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IFPA
GLOBAL LEADER IN FIGHTING PSORIATIC DISEASE

6TH WORLD PSORIASIS & PSORIATIC ARTHRITIS CONFERENCE 2021

CONNECTED, INFORMED, AND UNITED TO IMPROVE MULTIDISCIPLINARY CARE FOR PEOPLE WITH PSORIASIS AND PSORIATIC ARTHRITIS

JUNE 30 – JULY 3, 2021, STOCKHOLM, SWEDEN
VIRTUAL CONFERENCE

Janssen-Sponsored Satellite Symposium at the
6th World Psoriasis & Psoriatic Arthritis Conference 2021 – VIRTUAL

Where do we begin? The key role of the IL-23 pathway in psoriasis and psoriatic arthritis

Scientific Committee
Kilian Eyerich (Sweden)
Rik Lories (Belgium)

Wednesday 30 June 2021
13:10–13:55 (CEST)

Please join us for this virtual satellite symposium focussing on the importance of the **IL-23 pathway** in the **management of psoriasis and psoriatic arthritis**. Also covered will be the **latest clinical updates on treatments** and the **drug efficacy and safety data** of various drug classes used in the management of these diseases in clinical practice.

With the support of Janssen Pharmaceutical Companies of Johnson & Johnson in EMEA

Janssen Pharmaceutica NV
Turnhoutseweg 30
B-2340 Beerse, Belgium

Date of preparation: June 2021
EM-63893

janssen Immunology
PHARMACEUTICAL COMPANIES OF Johnson&Johnson

TABLE OF CONTENTS

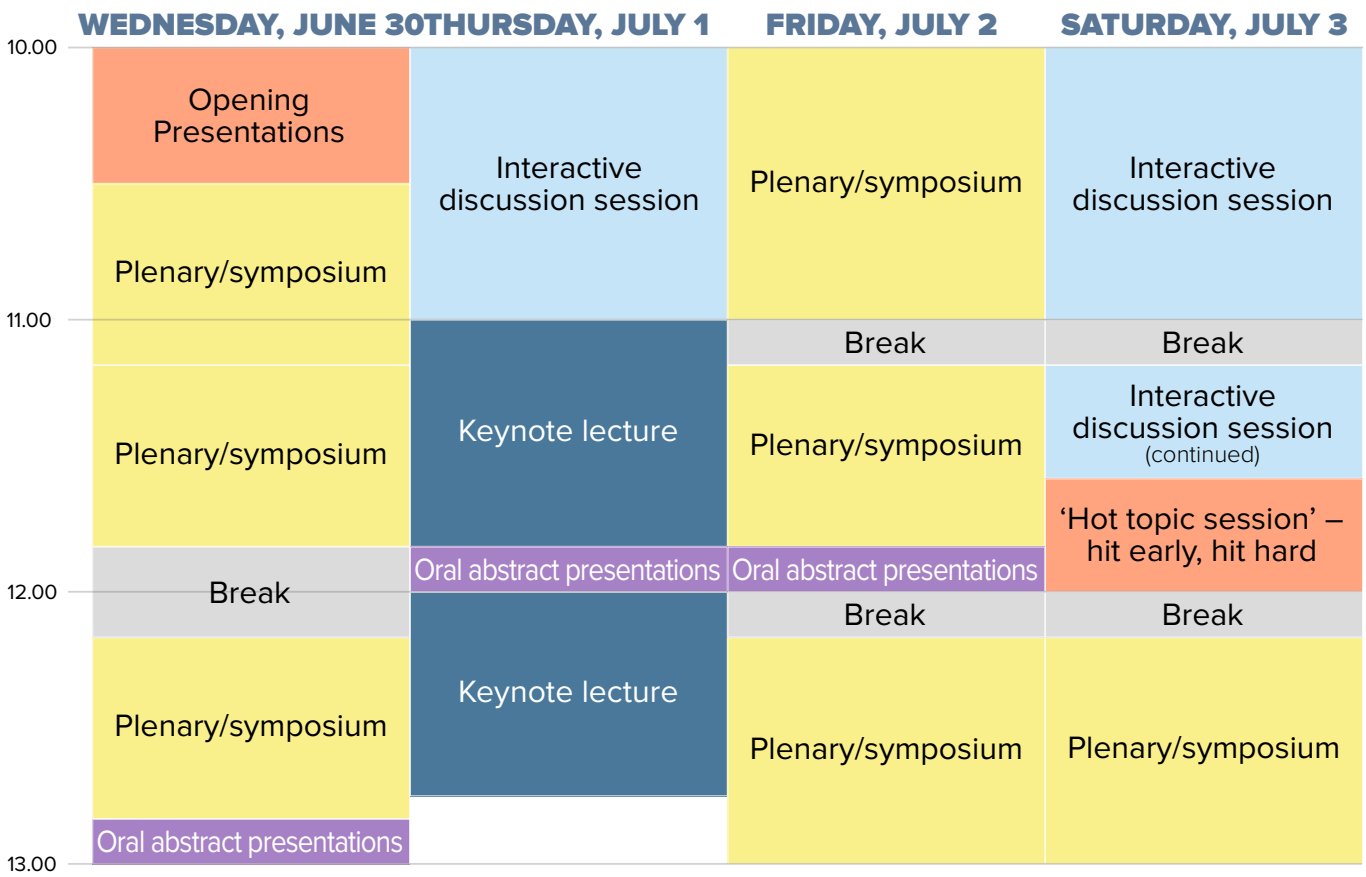
CONFERENCE HOURS

All times are listed in CEST (GMT + 2 hours)

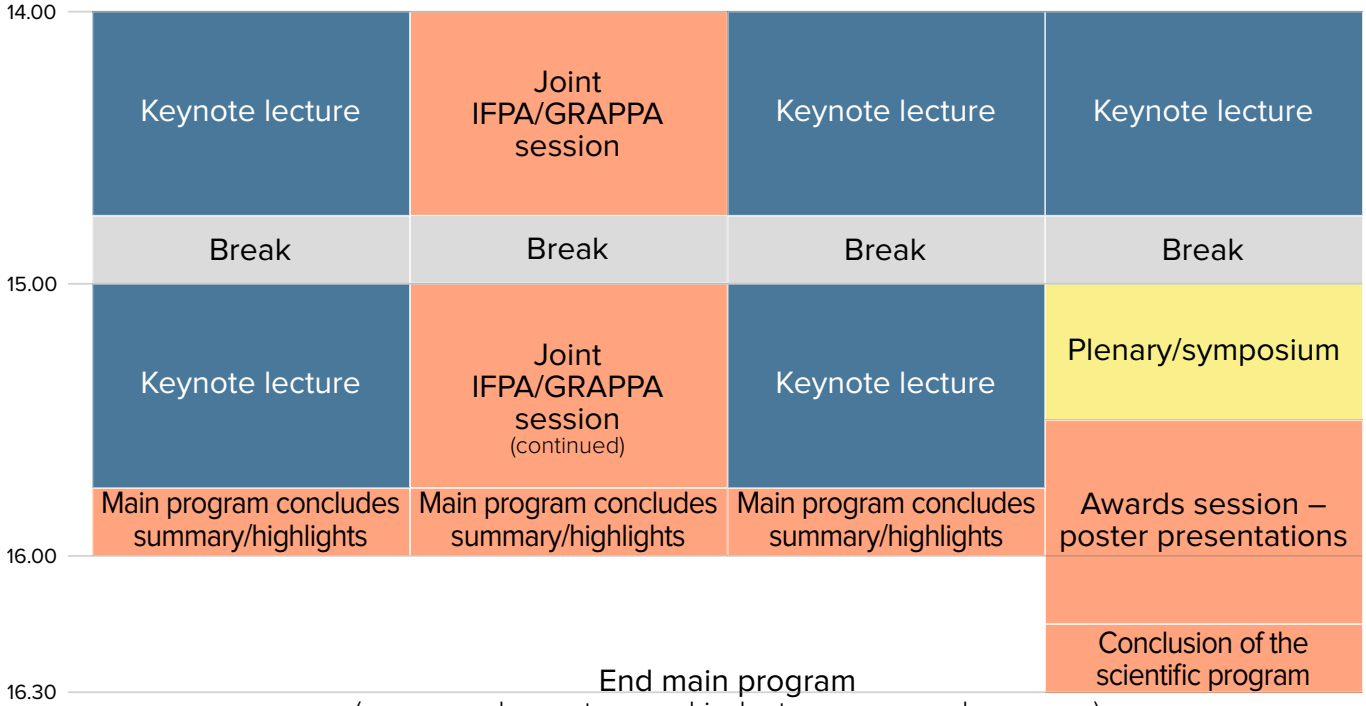
Program	
Wednesday, June 30	10.00 – 17.00
Thursday, July 1	09.00 – 17.00
Friday, July 2	10.00 – 17.00
Saturday, July 3	10.00 – 17.15

Please note that the commercial exhibition is open to registered HCP delegates only and open for the duration of the conference.

SCIENTIFIC PROGRAM



Break main program
(see complementary and industry sponsored program)



End main program
(see complementary and industry sponsored program)

COMPLEMENTARY PROGRAM

	WEDNESDAY, JUNE 30	THURSDAY, JULY 1	FRIDAY, JULY 2	SATURDAY, JULY 3
	Theme of the day: Focus on the Burden of Psoriasis/Psoriatic Arthritis COVID-19 and Vaccinations	Theme of the day: Lifestyle, dealing with daily life problems, latest research and mental health	Theme of the day: Access to care and management. Focus on unmet needs	
13.00	Session 1: Global burden of psoriasis and epidemiology	Session 3: Lifestyle, intervention and psoriatic disease	Session 5: Rapid access and early intervention	Session 7: International Psoriasis Council Symposium - On latest research and updates
14.00				
15.00				
16.00	Session 2: Psoriatic disease and COVID-19	Session 4: Psoriatic disease and its impact on mental health	Session 6: Focus on unmet needs: Taking global knowledge and implementation at national level	
17.00				Complementary Program - closing session
17.15				

WELCOME TO THE 6TH WORLD PSORIASIS & PSORIATIC ARTHRITIS CONFERENCE

Dear friends,

In the last 10 years, we have seen tremendous expansion of knowledge of psoriasis and psoriatic arthritis (psoriatic disease). As we usher in the new decade, we hope to continue sharing these insights in our international conference held once every three years. It is therefore my great pleasure to welcome you to the virtual 6th World Psoriasis and Psoriatic Arthritis Conference (6th WPPAC Virtual) organized by IFPA.

The decade began with some unique challenges—namely the global spread of COVID-19 and restriction of movement in many countries— however, we also witnessed a strong sense of solidarity, as people came together to support one another through the situation. As the world adapted to current realities, new digital solutions allowed us to remain connected. We bring the value of these newly developed communication channels to this fully virtual edition of the 2021 conference.

The great journey which began with the adoption of the World Health Organisation (WHO) resolution in 2014 and the Global Report on Psoriasis in early 2016, has resulted in bringing to focus the public health impact of psoriatic disesase. Following this important milestone, the WPPACs have led the way to ensuring that there are engaged interactions among healthcare professionals , advocates and people living with the disease. Just as its predecessors, the 6th WPPAC conference, aims to reflect patient perspectives. IFPA´s national member associations have continued to play an important role in raising key issues which are underscored on the conference agenda.

The WPPAC remains one of IFPA´s core activities and provides a platform to share recent research. -We look forward to engaged discussions with a patient-oriented focus,strengthening advocacy efforts to ensure that psoriatic disease is placed firmly on the international non-communicable disease agenda.

This 6th WPPAC will be a wonderful opportunity to see you all and actualize the theme “Connected, informed and united to improve multidisciplinary care for people with psoriasis and psoriatic arthritis.”

We warmly welcome you to the fully virtual IFPA World Conference 2021!

Dr. Hoseah Waweru
President International Federation of Psoriasis Associations

Dear Colleagues and Friends,

Be invited to join the fully virtual 6th World Psoriasis & Psoriatic Arthritis Conference!

The worldwide community of patients and physicians had to cope very differently with a situation new to all of us. As the elected President for the 6th WPPAC I am honoured to be part of the organization of this fully virtual conference. We believe that a virtual meeting is the best solution at the time being. With new ways of communication and interaction, we hope our entire community can join and take part of the exiting program of the 6th WPPAC.

Our activities for a successful conference are centered on the best possible engagement and interaction between clinicians, scientists and patients/patient representatives. People-centered health care and personalized medicine including share-to-care concepts challenge traditional ways of delivering care. Talking with people and not about them requires a change of mindset of many physicians but this will be rewarded by an improved level of well-being of the patients with psoriasis and/or psoriatic arthritis

The philosophy of the past WPPACs and the mission of IFPA are to make the progress in understanding psoriasis and psoriatic arthritis in all facets of care available to those who suffer from the disorders. The 6th WPPAC will continue along these lines in a modern way of knowledge exchange.

We look forward to virtually welcoming you all to the 6th WPPAC!

Prof. Dr. med. Ulrich Mrowietz
President 6th World Psoriasis & Psoriatic Arthritis Conference
Chair Scientific Executive Committee

Boehringer Ingelheim

Boehringer Ingelheim kindly invites you to a virtual satellite symposium at the **6th World Psoriasis & Psoriatic Arthritis Conference 2021**

One Disease

Two Perspectives

Generalized Pustular Psoriasis
Through the Eyes of the **Patient** and the **Dermatologist**

Friday, 2 July 2021 | 16:15–16:55 CEST

Objectives

- Recognize the enormous burden of GPP on patients
- Understand the potentially life-threatening nature of GPP and the need for therapies that rapidly and completely resolve GPP flares
- Highlight the role of IL-36 in the pathogenesis of GPP, and describe the results of trials using IL-36 inhibitors to treat GPP

Agenda

16:15	Welcome Message		Alexander Navarini (Chair)
16:16	The Desire for Clear Skin: The Patient Perspective of a GPP Flare		Christine Jones (a person living with GPP)
16:26	The Desire to Reduce Mortality and Morbidity with Limited Options: The Dermatologist Perspective		Joel Gelfand (USA)
16:36	The Desire for New Options in GPP Treatment: IL-36 Inhibitors		Alexander Navarini (Switzerland)
16:46	Live Q&A Panel		Alexander Navarini (Switzerland) & Joel Gelfand (USA)

CONFERENCE MISSION

IFPA WORLD CONFERENCE

The World Psoriasis & Psoriatic Arthritis Conference is an established scientific conference organized by IFPA. It presents the latest developments in psoriasis and psoriatic arthritis research. Because medical professionals from both the dermatology and rheumatology field attend, the conference provides a unique cross-specialty forum.

Delegates can explore the psoriasis disease from different perspectives by networking with patients and industry representatives in attendance. Since 2006, we have organized the World Conference every third year. The latest conference drew over 1,200 delegates from more than 70 countries around the world.

CONFERENCE OBJECTIVES

Our aim with the World Psoriasis & Psoriatic Arthritis Conference is to:

- Increase global recognition of the psoriasis disease and its severity;
- Unite psoriasis stakeholders, to strengthen international collaboration;
- Share the latest scientific and clinical developments on psoriasis and psoriatic arthritis;
- Encourage new research projects;
- Highlight the patient perspective, so that the conference will ultimately improve living conditions for the international psoriasis community.

COMMON ABBREVIATIONS

AHP	allied health professional
ANA	antinuclear antibody
AS	ankylosing spondylitis
BSA	body surface area
CASPAR	Classification Criteria for Psoriatic Arthritis
CRP	C-reactive protein
DLQI	Dermatological Quality of Life Index
DMARD	disease-modifying antirheumatic drug
EQ-5D	European Quality of Life-5 Dimensions
HAQ	Health Assessment Questionnaire
HAQ-DI	Health Assessment Questionnaire-Disability Index
HCP	health care professional
HLA	human leukocyte antigen
HRQoL	health-related quality of life
IL	interleukin
IPD	individual patient data
MTX	methotrexate
NCD	noncommunicable disease
NSAID	non-steroidal anti-inflammatory drug
PASI	Psoriasis Area and Severity Index
PsA	psoriatic arthritis
PsARC	Psoriatic Arthritis Response Criteria
PsO	psoriasis
TNF	tumor necrosis factor
TJC	tender joint count
UV	ultraviolet light
VAS	visual analogue scale

CONTACT INFORMATION

Practical information	General questions	Conference content
Do you have a practical question?	Do you have a general question?	Do you have a question about the conference content?
Please contact the conference bureau, Meetagain. ifpaworldconference@meetagain.se	Do you want to know more about the organization behind the conference, the conference's history or how patients can get involved? Please contact the conference organizer, IFPA. info@ifpa-pso.com	Do you want to comment on the scientific program, the program committees or the conference's official speakers? Please contact Barbra Bohannan, secretary of the scientific executive committee. barbra.bohannan@pso.se

ABOUT IFPA

IFPA is the global leader in fighting psoriatic disease.

IFPA unites psoriatic disease associations from around the world so that their global campaign for improved medical care, greater public understanding and increased research will improve the lives of people who live with psoriasis and psoriatic arthritis.

TOGETHER, FOR PEOPLE LIVING WITH PSORIATIC DISEASE EVERYWHERE

IFPA unleashes the global patient voice to campaign on behalf of people who have psoriasis and psoriatic arthritis. IFPA provides the unity that strengthens everyone's ability to support research that will someday find a cause and a cure for these diseases.

IFPA VISION

A future where all people living with psoriatic disease enjoy good health and wellbeing, free from stigma and preventable disability and comorbidities.

IFPA MISSION

Unite, strengthen and lead the global psoriatic disease community to improve the lives of all people affected by psoriatic disease.

For more information about IFPA and our activities, please visit www.ifpa-pso.com.

Live Symposium
Thursday 1 July 2021, 16:15–17:00 CEST

Advanced Therapeutic Options in PsA: A Multidisciplinary Team Approach

Laura Coates, MBChB, MRCP, PhD
University of Oxford, UK

Diamant Thaçi, MD
University of Lübeck, Germany

Date of preparation: May 2021. PP-XEL-SWE-1087

GENERAL INFORMATION

ABSTRACTS

All conference abstracts are available in this program book.

CME CREDITS

The European Accreditation Council for Continuing Medical Education (EACCME) has granted the 6th World Psoriasis & Psoriatic Arthritis Conference 15 European CME credits.

You are able to claim your accrediaton points after the conference. For more details please visit the conference website.

EVALUATION

After the conference you will receive an evaluation form by e-mail. Your opinion is very important for us and we appreciate that you take your time to fill it out.

EXHIBITION

Please note that the commercial exhibition is open to registered HCP delegates only and open, on the platform, for the duration of the conference.

To ensure that the 6th World Psoriasis & Psoriatic Arthritis Conference complies with national and regional regulations and guidelines for the Pharmaceutical Industry, access to the commercial exhibition area and to any industry-sponsored satellite symposia dealing with development, research or such like pertaining to prescription medication will be restricted to health-care professionals only.

INSURANCE DISCLAIMER/LIABILITY

All reasonable endeavors will be made to hold the 6th World Psoriasis & Psoriatic Arthritis Conference 2021 and to present its program as scheduled under circumstances which assure the comfort and safety of all participants. However, neither IFPA nor its committees, representatives or agents shall be held liable by any person as a result of the cancellation of the Conference or of any of the arrangements, programs or plans connected therewith.

LANGUAGE

The official conference language is English. Simultaneous interpretation will not be offered.

POSTERS

Posters are available on the platform for the duration of the conference.

TWITTER

Make sure to #WPPAC21 in your tweets!

SCIENTIFIC PROGRAM

WEDNESDAY, JUNE 30

10.00-10.30 **Opening presentations**
Hoseah Waweru, President IFPA
Ulrich Mrowietz, President of the 6th WPPAC

10.30-11.10 **Plenary/symposium session – Pathogenesis**
Chairs: *Oliver FitzGerald, Ireland and Ulrich Mrowietz, Germany*

Pathogenesis of psoriasis
Johan Gudjonsson, US

Pathogenesis of psoriatic arthritis
Vinod Chandran, Canada

Live Q&A

11.10-11.50 **Plenary symposium session – Treatment guidelines**
Chairs: *Oliver FitzGerald, Ireland and Ulrich Mrowietz, Germany*

Treatment guidelines/best practice psoriasis
Alexander Nast, Germany

Treatment guidelines/best practice PsA
Arthur Kavanaugh, US

Live Q&A

11.50-12.10 **Break/digital mingle and meet-ups**

12.10-12.50 **Plenary/symposium session – New treatments**
Chairs: *Oliver FitzGerald, Ireland and Ulrich Mrowietz, Germany*

New treatments/pipeline psoriasis
Kristian Reich, Germany

New treatments/pipeline PsA
Philip Mease, US

Live Q&A

12.50-13.00 **Oral abstract presentations**

Effisayil 1: A multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of spesolimab in patients with a generalized pustular psoriasis flare
Mark Lebwohl, US

Deucravacitinib, an Oral, Selective Tyrosine Kinase 2 (TYK2) Inhibitor, Compared With Placebo and Apremilast in Moderate to Severe Plaque Psoriasis: Efficacy and Safety Results From the Phase 3 POETYK PSO-1 and POETYK PSO-2 Trials
April Armstrong, US

13.10-13.55 **Industry sponsored satellite symposium**

14.00-14.45 **Keynote lecture**
Chairs: *Ulrich Mrowietz, Germany and Mona Ståhle, Sweden*

New pathways/drivers of immunity
Kenji Kabashima, Japan

Live Q&A

14.45-15.00 **Break/digital mingle and meet-ups**

15.00-15.45 **Keynote lecture**
Chairs: *Ulrich Mrowietz, Germany and Mona Ståhle, Sweden*

Patient reported outcomes measures – measuring wellbeing not only burden of disease
Rachel Sommer, Germany

Live Q&A

15.45-16.00 **Main program concludes – summary/highlights**
Ulrich Mrowietz, President of the 6th WPPAC

16.15-17.00 **Industry sponsored satellite symposium**

THURSDAY, JULY 1

09.00-09.45 **Industry sponsored satellite symposium**

10.00-10.50 **Interactive discussion session - The role of doctor/patient communication in improving outcomes and wellbeing**

Chair: *Matthias Augustin, Germany*

Listening is learning – the patient perspective
Silvia Fernandez Barrio, Argentina

The importance of communication in treating persons with chronic, inflammatory disease
Katy Leung, Singapore

Telemedicine as a tool for communication
Christian Greis, Switzerland

Live Q&A

10.50-11.00 **Short break**

11.00-11.45 **Keynote lecture**
Chairs: *Oliver FitzGerald, Ireland and Mona Ståhle, Sweden*

Self-responsibility and self-management – encouraging lasting behaviour change in patients with psoriasis/psoriatic arthritis
Christine Bundy, United Kingdom

Live Q&A

11.45-11.50 **Short break**

11.50-12.00 **Oral abstract presentations**

Changes in Patient Perceptions of Psoriatic Arthritis From 2012 to 2020: Results From the UPLIFT Survey
Alexis Ogdie, US

Psoriasis and Psoriatic Arthritis in Transgender Patients on Hormone Therapy: A Retrospective Comparative Cohort Study
Julia Gao, US

12.00-12.45 **Keynote lecture**
Chairs: *Oliver FitzGerald, Ireland and Ulrich Mrowietz, Germany*

The general impact of the microbiome in chronic, inflammatory disease
Dirk Elewaut, Belgium

Live Q&A

13.10-13.55 **Industry sponsored satellite symposiu**

14.00-14.45 **Joint IFPA/ GRAPPA session; Palmoplantar pustulosis**
Chairs: *Kristina Callis Duffin, US; Ulrich Mrowietz, Germany*

The challenge of living with PPP- Filmed testimonials from people living with PPP
Ellen Nordgren and Lucía Estrada Csaky

Skin manifestations and clinical features
Alexander Navarini, Switzerland

Rheumatological manifestations and clinical features
Philip Helliwell, UK

Outcomes measures
Melissa Oliver, US

Live Q&A

14.45-15.00 **Break/digital mingle and meet-ups**

15.00-15.45 **Joint session continued Presentation of GRAPPA projects**
Chairs: *Kristina Callis Duffin, US; Ulrich Mrowietz, Germany*

Introduction
Kristina Callis Duffin, US

Axial PsA – the AXIS project
Dafna Gladman, Canada

Composite measures
William Tillet, United Kingdom

Innovative Medicines Initiative grant: Unmet needs in psoriatic arthritis
Oliver FitzGerald, Ireland

Educational projects
Philip Mease, US

Live Q&A

15.45-16.00 **Main program concludes – summary/highlights**
Ulrich Mrowietz, President of the 6th WPPAC

16.15-17.00 **Industry sponsored satellite symposium**

FRIDAY, JULY 2

10.00-11.00 **Plenary/symposium session - Comorbidity update**
Chairs: *Frank Behrens, Germany and Mona Ståhle, Sweden*

Comorbidity in adult psoriasis
Lone Skov, Denmark

Matching comorbidity in psoriasis and PsA
Alexis Ogdie-Beatty, US

Comorbidity in children and young adults
Josefin Lysell, Sweden

Live Q&A

11.00-11.10 **Short break**

11.10-11.50 **Session continues - Prevention series**
Chairs: *Alexis Ogdie-Beatty, US and Mona Ståhle, Sweden*

Can we prevent disease progression in psoriasis?
Wayne Gulliver, Canada

Can we prevent progression to psoriatic arthritis?
Frank Behrens, Germany

Prevention and reduction of disease through weight-loss
Alexander Egeberg, Denmark

Live Q&A

11.50-12.00 **Oral abstract session**

Identification of serum protein biomarkers at baseline to distinguish radiographic progressors from non-progressors in patients with active Psoriatic Arthritis (PsA)
Orla Coleman, Ireland

Immune checkpoint inhibitors in patients with preexisting psoriasis associated with manageable disease exacerbations and excellent tumor outcomes
Briana Halle, US

12.00-12.10 **Short break**

12.10-13.00 **Plenary/symposium session - 20 years of biologics**

Chairs: *Oliver FitzGerald, Ireland and Ulrich Mrowietz, Germany*

Looking back and looking ahead – long-term safety, risk management and future potential
Carle Paul, France; Kurt de Vlam, Belgium

Treatment strategies – unmet needs of treating psoriasis/psoriatic arthritis
Kilian Eyerich, Sweden; Laura Coates, UK

Potential for prevention of comorbidity
Alexander Egeberg, Denmark; Dafna Gladman, Canada

Live Q&A

13.10-13.55 **Industry sponsored satellite symposium**

14.00-14.45 **Keynote lecture**
Chairs: *Ulrich Mrowietz, Germany and Mona Ståhle, Sweden*

Vascular inflammation in chronic inflammatory disease
Nehal Mehta, US

Live Q&A

14.45-15.00 **Break/digital mingle and meet-ups**

15.00-15.45 **Keynote lecture**
Chairs: *Ulrich Mrowietz, Germany and Mona Ståhle, Sweden*

Pathogenesis of depression in inflammation (chronic and acute)

Mats Lekander, Sweden

Live Q&A

15.45-16.00 **Main program concludes – summary/highlights**
Ulrich Mrowietz, President of the 6th WPPAC

16.15-17.00 **Industry sponsored satellite symposium**

SATURDAY, JULY 3

10.00-11.00 **Interactive discussion session - Addressing unmet needs in psoriasis and psoriatic arthritis**
Chairs: *Oliver FitzGerald, Ireland and Ulrich Mrowietz, Germany*

The WHO Global report on psoriasis – suggested actions to improve treatment and care for people with psoriasis
Paul Mendoza, Phillipines

Unmet needs in psoriatic arthritis
Christopher Ritchlin, US

Health economics and access to treatment
Ricardo Romiti, Brazil

Interactive discussion

Live Q&A

11.00-11.10 **Short break**

11.10-11.35 **Unmet needs session continued - Addressing stigmatization in psoriasis**
Chairs: *Oliver FitzGerald, Ireland and Ulrich Mrowietz, Germany*

The global need for active measures against stigmatization
Ncoza Dlova, South Africa

Strategies to reduce stigma – learnings from the German national programme against stigmatization
Matthias Augustin, Germany

Live Q&A

11.35-12.00 **"Hot topic session" – hit early, hit hard**
Chair: *Mona Ståhle, Sweden*

Robert Gniadecki, Canada and Mona Ståhle, Sweden

Live Q&A

12.00-12.10 **Short break**

12.10-13.00 **Plenary/symposium session - Topical therapy**
Chairs: *Ulrich Mrowietz, Germany*

Is there still a place for topical treatment?
Lars Iversen, Denmark

New topical developments
Mark Lebwohl, US

Measures to improve adherence to topical treatment
Wolfgang Weger, Austria

Live Q&A

13.00-14.00 **Break in the main program**

14.00-14.45 **Keynote lecture**
Chairs: *Oliver FitzGerald, Ireland and Mona Ståhle, Sweden*

Psoriasis, psoriatic arthritis and infectious disease
Curdin Conrad, Switzerland

Live Q&A

14.45-15.00 **Break/digital mingle and meet-ups**

15.00-15.30 **Plenary/symposium session - Consequences of the corona pandemic on the management of psoriasis and psoriatic arthritis**
Chairs: *Oliver FitzGerald, Ireland and Mona Ståhle, Sweden*

Are early registry data helpful for risk assessments?
Jo Lambert, Belgium

SARS-CoV-2 vaccination management in psoriasis and PsA
Paolo Gisondi, Italy

15.30-16.15 **Awards session – Poster presentations**
Oliver FitzGerald, Ireland; Mona Ståhle, Sweden; Ulrich Mrowietz, Germany

Best scientific poster

Best educational poster

Best clinical poster

Best patient organization poster

Best young researcher poster

6th WPPAC Nature Reviews Rheumatology Poster Prize

16.15-16.30 **Conclusion of scientific program**

Final panel discussion on conference theme and highlights
Oliver FitzGerald, Ireland; Mona Ståhle, Sweden; Ulrich Mrowietz, Germany; Hoseah Waweru, President IFPA

COMPLEMENTARY PROGRAM

WEDNESDAY, JUNE 30

13.00-14.00 **Theme of the day - Focus on the burden of psoriasis/psoriatic arthritis COVID - 19 and vaccinations**

Session 1 - Global burden of psoriasis and epidemiology
Chairs: *Colin Theng, Singapore; Hoseah Waweru, Kenya; Chris Griffiths, UK*

Introduction and global burden of disease
Chris Griffiths, UK

Global Psoriasis Atlas: Latest research update & projects
Darren Ashcroft, Global Psoriasis Atlas Research Team

Improving access to care
Luca Borradori, Switzerland

Live Q&A

16.00-17.00 **Session 2: Psoriatic disease and COVID-19**
Chairs: *Colin Theng, Singapore; Hoseah Waweru, Kenya;*
Peter van de Kerkhof, The Netherlands; Ulrich Mrowietz, Germany

Psoriasis and COVID-19 – Findings from PsoProtectMe
Satveer Mahil, UK – PsoProtect.org

Insights on how COVID-19 affects the care of patient: Innovations in the research landscape in the past year

Peter van de Kerkhof, The Netherlands

COVID-19 : Vaccination against SARS-CoV-2 in people with psoriatic disease
Ulrich Mrowietz, Germany

Live Q&A

Summary and highlights

THURSDAY, JULY 1

13.00-14.00 **Theme of the day: Lifestyle, dealing with daily life problems, latest research and mental health**

Session 3: Lifestyle, intervention and psoriatic disease
Chairs: *Colin Theng, Singapore; Hoseah Waweru, Kenya; Alan Menter, US*

Psoriatic arthritis for the dermatologist
Alan Menter, US

A focus on alcohol and food systems; the latest in the prevention policy landscape for the psoriasis community
Lucy Westerman, Policy and Campaigns Manager, NCD Alliance

Lifestyle intervention programs
Luigi Naldi, Italy

Relevance of the gut microbiome to psoriasis
Ignacio Dei-Cas, Argentina

Live Q&A

16.00-17.00 **Session 4: Psoriatic disease and its impact on mental health**
Chairs: *Colin Theng, Singapore; Hoseah Waweru, Kenya; Anthony Bewley, UK*

Psychotherapy and psoriasis
Anthony Bewley, UK

Making use of placebo effects in clinical care for the well-being of psoriasis patients: role of cognitive behavioral therapy
Andrea Evers Leiden, Netherlands

Support group sessions and functioning – an interactive workshop with advocates
Kathleen Gallant, US; Paul Mendoza, Phillipines;
Silvia Fernandez Barrio, Argentina

Live Q&A

Summary and highlights

FRIDAY, JULY 2

13.00-14.00 **Theme of the day: Access to care and management. Focus on unmet needs**

Session 5: Rapid access and early intervention
Chairs: *Colin Theng, Singapore; Hoseah Waweru, Kenya; Jörg Prinz, Germany*

Climate treatment in the Nordic region - Presentation white paper
Lars Werner, Denmark

Inflammatory disease – a new way of thinking
Jörg Prinz, Germany

The Psoriatic Disease Response Index: Measuring health systems' responses to psoriatic disease - Global Psoriasis Coalition
Elisa Martini, Sweden

Live Q&A

16.00-17.00 **Session 6: Focus on unmet needs. Taking global knowledge and implementation at national level**
Chairs: *Colin Theng, Singapore; Hoseah Waweru, Kenya; Cristina Echeverría, Argentina; Barbra Bohannan, Sweden*

Introduction – More than skin deep
Silvia Fernandez Barrio, Argentina

More than skin deep – Global psoriatic disease beyond survey
April Armstrong, US

Improving treatment and care at primary care setting -Learnings from Sweden
Barbra Bohannan, Sweden

National guidelines implementation – Latest therapeutic guidelines for the management of Psoriasis, Argentina
Cristina Echeverría, Argentina

Putting psoriasis into focus at a national level – unmet needs in Africa – Learnings from Kenya
Roop Saini, Kenya

Live Q&A

Summary and highlights

AMGEN®

AMGEN Medical-sponsored symposium at the virtual WPPAC 2021 Congress

THE PSORIATIC DISEASE SPECTRUM: THE DATA. THE CLINIC. THE PATIENT.

16:15–17:00 CEST, Wednesday 30 June 2021

AGENDA

16:15–16:17	Welcome and introduction	Diamant Thaçi
16:17–16:32	The dermatologist's perspective: How well can we understand our patients?	Diamant Thaçi
16:32–16:47	The rheumatologist's perspective: How to define and achieve treatment goals?	Kurt de Vlam
16:47–16:57	Panel discussion and Q&A	Diamant Thaçi and Kurt de Vlam
16:57–17:00	Summary and close	Kurt de Vlam

FACULTY


Diamant Thaçi


Kurt de Vlam

We look forward to welcoming you to this session.

This meeting is funded by Amgen Medical. Speakers are compensated by Amgen Medical.
SC-EU-apremilast-00150 | June 2021

AMGEN®

SATURDAY, JULY 3

13.00-14.00 **Session 7: International Psoriasis Council – On latest research and updates**
Chair: *Lone Skov, Denmark*

Welcome and introduction
Lone Skov, Denmark

IPC's disease severity classification: What it means in the clinic
Lone Skov, Denmark

The future of teledermatology
Alexander Navarini, Switzerland

Psoriasis and diet
Jo Lambert, Belgium

Live Q&A and closing comments

16.45-18.00 **IFPA 50th Anniversary and Awards**
Hoseah Waveru, IFPA President

INDUSTRY SPONSORED SATELLITE SYMPOSIA

WEDNESDAY, JUNE 30

13.10-13.55 **Where do we begin? The key role of the IL-23 pathway in psoriasis and psoriatic arthritis.**

Janssen Immunology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Audience: HCPs only

Welcome and introduction
Kilian Eyerich, Sweden

Where it all started
Kilian Eyerich, Sweden and Rik Lories, Belgium

The IL-23 pathway: navigating the latest updates in skin research
Kilian Eyerich, Sweden

Learnings from IL-23 pathway data in PsA
Rik Lories, Belgium

Summary and close
Rik Lories, Belgium

16.15-17.00 **The psoriatic disease spectrum: The data. The clinic. The patient.**

AMGEN®

Audience: HCPs only

Welcome and introduction
Diamant Thaçi, Germany

The dermatologist's perspective: How well can we understand our patients?
Diamant Thaçi, Germany

The rheumatologist's perspective: How to define and achieve treatment goals?
Kurt de Vlam, Belgium

Panel discussion and Q&A Live session
Diamant Thaçi and Kurt de Vlam

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Changing the Vision for Patients With Psoriatic Disease

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1 July 2021
9:00–9:45 CEST

Guest speakers:

Addressing the unmet needs of patients with psoriasis and psoriatic arthritis

Prof. Diamant Thaçi, MD

University Hospital Schleswig-Holstein
Campus Lübeck

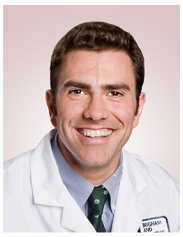
Comprehensive Center for Inflammation Medicine
University of Lübeck
Lübeck, Germany

Small molecules in drug development

Symposium Chair
Prof. Kilian Eyerich, MD, PhD

Karolinska Institute
Stockholm, Sweden

Technical University of Munich
Munich, Germany



Understanding the role of IL-23/TYK2/JAK/STAT pathways in psoriasis and psoriatic arthritis

Dr. Joseph F. Merola, MD, MMSc

Brigham and Women's Hospital
Harvard Medical School
Boston, Massachusetts, USA

Please join this Bristol Myers Squibb–sponsored symposium that will focus on the unmet needs of patients with psoriatic disease, drug development, and the role of IL-23/TYK2/JAK/STAT pathways in psoriasis and psoriatic arthritis. These expert presenters will engage in lively discussions about patients' needs, small-molecule drug development, and the downstream effects of cytokine signaling in psoriasis and psoriatic arthritis.

See you virtually at the 6th World Psoriasis & Psoriatic Arthritis Conference 2021!

Commit to clear:
Empowering a better patient journey

13:10–13:55 CET (Session 4)
01 July 2021
AbbVie symposium held at the 6th World Psoriasis and Psoriatic Arthritis Conference 2021 (virtual)

Join us at this AbbVie-sponsored session, where world-renowned dermatologist, Prof. Peter van der Kerkhof, will ask lifelong psoriasis sufferer, Lianne, the probing questions that we do not have time for in our everyday clinics:

- How do the physical and psychological effects of psoriasis materially impact the everyday activities and life-changing decisions of patients?
- How does the achievement of clear skin and experiences of healthcare provision alter the impact of disease?
- What can dermatologists do to better understand the patient journey and make an impact for the better?

We look forward to welcoming you at this symposium in July

abbvie

This meeting is organized and funded by AbbVie

Date of preparation: May 2021 | ALL-IMMD-210051

THURSDAY, JULY 1

09.00-09.45 **Changing the vision for patients with psoriatic disease.**

Bristol Myers Squibb™

Audience: HCPs only

Addressing the unmet needs of patients with psoriasis and psoriatic arthritis
Diamant Thaci, Germany

Small molecules in drug development
Kilian Eyerich, Sweden

Understanding the role of IL23/TYK2/JAK/STAT pathways in psoriasis and psoriatic arthritis
Joseph Merola, US

Achieving More for Patients with Psoriasis: Targeting Key Drivers of Disease

This session will discuss patients' needs and expectations, explore the impact of comorbidities on the burden of disease and provide an understanding of the pathophysiology of psoriasis

Friday, 2 July, 2021 | Time: 13:10 – 13:50 CEST

Faculty

Mona Ståhle (Chair)
Karolinska Institutet, Sweden

Lars Iversen
Aarhus University Hospital, Denmark

Diamant Thaçi
University Medical Center Schleswig-Holstein, Germany

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GL-N-DA-PSO-2100091 Date of preparation: May 2021

13.10-13.55 **Commit to clear: empowering a better patient journey.**

Audience: HCPs and non-HCPs

Chair/speaker: Peter van der Kerkhof (dermatologist), The Netherlands
Speaker: *Lianne Hunter* (patient)

Open and welcome
Peter van der Kerkhof

Perspectives on the patient journey
Peter van der Kerkhof and Lianne Hunter

The value of clear skin
Peter van der Kerkhof and Lianne Hunter

Barriers around healthcare provision
Peter van der Kerkhof and Lianne Hunter

Empowering a better patient journey
Peter van der Kerkhof and Lianne Hunter

Q&A with audience

Summary and close
Peter van der Kerkhof

16.15-17.00 **Advanced Therapeutic Options in PsA: A Multidisciplinary Team Approach**

Audience: HCPs only

Speakers: *Laura Coates, UK; Diamant Thaçi, Germany*

Discussion of the approaches and priorities dermatologists and rheumatologists consider when selecting advanced treatments for the personalised management of PsA

FRIDAY, JULY 2

13.10-13:55 **Achieving more for patients with psoriasis: targeting key drivers of disease.**

Audience: HCPs only

Chair: *Mona Ståhle, Sweden*

Speakers: *Mona Ståhle, Sweden; Diamant Thaçi, Germany; Lars Iversen, Denmark*

Welcome and Introduction from the Chairperson
Mona Ståhle

Treating to target: helping patients achieve more from their psoriasis treatment
Mona Ståhle

Not just psoriasis: the impact of comorbidities on patients' lives
Diamant Thaçi

The pathogenesis of psoriasis: what do we know about the key drivers of disease?
Lars Iversen

Close and Panel Discussion
All, moderated by Mona Ståhle

16.15-17.00 **One Disease, Two Perspectives: Generalized Pustular Psoriasis Through the Eyes of the Patient and the Dermatologist.**

Audience: HCPs only

Chair: *Alexander Navarini, Switzerland*

Speakers: *Joel Gelfand, US, Christine Jones* (a person living with GPP)

Welcome Message
Alexander Navarini

The Desire for Clear Skin: The Patient Perspective of a GPP Flare
Christine Jones (a person living with GPP)

The Desire to Reduce Mortality and Morbidity with Limited Options: The Dermatologist Perspective
Joel Gelfand

The Desire for New Options in GPP Treatment: IL-36 Inhibitors
Alexander Navarini (Switzerland)

Live Q&A Panel (excluding Christine Jones)

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INVITED SPEAKERS' ABSTRACTS

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6TH WORLD PSORIASIS & PSORIATIC ARTHRITIS CONFERENCE 2021

COMORBIDITY IN CHILDREN AND YOUNG ADULTS

Josefin Lysell1

1 Karolinska Institutet, Karolinska University Hospital

Abstract: Association with several comorbidities is established in the pediatric psoriasis population, althogh not as robust as in the adult population. After establishment of this risk for comorbidities, next level in caring for pediatric patients is to find, treat and when possible prevent development of comorbidities in the group of patients with early onset of disease. Early intervention with systemic treatment is a theoretical possibility to prevent development of comorbidities and data in the adult population is promising. However, many children and adolescents with psoriasis will develop mild psoriasis without comorbidities where systemic treatment might entail more risks and costs than benefits. The lack of clinical and biochemical biomarkers for who to treat more aggressively still leaves us with detecting and treating comorbidities when not possible to prevent. The presentation will focus on selected comorbidities in children and young adults, including PsA, obesity and psychological impact of disease, mainly quality of life aspects. What and how should we as dermatologists ask for and how can we help? For recent updates in the field selected pepers will be presented and commented on.

GUIDELINES IN PSA

Arthur Kavanaugh1

1 UCSD

Abstract: With recent progress in the approach to treatment of rheumatic diseases, many therapeutic approaches and agents have been introduced into the clinic. As a means of optimizing care for patients, guidelines for the treatment of patients with rheumatic diseases, including Psoriatic Arthritis (PsA) have been created. Societies involved in the creation of PsA guidelines include EULAR (European League Against Rheumatism), American College of Rheumatology / National Psoriasis Foundation (ACR/NPF), and GRAPPA (Group for Research and Assessment of Psoriasis and Psoriatic Arthritis). These guidelines aim to excerpt key data from the best available scientific evidence, to inform choices about therapy to patients with PsA and their providers.

OUTCOME MEASURES

Melissa Oliver[1]

1 Indiana University School of Medicine

Abstract: There is a lack of validated outcome measures for patients with pustular disease and related disorders including Synovitis, Acne, Pustulosis, Hyperostosis, Osteitis (SAPHO), and Chronic nonbacterial osteomyelitis (CNO). Some response criteria sets have been developed but these measures were not formed through a consensus-driven validated process and generally do not include input from patient and caregiver stakeholders on which items constitute the disease and are of major importance to them. An international research group under the guidance of the Outcome Measures in Rheumatology (OMERACT) initiative is currently working on the development of a core domain set for CNO and SAPHO. Additionally, at the recent first annual Consortium for Harmonizing Outcome Research in Dermatology (CHORD) conference, a group of physician experts and patient research partners discussed the need for reliable outcome measures for pustular psoriasis and associated syndromes. In this talk, we will briefly discuss the current measures being used for pustular disease and related disorders, the development of an outcome measure set through the OMERACT framework, and the preliminary results from the CNO/SAPHO OMERACT working group on candidate domain selection for CNO/SAPHO.

PATHOGENESIS OF PSORIATIC ARTHRITIS

Vinod Chandran1, 2

1 Faculty of Medicine, University of Toronto, Toronto, Canada
2 Schroeder Arthritis Institute, Krembil Research Institute, University Health Network, Toronto, Canada

Abstract: Psoriatic arthritis (PsA) is an inflammatory arthritis that most often occurs after the onset of cutaneous psoriasis. It is characterised by heterogeneous musculoskeletal features including synovitis, enthesitis and axial arthritis. There is a strong genetic predisposition to psoriatic disease; markers specifically associated with PsA have been identified in the HLA region on human chromosome 6. Musculoskeletal injury, obesity and infection have been identified as triggers for PsA in patients with psoriasis. Given the strong association with HLA class I alleles and Th17 immune response, a model for pathogenesis of PsA proposes that primed antigen-presenting cells at sites such as the skin or enthesis engage with innate lymphoid cells and naive T cells, leading to local clonal expansion of type 1 cells (T helper 1 (TH1) and type 1 CD8+ (Tc1) cells) and type 17 cells (TH17 and type 17 CD8+ (Tc17) cells). The interplay between the effector T cell subsets, stromal cells, and the cytokine milieu at the local sites determines disease features including enthesitis, synovitis, bone and cartilage loss as well as new bone formation in the axial and peripheral musculoskeletal system.

PSYCHOTHERAPY AND PSORIASIS

Anthony Bewley[1]

1 Consultant Dermatologist, Barts Health NHS Trust, London UK; Hon Professor QMUL, London, UK

Abstract: There is a significant prevalence of anxiety and depression in patients with psoriasis. Studies have shown that between 10-40% of individuals with psoriasis experience depression, with a 72% higher prevalence in those with more severe disease. Approximately 31% of patients experience symptoms anxiety. Psoriasis has been shown to cause greater psychological distress for patients than conditions such as cancer and heart disease. A study by Griffiths et al. in 2000 showed that 38% of psoriasis patients have features of pathological worry, and 25% fulfilled the criteria for generalised anxiety disorder. Interestingly, this seems to be irrespective of symptoms or their frequency. Anxiety appears to be related to concerns regarding societal beliefs, and worry that their own anxiety was the main cause of their psoriasis. In women, pathological worry appears to be more prevalent and is not always related to the degree of skin severity.

Cognitive behavioural therapy (CBT) is a psychological intervention that involves identifying and challenging unhelpful thoughts and behaviours, and learning competing coping mechanisms in order to break the negative cycle. It is well established that stress and distress are frequent exacerbators of psoriasis, but this recognition can also cause patient anxiety which can perpetuate a worsening of their physiological and psychological state. CBT aims to break this cycle. There is evidence that just 6 weeks of weekly CBT sessions combined with standard treatment, versus standard treatment alone, has a significant improvement in the clinical severity of the skin, and improves symptoms of anxiety, depression, stress and disability. In one study, these results persisted at the 6-month follow up, with 64% patients achieving a greater than 75% improvement in the clinical extent of their psoriasis, compared with 23% in the control group. Other evidence suggests that CBT is effective at improving anxiety levels but less effective at treating depression. Another study has shown that just seven psychotherapy sessions delivered over 12-weeks resulted in clinical improvement although the perception of stress remained similar. Promising results have also been demonstrated using an internet-based electronic CBT intervention, with an improvement in anxiety and quality of life.

RELEVANCE OF THE GUT MICROBIOME TO PSORIASIS.

Ignacio Dei-Cas1

1 H.I.G.A. Pte Perón. School of Medicine. Buenos Aires, Argentina (UBA).

Abstract: The Human Microbiome Project created a new view of ourselves as 'super-organisms' consisting of a human host and up to 100 trillion bacteria and microbial symbionts, with around 3.3 million microbial genes.

Imbalance of gut microbial populations or dysbiosis has important functional consequences and has been implicated in many digestive diseases, diabetes, obesity, psoriatic arthritis, celiac disease, psychiatric disorders, severe COVID-19 disease, and others.

Bowel mucosa of active psoriasis patients without bowel symptoms shows microscopic lesions with immune cellular infiltrates capable of producing pro-inflammatory cytokines. Bacterial DNA translocation from the intestinal lumen has been described in patients with psoriasis suggesting that the gut microbiota may potentially act in skin diseases.

Adhesion of specific members of gut the microbiota to intestinal epithelial cells is found to be essential for the induction of Th17 cells. In the process of non-digestible carbohydrates fermentation, bacteria inhabiting our intestines produce short-chain fatty acids (SCFA) and their metabolites influence T-cell differentiation with an increase in Treg-cells. Bacteria in the gut can produce many types of neurotransmitters, which regulate the function of immune cells via the nervous system, and this cross-talk may be implicated in the relationship between mental health disorders and psoriasis. Mice exposed to antibiotics showed inhibition of psoriasis induction by a dysregulation of the gut and skin microbiota.

Only limited studies of gut microbiota have been conducted in psoriasis patients which showed contradicting results. These studies involved relatively small numbers of subjects, the use of different molecular biology techniques, and unmatched study designs. Almost all studies demonstrated that gut microbiota in psoriasis shows differences compared to healthy controls. Most relevant findings were an elevated Firmicutes/Bacteroidetes ratio in psoriasis patients, similar to some comorbid diseases associated with psoriasis. At the genus level, an increase in the abundance of *Faecalibacterium*, *Blautia*, *Ruminococcus* and *Collinsella,* and a decrease in *Paraprevotella* in psoriatic patients, were reported in more than 1 study. In general, the biodiversity of the gut microbiota in psoriatic patients was decreased, with lower biodiversity in moderate-to-severe patients compared to mild-psoriatic patients. Gut microbiota changes have also been found after successful treatment with secukinumab in psoriatic patients. Probiotics administration in psoriasis showed benefits, with significant reduction in PASI score and lower risk of relapse at 6 months of follow up. Fecal microbial transplant from healthy individuals may help restore microbiota composition in psoriasis patients.

Current data support the idea that gut microbiota may be implicated in psoriasis pathogenesis.

RHEUMATOLOGICAL MANIFESTATIONS OF SAPHO

Philip Helliwell1

1 University of Leeds, UK

Abstract: The syndrome of synovitis, acne, pustulosis, hyperostosis and osteomyelitis (SAPHO) is rare in rheumatological practice generally with higher frequencies in Japan and North Africa. Most patients have anterior chest wall pain due to osteitis of the bones of the anterior chest and inner third of the clavicle, and synovitis of the sterno-clavicular and manubrio-sternal joints. Others may show peripheral arthritis and spondyloarthritis. Sterile osteomyelitis, and chronic recurrent multifocal osteomyelitis (CRMO) may be prominent in some patients, particularly in the paediatric population. The Khan criteria are most often applied to this group but they are in need of an update. Treatment is still empirical and consists of NSAIDs, colchicine, csDMARDs and biologic drugs.

ORAL & POSTER
ABSTRACTS

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ORAL

1. BIOMARKERS AND IMAGING

O1 - Identification of serum protein biomarkers at baseline to distinguish radiographic progressors from non-progressors in patients with active Psoriatic Arthritis (PsA).

1. Biomarkers and imaging

Orla Coleman[1]
Bruna Wundervald[1, 2], Ruoyi Zhou[1], James C. Waddington[1], Robert L.J. Graham[3], Ciaren Graham[3], Geoff McMullan[3], Andrew C. Parnell[2], Vinod Chandran[4], Philip J. Mease[5], Stephen R. Pennington[1, 6], Oliver FitzGerald[6]
[1] Atturos Ltd, Conway Institute, University College Dublin, Ireland.
[2] Hamilton Institute, Insight Centre for Data Analytics, Maynooth University, Kildare, Ireland.
[3] School of Biological Sciences, Queen's University Belfast, Chlorine Gardens, Belfast, BT9 5DL, UK.
[4] Schroeder Arthritis Institute, Krembil Research Institute, University Health Network & Departments of Medicine and Laboratory Medicine and Pathobiology, University of Toronto, Toronto, Canada.
[5] Swedish Medical Center/Providence St. Joseph Health and University of Washington, Seattle, WA, USA
[6] Conway Institute of Biomolecular & Biomedical research, University College Dublin, Ireland.

Introduction: A delay in diagnosis and management of patients with PsA leads to poor radiographic and functional outcomes [1]. The need to identify which patients might progress radiographically has been recognised by the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) as a key area of unmet need within PsA [2]. It is anticipated that biomarkers for radiographic joint damage will help in patient stratification so that those with greater likelihood of poor outcome may be treated more aggressively. The SPIRIT-P1 Phase 3 randomized controlled trial (RCT) of ixekizumab, a high-affinity IL-17A antagonist, in active PsA patients resulted in reduced progression of structural damage [3] however 5-10% of patients who did progress would suitably benefit from more aggressive treatment if identified using biomarkers at the outset.
Objectives: The aim of this study was to use mass spectrometry-based proteomics to identify protein biomarkers which might distinguish at baseline those patients who progress to joint damage from those who did not.
Methods: Baseline serum samples from 83 PsA patients (28 progressors and 55 non-progressors) were obtained from the SPIRIT-P1 RCT. Radiographic progressors were defined as those who showed a >0.5 change from baseline modified total Sharp score (mTSS) at week 24 or 52. Two proteomic analyses were performed: 1) targeted analysis of in-house panel (PAPRICA) of 206 proteins originally developed to distinguish between arthropathies and 2) unbiased discovery using LC-MS/MS of the 83 baseline samples. Univariate and multivariable machine learning random forest modelling (RFM) statistics were performed on the two proteomic datasets.
Results: On univariate analysis, targeted proteomics identified 4 differentially expressed (DE) candidate peptides ($p<0.01$) and RFM revealed the top 15 candidate peptides which distinguish progressors from non-progressors with a ROC AUC of 0.85 [95% CI 0.82 to 0.88]). Unbiased proteomics resulted in the identification of 74 peptides which were significantly DE ($p<0.01$). RFM identified the 15 peptides, distinct from those identified by targeted analysis and which could distinguish non-progressors from progressors with a ROC AUC of 0.94 [95% CI 0.88 to 0.99].
Conclusions: Using two complimentary proteomic approaches and a combination of univariate and machine learning statistical analysis, 103 biomarker peptides corresponding to 69 proteins that can potentially discriminate PsA patients who progress to radiographic damage from those who do not have been identified. In future studies, these candidate protein biomarkers will be subjected to further evaluation.

References: [1] V Ocampo *et al*. “Psoriatic arthritis” *F1000Research*.2019
[2] CT Ritchlin *et al.* “Biomarkers in psoriasis and psoriatic arthritis GRAPPA 2008” *J.Rheumatol*.2010
[3] PJ Mease *et al.* “Ixekizumab, an interleukin-17A specific monoclonal antibody, for the treatment of biologic-naïve patients with active psoriatic arthritis: Results from the 24-week SPIRIT-P1” *Ann.Rheum.Dis*.2017

This study is funded and supported by Eli Lilly and Company

Lilly Corporate Center #1534, Indianapolis, IN, 46285 USA.

3. COMORBIDITIES

O2 - Immune checkpoint inhibitors in patients with preexisting psoriasis associated with manageable disease exacerbations and excellent tumor outcomes

3. Comorbidities

Briana Halle[1]
Allison Warner[2], Farzana Zaman[3], Andrew Haydon[3], Prachi Bhave[4], Matteo Carlino[4], Anna Dewan[5], Fei Ye[6], Rebecca Irlmeier[6], Paras Mehta[2], Nicholas Kurtansky[2], Jessica Hassel[7], Jacob Choi[8], Sunandana Chandra[8], Tracey Otto[9], Meghan Mooradian[9], Florentia Dimitriou[10], Alexander Menzies[10], Douglas Johnson[11], Veronica Rotemberg[2]
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[11] Vanderbilt University Medical Center, Division of Hematology/Oncology, USA

Introduction: Immune checkpoint inhibitors (ICIs) are approved to treat multiple cancers. Retrospective analyses demonstrate acceptable safety of ICIs in patients with autoimmune disease, although disease exacerbations may occur. Psoriasis vulgaris is a common, immune-mediated disease, and outcomes of ICI treatment in patients with psoriasis are not well-described.
Objectives: The goal of this study is to further define the safety profile and effectiveness of ICIs with preexisting psoriasis.
Methods: In this retrospective, cohort study, patients with preexisting psoriasis who received ICI treatment for cancer were evaluated from 8 academic centers. Main safety outcomes were psoriasis exacerbations and immune-related adverse events (irAEs), graded based on Common Adverse Criteria for Adverse Events, version 5.0. Measures of ICI effectiveness included progression-free survival (PFS) and overall survival (OS).
Results: Of 76 patients studied (50 [66%] male; median age, 67 years), 51 patients (67%) received anti-PD-1/anti-PD-L1 antibodies, 8 (11%) anti-CTLA-4 antibodies, and 17 (22%) combination PD-1/CTLA-4 blockade. All patients had preexisting psoriasis, most frequently plaque psoriasis (46 patients [61%]); 15 (20%) had psoriatic arthritis. Forty-one patients (54%) had received prior therapy for psoriasis although only 2 (3%) were on active immunosuppression at ICI initiation. With ICI treatment, 43 patients (57%) experienced a psoriasis flare of cutaneous or extracutaneous disease. Median time from ICI start to psoriasis flare was 44 days. Of those that experienced a flare, 23 patients (53% of those who flared) were managed with topical therapy only. Other treatments included acitretin in 5 patients, biologics in 4, methotrexate in 1, and prednisone in 10. Only 5 patients (7%) required immunotherapy discontinuation for psoriasis flare. PFS and OS were significantly longer in patients with a psoriasis flare versus without a flare (median PFS 39 vs. 5.5 months, p=0.034; median OS not reached vs. 29.3 months, p=0.045, respectively), although longer time on therapy was associated with presence of psoriasis flare (p=0.035).
Conclusions: In this multicenter study, ICI therapy was associated with exacerbations of preexisting psoriasis, although the majority of flares were manageable with topical treatment and few patients required ICI discontinuation. Furthermore, presence of psoriasis flare was associated with improved PFS and OS, demonstrating excellent tumor outcomes.

References: Vaddepally RK, Kharel P, Pandey R, Garje R, Chandra AB. Review of Indications of FDA-Approved Immune Checkpoint Inhibitors per NCCN Guidelines with the Level of Evidence. *Cancers (Basel)*. 2020;12(3).

Johnson DB, Sullivan RJ, Ott PA, et al. Ipilimumab Therapy in Patients With Advanced Melanoma and Preexisting Autoimmune Disorders. *JAMA Oncol*. 2016;2(2):234-240.

De Bock M, Hulstaert E, Kruse V, Brochez L. Psoriasis Vulgaris Exacerbation during Treatment with a PD-1 Checkpoint Inhibitor: Case Report and Literature Review. *CDE*. 2018;10(2):190-197.

4. CURRENT AND NEW THERAPEUTIC MODALITIES

O3 - Effisayil 1: A multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of spesolimab in patients with a generalized pustular psoriasis flare

4. Current and new therapeutic modalities

Hervé Bachelez[1, 2]
Siew Eng Choon[3], Slaheddine Marrakchi[4], David Burden[5], Tsen-Fang Tsai[6], Akimichi Morita[7], Alexander A. Navarini[8], Min Zheng[9], Jinhua Xu[10], Hamida Turki[4], Milan J. Anadkat[11], Sushmita Rajeswari[12], Hairui Hua[13], Sebastian D. Vulcu[14], David Hall[12], Kay Tetzlaff[14, 15], Christian Thoma[16], **Mark Lebwohl**[17]
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Introduction: IL-36 is central to the pathogenesis of generalized pustular psoriasis (GPP),[1] a rare, potentially life-threatening autoinflammatory disease characterized by widespread recurrent flares of sterile pustules on the skin that occur with or without systemic inflammation.[2,3] Currently, there are no approved therapies for GPP flares in the USA or Europe. In a Phase I, open-label study, a single intravenous dose of spesolimab, an anti-IL-36 receptor antibody, resulted in rapid pustule clearance in patients with GPP.[4]

Objectives:

1. To report the efficacy of spesolimab from the first placebo-controlled trial in patients with a GPP flare
2. To assess the safety and tolerability of spesolimab in patients with a GPP flare

Methods: Effisayil 1 (NCT03782792) is a 12-week, double-blind, randomized, placebo-controlled Phase II study in patients with a GPP flare. In total, 53 patients were randomized 2:1 to receive a single 900 mg intravenous dose of spesolimab or placebo. The primary endpoint was a GPP Physician Global Assessment (GPPGA) pustulation subscore of 0 (pustule clearance) at Week 1. The key secondary endpoint was a GPPGA score of 0/1 (clear/almost clear) at Week 1. Other secondary endpoints at Week 4 included a 75% improvement in the Generalized Pustular Psoriasis Area and

Severity Index (GPPASI) and patient-reported outcomes such as pain visual analog scale (VAS). Safety endpoints included the occurrence of treatment-emergent adverse events and serious adverse events.

Results: A GPPGA pustulation subscore of 0 at Week 1 was achieved by 54.3% of patients (19/35) receiving spesolimab versus 5.6% (1/18) receiving placebo (one-sided p=0.0004; Figure 1A). These results were sustained throughout the 12-week study. A GPPGA score of 0/1 at Week 1 was achieved by 42.9% of patients (15/35) receiving spesolimab versus 11.1% (2/18) receiving placebo (one-sided p=0.012; Figure 1B). At Week 4, 45.7% of patients (16/35) receiving spesolimab achieved 75% improvement in GPPASI versus 11.1% (2/18) receiving placebo (risk difference 34.6 [95% confidence interval 5.8–55.4]; one-sided p=0.008). Patients receiving spesolimab reported greater reductions in pain VAS (p=0.001) at Week 4 versus patients receiving placebo. Overall, most adverse events were mild to moderate and similar between both study arms. Non-serious infections rates were higher in the spesolimab group, 34.3% (12/35) compared with the placebo group 5.6% (1/18), with no patterns in pathogen or affected organs.

Conclusions: To date, this is the largest clinical trial and first randomized, placebo-controlled trial in patients with GPP. IL-36 receptor inhibition with spesolimab demonstrated unprecedented rapid improvements in signs and symptoms of GPP flares versus placebo, with sustained effects and a favorable benefit–risk profile.

References:

1. Gooderham MJ, et al. *Expert Rev Clin Immunol* 2019;15:907–919.
2. Navarini AA, et al. *J Eur Acad Dermatol Venereol* 2017;31:1792–1799.
3. Ryan TJ and Baker H. *Br J Dermatol* 1971;85:407–411.
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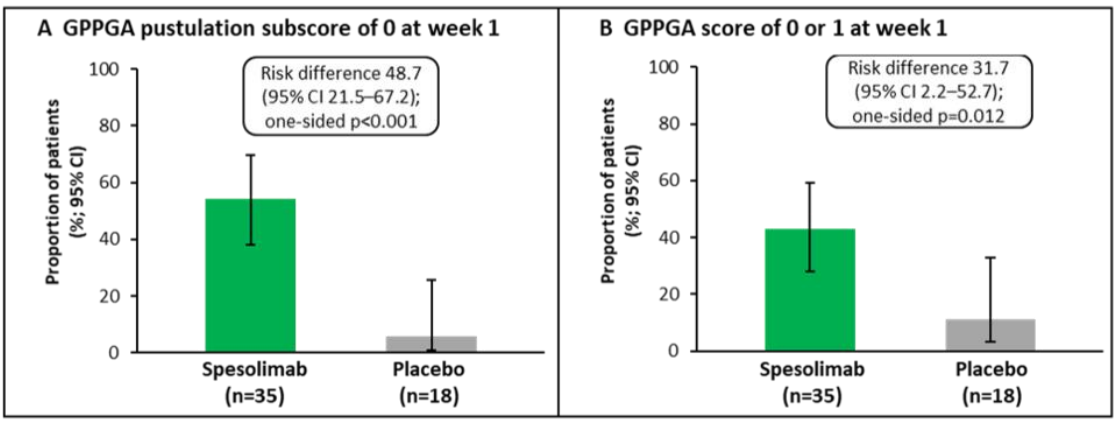
Figure 1. Primary (A) and key secondary (B) endpoints



CI, confidence interval; GPPGA, Generalized Pustular Psoriasis Physician Global Assessment.

5. EPIDEMIOLOGY

O4 - Psoriasis and Psoriatic Arthritis in Transgender Patients on Hormone Therapy: A Retrospective Comparative Cohort Study

5. Epidemiology

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Introduction: The current state of transgender dermatologic literature is limited, and no data exists on the prevalence of psoriasis and psoriatic arthritis in the transgender/gender diverse (TGD) populations.
Objectives: To determine the prevalence of psoriasis and psoriatic arthritis among TGD patients on gender-affirming hormone therapy (GAHT) compared to cisgender patients.
Methods: We conducted a retrospective comparative cohort study via electronic health records of TGD adults on masculinizing or feminizing hormone therapy (MHT, FHT) and cisgender adults seen at Fenway Health between August 1, 2014 and August 1, 2020. Outcomes were identified via International Statistical Classification of Diseases, 9th/10th Revisions, Clinical-Modification (ICD-9-CM, ICD-10-CM) codes for psoriasis (696.1, 696.8, L40.0-L40.4, L40.8-L40.9) and psoriatic arthritis (696.0 and/or L40.50).[1] Odds ratios (OR) and 95% confidence intervals (95% CI) were used to compare the risk of disease for TGD patients on GAHT to cisgender patients.
Results: The sample (n = 46,534) included 1,394 patients on feminizing GAHT, 1,576 patients on masculinizing GAHT, 25,605 cisgender men 16,977 cisgender women, 535 transmasculine patients not on GAHT, and 447 transfeminine patients not on GAHT (Table 1). Of the cisgender patients, 24,896 cisgender men and 11,178 cisgender women were not receiving exogenous hormone therapy (e.g. testosterone replacement, hormonal birth control, menopausal hormone replacement therapy).

Patients on feminizing GAHT were significantly less likely to have psoriasis compared to all cisgender men (OR: 0.59 (95% CI: 0.33, 0.96), p = 0.0339) or when compared to cisgender men not receiving exogenous hormone therapy (OR: 0.59 (95% CI: 0.34, 0.98), p = 0.0388). Patients on masculinizing GAHT were not at a significantly higher risk of having psoriasis compared to all cisgender women (OR: 1.04 (95% CI: 0.59, 1.72)).

We did not find a significant difference in risk of psoriatic arthritis between patients on feminizing GAHT compared to all cisgender men (OR: 1.35 (95% CI: 0.15, 5.74)) nor between patients on masculinizing GAHT compared to all cisgender women (OR: 1.35 (95% CI: 0.15, 5.74)).
Conclusions: Feminizing GAHT may decrease the risk of psoriasis, but not psoriatic arthritis, in transfeminine patients. Masculinizing GAHT had no significant impact the risk of developing psoriasis or psoriatic arthritis.

References:

1. Loft, N.D., et al., *Validation of psoriasis diagnoses in the Danish national patient register*. Acta dermato-venereologica, 2019. **99**(11-12): p. 1037-1038.

Table 1. Summary of patient characteristics.

Patient population	N	Median age (IQR*) (in years)	Race			Diagnosed with psoriasis	Diagnosed with psoriatic arthritis
			White	Racial minority	Race unknown		
Transfeminine on feminizing GAHT§	1,394	25 (IQR 21-32)	1,014 (72.7%)	278 (19.9%)	102 (7.3%)	16	2
Transmasculine on masculinizing GAHT	1,576	23 (IQR 20-28)	1,205 (76.5%)	301 (19.1%)	70 (4.44%)	17	2
Cisgender men	25,605	30 (IQR 24-44)	17,482 (68.3%)	5,798 (22.6%)	2,325 (9.1%)	498	48
Cisgender women	16,977	25 (IQR 21-32)	10,566 (62.2%)	4,953 (29.2%)	1,458 (8.6%)	176	16
Transmasculine not receiving GAHT	535	23 (IQR 20-27)	398 (74.4%)	123 (23.0%)	14 (2.6%)	3	0
Transfeminine not receiving GAHT	447	25 (IQR 21-35)	319 (71.4%)	92 (20.6%)	36 (8.1%)	3	0

*IQR = interquartile range
§GAHT = gender-affirming hormone therapy

10. PSORIASIS AND PSORIATIC ARTHRITIS RELATIONSHIP

O5 - Changes in Patient Perceptions of Psoriatic Arthritis From 2012 to 2020: Results From the UPLIFT Survey

10. Psoriasis and Psoriatic Arthritis relationship

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Introduction: Patients with psoriatic arthritis (PsA) experience a wide range of disease burden and comorbidities that negatively impact quality of life (QoL). The 2012 Multinational Assessment of Psoriasis and Psoriatic Arthritis (MAPP) survey assessed the impact of psoriasis and PsA on patients and provided valuable patient- and physician-reported information on QoL and unmet treatment needs. MAPP results showed a high disease burden and significant impact of PsA on physical function and need for improved treatment. As the therapeutic landscape has evolved since the MAPP survey, the Understanding Psoriatic Disease Leveraging Insights for Treatment (UPLIFT) survey was conducted to evaluate how patient perceptions and behaviors may have changed since MAPP and identify persisting areas of unmet need.
Objectives: Examine PsA treatment characteristics and patient-reported disease burden of patients surveyed in UPLIFT and MAPP.
Methods: UPLIFT was a multinational online survey conducted from March 2 to June 3, 2020 in the USA, Canada, UK, France, Germany, Italy, Spain, and Japan. The MAPP survey was conducted in the same countries, except Japan. Consistent with the MAPP telephone survey, the UPLIFT patient survey included adults with self-reported, healthcare provider (HCP)-diagnosed psoriasis and/or PsA. We report demographic, disease activity, disease burden, and treatment data from patients with PsA with or without comorbid psoriasis in both surveys. UPLIFT disease characteristics, such as patient-rated PsA severity (1 [very mild] to 10 [very severe]), enthesitis, dactylitis, pattern of joint involvement (oligoarticular/polyarticular), and other comorbidities, were also evaluated and presented with results from the MAPP survey.
Results: Of 1256 patients with PsA with or without psoriasis surveyed, the UPLIFT population was younger (mean age: 43 vs 56 years), included more men (54% vs 40%), and was less obese (20% vs 36%) than the MAPP population. The proportion of patients with dactylitis was similar in UPLIFT and MAPP, as was the proportion of patients reporting oligoarticular PsA, which was common in both populations (Table). A greater prevalence of comorbidities and enthesitis was observed in UPLIFT (Table). A considerable decrease in the number of untreated patients was observed in UPLIFT vs MAPP (17% vs 28%) (Table). However, fewer patients reported seeing an HCP in the past year in UPLIFT than in MAPP (Table). Although 78% of UPLIFT patients were receiving some form of PsA treatment, nearly 75% characterized their PsA as moderate or severe (vs 88% in MAPP; Table).
Conclusions: While a greater proportion of patients in the 2020 UPLIFT survey received current treatment than in the 2012 MAPP survey, there remains a substantial proportion of patients reporting their disease as moderate or severe. These results suggest that, although the number of available treatment options has increased since MAPP, an unmet need for PsA patient care remains.

Patient Demographics and Clinical Characteristics

Characteristic, %	MAPP N=712	UPLIFT N=1256
Enthesitis	31	43
Dactylitis	45	46
Joint count*		
>4 joints (polyarthritis)	60	56
≤4 joints (oligoarthritis)	40	44
Patient-perceived severity†		
Mild (1-3)	12	26
Moderate to severe (4-10)	88	74
Seen an HCP in past year‡		
Yes	83	50§
Comorbidities		
Cancer	7	29
Depression	28	40
Diabetes	18	35
Heart disease	15	22
Hypertension	41	42
Inflammatory bowel disease§	8	24
Current treatment		
No treatment‖	28	17
Topical only¶	31	8
Oral#	19	30
Biologic**	14	17
Oral and biologic††	8	24
Other‡‡	–	5

The N represents the total sample; the number of patients with data available may vary. *Percentage of patients reporting joint involvement. †Scale used in MAPP: 1-3=mild, 4-7=moderate, 8-10=severe. Scale used for UPLIFT: 1-3=mild, 4-6=moderate, 7-10=severe. ‡COVID-19 restrictions may have impacted a patient's ability to have an HCP visit from March 2 to June 3. §UPLIFT patients responded to questions on inflammatory bowel disease; MAPP patients responded to questions on Crohn's disease or ulcerative colitis. ‖MAPP: no Rx, UPLIFT: no treatment other than oral OTC or topical OTC. ¶MAPP: topical only, UPLIFT: topical Rx only. #MAPP: oral ± topical, UPLIFT: oral Rx ± topical Rx. **MAPP: biologic ± topical, UPLIFT: biologic ± topical Rx. ††MAPP: oral + biologic, UPLIFT: oral Rx + biologic ± topical Rx. ‡‡MAPP: patients were not asked about phototherapy use, UPLIFT: other only or phototherapy ± other. OTC=over the counter; Rx=prescription.

O6 - Deucravacitinib, an Oral, Selective Tyrosine Kinase 2 (TYK2) Inhibitor, Compared With Placebo and Apremilast in Moderate to Severe Plaque Psoriasis: Efficacy and Safety Results From the Phase 3 POETYK PSO-1 and POETYK PSO-2 Trials

10. Psoriasis and Psoriatic Arthritis relationship

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Introduction: TYK2 is an intracellular kinase that mediates interleukin (IL)-23, IL-12, and Type 1 interferon signaling in psoriasis pathogenesis. Deucravacitinib (DEUC) is a novel, oral, selective inhibitor that acts via binding to the unique TYK2 regulatory domain.[1] DEUC was efficacious and well tolerated vs placebo (PBO) in Phase 2 trials of moderate to severe plaque psoriasis or active psoriatic arthritis.[2,3]
Objectives: To compare the efficacy and safety of DEUC vs PBO and apremilast (APR) in 2 Phase 3 trials of plaque psoriasis.
Methods: Two double-blinded, 52-week trials (POETYK PSO-1, NCT03624127; POETYK PSO-2, NCT03611751) randomized patients (1:2:1) with moderate to severe plaque psoriasis (BSA ≥10%, PASI ≥12, sPGA ≥3) to PBO, DEUC 6 mg once daily, or APR 30 mg twice daily. Patients receiving PBO switched to DEUC at Week 16 and patients receiving APR who failed to meet trial-specific efficacy thresholds (PASI 50 in PSO-1; PASI 75 in PSO-2) switched to DEUC at Week 24. Coprimary endpoints were PASI 75 and sPGA 0/1 response vs PBO at Week 16. Key secondary endpoints included superiority vs PBO and APR, assessed via multiple measures.
Results: 666 and 1020 patients were randomized in PSO-1 and PSO-2, respectively. Demographic and baseline disease characteristics were balanced across groups. The coprimary endpoints in each trial were achieved; additionally, statistical significance was met for DEUC vs PBO and APR for multiple ranked secondary endpoints. Significantly greater proportions of patients in the DEUC vs PBO and APR arms achieved PASI 75 (PSO-1: $P<0.0001$; PSO-2: $P\leq0.0003$) and sPGA 0/1 (both trials: $P<0.0001$) responses at Week 16. DEUC responses increased beyond Week 16 and were also superior to APR at Week 24 in both trials ($P<0.0001$ for all comparisons; **Figure**). In both trials, more than 80% of DEUC patients who achieved PASI 75 at Week 24 and continued treatment maintained PASI 75 response at Week 52. In PSO-2, median time to loss of PASI 75 response was 85 days after DEUC withdrawal at Week 24. During the 16-week, PBO-controlled periods, the most common AEs (≥5% in any arm [pooled safety data]) were nasopharyngitis (8.6% [PBO]/9.0% [DEUC]/ 8.8% [APR]), upper respiratory tract infection (4.1%/5.5%/4.0%), headache (4.5%/4.5%/10.7%), diarrhea

(6.0%/4.4%/11.8%), and nausea (1.7%/1.7%/10.0%). Overall AEs, SAEs, and AEs leading to discontinuation were similar across the 3 groups. No clinically meaningful changes were observed in laboratory parameters during the 2 trials.

Conclusions: DEUC was superior to PBO and APR across multiple efficacy endpoints and was well tolerated in patients with plaque psoriasis in the Phase 3 POETYK PSO-1 and PSO-2 trials. These efficacy and safety results are consistent with the mechanism of action of DEUC, a selective TYK2 inhibitor.[1]

References:

1. Burke JR et al. *Sci Transl Med.* 2019;11:1-16.
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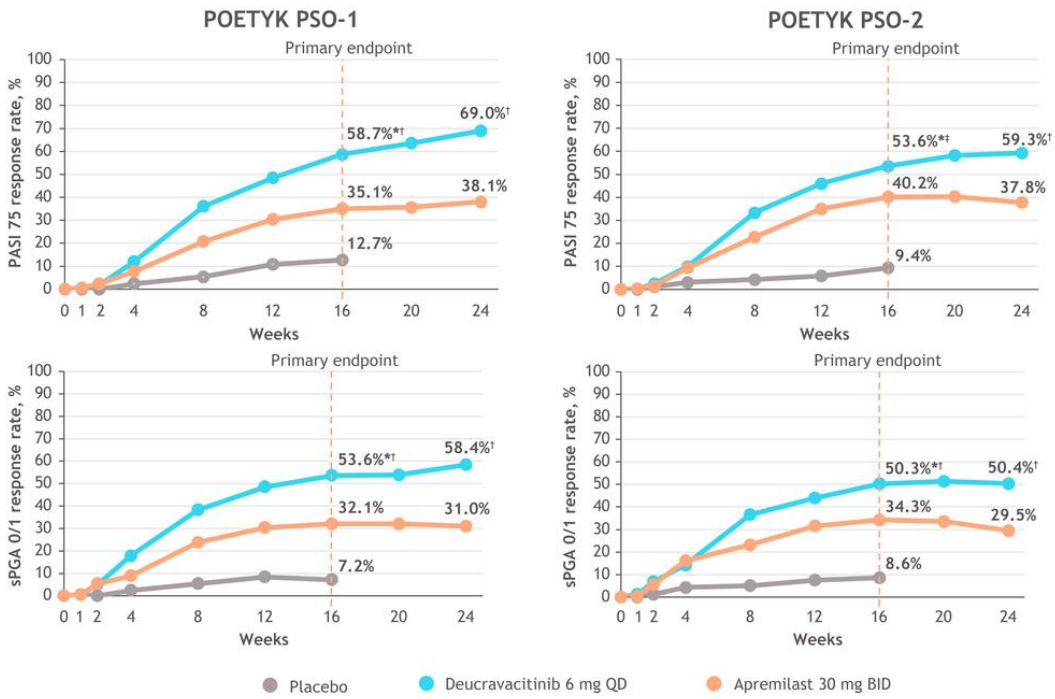
Figure. Coprimary endpoint efficacy responses (NRI)



PASI 75: *P<0.0001 vs placebo; †P<0.0001 vs apremilast; ‡P=0.0003 vs apremilast. sPGA 0/1: *P<0.0001 vs placebo; †P<0.0001 vs apremilast.
NRI, nonresponder imputation; PASI, Psoriasis Area Severity Index; sPGA, static Physician's Global Assessment.

POSTER

1. BIOMARKERS AND IMAGING

P1 - Atherogenic Index of Plasma as a predictor of carotid plaque in Psoriatic Arthritis patients

1. Biomarkers and imaging

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Introduction: It is well accepted that patients with psoriasis and psoriatic arthritis (PsA), are at an increased risk of cardiovascular disease (CVD). An ultrasound (US) scan of the common carotid artery wall can identify areas of increased thickness and non-occlusive atherosclerotic plaques, which represent subclinical markers of CVD.[1] The atherogenic index of plasma (AIP) is a logarithmically transformed ratio of triglycerides (TG) and high-density lipoprotein cholesterol (HDL-c), that has become a useful predictor of CVD risk. [2]
Objectives: To determine the association of subclinical atherosclerosis detected by carotid US and the AIP in PsA patients.
Methods: Cross-sectional, observational, and comparative study. A total of sixty-four patients from 30 to 80 years who fulfilled the 2006 international Classification of Psoriatic Arthritis criteria (CASPAR) were included. Those with a previous history of atherosclerotic CVD (myocardial infarction, stroke, or peripheral artery disease), diagnosis of any other connective tissue disease, chronic kidney disease, overlap syndrome, and pregnancy were excluded. A high-resolution B-mode carotid US was performed in all patients to evaluate the presence of carotid plaque (CP), which was defined as a carotid intima media thickness ≥1.2mm or a focal narrowing ≥0.5mm of the surrounding lumen. Patients were divided into two groups according to CP presence, 31 patients with CP and 34 patients without CP. A blood sample was obtained to measure HDL-c and TG. The AIP was calculated by using logarithm with base 10 of ratio TG to HDL-c. Distribution was evaluated with the Kolmogorov-Smirnov test. Comparisons were done with $\chi 2$ test for qualitative variables and Student's t test and Mann-Whitney's U test for quantitative variables. A p-value <0.05 was considered statistically significant.
Results: Demographic and clinical characteristics are shown in Table 1. There were no differences found in the demographic characteristics between both groups. Type 2 diabetes mellitus (T2DM) was more prevalent in patients with CP 35.5% vs 12.1%, p= 0.02. Patients with CP showed higher AIP values than patients without CP (0.59 ± 0.34 vs 0.38 ± 0.25 respectively, p=0.005).
Conclusions: Patients with PsA and CP have a higher AIP than patients without CP. These findings suggest that the AIP could be a useful marker to predict the presence of subclinical atherosclerosis in PsA patients.
References:

1. Martínez-Vidal MP, Andrés M, Jovaní V, Santos-Ramírez C, Romera C, Fernández-Carballido C. Role of carotid ultrasound and Systematic Coronary Risk Evaluation charts for the cardiovascular risk stratification of patients with psoriatic arthritis. J Rheumatol. 2020;47(5):682–9.

2. Fernández-Macías JC, Ochoa-Martínez AC, Varela-Silva JA, Pérez-Maldonado IN. Índice aterogénico del plasma: nuevo biomarcador predictivo de enfermedades cardiovasculares. Arch Med Res. 2019; 50 (5): 285–94.

Table 1. Demographic and clinical characteristics in psoriatic arthritis patients.

	PsA patients with CP (n=3)	PsA patients without CP (n=3)	*p*
Age years, mean ± SD	56.35 ± 11.88	54.30 ± 7.29	NS
Women, n (%)	14 (45.2)	21 (63.6)	NS
T2DM, n (%)	11 (35.5)	4 (12.1)	**0.027**
HTN, n (%)	13 (41.9)	14 (42.4)	NS
Dyslipidemia, n (%)	17 (54.8)	11 (33.3)	NS
Obesity, n (%)	10 (32.3)	14 (42.4)	NS
Active smoking, n (%)	5 (16.1)	8 (24.2)	NS
BMI kg/m^2, mean ± DE	29.16 ± 5.08	29.75 ± 6.64	NS
Disease duration years, median (p25-p75)	6.0 (3.0-10.0)	5.0 (3.0-8.0)	NS
DAPSA, median (p25-p75)	15.84 ± 15.61	17.06 ± 13.47	NS
MTX, n (%)	23 (74.2)	20 (60.6)	NS
bDMARD, n (%)	13 (41.9)	13 (39.4)	NS
Lipid Profile			
TC, mean ± SD	181.83 ± 40.27	178.66 ± 30.04	NS
LDL-C, mean ± SD	92.08 ± 35.99	99.51 ± 30.97	NS
TG, mean ± SD	204.92 ± 135.83	136.4 ± 64.74	**0.012**
HDL-C, median (p25-p75)	44.30 (31.40-52.10)	48.50 (42.05-54.60)	NS
AIP, mean ± SD	0.59 ± 0.34	0.38 ± 0.25	**0.005**

PsA, psoriatic arthritis; CP, carotid plaque; SD standard deviation; NS, not significant; T2DM, type 2 diabetes mellitus; HTN, hypertension; BMI, body mass index; DAPSA, disease activity score for psoriatic arthritis; MTX, methotrexate; bDMARD, biological disease modifying antirheumatic drugs; TC total cholesterol; LDL-C, low density lipoprotein cholesterol; TG, triglycerides; HDL-C, high density lipoprotein cholesterol; AIP, atherogenic index of plasma.

P2 - Effect of systemic methotrexate monotherapy on surrogate markers of cardiovascular risk in psoriasis

1. Biomarkers and imaging

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Introduction: The concept of "psoriatic march" implicates systemic inflammation, leading to oxidative stress and insulin resistance, resulting in endothelial dysfunction, the major causative factor in increased cardiovascular co-morbidity in psoriatic patients. There are conflicting reports regarding the effect of methotrexate on the risk of cardiovascular events among patients with psoriasis.
Objectives: This study was undertaken to assess the effect of methotrexate-monotherapy on surrogate markers of cardiovascular risk among patients with psoriasis.
Methods: Cases included 87 patients of moderate to severe psoriasis and controls included 87 age and gender-matched healthy volunteers. Cases were followed up after 12 weeks of methotrexate-monotherapy. Non-invasive assessment of endothelial dysfunction and the biochemical markers were estimated at baseline in all subjects and after 12 weeks of methotrexate-monotherapy in cases. All subjects underwent clinical assessment and non-invasive assessment of endothelial function and early atherosclerosis - brachial artery flow-mediated dilatation (FMD), carotid intima-media thickness (CIMT) and epicardial pad of fat (EPF). Readings were taken by two experienced cardiologists, blinded to patient details and the mean of measurements computed. Systemic methotrexate was started at a dose of 2.5 mg/week, gradually increased by 2.5
mg/week in the first month to 10 mg/week till 4 weeks and then to 15 mg/week at 8 weeks.
Results: The markers of systemic inflammation, insulin resistance, oxidative stress, endothelial dysfunction and atherothrombosis were significantly elevated along with non-invasive markers of cardiovascular risk (FMD%) at baseline in patients with psoriasis, correlating significantly with PASI and showed a significant decline in their levels, after 12 weeks of methotrexate-monotherapy. (Table)
Conclusions: This study suggest that methotrexate-monotherapy significantly ameliorates systemic inflammation, insulin resistance, oxidative stress, endothelial dysfunction and atherothrombosis which might reduce the cardiovascular co-morbidity in psoriasis.
References:

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2. Ahlehoff O, Skov L, Gislason G, Gniadecki R, Iversen L, Bryld LE, Lasthein S, Lindhardsen J, Kristensen SL, Torp-Pedersen C, Hansen PR. Cardiovascular outcomes and systemic anti-inflammatory drugs in patients with severe psoriasis: 5-year follow-up of a Danish nationwide cohort. *J Eur Acad Dermatol Venereol.* 2015;29:1128–1134.

Table 3- Comparison of biomarkers of systemic inflammation, insulin resistance and oxidative stress in psoriasis patients at baseline and at 12 weeks post-therapy.

Parameter	Baseline (n=87) Mean ± SD/ Median (IQR)	12 weeks post-therapy (n=87) Mean ± SD/ Median (IQR)	p value†
Markers of systemic inflammation			
IL-6 (pg/ml)	11.48 ± 2.61	4.52 ± 1.08	<0.0001*
IL-17 (ng/ml)	11.32 (9.37 - 13.62)	5.13 (3.38 – 7.14)	<0.0001#
hs-CRP (mg/l)	6.62 (3.20-22.98)	1.05 (0.50-3.08)	<0.0001#
Protein-bound sialic acid (µg/mg protein)	53.10 (43.14 -67.90)	25.46 (19.18 – 32.98)	<0.0001#
Pentraxin-3 (ng/ml)	5.38 (3.86-9.93)	3.17 (1.29-3.71)	<0.0001#
Prolactin (ng/ml)	34.2 (17.6 – 44.5)	17.6 (12.5 – 21.5)	<0.0001#
Markers of insulin resistance and adipokines			
Insulin(µIU/ml)	14.8 (8.9 -18.1)	12.8 (8.0 – 18.0)	0.128#
HOMA-IR	3.15 (2.03 – 4.96)	2.16 (1.49 – 3.45)	< 0.0001#
Leptin(ng/ml)	23.70 (12.94-41.93)	21.14 (11.51-33.30)	0.354#
Adiponectin(ng/ml)	10.31 (7.36-13.19)	11.91 (10.70-13.99)	0.001#
Resistin (ng/ml)	11.36 (10.39 –12.06)	3.21 (3.17-3.30)	< 0.0001#
Markers of oxidative stress			
MDA (µmol/L)	14.13 ± 2.72	10.15 ±1.93	<0.0001*
Lp(a) (mg/dl)	28.5 (20.4 – 33.2)	22.0 (15.4 – 28.1)	<0.0001#
SOD (U/gm Hb)	74.23 (61.36 –80.31)	165.36 (95.37-190.36)	<0.0001#
GPx (U/gm Hb)	41.45 ± 5.93	124.14 ± 15.41	<0.0001*
CAT (U/gm Hb)	3.15 (2.79 – 3.36)	5.94 (5.9 – 5.99)	<0.0001#
GSH (mg/dL)	18.16 (17.3 – 19.36)	31.74 (29.19 – 34.36)	<0.0001#
Protein carbonylation (nmol/mg protein)	6.43 (6.18 – 6.76)	2.75 (2.66 – 2.87)	<0.0001#
TOS (µmol H_2O_2 Eq/l)	8.80 ± 1.86	6.20 ± 1.39	<0.0001*
TAS (nmol/Trolox status)	2.14 (1.48-3.10)	3.98 (3.33-4.62)	<0.0001#
OSI	4.03 (2.55-6.38)	1.46 (1.19-1.94)	<0.0001#

* Paired Student's t-test, # Wilcoxon signed rank test

† p<0.001 considered statistically significant after adjusting for multiple comparisons

P3 - Identifying predictors of high response levels in ixekizumab-treated patients with moderate-to-severe plaque psoriasis

1. Biomarkers and imaging

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Introduction: The UNCOVER-1, -2, -3, and IXORA-S trials demonstrated ixekizumab's (IXE) efficacy in treating patients with moderate-to-severe plaque psoriasis (PsO), which has been confirmed by several network meta-analyses. Since patient baseline profiles may influence their response to treatment, it is important to assess whether these characteristics can also affect the response to IXE treatment. Additionally, understanding which patients are most likely to benefit from treatment can help provide patients with effective treatment more rapidly.
Objectives: The aim of this analysis was to evaluate whether patient baseline characteristics or early clinical responses could predict achievement of Psoriasis Area and Severity Index (PASI)90 or PASI100 responses in IXE-treated patients at Week (W) 12 and W52.
Methods: This post hoc analysis pooled 375 patients from the Phase 3, randomized clinical trials, UNCOVER-1, -2, -3, and IXORA-S, who received IXE as per label through W52. Specifically, patients received IXE 160 mg at W0, 80 mg every 2 weeks through W12, and 80 mg every 4 weeks thereafter. Patients were ≥18 years old with moderate-to-severe PsO defined as ≥10% Body Surface Area, a static Physician Global Assessment ≥3 and a PASI ≥12 in UNCOVER-1, -2 and -3, and a PASI ≥10 in IXORA-S. Baseline characteristics and PASI75 responses at W2 and W4 were evaluated as potential predictors of PASI90 or PASI100 achievement at W12 and W52 using multivariate logistic regression models which were adjusted for all reported patient variables at baseline. Accuracy ranged between 0.68 and 0.78 for all models. Results are presented as odds ratio (OR) with 95% confidence intervals. Non-responder imputation was used for missing data.
Results: Associations of patient baseline characteristics and early PASI75 responses with W12 and W52 achievement of PASI90 or PASI100 responses are shown in Table 1 and 2 (OR, p value), respectively. Higher baseline PASI and achievement of PASI75 at W2 or W4 were predictors of PASI90 responses at W12 and W52. In addition, achieving PASI75 at W4 was predictive of PASI100 responses at both timepoints, while reaching PASI75 at W2 was predictive of a PASI100 response at W12 only. Males were more likely to achieve PASI90 and PASI100 at W52. Higher weight and presence of palmoplantar PsO at baseline were associated with reduced odds of achieving PASI90 or PASI100 at W12 and W52. Additionally, patients with prior biologic treatment were less likely to achieve PASI90 at W52 but not at W12. Concomitant psoriatic arthritis, presence of nail or scalp PsO, or higher age at baseline were not predictive of PASI90 or PASI100 responses at W12 or W52.
Conclusions: Although most patients respond well to IXE, this analysis demonstrates that certain baseline characteristics (male, lower weight, higher PASI, absence of palmoplantar PsO, biologic

naive) are associated with higher level responses to IXE over time. Partial response rates at W2 and W4 reliably predicted high clinical response rates at later time points.

	PASI 90 at Week 12			PASI 90 at Week 52		
Variable	Odds ratio	95% Confidence Intervals	P value	Odds ratio	95% Confidence Intervals	P value
Age, years	1.00	0.98, 1.01	0.546	1.00	0.99, 1.02	0.665
Sex, male	1.05	0.71, 1.56	0.806	**1.60**	1.09, 2.35	**0.016**
Weight, kg	**0.98**	0.98, 0.99	**<0.001**	**0.99**	0.98, 1.00	**0.001**
Psoriasis duration, years	0.99	0.97, 1.00	0.107	1.00	0.98, 1.01	0.701
PASI	**1.03**	1.00, 1.06	**0.041**	**1.05**	1.02, 1.08	**0.003**
Previous biologic treatment (Y/N)	1.05	0.86, 1.28	0.613	**0.77**	0.64, 0.92	**0.004**
Psoriatic arthritis diagnosis (Y/N)	1.07	0.71, 1.62	0.754	0.89	0.59, 1.34	0.587
Nail Psoriasis (Y/N)	1.16	0.80, 1.68	0.441	1.10	0.75, 1.62	0.610
Scalp Psoriasis (Y/N)	0.85	0.47, 1.53	0.589	0.97	0.54, 1.75	0.913
Palmoplantar Psoriasis (Y/N)	**0.67**	0.45, 0.99	**0.044**	**0.53**	0.36, 0.78	**0.001**
PASI 75 at Week 2	**3.27**	1.48, 7.19	**0.003**	**1.72**	1.00, 2.98	**0.051**
PASI 75 at Week 4	**6.50**	4.37, 9.66	**<0.001**	**1.56**	1.07, 2.27	**0.020**

Table 1: Logistic regression analysis of variables associated with PASI 90 response at Weeks 12 and 52. Data are presented by odds ratios and 95% confidence intervals. All variables show baseline values unless otherwise stated. Reference categories were 'Female' for sex and 'No' for previous biologic treatment, psoriatic arthritis diagnosis and presence of palmoplantar, scalp and nail psoriasis. PASI = Psoriasis Area and Severity Index, Y/N = Yes/No.

	PASI 100 at Week 12			PASI 100 at Week 52		
Variable	Odds ratio	95% Confidence Intervals	P value	Odds ratio	95% Confidence Intervals	P value
Age, years	1.00	0.98, 1.01	0.623	1.01	1.00, 1.03	0.089
Sex, male	0.94	0.67, 1.31	0.698	**1.46**	1.03, 2.06	**0.034**
Weight, kg	**0.99**	0.98, 0.99	**<0.001**	**0.98**	0.98, 0.99	**<0.001**
Psoriasis duration, years	1.00	0.98, 1.01	0.535	0.99	0.98, 1.00	0.142
PASI	1.01	0.99, 1.03	0.457	1.02	1.00, 1.05	0.061
Previous biologic treatment (Y/N)	0.99	0.83, 1.17	0.879	0.83	0.68, 1.00	0.053
Psoriatic arthritis diagnosis (Y/N)	1.11	0.76, 1.61	0.586	1.16	0.79, 1.71	0.438
Nail Psoriasis (Y/N)	0.94	0.68, 1.29	0.690	0.92	0.66, 1.28	0.630
Scalp Psoriasis (Y/N)	0.61	0.36, 1.04	0.069	1.18	0.67, 2.08	0.569
Palmoplantar Psoriasis (Y/N)	**0.54**	0.37, 0.78	**0.001**	**0.36**	0.24, 0.52	**<0.001**
PASI 75 at Week 2	**2.23**	1.51, 3.31	**<0.001**	1.34	0.88, 2.03	0.178
PASI 75 at Week 4	**3.79**	2.68, 5.37	**<0.001**	**1.63**	1.17, 2.29	**0.004**

Table 2: Logistic regression analysis of variables associated with PASI 100 response at Weeks 12 and 52. Data are presented by odds ratios and 95% confidence intervals. All variables show baseline values unless otherwise stated. Reference categories were 'Female' for sex and 'No' for previous biologic treatment, psoriatic arthritis diagnosis and presence of palmoplantar, scalp and nail psoriasis. PASI = Psoriasis Area and Severity Index, Y/N = Yes/No.

P4 - Subclinical atherosclerosis is associated with rheumatoid factor seropositivity in Psoriatic Arthritis patients

1. Biomarkers and imaging

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Introduction: Psoriatic arthritis (PsA) patients have a higher risk of developing a cardiovascular (CV) event than the general population due to a higher prevalence of CV risk factors and disease related characteristics such as systemic inflammation. Antibodies, including rheumatoid factor (RF) and anti-cyclic citrullinated peptide (anti-CCP) antibodies, have been associated with a worse CV prognosis in patients with rheumatoid arthritis (1,2), however, this has not been studied in PsA patients.
Objectives: The aim of this study was to determine the association of subclinical atherosclerosis detected by carotid ultrasound (US) and the seropositivity of RF and anti-CCP antibodies in PsA patients.
Methods: This was a cross-sectional, observational, and comparative study. A total of 64 PsA patients aged 40-75 years old, who fulfilled the 2006 CASPAR criteria were included for this study. Patients with history of a previous CV event, such as myocardial infarction, cerebrovascular event and peripheral arterial disease, another connective tissue disease and pregnant women were excluded. A high-resolution B-mode carotid US was performed in all patients to evaluate the presence of carotid plaque (CP), which was defined as a carotid intima media thickness ≥1.2mm or a focal narrowing ≥0.5mm of the surrounding lumen. A blood sample was obtained from all patients to measure RF and anti-CCP antibody titers. Values ≥20 U/ml for RF and ≥5 U/ml for anti-CCP antibody were considered as cut-off points for antibody seropositivity. Patients were divided into two groups according to CP presence, 32 patients with CP and 32 patients without CP. Distribution was evaluated with Kolmogorov-Smirnov test. Comparisons were done with χ^2 test for qualitative variables and Student's t test and Mann-Whitney's U test for quantitative variables. A *p*-value <0.05 was considered statistically significant.
Results: There were no differences found in the demographic and clinical characteristics between PsA patients with and without CP. PsA patients with CP showed a higher prevalence of IgM RF seropositivity than patients without CP (59.4% vs 34.4% respectively, *p=0.045*). There were no differences found in the other RF isotypes and anti-CCP antibody positivity (Table 1).
Conclusions: Patients with PsA and CP have a higher prevalence of IgM RF seropositivity than patients without CP. These findings suggest that IgM RF, with a cut-off point of 20 U/mL, could be a useful marker to predict the presence of subclinical atherosclerosis in PsA patients.
References: 1.- Tomasson G, Aspelund T, Jonsson T, et al. Effect of rheumatoid factor on mortality and coronary heart disease. *Ann Rheum Dis* 2010;69(9):1649-54. doi: 10.1136/ard.2009.110536

2.- Lopez-Longo FJ, Oliver-Minarro D, de la Torre I, et al. Association between anti-cyclic citrullinated peptide antibodies and ischemic heart disease in patients with rheumatoid arthritis. *Arthritis Rheum* 2009;61(4):419-24. doi: 10.1002/art.24390

Table 1. Demographic characteristics and antibody seropositivity in psoriatic arthritis patients.

	PsA patients with CP (n=32)	PsA patients without CP (n=32)	*p*
Age years, mean (IQR)	56.0 (46.5-69.7)	56.0 (52.0-59.0)	NS
Women, n (%)	16 (50.0)	16 (50.0)	NS
T2DM, n (%)	11 (34.4)	5 (15.6)	NS
HTN, n (%)	14 (43.8)	14 (43.8)	NS
Dyslipidemia, n (%)	17 (53.1)	12 (37.5)	NS
Obesity, n (%)	11 (34.4)	13 (40.6)	NS
Active smoking, n (%)	5 (15.6)	8 (25.0)	NS
BMI kg/m^2, mean ± SD	29.5 ± 4.8	29.4 ± 6.0	NS
Disease duration years, median (IQR)	6.5 (3.0-10.0)	4.5 (2.2-8.0)	NS
DAPSA, median (IQR)	10.7 (5.0-20.9)	13.0 (5.5-22.2)	NS
Antibody seropositivity			
IgG RF, n (%)	0 (0.0)	2 (6.3)	NS
IgM RF, n (%)	19 (59.4)	11 (34.4)	**0.045**
IgA RF, n (%)	6 (18.8)	5 (15.6)	NS
Anti-CCP antibody, n (%)	4 (12.5)	3 (9.4)	NS

PsA, psoriatic arthritis; CP, carotid plaque; NS, not significant; T2DM, type 2 diabetes mellitus; HTN, hypertension; BMI, body mass index; DAPSA, disease activity score for psoriatic arthritis; RF, rheumatoid factor; anti-CCP, anti-cyclic citrullinated peptide.

P5 - Targeted Metabolomic Profiling and Prediction of Cardiovascular Events: A Prospective Study of Patients with Psoriasis and Psoriatic Arthritis

1. Biomarkers and imaging

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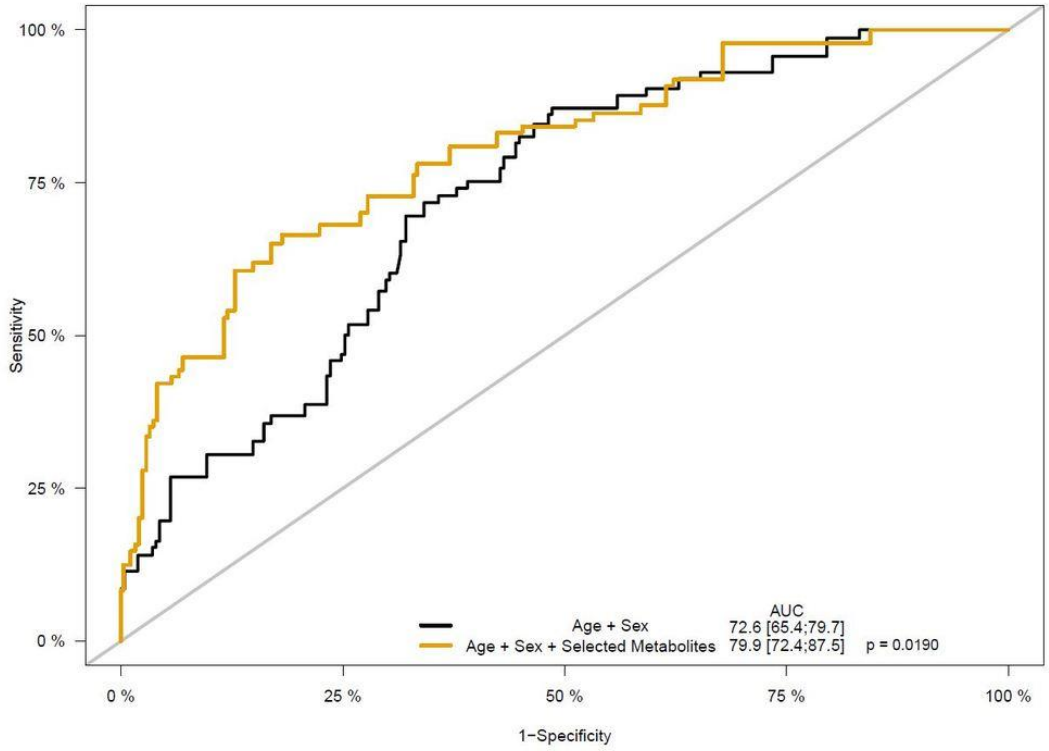
Introduction: Psoriatic disease (PsD) is associated with increased cardiovascular (CV) risk. Metabolites comprise biomarkers that may add predictive value over traditional CV risk factors.
Objectives: We aimed to identify metabolites associated with CV events (CVEs) and to determine whether they could improve CV risk prediction beyond traditional CV risk factors.
Methods: Patients from a longitudinal PsD cohort without a prior history of CVEs were included. In the first available serum sample, a targeted nuclear magnetic resonance (NMR) metabolomics platform was used to quantify 64 metabolite measures comprised of lipoprotein subclasses, fatty acids, glycolysis precursors, ketone bodies and amino acids. The study outcome included any of the following CVEs occurring within the first 10 years of biomarker assessment: angina, myocardial infarction, congestive heart failure, transient ischemic attack, cerebrovascular accident, revascularization procedures and CV death. The associations of each metabolite with incident CVEs were analyzed separately using Cox proportional hazards regression models adjusted for age and sex, and age, sex and traditional CV risk factors. Variable selection was then performed using the proportional sub-distribution hazards regression model adjusted for age and sex via penalization with boosting. The added predictive value of the selected metabolites to improve risk prediction beyond traditional CV risk factors was assessed using the area under the receiver operator characteristic curve (AUC).
Results: A total of 977 patients with PsD, followed between 2005 and 2019, were analyzed (mean age 49.1 ± 12.6 years, 45.1% female). During a mean follow-up of 7.1 years, 70 (7.2%) patients developed incident CVEs. In Cox regression models adjusted for CV risk factors, alanine, tyrosine, degree of unsaturation, high-density lipoprotein (HDL) cholesterol, and medium and large HDL particles were significantly associated with decreased CV risk. Glycoprotein acetyls, apolipoprotein B, remnant cholesterol, very low-density lipoprotein (VLDL) cholesterol, and very small VLDL particles were associated with an increased CV risk.

Thirteen metabolites were selected based on the penalization and boosting algorithm. The age- and sex-adjusted expanded model (base model + 13 metabolites) significantly improved prediction of CVEs beyond the base model (only age and sex) with an AUC of 79.9 vs. 72.6, respectively (p=0.02) (Figure 1).
Conclusions: Using NMR metabolomics profiling, we identified a variety of metabolites associated with a lower and higher risk of developing CVEs in patients with PsD. Since CV risk is underestimated in this patient population, further study of the underlying association with CVEs is needed to clarify the clinical utility of these biomarkers to guide CV risk assessment.
References:

1. Soininen P, Kangas AJ, Wurtz P, et al. Quantitative serum nuclear magnetic resonance metabolomics in cardiovascular epidemiology and genetics. *Circ Cardiovasc Genet* 2015;8(1):192-206.



2. CLINICAL PHENOTYPES

P6 - ASSOCIATION OF AXIAL INVOLVEMENT WITH MORE SEVERE DISEASE STATUS IN PSORIATIC ARTHRITIS PATIENTS

2. Clinical phenotypes

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Introduction: The latest data show that axial involvement in psoriatic arthritis (PsA) patients (pts) is associated with significantly more severe disease status (1).
Objectives: To analyze, in clinical practice, disease activity and characteristics of PsA pts with and without radiographic sacroiliitis (rSI).
Methods: 385 pts (M/F–172 /213) with PsA according to CASPAR criteria were included. Median age 45 (Min 20-Max 80) years (yrs), disease duration 3.4 yrs (4 months-32 yrs). Pts underwent standard clinical examination of PsA activity. Disease activity was measured by DAPSA, BASDAI. The examination involved HLA B27 antigen status and X-ray of sacroiliac joints (pelvic radiographs). rSI was defined as bilateral grade ≥2 or unilateral grade ≥3. Skin lesion severity was evaluated in terms of body surface area (BSA) affected, and Psoriasis Area Severity Index (PASI). Pts were split into two groups (gr.): those with rSI [rSI(+)] and those without rSI [rSI(-)]. Medians and quartiles [Me (Q25; Q75)], [Min; Max], U-test and ORs with 95% CI were performed.
Results: Gr. rSI(+) included 214 (55.6%) cases (M/F–106/108), gr. rSI(-) 171 (44.4%) cases (M/F–66/105). Significant differences were revealed between gr. rSI(+) and gr. rSI(-). **In HLA-B27 antigen status:** in gr. rSI(+) it was positive in 62 pts, negative in 64 pts, while in gr. rSI(-) it was positive in 26 pts, negative in 52 pts. OR 1.9 [1.1-3.5]. **In tender joint count (TJC):** in gr. rSI(+) TJC was 9 [14-18], in gr. rSI(-) it was 6 [3-12] (p=0.02). **In disease activity measured by DAPSA:** in gr. rSI(+) DAPSA was 28.40 [15.65-43.65], in gr. rSI(-) it was 20.0 [12.45-30.0] (p=0.00). **In disease activity measured by BASDAI:** in gr. rSI(+) BASDAI was 1.6 [0-5.1], in gr. rSI(-) it was 0 [0-4.5] (p=0.00). **In Leeds Enthesitis Index (LEI):** in gr. rSI(+) LEI was 0 [0-2], in gr. rSI(-) it was 0 [0-1] (p=0.02). **In frequency of dactylitis:** in gr. rSI(+) 71 pts had dactylitis, 143 did not have; in gr. rSI(-) 32 pts had dactylitis, 139 did not have. OR 2.2 [1.3-3.5]. **In frequency of erosive radiographic arthritis of feet:** in gr. rSI(+) 58 pts had erosive arthritis of feet, 156 did not have, while in gr. rSI(-) 29 pts had erosive arthritis of feet, and 142 did not have. OR 1.8 [1.1-3.0]. **In more extensive skin lesion area:** in gr. rSI(+) BSA <3% had 120 pts, BSA >3% had 94 pts; while in gr. rSI(-) BSA <3% had 141 pts, BSA >3% had 57 pts. OR 0.6 [0.4-0.97]. **In CRP:** in gr. rSI(+) CRP was 0.9 [0.4-2.2] mg/dl, in gr. rSI(-) it was 0.8 [0.3-1.3] mg/dl (p=0.03).
Conclusions: Axial involvement is identified in more than half (55.6%) of the PsA pts. The presence of axial involvement in PsA pts is associated with significantly worse disease status. Consequently, the diagnostics of axial involvement is critical in clinical practice.
References: PJ Mease et al. J Rheumatol 2018; 45: 1389-96.

P7 - Baseline characteristics of psoriasis patients participating in the VALUE multi-national post-marketing observational study

2. Clinical phenotypes

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Introduction: Risankizumab, a humanized IgG1 monoclonal antibody, specifically inhibits IL-23 by binding its p19 subunit and is approved for treatment of moderate-to-severe plaque psoriasis.
Objectives: This report assesses baseline characteristics of patients prescribed risankizumab or other biologics in routine clinical practice, using interim data from the ongoing VALUE study.
Methods: VALUE (NCT03982394), a 3-year post-marketing observational study, evaluates real-world durability of response and time to first treatment change (including discontinuation, dose escalation and dosing interval shortening) for risankizumab compared to other commonly used biologics (2:1 allocation ratio). Demographics, disease characteristics, and medication history were evaluated upon study entry.
Results: Overall, 283 and 129 patients initiated risankizumab and other biologics, respectively. Patients receiving risankizumab reported similar disease severity as those receiving other biologics; Psoriasis Area and Severity Index (16.5 vs 15.2, p=0.1750), static Physican's Global Assessment (2.7 vs 2.7, p=0.8531), Dermatology Life Quality Index (13.3 vs 13.4, p=0.9151). A greater proportion of risankizumab initiators had ≥10% Body Surface Area involvement (81.3% vs 76.0%), anogenital (27.6% vs 25.5%), nail (40.3% vs 36.7%), scalp (73.1% vs 68.8%), or erythrodermic (2.8% vs 0.8%) psoriasis. While most patients were biologic-naïve, a larger proportion of risankizumab initiators had previous biologic exposure (48.1% vs 36.4%). The treatment Satisfaction Questionnaire for Medication global satisfaction scores for treatment prior to risankizumab were 54.4% vs 56.5% prior to other biologics.
Conclusions: Baseline characteristics from real-world data, particularly on treatment satisfaction of prior treatment as well as prior biologic use, highlight the unmet medical need in the treatment of moderate-to-severe psoriasis.

P8 - THE BURDEN OF NAIL DISEASE IN PSORIATIC ARTHRITIS PATIENTS

2. Clinical phenotypes

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Introduction: Limited data are available regarding the burden of nail disease in psoriatic arthritis (PsA). The latest data shows that nail involvement in PsA patients (pts) is associated with significantly more severe disease status (1).
Objectives: To analyze, in clinical practice, the association of nail psoriasis with disease characteristics in PsA pts.
Methods: 588 pts (M/F–277 /311) with PsA according to CASPAR criteria were included in the study. Pts' age 48.6±0.5 years (yrs), disease duration 7.0±0.3 yrs. Pts underwent standard clinical examination of PsA activity. Pts were split into two groups (gr.): those with nail psoriasis – gr.1, and those without it – gr.2. Demographics, disease activity and clinical characteristics were compared between pts with and without nail psoriasis using Pearson's chi-square test and Mann–Whitney U test.
Results: Gr.1 includes 312 (53.1%) cases, gr.2 – 276 (46.9%) cases. More pts in gr.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 pts in gr.2. Pts in gr.1 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. Gr.1 pts had higher disease activity measured by DAPSA 25 [15-39] vs 20 [12-33] (p= 0.001), higher frequency of dactylitis (24.4% vs 16.7% p=0.022) and heel enthesitis (17.0% vs 10.1% p=0.016) respectively, higher frequency of erosive radiographic arthritis of feet (45.0% vs 31.2% p=0.003) compared to gr.2 pts. Pts in gr.1 had worse skin psoriasis measured by Psoriasis Area Severity Index – 6 [2-14] vs 3 [1-6] (p=0.000). Less pts in gr.1 than in gr.2 (27.0% vs 52.0% p=0.004) achieved minimal disease activity (MDA).
Conclusions: Nail involvement in PsA pts is significantly more frequent in males. PsA pts with nail involvement are more often disabled, more often are chronic smokers, more often have axial disease, 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. These results emphasize the importance of identification and management of nail disease in patients with PsA.
References: Mease PJ et al.J Rheumatol, 2020

3. COMORBIDITIES

P9 - Cardiovascular risk reclassification according to traditional cardiovascular risk algorithms and a carotid ultrasound in Psoriatic Arthritis patients

3. Comorbidities

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Introduction: Patients with psoriatic arthritis (PsA) have a higher risk of developing a cardiovascular (CV) event than the general population. This could be attributed to a higher prevalence of traditional CV risk (CVR) factors and to disease characteristics such as systemic inflammation (1). There are multiple algorithms to estimate the CVR for the general population, however there is not one for PsA patients.
Objectives: The aim of this study was to compare the CVR reclassification using six CVR algorithms and a carotid ultrasound (US) in PsA patients and controls.
Methods: This was a cross-sectional, observational, and comparative study. A total of 75 patients aged 40-75 years old, who fulfilled the 2006 CASPAR criteria and 75 controls without PsA matched by age (±5 years), gender and comorbidities were recruited for this study. Initially CVR was evaluated according to six CVR algorithms, including Framingham Risk Score (FRS)-lipids, FRS-body mass index (BMI), American College of Cardiology and American Heart Association (ACC/AHA) Risk Algorithm, Systematic Coronary Risk Evaluation (SCORE), QRISK3 and Reynolds Risk Score (RRS). Posteriorly a carotid US was performed in all subjects to identify the presence of carotid plaque (CP) defined as a carotid intima media thickness ≥1.2mm or a focal narrowing of the surrounding lumen ≥0.5mm. Patients with presence of CP but classified in the low-moderate risk by the CVR algorithms were reclassified to a higher risk category. Distribution was evaluated with the Kolmogorov-Smirnov test. Comparisons were done using χ^2 test for qualitative variables, and Student's t test and Mann-Whitney's U test for quantitative variables. A *p*-value <0.05 was considered statistically significant.
Results: Mean age was 53.89 ± 10.59 in PsA patients and 54.25 ± 7.08 in the control group (*p*=0.807), 57.3% were women in both groups. A difference was found in the presence of CP, being more prevalent in PsA patients (44.0% vs 26.7%, *p*=0.026). When comparing the CVR reclassification to a higher risk category a difference was found in five of the six CVR algorithms. The reclassification was more prevalent in PsA patients: 29.3% vs 13.3%, *p*=0.017 with FRS-lipids; 26.7% vs 10.7%, *p*=0.012 with FRS-BMI; 40.0% vs 21.3%, *p*=0.013 with SCORE; 33.3% vs 17.3%, *p*=0.024 with QRISK3; and 36.0% vs 21.3%, *p*=0.047 with RRS (Table 1).
Conclusions: The CVR algorithms underestimate de real CVR of PsA patients. This could be attributed to the fact that these algorithms do not include disease characteristics that can affect the CV prognosis of PsA patients. For this reason, a carotid US should be done to correctly classify the CVR of PsA patients and identify those who would benefit from an opportune treatment.

References: 1.- Polachek A, Touma Z, Anderson M, et al. Risk of Cardiovascular Morbidity in Patients With Psoriatic Arthritis: A Meta-Analysis of Observational Studies. *Arthritis Care Res (Hoboken)* 2017;69(1):67-74. doi: 10.1002/acr.22926

Table 1. Demographic characteristics and cardiovascular risk reclassification.

	PsA (n=75)	Controls (n=75)	*p*
Traditional cardiovascular risk factors			
T2DM, n (%)	16 (21.3)	15 (20.0)	NS
HTN, n (%)	28 (37.3)	21 (28.0)	NS
Dyslipidemia, n (%)	33 (44.0)	28 (37.3)	NS
Obesity, n (%)	31 (41.3)	32 (42.7)	NS
Active smoking, n (%)	14 (18.7)	18 (24.0)	NS
Cardiovascular risk reclassification			
FRS-lipids			
Reclassification, n (%)	22 (29.3)	10 (13.3)	**0.017**
Low risk, n (%)	16 (21.3)	3 (4.0)	**0.001**
Moderate risk, n (%)	6 (8.0)	7 (9.3)	NS
FRS-BMI			
Reclassification, n (%)	20 (26.7)	8 (10.7)	**0.012**
Low risk, n (%)	13 (17.3)	3 (4.0)	**0.008**
Moderate risk, n (%)	7 (9.3)	5 (6.7)	NS
SCORE			
Reclassification, n (%)	30 (40.0)	16 (21.3)	**0.013**
Low risk, n (%)	9 (12.0)	1 (1.3)	**0.009**
Moderate risk, n (%)	17 (22.7)	11 (14.7)	NS
High risk, n (%)	4 (5.3)	4 (5.3)	NS
ACC/AHA algorithm			
Reclassification, n (%)	23 (30.7)	13 (17.3)	0.056
Low risk, n (%)	17 (22.7)	10 (13.3)	NS
Moderate risk, n (%)	6 (8.0)	3 (4.0)	NS
RRS			
Reclassification, n (%)	27 (36.0)	16 (21.3)	**0.047**
Low risk, n (%)	17 (22.7)	7 (9.3)	**0.026**
Moderate risk, n (%)	10 (13.3)	9 (12.0)	NS
QRISK3			
Reclassification, n (%)	25 (33.3)	13 (17.3)	**0.024**
Low risk, n (%)	19 (25.3)	9 (12.0)	**0.036**
Moderate risk, n (%)	6 (8.0)	4 (5.3)	NS

PsA, psoriatic arthritis; NS, not significant; T2DM, type 2 diabetes mellitus; HTN, hypertension; FRS, Framingham Risk Score; BMI, body mass index; SCORE, Systematic Coronary Risk Evaluation; ACC/AHA, American College of Cardiology and American Heart Association; RRS, Reynolds Risk Score.

P10 - Clinical and epidemiological characteristics of hidradenitis suppurativa patients with paradoxical psoriasiform reactions following treatment with adalimumab

3. Comorbidities

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Introduction: Paradoxical psoriasiform reactions (PPR) are a well-recognized side effect occurring in patients with autoimmune or autoinflammatory diseases, such as inflammatory bowel diseases or rheumatic diseases, following treatment with anti-TNFα agents. Scarce data are available regarding these reactions in hidradenitis suppurativa (HS) patients.
Objectives: Our aim was to investigate the clinical and epidemiological characteristics of patients with moderate to severe HS, who developed PPR following standard treatment with adalimumab.
Methods: This was a retrospective observational case series study. We reviewed the medical files of 162 patients with HS under our care during a three-year period (2018 – 2021), who were treated with the standard regime of adalimumab for HS. Demographics, family history, severity and duration of HS, response of HS to treatment, as well as clinical characteristics of PPR presentation (BSA, anatomical sites, duration of adalimumab treatment before onset of lesions, response to treatment for PPR) were recorded.
Results: Among our patients, four cases of PPR were identified. All patients were middle aged (mean value 49 years, range: 44-58 years), smokers, overweight or obese. There were 2 males (50%) and two females, all with Hurley stage III, with a mean duration of HS of 20 years (9-26 years). Two patients had a family history of psoriasis. Patients were at least for 5 months on successful treatment with adalimumab before the onset of PPR (range 5 months – 7 years). In all four cases, the extent of PPR was very limited (1-2%) affecting specific psoriasis-prone sites (elbows, soles), while morphology was that of psoriasis vulgaris (chronic plaque type) in 3 out of 4 patients and pustular psoriasis in the remaining 1 patient. In all four patients, PPR did not respond to continuing adalimumab therapy. Two patients improved by switching to secukinumab, while in the remaining two, PPR was controlled by the addition of calcipotriol/betamethasone foam.
Conclusions: Based on the results from our small case series, the clinical and epidemiological profile of a HS patient under adalimumab treatment who developed PPR is that of a middle aged, overweight patient with severe, long standing HS, responding successfully to adalimumab, while developing PPR a few months later. The reactions were that of typical, limited plaque psoriasis, with varied response to treatment. Further data are needed so that reliable predictive factors of HS patients will be outlined in terms of risk identification for developing PPR following adalimumab treatment.
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P11 - Comorbid Conditions Influence Prescription of Systemic Pharmaceutical Treatment in Swedish Patients with Psoriasis and Psoriatic Arthritis

3. Comorbidities

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Introduction: Psoriasis (PsO) is a heterogeneous chronic inflammatory multisystem disorder characterised by debilitating skin manifestations resulting in pain, itch and impaired quality of life, and, in around a third of patients, arthritis. Treatment selection is complicated by the high frequency/burden of comorbid conditions[1], which place high demands on long-term safety as treatment typically is life-long[2].
Objectives: To compare the presence of comorbidities in Swedish patients prescribed different systemic treatments for PsO and/or psoriatic arthritis (PsA).
Methods: This retrospective registry study included patients ≥18 years of age with ≥1 PsO and/or PsA diagnosis between January 1st, 2006 and May 31st, 2020, and ≥1 systemic treatment (index event[s]; including biologics, methotrexate, apremilast) for PsO/PsA recorded on or after the date of first PsO/PsA diagnosis. Treatment periods before June 1st, 2015 and those following a diagnosis of rheumatoid arthritis, Crohn's disease or another condition for which PsO/PsA systemic treatments can be used were excluded. Patients could have multiple index events and treatment periods. Comorbidity level at each index event was assessed using the Charlson Comorbidity Index (CCI)[3] comprising 17 categories (determined by ICD-10 codes), each assigned a weight from 1 to 6 depending on the associated mortality risk. If at least one diagnosis of a specific comorbidity was recorded prior to the index event, the relevant category was given the assigned weight. For each patient, the final CCI score was the sum of all weights, categorised as low (0-2), moderate (3-4) and high (≥5)[4]. Mean CCI comparison between treatments was done by the Wilcoxon rank-sum test.
Results: 31,722 eligible patients were included; Table 1 summarises patient characteristics by treatment. At first prescription, patients receiving anti-ILs had the longest disease duration (median time from first PsO/PsA outpatient visit; 10.7 years) and those treated with methotrexate the shortest (8.6). Patients receiving anti-TNFs had the lowest mean CCI score (0.46), indicating the lowest degree of comorbidities. Patients prescribed apremilast had the highest mean CCI score (0.81), significantly higher than all other treatments ($p<0.001$ for each comparison), and were more likely to have a moderate or high CCI score.
Conclusions: Patients prescribed systemic treatments for PsO and/or PsA differed in comorbidity profiles, with apremilast patients displaying the highest frequency of comorbid conditions. These data suggest individual drug profiles influence treatment selection in PsO/PsA and highlight comorbidities as an important factor in individual treatment decisions. Monitoring over time is also essential to detect changes that may eventually impact treatment effectiveness and/or safety.

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Table 1: Patient characteristics per treatment group summarised at index date

	All treatments (N patients = 31,722)	Anti-TNFs (N patients = 8,337)	Anti-ILs (N patients = 2,786)	Apremilast (N patients = 2,489)	Methotrexate (N patients = 21,831)
Age at first PsO diagnosis, mean (SD)	49.6 (15.0)	43.2 (13.3)	43.3 (13.5)	48.6 (14.6)	51.2 (15.1)
Age at first PsA diagnosis, mean (SD)	49.3 (13.5)	44.9 (12.3)	46.0 (11.9)	49.4 (12.8)	51.5 (13.7)
Years from first out-patient PsO/PsA visit (median, Q1-Q3)	9.0 (4.7 – 13.4)	9.7 (5.4 – 13.9)	10.7 (6.9 – 14.4)	9.2 (5.5 – 13.6)	8.6 (4.4 – 13.2)
Mean CCI score (SD)	0.65 (1.37)	0.46 (1.05) ***	0.61 (1.27) ***	0.81 (1.55)	0.60 (1.30) ***
Low CCI score, N (%)	41,192 (92%)	7,919 (95%)	2,570 (92%)	2,215 (89%)	20,275 (93%)
Moderate CCI score, N (%)	2,404 (5%)	312 (4%)	161 (6%)	174 (7%)	1,107 (5%)
High CCI score, N (%)	1,133 (3%)	106 (1%)	55 (2%)	100 (4%)	449 (2%)

Age at diagnosis, disease duration and CCI scores for patients receiving systemic treatments for PsO and/or PsA, divided by treatment type.

PsO, psoriasis; PsA, psoriatic arthritis; CCI, Charlson Comorbidity Index; SD, standard deviation; TNF, tumour necrosis factor; IL, interleukin; Q1, first quartile; Q3, third quartile

*** denotes p<0.001 for difference in mean CCI score vs apremilast (Wilcoxon rank-sum test)

P12 - Does substance use in patients with psoriasis predict development of mental health disorders?

3. Comorbidities

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Introduction: Psoriasis is a chronic disease that may result in physical pain, psychological anguish, and social stigmatization. Epidemiologic studies have demonstrated a significant burden of mental health disorders (MHDs) in patients with psoriasis. The association between MHD and substance abuse has been well-described, yet the influence of past or present substance abuse or dependence on the development of subsequent MHD in patients with psoriasis is undetermined.
Objectives: To determine whether substance abuse or dependence among patients with psoriasis increases the probability of subsequent new-onset development of a MHD.
Methods: The NYS Statewide Planning and Research Cooperative System (SPARCS) was queried to identify all psoriasis patient with prior or current substance abuse or dependence (Psoriasis-SA: alcohol, tobacco, marijuana, amphetamine, opioid, or polysubstance) from 2009-11 for 2 year follow-up. Patients with prior or current MHDs were excluded. The Psoriasis-SA cohort were propensity-score matched by age, sex, race, and Charlson/DEYO comorbidity index to psoriasis patients without substance abuse or dependence (Psoriasis-NoSA). Cohorts were compared for subsequent incidence of individual or general MHDs (depressive, anxiety, stress, sleep, and/or eating disorders). Multivariate binary stepwise logistic regressions were utilized to calculate odds ratios (OR) of developing individual or any MHDs based on previous substance abuse or dependence.
Results: 4980 psoriasis patients were included (n=2490 in each cohort). Psoriasis-SA and Psoriasis-NoSA cohorts had comparable demographics including age (54.38 vs. 54.53 years), sex (67.2% vs. 67.3% male), race (70.0% vs. 72.4% white), insurance (31.8% vs. 33.2% Medicare), and Charlson/DEYO index (1.7779 vs. 1.8157) respectively. Psoriasis-SA patients exhibited a significantly increased rate of development of any subsequent MHDs (18.4% vs. 11.8%, $p<0.001$), including depressive disorders (9.8% vs. 4.9%, $p<0.001$) and anxiety disorders (5.0% vs. 2.7%, $p<0.001$). Baseline substance abuse or dependence independently predicted development of depressive disorders (OR=2.192, 95% CI, 1.746-2.752; $p<0.001$) and anxiety disorders (OR=1.983, 95% CI, 1.462-2.691, $p<0.001$).
Conclusions: Patients with psoriasis who had baseline substance abuse or dependence were at increased risk of developing any new MHD, specifically depressive and anxiety disorders, over a two-year period. These results may encourage primary care physicians and dermatologists to screen for MHDs in patients with psoriasis who exhibit substance abuse or dependency.
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		Psoriasis-SA	Psoriasis-NoSA	p-value
Sample Size		2,490	2,490	-
Mean Age (years)		54.38	54.53	0.733
Mean DEYO Index Score		1.7779	1.8157	0.617
Gender	*Male*	67.2%	67.3%	0.928
	Female	32.8%	32.7%	
Race	*White*	70.0%	72.4%	0.86
	Black	10.2%	6.0%	
	Hispanic	10.5%	10.8%	
	Asian or Pacific Islander	1.5%	2.9%	
	Native American	0.3%	0.2%	
	Other	7.6%	7.7%	
Insurance	*Medicare*	31.8%	33.2%	0.228
	Medicaid	26.3%	16.1%	
	Private Insurance	30.4%	43.1%	
	Self-Pay	8.5%	4.7%	
	Other	2.7%	2.9%	
Subsequent New-Onset MHD Diagnosis		18.4%	11.8%	**<0.001**
Depressive Disorders		9.8%	4.9%	**<0.001**
Anxiety Disorders		5.0%	2.7%	**<0.001**
Stress Disorders		0.9%	0.4%	0.033
Sleep Disorders		2.6%	3.8%	0.019
Eating Disorders		0%	0.1%	0.564

Table. Comparison of demographics and rates of subsequent development of new-onset mental health disorders (overall and individual) among psoriasis patients with and without baseline substance abuse/dependence (Psoriasis-SA vs. Psoriasis-NoSA).

P13 - Nail involvement in Psoriatic Arthritis patients is an independent risk factor for subclinical atherosclerosis

3. Comorbidities

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Introduction: Psoriatic Arthritis (PsA) is an inflammatory musculoskeletal disease associated with psoriasis. 30-50% of the patients with PsA have nail involvement[1]. The risk of developing cardiovascular events in PsA patients is higher than in the general population[2]. However, the prevalence of subclinical atherosclerosis using carotid ultrasound in PsA patients with nail involvement has not yet been well described.
Objectives: We aim to determine if nail involvement in PsA patients is associated with a higher prevalence of subclinical atherosclerosis using carotid ultrasound.
Methods: This was a cross-sectional, observational, and comparative study. A total of sixty-six patients aged 40-75 years old, who fulfilled the 2006 CASPAR (Classification Criteria for Psoriatic Arthritis) were included for this study. They were divided into two groups according to the presence of nail involvement and matched by age, gender and comorbidities. Patients with a history of previous atherosclerotic cardiovascular disease (ischemic heart disease, cerebrovascular accident or peripheral arterial disease) and pregnancy were excluded. A carotid B-mode ultrasound was performed in all study subjects, subclinical atherosclerosis was evaluated as the presence of carotid plaque (CP) or an increased intima-media thickness (cIMT). CP was defined as a cIMT≥1.2mm or a focal narrowing ≥0.5mm of the surrounding lumen, and an increased cIMT was defined as a value ≥0.8mm. Comparisons were done with X^2 and Mann-Whitneys' U test.
Results: Clinical and demographic characteristics are shown in Table 1. Carotid plaque was significantly more prevalent in PsA patients with nail involvement (48.5% vs 24.2%, *p=0.041*). A binary logistic regression was performed, which demonstrated that nail involvement is an independent risk factor for the presence of CP with an OR 3.53 (95% CI: 1.06-11.71) *(p=0.039).*
Conclusions: This study shows that patients with PsA and nail involvement have a higher prevalence of CP. Therefore, it is necessary to perform a carotid ultrasound in PsA patients with nail involvement to attain an optimal management of the disease. The rheumatologist must acknowledge the importance of performing a complete cardiovascular evaluation.
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Table 1. Comparison of demographic characteristics and carotid ultrasound findings between PsA patients with nail involvement and matched PsA patients without nail involvement.

	Nail involvement (n=33)	**Without nail involvement (n=33)**	***p-value***
Age, years ± SD	54.4 ± 11.0	52.0 ± 10.2	NS
Female, n (%)	16 (48.5)	21 (63.6)	NS
T2DM, n (%)	6 (18.2)	6 (18.2)	NS
Hypertension, n (%)	10 (30.3)	13 (39.4)	NS
Dyslipidemia, n (%)	15 (45.5)	12(36.4)	NS
Obesity, n (%)	14 (42.4)	14 (42.4)	NS
Active smoking, n (%)	10 (30.3)	7 (21.2)	NS
Disease duration, years (p25-p75)	6 (3.5-10)	4 (2-6.5)	NS
DAPSA, median (p25-p75)	12.9 (6.6-27.5)	12.8 (4.7-19.6)	NS
Glucocorticoids, n (%)	6 (18.2)	3 (9.1)	NS
Methotrexate, n (%)	21 (63.6)	25 (75.8)	NS
Biologics, n (%)	6 (18.2)	12 (26.4)	NS
Carotid ultrasound findings			
Any carotid plaque, n (%)	16 (48.5)	8 (24.2)	**0.041**
Increased cIMT, n (%)	5 (15.2)	4 (12.1)	NS
Right cIMT, mm (p25-p75)	0.73 (0.55-1.20)	0.59 (0.46-0.84)	**0.035**
Left cIMT, mm (p25-p75)	0.69 (0.57-1.20)	0.58 (0.49-0.74)	**0.029**
Presence of subclinical atherosclerosis, n (%)	18 (54.4)	11 (33.3)	NS

NS, non-significant; T2DM, type two diabetes mellitus ; BMI, body mass index; DAPSA, disease activity score for psoriatic arthritis; cIMT, carotid intima-media thickness.

P14 - Predictive capacity of six cardiovascular risk algorithms to detect the presence of carotid plaque

3. Comorbidities

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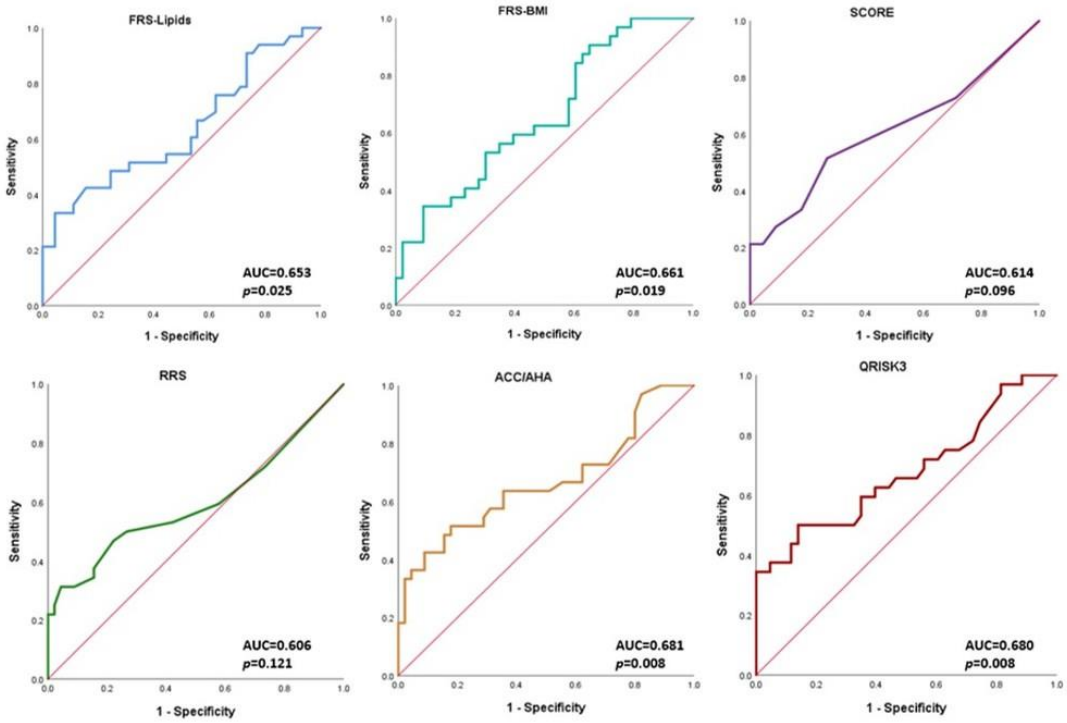
Introduction: Systemic inflammation in psoriatic arthritis (PsA) patients accelerates the process of atherosclerosis; this increases the risk of presenting a major cardiovascular (CV) event than the general population (1). The carotid ultrasound (US), a non-invasive diagnostic tool, has the ability of detecting subclinical atherosclerosis, but it is not available to all patients.
Objectives: The aim of this study was to determine which is the best CV risk (CVR) algorithm to predict the presence of carotid plaque (CP) in PsA patients.
Methods: This was a cross-sectional and observational study. A total of 78 patients aged 40-75 years, who fulfilled the 2006 CASPAR classification criteria for PsA diagnosis were included. Patients with history of a previous CV event were excluded. The CVR of each patient was assessed by six different CVR calculators, including: Framingham Risk Score (FRS)-lipids, FRS-body mass index (BMI), American College of Cardiology and American Heart Association (ACC/AHA) Risk Algorithm, Systematic Coronary Risk Evaluation (SCORE), QRISK3 and Reynolds Risk Score (RRS). A carotid US was performed in all study subjects to identify the presence of CP defined as a carotid intima media thickness ≥1.2mm or a focal narrowing of the surrounding lumen ≥0.5mm. A ROC-curve analysis was done to establish the cut-off points of each algorithm to predict the presence of CP, calculating sensitivity, specificity and area under the curve (AUC) to determine the discriminative capacity. A *p*-value <0.05 was considered statistically significant.
Results: Most patients were women (55.1%) with a mean age of 53.46 (±10.86) years. The prevalence of CP was 42.3%. Four of the six CVR algorithms showed the capacity of predicting CP in PsA patients. FRS-lipids showed an AUC 0.653 (0.523-0.783), *p*=0.025, a cut-off point ≥11.55, a sensitivity of 51.5% and specificity of 68.9%. FRS-BMI showed an AUC 0.661 (0.536-0.786), *p*=0.019, a cut-off point ≥13.8, sensitivity of 59.4% and specificity of 60.5%. ACC/AHA showed an AUC 0.681 (0.551-0.812), *p*=0.008, a cut-off point ≥4.8, sensitivity of 63.6% and specificity of 64.4%. QRISK3 showed an AUC 0.680 (0.551-0.810), *p*=0.008, a cut-off point ≥5.15, sensitivity of 62.5% and specificity of 60.5% (Figure 1).
Conclusions: The best CVR algorithm to predict CP in PsA patients was the ACC/AHA risk score. However, there is a need of lower cut-off points to have the capacity of identifying patients classified in the low-moderate risk according to these calculators with subclinical atherosclerosis, who would benefit from an opportune treatment.
References: 1.- Yim KM, Armstrong AW. Updates on cardiovascular comorbidities associated with psoriatic diseases: epidemiology and mechanisms. *Rheumatol Int* 2017;37(1):97-105. doi: 10.1007/s00296-016-3487-2

Figure 1. ROC-curve of the six cardiovascular calculators.



P15 - Prevalence of carotid subclinical atherosclerosis in patients with Psoriatic Arthritis vs Rheumatoid Arthritis.

3. Comorbidities

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Introduction: Psoriatic Arthritis (PsA) and Rheumatoid Arthritis (RA) are associated with increased morbidity and mortality, mainly due to cardiovascular (CV) causes. CV outcomes in patients with PsA and RA cannot be completely explained by traditional cardiovascular risk factors, suggesting that the systemic inflammation that characterizes these diseases may have an important role on accelerated atherosclerosis.[1] The carotid ultrasound (US) which measures carotid intima-media thickness (cIMT) and carotid plaque (CP), is a non-invasive tool useful in the detection of subclinical atherosclerosis [2]
Objectives: To compare cIMT and asymptomatic CP prevalence, between patients with PsA, RA and controls.
Methods: Cross-sectional observational study. Seventy patients aged 35-75 years, with PsA and RA who fulfilled the CASPAR and ACR/EULAR 2010 classification criteria, respectively. Were matched with 70 healthy controls. All groups underwent a noninvasive examination using B-mode ultrasonography of the right and left common carotid artery. CP was defined as a focal narrowing ≥0.5 mm of the surrounding lumen or cIMT ≥1.2 mm; hyperplasia of the carotid intima was defined as cIMT ≥ 0.9 mm to 1.1 mm. Descriptive data were analyzed by continuous and categorical variables. Continuous variables with normal distribution are shown as mean ± standard deviation (SD), and non-normal distribution as median and quartiles (25q-75q). ANOVA, Kruskal Wallis, X^2 and Mann-Whitney U were used to compared data. A p value ≤0.05 was considered statistically significant. Statistical analysis was done using SPSS version 24.
Results: Clinical, demographic and carotid US characteristics are shown in Table 1. The global prevalence of carotid atherosclerosis was 25.7% and 38.6% in RA and PsA respectively, and 27.1% in controls (p=0.170). Intimal hyperplasia was found in 20%, 12.9% and 0% in RA, PsA and controls (p=0.001), respectively.
Conclusions: This study shows the high prevalence of asymptomatic atherosclerosis in RA and PsA compared to general population. Even though it was shown a higher prevalence of CP in PsA, subclinical atherosclerosis in RA patients may have an increased clinical significance. We observed increased prevalence of carotid intimal hyperplasia in RA and PsA compared with age-matched controls. We emphasize the value of carotid US as part of the CV evaluation in all PsA patients to detection of early atherosclerosis lesions and identifying those who would benefit from an opportune treatment.
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Table 1. Clinical, demographic and carotid US characteristics

	RA (n=70)	PsA (n=70)	Controls (n=70)	*P* value
Age, years ± SD	54.51±9.657	53.1±10.87	53.54±7.48	NS
Women, n (%)	61 (87.1)	39 (55.7)	59 (84.3)	NS
BMI, kg/m^2	28.9 (25.9-32.3)	29 (26.2-31.9)	27.4 (24.9-30.9)	NS
Comorbidities				
T2DM, n (%)	11 (15.7)	14 (20)	8 (11.4)	NS
HTN, n (%)	24 (34.3)	27 (38.6)	15 (21.4)	NS
Dyslipidemia, n (%)	19 (27.1)	30 (42.9)	18 (25.7)	NS
Active smoker, n (%)	7 (10)	16 (22.9)	15 (21.4)	NS
Statins	9 (12.9)	12 (17.1)	10 (14.3)	NS
Disease duration				
Duration, years ± SD	8.45 (3.34-15.88)	5 (2.75-8)	-	**0.005**
Carotid ultrasound findings				
Right cIMT, mm± SD	0.8 (0.6-1.1)	0.6 (0.5-0.9)	0.6 (0.5-0.8)	**<0.001**
Left cIMT, mm ± SD	0.8 (0.6-0.9)	0.6 (0.5-0.7)	0.6 (0.5-1.2)	**0.002**
Hyperplasia intimal, n (%)	14 (20)	9 (12.9)	0	**0.001**
CP, n (%)	18 (25.7)	27 (38.6)	19 (27.1)	NS

RA, rheumatoid arthritis; PsA, psoriatic arthritis; SD, standard deviation; NS, no significative; BMI, Body Mass Index; T2DM, type 2 Diabetes Mellitus; HTN, hypertension; cIMT, carotid intima-media thickness, CP carotid plaque.

P16 - Psoriatic Arthritis patients have higher prevalence of subclinical atherosclerosis: a case-control study

3. Comorbidities

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Introduction: Psoriatic arthritis (PsA) patients have a higher risk of developing a cardiovascular (CV) event than the general population due to an increased prevalence of traditional CV risk factors and to disease characteristics such as disease duration and activity. The carotid ultrasound is a non-invasive diagnostic tool that can detect the presence of subclinical atherosclerosis which is directly associated with the risk of developing a CV event.
Objectives: The aim of this study is to compare the prevalence of subclinical atherosclerosis detected by carotid ultrasound in PsA patients and controls.
Methods: This is a case-control study. A total of 75 PsA patients aged 40-75 years old, who fulfilled the 2006 CASPAR criteria and 75 matched controls by age (±5 years), gender and comorbidities were recruited for this study. Patients with history of a previous CV event and pregnant women were excluded from this study. A high-resolution B mode carotid ultrasound was performed in all study subjects by a certified radiologist. Subclinical atherosclerosis was defined as the presence of a carotid plaque (CP) or an increased carotid intima media thickness (cIMT). The presence of CP was defined as a cIMT ≥1.2mm or a focal narrowing ≥0.5mm in the surrounding lumen. An increased cIMT was considered as a value ≥0.8mm. Distribution was evaluated with the Kolmogorov-Smirnov test. Comparisons were done with Chi-square test for qualitative variables and Student´s t test and Mann-Whitney's U test for quantitative variables.
Results: There were no differences when comparing the demographic characteristics between both groups. When comparing the carotid ultrasound findings, a statistically significant difference was found in the prevalence of CP, which was higher in the PsA group (44.0% vs 26.7%, p=0.026), in the presence of unilateral CP (25.3% vs 10.7%, p=0.019) and in the presence of subclinical atherosclerosis (52.0% vs 34.7%, p=0.032). Results are shown in Table 1.
Conclusions: The prevalence of subclinical atherosclerosis was higher in PsA patients than controls, and this could be attributed to an increase in the inflammatory burden of these patients. The carotid ultrasound should be considered as part of the CV evaluation in all PsA patients, identifying those who would benefit from an opportune treatment preventing the development of a CV event.
References: 1.- Yim KM, Armstrong AW. Updates on cardiovascular comorbidities associated with psoriatic diseases: epidemiology and mechanisms. Rheumatol Int. 2017;37(1):97–105.

Table 1. Comparison of demographic, clinical characteristics and carotid ultrasound findings between psoriatic arthritis patients and controls.

	PsA patients (n=75)	Controls (n=75)	*p-value*
Age years, mean ± SD	53.89 ± 10.59	54.25 ± 7.08	NS
Female gender, n (%)	43 (57.3)	43 (57.3)	NS
T2DM, n (%)	16 (21.3)	15 (20.0)	NS
HTN, n (%)	28 (37.3)	21 (28.0)	NS
Dyslipidemia, n (%)	33 (44.0)	28 (37.3)	NS
Obesity, n (%)	31 (41.3)	32 (42.7)	NS
Active smoking, n (%)	14 (18.7)	18 (24.0)	NS
Disease duration years, median (p25-p75)	5.0 (3.0-10.0)	-	-
DAPSA, median (p25-p75)	12.6 (5.3-22.9)	-	-
Glucocorticoids, n (%)	10 (13.3)	-	-
MTX, n (%)	51 (68.0)	-	-
bDMARD, n (%)	28 (37.3)	-	-
Carotid ultrasound findings, n (%)			
Carotid plaque	33 (44)	20 (26.7)	**0.026**
Unilateral carotid plaque	19 (25.3)	8 (10.7)	**0.019**
Bilateral carotid plaque	14 (18.7)	12 (16)	NS
cIMT ≥0.8mm	14 (18.7)	9 (12)	NS
Unilateral cIMT ≥0.8mm	12 (16)	8 (10.7)	NS
Bilateral cIMT ≥0.8mm	1 (1.3)	1 (1.3)	NS
Presence of subclinical atherosclerosis	39 (52.0)	26 (34.7)	**0.032**

PsA, psoriatic arthritis; NS, not significant; T2DM, type 2 diabetes mellitus; HTN, hypertension; BMI, body mass index; DAPSA, disease activity for psoriatic arthritis; MTX, methotrexate; bDMARD, biological disease modifying antirheumatic drug; cIMT, carotid intima media thickness.

P17 - Subclinical inflammation in the duodenum with increased numbers of activated immune cells in patients with mild to moderate psoriasis

3. Comorbidities

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Introduction: Psoriasis is not only a skin disease: WHO acknowledged in 2014 psoriasis as a serious, non-contagious disease with increased risk of other serious sequelae (1). Psoriasis has a known association with inflammatory bowel disease (IBD) (2), but even patients without IBD may have subclinical bowel changes as previous studies showed elevated numbers of mast cells and eosinophils in the duodenal mucosa of psoriasis patients (3). These cells are implicated in colonic barrier dysfunction in IBD, but their role in psoriasis remains obscure.
Objectives: The aim of this study is to explore properties of the intestinal mucosa in patients with psoriasis, with the focus on intestinal permeability and immune cells in duodenum and colon.
Methods: Biopsy samples from duodenum and sigmoid colon were mounted in Ussing chambers for analyses of transcellular transcytotic and paracellular permeability with horse radish peroxidase (HRP) and 4kDa FITC-Dextran (FD4) as respective probes. Immune cells were analysed by flow cytometry and immunohistochemistry (IHC).The study includes18 patients with psoriasis and 15 healthy controls. Exclusion criteria: coeliac disease, IBS, IBD, intestinal infection.
Results: The macroscopical appearance of the intestinal mucosa was normal in all subjects. We found no general increase in paracellular permeability in the psoriasis group, but in duodenum there were two distinct populations in which half of the psoriasis patients had increased FD4 permeability and the other half were similar to controls. In contrast, only one of fifteen controls had higher FD4 permeability than the mean control population (Figure 1).Transcellular permeability was similar in both groups, and there were no differences in permeability in the sigmoid colon.

Flow cytometry and IHC revealed increased numbers of mast cells, eosinophils, neutrophils, $CD8^+$T cells and macrophages in the duodenal mucosa of psoriasis patients. Macrophages in the psoriasis group had higher surface expression of HLA-DR and lower CD206, indicating a pro-inflammatory M1 phenotype. Duodenal $CD8^+$ T-cells also showed signs of activation with higher CD69-expression, and there was a tendency of eosinophil activation (CD66b-expression) in duodenum of psoriasis patients. No significant differences in cell number or activation were found in sigmoid colon.
Conclusions: We found a subclinical inflammation in the duodenum of psoriasis patients, with increased numbers of activated immune cells in the mucosa and indications of increased intestinal permeability in duodenum in some of the patients. Collectively, these findings confirm an immunological link between the skin and the gut even in psoriasis patients without manifest intestinal disease.
References:

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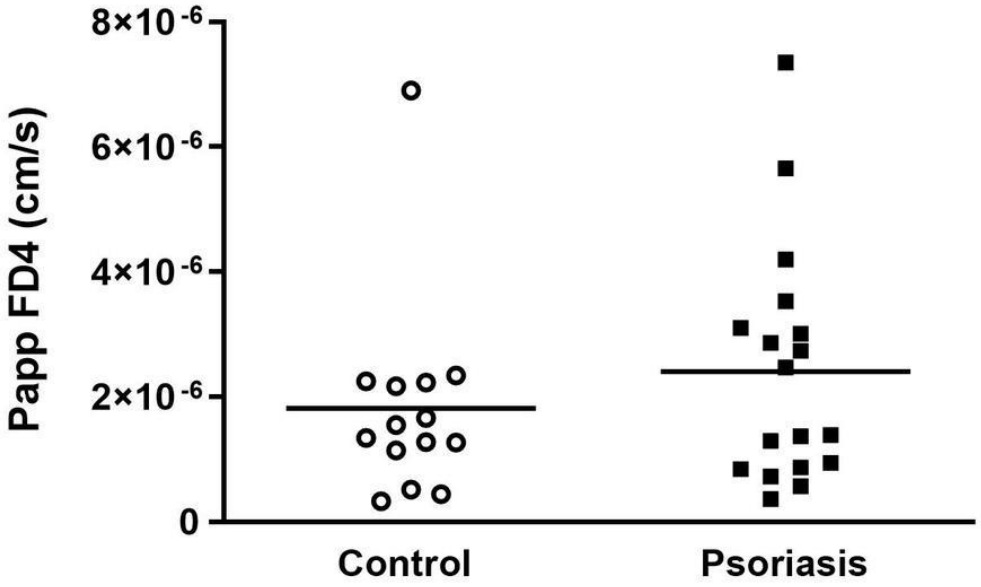
Figure 1 FD4 permeability, duodenum



P18 - The relationship of psoriatic arthritis with cardiovascular diseases: role of systemic inflammation and traditional risk factors

3. Comorbidities

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Introduction: Psoriatic arthritis (PsA) is associated with an increased risk of cardiovascular disease (CVD). In addition to traditional risk factors (TRF), chronic inflammation emerges important contributors to accelerated atherosclerosis and elevated CVD in patients (pts) with PsA.
Objectives: Our aim was to study associations between TRF, chronic inflammation and cardiovascular co-morbidities in pts with PsA.
Methods: A total of 48 pts with PsA were included in the study: 48% of women, age - 36 [27;46] years, disease duration - 6 [4; 8] months; psoriasis duration -13 [9; 84] 15[6; 26] months, DAS - 4,1 [3,5; 4,9]. All patients underwent standard clinical examination, screening TRF of CVD, C-reactive protein (CRP), blood pressure monitoring (BPM), 24-hour (24-h) ECG monitoring, SCORE index (Systematic Coronary Risk Evaluation), echocardiography. Carotid intima-media thickness (IMT) and the presence of carotid plaques (CP) were assessed with carotid ultrasound.
Results: The incidence rate of arterial hypertension (AH) 12 (25%), cardiac arrhythmia (ventricular and supraventricular extrasystole) - 12 (25%), diastolic dysfunction of the left ventricles - 5(10.4%), ischemic stroke (IS) - y 1 (2%) pts. The frequency of TRF: overweight 11(22.9%), abdominal obesity 14(29.2%), family history of CVD - 6(12.5%), smokers/ex-smokers16(33.3%), dyslipidemia 31(64.5%). Increased cIMT was found in 14(29.2%), atherosclerotic plaques - in 15(31.3%), mSCORE≥5% - in 15(31.2%). We found significant correlations between carotid IMT and CRP level (R=0.33), mSCORE (R=0.56), abdominal obesity (R=0.55), for all $p<0.05$. Significant negative correlations were found between CRP level and high-density lipoproteins (R=-0.41), $p<0,01$.
Conclusions: PsA pts have a high prevalence of AH, cardiac arrhythmia and subclinical atherosclerosis. The most common TRF were abdominal obesity, smoking, dyslipidemia. A complex interplay between TRF and chronic inflammation is implicated in the development of premature atherosclerosis and consequently in the higher incidence of cardiovascular events observed in PsA pts.

P19 - Waist to Height Ratio as An Indicator of Metabolic Risk in Psoriatic Arthritis

3. Comorbidities

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Introduction: Patients with psoriatic arthritis (PsA) have a higher burden of cardio-metabolic comorbidities compared to the general population. Abdominal obesity is associated with the development of metabolic syndrome and has an impact on the morbidity in PsA patients.[1]

The waist to height ratio (WHtR) is a simple and non-invasive method that shows superiority over body mass index (BMI) to detect cardiometabolic risk factors in both sexes [2]. A value greater than 0.5 has shown to have a high correlation with the percentage of abdominal fat. Therefore, the waist-to-height ratio should be considered as a screening tool.
Objectives: To compare the sensitivity of WHTR vs BMI to detect metabolic risk in patients with PsA.
Methods: Observational, cross-sectional study. Patients aged 30-80 years with a diagnosis of PsA (CASPAR) were included. A clinical history, anthropometry and laboratory analysis were carried out. The values considered altered for BMI and WHtR were > 25 and > 0.5, respectively. Descriptive analysis was performed with frequencies (%), mean (± SD) and ROC curves to determine the sensitivity of the methods.
Results: A total of 85 patients were included. Table 1 shows the demographic and clinical characteristics. When comparing the diagnostic efficacy of WHtR with BMI for hyperglycemia, WHtR showed an AUC 0.962 (0.57-0.81), a sensitivity of 100% vs. an AUC 0.492 (0.34-0.64) with a sensitivity of 75%. Respect to hypercholesterolemia, the WHtR showed an AUC 0.415 (0.28-0.54), with a sensitivity of 100% vs. an AUC 0.539 (0.40-0.67) for BMI with a sensitivity of 95% . And a sensitivity of 100% for WHtR vs. 88% for BMI in hypertriglyceridemia with an AUC 0.638 (0.51-0.76) and an AUC 0.563 (0.43-0.69), respectively.
Conclusions: The WHtR demonstrated greater sensitivity than the BMI for metabolic risk screening in patients with PsA. Suggesting it is a useful marker in PsA patients.
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Table 1. Demographic and clinical characteristics

	PsA (n=85)
Age, years ± SD	53.47±11.496
Sex, n (%)	
Women	48(56.5)
Men	37(43.5)
Comorbidities	
DMT2, n (%)	16(18.8)
HTN, n (%)	31(36.5)
Dyslipidemia, n (%)	35(41.2)
Classification by BMI, n (%)	
Low weight	1 (1.2)
Normal	14 (16.3)
Overweight	38 (44.2)
Obesity grade 1	21(24.4)
Obesity grade 2	6 (7)
Obesity grade 3	5 (5.8)
HWtR, n, (%)	
>0.5	4 (4.9)
<0.5	77 (95.1)

SD, standard deviation; HTN, hypertension; DMT2, diabetes mellitus type 2; BMI, Body Mass Index; HWtR, Waist to Height Ratio.

4. CURRENT AND NEW THERAPEUTIC MODALITIES

P20 - Bimekizumab versus Secukinumab for Moderate to Severe Plaque Psoriasis: Comparison of Absolute PASI Thresholds in the BE RADIANT Phase 3b Trial

4. Current and new therapeutic modalities

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Introduction: BE RADIANT (NCT03536884) is the first phase 3 trial to directly compare inhibition of both interleukin (IL)-17A and IL-17F with bimekizumab versus (vs) inhibition of IL-17A alone with secukinumab. Absolute Psoriasis Area and Severity Index (PASI) thresholds (e.g. PASI≤2) represent relevant treatment targets for patients (pts) with psoriasis,[1] providing more reliable estimates of residual disease activity compared with percentage PASI improvement.[2]
Objectives: To compare the proportions of pts achieving absolute PASI thresholds with inhibition of both IL-17A and IL-17F with bimekizumab and inhibition of IL-17A alone with secukinumab.
Methods: Pts with moderate to severe plaque psoriasis were randomised 1:1 to bimekizumab 320mg every 4 wks (Q4W) or secukinumab 300mg weekly to Wk4 then Q4W. At Wk16, pts receiving bimekizumab were re-randomised to bimekizumab 320mg Q4W or every 8 wks (Q8W) maintenance dosing. The percentages of pts who achieved PASI=0, PASI≤1, and PASI≤2 are reported for the intention-to-treat (ITT) population (all randomised pts), and the maintenance set (received ≥1 dose of study treatment at Wk16 or later). Nominal p values for comparisons between treatment groups were based on the stratified Cochran-Mantel-Haenszel test with region and prior biologic exposure (yes/no) as stratification variables and were not controlled for multiple comparisons. Missing data were imputed as non-response (NRI).
Results: 373 pts were randomised to bimekizumab, and 370 pts to secukinumab. At Wk16, a higher percentage of pts receiving bimekizumab achieved PASI=0 (61.7%) vs secukinumab (48.9%; nominal p<0.001; ITT population). Similarly, more pts treated with bimekizumab vs secukinumab achieved PASI≤1 (76.7% vs 64.1%; nominal p<0.001; ITT population) and PASI≤2 (85.3% vs 76.5%; nominal p=0.001; ITT population).
Through Wk48, response rates with bimekizumab remained higher than secukinumab. The percentage of pts in the ITT population receiving bimekizumab (Q4W or Q8W) vs secukinumab who achieved absolute PASI thresholds were: 67.0% vs 46.2% for PASI=0 (nominal p<0.001); 79.1% vs 59.7% for PASI≤1 (nominal p<0.001); and 83.9% vs 72.7% for PASI≤2 (nominal p<0.001). High levels of response were observed at Wk48 with both bimekizumab maintenance dosing regimens; PASI=0 was achieved by 73.5% pts receiving bimekizumab Q4W and 66.0% pts receiving bimekizumab Q8W (maintenance set; Table).
Conclusions: Higher and more durable rates of skin clearance were observed with bimekizumab compared with secukinumab; based on the percentage of pts achieving PASI=0, PASI≤1, and PASI≤2

through 48 wks, residual disease was lower in pts treated with bimekizumab. Response rates with bimekizumab were numerically similar with Q4W and Q8W maintenance dosing.

References: 1. Mahil SK. *Br J Dermatol* 2020;182:1158–66; **2.** Gordon KB. *J Dermatolog Treat* 2020;30:1–10.

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Table. Percentage of pts achieving absolute PASI thresholds at Wk48 (maintenance set;[a] NRI)

	Bimekizumab 320 mg Q4W[b] N=147 (%)	Bimekizumab 320 mg Q8W[b] N=215 (%)	Secukinumab 300 mg Q4W N=354 (%)	Bimekizumab Q4W vs secukinumab nominal p value	Bimekizumab Q8W vs secukinumab nominal p value
PASI=0	73.5	66.0	48.3	<0.001	<0.001
PASI≤1	83.0	80.5	62.4	<0.001	<0.001
PASI≤2	86.4	86.5	76.0	0.007	0.002

[a]Includes pts who received ≥1 dose of study treatment at Wk16 or later; [b]Pts received bimekizumab 320mg dosed Q4W through Wks 0–16 and were re-randomised at Wk16 to bimekizumab 320mg dosed Q4W or Q8W. NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; pts: patients; Q4W: every 4 weeks; Q8W: every 8 weeks; wk: week.

P21 - Bimekizumab versus Ustekinumab in Plaque Psoriasis: Cumulative Clinical and Quality of Life Benefit for Patients in the BE VIVID Phase 3 Trial

4. Current and new therapeutic modalities

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Introduction: Psoriasis can have a significant burden on patient (pt) quality of life (QoL).[1] In the BE VIVID phase 3 trial (NCT03370133), bimekizumab demonstrated superior efficacy to ustekinumab for the treatment of moderate to severe plaque psoriasis.[2] In addition to assessments of treatment efficacy at prespecified timepoints, evaluating cumulative benefit can offer greater insight into the impact of treatment on a pt's disease and QoL, through assessment of the total treatment effect over time.[3]
Objectives: Compare the cumulative benefit of bimekizumab versus (vs) ustekinumab treatment on skin clearance, as measured by a 90%/100% improvement in Psoriasis Area and Severity Index (PASI90/100), and impact of psoriasis on QoL, as measured by Dermatology Life Quality Index (DLQI), using area under the curve (AUC) analyses.
Methods: The analyses reported include pts randomised to 320mg bimekizumab every 4 weeks (wks) (Q4W) or 45mg/90mg ustekinumab (dosed by baseline weight: 45mg for patients ≤100kg, 90mg for patients >100kg) at Wk0 and Wk4, then every 12 wks through Wk52.[2] Data are reported as the total AUC through 52 wks ($AUC_{0–52}$) for patients achieving PASI90, PASI100 and DLQI0/1. Normalised cumulative clinical and QoL benefit, calculated as $AUC_{0–52}$ divided by 52 wks, reports the estimated percentage of wks that pts achieved each clinical or QoL outcome in this trial. Missing data were imputed as non-response (NRI).
Results: These analyses include 321 pts randomised to bimekizumab and 162 pts randomised to ustekinumab at baseline. Total $AUC_{0–52}$ for the percentage of pts achieving PASI90, PASI100 and DLQI0/1 was greater with bimekizumab vs ustekinumab: 4021.3 vs 2518.5 for PASI90; 2882.9 vs 1488.6 for PASI100; 3422.3 vs 2514.5 for DLQI0/1. Bimekizumab-treated pts achieved PASI90, PASI100 or DLQI0/1 for a greater percentage of wks over the course of the 52-wk trial, compared with ustekinumab-treated pts: 77.3% vs 48.4% for PASI90; 55.4% vs 28.6% for PASI100; 65.8% vs 48.4% for DLQI0/1 (Table).
Conclusions: The superior efficacy previously reported with bimekizumab in the BE VIVID trial translated to greater cumulative benefit through 52 wks, in terms of both skin clearance and improved QoL benefit, for pts with moderate to severe plaque psoriasis, as compared with ustekinumab.
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This study was funded by UCB Pharma. Medical writing support was provided by Costello Medical.

Table. Normalised cumulative clinical and QoL benefit for pts achieving PASI90, PASI100 and DLQI0/1 through 52 wks (NRI)

	Mean number and percentage of wks during which pts achieved clinical and QoL outcomes in BE VIVID (n/N [%])	
	Bimekizumab N=321	**Ustekinumab N=162**
PASI90	40.2/52 (77.3)	25.2/52 (48.4)
PASI100	28.8/52 (55.4)	14.9/52 (28.6)
DLQI0/1	34.2/52 (65.8)	25.1/52 (48.4)

Data are presented as mean total number of wks during which pts achieved clinical and QoL outcomes divided by the number of wks in the BE VIVID phase 3 trial (52 weeks), with the corresponding percentage of wks that pts achieved each outcome. DLQI: Dermatology Life Quality Index; NRI: non-responder imputation; PASI 90/100: 90%/100% improvement from baseline in Psoriasis Area and Severity Index; pts: patients; QoL: quality of life; wks: weeks.

P22 - DLQI 0/1 Association with Relative PASI Improvements in Patients with Moderate to Severe Plaque Psoriasis Treated with Certolizumab Pegol: Three-Year Results from Two Phase 3 Trials (CIMPASI-1 and CIMPASI-2)

4. Current and new therapeutic modalities

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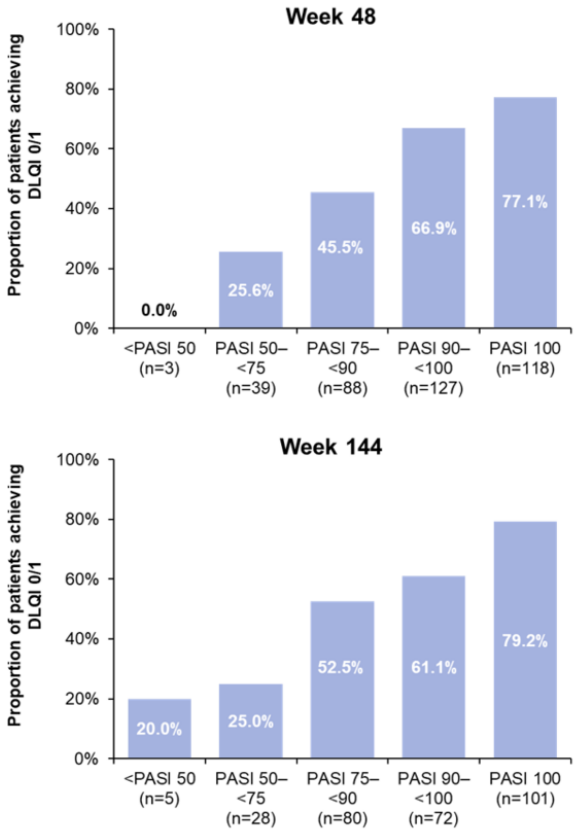
Introduction: In addition to physical manifestations, plaque psoriasis (PSO) negatively impacts quality of life (QoL), with links to social stigmatisation and psychological distress.[1] Therefore, it is important to understand whether clinical responses translate into long-term improvements in health-related (HR)QoL. The Dermatology Life Quality Index (DLQI) measures QoL specifically in relation to skin disease. DLQI is measured on a scale of 0–30,[2] with a score of 0 or 1 (DLQI 0/1) representing no impact of skin disease on QoL. Here, Psoriasis Area and Severity Index (PASI) and DLQI data are evaluated over three years of treatment in two phase 3 trials of certolizumab pegol (CZP), the Fc-free, PEGylated anti-tumour necrosis factor biologic.[3,4]
Objectives: To explore the relationship between PASI response and HRQoL with CZP treatment over time in patients with moderate to severe PSO.
Methods: Data were pooled from the CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326272) phase 3 trials; full study designs have been reported previously.[3] Adults with PSO ≥6 months (PASI ≥12, body surface area affected ≥10%, Physician's Global Assessment ≥3 on a 5-point scale) were randomised 2:2:1 for up to 48 weeks of double-blinded treatment with CZP 200 mg every 2 weeks (Q2W) (400 mg loading dose Weeks 0/2/4), 400 mg Q2W, or placebo (PBO). All patients received open-label CZP from Week 48. We report DLQI 0/1 in patients with PASI 100, PASI 90–<PASI 100, PASI 75–<PASI 90, PASI 50–<PASI 75, and <PASI 50, pooled across all patients at Weeks 48 and 144. Data are reported as observed.
Results: At Week 0, mean PASI across all 461 randomised patients was 19.2 (standard deviation [SD]: 7.1). Mean total DLQI at baseline was 13.8 (SD: 7.3). At both Week 48 and Week 144, the proportion of patients achieving DLQI 0/1 increased as relative skin clearance increased. At Week 48, 77.1% patients who achieved PASI 100 also achieved DLQI 0/1 (**Figure**). For patients achieving PASI 90–<100, PASI 75–<90, PASI 50–<75 and <PASI 50, 66.9%, 45.5%, 25.6% and 0% also achieved DLQI 0/1, respectively. Similarly, at Week 144, 79.2% of those who achieved PASI 100 also achieved DLQI 0/1, compared with 61.1%, 52.5%, 25.0% and 20.0% of those who achieved PASI 90–<100, PASI 75–<90, PASI 50–<75 and <PASI 50, respectively.
Conclusions: More patients who achieved higher PASI responses also achieved DLQI 0/1, consistent with previous literature reports.[5] The relationship between skin clearance and QoL observed at Week 48 was maintained at Week 144 among CZP-treated patients with PSO.

Funding: Dermira Inc. and UCB Pharma. Medical writing support provided by Costello Medical.
References: 1. Bhosle M. Health Qual Life Outcomes 2006;4:35; **2.** Finlay AY. Clin Exp Dermatol 1994;19:210–6; **3.** Gordon KB. BJD 2020; DOI:10.1111/bjd.19393; **4.** Blauvelt A. BJD 2020; DOI:10.1111/bjd.19314. **5.** Strober B. J Am Acad Dermatol 2016;75:77–82.

Figure. Proportion of patients achieving DLQI 0/1 by relative PASI improvement at Week 48 and Week 144



Results are pooled across all patients. Data are reported as observed. A DLQI score of 0 or 1 (DLQI 0/1) represents no impact of skin disease on quality of life. DLQI: Dermatology Life Quality Index; PASI 50/75/90/100: ≥50%/75%/90%/100% improvement from baseline in Psoriasis Area and Severity Index.

P23 - Efficacy and Safety of Deucravacitinib, an Oral, Selective Tyrosine Kinase 2 Inhibitor, in Patients With Active Psoriatic Arthritis: Results From a Phase 2, Randomized, Double-Blind, Placebo-Controlled Trial

4. Current and new therapeutic modalities

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Introduction: Tyrosine kinase 2 (TYK2) is an intracellular kinase that mediates signaling by key cytokines involved in psoriatic arthritis (PsA) pathophysiology. Deucravacitinib is a novel oral agent that selectively inhibits TYK2 through an allosteric mechanism by binding to the regulatory domain of TYK2, in contrast to inhibitors of the closely related Janus kinases (JAK 1–3) that bind to the active site in the kinase domain.[1]
Objectives: This trial evaluated the efficacy and safety of deucravacitinib in PsA.
Methods: In this ongoing, 1-year, randomized, double-blind, PBO-controlled (initial 16 weeks), multicenter, Phase 2 trial (NCT03881059), eligible patients had a PsA diagnosis for ≥6 months, met CASPAR criteria, and had active disease (≥3 tender and ≥3 swollen joints), C-reactive protein ≥3 mg/L (ULN, 5 mg/L), and ≥1 psoriatic lesion (≥2 cm). Patients had failed or were intolerant (IR) to ≥1 nonsteroidal anti-inflammatory drug, corticosteroid, and/or conventional synthetic disease-modifying antirheumatic drug (csDMARD), or 1 TNF inhibitor (TNFi; ≤30%). Patients were randomized 1:1:1 to deucravacitinib 6 mg once daily (QD) or 12 mg QD, or PBO. The primary endpoint was ACR 20 response at Week 16. Key secondary endpoints included improvement from baseline in the Health Assessment Questionnaire–Disability Index (HAQ-DI) and Short Form-36 Physical Component Score (SF-36 PCS). Additional endpoints included the proportion of patients achieving ACR 50/70, HAQ-DI response (≥0.35 improvement from baseline), minimal disease activity, enthesitis resolution (Leeds Index), and AEs.
Results: Of 203 patients randomized, 180 (89%) completed 16 weeks of treatment. Demographic and baseline disease characteristics were similar across the 3 groups. Mean age was 49.8 years, median PsA duration was 4.5 years, 66% of patients were using csDMARDs at baseline, and 15% were TNFi-IR. Both deucravacitinib 6 mg (n=70) and 12 mg QD (n=67) demonstrated significantly greater ACR 20 responses versus PBO (n=66) at Week 16 (52.9% and 62.7% vs 31.8%, respectively, $P<0.0001$). Key secondary objectives were achieved with significant and generally similar improvements in secondary endpoints for both deucravacitinib doses versus PBO. The most common AEs in the deucravacitinib 6 mg/12 mg/PBO groups were nasopharyngitis (5.7%/17.9%/7.6%), sinusitis (0/7.5%/0), headache (7.1%/1.5%/4.5%), and rash (4.3%/6.0%/0). No serious AEs were reported in deucravacitinib-treated patients, including no serious infections, herpes zoster, opportunistic infections, or thrombotic events.
Conclusions: Deucravacitinib was efficacious versus PBO over 16 weeks of treatment in patients with active PsA. Treatment was well tolerated and the safety profile was consistent with that observed in an earlier Phase 2 psoriasis trial.[2]

References:

1. Burke JR et al. *Sci Transl Med.* 2019;11:1-16.
2. Papp K et al. *N Engl J Med.* 2018;379:1313-21.

P24 - Efficacy and Safety of Guselkumab, a Monoclonal Antibody Specific to the p19-Subunit of Interleukin-23, Through 2 Years: Results from a Phase 3, Randomized, Double-blind, Placebo-controlled Study Conducted in Biologic-naïve Patients with Active Psoriatic Arthritis

4. Current and new therapeutic modalities

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Introduction: Guselkumab (GUS),a selective IL-23 inhibitor dosed Q4W or Q8W, demonstrated efficacy for joint & skin symptoms, inhibition of structural damage progression (Q4W),& safety vs PBO through W24 of Ph3, double-blind, PBO-controlled trial in biologic-naïve PsA pts (DISCOVER-2).[1]Favorable benefit-risk was also seen through 1 yr.[2]
Objectives: Assess GUS efficacy & safety through 2 yrs.
Methods: Biologic-naïve adults with active PsA (≥5 SJC + ≥5 TJC; CRP ≥0.6 mg/dL) were randomized to GUS 100mg Q4W; GUS 100mg at W0,4, Q8W; or PBO with crossover to GUS 100mg Q4W (PBO→Q4W) at W24. ACR responses were analyzed by baseline (BL) PASI scores. Clinical efficacy was assessed through W100 with missing data imputation (NRI for categorical endpts; no change/multiple imputation for continuous endpts). Observed PsA-modified van der Heijde Sharp (vdH-S) scores derived from blinded radiographic images taken at W0, W24, W52, W100 (or at d/c); AEs collected through W112.
Results: Among 739 randomized pts, 97% cont'd GUS at W24; 93% at W52; 88% completed W100. ACR20 responses (NRI) cont'd to increase after W24& at W100 were 76% (Q4W), 74% (Q8W). Similar response patterns were seen for ACR50/70, HAQ-DI& PASI90/100; IGA0/1& PASI75 responses were consistent through W100 in pts randomized to Q4W& Q8W. W100 data for PBO→Q4W pts were consistent with Q4W& Q8W pts. GUS improvements in SF-36 PCS/MCS at W52 persisted through W100. Low rates of radiographic progression (by mean PsA-modified vdH-S scores) were observed during W52-100 compared to W0-W52 for Q4W (0.75 vs 1.06)& Q8W (0.46 vs 0.99). In PBO→Q4W grp (n=228), radiographic progression was 1.12 during W0-24 (PBO), 0.51 during W24-100 (Q4W), & 0.13 during W52-100. Regardless of BL skin disease severity (PASI <12, ≥12 to <20, ≥20), pts with active PsA consistently achieved greater ACR responses with GUS (Q4W & Q8W) than with PBO at W24; responses achieved with GUS were maintained through W100.Through W112, incidences of AEs, SAEs, AEs leading to d/c, infections, serious infections & ISRs were generally consistent with PBO-controlled period & through 1 yr. Of pts in Q4W (n=245), Q8W (n=248), & PBO→Q4W (n=238) grps, 9%, 9%, 7% had ≥1 SAE; 2%, 3%, 3% had ≥1 serious infection; 2 Q8W pts (fungal esophagitis, disseminated herpes zoster) & 1 PBO→Q4W pt (listeria

meningitis) had opportunistic infections; 1 PBO→Q4W pt died (traffic accident); 1 PBO-treated pt had IBD; no pt had anaphylactic/serum sickness reaction or active TB.

Conclusions: GUS benefits for joint & skin symptoms, physical function, & low rates of radiographic progression persisted through 2 yrs. Joint efficacy was maintained through 2 yrs regardless of BL skin disease severity. GUS safety in PsA through 2 yrs was comparable to safety at 6 mos & 1 yr, similar btwn Q4W & Q8W, & consistent with GUS safety in PsO.

References: [1]Mease PJ, et al. *Lancet* 2020.
[2]McInnes IB, et al. *Arthritis Rheumatol* 2020.

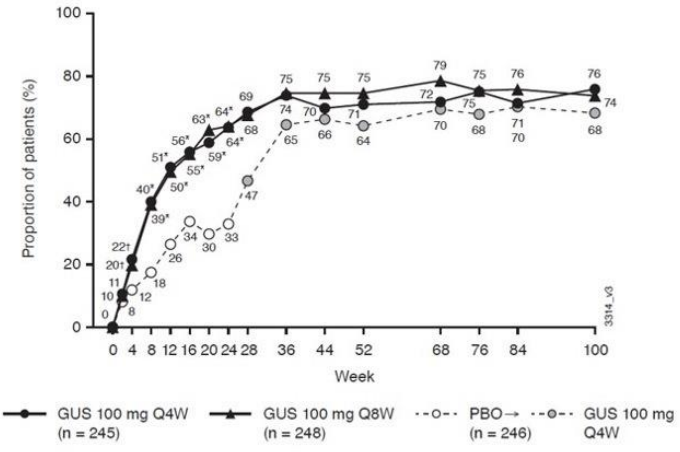
Select results were presented at Innovations in Dermatology; March 16-20, 2021.

Table: Efficacy Through W100 (NRI)

Data are %	GUS Q4W			GUS Q8W			PBO→GUS Q4W		
	W24	W52	W100	W24	W52	W100	W24	W52	W100
Analysis set, n	245			248			246		
ACR 50	33	46	56	32	48	55	14	41	48
ACR 70	13	26	35	19	28	36	4	18	30
BL HAQ-DI ≥0.35, n	228			228			236		
Improvement ≥0.35[a]	56	59	63	50	58	64	31	48	56
BL ≥3% BSA psoriasis + IGA ≥2, n	184			176			183		
IGA0/1	69	80	76	71	74	72	19	79	77
PASI75	78	87	83	79	86	82	23	83	80
PASI90	61	77	74	69	74	70	10	72	77
PASI100	45	58	59	45	53	53	3	52	61

BL, Baseline; BSA, Body surface area; HAQ-DI, Health assessment questionnaire disability index; IGA, Investigator global assessment; NRI, nonresponder imputation; PASI, Psoriasis area and severity index. [a]≥0.35 improvement among pts with HAQ-DI ≥0.35 at BL.

Figure. ACR 20 Response Through W100 (NRI)
(Note: Patients randomized to PBO crossed over to GUS 100 mg Q4W at W24)



*p ≤ 0.001; †p < 0.05

P25 - Efficacy and Safety of Risankizumab in Patients With Active Psoriatic Arthritis After Inadequate Response or Intolerance to DMARDs: 24-Week Results From the Phase 3, Randomized, Double-Blind KEEPsAKE 1 Trial

4. Current and new therapeutic modalities

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Introduction: Risankizumab (RZB) is a humanized immunoglobulin G1 monoclonal antibody that specifically inhibits interleukin 23 by binding to its p19 subunit. RZB is being investigated as a treatment for adults with psoriatic arthritis (PsA).
Objectives: To compare the efficacy and safety of RZB vs placebo (PBO) for the treatment of active PsA in patients who have had inadequate response or intolerance to ≥ 1 conventional synthetic disease modifying antirheumatic drug (csDMARD-IR).
Methods: In KEEPsAKE 1 (NCT03675308), eligible adults (csDMARD-IR with ≥ 5 swollen joints [SJC] and ≥ 5 tender joints [TJC]) were randomized (1:1) to receive blinded subcutaneous RZB 150 mg or PBO at weeks 0, 4, and 16. The primary endpoint was the proportion of patients achieving 20% improvement in American College of Rheumatology score (ACR20) at week 24. Ranked secondary and other secondary endpoints are shown in the **Table**. Safety was assessed throughout the study. Results reported here are from the 24-week double-blind period[1]; the open-label period with all patients receiving RZB is ongoing.
Results: 964 patients (RZB, N = 483; PBO, N = 481) were evaluated at week 24. Demographics and baseline characteristics were generally balanced between treatment groups (mean duration of PsA: 7.12 years; mean SJC: 12.2; mean TJC: 20.6; mean body surface area involved with psoriasis [BSA] in patients with BSA ≥ 3%: 16.7%). A significantly greater proportion of RZB- vs PBO-treated patients (57.3% and 33.5%, respectively) achieved the primary endpoint of ACR20 at week 24 (P < .001; **Table**). Significant differences were also observed for RZB vs PBO for the first 8 ranked secondary endpoints (P < .001 for all; **Table**). Serious adverse events were reported for 2.5% and 3.7% of RZB- and PBO-treated patients, respectively; serious infections were reported for 1.0% and 1.2%. There was 1 death in the RZB group.
Conclusions: RZB resulted in significantly greater improvements in signs and symptoms of PsA compared with PBO and was well tolerated in patients who were csDMARD-IR.

References:

1. Kristensen LE, Keiserman M, Papp K, et al. AB0559 EFFICACY AND SAFETY OF RISANKIZUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS AFTER INADEQUATE RESPONSE OR INTOLERANCE TO DMARDs: 24-WEEK RESULTS

FROM THE PHASE 3, RANDOMIZED, DOUBLE-BLIND KEEPsAKE 1 TRIAL.Annals of the Rheumatic Diseases 2021;80 (Suppl 1):1315-1316.

Table. Efficacy Results

	RZB 150 mg N = 483	PBO N = 481	Difference (95% CI)	*P* value
Primary endpoint				
ACR20, %	57.3	33.5	24.0 (18.0, 30.0)	< .001***
Ranked secondary endpoints				
HAQ-DI, change	−0.3	−0.1	−0.2 (−0.3, −0.1)	< .001***
PASI 90,[a] %	52.3	9.9	42.5 (35.6, 49.3)	< .001***
ACR20 at week 16, %	56.3	33.4	23.1 (16.8, 29.4)	< .001***
MDA, %	25.0	10.2	14.8 (10.2, 19.4)	< .001***
mNAPSI,[a] change	−9.8	−5.6	−4.2 (−5.7, −2.7)	< .001***
PGA-F,[a] change	−0.8	−0.4	−0.4 (−0.6, −0.3)	< .001***
Resolution of enthesitis,[a,b] %	48.4	34.8	13.9 (7.6, 20.2)	< .001***
Resolution of dactylitis,[a,b] %	68.1	51.0	16.9 (7.5, 26.4)	< .001***
PsA-mTSS, change	0.2	0.3	−0.1 (−0.4, 0.2)	.50
SF-36 PCS, change	6.5	3.2	3.3 (2.4, 4.2)	< .001†
FACIT-Fatigue, change	6.5	3.9	2.6 (1.5, 3.7)	< .001†
Other Secondary Endpoints				
ACR50, %	33.4	11.3	22.2 (17.3, 27.2)	< .001†
ACR70, %	15.3	4.7	10.5 (6.9, 14.2)	< .001†

ACR20/ACR50/ACR70, ≥ 20/50/70% improvement in American College of Rheumatology score; HAQ-DI, Health Assessment Questionnaire-Disability Index; FACIT-Fatigue, Functional Assessment of Chronic Illness Therapy-Fatigue Questionnaire; MDA, minimal disease activity; mNAPSI, modified Nail Psoriasis Severity Index; PASI 90, ≥ 90% reduction in Psoriasis Area Severity Index; PBO, placebo; PGA-F, Physician Global Assessment of Fingernail Psoriasis; PsA-mTSS, psoriatic arthritis modified Total Sharp Score; RZB, risankizumab; SF-36 PCS, 36-Item Short Form Health Survey Physical Component Summary.
All endpoints assessed at week 24 unless otherwise noted. All changes are mean changes from baseline.
***: Statistically significant at 0.001 level; multiplicity controlled.
†: Nominal *P* value.
[a]For patients with involved body surface area ≥ 3% (PASI 90; RZB N = 273; PBO N = 272), nail psoriasis (mNAPSI, PGA-F; RZB N = 309; PBO N = 338), enthesitis (RZB N = 444; PBO N = 448), or dactylitis (RZB N = 188; PBO N = 204) at baseline.
[b]Based on results pooled from KEEPsAKE 1 and KEEPsAKE 2 (NCT03671148).

P26 - Efficacy and safety of tildrakizumab, a high-affinity anti–interleukin-23p19 monoclonal antibody, in patients with active psoriatic arthritis

4. Current and new therapeutic modalities

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Introduction: Tildrakizumab (TIL), a high-affinity anti–interleukin-23p19 monoclonal antibody, is approved for moderate-to-severe plaque psoriasis treatment and is under investigation for psoriatic arthritis (PsA).
Objectives: A randomised, double-blind, placebo-controlled, multiple-dose, phase 2b study in PsA evaluated the efficacy and safety of TIL up to week (W)52 (NCT02980692).[1]
Methods: Patients ≥18 years with active PsA were randomised 1:1:1:1:1 to TIL 200 mg every 4 weeks (Q4W)→W52, TIL 200 mg Q12W→W52, TIL 100 mg Q12W→W52, TIL 20 mg Q12W→W24 then TIL 200 mg Q12W→W52, or placebo (PBO) Q4W→W24 then TIL 200 mg Q12W→W52. Efficacy assessments included the proportion of patients who achieved a 20% reduction from baseline by American College of Rheumatology response criteria (ACR20) and 75% improvement in Psoriasis Area and Severity Index (PASI 75). Treatment-emergent adverse events (TEAEs) were monitored.
Results: Of 500 patients screened, 391 were randomised and received ≥1 dose of drug. Demographics and baseline disease characteristics were generally consistent across treatment arms. At baseline, the mean (standard deviation) PASI score was 6.8 (8.2), 235 patients had body surface area (BSA) ≥3%, and 23.3% were anti–tumour necrosis factor-experienced. At W24, 71.4%–79.5% patients in TIL arms vs 50.6% in the PBO arm achieved ACR20 (P <0.01 TIL arms vs PBO). At W52, ACR20 response rates were maintained for the TIL 200 mg Q4W (79.5%), 200 mg Q12W (72.2%), and 100 mg Q12W (67.5%) arms and further increased for the TIL 20→200 mg Q12W (78.2%) and PBO→TIL 200 mg Q12W (77.2%) arms. Among patients with baseline BSA ≥3%, TIL treatment significantly increased the proportion of PASI 75 responders (46.3%–79.6%) vs PBO (16.7%) at W24 (P <0.01); the proportion of responders continued to increase thereafter and was sustained through W52 including in the PBO→TIL 200 mg Q12W arm (64.3%). TEAEs and serious TEAEs occurred in 64.5% and 3.3% of patients, respectively. No deaths or major adverse cardiac events occurred.

Conclusions: TIL improved joint and skin manifestations of PsA through W52 and was well tolerated among all treatment arms.

References: 1. Mease PJ, et al. *Ann Rheum Dis*. 2020;79(S1):145.

P27 - High levels of efficacy are well maintained over 5 years of treatment with tildrakizumab 100 mg in European patients who achieved PASI<3 response at week 28: pooled analysis from reSURFACE 1 and reSURFACE 2 phase 3 trials

4. Current and new therapeutic modalities

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Introduction: Tildrakizumab (TIL) is a high-affinity anti-interleukin-23p19 monoclonal antibody approved for the treatment of plaque psoriasis that has shown to be effective and safe for up to 5 years[1-3].
Objectives: To evaluate maintenance of absolute Psoriasis Area and Severity Index (PASI) <3 through 244 weeks (W) of treatment with TIL 100 mg in European patients who achieved absolute PASI <3 (PASI <3 response) at W28 and who continued treatment with the same dose of TIL from two phase 3 trials: reSURFACE 1 (NCT01722331) and reSURFACE 2 (NCT01729754).
Methods: *Post-hoc* pooled analysis of adult patients with moderate-to-severe plaque psoriasis from two 3-part, parallel-group, double-blinded, randomised controlled trials: reSURFACE 1 (64W) and reSURFACE 2 (52W). At W52/64, patients who had at least a PASI 50 response entered an optional 4-year extension period, with a total possible exposure of 256W (reSURFACE 1)/244W (reSURFACE 2). TIL was administered at W0 and W4, and every 12W thereafter. The study population included European patients on TIL 100 mg treatment who achieved absolute PASI <3 at W28 (PASI <3 responders) and who were randomised to continue the same TIL dose and followed-up until W244. Missing data were imputed using multiple imputation.
Results: At W28, 118 European patients who were PASI <3 responders to TIL 100 mg continued with the same dose. At W52, after two additional doses of TIL, 95.7% of patients maintained a PASI <3 response. At W148, 87.4% of patients had a PASI <3. After 5 years of treatment, at W244, 92.7% of patients had a PASI <3. Incidence of adverse events was similar to what was reported before[2].
Conclusions: Tildrakizumab 100 mg has demonstrated high levels of efficacy that were maintained throughout 5 years in European patients who achieved PASI <3 at W28. Tildrakizumab also had a favourable long-term safety profile over 5 years, which was comparable with that reported previously.
References: [1]Reich K, et al. Lancet 2017;390:276-88. [2]Reich K, et al. BJD 2020;182:605-17. [3]Thaçi D, et al. BJD 2021; online ahead of print.

P28 - Improvement in Absolute Psoriasis Area and Severity Index Through 5 Years of Continuous Treatment with Guselkumab in the VOYAGE 1 Trial

4. Current and new therapeutic modalities

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Introduction: VOYAGE 1 is a Phase 3 trial comparing guselkumab (GUS; a fully human anti-interleukin-23 monoclonal antibody) with adalimumab (ADA) in patients with psoriasis. GUS demonstrated significant efficacy in treating patients with moderate to severe plaque psoriasis in VOYAGE 1 studies.[1,2]
Objectives: Absolute Psoriasis Area and Severity Index (PASI) response was assessed up to 5 years of continuous GUS treatment. Safety of GUS treatment through 5 years was also evaluated.
Methods: Overall, 837 patients were randomized to receive GUS 100mg at Weeks 0/4, then every-8-weeks (q8w); PBO at Weeks 0/4/12, then GUS 100mg at Weeks 16/20, then q8w; or ADA 80mg at Week 0, 40mg at Week 1, and 40mg q2w through Week 47, then GUS 100mg q8w starting at Week 52 (ADA→GUS). Absolute PASI thresholds of ≤1, ≤2, ≤3, ≤4, and ≤5 were evaluated through Week 252. Patients randomized to GUS and PBO were combined to form the GUS group. This analysis was performed using observed data after applying treatment failure rules, which considered those who discontinued due to lack of efficacy, adverse event of worsening of psoriasis, or use of protocol-prohibited psoriasis treatment as nonresponders.
Results: In the GUS group, the proportions of patients with PASI≤1, PASI≤2, PASI≤3, and PASI≤4 were 66.0%, 81.2%, 88.9%, and 92.3% at Week 52 (n=468) and 69.8%, 84.4%, 89.5%, and 91.3% at Week 252 (n=391), respectively. In the ADA→GUS group, corresponding proportions were 36.2%, 50.2%, 63.8%, and 68.1% at Week 52 (n=279) with ADA treatment and 64.6%, 80.1%, 87.0%, and 92.3% at Week 252 (n=246) after switching to GUS at Week 52. Most patients (92.3% [GUS] and 92.7% [ADA→GUS]) achieved PASI≤5 by Week 252. No new safety concerns were reported for GUS through Week 252.
Conclusions: Continuous treatment with GUS was well tolerated and provided robust and durable skin responses based on absolute PASI through 5 years.

References:

1. Blauvelt A, et al. *J Am Acad Dermatol*. 2017;76:405-417.
2. Reich K, et al. *J Am Acad Dermatol*. 2020;82:936-945.

Selected results from this analysis were presented previously at the American Academy of Dermatology Virtual Meeting and Experience (AAD VMX); April 23-25, 2021.

P29 - Long-term drug survival over 5 years of continuous guselkumab treatment in patients with moderate-to-severe psoriasis: a post hoc analysis of the VOYAGE 1 trial

4. Current and new therapeutic modalities

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Introduction: Drug survival is an important surrogate measure of treatment outcome and can be derived from analysis of long-term (>1 year) follow-up of randomized clinical trials. VOYAGE 1 was a phase 3 trial that demonstrated superior efficacy of the interleukin-23 inhibitor guselkumab compared with adalimumab in patients with moderate-to-severe psoriasis.
Objectives: The aim of this *post hoc* analysis was to evaluate long-term drug survival in patients who received guselkumab for up to 5 years (252 weeks).
Methods: The analysis population included all patients randomized to guselkumab in VOYAGE 1. The primary analysis of data from Week 0 through to Week 252 measured drug survival as time to treatment discontinuation for any reason, by the Kaplan–Meier method. Secondary analyses were performed for treatment discontinuation due to: (a) lack of efficacy; and (b) adverse events.
Results: The analysis population included a total of 329 patients randomized to guselkumab. In the primary analysis, 74.8% (246/329) of patients were still on guselkumab at Week 252. The reasons for discontinuation included lack of efficacy (n=10/83), adverse events (n=25/83), and other reasons (n=48/83), including 2 patients for COVID-19 related reasons.
Conclusions: The results from this *post hoc* analysis of VOYAGE 1 showed a drug survival rate of almost 75% over 5 years for patients randomized to guselkumab. The high long-term drug survival rate of guselkumab in patients with moderate-to-severe psoriasis is of importance to clinical decision-making. This is the first time a clinical trial program for a biologic has been used to present drug survival analyses similar to those seen in real-world studies; however, these findings still need to be confirmed in a real-world setting.

P30 - Long-term Response for Ixekizumab is Demonstrated Through Five years for Early- and Mid-Term Responders for Patients with Moderate-to-Severe Psoriasis

4. Current and new therapeutic modalities

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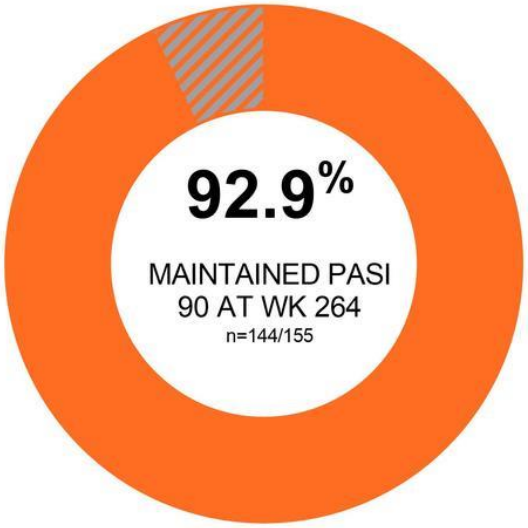
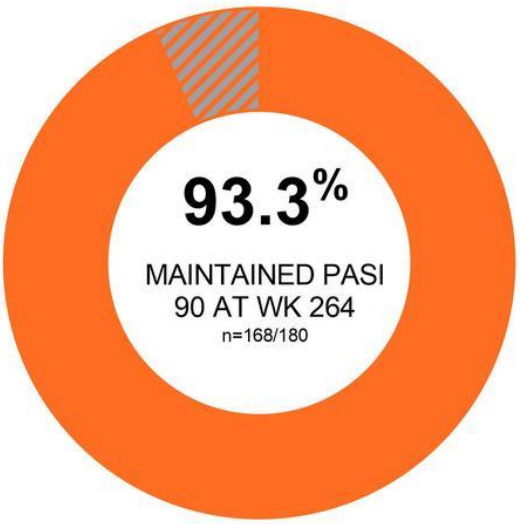
Introduction: Ixekizumab (IXE), a high-affinity monoclonal antibody that selectively targets interleukin-17A, is approved for treatment of moderate-to-severe plaque psoriasis.[1] Early- and mid-term (12-60 Week (Wk)) responder status are important benchmarks that can be predictive of patient satisfaction and long-term response to therapy.
Objectives: To assess if achievement of Psoriasis Area and Severity Index (PASI) 90 at early- (Wk12) and mid-term (Wk60) correlates with longer term response at 5 years in patients with moderate-to-severe plaque psoriasis from UNCOVER-3 (NCT01646177).[1]
Methods: Full study methods for UNCOVER-3 have been published previously [1]. In this analysis, we evaluated early- and mid-term response with long-term clinical outcomes. We considered early responders as patients achieving PASI90 at Wk12, and mid-term as patients achieving PASI90 at Wk60. Data included long-term (to Wk264) PASI90 response rates in those achieving early- (Wk12) and mid-term (Wk60) PASI90 response at the approved label dose (initial 160 mg, IXE 80 mg every 2weeks up to Wk12, and IXE 80 mg every 4weeks thereafter). Missing data was controlled for using modified NRI (mNRI), both observed and mNRI are included.
Results: For observed data, PASI90 response rates at Wk12 were achieved in 68.1% (n=262/385) of patients; 59.2% (n=155/262) of these patients had available data at Wk264, with 92.9% (n=144/155) maintaining a long-term PASI90 response (Fig 1). Based on mNRI data, 74.8% of Wk12 PASI90 responders maintained a long-term PASI90 response at Wk264. For observed data, PASI90 response rates were achieved in 73.2% (n=282/385) of patients at Wk60; 63.8% (n=180/282) of these patients had available data at Wk264 with 93.3% (n=168/180) maintaining a long-term PASI90 response (Fig 1). Based on mNRI data, 79.4% of Wk60 PASI90 responders maintained a long-term PASI90 response at Wk264.
Conclusions: This study demonstrates that significant early efficacy (PASI90) responses to IXE show long-term efficacy. Patients who respond to therapy with PASI90 achievement at early- (Wk12) and mid- (Wk60) time points show a sustained high level of response for PASI90 at Wk264.
References: Blauvelt et al. (2020). J Am Acad Dermatol.

UNCOVER-3: MAINTENANCE OF RESPONSE

IN PATIENTS WHO ACHIEVED PASI 90 AT **WEEK 12** AND HAD AVAILABLE DATA AT WEEK 264 (observed)



IN PATIENTS WHO ACHIEVED PASI 90 AT **WEEK 60** AND HAD AVAILABLE DATA AT WEEK 264 (observed)



P31 - Long-term Safety of Guselkumab: Results From the VOYAGE 1 and VOYAGE 2 Trials With up to 5 Years of Treatment

4. Current and new therapeutic modalities

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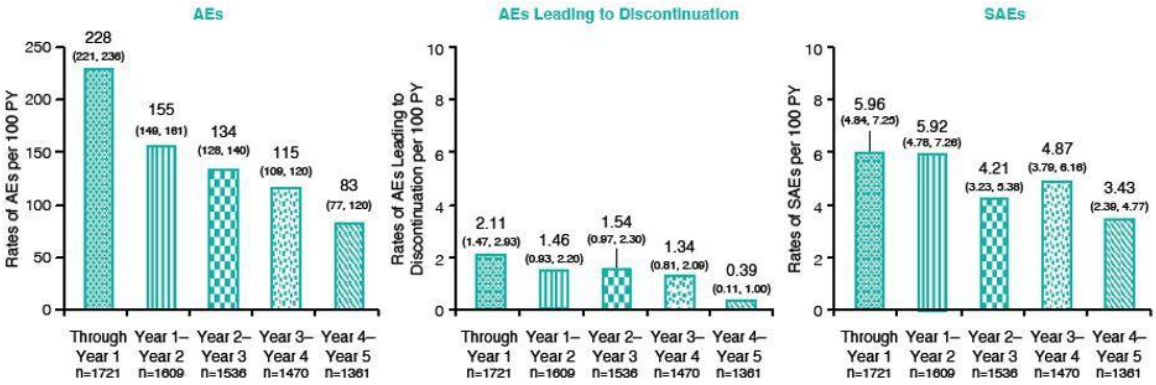
Introduction: Guselkumab (GUS) is a fully human monoclonal antibody that binds and inhibits the p19 subunit of interleukin-23. VOYAGE 1 and 2 are Phase 3, randomized, double-blind, placebo (PBO)- and active-controlled studies of GUS in adults with moderate to severe plaque psoriasis (ie, Investigator's Global Assessment ≥3, Psoriasis Area and Severity Index ≥12, and body surface area ≥10%, and candidates for systemic therapy or phototherapy).[1,2]
Objectives: This analysis evaluated the cumulative safety of GUS using pooled data from the VOYAGE 1 and 2 studies through 5 years.
Methods: In both studies, patients were randomized to GUS, PBO, or adalimumab (ADA) with PBO crossover to GUS at Week (W)16. In VOYAGE 1, patients randomized to ADA crossed over to GUS at W52, and all patients received open-label GUS treatment from W52 to W252. VOYAGE 2 assessed randomized withdrawal/retreatment from W28 to W76, and all patients received open-label GUS from W76 to W252. In both studies, safety data were collected through W264. Pooled safety data were adjusted by exposure and analyzed through W264 in the GUS group (including W16 PBO crossover; n=1221), the ADA→GUS group (n=500), and the Combined GUS group (GUS and ADA→GUS groups; n=1721).
Results: Of 1721 patients treated with GUS, 1349 (78.4%) completed the study through W252 (7166 patient-years [PY] of follow-up). The proportion of patients discontinuing due to adverse events (AEs) was low (6.0% [104/1721]). Through W264, AE rates per 100 PY were generally comparable in the GUS and ADA→GUS groups, respectively: AEs (155 and 133), AEs leading to discontinuation (1.45 and 1.46), and serious AEs (5.18 and 4.55). Rates of AEs of interest remained low through W264 in both the GUS and ADA→GUS groups, respectively: serious infections (0.97/100 PY and 0.52/100 PY), malignancies other than nonmelanoma skin cancer (NMSC) (0.50/100 PY and 0.31/100 PY), NMSC (0.31/100 PY and 0.42/100 PY), and major adverse cardiovascular events (0.30/100 PY and 0.26/100 PY). Through W264, 67 (3.9%) patients reported 171 (0.4%) injection-site reactions for GUS injections in VOYAGE 1 and 2; most were mild in intensity. Over time, there was some year-to-year variability in rates of AEs, AEs leading to discontinuation, and serious AEs in the Combined GUS group (Figure), but no increasing trends were evident. The GUS safety profile was consistent from Year 1 to Year 5.
Conclusions: The long-term extensions of pivotal studies of GUS in patients with moderate to severe psoriasis identified no new safety concerns and demonstrated that AE rates were low and generally stable with GUS exposure through 5 years.

References:

1. Blauvelt A, et al. *J Am Acad Dermatol*. 2017;76(3):405-17.
2. Reich K, et al. *J Am Acad Dermatol.* 2017;76(3):418-31.

Selected results from this analysis were presented previously at the American Academy of Dermatology Virtual Meeting and Experience (AAD VMX); April 23-25, 2021.

Figure. Overall AEs, AEs leading to discontinuation, and SAEs per 100 PY of follow-up (95% CI) by year of exposure for the Combined GUS group (pooled data from VOYAGE 1 and VOYAGE 2).



AE, adverse event; CI, confidence interval; GUS, guselkumab; PY, patient-years; SAE, serious adverse event.

P32 - Long-term safety of ustekinumab in adolescent patients with moderate-to-severe plaque psoriasis: results from an ongoing observational study

4. Current and new therapeutic modalities

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Introduction: Biologics are recommended for treating moderate-to-severe plaque psoriasis. In 2015, the European Medicines Agency approved ustekinumab for the treatment of adolescent psoriasis; however, long-term data regarding ustekinumab in adolescent patients are limited.
Objectives: This post-marketing study (NCT03218488) aims to evaluate the long-term safety profile of ustekinumab in adolescents (12–18 years of age) with moderate-to-severe plaque psoriasis.
Methods: This ongoing, prospective, multi-centre study enrolled eligible patients diagnosed with moderate-to-severe plaque psoriasis initiating ustekinumab; clinical data are collected until the patient is 18 years old, or until withdrawal or study closure. All adverse events (AEs), including those potentially related to immune modulation, are evaluated. Here we report findings up to 30 months from the start of data collection; some of these data have been presented previously.[1] Due to low patient numbers, only descriptive analyses were performed.
Results: This analysis included 39 patients, of whom two discontinued due to withdrawal of consent and the parents' decision, and 11 (enrolment age 16 or 17 years) completed the study. The mean (SD) patient age was 14.7 (1.8) years, and 64.1% of patients were female. The majority (84.2%) of patients received ustekinumab 45 mg as the first dose and six (15.4%) patients stopped or interrupted ustekinumab therapy. The mean (SD) time from diagnosis to ustekinumab initiation was 6.7 (4.8) years; the mean (SD) age at psoriasis onset was 8.1 (4.9) years. A total of 26 patients (66.7%) reported using other therapies for psoriasis during the study period. A total of 12.8% of patients had prior exposure to biologics. Dermatologics (e.g. topical corticosteroids), antineoplastic/immunomodulating agents and folic acid were used by 64.1%, 10.3% and 2.6% of patients, respectively. The most common ongoing medical conditions were nail psoriasis (28.2%), asthma (15.4%) and fatigue (10.3%). Twenty-one patients (53.8%) reported 116 AEs. Of these, 36 (31.0%), 3 (2.6%) and 10 (8.6%) were rated as possibly, probably, or very likely related to ustekinumab by the investigator. Four patients reported five serious AEs of which one (appendicitis) was considered possibly related and four (buttock injury, ligament rupture, testicular torsion and psoriasis) were considered unrelated to ustekinumab. Most AEs were mild in severity and did not result in any change in ustekinumab treatment. AEs occurring in >1 patient are shown in the Table. No malignancies or autoimmunity adverse events were reported.
Conclusions: The safety data collected for this analysis revealed no new safety concerns, and findings are generally consistent with the known safety profile for ustekinumab in paediatric and adult patients.
References:

1. Mahé E, et al. *ESPD* 2021, Poster P106.

TABLE. AEs occurring in more than one patient by system organ class and preferred term

	Patients, n (%) (N=39)	Number of events
Patients with any AE	21 (53.8)	116
General disorders and administration site conditions	13 (33.3)	19
Fatigue	9 (23.1)	10
Influenza-like illness	3 (7.7)	3
Peripheral swelling	2 (5.1)	2
Pyrexia	2 (5.1)	2
Infections and infestations	9 (23.1)	16
Nasopharyngitis	4 (10.3)	5
Rhinitis	3 (7.7)	3
Nervous system disorders	8 (20.5)	14
Headache	7 (17.9)	8
Hypoaesthesia	2 (5.1)	3
Musculoskeletal and connective tissue disorders	8 (20.5)	17
Arthralgia	3 (7.7)	4
Myalgia	3 (7.7)	3
Back pain	2 (5.1)	2
Musculoskeletal pain	2 (5.1)	2
Respiratory, thoracic and mediastinal disorders	7 (17.9)	9
Oropharyngeal pain	6 (15.4)	6
Skin and subcutaneous tissue disorders	7 (17.9)	7
Psoriasis[a,b]	2 (5.1)	2
Gastrointestinal disorders	6 (15.4)	14
Abdominal pain	3 (7.7)	5
Nausea	3 (7.7)	3
Abdominal pain upper	2 (5.1)	3
Reproductive system and breast disorders	3 (7.7)	4
Dysmenorrhoea	2 (5.1)	2

[a]One case of psoriasis was a superinfection misreported as psoriasis.
[b]Worsening of psoriasis was captured as psoriasis.

P33 - Long-term safety profile of tildrakizumab: Incidence of gastrointestinal adverse events over 5 years of treatment in patients with moderate-to-severe psoriasis from reSURFACE 1 and reSURFACE 2 phase 3 trials

4. Current and new therapeutic modalities

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Introduction: Patients with psoriasis have an increased risk of inflammatory bowel disease (IBD)[1]. We present new IBD cases and rates of gastrointestinal adverse events (AEs) for up to 5 years in patients receiving tildrakizumab (TIL), an anti–interleukin-23p19 monoclonal antibody approved for the treatment of plaque psoriasis.
Objectives: To evaluate the rates of gastrointestinal AEs through 5 years in two phase 3 trials: reSURFACE1 (NCT01722331) and reSURFACE2 (NCT01729754).
Methods: *Post-hoc* pooled analysis of adult patients with moderate-to-severe plaque psoriasis from two 3-part, parallel-group, double-blinded, randomised, controlled trials: reSURFACE 1 (64 weeks) and reSURFACE 2 (52 weeks). Detailed methodology has previously been published[2]. After completing the base study, patients who had at least a PASI 50 response entered an optional 4-year extension period of up to week 256 (reSURFACE 1)/week 244 (reSURFACE 2). Safety data over 256 weeks pooled across trials and treatment groups were included. Groups were defined as: TIL 200 mg (patients who received TIL 200 mg in at least one part of the study) and TIL 100 mg (patients who received TIL 100 mg in at least one part of the study). Exposure-adjusted incidence rates (EAIR) of gastrointestinal AEs are reported (i.e., patients with event per 100 patient-years [PYs] of exposure) for the all subjects as treated population.
Results: Overall, 928 patients on TIL 200 mg and 872 patients on TIL 100 mg were included, with a total exposure of 2753.5 and 2688.4 years, respectively. The EAIR of gastrointestinal AEs was 8.53/100 PYs of exposure for TIL 200 mg and 8.37/100 PYs for TIL 100 mg groups over the 5 years of treatment. Most commonly reported types of gastrointestinal AEs included diarrhoea (57 patients in the TIL 200 mg group [2.07 patients per 100 PYs] and 60 patients in the TIL 100 mg group [2.23 patients per 100 PYs]), nausea (33 patients in the TIL 200 mg group [1.20 patients per 100 PYs] and 27 patients in the TIL 100 mg group [1.00 patients per 100 PYs]) and toothache (22 patients in the TIL 200 mg group [0.80 patients per 100 PYs] and 31 patients in the TIL 100 mg group [1.15 patients per 100 PYs]). Over 5 years, 1 ischaemic colitis in the TIL 200 mg group and 1 Crohn’s disease event in the TIL 100 mg group were reported (both 0.04 patients per 100 PYs in the corresponding dose group), none of which led to treatment discontinuation.
Conclusions: Tildrakizumab had a favourable long-term safety profile as demonstrated by a low rate of gastrointestinal events through 5 years in patients with moderate-to-severe plaque psoriasis.
References: [1]Li WQ, et al. Ann Rheum Dis 2013;72(7):1200-5. [2]Reich K, et al. Lancet 2017;390:276-88.

P34 - Maintenance of Response Through 5 Years of Continuous Guselkumab Treatment: Results from the Phase 3 VOYAGE 1 Trial

4. Current and new therapeutic modalities

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Introduction: VOYAGE 1, a Phase 3, double-blinded, placebo (PBO)- and active comparator-controlled study evaluated the efficacy and safety of guselkumab (GUS; a fully human anti-interleukin-23 monoclonal antibody) in patients (pts) with moderate-to-severe plaque psoriasis (PsO).[1,2]
Objectives: Assess efficacy and safety through 5 years of continuous GUS treatment.
Methods: In VOYAGE 1, pts were randomized to GUS 100 mg at Weeks (W) 0, 4, 12, then every-8-weeks (q8w); PBO at W0, 4, 12 followed by GUS 100 mg at W16, 20 then q8w; or adalimumab 80 mg at W0, 40 mg at W1, then 40 mg q2w through W47. At W52, all pts continued open-label GUS through W252. Efficacy assessments included proportions of pts achieving ≥90% or 100% improvement in PsO Area and Severity Index (PASI 90, PASI 100), and Investigator's Global Assessment scores of cleared/minimal or cleared (IGA 0/1, IGA 0). Three statistical methods were used to analyze efficacy: prespecified Treatment Failure Rules (TFR), Nonresponder Imputation (NRI), and As Observed (OBS). For TFR analyses, pts who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a protocol-prohibited PsO treatment were considered nonresponders. For NRI analyses, pts with missing efficacy data (regardless of reason) after application of TFR were counted as nonresponders. For OBS analyses, missing data were not imputed. Safety was assessed through W264.
Results: Among 494 pts randomized to GUS at W0 (N=329) and PBO pts who crossed over to GUS at W16 (N=165), 76.9% (380/494) continued through W252. Primary reasons for discontinuation included withdrawal by pt (n=33 [6.7%]), adverse events (AEs; n=30 [6.1%]), and lost to follow-up (n=15 [3.0%]). PASI 90 responses were well-maintained with up to 5 years of continuous GUS use. At W52, PASI 90 response rates were 79.7%, 75.5%, and 80.6% based on TFR, NRI, and OBS analyses, respectively; corresponding rates at W252 were 84.1%, 66.6%, and 86.6%. Likewise, PASI 100, IGA 0/1, and IGA 0 responses were maintained from W52 through W252 (Table). Efficacy was also maintained through W252 in pts randomized to GUS at W0 (N=329). Through end of the study for all pts (GUS group and adalimumab→GUS crossover group; N=774), the proportion of pts reporting at least one AE or serious AE were 87.7% and 16.4%, respectively. Rates of AEs of interest through W264 were as follows: serious infections (2.8%), malignancies (nonmelanoma skin cancer [1.7%]; cancer other than nonmelanoma skin cancer [2.3%]), major adverse cardiovascular events (1.0%), and suicidal ideation and behavior (0.6%).
Conclusions: High efficacy response rates were maintained (regardless of the method used to analyze data) and no new safety concerns were identified through 5 years of continuous GUS treatment in VOYAGE 1.
References:

1. Blauvelt A., et al. *J Am Acad Dermatol.* 2017;76:405-17.
2. Griffiths CEM, et al. *J Dermatol Treat.* 2020;13:1-9.

Selected results from this analysis were presented previously at the 16th Annual Coastal Dermatology Symposium, October 15-16, 2020.

Table. Proportion of Patients in the GUS Group[a] Achieving Clinical Responses by Analysis Type at Week 52 and Week 252

	Week 52			Week 252		
	TFR (N=468)	NRI (N=494)	OBS (N=463)	TFR (N=391)	NRI (N=494)	OBS (N=380)
PASI 90	79.7%	75.5%	80.6%	84.1%	66.6%	86.6%
PASI 100	49.1%	46.6%	49.7%	52.7%	41.7%	54.2%
IGA 0/1	84.6%	80.2%	85.5%	82.4%	65.2%	84.7%
IGA 0	53.6%	50.8%	54.2%	54.7%	43.3%	56.3%

IGA, Investigator's Global Assessment; GUS, guselkumab; NRI, nonresponder imputation method; OBS, As Observed method; PASI, Psoriasis Area and Severity Index; TFR, treatment failure rules method.

[a]Includes patients randomized to GUS and placebo patients who crossed over to GUS at Week 16

P35 - Pharmacokinetics and Pharmacodynamics of the Phosphodiesterase 4 (PDE4) Inhibitor HPP737 Following Single-dose Oral Administration in Healthy Subjects.

4. Current and new therapeutic modalities

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Introduction: HPP737 is a potent, selective, orally administered PDE4 inhibitor being studied for the treatment of moderate to severe psoriasis. HPP737 was designed to be selective for PDE4B2 (3-fold more potent at PDE4B2 than PDE4D) and to have limited CNS penetrance and limited activity at the locus coeruleus, thereby potentially reducing the likelihood of dose- limiting adverse effects associated with PDE4 inhibitors.
Objectives: The primary objective of this Phase 1 study was to evaluate the safety and tolerability of HPP737 following single-dose administration to healthy subjects. The secondary objective was to evaluate the single-dose pharmacokinetic (PK) profile of HPP737 including the assessment for an effect of food on the PK profile. An exploratory objective was to assess potential ex-vivo TNF α response to single-dose HPP737.
Methods: This was a Phase 1, First-in-Human, single-center, single-blind, within-cohort ascending-dose, 3-period crossover with placebo substitution trial. A fourth open-label period in each cohort evaluated the effect of food (US FDA high fat meal) on HPP737 PK. Twelve healthy subjects were enrolled in each cohort and randomized to a sequence of HPP737 doses/placebo such that in each period 9 received active and 3 received placebo. Each subject received 2 single doses of HPP737 (0.5 mg, 1.5 mg or 3 mg for Cohort 1; 6 mg, 12 mg or 20 mg for Cohort 2) and one placebo dose, administered following an overnight fast, with at least a 7-day washout between doses. The effect of food was evaluated for 3 mg (i.e. 3mg FED) and 12 mg (i.e. 12mg FED) doses. Ex vivo lipopolysaccharide (LPS) stimulated TNF assays were performed prior to and 1, 4, 8, 24 and 48 hours following dose administration.
Results: HPP737 was well tolerated with no dose-limiting treatment-emergent adverse events (AEs), effects on ECG, vital signs, or clinical pathology measures. All AEs were mild and resolved without sequelae. No Serious Adverse Events were reported. Absorption of HPP737 was rapid with maximal concentrations achieved within 4-5 hours post dose. Exposure increased in a dose proportional manner. Across doses, mean terminal elimination half-life ranged from 14.7 to 21.1 hours, supporting once daily administration. Less than 1% of administered doses was excreted unchanged in urine. A mild food effect was identified for the 12 mg FED dose with time to maximal concentration (Tmax) delayed (9-11h FED vs 4-4.5h fasted), area under the curve (AUC) increased (~29%) and maximal concentration (Cmax) unchanged. A decrease in ex-vivo LPS stimulated TNF-α was noted around HPP737 Tmax following administration of doses ≥12 mg.
Conclusions: Single dose administration of HPP737 was well tolerated and suggestive of a functional pharmacologic effect on TNF-α, consistent with PDE4 inhibition, noted at doses ≥12mg. Results support advancement of HPP737 into multiple ascending dose studies to assess the safety, tolerability, and PK.

P36 - Psoriasis skin and nail disease: effect of skin symptoms on disease impact and drug persistence in patients with psoriatic arthritis receiving the IL-12/23 inhibitor ustekinumab or TNF inhibitors in the real-world PsABio study

4. Current and new therapeutic modalities
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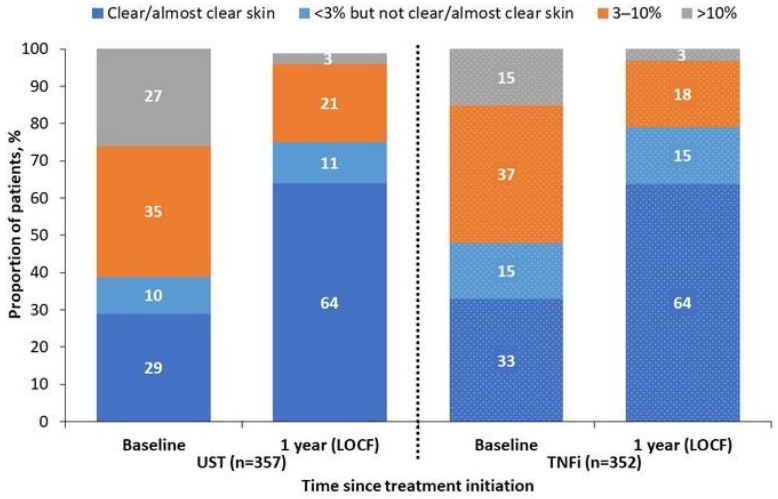
Introduction: Psoriatic arthritis (PsA) is characterised by musculoskeletal symptoms, and patients (pts) with PsA usually experience psoriasis concurrently. Nail symptoms are another hallmark and risk factor for PsA. Real-world data assessing impact of skin and nail symptoms on disease burden of PsA are limited.
Objectives: To analyse effectiveness of ustekinumab (UST) and tumour necrosis factor inhibitor (TNFi) therapy on skin and nail symptoms, and impact of baseline (BL) skin involvement on PsA disease burden and drug persistence.
Methods: PsABio (NCT02627768) is a prospective, observational study of 1st/2nd/3rd-line UST or TNFi in pts with PsA in 8 European countries. Extent of skin involvement was categorised as body surface area (BSA): clear/almost clear, <3% but not clear/almost clear, 3─10%, or >10%. Pt-reported disease impact was evaluated by PsAID-12, which includes 2 skin-related domains: D3 (skin problems) and D10 (embarrassment and/or shame because of appearance). Treatment persistence at 1 year was assessed by BL BSA categories.
Results: At BL, 27% of 357 pts with available follow-up data in the UST group had BSA >10%, compared with 15% of 352 in the TNFi group (**Figure**); of those with available follow-up data, 43% of 420 UST and 40% of 413 TNFi-treated pts had psoriatic nail lesions at BL. The mean (95% CI) number of affected nails was 8.9 (7.7; 10.1) and 8.7 (7.5; 9.9) for UST and TNFi groups, respectively. BL disease impact (PsAID-12 total and D3/D10) was worse in pts with more severe skin disease (BSA >10%; non-overlapping 95% CIs suggest significance) (**Table**). BSA improved with both treatments, and at 1 year, only 3% of pts with available follow-up data in each group had BSA >10% (**Figure**). Improvements in nail lesions were delayed; 27% of UST and 31% of TNFi-treated pts with available follow-up data continued to have nail lesions at 1 year, despite reductions in the number of affected nails (mean [95% CI]: -2.2 [-3.2; -1.3] and -2.0 [-2.9; -1.0], respectively). Both treatments significantly reduced disease impact (PsAID-12 total and D3/D10 scores), irrespective of BL BSA category, most markedly in pts with higher BL BSA (**Table**). Worse BL psoriasis was generally associated with longer persistence for both treatments; however, at 1 year, pts with BSA >10% had significantly shorter drug persistence with TNFi (mean [95% CI]: 361 [336; 387] days) compared with UST (410 [394; 426] days).

Conclusions: In pts with PsA, routine care with UST is largely used in more severe skin disease. Both UST and TNFi therapy rapidly and substantially reduced the extent of skin involvement and related disease impact; nail lesion improvement was less pronounced. Pts with the highest BL skin involvement had significantly longer drug persistence with UST than with TNFi. Overall, these data suggest that successful treatment of skin involvement in PsA with these biologic treatments reduces disease burden and may improve persistence, especially in pts with severe BL psoriasis.

Figure. Proportions of patients in each BSA category at baseline and 1 year (LOCF)



Proportions do not all add up to 100% because of rounding to the nearest integer.

Table. PsAID-12 scores at BL and change from BL at 1 year, by BL body surface area category

Mean (95% CI)	Domain 3 (skin problems, including itching)		Domain 10 (embarrassment and/or shame because of appearance)		Total PsAID-12	
	UST	TNFi	UST	TNFi	UST	TNFi
PsAID-12 score at BL by BL BSA						
<3%	4.2 (3.7; 4.8)	3.1 (2.7; 3.6)	3.9 (3.3; 4.4)	3.1 (2.6; 3.6)	5.7 (5.3; 6.0)	5.0 (4.6; 5.3)
3–10%	6.4 (5.9; 6.8)	5.8 (5.3; 6.3)	4.1 (3.5; 4.7)	4.5 (3.9; 5.1)	5.4 (5.1; 5.8)	5.8 (5.4; 6.1)
>10%	7.9 (7.5; 8.3)	6.7 (6.0; 7.5)	6.1 (5.4; 6.8)	5.8 (4.8; 6.8)	6.2 (5.7; 6.6)	6.1 (5.6; 6.7)
Change from BL in PsAID-12 score at 1 year (LOCF) by BL BSA						
<3%	-1.5 (-2.1; -0.9)	-0.8 (-1.3; -0.3)	-1.6 (-2.2; -1.1)	-1.2 (-1.7; -0.7)	-1.6 (-2.0; -1.2)	-1.9 (-2.3; -1.5)
3–10%	-3.5 (-4.0; -2.9)	-3.2 (-3.7; -2.7)	-2.0 (-2.6; -1.4)	-2.5 (-3.0; -2.0)	-2.2 (-2.6; -1.7)	-3.0 (-3.4; -2.6)
>10%	-4.9 (-5.5; -4.3)	-3.1 (-4.0; -2.3)	-3.5 (-4.2; -2.8)	-2.7 (-3.7; -1.8)	-2.9 (-3.4; -2.4)	-2.9 (-3.5; -2.2)

PsAID-12 total score range: 0–10, higher values representing more severe disease impact; PsAID-12 total score ≤4: patient-acceptable symptom state; reduction ≥1.25: minimal clinically important improvement; non-overlapping 95% CIs suggest significance.

BL, baseline; BSA, body surface area; CI, confidence interval; LOCF, last observation carried forward; PsAID-12, 12-item Psoriatic Arthritis Impact of Disease questionnaire; TNFi, tumour necrosis factor inhibitor; UST, ustekinumab

P37 - Psoriasis Symptoms and Impacts Measure Responses from a Phase 3b Trial with Bimekizumab (BE RADIANT)

4. Current and new therapeutic modalities

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Introduction: The Psoriasis Symptoms and Impacts Measure (P-SIM) is a novel, reliable, fit for purpose, patient (pt)-reported outcome tool capturing signs, symptoms, and impacts of plaque psoriasis in the bimekizumab clinical programme.[1] BE RADIANT (NCT03536884) is the first phase 3 trial to directly compare dual inhibition of interleukin (IL)-17A and IL-17F with bimekizumab, with inhibition of IL-17A alone with secukinumab.
Objectives: To compare the experience of pts with moderate to severe plaque psoriasis treated with bimekizumab versus (vs) secukinumab in the randomised, double-blinded, active comparator-controlled phase 3b trial, BE RADIANT, using 3 key items of the P-SIM (itch, pain, scaling).
Methods: Pts were randomised 1:1 to bimekizumab 320mg every 4 weeks (wks) (Q4W) or secukinumab 300mg weekly to Wk4, then Q4W. At Wk16, pts receiving bimekizumab were re-randomised to 320mg Q4W or every 8 wks (Q8W). The proportions of pts achieving marked clinically meaningful improvements (≥4-point reduction from baseline) in the 3 P-SIM items are reported (only pts with baseline score ≥4 for each item were included). Data are reported for two analysis sets: the intention-to-treat (ITT) population (all randomised pts) and the maintenance set (received ≥1 dose of study treatment at Wk16 or later). Nominal p values for comparisons between treatment groups were based on the stratified Cochran-Mantel-Haenszel test for the general association and were not controlled for multiple comparisons. Missing data were imputed as non-response (NRI).
Results: 373 pts were randomised to bimekizumab, 370 to secukinumab. Baseline mean P-SIM scores for all pts randomised to bimekizumab and secukinumab were: 6.6 and 6.8 for itch; 4.5 and 4.8 for pain; 6.7 and 6.8 for scaling. At Wk4, the proportions of pts receiving bimekizumab Q4W vs secukinumab who achieved a ≥4-point reduction from baseline were: 256/309 (82.8%) vs 234/319 (73.4%) for itch (nominal p=0.003); 195/221 (88.2%) vs 183/235 (77.9%) for pain (nominal p=0.006); 286/328 (87.2%) vs 241/324 (74.4%) for scaling (nominal p<0.001).
At Wk48 the proportions of pts in the ITT population receiving bimekizumab (Q4W or Q8W) vs secukinumab who achieved a ≥4-point reduction from baseline were: 259/309 (83.8%) vs 238/319 (74.6%) for itch (nominal p=0.005); 187/221 (84.6%) vs 175/235 (74.5%) for pain (nominal p=0.009); 286/328 (87.2%) vs 252/324 (77.8%) for scaling (nominal p=0.002). Responses were consistent between the Q4W and Q8W bimekizumab maintenance dosing regimens (maintenance set; Table).

Conclusions: Through 48 wks, more pts reported marked clinically meaningful improvements in itch, pain, and scaling with bimekizumab vs secukinumab. Response with bimekizumab was consistent with both maintenance dosing regimens.

References: 1. Gottlieb AB. *Dermatol Ther (Heidelb)* 2020;10:1255–72.

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Table. Proportions of pts achieving ≥4-point reduction from baseline in the itch, pain, and scaling items of the P-SIM at Wk48[a] (maintenance set;[b] NRI)

	Bimekizumab 320 mg Q4W[c] n/N (%)	Bimekizumab 320 mg Q8W[c] n/N (%)	Secukinumab 300 mg Q4W n/N (%)	Bimekizumab Q4W vs secukinumab nominal p value	Bimekizumab Q8W vs secukinumab nominal p value
Itch	112/127 (88.2)	147/172 (85.5)	238/304 (78.3)	0.014	0.061
Pain	79/91 (86.8)	108/122 (88.5)	175/223 (78.5)	0.083	0.028
Scaling	123/136 (90.4)	163/183 (89.1)	252/309 (81.6)	0.016	0.033

[a]Only patients with a baseline score ≥4 for each item were included; [b]The maintenance set includes all pts who received ≥1 dose of study treatment at Wk16 or later; [c]All pts randomised to bimekizumab received bimekizumab 320mg dosed Q4W through Wks 0–16 and were re-randomised at Wk16 to bimekizumab 320mg dosed Q4W or Q8W. NRI: non-responder imputation; P-SIM: Psoriasis Symptoms and Impacts Measure; pts: patients; Q4W: every 4 weeks; Q8W: every 8 weeks; wk: week.

P38 - Safety, tolerability and pharmacokinetics of single oral doses of IMU-935 in healthy volunteers: First clinical experience with an orally available small molecule inhibitor of IL-17

4. Current and new therapeutic modalities

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Introduction: IMU-935 is an inverse agonist of the RAR-related orphan receptor RORγt, with additional but less potent inhibition of dihydroorotate dehydrogenase (DHODH). IMU-935 inhibits the secretion of several pro-inflammatory cytokines, including interleukin (IL)-17A, IL-17F and IFN-γ, differentiation of T helper 17 (Th17) cells, and proliferation of activated T cells. With the availability and success of IL-17 targeting antibodies, IMU-935 is designed to provide an oral medication option targeting IL-17 for plaque psoriasis patients.
Objectives: The objectives of this clinical trial are to assess safety, tolerability, pharmacokinetics, and pharmacodynamics (the latter data are not yet available) of IMU-935.
Methods: This is a first-in-human, double-blind, randomized, placebo-controlled clinical trial comprising three parts. In part A, healthy volunteers in cohorts of 8 subjects each were enrolled and received single ascending doses (SAD) of IMU-935 (25 to 400 mg) or placebo (ratio 3:1). In part B, healthy volunteers will receive multiple ascending doses (MAD) of IMU-935 or placebo for 14 days, and in part C, patients with moderate to severe plaque-type psoriasis will take either two different dose levels of IMU-935 or placebo.
Results: First clinical experience with IMU-935 comes from part A of this clinical trial which has recently been completed. Pharmacokinetic evaluation showed first measurable plasma concentrations of IMU-935 in most subjects at 1 hour post-dose, T_{max} between 2 to 6 hours post-dose, half-life ranging from 16.5 to 31.0 hours and strict dose proportional increases of C_{max} and area under the plasma concentration-time curve (AUC) across the investigated dose range. Treatment-emergent adverse events (TEAEs) related to study drug administration were reported in 29 of 71 (41 %) subjects, with a total of 50 drug-related TEAEs. Most related TEAEs were mild in severity (48), and only 2 were moderate. Across all SAD cohorts, related TEAEs (independent of study arm) occurring in more than 2 subjects were diarrhoea (6), headache (6), abdominal distension (4), gastroesophageal reflux (4), constipation (3) and nausea (3). Overall, the number or severity of adverse events did not increase with ascending doses. There were no serious adverse events or adverse events that led to study discontinuation. There were no other clinically meaningful findings relative to safety and tolerability, as assessed by physical examination, clinical laboratory tests, vital signs, and 12-lead electrocardiograms (ECGs).
Conclusions: IMU-935 has linear pharmacokinetics after single oral doses that allow for once daily dosing. IMU-935 is safe and well tolerated with a benign adverse event profile up to 400 mg as a single dose. Monitoring of laboratory parameters, vital signs, and 12-lead ECGs showed no clinically relevant abnormalities. Ongoing recruitment into parts B and C of the clinical trial will characterise multiple doses of IMU-935 and provide intitial data on anti-psoriasis activity.
References: None

P39 - Secukinumab treatment results in sustained drug survival in biologic-naïve and -experienced patients with moderate-to-severe plaque psoriasis: Analysis of 24 months of follow-up data from the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR)

4. Current and new therapeutic modalities

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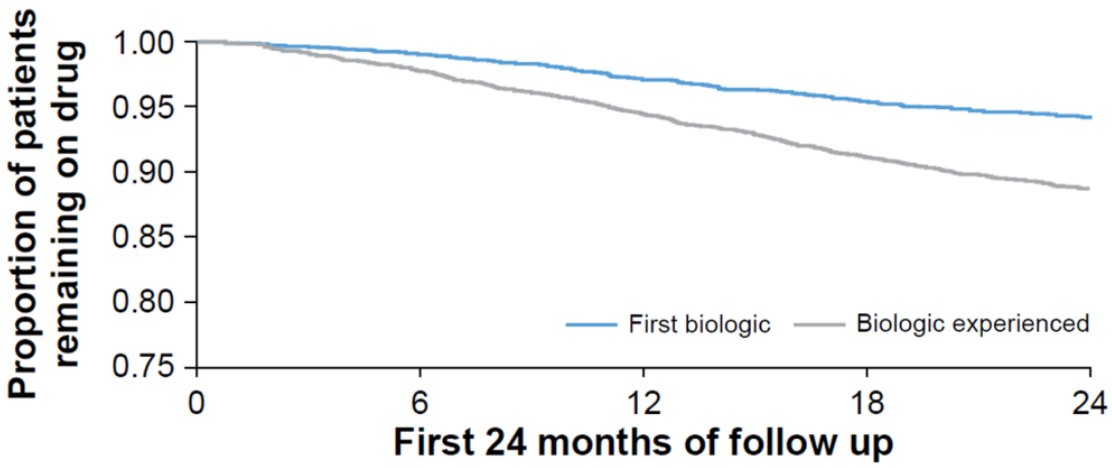
Introduction: Secukinumab (SEC) is a fully human anti-IL-17A monoclonal antibody for the treatment of moderate-to-severe plaque psoriasis. BADBIR, an ongoing, longitudinal observational study,[1] is an ideal resource to assess drug survival in real-world practice. In previous analyses of BADBIR, SEC showed sustained drug survival over 24 months in biologic-naive patients (pts; 82%–86%) comparable with ustekinumab (82%–84%).[2,3] In this updated analysis we report drug survival for a larger cohort of SEC-treated pts with a longer median follow-up.
Objectives: To determine overall drug survival of SEC in biologic-naïve and -experienced pts with psoriasis enrolled in BADBIR (data cut-off Sept 2020).
Methods: Pts prescribed SEC at baseline (biologic-naïve) or after switching therapies during follow-up (biologic-experienced) as of 1 Sept 2020 were included. Drug survival up to 24 months was evaluated using the Kaplan–Meier (KM) method. Drug survival was defined as the duration between date of first exposure to SEC and date of stopping SEC or the end of the study censoring period.
Results: Data from 2683 pts, 913 biologic-naïve and 1770 biologic-experienced, were analysed. Mean duration of follow-up was 2.3 years (median 2.1 years) for biologic-naïve and 2.2 years (median 1.9 years) for biologic-experienced pts. Among biologic-naïve and experienced pts, the majority were male (62% and 56%, respectively); mean age was 46.4 and 45.1 years, respectively. Mean body mass index was 31.6 and 32.5 kg/m^2, mean age of disease onset was 25.5 and 23.6 years, and mean disease duration was 21.0 and 21.6 years in biologic-naïve and experienced pts, respectively. Fewer biologic-naïve pts had psoriatic arthritis (20.0% vs 27.6%). Similar proportions of biologic-naïve and -experienced pts received prior methotrexate (73.7% vs 76.4%); fewer biologic-naïve pts received prior ciclosporin (50.1% vs 60.1%). Overall KM drug survival for both subgroups was comparably high after 12 months (97% vs 94%) and 24 months (94% vs 89%) (Fig). Drug survival for biologic-experienced pts was higher than previously reported (89% vs 63% at 24 months).[2]
Conclusions: This analysis involved more pts and a longer follow-up than previous reports, supporting and extending previous findings of sustained drug survival of SEC in pts with moderate-to-severe plaque psoriasis.[2] SEC demonstrated high durability and sustained drug survival after 12 and 24 months in real-world practice. As expected, drug survival is higher in pts who initiated SEC than those who switched to SEC after other biologic therapy. However, overall drug survival of 94% and 89% at 12 and 24 months in biologic-experienced pts exceeds that reported previously.[2]

References:

1. Burden AD, et al. *Br J Dermatol* 2012;166:545–554
2. Bewley A, et al. *JAAD* 2020;83(Supp):AB94
3. Yiu ZZN, et al. *Br J Dermatol* 2021;183:294–302

Overall drug survival by biologic experience



Biologic naive:
12 months: 97% (95% CI 96, 98)
24 months: 94% (95% CI 94, 95)

Biologic experienced:
12 months: 94% (95% CI 94, 95)
24 months: 89% (95% CI 88, 90)

P40 - Secukinumab treatment results in sustained improvement in aPASI and DLQI in biologic-naïve and -experienced patients with moderate-to-severe plaque psoriasis: Analysis of 12 months of follow-up data from the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR)

4. Current and new therapeutic modalities

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Introduction: Secukinumab (SEC) is a fully human anti-IL-17A monoclonal antibody for the treatment of moderate-to-severe plaque psoriasis. BADBIR, an ongoing longitudinal pharmacovigilance register,[1] is an ideal resource to assess real-world drug effectiveness. In a previous analysis of BADBIR, 77% of biologic-naïve and 43% of biologic-experienced patients (pts) with psoriasis achieved an absolute Psoriasis Area and Severity Index (aPASI) score ≤2 after 12 months of SEC treatment.[2] Here we report effectiveness and quality of life (QoL) data for a larger cohort of SEC-treated pts.
Objectives: To evaluate effectiveness and QoL, using aPASI and Dermatology Life Quality Index (DLQI), of SEC in biologic-naïve and -experienced pts with psoriasis enrolled in BADBIR.
Methods: Pts prescribed SEC at baseline (biologic-naïve) or after switching therapies during follow-up (biologic-experienced) as of 1 Sept 2020 were included. aPASI and DLQI scores were recorded between 4–8 months and 10–14 months after starting SEC for the 6- and 12-month time points, respectively.
Results: Data from 2683 pts, 913 biologic-naïve and 1770 biologic-experienced, were analysed. Mean duration of follow-up was 2.3 years for biologic-naïve and 2.2 years for biologic-experienced pts. Among biologic-naïve and -experienced pts, the majority were male (62% and 56%, respectively); mean age was 46.4 and 45.1 years, respectively. Mean body mass index was 31.6 and 32.5 kg/m^2, mean age of disease onset was 25.5 and 23.6 years, and mean disease duration was 21.0 and 21.6 years in biologic-naïve and -experienced pts, respectively. Fewer biologic-naïve pts had psoriatic arthritis (20.0% vs 27.6%). Similar proportions of biologic-naïve and -experienced pts received prior methotrexate (73.7% vs 76.4%); fewer biologic-naïve pts received prior ciclosporin (50.1% vs 60.1%). aPASI scores ≤2 after 6 and 12 months were achieved in a higher proportion of biologic-naïve pts (76.2% and 74.9%) than experienced pts (51.1% and 44.8%). DLQI scores of 0/1 after 6 and 12 months were achieved in a higher proportion of biologic-naïve pts (60.1% and 62.0%) than experienced pts (43.1% and 40.4%) (Table).
Conclusions: These data, including more pts and longer follow-up than previous analyses, confirm and extend previous findings.[2] In this analysis, more than half of hard -to-treat biologic-experienced pts had aPASI scores ≤2 after 12 months of SEC treatment, exceeding that reported previously.[2] SEC treatment resulted in sustained improvement in a large proportion of pts with moderate-to-severe plaque psoriasis. As expected, the proportion of pts with favourable outcomes (aPASI ≤2, DLQI 0/1) was higher in biologic-naïve vs biologic-experienced pts, highlighting the importance of initiating the right treatment at the right time.

References:

1. Burden AD, et al. *Br J Dermatol* 2012;166(3):545–554
2. Bewley A, et al. *JAAD* 2020;83(Supp):AB94

Table. Proportion of patients achieving aPASI and DLQI outcomes by biologic experience

Outcome		Month	Biologic-naïve n/n (%)	Biologic-experienced n/n (%)
aPASI	≤2	6	327/429 (76.2)	384/751 (51.1)
		12	289/386 (74.9)	301/672 (44.8)
	>2	6	102/429 (23.8)	367/751 (48.9)
		12	97/386 (25.1)	371/672 (55.2)
DLQI	0/1	6	179/298 (60.1)	163/378 (43.1)
		12	202/326 (62.0)	129/319 (40.4)
	>1	6	119/298 (39.9)	215/378 (56.9)
		12	124/326 (38.0)	190/319 (59.6)
DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index				
There was a high proportion of patients with missing data due to the COVID-19 pandemic in 2020 and the nature of cut-offs for the analysis meaning scores were not provided while patients were on other biologics.				

P41 - Tapinarof Cream 1% Once Daily for Plaque Psoriasis: Patient-reported Outcomes from Two Pivotal Phase 3 Trials

4. Current and new therapeutic modalities

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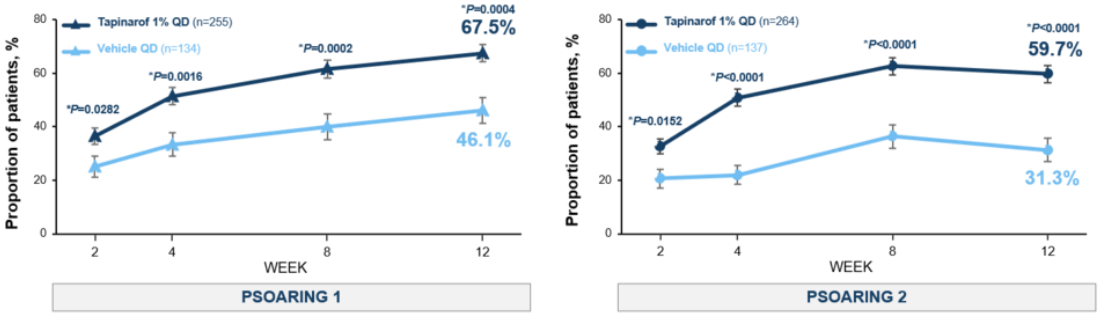
Introduction: Tapinarof is a novel therapeutic aryl hydrocarbon receptor modulating agent (TAMA) in development for treatment of psoriasis and atopic dermatitis. Tapinarof cream 1% once daily (QD) demonstrated statistically significant efficacy vs vehicle QD at 12 weeks and was well tolerated in adults with mild to severe plaque psoriasis in two identical Phase 3 trials (PSOARING 1 and PSOARING 2).[1]
Objectives: To present patient-reported efficacy and tolerability outcomes from the pivotal Phase 3 trials PSOARING 1 and PSOARING 2.
Methods: Two identical, randomized, double-blind, vehicle-controlled trials assessed efficacy and safety of tapinarof cream 1% QD in patients with mild to severe plaque psoriasis. Adults with baseline Physician Global Assessment (PGA) score ≥2 and body surface area (BSA) involvement ≥3–≤20% were randomized 2:1 to tapinarof cream 1% or vehicle QD for 12 weeks. Patient-reported outcomes included the proportion of patients achieving ≥4-point improvement of Peak Pruritus Numeric Rating Scale (PP-NRS) score and the mean change from baseline to Week 12 in PP-NRS, Dermatology Life Quality Index (DLQI), and Psoriasis Symptom Diary (PSD) scores. Local tolerability was evaluated by physicians and patients with scores representing an average across all application sites.
Results: Mean baseline scores for tapinarof vs vehicle in PSOARING 1 and 2, respectively, were: PP-NRS, 5.7 vs 6.1 and 5.9 vs 6.1; DLQI, 8.2 vs 8.7 and 8.5 vs 8.6; PSD, 73.1 vs 74.9 and 74.0 vs 76.0. The proportion of patients achieving ≥4-point improvement in PP-NRS was significantly higher vs vehicle from Week 2 onward, reaching 67.5% vs 46.1% (P=0.0004) and 59.7% vs 31.3% (both P<0.0001) at Week 12 in PSOARING 1 and 2, respectively (**Figure 1**). Mean PP-NRS scores significantly improved with tapinarof vs vehicle from Week 2 onward, reaching –3.9 vs –2.9 (P=0.0002) and –3.0 vs –1.4 (P<0.0001) at Week 12 in PSOARING 1 and 2, respectively. Significant improvements in mean DLQI were achieved by Week 4 with minimal clinically important difference (–4.0) at Week 12 vs vehicle: –5.0 vs –3.0 and –4.7 vs –1.6 (both P<0.0001) in PSOARING 1 and 2, respectively. Significant improvements were reported with tapinarof vs vehicle from Week 2 onward on the PSD, reaching –51.9 vs –34.6 and –43.5 vs –17.1 (both P<0.0001) by Week 12 in PSOARING 1 and 2, respectively. Tapinarof was well tolerated regardless of anatomic location treated, as reported subjectively by patients and measured objectively by investigators.
Conclusions: Tapinarof cream 1% QD demonstrated rapid, statistically significant, and clinically meaningful improvements in patient-reported outcomes and was well tolerated, consistent with previously reported significant clinical efficacy and good tolerability.[1]
References:

1. Lebwohl M, et al. *SKIN The Journal of Cutaneous Medicine*. 2020;4:s75.

Figure 1. ≥4-point Improvement in PP-NRS Score from Baseline at Weeks 2, 4, 8, and 12



*Denotes statistical significance.

Intent to treat, observed cases. Mean proportion (standard error).

PP-NRS, Peak Pruritus Numeric Rating Scale; QD, once daily.

P42 - Tapinarof Cream 1% Once Daily for Plaque Psoriasis: Secondary Efficacy Outcomes from Two Pivotal Phase 3 Trials

4. Current and new therapeutic modalities

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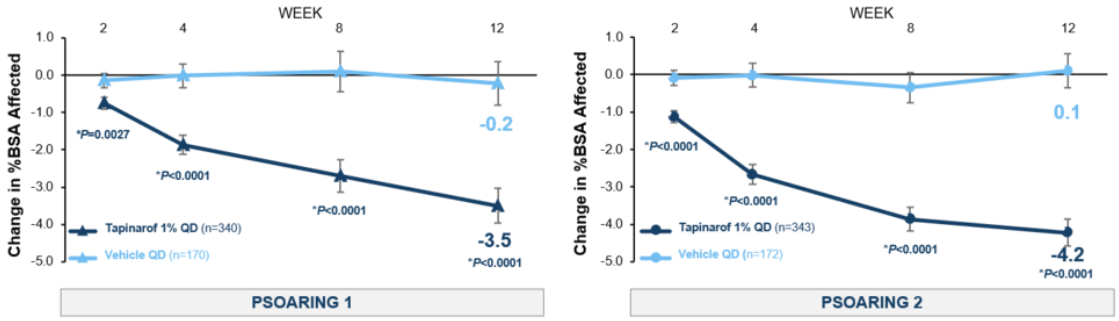
Introduction: Tapinarof is a novel therapeutic aryl hydrocarbon receptor modulating agent (TAMA) in development for treatment of psoriasis and atopic dermatitis. Tapinarof cream 1% once daily (QD) demonstrated highly statistically significant efficacy vs vehicle at 12 weeks and was well tolerated in adults with mild to severe plaque psoriasis in two identical Phase 3 trials (PSOARING 1 and 2).[1]
Objectives: To present secondary efficacy endpoints from PSOARING 1 and PSOARING 2 including Physician Global Assessment (PGA) scores, change in body surface area (BSA) affected, and ≥90% reduction in Psoriasis Area and Severity Index (PASI90) – an endpoint more commonly assessed for systemic agents.
Methods: Two identical, randomized, double-blind, vehicle-controlled trials assessed efficacy and safety of tapinarof cream 1% QD in patients with mild to severe plaque psoriasis. Adults with baseline PGA score ≥2 and BSA involvement ≥3–≤20% were randomized 2:1 to tapinarof cream 1% or vehicle QD for 12 weeks. Secondary efficacy endpoints, PGA score, %BSA affected and PASI90 at baseline and Weeks 2, 4, 8, and 12 are reported.
Results: Mean overall baseline PASI was 8.9 and 9.1 and BSA affected was 7.9% and 7.6% in PSOARING 1 (N=510) and 2 (N=515), respectively. At Week 12, significantly more patients achieved PGA score of 0 or 1 with tapinarof vs vehicle: 37.8% vs 9.9% (*P*=0.0001) and 43.6% vs 8.1% (*P*<0.0001). %BSA affected was rapidly reduced with tapinarof vs vehicle, with significant improvements from Week 2 (*P*≤0.0027) reaching –3.5 vs –0.2 and –4.2 vs 0.1 at Week 12 in PSOARING 1 and 2, respectively (*P*<0.0001 in both studies) (**Figure 1**). Significantly more tapinarof-treated patients achieved PASI90 at Week 12 vs vehicle: 18.8% vs 1.6% (*P*=0.0005) and 20.9% vs 2.5% (*P*<0.0001) with separation from vehicle becoming significant by Week 8 (*P*=0.0046 and *P*=0.0004) in PSOARING 1 and 2, respectively.
Conclusions: Tapinarof cream 1% QD significantly improved all measures of disease activity and showed rapid, clear, and consistent separation vs vehicle as early as the first clinical assessment (Week 2). Improvements were consistent with previously reported efficacy endpoints.[1] Early improvements continued throughout the study and did not reach maximal effect by Week 12, as confirmed in a long-

term extension study.[2] Tapinarof cream 1% QD is effective and well tolerated with the potential to be a novel non-steroidal topical treatment option.

References:

1. Lebwohl M, et al. SKIN The Journal of Cutaneous Medicine. 2020;4:s7.
2. Strober B, et al. Tapinarof Cream 1% Once Daily for Plaque Psoriasis: Interim Analysis of a Long-Term Extension Trial of a Novel Therapeutic Aryl Hydrocarbon Receptor Modulating Agent. Innovations in Dermatology Virtual Spring Conference 2021, Poster Presentation, March 16–20, 2021.

Figure 1. Change in %BSA Affected from Baseline at Weeks 2, 4, 8, and 12



*Denotes statistical significance.

Intent to treat, multiple imputation. Least squares mean (standard error)

BSA, body surface area; QD, once daily.

P43 - The role of methotrexate in patients with concomitant psoriasis and psoriatic arthritis: History or mystery?

4. Current and new therapeutic modalities
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Introduction: Psoriasis (PsO) is a common disease that mainly affects the adult population, and is more frequent in high-income countries.[1] Psoriatic arthritis (PsA) is an inflammatory musculoskeletal disease associated with cutaneous psoriasis.[2] Methotrexate (MTX) is a folate antagonist with anti-inflammatory properties and has been used as a first-line treatment for moderate to severe psoriasis.[3]
Objectives: The aim of this audit was to review the use and efficacy of MTX in the management of PsO and PsA in the specialist combined rheumatology/dermatology clinic (CRDC) at a District General Hospital (DGH) where both rheumatology and dermatology consultants are present for difficult cases.
Methods: A cohort study was conducted in a DGH including all patients with PsO and PsA who had attended the CRDC between February 2018- March 2021. Clinic lists were used to identify the patients and clinic letters were reviewed retrospectively to collect data on age, gender, disease duration, medication, severity of disease, monitoring and drug side effects.
Results: 30 patients were reviewed over the 3 year period: 100% had PsO and 70 % had both PsO and PsA. Patients in age groups 30-50, 50-70 and >70 were 40% (12), 36.67% (11) and 26.67 (8) respectively. While the other two age groups revealed equal prevalence amongst both genders, the male population was predominant 75% (6/8) over the age of 70 years. Disease duration was greater than five years in 96.67 % (29/30) of patients.

MTX had been used as first line in 76.67 % (23/30) of patients. An additional 6.67 % (2/30) were subsequently started on MTX. Of the 25 who were treated with MTX at some point, 12 stopped MTX (due to side effects or inefficacy) and 13 continued to take MTX without side effects. In those who continued to take MTX: 30.7 % (4/13) remain in remission with monotherapy; 69.2% (9/13) started an additional drug (combination therapy). Of the 9 patients receiving combination therapy, 44.44% (4/9) did not achieve remission despite biologic use.

Review of patients who failed MTX revealed that 41.67 % and 8% failed to meet remission in skin and arthritis respectively despite later use of various other therapies.
Conclusions: Our study concludes that despite the availability of multiple treatment options, methotrexate still remains an effective potential option considering cost effectiveness and remission rates.
References: 1. Parisi R, Iskandar IYK, Kontopantelis E, et al. National, regional, and worldwide epidemiology of psoriasis: systematic analysis and modelling study. BMJ. 2020;369:m1590. Published 2020 May 28. doi:10.1136/bmj.m1590.

2. Ocampo D V, Gladman D. Psoriatic arthritis. F1000Res. 2019;8:F1000 Faculty Rev-1665. Published 2019 Sep 20. doi:10.12688/f1000research.19144.1

3. Yan K, Zhang Y, Han L, et al. Safety and Efficacy of Methotrexate for Chinese Adults With

Psoriasis With and Without Psoriatic Arthritis [published correction appears in JAMA Dermatol. 2019 Mar 1;155(3):397]. JAMA Dermatol. 2019;155(3):327-334. doi:10.1001/jamadermatol.2018.5194

P44 - Viral Infections in Patients with Plaque Psoriasis Treated with Certolizumab Pegol: Pooled Three-Year Data

4. Current and new therapeutic modalities

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Introduction: Certolizumab pegol (CZP) is an Fc-free, PEGylated anti-tumour necrosis factor (TNF) biologic.[1,2] The COVID-19 pandemic and seasonal influenza epidemics have refocused attention to treatment-emergent viral infections in patients treated with anti-TNF therapies. Here, we report pooled three-year safety data from three phase 3 trials of CZP in psoriasis (PSO), focusing on viral infectious disorders.
Objectives: To establish the risk of viral infection in patients with PSO with prolonged CZP treatment exposure.
Methods: Safety data were pooled from three phase 3 trials: CIMPASI-1 (NCT02326298), CIMPASI-2 (NCT02326272), and CIMPACT (NCT02346240).[1,2] Adults with PSO ≥6 months (Psoriasis Area and Severity Index ≥12, body surface area affected ≥10%, Physician's Global Assessment ≥3) were randomised to CZP 400 mg every 2 weeks (Q2W), CZP 200 mg Q2W (400 mg at Weeks 0/2/4), placebo, or etanercept (CIMPACT only). We report data for patients who received ≥1 dose of CZP with up to 144 weeks' exposure prior to study completion. Exposure-adjusted incidence rates (EAIRs; incidence of new cases) per 100 patient-years (PY) are presented through 16 weeks for both CZP and placebo treatment, and through 144 weeks for CZP treatment. Treatment-emergent adverse events (occurring during treatment or ≤70 days after the last CZP/placebo dose) were classified using MedDRAv18.1. All data were recorded prior to the COVID-19 pandemic.
Results: Through Weeks 0–16, 157 patients received placebo (total exposure: 47 PY; median days of exposure: 112) and 692 patients received ≥1 dose of CZP (211 PY; 112 days) (**Table**). Through Weeks 0–144, 995 patients received ≥1 dose of CZP (2,231 PY; 952 days). During Weeks 0–16, the EAIR/100 PY for infections and infestations was 136.2 for placebo-randomised and 133.8 for CZP-randomised patients, and over 144 weeks, the EAIR/100 PY for CZP-treated patients was 59.1.

Within the infections and infestations category, the EAIR/100 PY of viral infectious disorders to Week 16 was 15.3 for placebo-randomised and 20.9 for CZP-randomised patients; through to Week 144, the EAIR/100 PY for CZP-treated patients decreased to 7.9. Of the viral infectious disorders, the EAIRs/100 PY of herpes viral infections, influenza viral infections and viral infections not elsewhere classified (NEC) were 4.3, 2.1 and 6.5 for placebo-randomised patients and 4.8, 2.4 and 12.5 for CZP-

randomised patients to Week 16, respectively, whereas to Week 144 the EAIRs/100 PY were 2.5, 1.4 and 3.7 for CZP-treated patients.

Conclusions: Across the CZP in PSO clinical programme, no increased risk was observed for the occurrence of viral infectious disorders for CZP treatment over 144 weeks compared to 16 weeks of exposure.

Funding: Dermira Inc. and UCB Pharma. Medical writing support provided by Costello Medical.

References: 1. Gordon KB. BJD 2020; DOI:10.1111/bjd.19393; **2.** Blauvelt A. BJD 2020; DOI:10.1111/bjd.19314.

Table: Pooled data for selected infections and infestations through Weeks 0–16 and Weeks 0–144

	n (%) EAIR/100 PY [95% CI]		
	Weeks 0–16		Weeks 0–144
	PBO (N=157)	CZP (N=692)	CZP (N=995)
Total exposure	47 PY	211 PY	2,231 PY
Median exposure	112 days	112 days	952 days
Infections and infestations	53 (33.8) 136.19 [102.02, 178.14]	232 (33.5) 133.80 [117.14, 152.17]	646 (64.9) 59.07 [54.60, 63.80]
Viral infectious disorders	7 (4.5) 15.32 [6.16, 31.57]	43 (6.2) 20.93 [15.15, 28.19]	158 (15.9) 7.95 [6.76, 9.29]
Herpes viral infections	2 (1.3) 4.31 [0.52, 15.55]	10 (1.4) 4.77 [2.29, 8.77]	53 (5.3) 2.48 [1.85, 3.24]
Influenza viral infections	1 (0.6) 2.14 [0.05, 11.92]	5 (0.7) 2.38 [0.77, 5.55]	31 (3.1) 1.41 [0.96, 2.01]
Viral infections NEC	3 (1.9) 6.46 [1.33, 18.88]	26 (3.8) 12.50 [8.17, 18.32]	78 (7.8) 3.70 [2.92, 4.62]
Infections – pathogen unspecified	44 (28.0) 109.41 [79.50, 146.88]	187 (27.0) 103.53 [89.23, 119.48]	534 (53.7) 42.18 [38.68, 45.92]
Lower respiratory tract and lung infections	2 (1.3) 4.30 [0.52, 15.54]	11 (1.6) 5.23 [2.61, 9.36]	69 (6.9) 3.24 [2.52, 4.10]
Upper respiratory tract infections	33 (21.0) 78.07 [53.74, 109.64]	150 (21.7) 80.58 [68.20, 94.55]	426 (42.8) 29.37 [26.65, 32.30]

CI: confidence interval; CZP: certolizumab pegol; EAIR: exposure-adjusted incidence rate; NEC: not elsewhere classified; PBO: placebo; PY: patient-years.

5. EPIDEMIOLOGY

P45 - LONGITUDINAL TRENDS IN THE BIOLOGIC TREATMENT OF SWEDISH PSORIATIC ARTHRITIS PATIENTS – FINDINGS FROM Q-PSA

5. Epidemiology

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Introduction: Biologic medications including tumor necrosis factor inhibitors (TNFi), interleukin 12/23 inhibitors (IL-12/23i), and interleukin 17 inhibitors (IL-17i) are safe and effective treatments for patients with psoriatic arthritis (PsA). The Quantify Psoriatic Arthritis Research Program (Q-PsA) contains real-world, nation-wide data from PsA patients and controls in Sweden with information on healthcare visits, medication use, demographics, and socioeconomics.
Objectives: This study describes population-level biologic drug dispensing from pharmacy and treatment switching in Sweden during 2005-2018.
Methods: PsA patients were identified during 2005-2018 through any ICD-10 diagnosis code in the L40.5 subcategory in secondary care using data from Q-PsA. Patients' first pharmacy-dispensed TNFi, IL-12/23i, or IL-17i following PsA diagnosis was defined as first line treatment. Patients were followed through potential second-, third- and fourth-line treatments based on the same treatment classes. Days of supply for each treatment class were calculated during 2005-2018 by multiplying each package's total Defined Daily Doses by the number of dispensed packages. Infliximab (often hospital administered) data was incomplete.
Results: 9,298 PsA patients (mean age=50, 47% female) with at least one dispensation of TNFi, IL-12/23i, or IL-17i were included. 62% had comorbid skin psoriasis diagnosed in secondary care. 10,251,000 days of TNFi were dispensed from pharmacy during 2005-2018, 810,000 days of IL-12/23i during 2009-2018 and 556,000 days of IL-17i during 2015-2018. From 2005-2018, days of biologic drug dispensed grew by an average of 141,000 annually, with larger increases in recent years. Almost all patients received TNFi in first line (95%). Of those who switched to a second line (N=1,259), a higher proportion of patients received IL-17i (62%) than IL-12/23i (38%). Of these, 395 and 89 patients switched to a third and fourth line of treatment, respectively.
Conclusions: Biologic medications are increasingly used to treat PsA. In Sweden, TNFi is often prescribed as patients' first line biologic therapy and IL-17i is most common in second line.

P46 - Mapping opportunities for the earlier diagnosis of psoriasis in primary care: a large retrospective analysis of general practice electronic health records in the United Kingdom

5. Epidemiology

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Introduction: Psoriasis has a variable clinical presentation which overlaps with other skin conditions making the diagnosis a challenging task. The current literature focuses on the clinical presentation of psoriasis when the diagnosis is made and not the pre-diagnostic period. To our knowledge, this is the first study to investigate potential missed opportunities for an earlier diagnosis of psoriasis.
Objectives: To examine the electronic health records (EHR) of individuals with and without psoriasis and to investigate whether a missed opportunity for an earlier diagnosis of psoriasis could be identified.
Methods: The study used a UK primary care electronic healthcare records database (CPRD, The Clinical Practice Research Datalink). Two matched case-control cohorts were generated from the CPRD GOLD and CPRD Aurum datasets each using their respective recording platforms to capture EHRs from contributing general practitioner (GP) practices. Cases were identified as individuals aged 18 years or above, with an incident diagnosis of psoriasis from 1 January 2010 to 29 December 2017. Cases were matched by age, gender, and registered GP practices with up to 6 individuals without psoriasis (controls). Documented healthcare events including differential diagnoses, clinical features and prescribed medications were examined and their annual incidence rate (IR) and incidence rate ratio (IRR) with 95% confidence interval (95% CI) for ten years before the index date (date of psoriasis diagnosis for cases) were compared between cases and controls. The frequency of GP consultations was also compared between both groups.
Results: 17,320 cases and 99,320 controls were included from CPRD GOLD and 11,442 cases and 65,840 controls were extracted from CPRD Aurum. Findings were similar from both databases.

Analysis of the EHR of individuals with and without psoriasis showed that, psoriasis patients were three and eight-times more likely to be diagnosed with pityriasis rosea at one year (IRR 3.24, 95% CI 2.24-5.27) and six months (7.82, 4.09-14.95) before the index date than controls, respectively. Cases were twice as likely to be diagnosed with eczema (1.90, 1.76 -2.05), or tinea corporis (1.99, 1.74-2.27) one year before diagnosis.

Cases were also more likely to report certain clinical features suggestive of psoriasis (including dry skin, skin rash, skin texture changes and itching) than controls up to 5 years before index date. The most frequently reported clinical feature was skin rash with IRR of (2.71, 2.53-2.92) at 1 year before diagnosis.

Cases were prescribed topical corticosteroids (1.97 ,1.88 -2.07) or topical antifungals (1.92 ,1.78 - 2.07) in the year before diagnosis twice as often as controls.

Conclusions: Missed opportunities for earlier diagnosis of psoriasis were identified from the EHR of patients with psoriasis. GPs may need additional training on how to diagnose psoriasis, thereby avoiding a potentially detrimental delay in establishing an appropriate treatment regimen.

P47 - Prevalence of generalized pustular psoriasis in the USA: Results from multiple administrative claims databases

5. Epidemiology

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Introduction: Generalized pustular psoriasis (GPP) is a rare, neutrophilic skin disease characterised by episodes of widespread sterile pustules that can occur with or without systemic inflammation and/or plaque psoriasis.[1,2] In the USA, GPP prevalence is not well characterised; however, estimating GPP prevalence is now facilitated by the introduction of a GPP-specific diagnosis code in the International Classification of Diseases, 10th revision. Here, we report GPP prevalence data identified from multiple large, nationwide US administrative claims databases in 2018 and 2019.
Objectives: To estimate GPP prevalence in the USA using two large administrative claims databases in 2018 and 2019.
Methods: Annual GPP prevalence was determined from the Optum® Clinformatics™ Data Mart (2019) and the IBM® MarketScan® (2018) research databases. Patients with at least one inpatient or outpatient diagnostic code for GPP (L40.1) were included; to increase sensitivity, an alternative GPP definition was also used to include patients with one inpatient or two outpatient codes for GPP. Prevalence was estimated as the number of patients with GPP divided by the total number of enrolees (with continuous enrolment for the study year; gaps of up to 30 days were permitted).
Results: Overall, GPP prevalence in patients with one inpatient or outpatient claim was reported as 0.9 per 10,000 persons in the Optum® Clinformatics™ database and 0.7 per 10,000 persons in the IBM® MarketScan® database (0.3 and 0.2 per 10,000 persons, respectively, in patients with one inpatient or two outpatient claims). In both databases, GPP was more prevalent in females than in males and in patients aged ≥65 years than those aged <65 years (Table 1). When applying the alternative GPP definition, GPP prevalence was approximately one-third lower across both stratifications.
Conclusions: The low prevalence of GPP estimated from these administrative databases further supports the theory that GPP is a rare disease. Limitations of this analysis include the lack of a validated algorithm to positively identify GPP in claims databases. Further research is needed to better understand the epidemiology and disease burden of GPP in this population in the USA.

References:

1. Navarini AA, et al. *J Eur Acad Dermatol Venereol* 2017;31:1792–1799.
2. Fujita H, et al. *J dermatol* 2018;45:1235-1270

Table 1. GPP prevalence in the USA stratified by sex and age

	GPP prevalence reported in the Optum® Clinformatics™ Data Mart research database in 2019 (per 10,000 persons)		GPP prevalence reported in the IBM® MarketScan® research database in 2018 (per 10,000 persons)	
	One inpatient or outpatient claim	One inpatient or two outpatient claims	One inpatient or outpatient claim	One inpatient or two outpatient claims
Overall prevalence	0.9	0.3	0.7	0.2
Sex				
Female	1.1	0.4	0.8	0.2
Male	0.6	0.2	0.5	0.2
Age				
<18 years	0.1	<0.1	0.1	<0.1
18–64 years	0.8	0.3	0.8	0.3
≥65 years	1.2	0.4	1.1	0.3

GPP, generalized pustular psoriasis.

P48 - Super responders to Guselkumab treatment in moderate-to severe psoriasis: a pilot real clinical practice series

5. Epidemiology

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Introduction: The term super responders define a subset of patients with moderate-to-severe psoriasis that present a rapid and higher rate of response to biological treatments in comparison to the general population. Little scientific evidence to explain the behavior and clinical characteristics of these PSO patients has been published so far. Its characterization could be important to improve therapeutic optimization and to identify profile of patients that will respond efficiently to biological treatments.
Objectives: The main objective of this study was to evaluate and characterize the proportion of super responder patients (who achieved PASI=0 at week 12 and 24) in a total of 87 patients with moderate-to-severe PSO treated with guselkumab. Also, to analyze and evaluate differences in response to guselkumab in absolute PASI, PASI75, PASI90, PASI100, BSA, VAS pruritus and DLQI between groups.
Methods: The objectives of this analysis were to identify the presence of SR individuals in our cohort composed of 87 patients with moderate-to-severe PSO treated with GUS. To do so, we performed a retrospective, longitudinal, observational study of real clinical practice of patients receiving treatment with GUS 100mg subcutaneous every 8 weeks in 5 tertiary hospitals in Andalusia (Spain).
Results: A total of 14 out of 87 patients treated with guselkumab were characterized as SR. No differences in demographic characteristics were found. The percentage of patients reaching PASI75, PASI90 and PASI100 was numerically greater for SR than N-SR at week 12, 24, 36 and 52. These differences were more pronounced for PASI100>PASI90>PASI75. SR performed better and faster to guselkumab treatment as assessed by absolute PASI, BSA, VAS pruritus and DLQI. Statistically significant differences were found in absolute PASI, BSA, VAS pruritus and DLQI between groups along the 52 weeks of study. No differences in drug survival were found between groups (p=0.3326).
Conclusions: Our study demonstrated for the first time in a real clinical practice setting, the presence of a subpopulation of patients that super respond to guselkumab, at week 12 and 24 and maintain this efficacy for 52 weeks. Further research must be performed to identify basal specific characteristics of this SR population.

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P49 - Therapeutic Inertia in Management of Psoriasis: Gender Specific Trends from a Quantitative Survey

5. Epidemiology

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Introduction: Psoriasis is a chronic, auto-immune disorder, with considerable physical and psychological burden. Patients with psoriasis require different treatments, based on their disease severity. Global evidence advocates that management of psoriasis may be associated with therapeutic inertia[1-2] (failure to start or intensify therapy by the treating physician). However, in the absence of India specific data, there is a need to identify its extent and causal factors in order to improve the management of psoriasis
Objectives: To identify attitudes and behaviors of dermatologists and patients towards the management of psoriasis and need gaps for improved care.
Methods: A cross-sectional, quantitative survey was conducted from September–November 2020, among patients and dermatologists across India. The interviews were conducted telephonically and face to face, using a structured and validated questionnaire, post approval from an Independent ethics committee. The patients were enquired on— initial symptoms, reaction, diagnosis, management, treatment expectation and need gaps with current treatment. The current analysis reports gender specific trends from the study
Results: Data from total of 303 dermatologists and 207 patients was analysed. Amongst the initial symptoms of disease, females recalled higher skin related symptoms including cracked dry skin (77%), rash (70%) and flaky skin (67%) (Table 1). At the onset of symptoms more females (35%) preferred to consult the dermatologist immediately and showed less time lag to seek medical help (3.2 months) and to reach a dermatologist via referral (5.3 months). On the other hand, males (14%) preferred to take over the counter medicines. Females expected clear skin from the treatment (57%) and were inclined towards aggressive therapy (54%). Higher proportion of females as compared to males did not undergo recommended treatment (32%) due to fear of side effects (52%) and seeking second opinion (48%). Further females showed a lower time lag between change in treatment from original treatment (7.2 months) due to side effects. With the current therapy the females expected longer remission with clear skin (48%) whereas males expected quicker relief (39%).

Conclusions: This is a first of its kind study that identified the difference between males and females with respect to the patient journey, management, treatment expectations and need gaps for psoriasis in India

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Table 1: Key Findings

	Overall (n=207)	Male (n=125)	Female (n=82)
Initial Symptoms			
Itching	77%	74%	83%
Cracked, dry skin	71%	68%	77%
Rash	65%	62%	70%
Flaky Skin	63%	60%	67%
Patient journey			
First point of contact-dermatologist	31%	29%	35%
Use of OTC medications	12%	14%	7%
Time lag			
To seek medical help after initial symptoms	3.6 months	3.8 months	3.2 months
To reach dermatologist via referral	7.8 months	8.8 months	5.3 months
Treatment Expectations			
Clear Skin	50%	45%	57%
Aggressive therapy	50%	48%	54%
Reasons for declining treatment			
Fear of side effects	42%	30%	52%
Seeking second opinion	31%	13%	48%
Need Gaps			
Longer remission	41%	37%	48%
Quick relief	34%	39%	28%

P50 - Therapeutic Inertia in management of Psoriasis: Zonal Trends from a Quantitative Survey

5. Epidemiology

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Introduction: Psoriasis is a systemic, auto-immune disorder, having profound impact on the overall quality of life of the patients. [1] Present limited evidence suggests psoriasis management to be associated with therapeutic inertia, wherein the physician fails to start or intensify the treatment as required. [2] As this concept is novel among Indian dermatologists, there is a need to investigate it and its underlying causes to improve the management of psoriasis
Objectives: To understand the attitudes and behaviors of dermatologists and patients towards the management of psoriasis and key barriers for enhanced care across different zones in India
Methods: A cross-sectional, quantitative survey was conducted from September-November 2020 among dermatologists and patients across different zones of India (north, south, east and west). The interviews were conducted either face to face or telephonically using a structured questionnaire validated by an Independent ethics committee. The patients and dermatologists were enquired about—patient journey, diagnosis, management, treatment satisfaction. The current analysis presents zonal trends only.
Results: Overall 303 dermatologists and 207 patients were interviewed. Patients from north went mostly to general physicians (50%) and consumed over the counter medicines (14%) after experiencing initial symptoms. Once diagnosed, the use of Psoriasis Area and Severity Index was highest in the west (42%) and Dermatology Life Quality Index (40%) in the east for the assessment of disease severity. For initial treatment initiation highest resistance was observed from east (33%) which can be attributed to lack of adequate counselling (54%). Patients from east were more likely to get their treatment changed (29%) due to lack of quick resolution (33%) and side effects (33%). Patients from east (47%) reported the lowest satisfaction with current treatment compared to other zones (Table 1).
Conclusions: This novel study identified the different factors impacting the patient journey and management in psoriasis in different zones in India.

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Table 1: Key Zonal Findings

	Overall (n=207)	North (n=62)	East (n=42)	West (n=50)	South (n=53)
Prior to Diagnosis					
First point of contact					
Dermatologist	31%	23%	36%	30%	40%
GP	17%	18%	19%	14%	17%
Diagnosing specialty					
Dermatologist	80%	66%	83%	78%	83%
Family Physician	19%	26%	14%	14%	15%
Diagnosis					
Tools to classify severity					
PASI	37%	36%	40%	42%	32%
BSA	28%	31%	23%	24%	32%
Clinical Examination	21%	20%	19%	20%	24%
Treatment					
Acceptability of treatment					
Treatment Acceptance	76%	77%	67%	80%	77%
Reasons for acceptance					
Received adequate counselling	65%	71%	46%	55%	80%
Wanted quick symptom alleviation	45%	31%	61%	53%	44%
Forced by family	41%	38%	39%	28%	61%
Treatment change					
After initial therapy	25%	24%	29%	24%	25%
Due to lack of quick resolution	28%	26%	33%	29%	26%
Side effects with current therapy	23%	20%	33%	19%	24%
Treatment satisfaction					
Satisfaction with current treatment	51%	48%	47%	54%	57%

6. GENETICS

P51 - HLA-C gene polymorphism is likely associated to the susceptibility of Psoriasis in Moroccan patients and to the response to methotrexate: Preliminary study

6. Genetics

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Introduction: Psoriasis (PsO) is a chronic, inflammatory skin disorder. Although its etiology is still unknown, there is a strong evidence for genetic predisposition in which the HLA system plays a principal role. Several studies reported the positive association between some specific HLA-alleles and PsO, especially HLA-C*0602 (1).
Moreover, in developing countries, even though many biotherapies have proven their efficacy in the treatment of PsO, methotrexate (MTX) is still used as first-line chemotherapy based on its high efficacy and its affordable cost. However, the differential response to MTX therapy observed in PsO patients seems also related to their immunogenetic background.
Objectives: Our study aims to analyze first the association between HLA-C polymorphism and the genetic predisposition to PsO and second to evaluate the impact of the HLA-C status on the response to MTX.
Methods: Thirty-six Moroccan PsO patients and 77 healthy controls (HC) were genotyped for the HLA-C locus using the polymerase chain reaction sequence specific oligonucleotide-Luminex typing method. The mean age of the patients was 40,05 years, with a sex-ratio of 1. The patient's group is divided into two subgroups based on the age on the onset: G1: 12 patients ≤ 30 years old (33,33%) and G2: 24 patients > 30 years old (66,66%). All had received MTX as a treatment of PsO. The patient's group was also clustered into two subgroups depending on the response to the MTX therapy (responders and non-responders).
As well, the mean age of the HC was 38,90 years, with a sex ratio of 1,02.
Results: Analysis of HLA-C* allele frequencies distribution revealed an increase of three alleles in patients than in HC but the statistical significance was not reached: C*02(19,44%) C*06(50%) C*07(47,22) vs C*02(9,09%) C*06(41,56%) C*07(35,06%), respectively. In contrast, we identified a significant increase of the HLA-C*7 allele frequency in G2 than G1 groups (84,62% vs26,09%, p = 0.005, Pc = 0.03, OR = 4, 89, 95% CI :1.35-15.57).

In the same way, only HLA-C*06 allele frequency was found significantly higher in responders when compared to non-responders, (p=0.028, OR=7,8, 95% CI: 0.96-63.59).
Conclusions: We reported here for the first time in the Moroccan population the possible involvement of the HLA-C (HLA-C*06 and HLA-C*7) gene polymorphism in the susceptibility to PsO, which seems significantly related to the age of psoriasis onset. Further work is recommended to confirm this interesting data by increasing the sample size of the population.
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P52 - Whole-exome sequencing of hundreds of microbiopsies reveals the somatic evolutionary landscape of psoriatic skin

6. Genetics

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Introduction: Recent technological advances have enabled the study of somatic evolution in normal non-neoplastic tissues. Martincorena et al and Fowler et al used deep sequencing of targeted panels to show that cancer drivers are common in normal skin and identify several genes under positive selection in skin from different body sites [1,2].
Previous work by us and others has shown that inflammatory bowel disease (IBD) is associated with large differences in the somatic evolutionary landscape of colonic mucosa compared with healthy colon [3–5]. In particular, immune related genes, including genes in the IL-17 pathway, were found to be recurrently mutated, suggesting a role in disease pathogenesis. Whether similar evolutionary forces operate in chronically inflamed skin is unknown.
Objectives: Here we study somatic evolution in skin biopsies from psoriasis patients, characterizing their clonal structure, mutation burden, mutagen exposure and selection landscape.
Methods: We use laser capture microdissection to isolate and whole-exome sequence hundreds of samples of epidermis, <0.01 mm2 in size, from lesonal and non-lesional skin from dozens of psoriasis patients [6].
Results: Preliminary results indicate that despite hyperproliferation of keratinocytes within psoriatic lesions, the clonal structure of psoriatic skin is similar to that of healthy skin, with clones rarely expanding over large distances. As in healthy skin, most mutations in psoriatic skin result from UV-light exposure. We reveal a large heterogeneity in exposure to UV-light between cells separated by less than 1 mm in the tissue, reminiscent of the heterogeneity which exists between cells in the lungs of ex-smokers [7] and indicating that some cells may be protected against the mutagenic effects of UV-light. We identify genes under selection and compare their mutational frequencies in normal and lesional skin, with preliminary results showing no enrichment of the IL-17 pathway, a key pathway in both IBD and psoriasis pathogenesis. Finally, we describe one patient with a history of photo treatment with psoralens. This cytotoxic treatment left a characteristic mutational signature, caused hundreds of thousands of mutations in the genomes of exposed cells and enabled the expansion of heavily mutated clones in the skin.
Conclusions: The cellular architecture and/or high driver prevalence of the skin places constraints upon clonal expansion in psoriasis. The large effect of, and variation in, external UV-exposure dominates the mutation burden, reducing power to detect a disease effect on intrinsic mutational processes. Genes outside previously used sequencing panels are under positive selection in the skin but so far the effect of chronic inflammation on colonic mucosa and epidermis seem different.
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7. HEALTH ECONOMICS AND HEALTH POLICIES

P53 - Healthcare resource utilization among paediatric patients with psoriasis based on real-world data from the EU5 and US

7. Health economics and health policies

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Introduction: Psoriasis is a chronic skin disease and one third of PsO patients experience disease onset before the age of 20
Objectives: To present the healthcare resource utilization in a real-world setting of pediatric psoriasis patients
Methods: This study uses data from the Adelphi paediatric PsO Disease Specific Program (DSP), a point-in-time survey of paediatric patients aged 4–17 years being treated for PsO in the EU5 (France, UK, Germany, Spain, Italy) and US between February–October 2020. Where data is represented as n/N, n=number of patients per group, N=total number of patients with available data.

Results: Data were collected from 324 physicians (EU5, n=248; US, n=76); this included 58% dermatologists (EU5, 56%; US, 62%), 20% paediatricians, (EU5, 20%; US, 16%) and 22% general/primary care practitioners (EU5, 24%; US, 22%) representing 2,877 paediatric PsO patients (EU5, n=2187[76%]; US, n=690[24%]) undergoing treatment for their PsO. Disease severity (mild, moderate, severe) was judged based on physician perception and was recorded retrospectively. Based on physician-judged severity at the time of sampling, 78.6%(n=2262) of PsO patients reported mild disease (EU5, n=1733, 79.2%; US, n=529, 76.7%), 19.8%(n=569) had moderate disease (EU%, n=425 19.4%; US, n=144, 20.9%) and 1.6% (n=46) had severe disease (EU5, n=29, 1.3%; US, n=17 2.5%).Within the previous 12 months from the time of sampling, pediatric PsO patients had consulted the DSP-physician once every 4 months (For mild disease: overall, 3.4±4.2 visits; EU5, 3.6±4.6 visits; US, 2.7±2.1 visits; For moderate disease: overall, 3.5±2.1 visits; EU5, 3.7±2.2 visits; US, 2.7±1.35 visits; For severe disease: overall, 3.8±3.3 visits; EU5, 4.4±3.9 visits; US, 2.8±1.5 visits). In the EU5, patients with mild disease at sampling had also consulted another health care professional (HCP) 1.5±3.3 times, while those with moderate and severe disease had consulted other HCPs 2.6±5.0 and 3.6±4.3 times, respectively, in the previous 12 months. In the US, the number of visits to other HCPs was higher for patients with moderate disease at sampling (mild, 0.89±1.5; moderate, 1.0±1.7; severe, 0.59±1.1). Regardless of disease severity, minimal hospitalizations related to their PsO treatment were recorded for patients both in the EU5 (mild, 0.05±0.5; moderate, 0.09±0.42; severe, 1.00±2.47) and US (mild, 0.03±0.46; moderate, 0.01±0.09; severe, 0.00±0.00). Overall and in the EU5 and US separately, PsO patients reported that they had missed school/college/work due to their PsO (Overall, 15.9%[125/788]; EU5, 15.8%[91/577]; US, 16.1%[34/211]). Overall, 12.5% of patients (66/528)

reported that this had a negative effect on their performance/grades and this trend was similar in the EU5 (11.4%[48/420]) and US (16.7%[18/108]).
Conclusions: Frequency of consultations (either PsO-treating physician or other HCP) increased with level of psoriasis severity. Impact of PsO on missing school/work and related performance was profound and was similar among patients in the EU5 and US.

P54 - Informing Patients about Biosimilar Medicines: The Role of European Patient Associations

7. Health economics and health policies

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Introduction: Biosimilar medicines support the sustainability of national healthcare systems, by reducing costs of biological therapies through increased competition. However, their adoption into clinical practice largely depends on the acceptance of healthcare providers and patients. Patients are different from health care professionals (HCPs), who are informing themselves professionally. For patients, the biosimilar debate only becomes actual when they are confronted with disease and drug choices.
Objectives: This study aimed to provide an overview of how patients are and should be informed about biosimilar medicines, with a focus on the role of European patient associations in particular.
Methods: A structured literature review searching in scientific databases (i.e., Medline, Embase) was performed. In addition, a web-based screening of European Patients' Forum (EPF) and International Alliance of Patients' Organizations (IAPO) member organizations on publicly available information about biosimilars was performed.
Results: Several large surveys have shown a lack of knowledge and trust in biosimilars among European patients in recent years. This review identified five main strategies to inform patients about biosimilars: (1) provide understandable information, (2) in a positive and transparent way, (3) tailored to the individual's needs, (4) with one voice, and (5) supported by audiovisual material. Moreover, the importance of a multistakeholder approach was underlined by describing the role of each stakeholder. Patients are a large and diffuse target group to be reached by educational programs. Therefore, patient associations have become increasingly important in correctly informing patients about biosimilar medicines. This has led to widespread biosimilar information for patients among European patient associations. A variety of information and educational material for patients about biosimilar medicines is made public by European patient organizations. Yet, the quality, tone, and level of detail vary among different associations, and it is not clear whether the identified information is effectively reaching the patient.
Conclusions: It is important to set up a close collaboration between all stakeholders to develop and effectively disseminate correct information about biosimilars to patients, bringing together scientific associations, professional associations (including physicians, nurses, and pharmacists), regulatory authorities, and patient associations. Informing and educating patients on biosimilars should be part of a wider approach supporting a sustainable market for off-patent biological and biosimilar medicines. A sustainable market ensures access for patients to biological therapies now and in the future.
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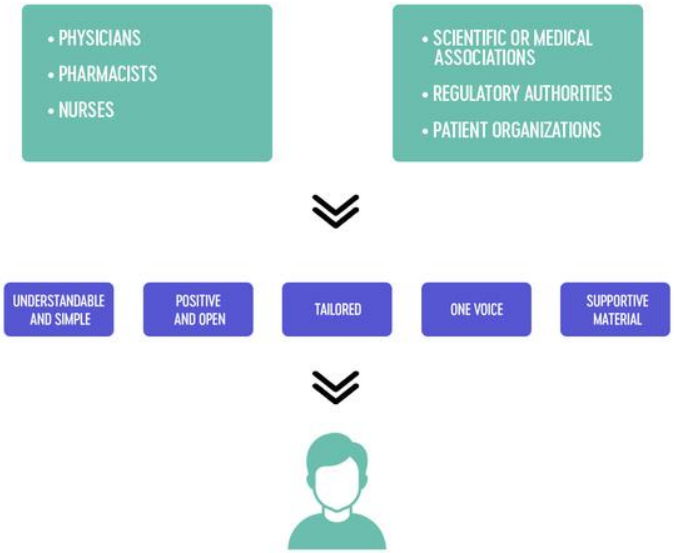
• PHYSICIANS
• PHARMACISTS
• NURSES
• SCIENTIFIC OR MEDICAL ASSOCIATIONS
• REGULATORY AUTHORITIES
• PATIENT ORGANIZATIONS
UNDERSTANDABLE AND SIMPLE
POSITIVE AND OPEN
TAILORED
ONE VOICE
SUPPORTIVE MATERIAL

P55 - Unmet educational needs and professional practice gaps in the management of generalized pustular psoriasis: global perspectives from the front line

7. Health economics and health policies

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Introduction: Generalized pustular psoriasis (GPP) is a rare, potentially life-threatening, neutrophilic, autoinflammatory skin disease characterised by recurrent flares of generalized sterile pustules and associated systemic features. Inconsistent diagnostic criteria and a lack of approved therapies pose serious challenges to the management of GPP
Objectives: To review current real-world standards of care in GPP and identify healthcare provider (HCP) educational needs and clinical practice gaps in GPP management.
Methods: On 24 July 2020, 13 dermatologists from 10 countries (Brazil, Canada, China, Egypt, France, Germany, Japan, Malaysia, the UK and the USA) attended a workshop to share experiences in managing patients with GPP. Educational needs and clinical practice gaps grouped according to healthcare system level (‘macro’, regulatory/economic factors; ‘meso’, organisation/hospital factors; ‘micro’, individual HCP factors) were discussed and ranked using interactive polls.
Results: Lack of experience of GPP among HCPs was identified as the highest priority individual-level clinical practice gap. The attendees agreed that a challenging aspect of GPP management is prompt, effective treatment to ensure rapid control of cutaneous and systemic features. Limited understanding of the presentation and pathogenesis of GPP among non-specialists means that misdiagnosis is common, delaying referral and treatment initiation. In countries where patients may present to general practitioners or emergency departments rather than to specialists, GPP is often mistaken for an infection. Among dermatologists who can accurately diagnose GPP, limited knowledge of treatments and follow up may still necessitate referral to a colleague with more experience in GPP management. At the organisational level, educating emergency department HCPs to recognise GPP as an autoinflammatory disease was seen as a high priority, along with improved communication, cooperation and definitions of roles and responsibilities within multidisciplinary teams involved in the treatment and ongoing support of patients with GPP. At the regulatory level, the

need for robust clinical trial data was identified as the highest priority, followed by the need for clear and consistent treatment guidelines and approved therapies. In addition to educational needs among HCPs, it is crucial for patients to be supported and empowered in their role in managing GPP, avoiding triggering factors and adhering to maintenance regimens.

Conclusions: The most important educational imperative across participating countries is for HCPs to understand that GPP can be life threatening if correct treatment initiation is delayed, and to recognise when to refer cases to a dermatologist with experience of GPP management. Robust clinical trial data, consensus diagnostic criteria, and guidelines for the treatment and prevention of GPP flares are also needed.

8. INTERESTING CLINICAL CASES

P56 - A Case of Paradoxical Eczema: Cytokine imbalance in Psoriasis.

8. Interesting clinical cases

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Introduction: A 39 year old boat builder with chronic plaque psoriasis had been managed with various agents over the years; Acitretin in 2015 (stopped due to adverse effects), Ciclosporin 2017-2018, Methotrexate 2018-2019, Ustekinumab 2018-19, and Adalimumab in 2019. However, despite successfully controlling his psoriasis (PASI 12 to 2.8), he subsequently developed biopsy confirmed eczema in flexural sites, secondary to ustekinumab. Biologic therapy was switched to a TNF-inhibitor and this resulted in a severe eczema flare (EASI 31, DLQI 18). Treatment along atopic dermatitis guidelines culminated in dupilimab therapy. He was otherwise healthy and not taking other medications. His father had psoriasis.

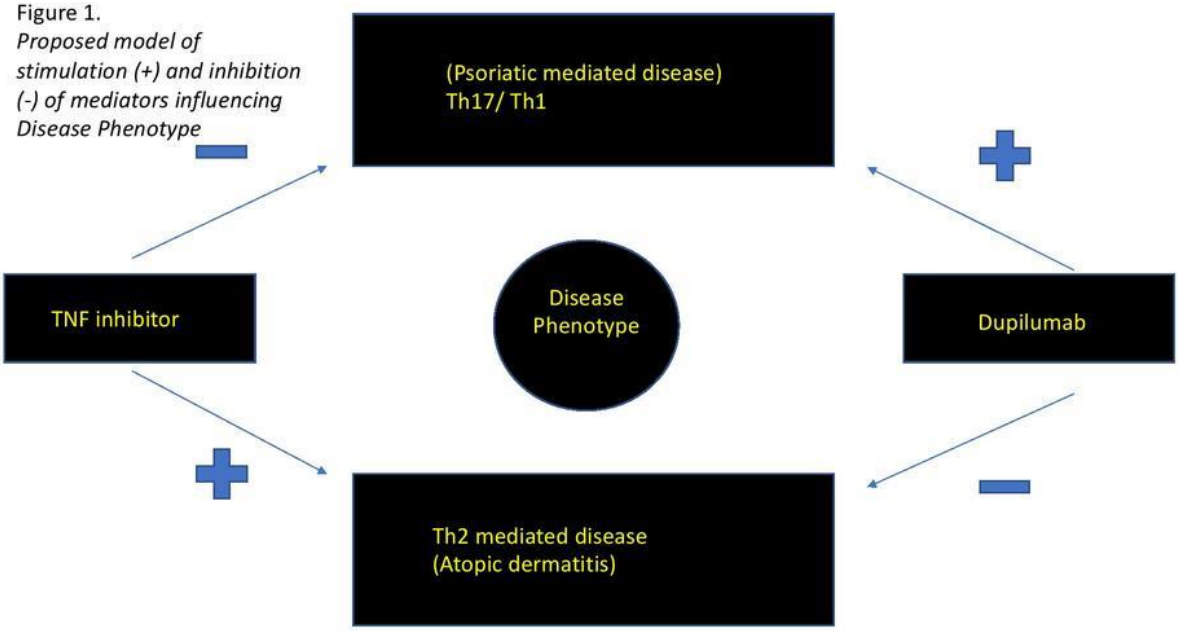
He was treated with dupilumab but after a short period had to discontinue this due to conjunctivitis and panic attacks. he is currently on ciclosporin with low EASI and PASI scores in keeping with mild disease.
Objectives: To highlight a clinical dilemma in management which may be encountered by the practicing dermatologist. We link this case to relevant pathobiology and propose a theory of the interplay of cytokine imbalance, influencing the psoriatic phenotype.
Methods: Literature search via pubmed. Interestingly, there are some case reports of the reverse scenario; Dupilumab induced psoriasis [1 2]. This may suggest a reversible phenotype spectrum (Fig 1). Limitations: Unknown individual genetics. No clear elucidated pathway can be inferred from case reports and their limited nature.
Results: This case report highlights the clinical dilemma a dermatologist faces in the era of immunomodulatory biologics. Many difficulties in management were noted due to a phenotypic switch to eczema, in a psoriatic patient.
Conclusions: Paradoxical eczema is a possibilty in patients who have tried mutliple biologics. There is likely cytokine imbalance driving phenotype. Inhibitors of Th17/Th1 (Psoriatic) mediated disease may stimulate Th2 mediated disease; potentially altering the pathobiology and disease phenotype in the same patient [3 4]. Further studies should explore and identify the individual factors, including genetics, which may predispose patients to a particular phenotype. This would enhance future goals of delivering personalised therapy.
References: 1) Tracey EH, Elston C, Feasel P, Piliang M, Michael M, Vij A. Erythrodermic presentation of psoriasis in a patient treatedwith dupilumab. JAAD Case Rep 2018; 4: 708–710.

2) Safa G, Paumier V. Psoriasis induced by dupilumab therapy. Clin Exp Dermatol 2019; 44: e49–e50.

3) Ono S, Honda T, Doi H, Kabashima K. Concurrence of psoriasis vulgaris and atopic eczema in a single patient exhibiting different expression patterns of psoriatic autoantigens in the lesional skin. JAAD Case Rep 2018; 4: 429–433.

4) Eyerich S, Onken AT, Weidinger S et al. Mutual antagonism of T cells causing psoriasis and atopic eczema. N Engl J Med 2011; 365: 231–238.

Figure 1.
Proposed model of stimulation (+) and inhibition (-) of mediators influencing Disease Phenotype



P57 - Subcutaneous sarcoidosis in-patient with psoriatic arthritis: a case report

8. Interesting clinical cases

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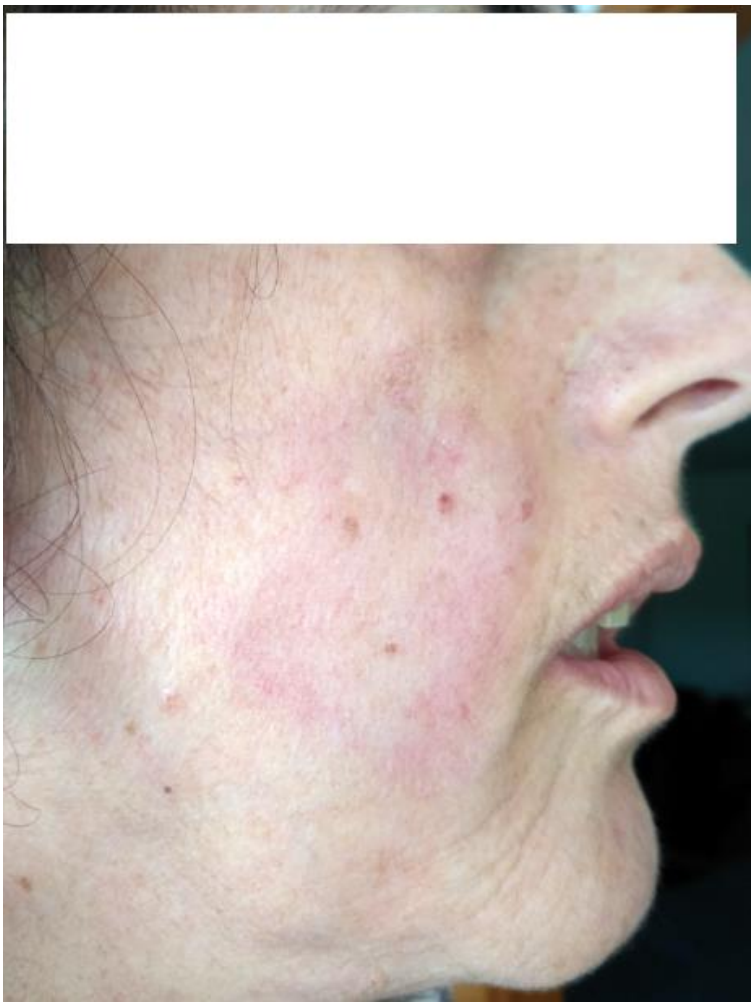
Introduction: Sarcoidosis is a multisystem chronic inflammatory disorder of unknown etiology characterized by the presence of noncaseating granulomas. It mainly affects the lungs, lymph nodes, skin and eyes. Excluding intrathoracic sarcoidosis, the incidence of isolated forms is rare and of these, the skin is the most common organ involved. Skin involvement may be the initial presentation. Given this challenge, though the biopsy specimen demonstrating non-caseating granulomas as the cornerstone diagnostic procedure, recent imaging modalities such as ultrasound and positron-emission tomography (PET) are being increasingly used for diagnosis.
Objectives: N/A
Methods: N/A
Results: Case Presentation:
A caucasian women in their early 50s with axial and peripheral psoriatic arthritis, with 16 years of evolution, presented in the follow up visit at the rheumatology department, complaining of inflammatory pain on some small joints of the hands and painful subcutaneous nodules around the face and in the arms. The physical examination showed arthritis at the 4th and 5th proximal interphalangeal joints in the right hand, four palpable subcutaneous nodules: two at the frontal and submandibular region measured 1,7cm x 1cm and 0,5cm x 0,8cm, respectively; one at right side of face measured 2,5cm x 3cm (Figure 1) and one at the proximal extensor surface of the right elbow. It was decided to perform a biopsy of the frontal subcutaneous nodule that revealed dermohypodermic granulomatous infiltrate, represented by large histiocytes and multinucleated cells, resembling sarcoid type (Figure 2). Facing these findings, it was requested an 18-FDG-PET that documented subcutaneous thick tracer all over the body, more concentrated to the upper limbs and axillar lymph nodes correlating with the suspected hypodermic sarcoid diagnosis. She started prednisone dose of 60 mg daily and hydroxychloroquine 6,5mg/kg/day and repeated 18-FDG-PET 12 weeks after the beginning of the treatment which revealed absence of hypodermic sarcoid activity.

Conclusions: We emphasize the importance of exploring all the new signs and symptoms of each disease during follow up, especially when an immune inflammatory condition like psoriatic arthritis is present. Further research is needed to create new tools for evaluation, treatment and long-term follow-up of these isolated cutaneous presentations.
References: 1. Leverenz, D.L., C. Henderson, and A. Shah, *Atypical Cutaneous Presentations of Sarcoidosis: Two Case Reports and Review of the Literature.* Curr Allergy Asthma Rep, 2018. **18**(8): p. 40.
2. Garcia-Colmenero, L., et al., *The natural history of cutaneous sarcoidosis. Clinical spectrum and histological analysis of 40 cases.* Int J Dermatol, 2019. **58**(2): p. 178-184.
3. Noe, M.H. and M. Rosenbach, *Cutaneous sarcoidosis.* Curr Opin Pulm Med, 2017. **23**(5): p. 482-486.
4. Ungprasert, P., et al., *Epidemiology of cutaneous sarcoidosis, 1976-2013: a population-based study from Olmsted County, Minnesota.* J Eur Acad Dermatol Venereol, 2016. **30**(10): p. 1799-1804.



9. PATHOPHYSIOLOGY AND IMMUNOBIOLOGY

P58 - Intestinal barrier and gut microbiota-derived metabolites in the pathophysiology of psoriasis

9. Pathophysiology and immunobiology
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Introduction: The growing number of experimental and clinical studies suggest a significant role of the interaction between altered intestinal microbiome (dysbiosis), intestinal barrier damage and the immune system in the pathogenesis of psoriasis. These observations became the basis for creating the concept of the gut-skin axis.
Objectives: The aim of the study was to assess the influence of psoriasis activity on the intestinal barrier permeability, blood concentration of bacterial metabolites and its clinical implications – presence of gastrointestinal symptoms and psoriasis comorbidities.
Methods: One hundred and twenty patients with mild to severe plaque psoriasis were included in the study. Intestinal barrier integrity was assessed with the serum concentrations of claudin-3, a modulator of intestinal tight junctions and an intestinal fatty acid-binding protein, a marker of enterocyte damage. The concentrations of trimethylamine N-oxide (TMAO) and trimethylamine (TMA), gut microbiota-associated metabolites, were measured with high-performance liquid chromatography. Gastrointestinal symptoms were evaluated with a validated version of the international GSRS questionnaire.
Results: Patients with psoriasis were characterized by higher concentration of claudine-3 (52.4 vs 43.5 ng/ml), intestinal fatty acid binding protein (256.2 vs 134.8 pg/ml), TMAO (327.9 vs 195.7 ng/ml) and TMA (1292.4 vs 813.5 ng/ml). Patients with a higher disease activity demonstrated high concentration of intestinal barrier damage biomarkers, as well as, reported more severe gastrointestinal symptoms. The concentration of the bacterial metabolite TMAO positively correlated with the cardiovascular risk calculated according to the Framingham and QRISK-2 scales ($r=0.679$; $p<0.05$), while TMA positively correlated with C-reactive protein ($r=0.548$; $p<0.05$) and neutrophil to lymphocyte ratio ($r=0.503$; $p<0.05$).
Conclusions: Psoriasis promotes disruption of the intestinal barrier integrity and translocation of bacterial metabolites, which can activate the inflammatory response and lead to exacerbation of skin lesions. translocation of bacterial metabolites by altered intestinal barrier in psoriasis is a potential mechanism linking gut dysbiosis with increased cardiovascular risk. Probiotics, prebiotics, antibiotics and molecules affecting intestinal barrier permeability are being intensively studied as therapies that can potentially break this "vicious circle."
References: 1. Sikora M. et al. Intestinal barrier integrity in patients with plaque psoriasis. J Dermatol. 2018;45:1468-1470.
2. Sikora M. et al. Claudin-3 - a new intestinal integrity marker in patients with psoriasis: association with disease severity. J Eur Acad Dermatol Venereol. 2019;33:1907-1912.
3. Sikora M. et al. Gut Microbiome in Psoriasis: An Updated Review. Pathogens. 2020;9:463.
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10. PSORIASIS AND PSORIATIC ARTHRITIS RELATIONSHIP

P59 - A comparision of psoriatic arthritis burden at early and long-standing stage. Data from RU-PsART cohort

10. Psoriasis and Psoriatic Arthritis relationship

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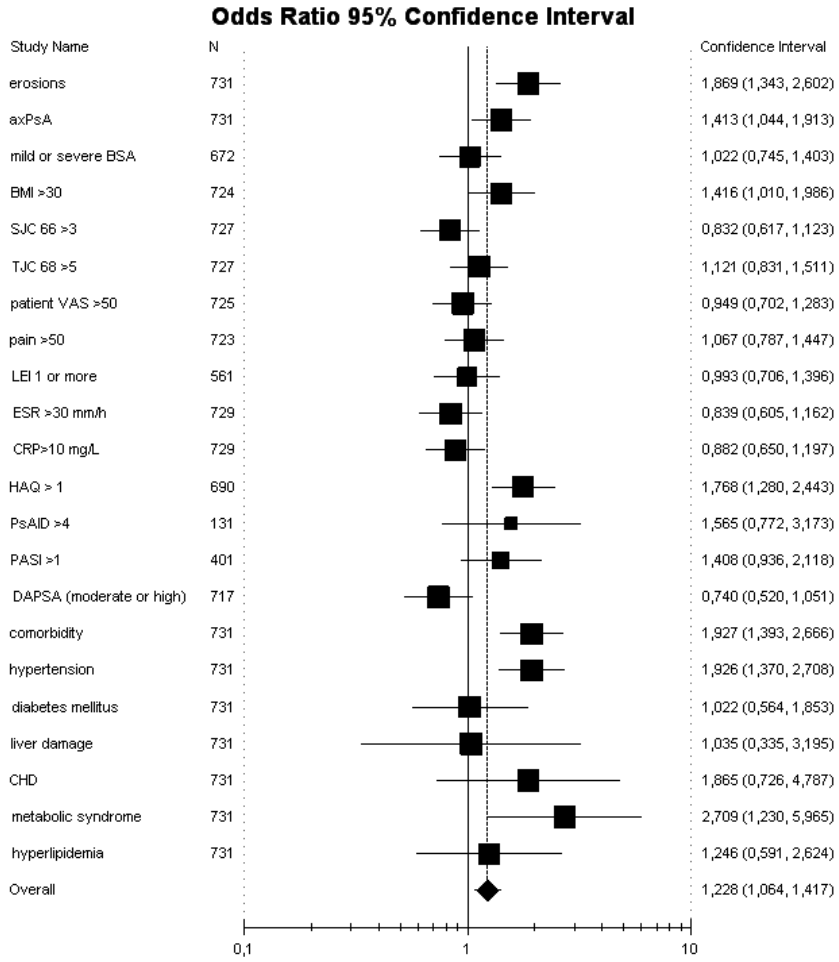
Introduction: Psoriatic arthritis (PsA) is a heterogeneous systemic disease that involves skin, nails and the musculoskeletal system. Potentially devastating nature of PsA increases over time
Objectives: To compare PsA burden at early and long-standing stage on data from an observational cohort
Methods: 737 (M/F=350(47.5%)/387(52.5%)) patients (pts) with PsA fulfilling the CASPAR criteria from the RU-PsART cohort were included. Mean age 47.4±12.7 yrs., duration of psoriasis (PsO) 200.6±158.9 mo., PsA duration 79.6±81.9 mo. All pts were divided into 2 groups by PsA duration: 1st group ≤36 mo. (449 out of 737 (60.9%) pts) and 2nd group >36 mo. (288 out of 737 (39.1%) pts). All pts underwent standard clinical examination of PsA activity. Tender (68) and swelling (66) joint count (TJC, SJC), DAPSA, LEI, tenderness of the plantar fascia, PsO BSA (%), PASI (0-72), HAQ-DI (HAQ-DI >1 represents the worst health related quality of life and more functional disability), The 12-item Psoriatic Arthritis Impact of Disease questionnaire (PsAID-12, 0-10, where 10 represents the worst health score), body mass index (BMI, kg/m^2), ESR (mm/h), CRP (mg/l) and comorbidities by ICD-10 were evaluated. Data of X-Ray of feet and hands were available in 622 out of 737 pts (84.4%). M±SD, Odds Ratio (OR), Pearson $\chi 2$ test were calculated
Results: In pts with PsA duration >36 mo. we found significant prevalence of erosions by X-Ray, axial PsA, BMI>30 kg/m^2, HAQ-DI>1, PsAID-12>4, arterial hypertension, metabolic syndrome and overall comorbidity ($p<0.05$). There were no significant differences between groups in PsO severity by BSA>3% (mild and severe PsO) and PASI>1, LEI>1, TJC, SJC, dactylitis, ESR >30 mm/h, CRP>10 mg/l, DAPSA (moderate and high), diabetes mellitus, hyperlipidemia, coronary heart disease (CHD) and liver damage ($p>0.05$) (Fig.1).
The analyzes of therapy in both groups show that NSAIDs and c/ts DMARDs were taken significantly more often in the 1st group compared to the 2nd one: in 117 out of 449 pts (61.46%)/ 234 (52.12%), p=0.012 and in 257 (89.24% /) 350 (77.95%), p=0.00009 respectively. bDMARDs were used significantly more often in pts from the 2nd group compared to the 1st one: 191 (42.54%) and 52 (18.06%) respectively (p=0.000001).
Conclusions: Long-standing stage PsA is associated with erosions, axial PsA, worst health related quality of life, functional disability and increased cardio-metabolic disorders and overall comorbidity. Our results from real clinical practice support the idea to start bDMARDs at early stage of PsA, it can improve better outcomes


Odds Ratio 95% Confidence Interval
Study Name
N
Confidence Interval
erosions 731 1,869 (1,343, 2,602)
axPsA 731 1,413 (1,044, 1,913)
mild or severe BSA 672 1,022 (0,745, 1,403)
BMI >30 724 1,416 (1,010, 1,986)
SJC 66 >3 727 0,832 (0,617, 1,123)
TJC 68 >5 727 1,121 (0,831, 1,511)
patient VAS >50 725 0,949 (0,702, 1,283)
pain >50 723 1,067 (0,787, 1,447)
LEI 1 or more 561 0,993 (0,706, 1,396)
ESR >30 mm/h 729 0,839 (0,605, 1,162)
CRP>10 mg/L 729 0,882 (0,650, 1,197)
HAQ > 1 690 1,768 (1,280, 2,443)
PsAID >4 131 1,565 (0,772, 3,173)
PASI >1 401 1,408 (0,936, 2,118)
DAPSA (moderate or high) 717 0,740 (0,520, 1,051)
comorbidity 731 1,927 (1,393, 2,666)
hypertension 731 1,926 (1,370, 2,708)
diabetes mellitus 731 1,022 (0,564, 1,853)
liver damage 731 1,035 (0,335, 3,195)
CHD 731 1,865 (0,726, 4,787)
metabolic syndrome 731 2,709 (1,230, 5,965)
hyperlipidemia 731 1,246 (0,591, 2,624)
Overall 1,228 (1,064, 1,417)
0,1
1
10

P60 - Correlation of Itch Response to Roflumilast Cream With Disease Severity and Patient-Reported Outcomes in Patients with Chronic Plaque Psoriasis

10. Psoriasis and Psoriatic Arthritis relationship

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Introduction: Roflumilast cream is a nonsteroidal, selective phosphodiesterase-4 inhibitor in development for plaque psoriasis (PsO). A Phase 2b, double-blinded trial randomized adults with PsO (2-20% body surface area) to once-daily roflumilast 0.3%, roflumilast 0.15%, or vehicle for 12 weeks (NCT03638258).[1] Throughout the trial, itch and its impact were evaluated via patient-reported outcomes (PROs): Worst Itch Numeric Rating Scale (WI–NRS), Itch-related Sleep Loss (IRSL), and Dermatology Life Quality Index (DLQI).
Objectives: This posthoc analysis reports correlation of WI–NRS with other PROs and with disease severity.
Methods: Overall, 331 patients were randomized (109 to roflumilast 0.3%, 113 to 0.15%, and 109 to vehicle).
Results: At baseline, the mean WI–NRS score was 5.87. Throughout the trial, both roflumilast doses showed similar improvements in WI–NRS starting at Week 2 and were significantly superior to vehicle ($P \leq 0.002$). At baseline, Pearson correlation coefficients (PCCs) for WI–NRS and Psoriasis Area and Severity Index (PASI) were 0.189, 0.282, 0.205 for roflumilast 0.3%, roflumilast 0.15%, and vehicle, respectively ($P \leq 0.033$ for all correlations); for WI–NRS and IRSL: 0.548, 0.646, 0.652 ($P<0.001$); for WI–NRS and DLQI: 0.445, 0.617, 0.422 ($P<0.001$). At Week 8, PCCs for WI–NRS and PASI were 0.420, 0.409, 0.365 ($P<0.001$); for WI–NRS and IRSL: 0.673, 0.725, 0.696 ($P<0.001$); for WI–NRS and DLQI: 0.607, 0.823, 0.529. Treatment with roflumilast resulted in rapid and robust improvement in the severity of itch associated with PsO.
Conclusions: Itch response to roflumilast was independent of disease severity and positively correlated with patient-reported sleep-loss and quality of life improvement.
References: [1]Lebwohl MG, et al. *N Engl J Med.* 2020;383(3):229-239.

P61 - EVALUATION OF THE PSORIASIS AND PSORIATIC ARTHRITIS ACTIVITY IN PATIENTS TREATED ACCORDING TO TREAT-TO-TARGET STRATEGY. 5 YEARS FOLLOW-UP

10. Psoriasis and Psoriatic Arthritis relationship

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Introduction: The treat to target (T2T) concept has already shown the benefits in management of psoriatic arthritis (PsA) patients [1]. However, the long-term assessment of psoriatic lesion and peripheral arthritis activity has not yet been evaluated in PsA patients.
Objectives: To study psoriasis and PsA activity in patients (pts) treated according to T2T strategy at the early stage of disease after 5 years (yrs) follow-up.
Methods: This study assessed 37 (M/F–18/19) PsA pts according to CASPAR criteria, mean age 43.3±11.7 yrs, median (Me) PsA duration 72 [60;90] month (mos), psoriasis duration 120 [88;180] mos, who were treated according to T2T at the early stage within 24 mos. All pts underwent standard clinical examination. Within 24 mos of T2T strategy all pts were taking Methotrexate (MTX) monotherapy at a dose of 20-25 mg/wk. When T2T study was stopped all pts were treated according to the standard care based on a PsA and psoriasis activity. Analyses of PsA and psoriasis activity by DAPSA and body surface area (BSA) affected by psoriasis were calculated at the 24 mos of T2T strategy and at 5 yrs follow-up. M±SD, Me [Q25; Q75] were performed. Wilcoxon range test was used, a value of $p<0.005$ was considered statistically significant.
Results: At baseline, Me DAPSA was 30 [20.75;56.5], Me BSA 2 [0;5]. At 24 mos Me DAPSA 11 [3;36.75], remission by DAPSA (REM-DAPSA) were seen in 20 out of 37 (54%) pts. At 5 yrs Me DAPSA 17 [6;34.35], REM-DAPSA was noted in 13 (35%) pts. No significant differences were found between DAPSA index at 24 mos and 5 yrs. Me BSA at 24 mos was 0.5 [0;2], Me BSA at 5 yrs 1 [0;2.5]. Analysis of psoriatic lesions by BSA at 24 mos and 5 yrs showed significant differences ($p=0.01$).
Conclusions: The T2T approach has shown high effectiveness for PsA treatment in clinical practice. Nevertheless, after transition to treatment according to standard care, patients showed an increase of psoriatic lesions. Further evaluations of the long-term outcomes of T2T strategy in PsA are required.
References: 1. Coates LC, Moverley AR, McParland L, et al. Lancet 2015; 386: 2489–98.

P62 - Infrequent Healthcare Professional Appointments Despite High Levels of Disease Burden in Psoriatic Arthritis: Results From the European Subgroup of the UPLIFT Survey

10. Psoriasis and Psoriatic Arthritis relationship

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Introduction: Patients with psoriatic arthritis (PsA) have substantial disease burden and wide-ranging disease manifestations that negatively impact quality of life. The 2012 Multinational Assessment of Psoriasis and Psoriatic Arthritis (MAPP) survey assessed the impact of psoriatic disease manifestations (PsA and/or psoriasis) on disease burden. To evaluate how these factors may have changed in recent years and identify persisting areas of unmet need, the 2020 Understanding Psoriatic Disease Leveraging Insights for Treatment (UPLIFT) survey was conducted among patients and physicians in 8 countries (USA, Canada, UK, France, Germany, Italy, Spain, and Japan).
Objectives: To understand patient characteristics, current treatment, and disease burden in the European subgroup (UK, France, Germany, Italy, and Spain) of patients with PsA in UPLIFT.
Methods: UPLIFT was a multinational online survey of adults with self-reported, healthcare provider (HCP)-diagnosed PsA and/or psoriasis conducted from March 2 to June 3, 2020. For patients with PsA (with or without comorbid psoriasis) in the European subgroup, we report patient demographics; presence of PsA manifestations (eg, enthesitis, dactylitis, joint/skin involvement); disease burden measured by patient-rated PsA severity (1 [very mild] to 10 [very severe]), Patient Health Questionnaire-2 (PHQ-2) score for depression, and Psoriatic Arthritis Impact of Disease 12-item questionnaire (PsAID12) score; visits to an HCP; and current treatment types.
Results: Of 3806 patients in the overall UPLIFT population, 566 from Europe had PsA and completed the survey (UK [n=93], France [n=94], Germany [n=174], Italy [n=106], Spain [n=99]). Within the European subgroup, 11% had PsA alone and 89% had PsA and comorbid psoriasis. The mean age of the European subgroup was 43 years and 55.5% of patients were men. Many patients reported enthesitis (39%) and dactylitis (48%), and almost half with joint involvement reported oligoarthritis (≤4 joints) (Table). The majority of patients (84%) reported skin manifestations (Table). About 70% of patients classified their disease burden as moderate to severe in intensity (scale 0-10), reported PHQ-2 scores ≥3 (consistent with positive screening for depression), and reported an unacceptable PsA symptom state (PsAID12 value >4) (Table). The majority (>80%) of patients reported some type of current therapy (Table); however, >50% of patients had not seen an HCP in the last 12 months (Table). Demographics and disease characteristics reported for the European subgroup were consistent with those of the overall UPLIFT population with PsA.
Conclusions: In the European subgroup of UPLIFT, the majority of patients reported moderate to severe PsA and substantial disease burden. About half of patients reported not seeing an HCP in the past year, suggesting an opportunity for enhanced patient-physician relationships to improve outcomes and address persistent unmet needs.

Patient Demographics and Clinical Characteristics

Characteristics	UPLIFT European Subgroup N=566
Duration of PsA, mean (SD), years	16.5 (13.5)
Enthesitis, n (%)	222 (39.2)
Dactylitis, n (%)	272 (48.1)
Skin manifestations, n (%)	476 (84.1)
Joint count,* n (%)	
>4 joints (polyarthritis)	303 (53.5)
≤4 joints (oligoarthritis)	263 (46.5)
Patient-perceived severity, n (%)	
Mild (0-3)	159 (28.1)
Moderate (4-6)	199 (35.2)
Severe (7-10)	208 (36.7)
PHQ-2 score <3, n (%)	177 (31.3)
PHQ-2 score ≥3, n (%)	389 (68.7)
PsAID12 score ≤4 (PASS) , n (%)	156 (27.6)
PsAID12 score >4, n (%)	410 (72.4)
Current treatment, n (%)	
No treatment	91 (16.1)
Topical only	45 (8.0)
Oral†	185 (32.7)
Biologic‡	76 (13.4)
Oral and biologic§	134 (23.7)
Other‖	35 (6.2)
Seen an HCP in the past year, n (%)¶	
Yes	270 (47.7)

The N represents the total sample; the number of patients with data available may vary. *In patients reporting joint involvement. †Oral Rx only or oral Rx + topical Rx. ‡Biologic only or biologic + topical Rx. §Oral Rx + biologic or oral Rx + biologic + topical Rx. ‖Other only, phototherapy only, other + phototherapy. ¶COVID-19 restrictions may have impacted a patient's ability to have an HCP visit from March 2 to June 3. PASS=Patient-Acceptable Symptom State; Rx=prescription.

P63 - Long-term safety and efficacy of roflumilast cream 0.3% in adult patients with chronic plaque psoriasis: results from a 52-week, phase 2b open-label study

10. Psoriasis and Psoriatic Arthritis relationship

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Introduction: Roflumilast cream is a potent phosphodiesterase-4 inhibitor in development for plaque psoriasis. Favorable efficacy and safety of roflumilast cream in psoriasis from a phase 2b, 12-week study was recently published.[1]
Objectives: To evaluate long-term (52 weeks) safety of once-daily roflumilast cream.
Methods: Patients from the phase 2b study could continue on open-label roflumilast cream 0.3% (Cohort-1, n=230) and patients naïve to roflumilast were enrolled (Cohort-2, n=102; NCT03764475). All psoriasis lesions (except scalp) were treated, including face and intertriginous areas.
Results: With cumulative treatment up to 64 weeks in Cohort-1 and 52 weeks in Cohort-2, long-term safety and tolerability were consistent with the 12-week, phase 2b study. Overall, 73.5% of patients completed the study; 3.9% discontinued due to adverse events (AE), and 0.9% due to lack of efficacy. Treatment-related AEs were reported in 2.7% patients; none were serious AEs. Investigator tolerability assessments at each visit demonstrated 99% of patients rated no evidence of irritation. At Week 52, Investigator Global Assessment (IGA) of clear/almost clear and 2-grade improvement from baseline, was achieved by 34.8% of patients in Cohort-1 and 39.5% in Cohort-2. Of patients in Cohort-2, 40% of patients achieved IGA success at week 12. Of patients receiving roflumilast cream 0.3% in the parent trial who achieved IGA of clear/almost clear at 12 weeks and continued in the open-label trial, 66.7% achieved IGA of clear/almost clear at 64 weeks or their last visit.
Conclusions: In this long-term safety study, roflumilast cream was well tolerated with no unexpected AEs, and effectively maintained clear/almost clear skin.
References: [1]Lebwohl MG, et al. NEJM 2020;383:229-39.

P64 - Low Incidence of Gastrointestinal-related and Overall Serious Adverse Events Among Guselkumab-treated Patients: Pooled Analyses of VOYAGE 1 & 2 and DISCOVER 1 & 2 Through 1-Year

10. Psoriasis and Psoriatic Arthritis relationship

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Introduction: Guselkumab (GUS), an interleukin (IL)-23 inhibitor, demonstrated efficacy in the Phase 3 VOYAGE (VOY) 1&2 trials of patients (pts) with moderate to severe plaque psoriasis (PsO)[1,2] and in the DISCOVER (DISC) 1&2 trials of pts with active psoriatic arthritis (PsA).[3,4] IL-17 inhibitors have been associated with exacerbation or new onset of inflammatory bowel disease (IBD), e.g. Crohn's disease and ulcerative colitis.[5]
Objectives: Evaluate the incidence of gastrointestinal (GI)-related and overall serious adverse events (SAEs) from pooled safety data through 1-year of GUS 100 mg treatment from the VOY 1&2 and DISC 1&2 trials.
Methods: Using pooled safety data from VOY 1&2 and DISC 1&2 trials, SAEs related to GI disorders were identified by MedDRA system-organ class "GI disorders". Pts with a previous history of IBD were not excluded; medical history of IBD was collected in DISC 1&2. Rates of overall SAEs and GI-related SAEs were calculated as the number of SAEs/100pt-years (PY) of follow-up (95% confidence intervals). Data are presented for the placebo (PBO)-controlled period (Weeks[WK]0-16 for VOY 1&2; WK0-24 for DISC 1&2) and through 1-year (defined as through WK48 for VOY 1&2; through WK60 for DISC 1, and through WK52 for DISC 2).
Results: Baseline skin disease characteristics were similar across treatment groups within the pooled VOY 1&2 and DISC 1&2 trials (Table 1). Through the PBO-controlled period, the overall rates of GI-related SAEs/100PY for VOY 1&2 were: PBO 0.78 (0.02, 4.34), GUS q8w 0; and for DISC 1&2: PBO 0.58 (0.01, 3.23), GUS q8w 0.58 (0.01, 3.21), GUS q4w 0. The GI-related SAEs (n=1 for each) included gastrointestinal hemorrhage (PBO) for VOY 1&2 and IBD (PBO) and mechanical ileus (GUS q8w) for DISC 1&2. Through 1-year, the overall rates of GI-related SAEs for VOY 1&2 were: Combined GUS group (GUS q8w and PBO→GUS) 0.51 (0.17, 1.20); and for DISC 1&2: GUS q8w 0.52 (0.06, 1.88), GUS q4w 0, Combined GUS group (GUS q8w, GUS q4w, and PBO→GUS) 0.21 (0.02, 0.74). GI-related SAEs (n=1 for each) in the Combined GUS group for VOY 1&2 included: gastritis, hemorrhoids, inguinal hernia, pancreatitis, and umbilical hernia (0.10/100PY [0.00, 0.57]);

and in the Combined GUS group for DISC 1&2: mechanical ileus and chronic pancreatitis (0.10/100PY [0.00, 0.57]). No cases of exacerbation or new onset of IBD were reported in GUS-treated pts, including 2 pts with a history of IBD in DISC 1&2 (total PY of follow-up for Combined GUS groups in VOY and DISC were 974 and 973, respectively).

Conclusions: A low incidence of GI-related and overall SAEs was observed in GUS-treated pts through 1-year follow up in VOY 1&2 and DISC 1&2 trials.

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3. Deodhar A., et al. *Lancet*. 2020;395:1115-25.
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Selected results from this analysis were presented at the European Congress of Rheumatology; June 2-5, 2021.

Table 1. Skin disease characteristics at baseline of treated patients in pooled VOY 1&2 and DISC 1&2 trials

	VOY 1&2		DISC 1&2			
	PBO (n=422)	GUS q8w (n=823)	PBO (n=372)	GUS q8w (n=375)	GUS q4w (n=373)	Combined GUS (n=748)
BSA, %	27.1 (16.3)	28.4 (16.7)	15.4 (18.9)	15.7 (20.0)	17.1 (19.7)	16.4 (19.9)
PASI score, 0-72	21.1 (8.3)	22.0 (9.1)	8.8 (9.5)	9.2 (11.1)	10.4 (11.2)	9.8 (11.1)
IGA score						
Cleared (0)	0	0	8 (2.2)	12 (3.2)	7 (1.9)	19 (2.5)
Minimal (1)	0	0	62 (16.7)	68 (18.1)	55 (14.7)	123 (16.4)
Mild (2)	0	0	143 (38.5)	130 (34.7)	132 (35.4)	262 (35.0)
Moderate (3)	322 (76.3)	631 (76.7)	133 (35.8)	136 (36.3)	139 (37.3)	275 (36.8)
Severe (4)	100 (23.7)	192 (23.3)	25 (6.7)	29 (7.7)	40 (10.7)	69 (9.2)

Data are presented as mean (SD), except for IGA score which is presented as number of pts (%).
BSA, body surface area; DISC, DISCOVER; GUS, guselkumab; IGA, Investigator's Global Assessment; PASI, Psoriasis Area and Severity Index; PBO, placebo; q4 w; every 4 weeks; q8w, every 8 weeks; SD, standard deviation; VOY, VOYAGE

P65 - Nail psoriasis severity association with enthesitis and bone erosion in psoriatic arthritis patients: data from RU-PsART cohort.

10. Psoriasis and Psoriatic Arthritis relationship

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Introduction: Psoriatic arthritis (PsA) is a progressive destructive joint disease affecting approximately 20% of people with psoriasis (PsO). Nail psoriasis and enthesitis has been proposed as a predictor for the development of PsA [1].
Objectives: to study association between nail PsO severity, enthesitis and bone erosion based on data from clinical practice (RU-PsART cohort).
Methods: 737 (M/F=350/387) PsA patients (pts) fulfilling the CASPAR criteria from RU-PsART cohort were included. Mean age 47.4±12.7 years (yrs), PsA duration 55[17;120] mos., PsO duration 165[74.5;292] mos. All pts underwent standard clinical examination, including enthesitis by LEI + Plantar Facia (PF). The presence/absent of nail PsO was evaluated. X-ray of feet and hand were done in 622 out of 737 pts. M±SD, Me [Q25; Q75], Min-Max, %, t-test, Pierson-χ2, Manna-Whitney tests, ORs with 95% CI were performed. All $p<0.05$ were considered to indicate statistical significance.
Results: Nail psoriasis were seen in 230 out of 737 pts (31.2%). Bone erosion was found in 237 out of 622 pts (38.1%). Among these pts nail PsO were seen in 67 out of 237 pts (28.3%). Bone erosion significantly associated with nail PsO severity – [1.699 (1.184; 2.440)]. Enthesitis found in 236 out of 737 pts (42.1%). Enthesitis significantly associated with nail PsO severity (p=0.04).
Conclusions: In our cohort of PsA pts nail PsO severity associated with enthesitis and bone erosion. Early diagnosis of these symptoms and treatment in clinical practice are very important for better outcomes of PsA.

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P66 - Once-daily Roflumilast Foam 0.3% for Scalp and Body Psoriasis: A Randomized, Double-blind, Vehicle-controlled Phase 2b Study

10. Psoriasis and Psoriatic Arthritis relationship

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Introduction: Scalp psoriasis (S-PsO) affects 40% of patients either alone or in combination with body psoriasis. Associated itch, scale and social embarrassment adversely impact quality of life. Hair limits efficacy of creams and ointments and reduces treatment adherence, making treatment of S-PsO difficult. Roflumilast foam 0.3%, is a potent, nonsteroidal, phosphodiesterase-4 inhibitor for once-daily treatment of scalp, face, and body psoriasis.
Objectives: We investigated roflumilast foam for S-PsO and body PsO in a phase 2b randomized, double-blind, vehicle-controlled 8-week study.
Methods: Patients ≥12 years old with at least mild disease (assessed separately for scalp and body) and ≤25% BSA were randomized to roflumilast foam (n=200) or vehicle (n=104).
Results: The primary endpoint of S-IGA success (clear/almost clear and ≥2-grade reduction from baseline) at Week 8 was achieved by 59.1% and 11.4% of patients receiving roflumilast foam and vehicle (P<0.0001), respectively; 34.3% and 3.4% rated clear at Week 8. Significant improvement occurred by Week 2. Body IGA success (clear/almost clear and ≥2-grade reduction from baseline) at Week 8 was achieved by 40.3% and 6.8% for roflumilast foam and vehicle (P<0.0001). Among the 88.5% of patients who reported Scalp Itch Numeric Rating Scale (SI-NRS) ≥4 at baseline, 71.0% and 18.5% who received roflumilast foam and vehicle, respectively, had ≥4-point improvement at Week 8 (P<0.0001). Roflumilast foam was well-tolerated. Treatment-related adverse events (AEs), application site AEs, and discontinuations due to AE were low and similar to vehicle.

Conclusions: Once-daily roflumilast foam improved both scalp and body PsO with improvement apparent as early as 2 weeks after treatment initiation.

P67 - Patient Perceptions of Psoriatic Disease in Five European Countries: Results From the European Subgroup of the Understanding Psoriatic Disease Leveraging Insights for Treatment (UPLIFT) Survey

10. Psoriasis and Psoriatic Arthritis relationship

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Introduction: Patients with psoriasis (PsO) and/or psoriatic arthritis (PsA), including those with limited skin involvement and minimal joint symptoms, report substantial disease burden. The Understanding Psoriatic Disease Leveraging Insights for Treatment (UPLIFT) survey was conducted among patients and physicians to better understand perspectives on disease characteristics, disease burden, and treatment goals, particularly for those with more limited skin involvement, PsO in special areas, and/or PsA.
Objectives: The aim of this analysis was to understand disease characteristics and burden in the European subgroup of patients with PsO and/or PsA who completed the UPLIFT survey.
Methods: UPLIFT was a multinational web-based survey fielded from March 2 to June 3, 2020. The patient survey included adults with self-reported, healthcare professional-diagnosed PsO and/or PsA. Demographics, PsO-involved body surface area (BSA), PsO in special areas (scalp, face, nails, palms/soles, or genitals), patient-perceived severity (1 [very mild] to 10 [very severe]), PsA joint involvement, Dermatology Life Quality Index (DLQI), and the 2-item Patient Health Questionnaire-2 (PHQ-2) were assessed in the European subgroup, comprising France (n=404), Germany (n=403), Italy (n=401), Spain (n=398), and the United Kingdom (n=400).
Results: A total of 3,806 patients with PsO and/or PsA completed the UPLIFT survey, including 2,006 in Europe. For the European subgroup, mean age was 44.1 years, 71.8% were diagnosed with PsO only, 25.1% had comorbid PsO and PsA, and 3.1% had PsA only. Comorbidities were common, including hypertension (34.4%), depression (32.6%), and diabetes (21.6%) (**Table**). PsO in special areas was reported by 80.3% of patients (scalp, 58.7%), and 59.2% of patients with PsA had oligoarticular involvement (≤4 joints). In all, 60.2% of patients had a DLQI of >5 (at least a moderate effect), mean DLQI score was 9.7, and 53.9% had a PHQ-2 score ≥3 (increased risk of major depressive disorder). Among patients with limited skin involvement (BSA ≤3%, n=1,437), 61.4% characterized their current PsO severity as moderate or severe, and 78.7% (n=1,131) had PsO in ≥1 special area.
Conclusions: In the European subgroup of UPLIFT, many of whom had limited skin involvement, prevalence of PsO in special areas was high and patients reported substantial disease, comorbidity, and

quality-of-life burden. More than half of patients with limited skin involvement reported their current PsO severity as moderate or severe, suggesting a persistent unmet need in this patient population.

Demographics and Disease Characteristics	
Characteristic	**UPLIFT European Subgroup N=2,006**
Age, mean (SD), years	44.1 (15.4)
Female, n (%)	1,008 (50.2)
BMI category (kg/m^2), n (%)	
Underweight (<18.5)	48 (3.0)
Normal (18.5–<25.0)	763 (47.9)
Overweight (25.0–<30.0)	503 (31.6)
Obese (≥30.0)	280 (17.6)
Selected comorbidities, n (%)	
Hypertension	691 (34.4)
Depression	654 (32.6)
Osteoarthritis or rheumatoid arthritis	557 (27.8)
Diabetes	433 (21.6)
Cancer	294 (14.7)
Inflammatory bowel disease	270 (13.5)
Heart disease	253 (12.6)
Liver disease	209 (10.4)
PsO in special areas[a], n (%)	1,404 (80.3)
Scalp	1,027 (58.7)
Face	509 (29.1)
Nails	277 (15.8)
Palms or soles	448 (25.6)
Genitals	212 (12.1)
PsA joint involvement, n (%)	
Oligoarticular (≤4 joints)	819 (59.2)
Polyarticular (>4 joints)	564 (40.8)
DLQI score >5, n (%)	1,053 (60.2)
PHQ-2 ≥3, n (%)	1,081 (53.9)
Patient-perceived severity 'moderate' or 'severe', n/N (%)[b]	
BSA ≤3%	883/1,437 (61.4)
BSA 4–10%	234/275 (85.1)
BSA >10%	30/37 (81.1)

N represents the total sample. The number of patients with data available may vary.
[a]A patient may have PsO involvement in >1 special area. [b]N=1,749 represents the number of patients with reported skin manifestations (BSA).

P68 - Psoriatic Disease – a heterogenous disease who needs a multidisciplinary care!

10. Psoriasis and Psoriatic Arthritis relationship

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Introduction: Rheumatologists and Dermatologists usually manage Psoriatic Arthritis (PsA) and Psoriasis (PsO) separately, but early diagnosis and integrated management could achieve better outcomes with gains in quality of life of the patients. A multidisciplinary care is essential to achieve these goals.
Objectives: The aim of this study is to describe a model of integrated multidisciplinary approach for early diagnosis and management of PsA patients.
Methods: A retrospective study including patients that attended the multidisciplinary clinical from January 2019 to December 2020 was performed. Patients with suspected PsO or PsA for diagnosis confirmation/exclusion and patients with skin or articular manifestations in treated PsO or PsA patients for differential diagnosis were referred to this clinical. Sociodemographic and clinical data were collected. Descriptive, Student's t and Fisher test and Odds Ratio were estimated.
Results: A total of 50 patients were referred to multidisciplinary clinical. In 40 patients were confirmed the diagnosis of PsO. Twenty-two (55%) were male with a median age of 49.5 ± 11.5 years. Family history of psoriasis was present in 19 (47.5%) and 7 (17.5%) had spondyloarthritis family history. Obesity and overweight were the comorbidities most found, 42.9% and 37.1%, respectively, followed by hypertension 25%, dyslipidaemia and depression 22.5%. Thirteen patients (32.5%) presented moderate to severe PASI.

Thirty-one patients (77.5%) met criteria for PsA according CASPAR criteria. Prolonged cutaneous and articular disease (>10 years duration) was found in 74.2% and 61.3% patients, respectively. Peripheral disease without axial involvement was present in 90.3%. The most frequent extra-articular manifestation was dactylitis (23.3%) and enthesitis (19.4%). Severe or moderate articular disease activity was present in 48.3% of the patients.

Comparing diagnosed PsO and PsA patients there was a statistically significant difference at the mean age and the presence of depression (p= 0.047 and p=0.049, respectively); there was no statistically significant differences in family history of PsO (p=0.711) and spondyloarthritis (p=0.174), nutritional status (p=0.732) and comorbidities such as diabetes mellitus (p=0.545), hypertension (p=0.404), dyslipidaemia (p=0.394) and depression (p=0.089). In our multivariated logistic regression model we found female gender (p=0.016) and prolonged articular disease (>10 years durations) (p= 0.039) as risk factors for the development of severe psoriatic arthritis.
Conclusions: Despite the small number of patients observed in our multidisciplinary clinical, we found that this multidisciplinary care may identify disease in an early stage and offers a more comprehensive treatment approach to an heterogenous and unpredictable disease.
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P69 - Roflumilast cream, a once-daily, potent phosphodiesterase-4 inhibitor, in chronic plaque psoriasis patients: Efficacy and safety from DERMIS-1 and DERMIS-2 Phase 3 trials

10. Psoriasis and Psoriatic Arthritis relationship

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Introduction: Novel nonsteroidal topical therapies for psoriasis have not been approved in over 20 years. Recent data suggest roflumilast 0.3% cream, a potent phosphodiesterase-4 inhibitor, may represent a highly-effective, well-tolerated, nonsteroidal, once-daily treatment for long-term management of chronic plaque psoriasis, including the face and intertriginous areas.
Objectives: Two identical Phase 3, randomized, double-blind, vehicle-controlled, multi-center trials (DERMIS-1 [n=439; NCT04211363] and DERMIS-2 [n=442; NCT04211389]) were conducted in patients ≥2 years old with chronic plaque psoriasis involving 2–20% of body surface area.
Methods: Patients were randomized 2:1 to receive roflumilast cream 0.3% or vehicle once-daily for 8 weeks. The primary efficacy endpoint was Investigator Global Assessment (IGA) success at Week 8.
Results: Significantly more roflumilast-treated patients reached IGA success (DERMIS-1: 42.4%; DERMIS-2: 37.5%) than vehicle-treated patients (DERMIS-1: 6.1%; DERMIS-2: 6.9%, P<0.001 for both). In patients with intertriginous area involvement, significantly more roflumilast-treated patients reached intertriginous-IGA (I-IGA) success at week 8 than vehicle-treated (DERMIS-1: 71.2% vs. 13.8%, P<0.0001; DERMIS-2: 68.1% vs 18.5%, P=0.0004). A majority of these patients achieved I-IGA=0. Approximately 40% of patients achieved 75% reduction in Psoriasis Area Severity Index

(PASI 75) by week 8 (DERMIS-1: 41.6% vs. 7.6%; DERMIS-2: 39.0% vs 5.3%, P<0.0001). Patients with baseline Worst Itch-Numeric Rating Scale (WI-NRS) ≥4 achieved a 4-point reduction in WI-NRS at week 8 (DERMIS-1: 67.5% vs 26.8%; DERMIS-2: 69.4% vs 35.6%, P<0.0001). Itch improvement was notable by 2 weeks, the earliest timepoint measured (DERMIS-2: P=0.0026). Incidence of treatment-emergent adverse events (TEAE) were low and similar between roflumilast and vehicle groups. Pooled rates of TEAE leading to discontinuation (1.0% roflumilast vs 1.3% vehicle) and application site pain (1.0% roflumilast vs 0.3% vehicle) were low and comparable to vehicle.

Conclusions: Roflumilast cream 0.3% demonstrated favorable safety and tolerability while delivering statistically superior efficacy vs vehicle across multiple endpoints in patients with chronic plaque psoriasis.

P70 - Tapinarof Cream 1% Once Daily for Plaque Psoriasis: Interim Analysis of a Long-term Extension Trial of a Novel Therapeutic Aryl Hydrocarbon Receptor Modulating Agent

10. Psoriasis and Psoriatic Arthritis relationship

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Introduction: Tapinarof cream 1% once daily (QD) demonstrated significant efficacy versus vehicle and was well tolerated in adults with mild to severe plaque psoriasis in two identical, 12-week, pivotal phase 3 trials (PSOARING 1 and 2).[1] Furthermore, in a 12-week phase 2b trial, efficacy was maintained 4 weeks post treatment, warranting investigation of a potential remittive effect.[2]
Objectives: Interim analysis of a long-term, open-label, multicenter extension trial assessing safety, efficacy, durability of response, and duration of remittive effect of tapinarof cream 1% QD in adults with plaque psoriasis (PSOARING 3).[3]
Methods: Eligible patients completing the 12-week pivotal trials could enroll for 40 weeks of tapinarof treatment with 4 weeks' follow-up in PSOARING 3. Patients entering with Physician Global Assessment (PGA) score ≥1 received tapinarof until complete disease clearance (PGA=0). Patients entering with or achieving PGA=0 discontinued treatment and were monitored for duration of remittive effect (maintenance of PGA=0 or 1, off-therapy). Patients with disease worsening (PGA≥2) were re-treated with tapinarof until PGA=0. Patients were followed for durability of response on-therapy (absence of tachyphylaxis), adverse events (AEs), and local tolerability. Efficacy endpoints included median time from PGA=0 to first worsening, and proportion of patients with PGA=0 or 1 after treatment.
Results: All enrolled patients (N=763) were included in the analysis. Most common AEs were folliculitis, contact dermatitis, and upper respiratory tract infection, similar to the pivotal trials. Incidence/severity of folliculitis and contact dermatitis remained stable with long-term use and led to a low study discontinuation rate (1.2% and 1.4%, respectively). Investigators assessed ≥90% of patients as having no irritation and 86–93% of patients reported "none/slight" or "mild" burning/stinging and itching over 40 weeks of treatment. Complete disease clearance was achieved by 39.2% of patients (n=299). Patients entering with PGA=0 (n=78) had a median duration of remittive effect of 115 days (**Figure 1**). Response measures improved beyond the 12-week pivotal trials, with 57.3% of patients entering with PGA≥2 achieving a PGA=0 or 1 during the study. Durability of response (on-therapy absence of tachyphylaxis) was up to 52 weeks.
Conclusions: Tapinarof cream 1% QD was well tolerated with a consistent safety profile with long-term use. A high rate of complete disease clearance, ~4-month remittive effect off-therapy, lack of tachyphylaxis, and good tolerability – even in sensitive areas – are key attributes differentiating tapinarof from other topical psoriasis therapies.

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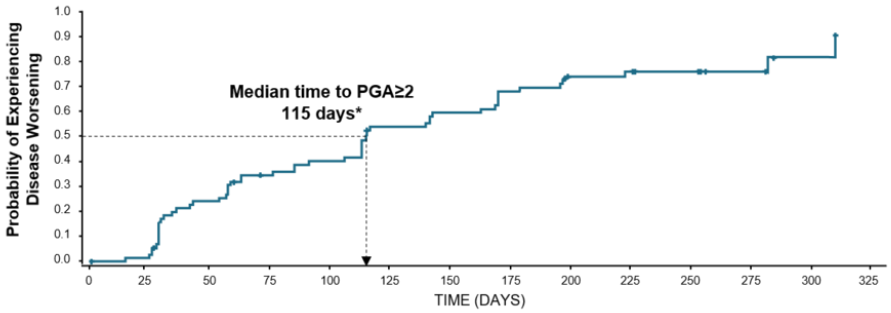
Figure 1. Approximately 4-Month Duration of Remittive Effect Among Patients Entering with a PGA of 0 (Clear) And Maintaining a PGA of 0 or 1 (Almost Clear) While Off Therapy



Number of Patients at Risk													
Overall	78	75	57	47	43	32	28	22	16	15	13	9	4	0
Tapinarof 1% QD (Pivotal)	73	70	53	44	40	29	25	19	13	12	10	6	3	0
Vehicle QD (Pivotal)	5	5	4	3	3	3	3	3	3	3	3	3	1	0

Intent to treat, observed cases. *Kaplan-Meier estimate

PGA, Physician Global Assessment; QD, once daily.

P71 - US Dermatologists Treatment of Recently Switched Biologic/Small Molecule Psoriatic Arthritis Patients and Co-Management Patterns

10. Psoriasis and Psoriatic Arthritis relationship

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Introduction: With a growing armamentarium of biologic/small molecule agents indicated for both psoriasis (PSO) and psoriatic arthritis (PsA), dermatologists are able to treat PsA patients more successfully than ever before.
Objectives: To better understand how US dermatologists are treating PsA patients with advanced systemic treatments and co-management patterns.
Methods: In February/March 2021, US dermatologists contributed chart review data for 510 biologic/small molecule PsA patients. Patients must have been switched from one biologic/small molecule brand to another brand in the past three months.
Results: US dermatologists report approximately 25% of their biologic/small molecule treated PsA patients were switched to a different brand in the past year, most notably to adalimumab (18%), ixekizumab (18%), and secukinumab (18%) followed by the newest market entrant, guselkumab (12%). Although not approved at the time of fielding, a few patients had been initiated on risankizumab due to positive experiences in PSO or patient requests. Patients were often switched from adalimumab (31%) or apremilast (29%) because of suboptimal efficacy in both skin and joints.

Most patients were switched to the current agent due to perceived skin efficacy (23%), prescribing habits (19%), and joint efficacy (17%). While skin efficacy was a major driver behind switches to both IL-23 and IL-17 inhibitors, IL-23 inhibitors were initiated more frequently for this reason, whereas IL-17 inhibitors were initiated more frequently due to joint efficacy.

Though to varying degrees, most dermatologists managed recently switched PsA patients with a rheumatologist. For half of the co-managed patients, the specialists decided together that switching the biologic/small molecule would be the best option. Of note, in 41% of co-managed patients, the dermatologist was the primary decision-maker. Of the 23% of switch patients not co-managed, few will be referred to a rheumatologist to assess joint involvement (14%). At approximately 9 weeks, a referral would be initiated if the patient required imaging, the dermatologist preferred to co-manage, the patient experienced worsening/uncontrolled joint symptoms, or the patient requested a referral.
Conclusions: Recently switched, dermatologist-treated PsA patients are more likely to be initiated on adalimumab, ixekizumab, and secukinumab. Once approved, risankizumab will likely be a top consideration for dermatologists due to positive experiences in PSO. The majority of PsA switch patients are co-managed with a rheumatologist, however, dermatologists often make the primary treatment decisions. Furthermore, few patients that are not currently co-managed are likely to be referred in the near future. Thus, dermatologists have increased confidence in their ability to treat PsA patients.

11. QUALITY OF LIFE OR PATIENT-RELATED OUTCOME MEASURES (PROMS)

P72 - Clinical research integrated with narrative-based research to understand living with facial and genital psoriasis: CNTO1959PSO4013 – the GULLIVER study.

11. Quality of Life or Patient-related Outcome Measures (PROMs)
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Introduction: Facial and genital psoriasis occur in about 17-46% [1] and 30–40% [2] of patients with psoriasis respectively. Besides many effective therapies for psoriasis, treatment of lesions on genitalia and face remains challenging. Facial and genital involvement of psoriasis contributes significantly to the burden of disease and has a considerable negative impact on quality of life (QoL) and personal relationships of patients. Narrative Medicine, the collection and analysis of written patients' experiences [3], is helpful to understand the patients' living with a particular condition, and its integration in clinical trials has been fostered by the European section of the WHO [4].
Objectives: The aim of the GULLIVER study is to describe the impact of guselkumab in the treatment of psoriasis patients with a significant involvement of genitals and/or facial area and the improvement of patients' QoL evaluated trough standard questionnaires and narrative plots.
Methods: GULLIVER is a prospective, non-interventional study on psoriasis patients with a significant involvement of genitals or facial area, who are receiving guselkumab for evaluating effectiveness, impact on QoL, safety and treatment satisfaction in a real-world clinical practice setting. The study started in July 2020 and will include 200 patients with genital psoriasis and 200 patients with facial psoriasis. Patients will be observed for 52 weeks. Within the study, patient reported outcomes (PRO) will be collected (DLQI, SF-36, pain/itch/discomfort VAS score and TSQM-9). Besides these questionnaires, narrative plots will be collected for the first time in a clinical study on psoriasis at enrollment and at last visit. Researchers will analyze the narratives according to content analysis methodology with the support of the NVivo 10 software.

Results: Due to COVID-19 emergency, there was a delay in patient enrollment. Up to date, 34 patients were enrolled in the study and almost 50% of them agreed to participate to the narrative research part of the study. We expect to receive 30 narratives by the end of April, in order to conduct an interim analysis by the end of May.

Conclusions: For the first time, a clinical study included patients' narratives as PROs to understand the impact of facial and genital psoriasis on patients' lives. The complete analysis will be able to evaluate not only the efficacy of the drug regimen in daily life but if and how patients' experiences influence clinical outcomes.

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P73 - Development and Validation of Optimal Psoriasis Assessment Tools (OPAT) Among Patients in the Corrona Psoriasis Registry

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

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Introduction: The Psoriasis Area and Severity Index (PASI) is time-consuming in a clinical setting and may not be sensitive to change in patient quality of life.
Objectives: We aimed to develop optimal psoriasis assessment tools (OPAT) to predict PASI and Dermatology Life Quality Index (DLQI) at a dermatologist visit using body surface area (BSA) and patient-reported outcomes (PROs).
Methods: Data was used from 33,605 dermatology visits among plaque psoriasis patients enrolled in the Corrona Psoriasis Registry from 4/15/15-7/11/20. Observations were randomly partitioned into development (60%) and testing (40%) datasets. Twelve linear regression models were specified *a priori* based on combinations of the following predictors: BSA, itch, skin pain, patient global assessment (PGA), age, sex, Body Mass Index (BMI), modified Charlson Comorbidity Index (mCCI), and prior biologic therapy use. Three additional models were constructed, two using stepwise selection procedures, and one using elastic net to select from 56 available variables. Models were run in the development dataset to calculate predicted PASI and DLQI, separately, and performance was compared in the test dataset using an adjusted coefficient of determination (R^2_{adj}) and root mean square error (RMSE).
Results: In the training dataset, mean (SD) age, BSA, and PASI were 51 (14) years, 6 (11), and 4 (6), respectively; 46% were women and 87% were biologic-experienced. In PASI models, BSA+1 PRO (itch, skin pain, or PGA) showed a moderate predictive performance (all R^2_{adj} =0.65-0.66, RMSE range 3.34-3.36). Excluding a univariable BSA model (Model 1), all other *a priori* specified models performed similarly (R^2_{adj} range 0.65-0.66, RMSE range 3.29-3.36). Models using selection methods performed better (R^2_{adj} range 0.728-0.729, RMSE range 2.94-2.95), but included ≥35 variables (Table 1). Models predicting DLQI showed a low performance (R^2_{adj} range 0.176-0.490, RMSE range 3.83-4.89).
Conclusions: Our findings suggest that an OPAT including BSA and one other PRO (i.e., itch, skin pain, or PGA) may produce a moderate ability to predict PASI among real-world patients with psoriasis. Models were, however, limited in their ability to predict DLQI. Simple models using two assessments are practical for use in clinical practice and, in our study, displayed only marginally lower predictive power than models including additional variables. Additional analyses are planned to assess the performance of the OPAT in a cohort of real-world patients with a disease severity profile like that among participants in clinical trials. Validation of the OPAT in other real-world populations is needed before its use in clinical practice for assessing PASI.

Table 1. Comparison of PASI prediction models on the testing set

Model	Predictors	PASI			DLQI		
		Adjusted R^2	RMSE	MAE	Adjusted R^2	RMSE	MAE
1	BSA	0.633	3.45	1.97	0.176	4.89	3.60
2	BSA + Itch	0.655	3.34	1.85	0.402	4.17	2.84
3	BSA + Itch + BSA * Itch	0.655	3.34	1.85	0.403	4.17	2.83
4	BSA + Itch + Age + sex + mCCI + BMI + Prior Biologic experience	0.657	3.32	1.83	0.410	4.14	2.81
5	BSA + Skin Pain	0.652	3.36	1.88	0.398	4.18	2.91
6	BSA + Skin Pain + BSA * Skin Pain	0.652	3.36	1.88	0.401	4.17	2.89
7	BSA + Skin Pain + Age + sex + mCCI + BMI + Prior Biologic experience	0.655	3.33	1.86	0.409	4.15	2.87
8	BSA + PGA	0.651	3.36	1.87	0.372	4.27	2.89
9	BSA + PGA + BSA*PGA	0.650	3.36	1.86	0.372	4.27	2.89
10	BSA + PGA + Age + sex + mCCI + BMI + Prior Biologic experience	0.653	3.34	1.85	0.382	4.24	2.85
11	BSA + Itch + Skin Pain + PGA	0.659	3.32	1.83	0.467	3.94	2.60
12	BSA + Itch + Skin Pain + PGA +Age + sex + mCCI + BMI + Prior Biologic experience	0.662	3.29	1.82	0.472	3.92	2.58
13	Variables* selected from stepwise forward selection	0.729	2.94	1.56	0.490	3.83	2.51
14	Variables* selected from stepwise backward elimination	0.729	2.94	1.56	0.490	3.83	2.52
15	Variables* selected from elastic net	0.728	2.95	1.56	0.488	3.84	2.52

PASI, Psoriasis Area Severity Index; BSA, Body Surface Area; BMI, Body Mass Index, RMSE, root mean square error; MAE, mean absolute error; mCCI, modified Charlson Comorbidity Index; PGA, Patient Global Assessment

P74 - Development of the Patient-Reported Impact of Dermatological Disease (PRIDD) measure

11. Quality of Life or Patient-related Outcome Measures (PROMs)
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Introduction: Global Research on the Impact of Dermatological Diseases (GRIDD) is the first systematic, international patient-initiated and patient-led multi-year study of the impact of living with dermatological conditions. Existing measures markedly underestimate the burden of dermatological conditions leading to under-investment in research and services for people with skin conditions.
Objectives: To develop a new Patient-Reported measure assessing the Impact of Dermatological Diseases (PRIDD).
Methods: GRIDD was designed with the novel methodology:
Phase 1 – Systematic Review of existing dermatology-specific patient-reported measures.
Phase 2 - Concept elicitation study: Interviews and focus groups were conducted with patients from all continents.
Phase 3 - Delphi surveys of patients determined whether the concepts identified in phase 2 are valid and endorsed by a wider group.
Phases 4/5 – Cognitive interviews to confirm understanding and psychometric analysis of the properties of the final instrument. The new PRIDD measure will be launched and the data disseminated.
Results: Our SR (Phase 1) revealed no specific measure of patient ***impact*** in dermatology exists. Examination of 36 existing patient-reported measures identified poor psychometric properties and / or measures were developed without adequate patient involvement. None could be recommended for use based on gold-standard COSMIN criteria. The concept elicitation study (Phase 2) included 63 people (68% female, across 29 dermatological conditions). Key and sub-themes emerged from the qualitative analysis. Findings provide a multifaceted concept of physical, psychological, social, and financial functioning as well as burdensome daily responsibilities and challenging healthcare issues forming the basis of PRIDD. The validity of the concepts from phase 2 were tested with the Delphi study (Phase 3) of 263 items. Round 1 included 1154 participants from 66 countries representing 90 dermatological conditions (majority of participants being psoriasis patients). Through quantitative statistics and qualitative feedback, the number of items was amended and deleted based on the consensus criteria. Currently, round 2 of Delphi is prepared.
Conclusions: Content validity is considered the most important measurement property in patient-reported outcome measures and is therefore fundamental to the development of a scientifically robust instrument. As most existing measures did not meet this criteria, this justified the need to develop a new measure with substantial patient engagement at each phase. Phase 2 study met the gold-standard COSMIN criteria for concept elicitation studies. The high levels of patient input throughout support the validity of the measure. Currently, phase 3 is testing further validity with a with a wider group of patients to determine if the concepts previously identified are recognised and endorsed and achieve patient consensus on the most important items to include in PRIDD.

P75 - Impact of psoriasis skin severity on health-related quality of life in patients with psoriatic arthritis

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

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Introduction: PsA is a chronic inflammatory arthritis with heterogeneous clinical manifestations. Health-related quality of life (HRQoL) is significantly affected by skin aspects of the disease.
Objectives: To assess the impact of psoriasis (PsO) skin severiry on HRQoL in PsA pts.
Methods: 187 (M/F=97 (50.2%)/90(48.8%) PsA pts fulfilling the CASPAR criteria were included. All pts underwent standard clinical examinations and PROs – PsAID-12, EQ-5D and WPAI. Analysis were performed in 2 groups: Body Surface Area (BSA) > 3% (40,5%) and BSA ≤ 3% (59.5%). Higher PsAID12 scores are considered to be worse and correspond to poorer PsA-specific health-related quality of life. M±SD, Me [Q25; Q75], %, t-test, Manna-Whitney tests were performed. All $p<0.05$ were considered to indicate statistical significance.
Results: Pts with BSA>3% had significantly worse HRQoL by PsAID-12, EQ-5D and WPAI compare to those with BSA≤ 3%: PsAID-12 total score – 4.46± 2.34 vs. 2.59±2.50 ($p<0.001$); EQ-5D – 0.56±0.2 vs. 0.73±0.17 ($p<0.01$); absenteeism 0.30±0.14 vs. 0.19±0.04 ($p<0.001$); presenteeism 0.26±0.24 vs 0.21± 0.14 ($p<0.001$); overall work productivity impairment 0.35±0.34 vs. 0.26± 0.17 ($p<0.001$) and daily activity impairment 0.51±0.26 vs. 0.29±0.26 ($p<0.001$), accordingly. In additional analyses of PsAID-12 domains was found significantly: pain, fatigue, work and/or leisure activity, functional capacity and discomfort.
Conclusions: In PsA real-world cohort half of pts had moderate and severe PsO wich affected HRQoL.

P76 - Quality of care and barriers to care for psoriasis in Europe - results of the PsoBarrier EU study

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

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Introduction: After a nationwide care study in 2007 found that a significant proportion of patients were not being treated according to the national guideline, the quality of care for psoriasis in Germany has continued to improve until today. Nevertheless, there are still deficits in psoriasis care, which have also been identified in other countries.
Objectives: This study aims to analyze psoriasis care in four European countries.
Methods: Standardized psoriasis care questionnaires were applied in dermatological centres in Denmark, Germany, Poland, and Spain. Clinical parameters such as severity (PASI, GCA), psoriatic arthritis, comorbidities, and current therapy were collected per patient. In addition, patient-reported characteristics such as quality of life (DLQI), mental well-being (HADS), health state (EQ-VAS), the influence of psoriasis on career choices, and satisfaction with care were recorded. A patient pathway was used to map the course of care - from the appearance of the first skin changes to the current therapy. Furthermore, the current care was analyzed with regard to time per appointment, waiting times, cooperation between different doctors, and the reimbursement of personal expenses by the health insurance companies.
Results: A total of 1,304 patients were enrolled in the study, 497 in Germany (41% female, mean age 50 years), 511 in Poland (34% female, mean age 46 years), 135 in Spain (38% female, mean age 51 years) and 161 in Denmark (31% female, mean age 48 years). The mean PASI (scale from 0-72) was 10.6 in Poland, 6.9 in Germany, 4.1 in Denmark, and 3.8 in Spain. The mean DLQI (scale from 0-30) was 4.3 in the Danish, 6.2 in the German, 6.3 in the Spanish and 11.5 in the Polish patients. That psoriasis had a strong influence on career decisions was reported by 24.5% of Spanish patients, 18.4% of Polish, 8.1% of German and 4.6% of Danish patients. Satisfaction with treatment was reported by 65.1% of Polish patients, 68.5% of German patients, 86.7% of Danish patients, and 90.9% of Spanish patients.

Conclusions: The systematic collection of comparable primary data from four European countries with different health care systems provides evidence for differences in care between these countries. Especially, the standardized comprehensive patient-reported characteristics are a novelty. Overall, the data suggest that despite high satisfaction with healthcare, Polish participants are more affected by psoriasis and its consequences than patients in other countries. However, although Spanish patients have a lower clinical severity, a significant proportion of patients report an impact on professional decisions, indicating a high burden in this area. Differences in the health care system, leading to various restrictions in access to certain treatment options, could be one of the reasons why patients are affected differently by psoriasis depending on the country.

P77 - Secukinumab 300 mg in 2 mL autoinjector for treatment of plaque psoriasis: Quality of life, usability, satisfaction, safety and tolerability results from the randomised, double-blind MATURE study

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

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Introduction: The MATURE study was conducted to evaluate the use of the secukinumab 300 mg autoinjector (AI) for subcutaneous delivery of secukinumab in patients with moderate to severe plaque psoriasis.
Objectives: Here, we report efficacy, quality of life outcomes, subject usability, satisfaction, safety and tolerability outcomes up to Week 12.
Methods: MATURE was a 52-week, multicentre, randomised, double-blind, placebo-controlled phase III trial. It consisted of 3 periods: screening (screening to baseline), treatment period 1 (baseline to Week 12; pre-dose), and treatment period 2 (Week 12 dose to Week 52). Eligible patients were randomised to receive secukinumab 300 mg or placebo in a 2 mL AI or 2x 1 mL pre-filled syringe (PFS). The co-primary endpoints were Psoriasis Area and Severity Index (PASI) 75 and Investigator's Global Assessment 2011 modified version (IGA mod 2011) response rates at Week 12 vs placebo. Other endpoints included Dermatology Life Quality Index (DLQI) score of 0/1, 2 mL AI usability, Self-Injection Assessment Questionnaire (SIAQ) and safety.
Results: In total, 122 patients were randomised: secukinumab 300 mg 2 mL AI (N=41), secukinumab 300 mg 2x 1 mL PFS (N=41), or placebo (N=40). At Week 12, the study met both of its co-primary endpoints, and demonstrated that treatment with secukinumab 300 mg 2 mL AI and 2x 1 mL PFS led to superior PASI 75 response rates (95.1% and 83.2%, respectively), and clear or almost clear skin per IGA mod 2011 (75.6% and 68.1%, respectively) vs placebo (PASI 75, 10.0%; IGA mod 2011, 7.6%; $p<0.0001$). The proportion of patients achieving DLQI 0/1 at Week 12 was similar between the secukinumab 300 mg treatment groups (2 mL AI [71.1%] and 2x 1 mL PFS [72.5%]) compared to placebo (8.1%). Overall, 95.7% of patients successfully performed the 4 critical steps as per the Instructions for Use (IFU) at Week 1 and successfully self-administered study drug at Week 1. Approximately 87% of patients successfully completed all IFU-indicated 14 steps required to administer secukinumab via the 2 mL AI at baseline and Week 1. No critical hazards were observed with the AI at baseline or Week 1, such as accidental needle stick injuries in critical areas or immediate-type allergic reactions. In the secukinumab 300 mg 2 mL AI group, the proportion of 'very satisfied' and 'satisfied' patients increased from 31.6% (pre-SIAQ) to 78.3% (post-SIAQ) after the

first injection and continued to increase, reaching 92.1% at Week 12. The safety profile of secukinumab in this study showed no new or unexpected signals.
Conclusions: The secukinumab 300 mg 2 mL AI demonstrated a rapid onset of response with superior efficacy and improved quality of life outcomes. Self-administration via the 2 mL AI posed no safety hazards, and the ability to follow the IFU was very good. SIAQ results showed high satisfaction with usability of the AI device among study participants.

P78 - Secukinumab Effects on Patient Reported Outcomes in Plaque Psoriasis Across Europe: Data from the PROSE Study

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

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Introduction: Cross-cultural differences in healthcare policies and patient-physician communication may influence the quality of care and patients' perceived benefits and satisfaction with psoriasis treatment.
Objectives: To compare across European regions the burden of psoriasis (PASI: Psoriasis Area and Severity Index, and DLQI: Dermatology Life Quality Index) and patient needs (PNQ: Patient Needs Questionnaire) before secukinumab treatment, as well as patient benefits (PBI: Patient Benefit Index) and treatment satisfaction (TSQM-9: Treatment Satisfaction Questionnaire for Medication) after 1 year of secukinumab treatment. To identify sociodemographic, clinical and psychosocial predictors of clinical improvement (PASI 100 and DLQI 0/1) after 1 year of secukinumab treatment.
Methods: PROSE was an open-label, prospective, non-randomized, multicentre study of 52 weeks of secukinumab treatment in 16 European countries. In this analysis, the PROSE study population was stratified by four European regions defined by the United Nations geoscheme. Cross-cultural comparisons were performed with Kruskal-Wallis test (ordinal variables) and analyses of variance (continuous variables). Predictors of clinical improvement were identified through hierarchical logistic regression analyses.
Results: Participants were 1629 adult patients with moderate-severe plaque psoriasis (44.4±13.7 years of age; 33.5% female). At baseline, patients from Eastern Europe (EE) reported a significantly higher DLQI impairment vs Northern Europe (NE) and Western Europe (WE), but differences were non-significant in PASI (Table 1). There were considerable differences in patients' needs (PNQ) between geographical regions, with WE focused more on reducing physical impairment (vs Southern Europe [SE]/EE), EE on reducing social impairment (vs NE/WE), and SE on reducing impairment due to therapy (vs NE/WE). At Week 52, patients from EE reported more benefits (PBI) with secukinumab treatment (vs WE/SE), while patients from NE reported higher TSQM-9 scores (vs SE; Table 1).[1]

At Week 52 of secukinumab treatment, 72.2% of patients achieved a DLQI 0/1 response and 48.7% of patients achieved a PASI 100 response. The likelihood of DLQI 0/1 response was increased in patients with fewer DLQI impairments, plaque localisation to the trunk vs upper limb, and better general health (EQ-5D VAS) at baseline. An increased likelihood of PASI 100 response was associated with a lower % BSA, shorter disease duration, plaque localisation to the trunk vs upper limb, greater EQ-5D VAS score, and a greater need of 'Having confidence in healing' at baseline.
Conclusions: Differences in patients' needs and treatment satisfaction across Europe are likely a result of diverse medical systems (e.g. strong vs weak medical paternalism), socio-economic status and infrastructural access. A patient-centred approach to treating psoriasis may fulfil patient needs and maximise treatment satisfaction.
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Baseline	Northern Europe (n = 219)	Western Europe (n = 823)	Southern Europe (n = 329)	Eastern Europe (n = 258)	F-test	Pairwise comparisons
PASI	20.6±7.8	20.1±8.4	21.1±8.8	20.9±7.9	1.6	-
DLQI	13.3±6.7	13.6±6.9	14.6±7.6	15.4±7.1	5.5***	EE > NE; WE
Patient needs (PNQ)					K-W	Pairwise comparisons
Reducing physical impairments	3.6±0.6	3.7±0.5	3.6±0.5	3.6±0.6	15.7**	WE > SE; EE
Reducing psychological impairments	3.4±0.7	3.5±0.7	3.5±0.7	3.6±0.6	3.6	-
Reducing social impairments	3.2±0.9	3.3±0.9	3.3±0.9	3.5±0.6	9.9*	EE > NE; WE
Reducing impairments due to therapy	3.3±0.8	3.3±0.8	3.5±0.7	3.5±0.7	20.6***	SE > NE; WE
Having confidence in healing	3.7±0.6	3.7±0.5	3.7±0.6	3.7±0.5	1.2	-

Week 52 of secukinumab treatment					F-test	Pairwise comparisons
PASI	1.3±2.7	2.1±4.7	1.4±3.2	1.2±2.0	6.0***	WE > all regions
DLQI	1.4±2.9	2.1±4.1	2.1±4.7	2.0±4.0	2.0	-
PBI	3.5±0.7	3.4±0.9	3.4±0.8	3.6±0.6	5.3**	EE > WE, SE
TSQM-9						
Effectiveness	86.6±18.7	82.2±24.5	78.8±25.2	81.6±20.7	4.8**	NE > SE
Convenience	84.7±14.8	83.1±16.6	80.0±15.4	82.3±12.3	4.7**	NE, WE > SE
Global satisfaction	84.8±16.8	81.2±21.8	79.3±18.9	81.4±16.2	3.3*	NE > SE

Univariate analysis of variance (ANOVA), with post-hoc pairwise comparisons and Kruskal-Wallis test. Data presented are mean ± SD. TSQM-9 is scored 0 (min. satisfaction) to 100 (max. satisfaction). PBI is scored from 0 (no benefit) to 4 (maximal benefit). *p<0.05; **p≤0.01; ***p≤0.001.
DLQI, Dermatology Life Quality Index; EE, Eastern Europe; NE, Northern Europe; PBI, patient benefit index; PASI, Psoriasis Area and Severity Index; PNQ, Patient Needs Questionnaire; SE, Southern Europe; TSQM-9, Treatment Satisfaction Questionnaire for Medication; WE, Western Europe.

P79 - Shared Decision Making in the Treatment of Psoriasis - Results of the "PsoBarrier EU" Study in Four European Countries

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

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Introduction: The aim of the "PsoBarrier EU" study is to identify barriers to guideline-based psoriasis care in four European countries. One objective is the extent of shared decision making in the treatment of psoriasis. According to a study by Coulter et al. (2005), Polish patients showed the lowest participation in treatment decisions in a European comparison.
Objectives: One research objective is the patient involvement in treatment decisions..
Methods: Barriers and quality of care were investigated in a multicentre cross-sectional study from a patient perspective. The present data analysis refers to data from 29 dermatology centres from Germany, 9 centres from Poland, 5 centres from Denmark and 6 centres from Spain.
Results: A total of 511 patients from Poland, 497 from Germany, 161 from Denmark and 135 from Spain were interviewed. 58.6% of the Polish, 76.2% of the German, 67% of the Danish and 70.7% of the Spanish patients were quite or very sure that their needs regarding the type of application were taken into account in the medical treatment decision. In addition, 53% of Polish, 71.4% of German, 70% of Danish and 75.9% of Spanish patients reported that their wishes regarding the avoidance of certain side effects were taken into account. Regarding the source of information about treatment options, 59.3% of Polish, 37.6% of German, 31.4% of Danish and 15.5% of Spanish patients reported that they obtained their knowledge from the internet, among other sources. 3.8% of the Polish, 10% of the German, 11.4% of the Danish and 7.5% of the Spanish patients had already participated in psoriasis educational trainings.
Conclusions: In comparison, patients from Poland are less likely to have the impression that their needs are taken into account in the treatment decision, also with regard to the avoidance of side effects. Differences between health care systems that limit access to certain treatment options could be reasons for this. Differences could also exist in the traditional role models of doctors in individual countries. The higher number of patients from Poland who search for information about treatment options on the internet could show their need to find alternatives that better meet their treatment goals. In all four countries, there seems to be potential for improvement from the patients' point of view when it comes to including their needs in the treatment decision.

The study received financial support from Sandoz Biopharmaceuticals (unrestricted grant).
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P80 - Smoking Status, Severity of Psoriasis, and Associated Issues in Daily Life

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

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Introduction: Prior research has established that smoking is a risk factor for psoriasis development, but may reduce the risk of complications like psoriatic arthritis in persons with psoriasis [1][2]. However, the impact of smoking status on psoriasis severity, as opposed to psoriasis development, has not been extensively studied in this population.
Objectives: This study aimed to explore the association between smoking status and severity of psoriasis. This study further analyzed the association between smoking status and the disease's perceived impact on everyday life.
Methods: The study population included 482 non-institutionalized civilians aged ≥18 years in the National Health and Nutrition Examination Survey (NHANES) 2003–2006 and 2011–2014. Survey participants reported their current degree of psoriasis on a 1–4 scale with '1' indicating little or no psoriasis and '4' indicating extensive psoriasis. NHANES 2003–2006 participants also reported how much of a problem psoriasis has been in everyday life on a 1–10 scale with '1' indicating no problem at all and '10' indicating a very large problem. Smoking status was determined using both self-reported information and serum cotinine values. Multivariable ordinal logistic regression was used to test the predictive effects of smoking status on severity of psoriasis and "problem" score. Analyzed covariates were age, gender, and race/ethnicity
Results: The mean reported degree of psoriasis was 1.80 among current smokers (95% CI: 1.58, 2.01) and 1.64 among non-smokers (95% CI: 1.51, 1.76). The mean reported "problem" score was 4.43 among current smokers (95% CI: 3.41, 5.46) and 3.67 among non-smokers (95% CI: 3.01, 4.34). In multivariable ordinal logistic regression analyses accounting for age, race, and gender, smoking was neither associated with degree of psoriasis ($p = 0.19$) nor "problem score" ($p = 0.37$). Smoking cessation within the past two years was similarly not associated with degree of psoriasis ($p = 0.59$).
Conclusions: Smoking is a known risk factor for the incidence of psoriasis, but this study showed that degree of psoriasis and associated issues in daily life do not significantly correlate with smoking status or cessation. Nonetheless, clinicians should encourage smoking cessation in these patients due to smoking's other damaging effects.
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P81 - UNDERSTANDING UNMET NEEDS FOR PSORIASIS PATIENTS

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

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Introduction: Psoriasis is a prevalent, chronic, systemic inflammatory disease that commonly affects the skin.[1] Psoriasis can greatly impact quality of life, impairing social functioning and potentially causing social stigmatization.[1, 2, 3] While the introduction of targeted immunomodulatory therapies has improved treatment outcomes for psoriasis, treatment gaps may still exist.[4]
Objectives: The aim of this investigation was to survey patients with psoriasis to identify their unmet treatment needs.
Methods: Participants aged 18 years or older, with an Amazon Mechanical Turk (online survey platform) account, who reported diagnosis of psoriasis and correctly answered an attention check question at the end of the survey were included. Results were analyzed using descriptive and inferential statistics, as appropriate.
Results: Of 1,345 respondents, 417 reported diagnosis of psoriasis and passed the attention check question. Of these respondents, 48.2% were male; 59.5% had a bachelor's degree; 19.9% made between $50,000 and $74,999 per year; 50.4% had private insurance, and 39.3% were between 31-40 years of age. In terms of disease severity, 61.2% claimed to have mild psoriasis, 25.4% moderate, and 13.4% severe. Only 74.8% of respondents reported currently receiving any form of psoriasis treatment. In terms of satisfaction, 51.6% of respondents were mostly or completely satisfied with treatment, while 24.5% were not at all or slightly satisfied. When asked with what treatment(s) they were most satisfied, respondents most often reported topical (59.5%), followed by oral (46.0%) and injectable treatments (19.9%). Additionally, 78.7% of respondents slightly or strongly agreed that there should be more cost-effective options. Most respondents suggested more affordable topical and oral treatments that work faster and do not require as frequent of use would fill the gap in terms of what is missing among available treatment options.
Conclusions: Based on our survey study, we believe there is space for improved topical and oral medications that work quickly, are more cost-effective, and better manage psoriasis symptoms.

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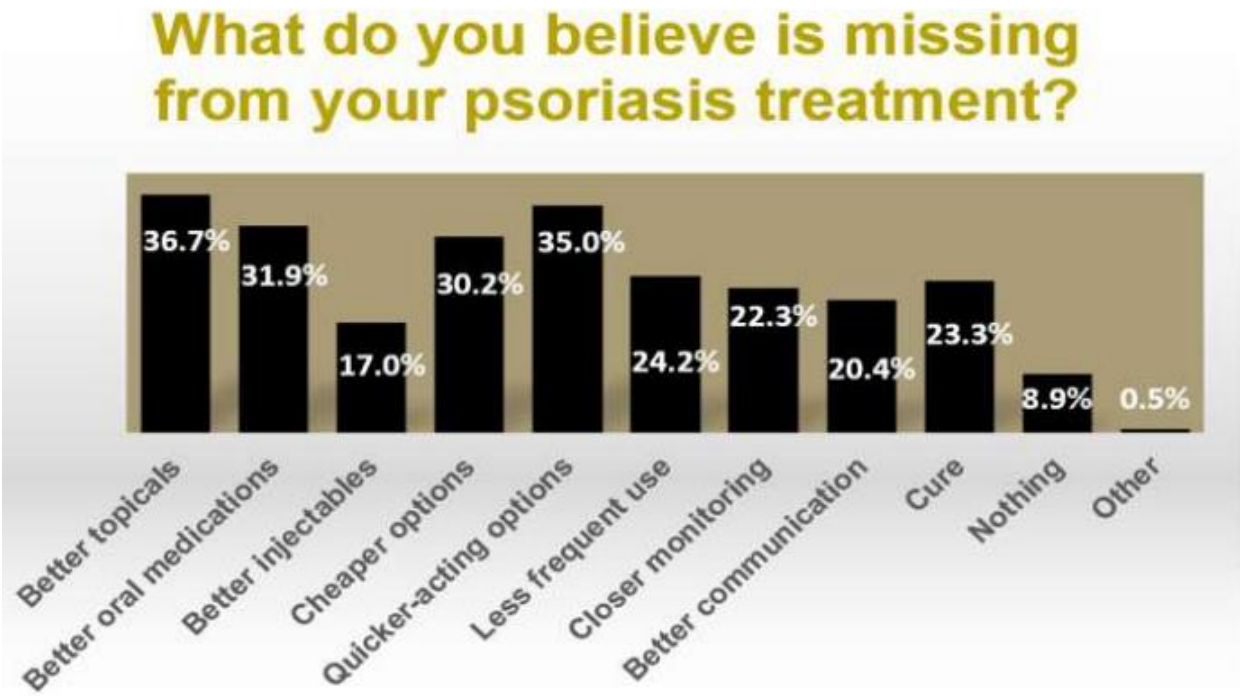
What do you believe is missing from your psoriasis treatment?
36.7%
31.9%
17.0%
30.2%
35.0%
24.2%
22.3%
20.4%
23.3%
8.9%
0.5%
Better topicals
Better oral medications
Better injectables
Cheaper options
Quicker-acting options
Less frequent use
Closer monitoring
Better communication
Cure
Nothing
Other

12. PATIENT ORGANIZATION PROJECTS/PATIENT RESEARCH PARTNERS

P82 - Correlation between patients´ needs and their access to Psoriasis Specialists

12. Patient organization projects/Patient research partners
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Introduction: Psoriasis is a chronic, noncommunicable, painful, disfiguring and disabling disease for which there is no cure and with great negative impact on patients' quality of life (QoL). Access to a specialist in psoriasis can sometimes prove to be quite a challenge. In 2015, AEPSO published a survey conducted with 400 psoriasis patients in Argentina that showed that 38% percent of patients with psoriasis were diagnose one year later of presenting symptoms and this extends to 6 month to 10 years in psoriatic arthritis. Also, patients needed to consult more than 5 dermatologists in order to reach a psoriasis diagnose. It also showed that patients with psoriasis tend to change dermatologist frequently because of the lack of response to the treatment for this chronic disease.
Objectives: To correlate patients', need of a specialist and their access to a health professional to treat psoriasis.
Methods: We use our data base of dermatologists and rheumatologists that treat psoriasis stating their name, specialty, phone number, office or clinic and position them on Google Maps for online consultation. Patients can enter the system and locate the area of the consultation and find an available dermatologist.
Results: We have more than 500 specialists (dermatologist and rheumatologists) in the database. There were 30000 searches for a specialist since 2016. There are more dermatologists than rheumatologists. At least 7 cities have no rheumatologist and one city has no dermatologist. We also found at least 7 cities with less than 2 dermatologists. In these areas with few or no health professionals, there were 100 patient consultations. Access to a health professional is therefore poor. See table 1 for more cities.
Conclusions: There is a disparity in consultations and the areas where psoriasis specialty is lacking. There is a need for dermatologists and rheumatologists in some cities of Argentina. This information can be useful to implement a psoriasis detection campaign to find available dermatologists and train them in treating psoriasis in order to improve patients' access to psoriasis specialists.
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Areas where psoriasis specialty is lacking (poor coverage)					
				Specialist Available	
City	State	Population	Searches	Dermatologists	Rheumatologists
Merlo	Buenos Aires	528000	136	0	0
Florencio varela	Buenos Aires	132000	100	1	0
Berazategui	buenos Aires	322000	84	1	0
Mar del plata	Buenos Aires	650000	188	3	1
Bahia Blanca	buenos Aires	300000	126	2	0
Santa Cruz	Santa cruz	322400	76	3	0
Resistencia	Chaco	350000	196	3	0
Tierra del fuego	Tierra del fuego	152300	42	6	0

Areas where psoriasis specialty has coverage					
				Specialist Available	
City	State	Population	Searches	Dermatologists	Rheumatologists
CABA	CABA	3100000	3778	56	11
Rosario	Santa fe	1000000	598	16	13
Santa fe	Santa fe	510000	244	10	1
Neuquen	Neuquen	202000	354	6	3
San migual de tucuman	Tucuman	606000	322	19	5

P83 - Psoriasis and Beyond: Interim results of the Global Psoriatic Disease survey capturing patient perspective

12. Patient organization projects/Patient research partners
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Introduction: Although scientific research in psoriasis (PsO) and psoriatic arthritis (PsA) has grown significantly, patient perspective remains insufficiently explored. Psoriasis is a systemic multifaceted disease[1], but the complexity of PsO and PsA and related manifestations are not yet widely understood, and it is unclear to what extent patients are aware about psoriatic disease and its comorbidities.
Objectives: The joint research initiative between the International Federation of Psoriasis Associations (IFPAs), dermatology experts and Novartis evaluates patients' understanding of psoriatic disease, associated comorbidities, and the humanistic and physical burden of living with the condition.
Methods: A cross-sectional, quantitative online survey, was conducted in patients with moderate to severe plaque PsO with or without concomitant PsA. The questionnaire was a combination of validated tools such as the Dermatology Life Quality Index and Work Productivity and Activity Impairment. The remainder of the questionnaire comprised non-validated questions used in previous 'Clear about Psoriasis'[2] survey to allow comparability, as well as newly defined questions (tailored to the objectives of this new survey). As of January 2021, 1678 responses were analyzed across 11 countries from Europe, North/South America and Asia. Final results are expected in the second half of 2021.
Results: Interim survey results demonstrated that 73% and 63% of all patients heard of "systemic disease" and "psoriatic disease" respectively, a high proportion of PsO patients remained unaware of PsA (71%) and all patients of axial symptoms (82%). High proportion of all patients also remained unaware of associated comorbidities like obesity (79%), high cholesterol (83%), cardiovascular diseases (82%), diabetes (83%) and axial disease (86%). Further, 30% of PsO patients have PsA, 70% of PsA patients experience swollen and tender joints, especially in finger(s) and/or toe(s).

84% patients experienced social stigma and discrimination in public. Mostly they were asked if it was contagious (36%), stared at in public (32%). 82% patients felt that their disease impacted past or current relationships (**Figure 1**).
Conclusions: The findings indicate that, while high percentage of moderate to severe plaque PsO patients with/without concomitant PsA heard about the terms systemic disease and psoriatic disease, they remain unaware of the systemic nature of the disease and the increased risk of associated

comorbidities. Additionally, psoriatic disease has a profound negative impact on patients' quality of life, including psychosocial wellbeing. The interim results underscore the need to recognize the systemic nature of psoriatic disease and its various manifestations and comorbidities. There remains a need for an awareness of human and physical aspects of all manifestations of psoriatic disease to ensure optimal management of patients.

References:

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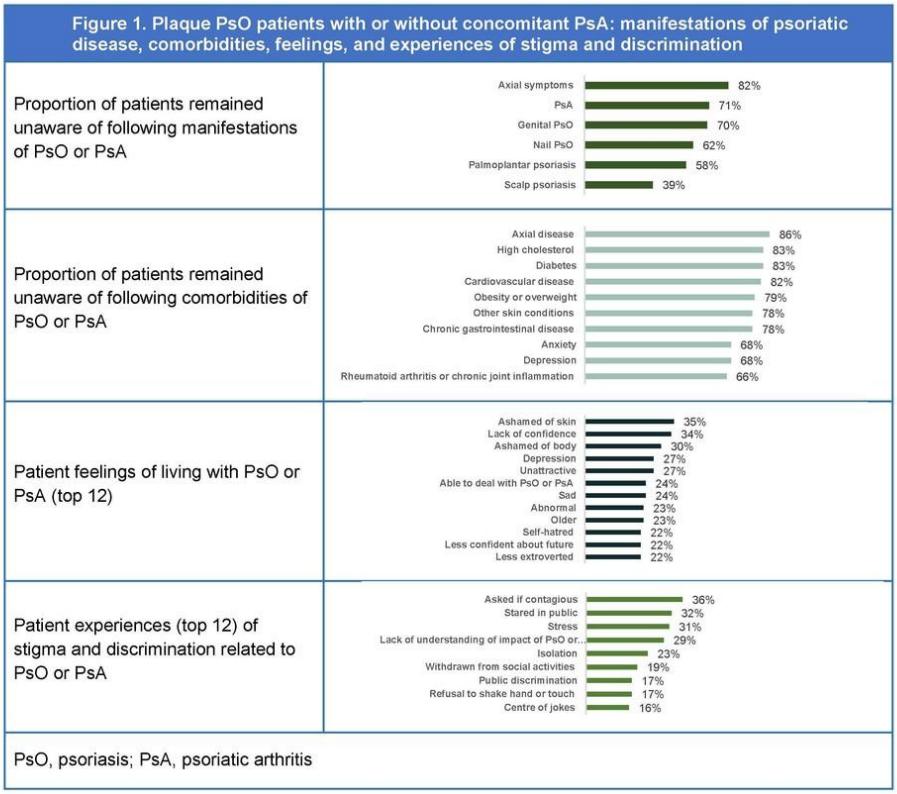
Figure 1. Plaque PsO patients with or without concomitant PsA: manifestations of psoriatic disease, comorbidities, feelings, and experiences of stigma and discrimination



PsO, psoriasis; PsA, psoriatic arthritis

13. SARS-COV-2/COVID-19

P84 - Association of anxiety and depression with worsening psoriasis in the COVID-19 pandemic: findings from a global cross-sectional study

13. SARS-CoV-2/Covid-19

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Introduction: Indirect excess morbidity is an increasing concern in the COVID-19 pandemic. People with psoriasis may be particularly vulnerable to this because of prevalent anxiety and depression, multimorbidity and therapeutic use of immunosuppression.
Objectives: We sought to characterise the factors associated with worsening psoriasis in the COVID-19 pandemic, using mental health status (anxiety and depression) as the main exposure of interest.
Methods: We conducted a global cross-sectional study. Individuals with psoriasis completed an online self-report questionnaire (PsoProtect*Me;* Psoriasis Patient Registry for Outcomes, Therapy and Epidemiology of COVID-19 Infection *Me*) between May 2020 and January 2021. The primary outcome was self-reported worsening of psoriasis. Participants completed a validated screen for anxiety (Generalized Anxiety Disorder-2) and depression (Patient Health Questionnaire-2). Odds ratios (OR) and 95% confidence intervals (CI) were estimated using multivariable logistic regression.
Results: 4,043 people with psoriasis (without COVID-19) from 86 countries completed PsoProtect*Me* (mean age 47.2 years [SD 15.1]; mean BMI 27.6kg/m^2 [SD 6.0], 2,684 [66.4%] female and 3,016 [74.6%] of white European ethnicity). 1,728 (42.7%) participants (1322 [77%] female) reported worsening of their psoriasis in the pandemic. A positive screen for anxiety or depression associated with worsening psoriasis in age and gender adjusted (OR 2.04, 95% CI 1.77-2.36), and fully adjusted (OR 2.01, 95% CI 1.72-2.34) logistic regression models. Female sex, obesity, shielding behaviour and systemic immunosuppressant non-adherence also associated with worsening psoriasis. The commonest reason for non-adherence was concern regarding complications related to COVID-19.
Conclusions: These data indicate an association between poor mental health and worsening psoriasis in the pandemic. Access to holistic care including psychological support may mitigate potentially

long-lasting effects of the pandemic on health outcomes in psoriasis. We also highlight an urgent need to address patient concerns about immunosuppressant-related risks, which may be contributing to non-adherence.

P85 - COVID-19 and psoriatic arthritis: clinical course and outcomes

13. SARS-CoV-2/Covid-19

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Introduction: Patients with psoriatic arthritis (PsA) are at an increased risk of respiratory tract infections due to the impact of the disease on their immune system and the long-term use of immunosuppressive drugs. Regarding COVID-19 there are still many questions that remain unanswered. Are patients with PsA at a higher risk of COVID-19 and a more severe clinical course of the infection? How does COVID-19 affect the course of psoriatic arthritis?
Objectives: To assess the clinical course of COVID-19 in patients with PsA and the infections' impact on psoriatic arthritis.
Methods: We've developed a google form questionnaire named PSARS *(P - Psoriatic arthritis, SARS - Severe Acute Respiratory Syndrome)* to assess the course of COVID-19 in patients with PsA. The google form consisted of 3 parts and 25 questions. First part was dedicated to the general information on the patient, including comorbidities. Second one was for patients with PsA, who had been diagnosed with COVID-19, and included questions about the symptoms, severity of the clinical course and used medications. Third part allowed us to assess the impacts of COVID-19 on psoriatic arthritis. Our questionnaire was completed by 107 patients with PsA.
Results: We've found that 22% of PsA patients (n=24) had COVID-19. The mean age was 46,3±13,2, disease duration - 8,1 years. Comorbidities were noted in 79% patients who had COVID-19. In the group of patients who didn't have COVID-19 a more frequent use of biological disease-modifying anti-rheumatic drugs (bDMARD) for the treatment of PsA was noted, as well as a bigger percentage of smokers ($p<0,05$). Most common symptoms for patients with PsA were fatigue (83,3%), loss of taste and smell (62,5%), cough (62,5%), fever (54,2%) and headache (50%). On average patients had symptoms for 2 weeks. 66,7% of patients with COVID-19 and PsA had a mild course of the infection and were treated at home. 8 patients had a moderate course of COVID-19 and were hospitalized. No patients had a severe course of COVID-19 and needed to be admitted to an intensive care unit. Pneumonia was diagnosed in 12 patients: in 8 of them CT images showed a <25% lung involvement, in 3 patients - 25-50%. One patient had a 50-75% lung involvement and had to receive baricitnib. There were no cases of a more severe lung damage. 45,8% patients reported a worsening of PsA, which manifested as painful and swollen joints, an increased need in taking NSAIDs. 37,5% patients had a psoriasis flare up.
Conclusions: Most patients with PsA (66,7%) had a mild course of COVID-19 infection. There were no cases of a severe clinical course of COVID-19 in patients with PsA. Patients who reported a long-term use of bDMARDs were at a lower risk of COVID-19. Further research is needed to assess the protective role of these medications.

P86 - Impact of COVID-19 on US Dermatology and Rheumatology Practices

13. SARS-CoV-2/Covid-19

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Introduction: In 2019, the novel coronavirus (COVID-19) was discovered in China, and by March 2020, it had quickly spread throughout the rest of the world. This caused widespread social, economic, and medical impacts.
Objectives: To provide insight into the impact of the COVID-19 pandemic on US dermatology and rheumatology practices.
Methods: An independent market analytics firm collaborated with US specialists (n=270), including dermatologists (n=54) and rheumatologists (n=50) from February 12 to 15, 2021 in order to gain insights on the impact of COVID-19 on their practice. Data collected included physician demographics, greatest impacts, attitudinal responses, and projected lasting change. Data has been collected on a rolling basis weekly, biweekly, or monthly since March 20, 2020.
Results: As of early February 2021, the majority of US dermatology and rheumatology practices have fully re-opened, with most practices operating at 75-100% capacity. Overall impact on practices has significantly reduced, with 48% of dermatologists and 34% of rheumatologists reporting a high impact compared to 96% and 90% in March 2020. Approximately half of dermatologists report appointment no shows, number of patient visits, and financial health of their practice as having the greatest impact; 58% of rheumatologists identify office calls regarding COVID-19 as having the largest impact.

Regarding financial health, 4% of dermatologists report there is a possibility their practice will close, a significant decline from March 2020 (42%). Conversely, 19% of rheumatologists report possible practice closure, compared to 26%. In order to offset the financial impact, the two specialists seek different approaches. Half of dermatologists have applied for a small business loan, and over two-thirds have reduced office hours, while 20% of rheumatologists have applied for small business loan or are foregoing bonuses; more rheumatologists opt to furlough employees. For both, medical assistants and administrative staff are the positions hardest hit.

Compared to a pre-COVID week, office visits are down 25% for dermatologists and 35% for rheumatologists, an improvement for both specialists. In order to offset this decline, telemedicine has been widely used to varying extents. Within the past week, dermatologists had an average of 14 telemedicine visits, while rheumatologists conducted 25; the virtual appointments are largely used for follow-up patients. Despite both agreeing that telemedicine will continue after the current crisis has abated, dermatologists estimate they would continue 6% of patients per week, compared to 16% of patients for rheumatologists. Although this new modality of care has increased in popularity, both specialists are facing challenges with the technology, namely establishing relationships with new patients and poor video connection.
Conclusions: COVID-19 has substantially impacted US dermatology and rheumatology practices in terms of how patients are seen, number of office visits, staffing, and financial health.

P87 - Incidence and prognosis of COVID-19 in psoriasis patients on biologic therapy: a multicenter retrospective cohort study

13. SARS-CoV-2/Covid-19

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Introduction: Current guidelines recommend continuing biologic therapy in dermatologic patients who have not tested positive for or exhibited signs/symptoms of COVID-19 and postponing biologic therapy in patients who have tested positive for or exhibited signs/symptoms of COVID-19.
Objectives: In order to help guide current recommendations, we aimed to investigate the incidence and prognostic outcomes of positive SARS-CoV-2 infection in moderate-to-severe psoriasis patients on biologic therapy.
Methods: A multicenter retrospective cohort study was undertaken at two tertiary academic hospitals and four community practices. Inclusion criteria was all adult and pediatric patients treated with a biologic for moderate-to-severe psoriasis since COVID-19 was declared a global pandemic. Data was obtained from Patient Support Program Case Managers of all major biologic suppliers and patient-reported clinical documentation.
Results: As of January 15, 2021, there were 2647 patients on biologic therapy who met the inclusion criteria. In this cohort, 10 patients (0.4%) had confirmation of SARS-CoV-2 infection via nasal swab. Incidence of COVID-19 was highest in those treated with interleukin (IL)-12/23 inhibitors (3/443, 0.7%) and IL-17a inhibitors (5/667, 0.7%), compared to IL-23 inhibitors (2/799, 0.2%) and tumor necrosis factor-alpha (TNF-α) inhibitors (0/738, 0%). Biologic specific incidence included that of adalimumab (0/336), brodalumab (1/80), certolizumab (0/60), etanercept (0/288), guselkumab (1/530), infliximab (0/54), ixekizumab (3/267), risankizumab (1/269), secukinumab (1/320) and ustekinumab (3/443). Of those who tested positive, mean age was 42±15 years, with the majority being male (7/10, 70%), Caucasian (7/10, 70%) and on a biologic for over 12 months (7/10, 70%; mean: 34±35 months). Six patients (60%) had symptoms of COVID-19, compared to three patients (40%) who were asymptomatic carriers. Seven patients (70%) discontinued biologic therapy due to COVID-19. Six patients restarted treatment with a mean restart time of 19±10 days, while one patient elected to remain off treatment due to persistently well-controlled disease.
Conclusions: Patients with moderate-to-severe psoriasis on a biologic agent have a similar or perhaps even lower incidence of COVID-19 compared to the general public (1.8%, reported Canada wide rate as of January 15, 2021). This supports current evidence that psoriasis patients should not discontinue their biologic therapy out of risk or fear of contracting COVID-19.[1] Our results suggest that interruption of biologic therapy should be reserved for clinically unwell patients as symptoms for COVID-19-positive psoriasis patients on a biologic were mild and no patients required oxygenation or hospitalization.
References: 1. Georgakopoulos JR, Mufti A, Vender R, Yeung J. Treatment discontinuation and rate of disease transmission in psoriasis patients receiving biologic therapy during the COVID-19 pandemic: A Canadian multicenter retrospective study. *J Am Acad Dermatol*. 2020;83(4):1212-1214.

P88 - Likelihood of receiving a novel vaccine for COVID-19 among patients with psoriatic disease and implications for dermatological and rheumatological practice: results from a real-world survey of U.S. patients.

13. SARS-CoV-2/Covid-19

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Introduction: Development and dissemination of novel vaccines to prevent COVID-19 represent an opportunity to end the current pandemic – if vaccination rates are high enough to achieve widespread immunity. Willingness to receive novel COVID-19 vaccines when available complicate the goal of achieving this goal.
Objectives: This study examined likelihood of receiving a novel COVID-19 vaccine and demographic and clinical factors influencing likelihood of receiving a novel COVID-19 vaccine among patients with psoriatic disease.
Methods: Data from a large real-world survey of individuals who contacted a U.S.-based patient advocacy organization were analyzed. Main outcome of interest was likelihood of receiving a COVID-19 vaccine. Chi-square tests, bivariate and multivariate logistic regression were used to determine effect of demographic and clinical characteristics and likelihood of receiving a COVID-19 vaccine.
Results: A total of 1,405 individuals completed the survey. Most participants (65%) received a flu vaccine in the last 12 months and are (52.7%) 'Very Likely'/'Likely' to receive a COVID-19 vaccine while 18.5% reported being 'Very Unlikely'/'Unlikely' to receive a vaccine. Chi square tests suggest the likelihood of received COVID-19 vaccine is associated with receiving the flu vaccine in the last 12 months, race, ethnicity, sex, body mass index, age, income, severity of PsO and PsA. Bivariate logistic regression results suggest individuals who received the flu vaccine in the last 12 months were 5 times more likely to receive a COVID-19 vaccine than those that did not receive the flu vaccine (OR = 5.03, 95% CI 3.96 -6.38, p<.001). In the multivariate model that controlled for ethnicity, race, sex, overweight/obese status, age, biologic use in the last 12 months, disease type, presence of comorbidities associated with higher risk of worse COVID-19 outcomes, PsA symptom state and skin disease severity, likelihood of receiving a COVID-19 vaccine were higher among individuals who received the flu vaccine in the last 12 months (OR = 4.01, 95%CI 2.54 – 6.33, p<.001) and those with annual household income over $75,000 (OR = 2.18, 95% CI 1.35 – 3.52, p<.01).
Conclusions: Enough patients with psoriatic disease are unlikely to receive the vaccine to complicate efforts to achieve widespread immunity. Individuals view their health care provider as an influential information source about novel vaccines. (1) Dermatologists and rheumatologists can play a role in attaining widespread immunity for COVID-19 by actively engaging their patients on this important topic. Guidance on managing psoriatic disease during the COVID-19 pandemic issued by the National Psoriasis Foundation can inform and guide these conversations.
References:

1. Maurer J, Uscher-Pines L, Harris KM. Perceived seriousness of seasonal and A(H1N1) influenzas, attitudes toward vaccination, and vaccine uptake among U.S. adults: does the source of information matter? Prev Med. 2010;51(2):185-7.

P89 - Socio-economic impact of COVID-19 on Psoriasis patients – Bangladesh outlook

13. SARS-CoV-2/Covid-19

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Introduction: COVID-19 is the newly emerged pandemic across the globe at the end of 2019 but still shivering the world. Coronavirus (COVID-19) pandemic has created an unprecedented loss and disruptions over all across the world. From developed to developing, no country has been spared from its brunt.

Increased stress is associated with psoriasis flares. In this way, the COVID-19 pandemic may place an extra burden on the mental health of people with psoriasis.

The spread of the COVID-19 pandemic, the lockdown, the disease intensity, weak governance in the healthcare system, insufficient medical facilities, unawareness, and the sharing of misinformation in the mass media has led to people experiencing fear and anxiety.
Objectives: A study was conducted on perception-based analysis to get an idea of psoriasis patients psychosocial and socio-economic crisis, and the possible environmental crisis, amidst the COVID-19 pandemic in Bangladesh.
Methods: A short questionnaire was sent to 500 hundred psoriasis patients randomly.
Results: 345 patients responded, data were analysed and found 58% of participants reported a moderate to severe exacerbation of their symptoms. This effect was associated with factors like lost income and outdoor activity restrictions, unavailability of medicine and unable to visit hospital due to the pandemic.
Conclusions: The rapid increase of NCDs mortality and morbid in Bangladesh has presented a major threat to Bangladesh's existing healthcare systems, which are mainly geared towards addressing communicable diseases. Psoriasis is not included in National NCD program, so patients access to the healthcare system is limited.

During ongoing COVID-19 pandemic,an estimated sixty million urban poor living in the low-income settlements across different cities and towns of Bangladesh are facing miserable condition due to the lack of employment, loss in income, insufficiency of water, sanitation and hygiene (WASH) facilities, food insecurity deficiency and malnutrition), inadequate access to healthcare/medicare, and increase in the violence against women and girls.

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