessed in patients with baseline Body Surface Area (BSA)≥3 (N=148).
Methods: Mean change from baseline in Health Assessment Disability Index (HAQ-DI) after 54 week of treatment with NTK was -0.7 (0.5) and remained stable up to week 154 (Table 1). No significant changes were observed in HR-QoL during the long-term observation period as assessed by SF-36. The improvement achieved by week 54 maintained without deterioration. Among patients with inflammatory back pain at baseline no increase in BASDAI or spinal pain was observed (Table 1). Patients with baseline BSA≥3 did not report any deterioration of HR-QoL as assessed by DLQI.
During the long-term observation the majority of patients reported no problems (Level 1) of slight problems (Level 2) in each of European Quality of Life Questionnaire (EQ-5D-5L) domains (Figure 1). The proportion of subjects with severe (Level 4) or extreme (Level 5) problems was low and did not increase over time.
Conclusions: NTK resulted in stable improvement in HR-QoL and PROs. No deterioration over time was observed.
References: This study was sponsored by JSC BIOCAD.
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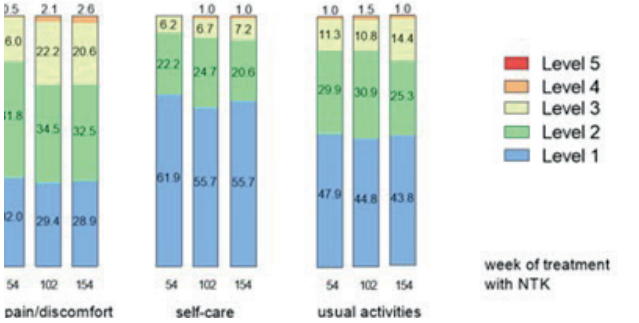
Table 1. Change from baseline in PROs

Parameter\ wk of treatment with NTK	Baseline	Change from baseline				
		54	78	102	126	154
HAQ-DI	1.2 (0.6)	-0.7 (0.5)	-0.6 (0.5)	-0.6 (0.6)	-0.6 (0.5)	-0.6 (0.6)
BASDAI*	5.7 (1.9)	-3.6 (2.1)	-3.4 (2.0)	-3.3 (2.1)	-3.2 (2.1)	-3.2 (2.2)
BASDAI50*	NA	68 (73.1%)	58 (66.7%)	61 (68.5%)	64 (70.3%)	58 (65.2%)
Spinal pain*	4.9 (2.2)	-2.7 (2.5)	-2.9 (2.6)	-2.8 (2.5)	-2.9 (2.4)	-2.7 (2.6)
Nocturnal pain*	5.1 (2.2)	-2.5 (2.6)	-2.7 (2.6)	-2.7 (2.6)	-2.7 (2.5)	-2.6 (2.6)
SF36 PCS	45.7 (11.1)	13.6 (10.8)	13.0 (11.5)	13.0 (11.6)	12.1 (11.2)	13.0 (11.8)
SF36 MCS	31.74 (9.2)	5.9 (12.0)	6.4 (11.7)	6.2 (11.9)	6.1 (11.7)	6.8 (11.9)
DLQI†	14.3 (0.6)	-10.7 (7.6)	-10.2 (7.1)	-10.4 (7.6)	-10.7 (7.8)	-10.7 (7.2)

Data are mean (SD) except of BASDAI50, where n (%) are presented.
*data for patients with inflammatory back pain at baseline; †data for patients with baseline BSA≥3;
HAQ-DI=Health assessment questionnaire disability index, BASDAI= Bath Ankylosing Spondylitis Disease Activity Index, WPAI= SF36=36-item Short Form Health Survey, MCS=Mental Component Summary, PCS=Physical Component Summary, DLQI=Dermatology Quality of Life Index



P-122
PATIENTS REPORTED OUTCOMES (PROS) IN PSORIATIC ARTHRITIS (PSA) WITH AXIAL INVOLVEMENT

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Introduction: PsA is a chronic, inflammatory disease characterized by damage to the nails and skin, peripheral arthritis, enthesitis, dactylitis and axial involvement in the process. The prevalence of axial involvement in psoriatic arthritis (axPsA) according to different samples varies from 25% to 70% of patients. [1] All this affects health-related quality of life.
Objective: To assess PROs in PsA with axial involvement.
Methods: 172 (m/f=90 (52.3%)/ 82(47.7%) PsA patient (pts) fulfilling the CASPAR criteria were included. Mean age 45.1 ± 11.8 years (yrs), DAPSA 28 ± 22.2 median (Me). All pts underwent standard clinical examinations and PROs (VAS global assessments (mm), VAS global pain (mm), BASDAI, PsAID-12, FACIT and HAQ). Subsequently, a comparative analysis of two groups of patients was carried out with axial involvement - 95 (55.2%) and without axial involvement - 77 (44.8%). Me [Q25; Q75], Pierson-χ2 M ± SD, %, *t*-test, Pierson-χ^2, Manna-Whitney tests were performed. All $p<0.05$ were considered to indicate statistical significance.
Results: A comparative analysis of the two groups showed that pts with axial involvement had significantly higher activity according to the DAPSA index (39.2±20.5 vs 25.5 ± 14.0, $p<0.0001$). Also in this group there was a significantly higher tender joint count (14.4 ± 9.82 and 8.37 ± 5.57, $p<0.0001$) and swollen joint count (11.1 ± 8.7 vs 4.84 ± 2 .89, $p<0.0001$), higher laboratory activity for ESR (mm/h) – 26.6 ± 23.2 vs 15. ± 13.3, $p<0.0001$ and CRP (mg/l) – 23.4 ± 22.0 vs 9.58 ± 6.0 $p<0.0001$, respectively. Both groups were comparable in the number of dactylitis (p=0.7). In the group of pts with axial involvement, psoriasis with moderate and severe BSA lesions was significantly more common - 27.75% (n=48), $p=0.003$. When assessing PROs, it was revealed that pts with axial involvement significant differences VAS global pain - 53.1 ± 20.4 vs 24.1 ± 20.7 ($p<.0001$) and VAS global assessments 58.5 ± 22.8 vs 24.8 ± 19.6 ($p<0.0001$) and BASDAI index – 5.66 ± 1.7 vs 1.57 ± 1.36, $p=0.002$, respectively. Analysis of functional status (HAQ) showed that pts with axial involvement had worse functional status - 1.14 ± 0.7 vs 0.81 ± 0.53 (p=0.003). Also, these pts experienced fatigue significantly more often (according to the FACIT-F) – 39.8 ± 8.95 vs 30.5 ± 11.1 ($p=0.03$). Assessment of the PsAID-12 showed that in groups with axial involvement and without axial involvement there were statistically significant differences on all scales of the questionnaires, $p<0.0001$ (figure 1).
Conclusion: Thus, analysis showed that pts with PsA and axial involvement had higher disease activity, moderate and severe forms of psoriasis were more often detected, PROs was significantly worse compared to the group of pts without axial involvement.
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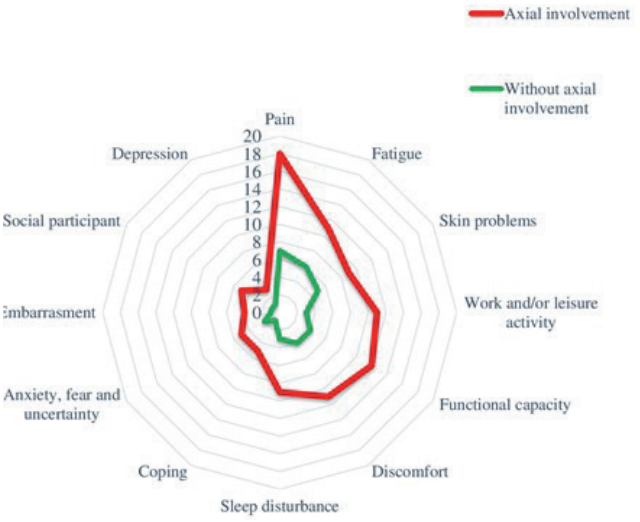

P-123

WHO ARE MORE ITCHY AND WHAT WORKS BETTER FOR PRURITUS IN PATIENTS WITH PLAQUE PSORIASIS?

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Introduction: Psoriasis is a chronic, systemic inflammatory disease with a prevalence of about 1% in Koreans and between 0.09% and 11.43% in the total population. Pruritus in patients with psoriasis has been reported as a common symptom; however, its significance has often been overlooked. Furthermore, the presence and intensity of pruritus vary among patients.

Objectives: The objectives of this study are to investigate the prevalence and factors associated with pruritus intensity in patients with plaque psoriasis and to understand the effectiveness of various treatments for pruritus in psoriasis.

Methods: We analyzed data from 593 patients with plaque psoriasis (365 male, 228 female) at Pusan National University Hospitals (Busan and Yangsan) from January 2020 to July 2022. Psoriasis severity was evaluated using the PASI score, and pruritus intensity was quantified using the NRS score.

Results: Pruritus was observed in 88.2% of psoriasis patients. Mild itch (NRS<3) was present in 15.7% of patients, moderate (NRS of 3-7) in 40.3%, and severe (NRS >= 7) in 32.2%. The odds ratio was higher in females compared to males (OR, 1.985). There was no positive correlation between the PASI score and the itch score. However, the erythema score, among the subcategories of the PASI score, was found to have a positive correlation with the itch NRS. Regarding itching relief according to the treatment, conventional systemic agents were the most effective.

Conclusion: Pruritus is a common clinical symptom of plaque psoriasis, considered to be important. Since the relationship between psoriasis severity and pruritus was unclear, special attention during treatment is required for pruritus in addition to improving skin lesions.

P-124

DEVELOPMENT OF THE PATIENT-REPORTED IMPACT OF DERMATOLOGICAL DISEASES (PRIDD) MEASURE

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Introduction: Dermatological conditions, including psoriasis, significantly impact patients' lives including their physical, psychological and social wellbeing. Existing dermatology-specific (can be used across dermatological conditions) patient-reported outcome measures (PROMs) do not fully capture this impact and cannot be recommended for use according to the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN). This is largely part because they are not theory-informed, were developed without sufficient patient involvement, and rely on classic over modern psychometric methods.

Objectives: The Global Research on the Impact of Dermatological Diseases (GRIDD) project was therefore initiated in 2017 to develop, in partnership with patients, a new measure of the impact of dermatological conditions on patients' lives called PRIDD (Patient-Reported Impact of Dermatological Diseases).

Method: Adults (≥ 18 years) worldwide living with a dermatological condition were recruited through GlobalSkin's membership network to participate in a mixed methods study consisting of five phases: 1) COSMIN systematic review of existing dermatology-specific PROMs; 2) Qualitative interview study to develop the conceptual framework of impact and generate impact items for PRIDD; 3) Delphi study to elicit consensus from patients on which impact items to prioritise for inclusion in PRIDD; 4) Cognitive interview study to evaluate PRIDD's content validity, as well as acceptability, and feasibility to patients; 5) Psychometric testing.

Results: 2,221 people representing 90 dermatological conditions from 61 countries participated overall. None of the 36 PROMs included in the systematic review could be recommended for use according to the COSMIN criteria. The conceptual framework depicted impact as a multifaceted construct involving physical, life responsibilities, psychological and social impacts. The Delphi study reduced the item pool of 263 to a 27-item draft of PRIDD. Cognitive interviews produced a 26-item version of PRIDD with evidence of content validity, feasibility, and acceptability from patients. Psychometric testing revealed that PRIDD fit the Rasch model and met the COSMIN criteria for structural validity, internal consistency, construct validity, and test-retest reliability. Measurement error and responsiveness will be tested in a future study.

Conclusion: PRIDD is a valid and reliable tool to evaluate the impact of dermatological disease on patients' lives. It is the first dermatology-specific PROM to meet the COSMIN criteria and should be considered the gold-standard. These results support the value of developing and validating PROMs in close partnership with patients and using classic and modern psychometric methods. PRIDD will greatly enhance patient perspectives by providing quantifiable patient impact data for better decision-making at the individual, national and global levels, and higher prioritisation of dermatological conditions, including psoriasis.

Psychometric testing – PRIDD results

		Requirement	Rating	Results
Structural validity	Unidimensionality	- No violation of unidimensionality - No violation of local independence - Adequate model fit: χ^2 >0.01	+	PRIDD and all subscales unidimensional with no local dependency. χ^2 = 0.11
	Structural validity	CFI or TLI or comparable measure > 0.95 OR RMSEA < 0.06 OR SRMR < 0.08	+	CFI = 0.96; TLI = 0.97; RMSEA = 0.09; SRMR = 0.03
Internal consistency		Person Separation Index ≥ 0.7	+	Person Separation Index = 0.89
Hypothesis testing for construct validity		75% of hypotheses met	+	76% of hypotheses met
Test-retest reliability		ICC or weighted Kappa ≥ 0.70	+	ICC = 0.93
Measurement error		SDC or LoA < MIC	+	LoA (1.3) < MIC (4.14) Unable to determine anchor-based MIC
Responsiveness		The result is in accordance with the hypothesis OR AUC ≥ 0.70	-	0 hypotheses met
Floor & ceiling effects		Considered present when > 15% of the patients achieved the minimum or maximum possible score	+	< 0.9% with minimum or maximum score
MIC		N/A		Unable to determine anchor-based MIC

"+" = sufficient, " –" = insufficient, "?" = indeterminate

CFI: Comparative Fit Index; TLI : Tucker-Lewis Index; RMSEA: Root Mean Square Error of Approximation; SRMR: Standardised Root Mean Square; ICC: Intraclass Correlation Coefficient; SDC: Smallest Detectable Change; LoA: Limits of Agreement; MIC: Minimally Important Change

P-125

TACKLING STIGMA AGAINST PERSONS WITH CHRONIC SKIN DISEASE AMONG HEALTH AND BODY CARE PROFESSIONALS

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Introduction: Social stigma is commonly experienced by people with chronic skin disease, which can have negative impact on their quality of life. In 2014, the World Health Assembly made a call for action against stigmatization of people with psoriasis. Consequently, the ECHT-project was set up in Germany aiming to educate about and destigmatize chronic skin conditions. A face-to-face group seminar consisting of self-awareness exercises, education, and a patient encounter was developed which was found to be effective in reducing stigmatizing attitudes in medical students and future educators (1, 2). As persons with chronic skin disease have repeatedly reported stigmatization from hairdressers and cosmetologists, we adjusted the seminar for health and body care professionals.

Objectives: This randomized controlled trial aimed to evaluate the effectiveness of the stigma reduction seminar in health and body care professionals.

Methods: Professionals working in the health and body care sector (i.e., cosmetologists, hairdressers, nurses, and physical therapists; $n = 129$) were randomized into an intervention or a control group, respectively. The intervention group received the seminar described above while the control group followed a seminar of similar structure focused at participants' own health at work. Measures assessed agreement to disease-related misconceptions, negative stereotypes, desire for social distance, and behavioural intentions at baseline, post-intervention, and 3 months follow-up.

Results: Professionals in the intervention group but not the control group showed significant reductions in disease-related misconceptions and stereotype endorsement from baseline to post-intervention and follow-up (all p´s ≤ .002). Surprisingly, desire for social distance decreased in the control group after the seminar ($p = .018$) but returned to the initial level after three months while no changes were found for the intervention group. Behavioural intentions did not change in either group. No differences between the different professions were observed. Satisfaction with the seminar was generally high, with slightly more favourable scores for the intervention seminar.

Conclusions: The seminar successfully improved stigmatizing beliefs about and attitudes towards people with skin diseases among health and body care professionals. Overall, these results are consistent with findings from similar studies with medical students (1), future educators (2), and the general public (3). Integrating the training into professional training or delivering it in workshops are promising avenues for dissemination and could increase knowledge about chronic skin disease and reduce prejudice in various professional groups on a larger scale. This would contribute to improving the psychosocial wellbeing of people with skin diseases.

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P-126

DETERMINANTS OF QUALITY OF LIFE IN MEXICAN PATIENTS WITH GENERALIZED PUSTULAR PSORIASIS

No consent given to publish in scientific journal.

P-127

A THEMATIC ANALYSIS OF THE PSORIASIS ASSOCIATION (UK) INSTAGRAM, FACEBOOK AND WEBSITE FORUMS IN DISCUSSING THE DIETARY MANAGEMENT OF PSORIASIS

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Introduction: The suggested link between diet and psoriasis is a target of interest in the management of psoriasis because diet is a modifiable factor [1]. Approximately 1.3-2.8% of the UK population have psoriasis [2]. As well as this, there are known comorbidities in psoriasis that affect the individual's quality of life. These comorbidities include: psoriatic arthritis, obesity, cardiometabolic diseases, gastrointestinal disease, chronic kidney disease,

mood disorders, infection, and malignancy [1]. Additionally, it is important to note that not everyone will react the same to a certain diet, highlighting the complexity of the association between diet and psoriasis. Therefore, expanding our understanding of diet and psoriasis can help provide evidence-based dietary advice to help manage psoriasis severity, reduce the risk of developing comorbidities and improve the quality of life of those affected.
Objectives: This study aimed to explore the impact of diet on managing psoriasis through the popular social media pages and the website of the Psoriasis Association (UK). Using public platforms, we aimed to discover honest opinions and spot any popular themes mentioned.
Methods: Data was collected from the Psoriasis Association (UK) Instagram, Facebook and website forums. From these sites, comments and posts that mentioned diet from July 2022-2023 were collated in a document and then manually categorised into themes and subthemes, illustrated in Figure 1.
Results: There was a total of 74 comments: 31 from Instagram, 17 from Facebook and 26 from the website. From these, we derived 3 overarching themes and then we determined subthemes for each theme. The three themes were restrictive food groups, dietary patterns and supplements. The 13 subthemes included: Reducing dairy, alcohol, red meat and caffeine; eating a plant-based diet, anti-inflammatory diet, gluten-free diet and a blueberry diet; taking vitamin D supplements, fish oil supplements, vitamin K2 supplements and probiotics. Table 1 illustrates the themes, subthemes and the number of comments.
Conclusion: We have been able to record individuals' honest and unfiltered opinions through our methodology and therefore gain a deeper understanding of the impacts of diet for managing psoriasis. Comparing our findings to existing literature highlighted that there is no strong evidence to support the public's opinions and the common themes that we identified. Therefore, large-scale studies and trials on certain nutrients and food groups, such as those identified in this thematic analysis, are needed. This will help us gain a deeper understanding of how we can manage the severity of psoriasis through diet. The lack of evidence-based advice has also led us to appreciate the confusion around which diet to follow as, evidently, there is a wide range of ideas shared online.

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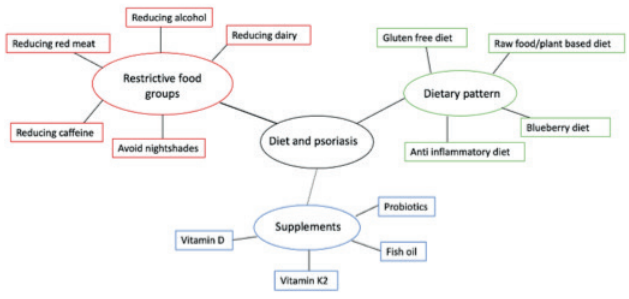
Figure 1: A flow diagram illustrating the three big categories and their subthemes



Note the size of the shapes of the three big categories correlates to the number of comments in each category; most comments were identified within restrictive food groups and then both dietary pattern and supplements had the same number of comments

Table 1: Summary of the themes and subthemes collated

Categories	Number of comments	Subthemes
Restrictive food groups	40	Reducing dairy (13) Reducing alcohol (13) Avoid nightshades (6) Reducing red meat (5) Reduce caffeine (3)
Dietary pattern	17	Raw food/ plant-based diet (7) Anti-inflammatory diet (4) Gluten free diet (3) Blueberry diet (3)
Supplements	17	Vitamin D (7) Fish oil (4) Vitamin K2 (3) Probiotics (3)

Note the number of comments '()' within each subtheme

P-128
TOWARDS AN INTERNATIONAL CONSENSUS ON OUTCOMES THAT MATTER TO PATIENTS WITH PSORIASIS: A MODIFIED DELPHI STUDY

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Introduction: Measuring outcomes that matter to patients is key in the concept of Value-Based Healthcare (VBHC). International consensus on which outcomes that should be measured in clinical practice is still lacking, also in the context of psoriasis. Psoriasis is a chronic inflammatory skin disease, known to have a high impact on patients' physical, psychological and social functioning. In recent work, we have proposed a 'value-based outcome set' aiming to define which outcomes that matter to patients. However, the relevance of these outcomes and the feasibility of using the outcome set in clinical practice may vary across countries, which is why international validation is needed.
Objectives: The aim is to define a standardized value-based outcome set for patients with psoriasis through international expert consensus.
Methods: A modified Delphi study will be conducted in accordance with the ICHOM guidelines to reach consensus. An international working group consisting of patients representatives and healthcare professionals will be set up. Experts will be recruited through the International Psoriasis Council (IPC) and the International Federation of Psoriasis Associations (IFPA) to obtain a mix of patients and healthcare professionals. Consensus will be reached on the following dimensions: case-mix variables, outcome definition, outcome measures and outcome relevance. Consensus is expected to be reached after three rounds and will be achieved when the working group votes surpasses the threshold of 80% agreement. The exercise will run from September 2024 to February 2025.
Conclusions: This international value-based outcome set for psoriasis will empower the use of outcomes in daily clinical practice, which is essential when adopting the principles of VBHC. The use of this outcome set will allow international benchmarking and support continuous improvement of patient value in the context of psoriasis.

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P-129

RELATIONSHIP BETWEEN EARLY AND LATE ONSET PRESENTATION IN PSORIATIC ARTHRITIS AND CARDIOVASCULAR RISK.

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Background: Patients with psoriatic arthritis (PsA) have high prevalence of cardiovascular risk factors. Recent studies determined the role of age at disease onset with several comorbidities and disease activity. As well, it has been observed that individuals in whom PsA was diagnosed > 60 years old had more aggressive disease, as assessed by the number of joints involved, inflammation levels at baseline, and outcome after 2 years, compared to those with onset ≤ 60 years of age.
Objective: To associate cardiovascular risk factors in patients with early and late onset psoriatic arthritis.
Methods: Cross-sectional, observational, and comparative study of patients with PsA who met the 2006 Classification Criteria for Psoriatic Arthritis (CASPAR), aged 18 years or older. Patients with a diagnosis of overlapping syndromes, history of major cardiovascular events (myocardial infarction, stroke and heart failure) and pregnant individuals were excluded. The age of onset was defined through clinical history and were divided accordingly into two groups: early onset (<40 years old) and late onset (≥60 years old), as well as their cardiovascular risk factors (diabetes mellitus, hypertension, dyslipidemia, obesity and active smoking). A carotid ultrasound in B-mode was performed on all patients by a certified radiologist blinded to clinical information. Subclinical atherosclerosis was defined as the presence of carotid plaque (CP), defined as carotid intima-media thickness (cIMT) ≥1.2 mm or focal narrowing ≥0.5 mm of the surrounding lumen, or the presence of increased cIMT (≥0.8 mm). Group distribution was assessed using the Shapiro-Wilk test. The comparisons were made using the chi-square test, the Kruskal-Wallis test, T- Student's test, and U- Mann Whitney Test, accordingly. A p-value of ≤ 0.05 was considered statistically significant.
Results: Forty-one patients with PsA were included, mostly women (58.5%), with a mean age of 51.7 ± 14.4 years. There was no difference between groups in the prevalence of traditional cardiovascular risk factors. A significant difference was found in the presence of subclinical atherosclerosis between the groups, with a higher prevalence reported in the late-onset group compared to the early-onset patients (71.8% vs 77.7%, $p = 0.007$) (Table 1).
Conclusions: Late-onset PsA patients exhibit different clinical characteristics compared to early-onset patients. Multifactorial variables, such as age and various comorbidities, might play an important role in the disease presentation and its implications in this specific group. Aging and age of onset of disease should be considered through all the medical examinations of this patients.

Table 1. Demographic characteristics.

Characteristics	Early Onset (n=32)	Late Onset (n=9)	*P value*
Age, years, mean ± SD	46.0 ± 10.4	71.6 ± 7.4	***<0.001***
Women, n (%)	19 (59.3)	5 (55.5)	NS
Diabetes, n (%)	6 (18.7)	3 (33.3)	NS
Hypertension, n (%)	9 (28.1)	5 (55.5)	NS
Dyslipidemia, n (%)	14 (43.7)	4 (44.4)	NS
Active smoking, n (%)	7 (21.8)	0 (0)	NS
Obesity, n (%)	12 (37.5)	1 (11.1)	NS
Disease age of onset, median (IQR)	34.0 (29-36)	67.0 (60.7-69)	***<0.001***
DAS28CRP, mean ± SD	2.80 ± 1.3	2.87 ± 1.5	NS
CRP, mean ± SD	0.82 ± 0.8	1.26 ± 1.6	NS
ESR, mean ± SD	21.4 ± 14.3	20.1 ± 8.9	NS
DAPSA, mean ± SD	17.2 ± 15.1	12.9 ± 10.5	NS
NAPSI, mean ± SD	8.3 ± 18.4	13.6 ± 22.2	NS
Tender joints, median (IQR)	4 (1.0-7.0)	4 (0.0-6.0)	NS
Swollen joints, median (IQR)	2 (0.0-5.0)	0 (0.0-1.0)	NS
Subclinical atherosclerosis, n (%)	23 (71.8)	7 (77.7)	***0.007***

DAS28CRP, disease activity score 28 c-reactive protein; CRP, c-reactive protein; ESR, erythrocyte sedimentation rate; DAP disease activity in psoriatic arthritis; NAPSI, nail psoriasis severity index; IQR, interquartile range; NS, not significant.

P-130

ASSOCIATIONS BETWEEN DISEASE ACTIVITY, CARDIOVASCULAR RISK, AND DIAGNOSIS DELAY IN PSORIATIC ARTHRITIS

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Background: Psoriatic Arthritis (PsA) diagnosis and treatment is commonly delayed, or even missed due to the manifold of clinical presentations that patients often experience. Diagnosis delay has been associated with a higher disease activity and a poorer functional outcome on PsA patients. The effect of diagnosis delay on cardiovascular risk has not been established.
Objectives: To compare disease activity, cardiovascular risk, prevalence of carotid plaque, and prevalence of increased carotid intima-media thickness(cIMT) in patients with a diagnosis delay lower or higher than one year.
Methods: We performed an observational, comparative, and transversal study on patients who fulfilled the 2006 Classification Criteria for Psoriatic Arthritis (CASPAR). Patients with a history of previous atherosclerotic cardiovascular disease and pregnancy were excluded. A clinical history and blood tests were performed to evaluate Disease activity. Cardiovascular risk was estimated

with six different calculators: Framingham risk score-BMI (FRS-BMI), atherosclerotic cardiovascular disease (ASCVD), QRISK3, SCORE, and OMS/BMI,
OMS/COL. The results were multiplied by 1.5 according to the EULAR recommendations. Carotid B- mode ultrasonography was used for measurements of cIMT and the presence of plaques. Descriptive analysis was done with frequencies (%), mean (± SD) and median (q25-q75), and comparisons with Chi square, Student´s t and Mann-Whitney U test. We considered $p < 0.05$ significative.
Results: A total of 63 patients were recruited. Patients who got a diagnosis after one year of the symptoms' onset had
significantly higher disease activity measured by Disease Activity in Psoriatic Arthritis (DAPSA) score [21.52 ±16.67 vs. 12.11 ±10.58; $p = 0.009$], by 28-Joint Disease Activity Score C Reactive Protein (DAS28-RCP) [2.887 ±1.168 vs. 2.175 ±1.025; $p = 0.012$], and by 28-Joint Disease Activity Score Erythrocyte Sedimentation Rate (DAS28-ESR) [4.453 ± 1.474 vs. 3.247 ± 1.284; $p = 0.001$]. Patients with a diagnosis delay higher than one year also reported a higher pain Numerical Rating Scale (NRS) than patients without diagnosis delay [3.5 (0-10.00) vs. 3.00 (0-10.00; $p = 0.018$]. There were no significant differences in Psoriatic Area Severity scale (PASI) or Nail Psoriasis Severity Index (NAPSI). The prevalence of carotid plaque had no significant difference between CP or incremented c-IMT. Patients with diagnosis delay higher than one year had significant higher risk in OMS-BMI cardiovascular risk calculator [6.88 (1.0-18.0) vs. 4.59 (1.0-13.0); $p = 0.034$], with no significant differences between the other cardiovascular risk calculators. All frequencies are described in Table 1.
Conclusion: Patients with a diagnostic delay higher than one year have an incremented disease activity than those diagnosed in a shorter period, without significant differences in prevalence for carotid plaque of cIMT hyperplasia. Early diagnosis and intervention are imperative to improve the patient´s outcome.

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Table. 1 Clinical and Sociodemographic Characteristics

	Diagnosis in less than one year n= 35	Diagnosis in more than one year n= 28	*p*-value
Age, Mean ±SD	53.47 ±11.31	56.75 ±10.77	NS
Female, n (%)	18 (51.42)	17 (60.71)	NS
Das28-CRP, Mean ±SD	2.175 ±1.025	2.887 ±1.168	**0.012**
Das28-ECR, Mean ±SD	3.247 ±1.284	4.453 ±1.474	**0.001**
NRS, Median (q25-q75)	3.00 (0-10.00)	3.5 (0-10.00)	NS
PASI, Median (q25-q75)	0.3 (0.00-11.8)	1.00 (0.00-10.20)	NS
NAPSI, Median (q25-q75)	0.00 (0.00-65.0)	1.00 (0.00-68.0)	NS
DAPSA, Mean ±SD	12.11 ±10.58	21.52 ±16.67	**0.009**
CP, n (%)	16 (45.71)	11 (39.28)	NS
Increased cIMT n (%)	6 (17.14)	4 (14.28)	NS
WHO-BMI, Median (q25-q75)	4.59 (1.0-13.0)	6.88 (1.0-18.0)	**0.034**
FRS-BMI, Mean ±SD	15.88 ±14.95	23.34 ±21.35	NS
ASCVD, Median (q25-q75)	4.45 (0.70-33.20)	12.050 (0.3-56.70)	NS
QRISK3, Median ±SD	5.20 (0.30-34.00)	9.35 (0.60-39.20)	NS
SCORE, Median (q25-q75)	1.00 (0.00-12.00)	2.00 (0.00-11.00)	NS

P-131

PHYSICAL EXERCISE AND MEDITERRANEAN DIET IN PSORIATIC PATIENTS AMID THE PANDEMIC COVID-19

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Introduction & Objectives: Psoriasis mainly affects the skin and is a common condition, affecting 1-3% of the general population. Although the etiology of the disease has not been fully elucidated, it is known that a combination of psychological and environmental factors acts on the pathophysiology of the disease, causing inflammation in genetically predisposed individuals. Psoriasis may affect patients' daily activities, their relationship with other members of society, as well as their professional and social life. The aim of this study was to investigate the effect of physical exercise and Mediterranean diet in patients with psoriasis, especially during the COVID-19 pandemic.
Materials & Methods: The research sample consisted of 83 patients, aged 18–65 years suffering from moderate to severe psoriasis. Structured questionnaires were used, including: Demographic and Historical Patient Questionnaire for Psoriasis, Dermatology Life Quality Index (DLQI), Psoriasis Area Severity Index (PASI), International Physical Activity Questionnaire (IPAQ), Med Diet Score and a questionnaire related to COVID-19 impacts on psoriasis patients was added. Statistical analysis of the data was performed.
Results: Interestingly, 95.2% of the participants reported high physical activity. The survey took place between March-December 2020, during the COVID-19 pandemic, when "physical exercise" was lawfully allowed, despite the strict government restrictions. Most of the respondents (70.8%) used "physical exercise" daily and spent at least 20 minutes. A positive correlation was found between the physical activity of psoriatic patients and Psoriasis Area Severity Index (PASI) as well as a strong positive correlation between the body weight and PASI score. Regarding the diet habits of the sample, it seems that they consumed 63.9%, unprocessed cereals, fruits 43.4% and legumes 45, 8% at least once a week. They reported that 50.6% they have introduced or consume fish at least once a week. Finally, 96.4% use olive oil daily and interestingly, 15.7% consumed alcoholic beverages at a rate of more than 700ml / day.
Taken together, the combination of healthy nutrition with exercise resulted in more than 60% seeing an improvement in their psoriasis. Meantime, their psoriasis did not worsen because they (63,9%) were very cautious, complying with the measures of social isolation, avoiding masks (Koebner effect) and practicing very good hand-washing hygiene (avoiding alcoholic hand lotions) for the fear of psoriasis exacerbation. Conclusively, 83.1% believe that psoriasis did not worsen during the COVID-19 pandemic, while 67.50% noticed an improvement in psoriasis.
Conclusions: Despite the pandemic, health-promoting levels of regular moderate exercise and healthy diet resulted in more than 60% improvement in patients with psoriasis. Therefore, physical exercise and the Mediterranean diet should be actively promoted for all people with psoriasis.

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P-132

NAVIGATING MENTAL HEALTH STRUGGLES AMONG PSORIATIC PATIENTS DURING THE COVID-19 PANDEMIC

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Introduction & Objectives: An estimated 125 million people worldwide live with psoriasis, including about 14 million Europeans. It is a common, chronic, inflammatory disease that mainly affects the skin. Psoriasis can develop into a painful disease that causes serious problems and social stigma, while having a significant social and psychological impact on a person's life, especially during the COVID-19 pandemic.
Materials & Methods: The research sample consisted of 83

patients, aged 18–65 years suffering from moderate to severe psoriasis. The data collection method was a structured questionnaire, which was analysed with Statistical Package for the Social Sciences (SPSS). The questionnaire of the present research is a synthesis of the following: Questionnaire of Demographic Data and of Medical History of Patient with Psoriasis, Dermatology Life Quality Index (DLQI), Psoriasis Area Severity Index (PASI), Beck Anxiety Inventory, WHICAP Sleep Form, Mood and Feelings Questionnaire. Additionally, a questionnaire on the impact of COVID-19 pandemic was created.

Results: The largest percentage of our sample were men with 44.5% having mean disease duration of over 11 years, mainly in the form of plaque psoriasis. In summary, the main disease trigger was reported to be stress and we observed that the largest percentage of the sample 63.9% presents with a mild form of stress, at the same time 26.5% presents with moderate stress, while 9.6% with high stress. Additionally, 42.1% have severe depression, while they reported increased levels of alcohol (43.2%) smoking (20%) and occasional substance abuse, during the pandemic. Regarding the sleep questionnaire, 27.7% consider that they had a restless sleep and others reported increase on sleep prescription drugs. The questionnaire on COVID-19 showed that 67.5% feared that he might die. Meanwhile 89.2% found it easy to access their doctor, hence, to comply with their treatment and not to run out of medication. Virtual prescription provided safety due to evading non-necessary hospital visits and coronavirus fear. During these times, patients and members of their families suffered human and job losses, which made the burden unbearable.

Conclusions: The patients who experienced an exacerbation and worsening of their psoriasis or showed increased stress, were those who experienced financial hardship or some change in the work environment. As economic activity almost stopped and job losses increased, the psycho-emotional changes turned to intense concern about their future ability to thrive and meet the inelastic costs and needs of every household. Millions of people suffered from insomnia before the COVID-19 pandemic and, unfortunately, the pandemic poses a host of challenges even for people who have not previously had sleep problems, as the results of our research have shown.

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P-133

BIMEKIZUMAB EFFICACY IN MODERATE TO SEVERE PLAQUE PSORIASIS: IMPROVEMENTS IN FATIGUE OBSERVED IN TWO PHASE 3 STUDIES

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Introduction: Patients with psoriasis can experience significant fatigue,[1] which can have a major impact on physical and social functioning.[2] Biologic agents have demonstrated benefits in reducing fatigue among this population.[2] Bimekizumab (BKZ) is a monoclonal IgG1 antibody biologic therapy which selectively inhibits interleukin (IL)-17F in addition to IL-17A.[3] Here, we assess the effect of BKZ on fatigue using the Psoriasis Symptoms and Impacts Measure (P-SIM), a novel, 14-item patient reported outcome tool which captures key symptoms and life impacts of psoriasis.[4]

Objectives: To assess the impact of BKZ on fatigue levels, using the P-SIM fatigue item, vs adalimumab (ADA), ustekinumab (UST), and placebo (PBO), in patients with moderate to severe plaque psoriasis from two phase 3 studies.

Methods: In BE VIVID, patients received BKZ 320 mg every 4 weeks (Q4W), UST at baseline and Week 4 then Q12W, or PBO for the 16-week active comparator-controlled initial treatment period.[5] In BE SURE, patients received BKZ Q4W to Week 16 then BKZ Q4W or Q8W thereafter (dosing groups combined; BKZ Total), or ADA Q2W for the 24-week active comparator-controlled period.[6] P-SIM data were collected to Week 16/24 of BE VIVID/BE SURE. The P-SIM fatigue item was scored daily from 0–10 (no fatigue–worst possible fatigue) and averaged weekly. Mean P-SIM fatigue scores are reported using observed case (OC) data. Additionally, proportions of patients recording a P-SIM fatigue score of 0 are reported, alongside proportions with baseline P-SIM fatigue scores ≥4 achieving a clinically meaningful improvement (≥4 point reduction from baseline in P-SIM fatigue score),[4] using non-responder imputation (NRI).

Results: In BE VIVID, 321 patients were randomised to BKZ, 163 to UST, and 83 to PBO; among BKZ, UST, and PBO patients with baseline P-SIM data, 164/260, 81/124, and 39/67 had P-SIM fatigue scores ≥4, respectively. In BE SURE, 319 patients were randomised to BKZ and 159 to ADA; among BKZ and ADA patients with baseline P-SIM data, 191/271 and 78/125 had P-SIM fatigue scores ≥4, respectively.

In both studies, mean P-SIM fatigue scores were similar at baseline across treatment groups; scores were numerically lower at Week 4 and Week 16/24 with BKZ vs comparators and PBO (Table 1). Proportions of patients recording a P-SIM fatigue score of 0 were low and similar at baseline across treatment groups; proportions increased by Week 4 and were numerically higher by Week 16/24 with BKZ vs comparators and PBO (Table 1).

In patients with baseline P-SIM fatigue scores ≥4, numerically greater proportions of BKZ-treated patients achieved a clinically meaningful ≥4-point reduction from baseline at Week 16/24 vs comparators and PBO (Table 2). Notably, numerically greater proportions of BKZ-treated patients demonstrated clinically meaningful improvement vs comparators and PBO at Week 4 (Table 2).

Conclusions: BKZ treatment resulted in numerically lower mean P-SIM fatigue scores vs ADA, UST, and PBO as early as Week 4 and through Week 16/24, with numerically greater proportions of BKZ-treated patients demonstrating clinically meaningful improvement at both timepoints and reporting no fatigue at Week 16/24.

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Table 1. Mean P-SIM fatigue scores (OC) and scores of 0 (NRI) in BKZ- and comparator-treated patients from BE VIVID and BE SURE

BE VIVID	BKZ Q4W N=321	UST Q12W[a] N=163	PBO N=83
P-SIM fatigue score, mean ± SD [N_{obs}]			
Baseline	5.1 ± 3.1 [260]	5.3 ± 3.0 [124]	4.9 ± 3.1 [67]
Week 4	2.4 ± 2.4 [291]	3.7 ± 2.9 [135]	4.8 ± 3.1 [72]
Week 16	1.2 ± 1.8 [258]	2.2 ± 2.6 [124]	4.7 ± 3.2 [59]
P-SIM fatigue score of 0, n (%)			
Baseline	26 (8.1)	9 (5.5)	5 (6.0)
Week 4	69 (21.5)	16 (9.8)	6 (7.2)
Week 16	130 (40.5)	43 (26.4)	8 (9.6)
BE SURE			
	BKZ Total N=319	ADA Q2W[b] N=159	
P-SIM fatigue score, mean ± SD [N_{obs}]			
Baseline	5.5 ± 3.0 [271]	5.0 ± 3.1 [125]	
Week 4	2.5 ± 2.4 [249]	3.6 ± 2.8 [123]	
Week 24	1.3 ± 2.2 [224]	2.3 ± 2.9 [108]	
P-SIM fatigue score of 0, n (%)			
Baseline	21 (6.6)	13 (8.2)	
Week 4	52 (16.3)	28 (17.6)	
Week 24	122 (38.2)	46 (28.9)	

BKZ Total includes all BKZ-randomised patients, regardless of dosing regimen. [a] Patients received UST at baseline, Week 4, then Q12W thereafter, per labelling recommendations (45 mg for patients weighing ≤100 kg and 90 mg for patients weighing >100 kg); [b] Patients received ADA 80 mg at baseline, then 40 mg Q2W from Week 1 until Week 24, per labelling recommendations. ADA: adalimumab; BKZ: bimekizumab; N_{obs}: N observed; NRI: non-responder imputation; OC: observed case; PBO: placebo; P-SIM: Psoriasis Symptoms and Impacts Measure; Q2W: every 2 weeks; Q4W: every 4 weeks; Q12W: every 12 weeks; SD: standard deviation; UST: ustekinumab.

Table 2. Clinically meaningful ≥4-point reduction from baseline in P-SIM fatigue scores in patients with baseline scores ≥4 from BE VIVID and BE SURE (NRI)

BE VIVID	BKZ Q4W N=164	UST Q12W[a] N=81	PBO N=39
≥4-point reduction from baseline, n (%)			
Week 4	68 (41.5)	9 (11.1)	4 (10.3)
Week 16	103 (62.8)	41 (50.6)	3 (7.7)
BE SURE			
	BKZ Total N=191	ADA Q2W[b] N=78	-
≥4-point reduction from baseline, n (%)			
Week 4	82 (42.9)	7 (9.0)	
Week 24	107 (56.0)	31 (39.7)	

BKZ Total includes all BKZ-randomised patients, regardless of dosing regimen. [a] Patients received UST at baseline, Week 4, then Q12W thereafter, per labelling recommendations (45 mg for patients weighing ≤100 kg and 90 mg for patients weighing >100 kg); [b] Patients received ADA 80 mg at baseline, then 40 mg Q2W from Week 1 until Week 24, per labelling recommendations. ADA: adalimumab; BKZ: bimekizumab; NRI: non-responder imputation; PBO: placebo; P-SIM: Psoriasis Symptoms and Impacts Measure; Q2W: every 2 weeks; Q4W every 4 weeks; Q12W: every 12 weeks; UST: ustekinumab.

P-134

REAL-WORLD PATIENT SATISFACTION AND QUALITY OF LIFE AMONG IXEKIZUMAB TREATED PATIENTS WITH AND WITHOUT NAIL PSORIASIS

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Introduction: In clinical trials, ixekizumab (IXE) improved nail PsO at 24 weeks and in long term 5-year post hoc analyses. However, real-world data (RWD) on treatment satisfaction and quality of life (QoL) in IXE-treated patients with PsO involving nails is lacking.

Objectives: This study evaluates RWD from the US IXE Customer Support Program (CSP) and describes patient-reported treatment satisfaction and QoL in IXE-treated patients with PsO, with (w/) and without (w/o) nail involvement, from baseline (BL) to 24 weeks.

Methods: In this 24-week prospective observational study, we analyzed patient-reported treatment satisfaction and QoL in patients with PsO, w/ and w/o nail (fingernails and toenails) involvement at BL. Treatment satisfaction was assessed from the first 3 items of the patient satisfaction questionnaire (PSQ): PSQ1 (my PsO is clear or almost clear), PSQ2 (my PsO is clearing quickly), and PSQ3 (my PsO is staying clear or almost clear while taking my medicine) starting at week 2. QoL was assessed from BL by the Dermatology Life Quality Index (DLQI). Here, we present percentages of patients reporting PSQ scores 4 (satisfied) or 5 (strongly satisfied), and DLQI (0,1). Descriptive statistics on observed data are reported, no data imputation was performed.

Results: This analysis included 523 IXE-treated patients with PsO: 140 w/ nail involvement and 383 w/o. At BL, patients w/ nail involvement had longer PsO duration vs those w/o (224.5 months vs 187.1), greater biologic treatment experience (54.3% vs 46.5%), and higher DLQI impact (mean (SD)): 11.6 (8.1) vs 9.2 (6.3). At BL, the proportions of patients reporting DLQI (0,1) were numerically similar between patients w/ nail involvement vs w/o: 8.0% vs 8.6%. These percentages increased steadily in both patient groups though week 24, when DLQI (0,1) was reached by half of the patients w/ nail involvement (50.5%) and w/o (55.1%). At week 2 (time of the PSQ first administration), the proportions of patients w/ nail involvement vs w/o reporting to be either satisfied or strongly satisfied were: 25.9% vs 32.4% for PSQ1, 47.2% vs 42.5% for PSQ2, and 34.3% vs 36.5% for PSQ3. These percentages increased steadily in both patient groups through week 24, when three-fourths of patients reported

to be either satisfied or strongly satisfied, and percentages were numerically similar between patients w/ nail involvement vs w/o: 78.4% vs 75.6% for PSQ1, 74.2% vs 72.3% for PSQ2, and 76.3% vs 75.2% for PSQ3.

Conclusion: This RWD analysis demonstrated that the proportion of IXE-treated patients with PsO who reported being satisfied or strongly satisfied with treatment. Increases in DLQI (0,1) over time to week 24 were similar for patients w/ vs w/o nail involvement at BL.

Disclosure: This study was funded by Eli Lilly and Company. Presented at the EADV2023.

P-135

DESIGNING A SHARED DECISION-MAKING TOOL FOR ADOLESCENTS WITH PSORIASIS USING A MODIFIED DELPHI METHOD

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Introduction: Medical decision-making in adolescents differs from that of younger children and older adults. Shared decision-making (SDM) in adolescent patients necessitates providing appropriate autonomy, educating patients and their families on treatment options, and communicating with patients in clear, age-appropriate language. Unfortunately, there are no widely adopted and publicly available psoriasis-specific shared decision-making tools designed for adolescent patients (12-21 years old).

Objectives: To design an evidence-based shared decision-making tool for adolescents with psoriasis that includes treatment, management, and screening for comorbidities.

Methods: A modified Delphi method was utilized to (1) review existing psoriasis-specific shared decision-making (SDM) tools and query the utility of using existing tools in adolescent patients, (2) build consensus on core content to include in a newly designed adolescent-focused SDM tool and (3) build consensus on format and language to include in a newly designed adolescent-focused SDM tool. Participants included clinicians with experience treating adolescent patients with psoriasis, staff from a clinic focused on dermatology care for adolescent patients, and trainees involved in dermatology care. The modified Delphi technique included an extensive review of PubMed articles that address SDM and clinical guidelines for managing psoriasis in pediatric and adolescent patients (last updated February 2024). PubMed searches included the following terms: (psoriasis) AND ((shared decision making) AND/OR (patient decision aid)). Articles then underwent an initial screening based on title and abstract. Relevant publications were then reviewed in full text and categorized by target population – adult, pediatric, and adolescent patients.

Results: Our modified Delphi method resulted in the identification, selection, and design of an adolescent-focused SDM tool with 5 key components – 1. Goal setting, 2. Review of past treatments, disease severity, and symptoms, 3. Patient-directed education, 4. Comorbidity screening and development of a treatment plan that aligns with the needs and values of patients and their families, 5. Coordinating care. These 5 components align with the Ottawa Decision Support Framework (ODSF) and the International Patient Decision Aid Standards (IPDAS) criteria. Further, the newly designed tool incorporates National Psoriasis Foundation guidelines and the American Academy of Dermatology recommendations for the management and treatment of psoriasis in pediatric and adult patients. Content was formatted for a 6th grade reading level per the Flesch-Kincaid grade level formula. In addition, the patient-facing component of the SDM tool underwent extensive rounds of consensus building to ensure the format and language allow adolescents to complete the tool independent of an accompanying adult.

Conclusions: A Delphi method-based strategy is a promising approach to bringing key stakeholders together to develop and implement novel shared decision-making tools for adolescent patients. Further studies are needed to understand how the development, validation, and implementation of shared decision-making tools or the absence of these endeavors, impact care for adolescent patients living with psoriasis.

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P-136

THE IMPACT OF PSORIASIS ON COVID-19 SUSCEPTIBILITY, SEVERITY, AND VACCINE EFFECTIVENESS: A NATIONWIDE COHORT STUDY IN SOUTH KOREA

No consent given to publish in scientific journal.

P-137

THE SONELOKIMAB NANOBODY® IN PATIENTS WITH PSORIATIC DISEASE: WEEK 12 MULTIDOMAIN OUTCOMES FROM THE PHASE 2 ARGO PSORIATIC ARTHRITIS TRIAL

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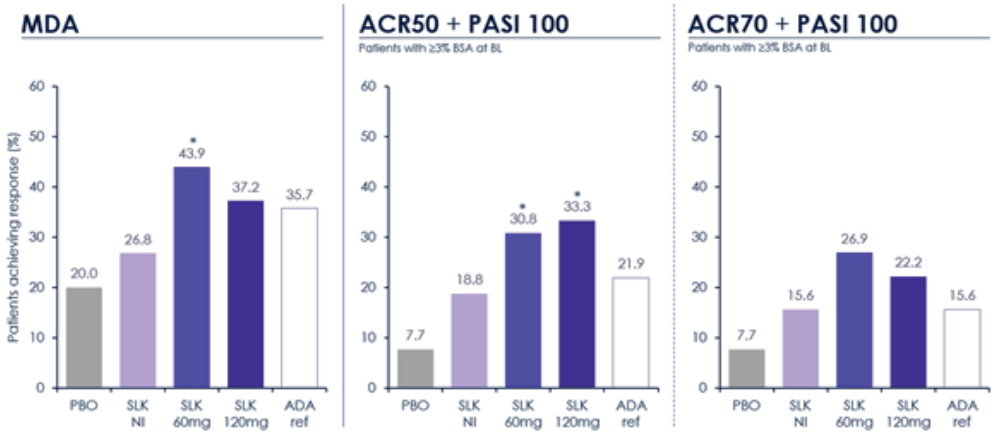
Introduction: Sonelokimab is a novel humanized Nanobody designed to inhibit IL-17A and IL-17F—central drivers of psoriatic disease—and penetrate difficult-to-reach sites of inflammation.
Objectives: We describe Week (W) 12 multidomain outcomes from the Phase 2 ARGO trial assessing the efficacy and safety of sonelokimab in patients with active PsA.

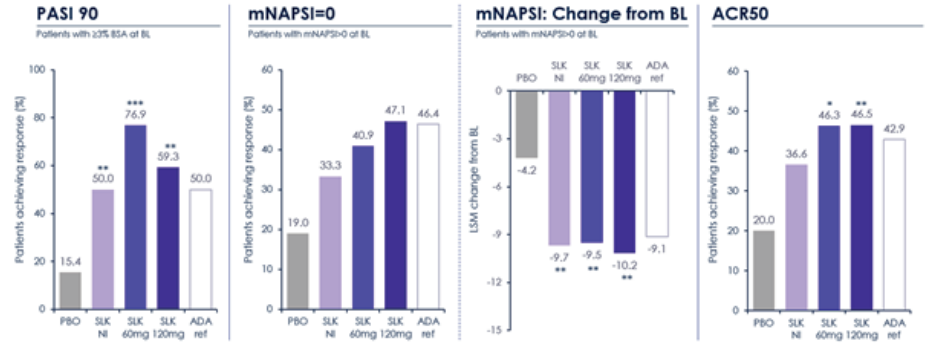
Methods: ARGO is a 24-week global, randomized, prospective, parallel-group, double-blind, placebo-controlled Phase 2 trial (NCT05640245). Eligible patients were ≥18 years old with active PsA (68-tender joint count ≥3, 66-swollen joint count ≥3), active psoriasis, and/or a dermatologist-confirmed psoriasis history. Patients were randomized (stratified by sex and biologic experience) to sonelokimab 120mg (with induction), sonelokimab 60mg (with induction), sonelokimab 60mg no induction (NI), placebo, or adalimumab 40mg (reference arm, not powered for statistical comparison); sonelokimab was administered every 4 weeks (Q4W; induction was Q2W until W8) and adalimumab Q2W. The primary endpoint was American College of Rheumatology (ACR) 50 response at W12. Other endpoints included Psoriasis Area and Severity Index (PASI) 90, PASI 100, minimal disease activity (MDA), ACR and PASI composites, and modified Nail Psoriasis Severity Index (mNAPSI). Analysis was intention-to-treat (PASI in patients with ≥3% body surface area at baseline [69%]; mNAPSI in patients with mNAPSI>0 at baseline [55%; mean 13.4]; non-

Figure 1. Multidomain composite endpoints at W12 (ITT-NRI)



*Nominal *P*<0.05. Missing data were imputed as a non-response. PASI/ACR+PASI responses are based on the number of patients at each visit in the full analysis set in each treatment group with BL psoriasis involving ≥3% BSA.
ACR, American College of Rheumatology; ADA, adalimumab; BL, baseline; BSA, body surface area; ITT, intention-to-treat; MDA, minimal disease activity; NI, no induction; NRI, non-responder imputation; PASI, Psoriasis Area and Severity Index; PBO, placebo; ref, reference arm; SLK, sonelokimab; W, week.

Figure 2. Skin, nail and joint endpoints at W12 (ITT-NRI)



***P*<0.001, **P*<0.01, **P*<0.05. *P*-values for mNAPSI and for SLK NI are nominal. Missing data were imputed as a non-response for categorical outcomes and analyzed by Mixed Model for Repeated Measures for continuous outcomes. PASI and mNAPSI responses are based on the number of patients at each visit in the full analysis set in each treatment group with BL psoriasis involving ≥3% BSA or mNAPSI>0 at BL, respectively. ACR50 response was defined as an improvement of ≥50% in tender and swollen joint counts and 3/5 other ACR components.
ACR, American College of Rheumatology; ADA, adalimumab; BL, baseline; BSA, body surface area; ITT, intention-to-treat; LSM, least squares mean; mNAPSI, modified Nail Psoriasis Severity Index; NI, no induction; NRI, non-responder imputation; PASI, Psoriasis Area and Severity Index; PBO, placebo; ref, reference arm; SLK, sonelokimab; W, week.

responder imputation for categorical endpoints).
Results: 207 patients were randomized (sonelokimab 120mg, $n = 43$; sonelokimab 60mg, $n = 41$; sonelokimab 60mg NI, $n = 41$; placebo, $n = 40$; adalimumab, $n = 42$); the discontinuation rate at W12 was<4%. The primary endpoint was met, with a significantly greater proportion of patients treated with sonelokimab achieving ACR50 vs. placebo at W12 (sonelokimab 120mg, 46.5%, $P = 0.009$; sonelokimab 60mg, 46.3%, $P = 0.012$; placebo, 20.0%); sonelokimab 60mg NI was not significant (36.6%). A significantly greater proportion of patients treated with sonelokimab achieved PASI 90 vs. placebo (sonelokimab 120mg, 59.3%, $P = 0.003$; sonelokimab 60mg, 76.9%, $P < 0.001$; placebo, 15.4%). Sonelokimab led to significant improvements vs. placebo in multidomain outcomes, such as in the achievement of complete skin clearance alongside high ACR thresholds: >30% patients simultaneously achieved both PASI 100 and ACR50 (sonelokimab 120mg, 33.3%; sonelokimab 60mg, 30.8%; placebo, 7.7%; Figure 1), and 26.9% in the sonelokimab 60mg arm achieved a composite of ACR70 and PASI 100 (placebo, 7.7%). In measures encompassing domains beyond skin and joints, 43.9% of patients in the sonelokimab 60mg arm achieved MDA (placebo, 20.0%), while >40% of patients with mNAPSI>0 at baseline achieved complete resolution of nail disease despite the typically longer time required for improvement in this domain (mNAPSI=0; sonelokimab 120mg, 47.1%; sonelokimab 60mg, 40.9%; placebo, 19.0%; Figure 2). The reference arm showed expected responses, supporting the validity of the trial. There were no unexpected safety findings, with two (1.6%) mild or moderate cases of oral candidiasis and no cases of IBD or MACE.
Conclusions: Sonelokimab 120mg and 60mg with induction achieved high levels of response in multidomain measures of psoriatic disease by W12 of the Phase 2 ARGO trial, with no new safety signals. These findings suggest a favorable benefit–risk profile in patients with active PsA that warrants further investigation in Phase 3 trials.

P-138
HIGH DISEASE CONTROL AND STATE OF REMISSION WITH RISANKIZUMAB IN PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS DURING THE 6-YEAR LIMMITLESS STUDY

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Introduction: Psoriasis is a chronic, inflammatory skin condition that impairs patients' quality of life.[1] Psoriasis often requires long-term treatment; however, data on long-term uninterrupted disease control with biologic therapies are very limited. Risankizumab, a humanized immunoglobulin G1 monoclonal antibody that specifically inhibits interleukin 23 by binding to its p19 subunit, is approved to treat moderate-to-severe psoriasis and active psoriatic arthritis.
Objectives: To evaluate the long-term durability of response with risankizumab treatment and the ability of risankizumab to maintain uninterrupted disease control in patients with moderate-to-severe psoriasis.
Methods: LIMMitless (NCT03047395) was a phase 3, global, multicenter, open-label extension study evaluating the long-term efficacy and safety of risankizumab 150 mg for moderate-to-severe psoriasis through up to 304 weeks of continuous treatment.[2] Adult patients randomized to receive risankizumab 150 mg who completed 1 of 5 double-blind, placebo-controlled phase 2/3 studies (UltIMMa-1, UltIMMa-2, SustaIMM, IMMvent, or NCT03255382) were eligible to enroll in LIMMitless, in which patients continued open-label risankizumab 150 mg once every 12 weeks. Durability of response was assessed as the proportion of patients who achieved ≥90%/100% improvement in Psoriasis Area and Severity Index (PASI 90/PASI 100) or Dermatology Life Quality Index score of 0 or 1 (DLQI 0/1) at week 52 and maintained the corresponding responses at weeks 100/160/208/252/304. Additional efficacy assessments included the proportion of patients with high disease control (defined as no loss of PASI 90 or DLQI 0/1) or state of remission (defined as no loss of PASI 100) at any visit after week 52 through >1/>2/>3/>4/>5 years. Results are presented for all patients and those with (bio-experienced) or without (bio-naïve) prior biologic therapy. Data are reported as observed cases with no imputation for missing data.
Results: A total of 897 patients enrolled in LIMMitless and 661 (73.7%) completed the study. At baseline of LIMMitless (week 52 of treatment), PASI 90, PASI 100, and DLQI 0/1 were achieved by 86.3% (n/n = 766/888), 58.3% (n/n = 518/888), and 77.9% (n/n = 680/873) of patients, respectively. Among patients who achieved the corresponding outcomes at week 52, PASI 90, PASI 100, and DLQI 0/1 were maintained at week 304 by 93.3%, 78.0%, and 91.4% of patients, respectively; similar trends were observed for bio-experienced and bio-naïve patients (Table 1). The proportion of patients with high disease control for >1/>2/>3/>4/>5 years was 89.3%/80.9%/75.4%/72.7%/68.0% for PASI 90 and 93.8%/88.4%/81.7%/78.3%/66.2% for DLQI 0/1 (Table 2). State of remission for >1/>2/>3/>4/>5 years was achieved by 70.5%/54.1%/45.6%/41.2%/37.1% of patients. High disease control and state of remission results for bio-experienced and bio-naïve patients were comparable to the overall population. Long-term risankizumab safety has been reported elsewhere.[3]
Conclusions: Patients with moderate-to-severe psoriasis who achieve treatment goals after 52 weeks of risankizumab therapy can maintain a high level of long-term durability, high disease control, and a state of remission for up to 5 additional years.

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Table 1. Proportion of patients who maintained efficacy over time during the LIMMitless open-label extension study (OC)

	Maintenance of clinical response					
Patients, n/n (%)	**Week 52**	**Week 100**	**Week 160**	**Week 208**	**Week 256**	**Week 304**
PASI 90						
Overall	766/766 (100)	685/731 (93.7)	630/681 (92.5)	464/497 (93.4)	559/614 (91.0)	491/526 (93.3)
Bio-experienced	260/260 (100)	234/252 (92.9)	209/234 (89.3)	153/168 (91.1)	190/212 (89.6)	173/193 (89.6)
Bio-naïve	453/453 (100)	405/429 (94.4)	376/399 (94.2)	267/283 (94.3)	331/357 (92.7)	318/333 (95.5)
PASI 100						
Overall	518/518 (100)	411/496 (82.9)	373/461 (80.9)	274/338 (81.1)	320/416 (76.9)	277/355 (78.0)
Bio-experienced	170/170 (100)	130/164 (79.3)	113/154 (73.4)	78/114 (68.4)	99/138 (71.7)	89/125 (71.2)
Bio-naïve	311/311 (100)	251/298 (84.2)	234/273 (85.7)	167/191 (87.4)	198/245 (80.8)	188/230 (81.7)
DLQI 0/1						
Overall	680/680 (100)	602/652 (92.3)	—[a]	409/450 (90.9)	497/545 (91.2)	427/467 (91.4)
Bio-experienced	225/225 (100)	204/221 (92.3)	—[a]	133/145 (91.7)	167/185 (90.3)	151/171 (88.3)
Bio-naïve	409/409 (100)	361/388 (93.0)	—[a]	240/264 (90.9)	295/320 (92.2)	276/296 (93.2)

DLQI 0/1, Dermatology Life Quality Index score of 0 or 1; OC, observed cases; PASI 90/100, ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index.
[a]DLQI was not assessed at week 160.

Table 2. Proportion of patients with high disease control (no loss of PASI 90 or DLQI 0/1 at any visit after week 52) or state of remission (no loss of PASI 100 at any visit after week 52) over time during the LIMMitless open-label extension study (OC)

	Duration of response[a]				
Patients, n/n (%)	**>1 year**	**>2 years**	**>3 years**	**>4 years**	**>5 years**
No loss of PASI 90					
Overall	458/513 (89.3)	415/513 (80.9)	387/513 (75.4)	373/513 (72.7)	349/513 (68.0)
Bio-experienced	166/191 (86.9)	148/191 (77.5)	137/191 (71.7)	129/191 (67.5)	119/191 (62.3)
Bio-naïve	292/322 (90.7)	267/322 (82.9)	250/322 (77.6)	244/322 (75.8)	230/322 (71.4)
No loss of PASI 100					
Overall	241/342 (70.5)	185/342 (54.1)	156/342 (45.6)	141/342 (41.2)	127/342 (37.1)
Bio-experienced	84/128 (65.6)	69/128 (53.9)	55/128 (43.0)	46/128 (35.9)	40/128 (31.3)
Bio-naïve	157/214 (73.4)	116/214 (54.2)	101/214 (47.2)	95/214 (44.4)	87/214 (40.7)
No loss of DLQI 0/1					
Overall	411/438 (93.8)	387/438 (88.4)	358/438 (81.7)	343/438 (78.3)	290/438 (66.2)
Bio-experienced	151/158 (95.6)	141/158 (89.2)	130/158 (82.3)	121/158 (76.6)	104/158 (65.8)
Bio-naïve	259/279 (92.8)	246/279 (88.2)	228/279 (81.7)	222/279 (79.6)	186/279 (66.7)

DLQI 0/1, Dermatology Life Quality Index score of 0 or 1; OC, observed cases; PASI 90/100, ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index.
[a]Duration of response was assessed in patients who reached year 4 or beyond and had ≤ 5% missing data; total duration includes responses achieved from week 0 through week 304. If a patient had a missing record at a visit but achieved the response before and after the visit, the patient was considered as no loss of response at that visit.

P-139

AUREOBASIDIUM PULLULANS PRODUCED BETA-1,3-1,6 GLUCANS IMPROVING CLINICAL PARAMETERS, AMELIORATING INFLAMMATION AND SKIN LYMPHOCYTE INFILTRATION IN PATIENTS WITH PSORIASIS VULGARIS

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Introduction: Psoriasis vulgaris is a chronic, inflammatory, relapsing disease which may progress to systemic manifestations such as arthritis and cardiovascular disease. Current treatments including methotrexate, cyclosporin, biologics, vitamin D3 analogues, and other combination therapies have several limitations as well as adverse effects. We have evaluated the safety and efficacy of a beta-1,3-1,6 glucan produced as an exopolysaccharide by novel strain of Aureobasidium pullulans (Neu-REFIX) in a randomized clinical trial for psoriasis vulgaris.
Methods: Thirty patients with moderate to severe psoriasis vulgaris were enrolled and randomized in a 1:2 ratio. The control arm ($n = 10$) received conventional treatment (liquid paraffin, anti-histamines and vitamin supplements), while the treatment arm ($n = 20$) received conventional treatment + oral Neu-REFIX for 28 days. Clinical assessment with Psoriasis Area and Severity Index (PASI), Investigator Global Assessment (IGA) score, blood evaluation for immune-inflammatory parameters, and histopathological examination of skin biopsy were performed in all patients at baseline and post-intervention.
Results: Oral consumption of Neu-REFIX beta-glucan along with conventional treatment regimen for Psoriasis vulgaris was safe. There was significant improvement in most clinical and biochemical parameters in 80% of patients. Specifically, PASI scores significantly improved from baseline in the treatment arm (p-value=0.0007) compared to the control arm (p-value=0.46). Six patients in the treatment arm achieved a clinically meaningful reduction of PASI by 50% (PASI 50) from baseline, with five of them achieving the benchmark PASI 75 (75% reduction). Conversely, only one patient in the control arm achieved PASI 50, and none achieved PASI 75. The Investigator Global Assessment (IGA) score improved in 67% of patients in the treatment arm, while it worsened in 60% of patients in the control arm. Skin biopsies revealed a greater reduction in lymphocyte infiltration and epidermal thickness in the treatment arm (p-value=0.02) compared to the control arm (p-value=0.97). Decrease of serum High-sensitivity CRP (hsCRP) from 1.218 ± 1.43 to 1.098 ± 1.127 (p-value=0.50), interleukin-6 (IL-6) from 3.575 ± 4.454 to 3.401 ± 2.21 (p-value=0.19), and platelet-to-lymphocyte ratio (PLR) from 0.08053 ± 0.0401 at baseline to 0.078 ± 0.043 (p-value=0.76) was observed in the treatment arm, while these parameters rather worsened in the control arm.
Conclusion: The safety and potential efficacy of Neu-REFIX beta-glucans have been demonstrated in patients with moderate to severe psoriasis vulgaris, when orally administered with conventional treatment in this 28-day randomized clinical trial. Larger, long-term clinical trials are warranted to validate these findings in psoriasis and its systemic manifestations such as arthritis and metabolic syndrome, to elucidate the potential of oral Neu-REFIX beta-glucans as an adjuvant therapy for autoimmune skin and systemic diseases

P-140

DEMOGRAPHICS, DISEASE CHARACTERISTICS AND TIME TO EFFECTIVE TREATMENT OF PSORIASIS PATIENTS IN THE GHENT PSOPLUS COHORT OF 2021

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Introduction: Psoriasis is a chronic immune mediated disease with several comorbidities and a considerable influence on quality of life. Several patients with moderate-to-severe psoriasis are undertreated and have a substantial disease duration before biologic treatment is started.
Objectives: The goal of this study is to analyze patient and disease characteristics and time to effective treatment of patients with pso-

riasis who consulted PsoPlus, a dedicated integrated practice unit for psoriasis in Gent, Belgium. Whether a treat-to-target (T2T)(Grine et al, 2019) approach, which is implemented in PsoPlus, has an impact on treatment choice and disease progression is also examined.
Methods: Through a single center, exploratory, retrospective study, 170 patients in the PsoPlus dedicated clinic were compared to identify differences at moment of enrollment in PsoPlus and at the last recorded consultation in 2021.
Results: Median disease duration at the first PsoPlus consultation was 16.0 years. A significant difference in Psoriasis Area and Severity Index (PASI) and Dermatology Life Quality Index (DLQI) between the first and the last recorded PsoPlus consultation (PASI 6.0 vs. 0.6; DLQI 11 vs. 2; $p < 0.001$) was found. A weak positive Spearman correlation (rs) was found between disease duration and PASI at the first PsoPlus consultation (rs=0.175; $p = 0.034$), while a weak negative correlation (rs=-0.2; $p = 0.013$) was found at the last registered PsoPlus consultation. Patients with a disease duration of more than 20 years, had significantly more switches of treatment than those with a shorter disease duration ($p < 0.001$). Median time from psoriasis onset until PASI ≤ 2 was 16.0 years. Median time from the first PsoPlus consultation until PASI ≤ 2 was reached, was 7.0 months.
Conclusion: By portraying the long journey of patients with psoriasis, we reconfirm that psoriasis is a systemic disease that needs a personalized and holistic approach. The T2T score prompts towards a more appropriate and timely approach of the disease, leading to improved disease severity and quality of life.
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P-141
EFFICACY OF STATINS IN THE TREATMENT OF PSORIASIS: A SYSTEMATIC REVIEW AND META-ANALYSIS
No consent given to publish in scientific journal.

P-142
EFFICACY AND SAFETY OF ROFLUMILAST IN THE TREATMENT OF PSORIASIS: A SYSTEMATIC REVIEW AND META-ANALYSIS
No consent given to publish in scientific journal.

P-143
REAL-WORLD EFFECTIVENESS OF RISANKIZUMAB IN THE MULTI-COUNTRY POST-MARKETING VALUE STUDY: 148-WEEK INTERIM ANALYSIS
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Introduction: Risankizumab is an optimized IL-23 inhibitor approved for the treatment of moderate-to-severe plaque psoriasis, psoriatic arthritis, and Crohn's disease. VALUE is an ongoing 3-year study evaluating the long-term durability of risankizumab compared to other approved biologics (OtherBios) in patients with psoriasis in real world practice. At the 100-week interim analysis, a higher proportion of patients maintained ≥ 90% improvement in psoriasis area and severity index (PASI 90) compared to patients in the OtherBios group[1]. This is an updated 148-week analysis.
Objective: The objective of this study is to characterize the durability of response of risankizumab compared to OtherBios in real world practice.
Methods: VALUE (NCT03982394) is a multi-country, prospective post-marketing observational study that enrolled patients (≥18 years) with moderate-to-severe psoriasis who the treating physician decided to treat with risankizumab or OtherBios, independent of this study and per local label, in a 2:1 ratio. Effectiveness endpoints included absolute PASI, Dermatology Life Quality Index (DLQI), and proportions of patients achieving PASI 90 and PASI 100, treatment Satisfaction Questionnaire for Medication (TSQM) score, and changes to treatment. Results (database lock: 7 December 2023) are reported by modified non-responder imputation (mNRI) where patients who switched or discontinued the initiated biologic due to ineffectiveness or intolerability were judged as treatment failures for subsequent visits. Propensity score match (PSM) with 1:1 ratio using greedy algorithm and exact match for bio-naive/bio-experienced status was employed to account for imbalance between treatment groups. Nominal p values are presented.
Results: Baseline demographics and characteristics were mostly comparable among 1765 (risankizumab) and 874 (OtherBios) patients enrolled in this study with a few exceptions. The risankizumab group had patients with a higher baseline PASI (15.0 vs 13.9; $p = 0.004$), history of psoriatic arthritis (259 [14.7%] vs 233 [26.7%]; $p < 0.0001$) and were bio-experienced (870 [49.3%] vs 324 [37.1%]; $p < 0.0001$). Most differences were balanced in the PSM set and results from PSM set are shown below.
The proportion of patients who achieved PASI 90 at week 16 and maintained the response up to week 148 was significantly higher in the risankizumab group compared to the OtherBios group (45.4% vs 29.6%; $p = 0.0002$). Significantly fewer patients in the risankizumab group changed treatment compared to the OtherBios group (10.9% vs 24.2%; $p < 0.0001$). At week 148, patients in the risankizumab group achieved significantly lower absolute PASI (1.4 vs 3.6; $p < 0.0001$) compared to OtherBios (Table). A significantly higher proportion of patients achieved PASI 90 (67.2% vs 45.3%; $p < 0.0001$) and PASI 100 (55.2% vs 34.6%; $p < 0.0001$) in the risankizumab group compared to OtherBios. DLQI in the risankizumab group was significantly lower than the OtherBios group (2.5 vs 5.2; $p < 0.0001$). Significantly higher TSQM global satisfaction scores were reported for patients in the risankizumab group compared to the OtherBios group (86.1 vs 75.5; $p < 0.0001$). Safety for risankizumab was consistent with previous studies.
Conclusion: This updated analysis from the VALUE study demonstrates that patients treated with risankizumab achieve higher durable clinical responses in real-world practice compared to OtherBios. This study is ongoing and not all patients have reached week 148.
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Table. Patient outcomes in the 148-week VALUE update

Responses	Week 52		Week 100		Week 148	
	RZB	OtherBios	RZB	OtherBios	RZB	OtherBios
Absolute mean PASI						
mNRI						
mean (95% CI)	1.2 (1.1, 1.4)***	2.3 (1.9, 2.6)	1.3 (1.2, 1.5)***	2.6 (2.2, 3.0)	1.8 (1.5, 2.1)***	3.7 (3.1, 4.4)
n	1355	659	1084	519	582	314
PSM						
mean (95% CI)	1.2 (1.0, 1.5)***	2.3 (1.9, 2.6)	1.1 (0.9, 1.4)***	2.5 (2.1, 2.9)	1.4 (1.1, 1.8)***	3.6 (3.0, 4.3)
n	614	587	489	478	260	268
PASI 90						
mNRI						
%	74.6 (72.2, 76.9)***	58.6 (54.7, 62.4))	70.9 (68.1, 73.6)***	51.5 (47.1, 55.9)	66.0 (62.0, 69.8)***	42.1 (36.6, 47.7)
n/N	1007/1350	385/657	770/1086	267/518	386/585	133/316
PSM						
%	74.5 (70.9, 77.9)***	59.6 (55.5, 63.5)	71.2 (66.9, 75.1)***	54.3 (49.7, 58.8)	67.2 (61.1, 72.9)***	45.3 (39.5, 51.3)
n/N	456/612	355/596	348/489	259/477	174/259	131/289
PASI 100						
mNRI						
%	54.6 (52.0, 57.3)***	39.8 (36.1, 43.7)	53.5 (50.5, 56.5)***	38.3 (34.1, 42.6)	51.5 (47.4, 55.7)***	32.3 (27.2, 37.7)
n/N	741/1356	263/660	583/1089	200/522	302/586	102/316
PSM						
%	54.4 (50.4, 58.4)***	40.3 (36.3, 44.4)	56.6 (52.1, 61.1)***	40.2 (35.8, 44.7)	55.2 (48.9, 61.4)***	34.6 (29.1, 40.4)
n/N	334/614	241/598	277/489	193/480	143/259	100/289
DLQI						
mNRI						
mean (95% CI)	2.0 (1.8, 2.2)***	3.3 (2.9, 3.7)	1.8 (1.6, 2.0)***	3.7 (3.2, 4.2)	2.4 (2.1, 2.8)***	5.3 (4.5, 6.1)
n	1322	646	1046	501	531	296
PSM						
mean (95% CI)	2.2 (1.9, 2.5)***	3.4 (2.9, 3.8)	1.9 (1.6, 2.3)***	3.6 (3.1, 4.1)	2.5 (1.9, 3.0)***	5.2 (4.4, 6.0)
n	605	583	465	461	233	272
TSQM (Global)						
mNRI						
mean (95% CI)	84.6 (83.5, 85.6)***	77.5 (75.7, 79.4)	86.0 (84.9, 87.2)***	78.8 (76.7, 80.8)	84.7 (83.0, 86.5)***	74.6 (71.3, 77.8)
n	1291	626	1010	470	483	259
PSM						
mean (95% CI)	85.0 (83.5, 86.4)***	77.8 (75.9, 79.7)	86.0 (84.4, 87.7)***	79.4 (77.4, 81.5)	86.1 (83.6, 88.7)***	75.5 (72.2, 78.9)
n	582	566	443	436	210	240

PASI, Psoriasis Area and Severity Index; DLQI, Dermatology Life Quality Index; TSQM, Treatment Satisfaction Questionnaire for Medication; n, number; CI, confidence interval; mNRI, modified non responder imputation; PSM, Propensity Score Matched; *p≤0.05; **p≤0.01;***p≤0.0001

P-144

DEVELOPMENT AND EVALUATION OF A MACHINE LEARNING MODEL FOR THE EARLY IDENTIFICATION OF PSORIATIC ARTHRITIS IN THE COMMUNITY

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Introduction: Delays in diagnosis of psoriatic arthritis (PsA) are associated with indolent and non-specific signs and symptoms, and often result in physical impairment and poorer global health outcomes in the long term [1,2,3,4]. Digital tools such as machine learning algorithms have the potential to address diagnostic delays by identifying patients earlier in their disease course [5].

Objective: To develop and evaluate a novel machine learning model for identifying patients at risk of having undiagnosed PsA among the community.

Methods: Patients from the community population ($n = 395{,}918$ patients) at Mayo Clinic between 2012 and 2022 were split into training and testing sets. Cases with PsA and controls with no evidence of PsA were identified in both sets. For model training, each patient was assigned a prediction date, which preceded the initial diagnosis of PsA for cases, and was randomly assigned to controls. A gradient boosted trees algorithm was trained using electronic medical record (EMR) data documented during the two years prior to each patient's prediction date. Input features included age, sex, diagnosis codes, medication prescriptions and laboratory results. The model was then evaluated in the test set on predictions made on 1 January 2018 with input data from the preceding two years. Area under the curve (AUC) was used to assess the model's ability to discriminate between new cases of PsA diagnosed during and after 2018 and controls.

Results: The testing set included 81 patients with PsA (60% female; mean age 54.2, standard deviation [SD] 14.0) and 284,480 control patients (167,018 females; mean age 51.9, SD 18.2). The AUC on the test was 79.6% (fig 1). Predictive features include diagnoses of psoriasis, joint pain and tenosynovitis, glucocorticoid and NSAID use, high body mass index, elevated CRP, ALT, triglycerides and decreased HDL (fig 2).

Conclusions: The model displayed good performance in its ability to discriminate between cases of PsA and controls. The model selected input features associated with preexisting psoriasis, joint inflammation and an adverse metabolic profile [6]. Implementation of the model may help identify patients with undiagnosed PsA in the primary care population using EMR. Improving time to diagnosis could help patients receive treatment and reduce burden of disease sequelae from untreated disease.

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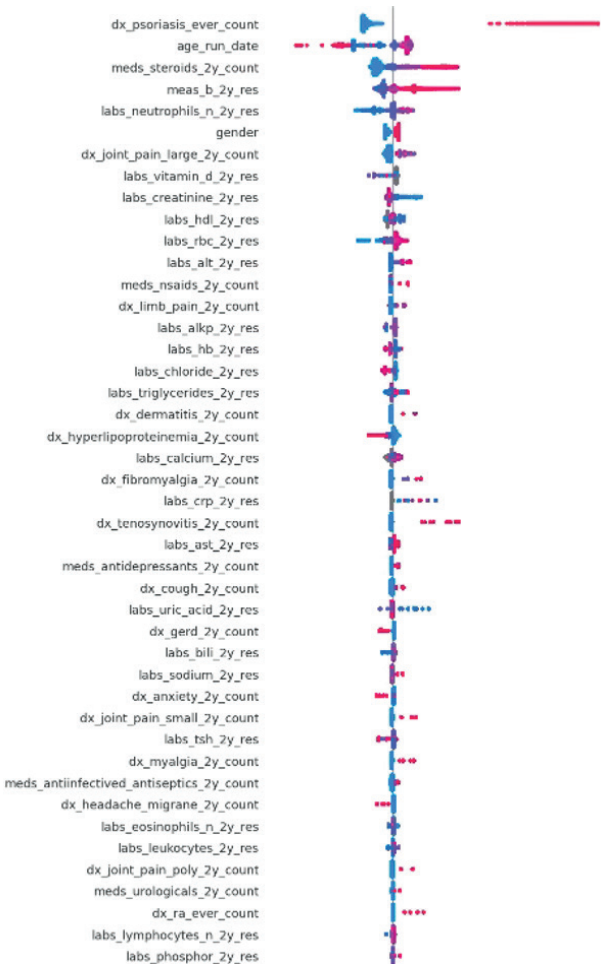

P-145

GENETICS AND FUNCTIONAL STUDIES OF PSORIATIC ARTHRITIS MUTILANS

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Introduction: Psoriatic arthritis mutilans (PAM) represents the rarest and most severe subtype of psoriatic arthritis1 2. Our recent research 3 has implicated elevated hydrogen peroxide levels, mediated by rare variants of NOX4, in the development of PAM.
Objectives: Building upon previous findings, our study aims to investigate the NOX4 regulatory regions in PAM patients without rare NOX4 coding variants. Specifically, we seek to identify these regions and elucidate their roles in PAM pathogenesis, potentially uncovering novel therapeutic targets associated with NOX4 regulation.
Methods: We will identify potential NOX4 regulatory regions through Whole Genome Sequencing analysis followed by genotyping in the PAM Nordic cohort. Dual-luciferase reporter assays and CRISPR-Cas9 knockout techniques will provide further insights into the functional significance of these regions.
Results: To investigate the NOX4 regulation in PAM patients, we look for rare variants that potentially affect NOX4 expression. We are using the ENCODE database, and we particularly focus on finding variants in the regions with signals in H3K4me3, H3K27ac, and H3K4me1. We will start by analyzing the whole genomic sequence from five PAM patients. Subsequently, to validate our findings, we plan to genotype the entire PAM Nordic cohort ($n = 61$) to observe if the rare variants are found in the rest of PAM patients. Dual-luciferase reporter assays in HEK293 cells will be utilized to evaluate the impact of identified regulatory SNPs on NOX4 activity. Furthermore, CRISPR-Cas9 knockout techniques in zebrafish will be used for functional validation.
Conclusions: Our study aims to deepen understanding of NOX4 variants in regulatory regions and their implications in PAM pathogenesis. By elucidating the regulatory mechanisms underlying NOX4 expression, we hope to identify novel therapeutic targets for PAM treatment.

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P-146

ANTI-PD-1 EXACERBATES PSORIATIC INFLAMMATION BY INCREASING IL-17A PRODUCTION FROM ΓΔ T CELLS

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Introduction: Programmed cell death 1 (PD-1) is a coinhibitory receptor that contributes to maintain peripheral immunotolerance. Therefore, blockade of this pathway may aggravate autoimmune symptoms such as psoriatic inflammation. There are several clinical reports of exacerbated psoriasis on cancer patients under anti-PD-1 therapy. However, the precise immunological mechanism of anti-PD-1 induced psoriasis remains unknown and the therapeutic strategy to alleviates anti-PD-1 induced psoriatic inflammation are yet to be identified.
Objectives: Our study aimed to investigate the immunological mechanism of anti-PD-1 induced psoriasiform inflammation and

the potential role of anti-PD-1 on the therapeutic efficacy of anti-IL-17 blocking antibody.

Methods: We used imiquimod (IMQ) induced psoriasiform inflammation mouse model and anti-PD-1 blocking antibody was injected. To identify the impact of anti-PD-1 on the efficacy of anti-IL-17 blocking antibody as a treatment, anti-IL-17 antibody was injected. Ear thickness was measured, and flow cytometry was used for immunological analysis.

Results: The ear thickness and the relative frequency of γδ T cells in SDLN had significantly increased after anti-PD-1 injection. Additionally, the frequency of CD27- Vγ1- γδ T cells showed substantial increase in anti-PD-1 treated group. Indeed, IL-17A production of CD27- Vγ1- γδ T cells was increased in anti-PD-1 treated group. Moreover, CD27- Vγ1- Vγ4- γδ T cells which are crucial effector T cell population in psoriasis produce IL-17A robustly in anti-PD-1 group especially on anti-CD3 stimulation. Interestingly, the therapeutic effects of anti-IL-17 antibody was attenuated by anti-PD-1 on psoriasiform dermatitis.

Conclusion: These finding suggests that anti-PD-1 exacerbates psoriatic inflammation by increasing IL-17A produced by CD27- Vγ1- Vγ4- γδ T cells. However, according to our results, further research is needed to investigate better therapeutic strategies for exacerbated psoriasis when injecting anti-PD-1 treatment. Therefore, we plan to identify the therapeutic efficacy of anti-IL-23 against anti-PD-1 induced psoriasis.

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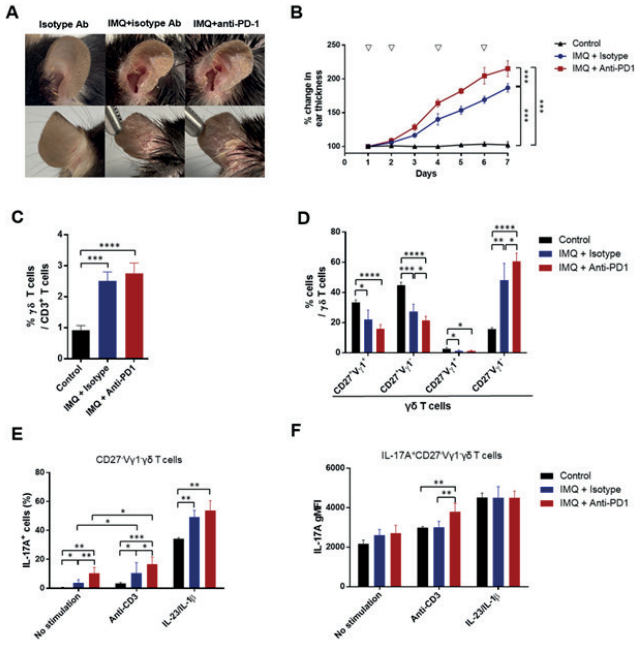

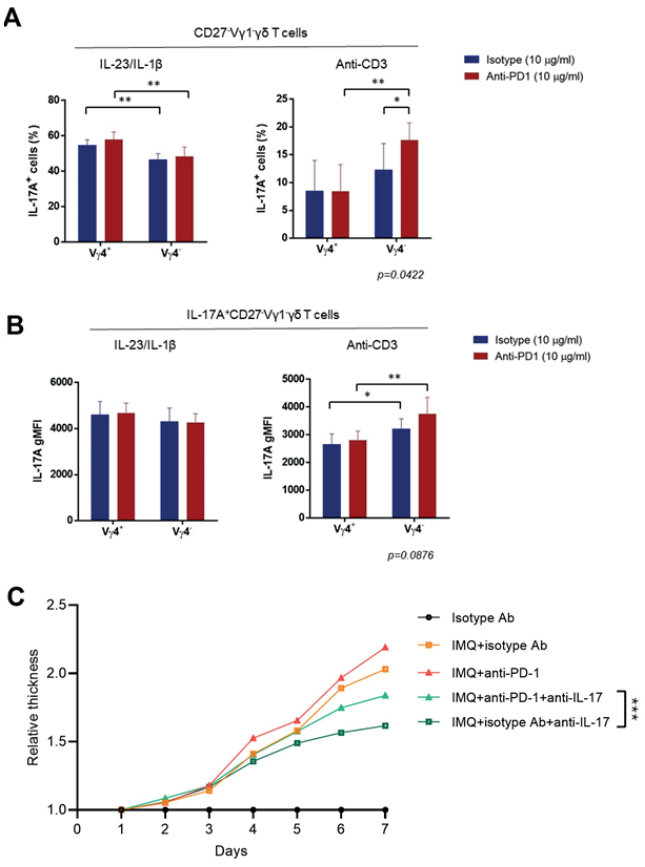

P-147

SOCIAL CHARACTERISTICS OF RUSSIAN PATIENTS WITH PSORIASIS AND ARTHROPATHIC PSORIASIS

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According to the International Federation of Psoriasis Associations (IFPA), about 125 million people worldwide suffer from this disease. In Russia, at the end of 2022, based on the results of applications to medical organizations, more than 371.2 thousand patients with psoriasis were registered; Also, during this period, 94.2 thousand new cases of psoriasis were identified. Features of the social characteristics of patients, including psoriasis, have not been sufficiently studied throughout the world. In order to study the impact of psoriasis and arthropathic psoriasis on the social activity of patients, an anonymous quantitative online survey of patients was conducted. The questionnaire included 36 questions. The object of the study is patients with a confirmed diagnosis of psoriasis and (or) arthropathic psoriasis aged 18 to 75 years. Patients were included in the study regardless of the duration and severity of the disease. 512 respondents took part in the survey. After the "repair" the sample amounted to 486 people. It was revealed that the overwhelming majority of respondents do not have disabilities caused by psoriasis/arthropathic psoriasis (90.5%), did not receive therapy with genetically engineered biological drugs and did not encounter help (except for medical care) from government or public organizations (more than 90%). More than 85% of surveyed patients with psoriasis/arthropathic psoriasis do not receive medications for free. Moreover, almost half of the respondents allocate up to 30% of their monthly income to medications necessary for treatment. In general, the presence of psoriasis/arthropathic psoriasis in patients does not interfere with their full work and study. At the same time, a significant portion of respondents had difficulties interacting with

colleagues and friends due to the presence of these diseases, and 40% of respondents had to refuse job offers due to the presence of the disease. About half of the respondents experience various difficulties in their personal lives (the corresponding restrictions are manifested by both reluctance to enter into a long-term relationship and problems in intimate life, including among married respondents). Also, about half of the respondents experienced various difficulties in communication with their sexual partner, as well as in their sexual life. At the same time, more than 80% of patients with psoriasis/arthropathic psoriasis have the support of their family, which is an important factor in building self-confidence and reducing discomfort in creating new social connections.

P-148
PSORIASIS AND NURSING CARE – AN EDUCATIONAL PROJECT TO HELP IMPROVE CLINICAL DEVELOPMENT AND QUALITY OF CARE

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Introduction: In Sweden there are no requirements for continued medical education for any health care professionals, and accessible CME for nursing staff is especially rare. Therefore, Psoriasisförbundet, the Swedish Psoriasis Association, initiated a three-year educational project for nursing staff, funded by Psoriasisfonden.
Objectives: To develop an accessible educational model aimed at improving diagnostic knowledge for nursing staff that they may take on a more autonomous, leading role regarding treatment and care of psoriasis patients.
Methods: The educational model and content were based on two surveys, one for psoriasis patients, and one for nursing staff within dermatology. The latter was a benchmark survey to ascertain level of knowledge and confidence regarding the care of psoriasis patients within the target group. The educational content was reviewed by the Swedish Dermatology Specialist Nurses Association and Psoriasisförbundet's Scientific Advisory Board. To ensure maximum accessibility the course was held digitally over four half-days, one per week, followed up by a webinar one year after the initial course. The attendees were also provided with cost-free printed materials. The attendees were surveyed four times, once before the course (benchmark), directly after the course, three months after, and approx. one year after. The surveys were based on EACCME and University of Washington School of Nursing guidelines for medical education evaluation.
Results: Regarding knowledge level the three main themes of the course were surveyed: diagnostic knowledge, treatment options, comorbidities. In diagnostic knowledge the share of responding attendees who answered that their level was "very high" rose from 11,1% to 12,9% and "high" from 20% to 64,5%; in treatment options "very high" rose from 13,3% to 19,4% and "high" from 26,7% to 61,3%. In comorbidities no change was seen in "very high" but "high" rose from 15,6% to 58,1%. The attendees were surveyed pre- and post-course on how confident they are regarding fulfilling patients' needs. The share of respondents who answered yes pre- and post-course: counselling/information on topical treatment (pre 60%, post 96,8%), systemic treatment (pre 28,9%, post 58,1%), sexual/ reproductive health (pre 33,3%, post 48,4%), lifestyle changes (pre 55,6%, post 51,6%), risk factors/ screening comorbidities (pre 24,4%, post 77,4%). The concluding survey aimed at understanding the perceived value of the project in clinical practice. One third of the respondents reported that they had absolute value of the project's content in clinical practice, 42% that they had great value, and one fourth that they had some value. One fourth reported they now feel confident in taking a more active role in improving quality of care in their clinical setting, 42% responded confidence to some degree.
Conclusions: The surveys indicate that the educational project has improved both knowledge and confidence level within the two target groups. Identifying both patient and nursing staff needs before developing both outline and content of the course ensured that it not only would be accessible but also that the knowledge gained would be of value in daily clinical practice and help improve the treatment and care provided.

P-149
INCLUSION OF THE PATIENT VOICE IN DEVELOPING HOLISTIC TREATMENT GOALS FOR RARE SKIN DISEASES

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Introduction: Treatment goals for generalised pustular psoriasis (GPP) are poorly defined, based mostly on data from plaque psoriasis, and are not reflective of the patient experience. Shared decision-making between patients and physicians around treatment goals can lead to improved outcomes and patient satisfaction [1]. Furthermore, health regulatory bodies have issued guidance on the integration of patient experience data, along with other insights from patients and caregivers into the development of new treatments [2]. Patient perspectives have been incorporated into consensus-shaping exercises to better understand treatment goals for plaque psoriasis [3], though a similar approach has been lacking in GPP. Here, we report insights from the first consensus-shaping exercise in GPP to incorporate the patient perspective.
Methods: An expert panel was assembled comprising patient representatives and dermatologists with recent or current experience in treating GPP. Through the use of a targeted questionnaire (based on a systematic literature review), the objective was to achieve consensus on key principles of GPP treatment, including short-term and long-term goals. Patients and physicians rated their level of agreement on 26 different statements and gave additional comments in a free-text field. Consensus per statement was defined as ≥80% agreement across the panel.
Results: The panel comprised 30 dermatologists and 3 patient representatives. Each of the 3 patients (Asia, $n = 2$; USA, $n = 1$) had >10 years' lived experience of GPP; one patient was a member of a GPP patient advocacy group. Consensus between physicians and patients was reached on all statements relating to effective disease management, including the need for tailored treatment plans. Overall, physicians considered the treatment of certain symptoms (e.g. skin pustules) as the most important clinical goal and metric for treatment success. However, patients considered alleviation of other symptoms (alongside skin and systemic symptoms) to be equally important due to the psychological and emotional impact of this in their daily lives.
Conclusion: Developing treatment goals for rare skin diseases such as GPP is challenging due to limited published evidence on symptom burden and a relative lack of approved treatment options. The inclusion of patient representatives in this consensus-shaping exercise for GPP provided personal insights regarding the wider impact of the disease on patients' lived experience. Patients should be empowered as active, shared decision-makers to ensure that treatment goals for chronic diseases are holistic, reflecting not only clinical outcomes, but also symptoms that have the greatest impact on quality of life.
Acknowledgements: The authors thank everyone who participated in this consensus-shaping exercise.
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P-150

PREDICTING PSORIATIC ARTHRITIS AT ONSET OF PSORIASIS: RESULTS FROM AN INCEPTION COHORT STUDY

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Objectives: The objectives of this study are to identify biomarkers and derive a prediction algorithm for the development of psoriatic arthritis (PsA) in patients with new onset psoriasis.

Methods: We extracted data from the Stockholm Psoriasis Cohort ("SPC"). The SPC is a prospective inception cohort study that enrolled patients with psoriasis within one year of first disease onset in the Stockholm area, Sweden (1). Patients were followed-up clinically at 5 and 10 years. Data on patient history, life-style factors, genotype, phenotype, systemics inflammation, and metabolomics were obtained. The study was also linked to national Swedish administrative registers to complement data from the examinations. We included patients aged 18 year or more and applied traditional statistical analysis to identify biomarkers for the development of PsA and implemented statistical learning methods to derive prediction algorithms.

Results: 629 participants (median [IQR] age 43 years [31-57]; 44% women) were eligible for analysis and 190 participants (30%) developed PsA.

We estimated associations between 258 potential predictors and PsA using logistic regression models controlling for sex and age. We divided predictors into ten categories with 5 to 117 variables each and compared the p-values of the estimates to the Benjamini and Hochberg (BH) critical values (BHcv) assuming a false discovery rate of 10% for each category. Table 2 presents variables with nominally significant p-values ($p < 0.05$) and p-values below the relevant BHcvs are marked in bold. Among the 43 potential clinical predictors, 31 (72.1%) had p-values below their BHcv. In contrast, among the biomarkers 16/258 variables (6.2%) had p-values below their BH critical values. However, there was a marked difference between different biomarker categories: 4/15 markers for systemic inflammation (27%) and 9/25 lipid markers (36%) had p-values below the BHcvs, compared to 1/42 (2.3%) for lipid subfractions, 0/15 (0%) for non-lipid metabolic markers, and 2/117 (1.7%) for genetic markers.

We also derived a white-box algorithm for PsA prediction using recursive partitioning in a conditional inference framework (Figure 1A). Based on five variables: Current arthralgia, pain at one of seven specified sites during the last year, peripheral enthesitis, dactylitis, and hs-CRP we derived an algorithm with a c-statistic of 0.82, indicating good discrimination. The best black-box model derived so far is a model using a random forest model ("RFM"), which has c-statistic of 0.88, indicating excellent discrimination. It is not possible to visualize the decision rule for a RFM, but the importance of included variables can be estimated and are presented in Figure 1B. In all analyses, arthralgia and symptoms related to PsA were most important, but inflammatory markers had a larger influence in the RFM (accounting for 3/10 most important predictors), potentially reflecting non-linear and interaction effects not captured by a simpler model.

Conclusions: These results indicate the importance of patient reported and anamnestic data for PsA prediction but also indicate that several biomarkers may have substantial predictive power. The prediction models developed have good discriminatory power and could be used to identify patients at high risk of PsA to allow for timely intervention or even prevention.

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Table 1 Markers nominally associated with development of PsA (p<0.05) with p-values below the Benjamini and Hochberg critical value given a false discovery rate of 10% in each category presented in bold.

Clinical and patient reported variables			Biomarkers derived from blood		
Variable	OR	p-value	Variable	OR	p-value
Patient characteristics (14 variables)			**Systemic inflammatory markers (15 variables)**		
Physical effort at work, (yes/no)	1.61	**0.000**	Hs-CRP	1.68	**0.000**
Heavy lifting at work (yes/no)	2.09	**0.000**	Serum Amyloid A	1.54	**0.000**
Female sex (yes/no)	1.67	**0.003**	GlycA	1.24	**0.014**
Family history of rheum disease (yes/no)	1.92	**0.005**	ICAM-1	1.23	**0.021**
Body mass index, kg/m2	1.06	**0.006**	IL-8	0.84	0.038
Gastric ulcer, (yes/no)	2.21	**0.033**			
Weight increase, (yes/no)	0.67	**0.043**			
Economic stress, (yes/no)	1.21	0.048			
Skin disease severity and manifestations (5 variables)			**Lipids (25 Variables)**		
Guttate onset, (yes/no)	0.34	**0.000**	HDL-z	0.68	**0.000**
Scalp lesions, (yes/no)	1.49	**0.020**	L-HDL-p	0.70	**0.000**
Nail lesions, (yes/no)	1.59	**0.028**	HDL-c	0.73	**0.001**
Arthralgia related variables (8 variables)			LPIR	1.28	**0.001**
Current arthralgia, (yes/no)	8.01	**0.000**	S-LDL-p	1.29	**0.003**
Pain in hands or wrist last year, (yes/no)	6.19	**0.000**	LDL-P	1.33	**0.004**
Pain in hip or knee last year, (yes/no)	3.88	**0.000**	LPIR	1.28	**0.007**
Pain in feet or ankles last year, (yes/no)	3.82	**0.000**	LDL-C	1.24	**0.010**
Pain in shoulders last year, (yes/no)	3.48	**0.000**	VLDL-P	1.21	**0.027**
Pain in neck last year, (yes/no)	3.41	**0.000**	**Lipid subfractions (42 variables)**		
Pain in lower back last year, (yes/no)	2.48	**0.000**	HL108	0.36	**0.002**
Pain in upper back last year, (yes/no)	2.59	**0.000**	LM210	1.20	0.037
Fatigue-related variables (6 variables)			**Other metabolic markers (15 variables)**		
Physically tired after work (1-5)	1.71	**0.000**	Citrate	0.75	0.018
Awake at night (1-5)	1.44	**0.000**	Insulin	1.19	0.042
Mentally tired after work (1-5)	1.44	**0.000**	HOMA-IR	1.18	0.047
Energetic during workday (1-5)	0.70	**0.001**			
Difficult to fall asleep (1-5)	1.23	**0.007**			
Rheumatic symptoms* (10 variables)			**Genetic markers (117 variables))**		
Enthesitis, (yes/no)	5.32	**0.000**	rs2853694 (IL12B), (yes/no)	2.03	**<0.001**
Arthrosynovitis, (yes/no)	5.32	**0.000**	HLA-B27 (HLA-B), (yes/no)	2.31	**0.001**
Tender joint count, (yes/no)	1.28	**0.001**	rs2293970 (NFKB1) , (yes/no)	0.34	0.007
Health visual analogue scale (1-10)	1.19	**0.008**	rs2397084 (IL17F) , (yes/no)	0.54	0.014
Dactylitis, (yes/no)	6.03	**0.020**	rs1791161 (B4GALT6) , (yes/no)	0.63	0.016
Tenosynovitis (yes/no)	5.51	**0.026**	rs34565481 (LINC00302) , (yes/no)	0.67	0.030
Joint pain visual analogue scale (1-10)	1.13	**0.038**	rs3027898 (IRAK1) , (yes/no)	1.55	0.030
			rs2289278 (TSLP) , (yes/no)	1.75	0.042

Note: Dichotomous variables are indicted by (yes/no), Likert scales with the range in parenthesis, and remaining variables are continuous and mean-standardized to facilitate comparisons of effect sizes.

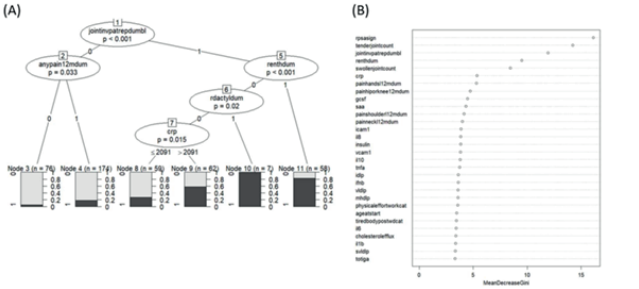

Figure 1. Prediction algorithms for psoriatic arthritis in patients with new onset psoriasis. Panel A presents the white-box algorithm and the constituent variables. The dark grey shades of the bar show the proportion of patients who develop PsA in each group. Panel B presents the Variable Importance Plot from the Random Forest model. Note: JointInvPatRepDumBL stands for current arthralgia at the enrolment examination Patients with arthralgia were subsequently examined by a rheumatologist. AnyPain12mDum stand for self-reported history of pain in at least one of seven sites (Neck, shoulders or elbows, hands or wrists, upper back, lower back, hip or knees, feet or ankles), RenthDum stands for enthesitis noted during the rheumatologist examination, RDactylDum stands for dactylitis reported noted during the rheumatologist clinical examination, CRP stands for high-sensitivity CRP measured from sera obtained in conjunction with the enrolment examination,