ISSN 0001-5555

ActaDV

ACTA DERMATO-VENEREOLOGICA

Volume 98 2018 **Supplement No. 219**

ADVANCES IN DERMATOLOGY AND VENEREOLOGY

A Non-profit International Journal for
Interdisciplinary Skin Research, Clinical and Experimental
Dermatology and Sexually Transmitted Diseases

Official Journal of
- European Society for Dermatology and Psychiatry

Affiliated with
- The International Forum for the Study of Itch

Abstracts from the 5th World Psoriasis & Psoriatic Arthritis Conference 2018

June 27–30, 2018

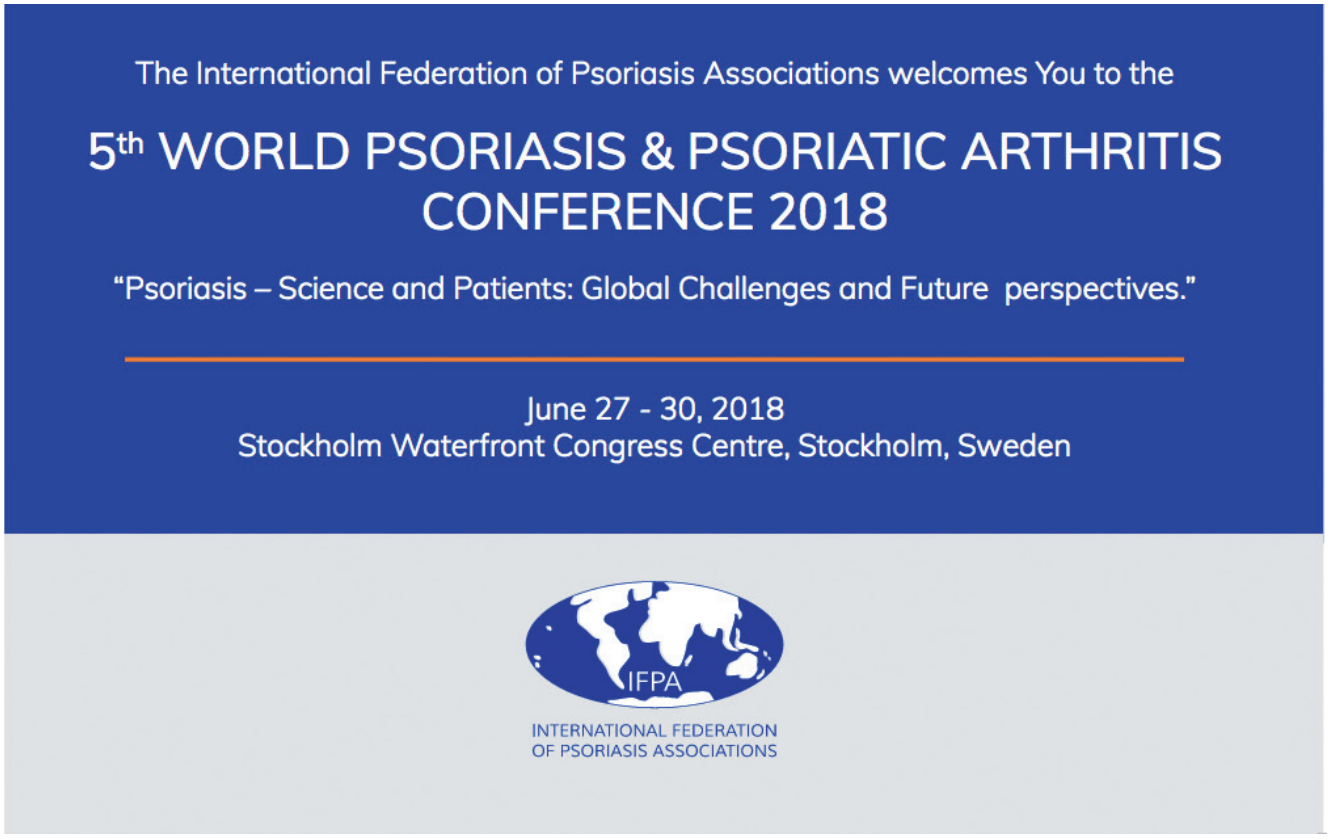
Stockholm, Sweden

Immediate Open Access

Society for Publication of
Acta Dermato-Venereologica

www.medicaljournals.se/adv

Abstracts from the 5th World Psoriasis & Psoriatic Arthritis Conference 2018



ActaDV ACTA DERMATO VENEREOLOGICA
Advances in Dermatology and Venereology

www.medicaljournals.se/acta

doi: 10.2340/00015555-2978
Acta Derm Venereol 2018; Suppl 219

Ref.no	Title
	Biomarkers and Imaging
001	A metagenomics study of the elbow of psoriasis subjects and their healthy relatives
	Clinical phenotypes
002	Nail disorders in patients with Psoriasis vulgaris
003	Psoriasis hidden in Gottron's papules
	Comorbidities
004	Characteristics of psoriasis in obese patients versus non-obese patients; a multicenter study
005	Psoriasis and comorbidity
006	Risk of periodontal disease in patients with chronic plaque psoriasis
007	Splenomegaly and Psoriasis - A case report
008	Psoriasis as predictor for cardiovascular and metabolic comorbidity in middle-aged women
009	A Case of Concurrent Psoriasis and Vitiligo
010	Successful long-term double disease control by adalimumab in a patient with psoriasis vulgaris and hidradenitis suppurativa
011	Clinical and epidemiological caracterization of psoriasis and psoriatic arthritis on a multidisciplinary assesment model.
012	Alcohol and Psoriasis- a Prospective Swedish Study
013	¨Psoriasis and Cancer. Retrospective study in the Psoriasis sector of the Dermatology Service at Ramos Mejia Hospital¨
014	Hematological disorders in the patient with psoriatic arthritis treated with methotrexate and tumor necrosis alpha (TNFalpha) inhibitor
015	The relationship between psoriasis, comorbidities, and depression onset: A nationwide observational control study
	Current and new therapeutic modalities
016	Efficacy of Adalimumab plus Methotrexate in Patients with Moderate to Severe Plaque Psoriasis
018	Attainment of remission and minimal disease activity after starting methotrexate subcutaneous therap
019	Secukinumab in pregnancy: outcomes in psoriasis, psoriatic arthritis and ankylosing spondylitis from the global safety database
020	Ixekizumab improves impact of genital psoriasis on sexual activity: Results from a Phase 3b study
021	Dose optimization of Secukinumab in subjects with moderate to severe plaque psoriasis: OPTIMISE study
022	Inhibition of anti-TNF-alpha cytokine in the treatment of psoriasis and the analysis of infectious complications
023	Treatment use and satisfaction among patients with psoriasis and psoriatic arthritis in Scandinavia
024	First Patient-Reported Insights From a Multinational, Retrospective, Cross-Sectional Study of Real-World Experience of Psoriasis Patients Treated With Apremilast in Clinical Dermatology Practice (APPRECIATE)
025	Physician- and Patient-Reported Outcomes With Apremilast for Patients With Plaque Psoriasis During Routine Dermatology Care in Germany: A Second Interim Analysis
026	Improvements in Work Productivity With Up to 104 Weeks of Apremilast Monotherapy: Results From a Phase 3b, Randomized, Controlled Study in Biologic-Naive Subjects With Active Psoriatic Arthritis
027	Examining Disease Severity and Symptom Improvement With Patient and Physician Assessments: Results From a Phase IV Analysis of Apremilast in Patients With Moderate Plaque Psoriasis
028	Hemoglobin A1c and Weight Changes With Apremilast in Patients With Psoriasis and Psoriatic Arthritis: Pooled Laboratory Analysis of the Phase 3 ESTEEM and PALACE Trials
029	Canadian Humira Post-Marketing Observational Epidemiological Study Assessing the Effectiveness of Adalimumab vs Non-Biologic DMARDs in Psoriatic Arthritis (Complete-PsA): 12-Month Effectiveness Data
030	Secukinumab Efficacy in Patients with Active Psoriatic Arthritis: Meta-analysis of 4 Phase 3 Trials
031	Impact of adalimumab vs. non-biologic treatments on skin outcomes of psoriatic arthritis patients: real-world data from the COMPLETE Study
032	Ixekizumab Improves Nail and Skin Psoriasis through 52 Weeks of Treatment in Patients with Active Psoriatic Arthritis: Results from Two Randomized, Double-Blind, Phase 3, Clinical Trials (SPIRIT-P1 and SPIRIT-P2)
034	Ixekizumab Makes Therapeutic Thresholds Possible in Active Psoriatic Arthritis Patients: Results from SPIRIT Trials
035	The macrophage modulator MP1032 shows safety and efficacy in a human phase IIa study for the treatment of moderate-to-severe plaque psoriasis
036	Secukinumab Improves Signs and Symptoms of Psoriatic Arthritis: Results from a Phase 3 Study, FUTURE 5
037	Incidence of Inflammatory Bowel Disease In Patients Treated With Secukinumab: Pooled Analysis of 21 Randomised Controlled Phase 3/4 Clinical Trials of Psoriasis, Psoriatic Arthritis, and Ankylosing Spondylitis
038	Analysis of the position of the fumaric acid esters in current European psoriasis guidelines
039	Secukinumab Provides Rapid and Sustained Resolution of Enthesitis in Psoriatic Arthritis Patients: Pooled Analysis of Two Phase 3 Studies, FUTURE 2 and FUTURE 3
041	Long-Term Safety of Adalimumab (HUMIRA) in Adult Patients From Global Clinical Trials Across Multiple Indications: An Updated Analysis in 29,987 Patients Representing 56,951 Patient-years
042	Clinical response after guselkumab treatment among adalimumab PASI 90 non- responders: Results from the VOYAGE 1 and 2 trials
043	Consistency of response by weight across subgroups of patients with psoriasis treated with guselkumab: Results from the VOYAGE 1 and 2 trials
044	Impact of Clinical Specialty Setting on Disease Management in Patients with Psoriatic Arthritis
045	Speed of response of guselkumab compared with adalimumab for the treatment of moderate-to-severe psoriasis: results through Week 24 from the phase 3, double-blinded, placebo- and active comparator-controlled VOYAGE 1 and VOYAGE 2 trials
046	Safety of Certolizumab Pegol over 48 Weeks in Chronic Plaque Psoriasis Phase 3 Trials
047	Secukinumab Provides Sustained Minimal Disease Activity (MDA) and Remission Related to Disease Activity Index for Psoriatic Arthritis (DAPSA): 2-year Results from a Phase 3 Study

104 Serum Glucocorticoid-inducible Kinase-1(SGK1) Levels in Patients with Psoriatic Arthritis
105 Differential NH2-terminal autoantigen trimming may explain epistasis between HLA-C*06:02 and ERAP1 variants in psoriasis risk
106 Environmental triggers of an HLA-C*06:02-restricted autoimmune response in psoriasis
107 A skewed pool of resident T cells triggers disease-associated tissue responses in never- lesional psoriasis

Psoriasis and Psoriatic Arthritis relationship

108 Nail involvement in psoriasis; is it a predictor of psoriatic arthritis?
109 Absolute and relative PASI improvements with ixekizumab treatment: Results at Week 12 from IXORA-P
110 Prevalence and sex differences of psoriatic arthritis in patients with severe plaque psoriasis.
111 Skin Lesion Severity In Early Axial and Peripheral Psoriatic Arthritis Patients
112 Gastrointestinal symptoms are common in U.S. patients with moderate-severe psoriasis
113 Secukinumab's Long-Term Safety Remains Favorable up to 5 Years of Treatment
114 Impact of Improvement in Skin and Joint on Quality of Life in Active Psoriatic Arthritis Patients
115 Secukinumab Shows High and Sustained Efficacy in Subjects with Moderate to Severe Palmoplantar Psoriasis: 2.5-Year Results From the GESTURE Study
116 Secukinumab Shows High and Sustained Efficacy in Nail Psoriasis: 2.5-Year TRANSFIGURE Study Results
117 The obesity and prevalence psoriatic arthritis in patients with plaque psoriasis: dermatological real-setting data.
118 Diagnosis of Psoriatic Arthritis in Patients with Moderate to Severe Chronic Plaque Psoriasis Treated with Secukinumab vs. Other Treatments in the PURE Registry: Indication of Selection Preferences and Underdiagnosis
119 Efficacy and Safety Results of Guselkumab in Patients with Active Psoriatic Arthritis over 56 Weeks
120 Tildrakizumab efficacy over time by week 28 response levels in two Phase 3 clinical trials in patients with chronic plaque psoriasis
122 Potential Disconnect: Co-Management of Patients with Psoriatic Arthritis Between Rheumatologists and Dermatologists
123 The Use of Tumor Necrosis Factor Inhibitors (TNF) in the Second-Line Biologic/Small Molecule Setting: A Cross-Specialty Comparison
124 Impact of Guselkumab versus Placebo and Adalimumab on Patient Reported Outcomes in Patients with and without Psoriatic Arthritis in VOYAGE 2

Quality of Life

125 The Dermatology Life Quality Index in Russian patients with psoriasis and psoriatic arthritis.
126 Effects of mindfulness-based cognitive therapy on self-reported psoriasis and psychological symptoms
127 A mixed methods study exploring the impact of mindfulness on psoriasis, anxiety, depression and QoL
128 A link between quality of patient-physician communication and patient healthcare needs in PsA
129 Psoriasis Patients Point of View: What bare we Missing when Managing Them?
130 The impact of psoriasis and psoriatic arthritis on quality of life and career in Scandinavia
131 Quality of life of patients with psoriasis in Khartoum dermatology hospital, December 2017
132 Mirikizumab Significantly Improves Self-Reported Disease Severity and General Health Status in Patients with Moderate-to-Severe Psoriasis
133 Effect of Tildrakizumab on Personal Relationships in Patients with Moderate-to-Severe Chronic Plaque Psoriasis
134 Pruritus severity assessment and correlation with baseline characteristics of patients with psoriasis vulgaris: an exploratory analysis of the Phase IIIb, PSORITUS study
135 Quality of life and psychosocial implications in patients with psoriasis
136 Swedish psoriatic patients' perspective of their disease. Results from an observational patient survey.
137 Ixekizumab Provides Greater Cumulative Benefits versus Ustekinumab over 24 Weeks for Patients with Moderate-to-Severe Psoriasis in a Randomized, Double-Blind Phase 3b Clinical Trial
138 Coach@Home: A Support Program for Patients Treated With Certolizumab Pegol
139 A Comprehensive Survey Assessing the Family Planning Needs of Women with Psoriasis
140 The Psychosocial Impact of Psoriasis: Differential Experiences of Men and Women in Early Adulthood
141 Certolizumab Pegol Improves Patient-Reported Outcomes in Chronic Plaque Psoriasis Over 1 Year
142 Translating WHO resolution into the public: the German program against stigmatization of people with chronic visible skin diseases
143 The Global Research on the Impact of Dermatological Diseases (GRIDD)

Young scientists (born on or after January 1, 1983)

144 Treatment of Nail Psoriasis with Different Pulse Durations of Pulsed Dye Laser
145 Neutropenia in a psoriasis patient: Secukinumab or micronutrient deficiency?
146 Establishment of a Psoriatic Skin Model for α-Irradiation
147 The History of Psoriasis
148 Comorbidities and treatments in patients with inverse psoriasis

Late Breakers

150 Development of the "PsO Sleepy-Q" and the "PsA Sleepy-Q": two questionnaires to characterize sleep in patients with psoriatic disease
151 Unstable forms of psoriasis – indicator of an intermediate state of systemic disease
152 Could biological agents foster suicide through its potential antidepressant mechanism? A Psychodermatological approach.
153 Treating the pain, not the problem? Results from a Swedish online survey on psoriatic arthritis and psoriasis with joint pain.
154 An International Delphi survey to define screening for psoriatic arthritis and measurement of psoriatic arthritis symptoms in psoriasis clinical trials
155 The impact of a diagnosis on the patients' perception of treatment and care. Results from an online survey on psoriatic arthritis and psoriasis with joint pain.

POSTERS

P001

A METAGENOMICS STUDY OF THE ELBOW OF PSORIASIS SUBJECTS AND THEIR HEALTHY RELATIVES

Hailun Wang[1], Michael Ni[1], Japio Fung[1], Kang Yan[1], Xiaoxin Yao[1], Yinpeng Wang[1], Martin Kriegel[2], Henry Chan[1], Herbert Pang[1]
[1]The University of Hong Kong, and [2]Yale University

Introduction: Psoriasis is a multifaceted immune-mediated skin disease and has been associated with other comorbidities. Previous studies in psoriasis reported the abundance of microbial taxa above the species rank (family *Firmicutes* and genus *Staphylococcus*), or the combined abundance of multiple taxa (*Corynebacterium*, *Propionibacterium*, *Staphylococcus*, and *Streptococcus*) were associated with psoriasis [1–3]. Characterizing the skin microbiome of psoriasis subjects and family controls can further our understanding of microbiota's role in this disease.
Objectives: This study aims to reveal the difference of skin microbiome between skin lesion area and normal area of the elbow as well as family controls.
Methods: DNA samples was extracted from 21 elbow-skin. 14 of 21 were from 7 psoriasis subjects' lesion side and normal side. The rest were from a healthy family member whom the subject lives with. Shotgun metagenomic sequencing was adapted to resolute the skin microbiota. Partially overlapping t-test was used to investigate differentially abundant taxa. PERMANOVA was used to test the difference of microbial community composition influenced by psoriasis and sampling families.
Results: Bacteria phyla *Proteobacteria*, *Actinobacteria*, and *Bacteroidetes* were three most abundant microbial taxa in both lesion and normal skin. Bacteria phyla *Cyanobacteria* and *Candidatus Parcubacteria*, family *Hymenobacteraceae* were less abundant on lesion skin than normal skin ($p < 0.05$). Sampling families had significantly different elbow-skin microbial composition for bacterial genus level profile ($p = 0.001$).
Conclusions: Several bacterial taxa different from those previously discovered are more abundant on normal skin than lesion skin in the elbow.
References:
[1] Unexplored diversity and strain-level structure of the skin microbiome associated with psoriasis. NPJ Biofilms Microbiomes. 3,14 (2017).
[2] Statnikov, A. et al. Microbiomic signatures of psoriasis: feasibility and methodology comparison. Sci. Rep. 3, 2620 (2013).
[3] Alekseyenko, A. V. et al. Community differentiation of the cutaneous microbiota in psoriasis. Microbiome. 1, 31 (2013).

P002

NAIL DISORDERS IN PATIENTS WITH PSORIASIS VULGARIS

Jasmina Muhovic
University Clinical Centre Sarajevo

Introduction: Psoriasis vulgaris is a chronic inflammatory skin disease characterized by T-cell-mediated hyperpfoliferation of keratinocytes in the skin. Approximately, 10–78% of patients with psoriasis have concurrent nail psoriasis while isolated nail involvement is seen in 5–10% of patients. Affected nail plates often thicken and crumble and because they are very visible patients tend to avoid normal day-to-day activities and social interactions. Importantly, 70–80% of patients with psoriatic arthritis have nail psoriasis. In this overview, we review the clinical manifestations of psoriasis affecting the nails.
Objectives: To correlate frequency of certain nail dissorders in patients with psoriasis vulgaris. The observed dissorders were:onicholysis, subungual hyperkeratosis, oil spots, and pitting in both male and female patients aged 15–75 and combined with psoriatic arthritis.
Methods: A total of 60 patients who were treated in our Inpatients Service with diagnosis of Psoriasis vulgaris from January 2017 to July 2017 at Dermatology Department, University Clinical of Sarajevo.We searched for specific nail dissorders.
Results: A total number of 60 patients with Psoriasis vulgaris, both male and female aged 15–75 werw examined. Out of that number, 43 patients reported to have specific nail dissorders and/or psoriatic arthritis, and 17 of them were without any nail dissorders or psoriatic arthritis. Among the number of 43 examined psoriatis patients with nail dissorders, there were 23 female and 20 male patients, all of them aged between 45–60. Seven female and eight male patients had previously diagnosed psoriatic arthritis combined with psoriasis and nail disorders, while the rest of them, 28 patients, only had psoriasis followed by progressive changes on their nails, but without any signs of psoriatic arthritis. The presented nail dissorders in all patients included in these two groups were: subungual hyperkeratosis, onicolysis and pitting all combined in 14 patients, only subungual hyperkeratosis in 10 patients, pitting in 7 patients, 7 of them showed only onycholysis on both hands and 6 patients had oil spotting and pitting together. In patients without psoriatic arthritis the prevalence of dissorders in all affected groups was in male patients.
Conclusion: Nail psoriasis engenders both physical and psychological handicap, leading to significant negative repercussions in the quolity of life. The presence of nail disease in a patient with psoriasis may indicate a severe form of the disease and must be taken into account when selecting a treatment otion, with an aim to reduce pain, functional impairment as well as emotional distress.

P003

PSORIASIS HIDDEN IN GOTTRON'S PAPULES

Florentina Berianu, Juan J. Maya
Mayo Clinic Florida

Introduction: Patients with Dermatomyositis (DM) present with rashes in a photosensitive distribution and occasionally a scaly rash over elbows, knees and scalp can resemble psoriasis. The biopsy of such lesions shows interface dermatitis which is highly distinguishing for DM. In rare occasions, patients can suffer from both DM and psoriasis (Ps). Objectives: To report a case of Dermatomyositis and Psoriatic arthritis
Method: 45 years old female presented with a red, itchy rash with diffuse swelling over the entire body associated with swallowing difficulties and weakness affecting mainly the proximal muscles of upper and lower extremities. She has pain and stiffness in her hands and feet. DM was confirmed based on specific findings on skin biopsy, EMG with myopathic features and a muscle biopsy that confirmed the myopathy. Patient had insulin dependent diabetes and IVIG was the initial choice of therapy to avoid steroid use. Patient responded excellent in regards to generalized rash and had reported improvement in regards to proximal muscle weakness and swallowing difficulties but she had persistence of the scaly rash over elbows, knees and developed what resembled dactylitis along with worsened asymmetric inflammatory arthritis of ankle, hand and feet joints. Based on her presentation, Ps and psoriatic arthritis (PsA) were diagnosed. Methotrexate was added and patient had improved in skin psoriasis along with inflammatory arthritis. Results: Ps and PsA were associated with DM in this patient. These are distinct diseases that have parallel courses and require different therapeutic approaches.
Conclusion: Ps has been reported in association with Connective Tissue Diseases. Gotron's papules can resemble Ps in patients with DM but rare case reports have described concomitant DM and Ps. The association of DM, Ps and PsA was even more rarely described.
References:
1. Tselios K, Yap KS, Pakchotanon R et al. Psoriasis in systemic lu-

pus erythematosus: a single-center experience. Clin Rheumatol. 2017 Apr;36(4):879-884.
2. Inkeles MS, No D, Wu JJ. Clinical improvement of a patient with both amyopathic dermatomyositis and psoriasis following treatment with cyclosporine. Dermatol Online J. 2017 Aug 15;23(8)
3. Kato Y, Yamamoto T . Development of psoriasis with relapse of dermatomyositis-associated interstitial lung disease. Int J Rheum Dis. 2017 May;20(5):660-661.
4. Ueno T, Kanzaki A et al. Association of psoriasis with Hashimoto's thyroiditis, Sjögren's syndrome and dermatomyositis. J Dermatol. 2016 Jun;43(6):711-2.

P004

CHARACTERISTICS OF PSORIASIS IN OBESE PATIENTS VERSUS NON-OBESE PATIENTS; A MULTICENTER STUDY

Omid Zargari[1], Seyyede Zeinab Azimi[2], Tara Barat[1], Vahideh Lajevardi[3], Ehsan Kazemnejad[4], Mohamad Shahidi Dadras[1]
[1]Department of Dermatology, Skin Research Center, Shahid Beheshti University of Medical Sciences, Tehran, [2]Department of Dermatology and [4]Department of Biostatistics, Guilan University of Medical Sciences, Rasht, and [3]Department of Dermatology, Tehran University of Medical Sciences, Tehran, Iran

Introduction: Psoriasis is a common chronic inflammatory skin disease, which is gradually being recognized as a systemic inflammatory disorder. Psoriasis and obesity are strongly linked, but there is not enough data whether obese psoriatic patients present differently from non-obese psoriatic patients.
Objective: To compare the phenotype, clinical features, severity, baseline comorbidities and laboratory findings among psoriatic patients with/without obesity.
Methods: All the psoriatic patients, from three centers, who were receiving systemic therapy were included in the study. Patients were divided into two groups: those with obesity and those without obesity.
Results: We included 497 patients: 154 (31%) patients were obese and 343 (69%) were non-obese. Obese patients had more comorbidities, particularly hyperlipidemia, followed by hypertension and diabetes. Fasting blood sugar and serum lipids were significantly higher among obese subjects.
Conclusions: Given the differences between obese patients and non-obese patients, the former group should be followed and managed more closely and with specific attention.
References:
1. Kimball AB, Gladman D, Gelfand JM, Gordon K, Horn EJ et al. National Psoriasis Foundation clinical consensus on psoriasis comorbidities and recommendations for screening. J Am Acad Dermatol. 2008; 58(6):1031-42.
2. Love TJ, Qureshi AA, Karlson EW, Gelfand JM, Choi HK. Prevalence of the metabolic syndrome in psoriasis: results from the National Health and Nutrition Examination Survey, 2003–2006. Arch Dermatol. 2011; 147(4):419-24

P005

PSORIASIS AND COMORBIDITY

Veranika Liubiankova, Sviatlana Makarava
Mogilev Regional Centre of Dermatology and Venerology

Introduction. In recent years special attention has been paid not only to the systemic nature of the process in psoriasis, but also to its association with comorbidities. Comorbidity is a regular combination of various diseases or conditions in one patient, it occurs in many inflammatory processes.
Objectives: The study of the incidence of concomitant diseases in patients with psoriasis in relation to patients with allergic contact dermatitis, analysis by age group.
Methods: A retrospective analysis of data of 804 patients, who were treated in 2016–2017 in Mogilev Regional Dermatology and Venerology Centre with different forms of psoriasis, was conducted. 492 males, 312 females. The mean age was 43.05 years. The control group consisted of patients with allergic contact dermatitis, comparable in age and sex, in an amount of 397 people.
Results: Specific gravity and incidence of comorbidity in patients with psoriasis: cardiovascular damage 41% (331), gastrointestinal tract - 30.4% (245), endocrine system - 22.7% (183), metabolic syndrome - 28.2% (227), chronic otorhinolaryngological diseases - 11.4% (92), diseases of urinary system - 6.2% (50), respiratory system - 4.7% (38). Significant differences between the groups were obtained for all the comorbidity except respiratory diseases. Psoriatic polyarthritis were observed in 219 patients (27.3%), nail psoriasis – in 117 patients (14.6%). The average body mass index in the psoriasis group was 27.2, in the allergic contact dermatitis group - 25.3. Significant differences between the groups were obtained for all the laboratory test changes except the general bilirubin, C-reactive protein and urinalysis. The percentage of diseases changed with increasing age: diseases of the cardiovascular system from 10% to 87%, gastrointestinal diseases from 20% to 61%, endocrine system diseases - from 14.5% to 38%, metabolic syndrome - from 11% to 34%, otorhinolaryngological diseases - from 15% to 8.5%, diseases of the urinary system - from 1.8% to 8.5%, respiratory system diseases – from 1.8% to 13%.
Conclusions: The analysis showed that in patients with psoriasis the most frequent comorbidity are: cardiovascular and gastrointestinal diseases, endocrine disorders, polyarthritis, nail psoriasis and metabolic syndrome. A rather high risk of comorbidity is established, in comparison with the population, which can directly affects the severity of the course of the disease, the effectiveness of the therapy and life expectancy.
References:
1. Potekaev N., Kruglova L. Psoriatic Disease. – Moscow. - 2014.- P. 94 (in Russian)
2. Cohen A.D., Sherf M., Vidavsky L., Vardy D.A. Association between psoriasis and the metabolic syndrome. A crosssectional study // Dermatology.— 2008.— Vol. 216(2).—P. 152
3. Eng S., Xing B., Caro I., Werther W. Selected cardiovascular diseases in psoriasis, nonpsoriasis, and efalizumabtreated psoriasis patients // Acad. Dermatol.— 2009.— P. 3381

P006

RISK OF PERIODONTAL DISEASE IN PATIENTS WITH CHRONIC PLAQUE PSORIASIS

Veronica Lopez Castillo, Inmaculada Lopez Castillo, Pedro Rodriguez, Jose Maria Ricart Vaya

Introduction: Psoriasis is a common, chronic, inflammatory, multisystem disease affecting approximately 2% of population. It has been associated with certain diseases and there is a strong link between metabolic syndrome and psoriasis. Chronic periodontitis is an infectious disease resulting in inflammation within the supporting tissues of the teeth, progressive attachment loss, and bone resorption and clinically characterized by pocket formation and/or gingival recession. Psoriasis and chronic periodontitis share common risk factors and co-morbidities.
Objective: The aim of our study was to determine how frequently chronic periodontitis is associated with patients with psoriasis compared to systemic healthy subjects and if its presence is associated to severity of psoriatic lesions.
Methods: Baseline demographic data including sex, age, smoking habits, family history of psoriasis or periodontal disease was recorded in 40 psoriasis subjects and 40 healthy subjects. Information on comorbidities and pharmacological treatment, daily tooth brushing, the presence of gingival bleeding, location of skin lesions, weight and height were also evaluated. The periodontal clinical parameters probing depth, periodontal attachment level, plaque index and presence or absence of radiographic bone loss were recorded. The severity of psoriasis was assessed by Psoriasis Area and Severity Index. A complete blood test was asked for all subjects included in the study.

Results: During the study enrolment period 40 patients with psoriasis and 40 age- and gender-matched controls were included in this study. Probing depth and periodontal attachment level showed significant higher values in psoriasis group compared to healthy subjects.
Conclusions: We found evidence of a psoriasis-associated increased risk of periodontitis. Thus, dermatologists should be aware of this comorbidity because these patients should be closely followed-up by a dentist for the adequate and early treatment of periodontitis. Periodontitis may be associated with psoriasis but further studies are needed to elucidate their relationship.
References:
1. Egeberg A, Mallbris L, Gislason G et al. Risk of periodontitis in patients with psoriasis and psoriatic arthritis. JEADV 2017, 31: 288-293.
2. Ungprasert P, Wijampreecha K, Wetter DA. Periodontitis and risk of psoriasis: a systematic review and meta-analysis. JEADV 2017, 31: 857-862.

P007

SPLENOMEGALY AND PSORIASIS - A CASE REPORT

Suzana Ozanic Bulic
Department of Dermatovenerology, KBC Sestre milosrdnice, Zagreb, Croatia

Psoriasis is a chronic, systemic, inflammatory disease associated with numerous comorbidities that have been well documented in the literature. Comorbidities often become clinically evident years after the onset of psoriasis and are related to persistent low-grade inflammation with secretion of proinflamamtory cytokines, as seen in metabolic syndrome(1). Nevertheless, the evidence shows new emerging comorbidities that share link with psoriasis. Hjuler et al. observed increased splenic inflammation in patients with moderate-to-severe psoriasis (2). They also showed that splenic activity was correlating with aortic wall inflammation in psoriasis patients, explaining the increased risk of heart disease (2).
A 56-year old patient with chronic plaque psoriasis (Fig 1) for more than thirty years, presented with splenomegaly, diabetes type two, arterial hypertension, chronic kidney disease stage III, obesity, with BMI >40, and depression. Psoriasis severely flared up in 2012, and on workup up for cataract operation, enlarged lymph nodes were observed and further confirmed on CT scans in axillae, inguinum, mediastinum and upper abdomen. Patient was hospitalized at haematology department and reactive lymphadenopathy due to skin inflammation was diagnosed. Acitretin was started and stopped after a week for worsening of pancytopenia, and Methotrexate was stopped after two weeks for triple increase in liver enzymes, although the dose was of only 5 mg weekly. In August 2017, repeated blood tests were normal and abdominal US showed no progression in hepato-splenomegaly, with spleen measuring 23 cm. Psoriasis was severe, with PASI 36, BSA 31% and DLQI 19. Ustekinumab 90 mg was started in October 2017 with PASI75 achieved after 12 weeks of treatment. Patient has been closely monitored with no haematological side-effects on last assessment.
Significant splenomegaly and lymphadenopathy with no underlying haematological disease has not been described as a comorbidity of psoriasis. The treatment with biologics was delayed in our patient as underlying haematological malignancy was suspected. The untreated severe psoriasis flared up in the mean time the whole spectrum of comorbidities, led by depression. Ustekinumab has significantly improved his psoriasis (Fig 2), with improvement in depression that was best observed in patient's motivation to lose weight and be referred for gastric bypass.
Effective control of psoriasis and associated conditions requires not only appropriate treatment, but also management of comorbidities, including screening and treatment by various specialists, as disease is known for its cumulative impairment over patient's lifetime (3).

P008

PSORIASIS AS PREDICTOR FOR CARDIOVASCULAR AND METABOLIC COMORBIDITY IN MIDDLE-AGED WOMEN

Christoffer Blegvad[1], Anne-Marie Nybo Andersen[2], Abdulfatah Adam[2], Claus Zachariae[1], Lone Skov[1]
[1]Copenhagen Research Group for Inflammatory Skin (CORGIS), Department of Dermatology and Allergy, Herlev and Gentofte Hospital, University of Copenhagen, Copenhagen, [2]Section of Epidemiology, Department of Public Health, University of Copenhagen, Denmark

Introduction: Cardiovascular and metabolic comorbidities such as ischemic heart disease and diabetes are known to be associated with psoriasis. However, it is less clear whether this is due to common life-style related risk factors such as overweight and smoking.
Objectives: We wished to investigate the association between psoriasis and cardiovascular and metabolic comorbidity in a cohort of middle-aged women, and at the same time taking the effect of body mass index (BMI) and smoking into account.
Methods: The study population consisted of expectant mothers in a large nationwide birth cohort established between 1996 and 2002. During pregnancy, the women were asked whether they have ever had any skin diseases including psoriasis, and whether the disease was diagnosed by a physician. The relation to self-reported cardiovascular and metabolic comorbidity 11 years after giving birth was assessed by multiple logistic regression. Furthermore, we performed an analysis where the cohort was followed up for hospital-diagnosed comorbidity including cardiac death until 31st December 2014. Here the risk was assessed by Cox proportional hazards regression. All analyses were adjusted for age, pre-pregnant BMI, and smoking status collected at time of inclusion during pregnancy.
Results: We identified 2,435 (2.90%) women with a history of psoriasis and 81,388 women without psoriasis. The women with and without psoriasis were on average respectively 30.4 (SD 4.5) and 29.9 (SD 4.3) years old at time of inclusion in the study. Women with psoriasis had slightly higher BMI and smoked markedly more than women without psoriasis (38.1% vs. 26.4%). A history of psoriasis was significantly associated with self-reported hypercholesterolemia (adjusted odds ratio 1.31; 1.01–1.70) and hospital-diagnosed hypertension (adjusted hazard ratio 1.33; 1.08–1.65). A positive association was also found with respectively hospital-diagnosed ischaemic heart disease, type 2 diabetes, and hypercholesterolemia, however, these findings were not statistically significant. No associations were found for self-reported hypertension, thrombosis, or type 2 diabetes.
Conclusions: Women with psoriasis are at increased risk of developing cardiovascular and metabolic comorbidity in early adult life. This may suggest an importance of awareness of these comorbidities also in younger patients with early screening for hypertension, hyperglycemia, and hypercholesterolemia.

P009

A CASE OF CONCURRENT PSORIASIS AND VITILIGO

Selma Poparic
Dermatology Department University Clinical Center of Ssrajevo

Introduction: Psoriasis and vitiligo are common dermatoses that affect 1~3% (psoriasis) and 0.5% (vitiligo) of the general population, respectively. Yet the pathogenesis of the association between these two dermatoses is still unknown.
Case report: We report a case of a 52-year-old patient who was admitted to our department with a 6-month history of squamous papules and plaques on his right elbow region and both right and left lower leg. He was also noticed with hypopigmented patches on his right and left wrist. Anamnestic questionnaire revealed that his mother has had similar discolorations on her skin, but never

underwent any diagnostic procedure, nor treatment. Clinical and hystopathological diagnosis of erythematosquamous areas on the patients right elbow and right and left lower leg was a plaque psoriasis, while hypopigmented patches on his wrists were diagnosed as vitiligo. Blood work up and T3, fT4, TSH, ANA laboratory tests were within normal ranges.
Conclusion: Psoriasis and vitiligo, although seemingly unrelated skin disorders, have a lot in common. Causes, incidence, and even distribution seem to strongly correlate between these two.

P010
SUCCESSFUL LONG-TERM DOUBLE DISEASE CONTROL BY ADALIMUMAB IN A PATIENT WITH PSORIASIS VULGARIS AND HIDRADENITIS SUPPURATIVA

Melita Vuksic Polic[1], Zlatica Jukic[1], Andrea Krnic[1], Renata Vukadin[1], Ivana Patrk[2]
[1]Osijek University Hospital: Faculty of Medicine Osijek, [2]Privat dermatovenerological clinic dr Ivana Patrk, Zadar

Introduction: Psoriasis vulgaris /PV/ is a chronic inflammatory skin disease[1]. Studies have shown the role of genes important for the transcription of inflammatory citokines, such as TNF alpha and IL-23, which play main role in the patoghenesis of psoriasis[2]. Hidradenitis suppurativa /HS/ is chronic inflammatory skin disease[3], in which pathogenesis are IL-23 and TNF alpha, supporting the theory of the immunologic disease[4]. Adalimumab is human monoclonal antibody that has a great affinity for the membrane of TNF alpha[5]. We report the case of a 44-year-old Caucasian woman with a history of PV and HS, both diseases are in remission during the therapy with adalimumab.
Case report: We report the case of a 44-year-old Caucasian woman with a history of PV and HS that started adalimumab therapy 3 years ago. PV started 14 years ago and was verified by skin biopsy. Initially, the clinical course of psoriasis was mild and later she took course to moderate psoriasis with PASI 10. Psoriasis was treated only with local therapy. HS started when she was 38-years-old in her left groin, as swelling and pain on palpation and in movement. Skin changes started to develop also on the right groin and perianal region as painful nodules, with pus draining, and fistula tracts. Skin biopsy confirmed HS.Chest X-ray and gastroenterology examination were performed to exclude any additional illnesses and she also did a psychologcal testing. She was treated with different antibiotics also prednisone and isotretinoin at a dose 1mg/kg/day. Topical therapy was consisting of antibiotics, antiseptics and hydrocolloid dressings. She had 3 surgical interventions. In 2015, she started adalimumab according to the scheme. On the day of the initial aplication of adalimumab, patient had 4 abscesses, 13 nodules and 16 fistula tracts. She had successful clinical response to the drug and is without psoriatic symptoms or HS active lesions. Both diseases are successfuly controled and quality of life has improved.
References:
1.Nevitt GJ, Hutchinson PE. Psoriasis in the community: prevalence, severity and patient´s beliefs and attidudes towards he disease. Br J Dermatol 1996;135:533-7.
2.Reich K, Hüffmeier U, König IR, Lasorz J, Lohman J, Wendler J, Traupe H, Mössner R, Reis A, Burhardt H.TNF polymorphisms in psoriasis association of psoriatic arthritis with the promoter polymorphism TNF-857 independent of th PSORS1 risk allele. Arthritis Rheum 2007,56:2056-64.
3. Fimmel S, Zouboulis CC. Comorbidities of hidradenitis suppurativa (acne inversa). Dermatoendocrinol 2010;2:9-16.
4. Matusiak I, Bieniek A, Szepietowski JC. Increaed serum tumour necrosis factor-alpha in hidradenitis suppurativa patients: is there a basis for treatment with anti-tumour necrosis factor-alpha agents? Acta Derm Venereol 2009;89:601-3.
5. Haslund P, Lee Ra, Jemec GB. Treatment of hidradenitis suppurativa with tumour necrosis factor-alpha inhibitors. Acta Derm Venereol 2009;89:595-600.

P011
CLINICAL AND EPIDEMIOLOGICAL CARACTERIZATION OF PSORIASIS AND PSORIATIC ARTHRITIS ON A MULTIDISCIPLINARY ASSESMENT MODEL

Karla Del Rocio Macias-Garcia, Dalila Alejandra Lopez Rodriguez
Dermatologico Country

Introduction: Presentation and clinical course in Psoriasis are heterogeneos. A multidisciplinary assessment model was designed by five specialties: dermatology, rheumatology, internal medicine, nutrition and psychiatry, to evaluate at the same time and place, patients with psoriasis.
Objetive: To ascertain frequency of comorbilities in psoriatic patients and conduct a clinical and epidemiological characterization.
Methods: Prospective study, from August 2016 to february 2018, patients attending to Multidisciplinary Clinic for psoriasis in Dermatologico Country were included.
Results: 53 patients were included. Median age was 42 years old and 62.3% were female. Family history of psoriasis was found in 26.4% patients and 19.4% had spodyloarthropathy family history. Most common comorbidities found obesity, metabolic syndrome, diabetes mellitus, dyslipidemia, hypertension and fatty liver. Affective assessment was found for 49.1% met criteria for anxiety. Psoriasis found 96.2% with psoriasis in skin and 56.6% in nails. Most common presentation of psoriasis, was plaque psoriasis in 66%. PASI score showed 50.9% with mild disease, 15.1% moderate, and 34% had severe. NAPSI score was from 0 to 61, with a median of 3 (0.13). DLQI indicated that only 13.2% had no condition in life quality, meanwhile 86.8% patients had impaired quality of life. Psoriatic arthritis, and identify 58.5% patients that met CASPAR criteria, axial disease was present in 51.6%, peripheral joint disease in 71% and in 13.2% both were present. 54.8%(17) patients had enthesitis and 16.1% had dactilitis. DAS28 was performed, and showed 45.2% with severe activity. Total number of subjects with peripheral disease 100%, did not met criteria for MDA. HAQ score to assess PsA patients quality of life, revealed a median of 1.38 (1.10, 2.25).
Conclusions: we found that more than half of the patients presented a severe form of psoriasis with significant quality of life impairment. The number of psoriatic arthritis was higher than expected with both axial and peripheral manifestations. We have found a high proportion of patients with comorbidities such as metabolic syndrome, diabetes mellitus, hypertension, dyslipidemia and obesity. We also found a high frequency of psychiatric illness. The limitations of our study are the small sample to highlight if comorbidities had an impact on the severity of skin and joint disease. This multidisciplinary model has identified psoriasis as a disease with an unpredictable course, which requires several evaluations by a multidisciplinary model, with a group of experts beyond Dermatologist and Rheumatologist.

P012
ALCOHOL AND PSORIASIS- A PROSPECTIVE SWEDISH STUDY

Caroline Svanström[1], Sol-Britt Lonne-Rahm[1], Ebru Bircan[2], Knut Stokkeland[3], Johan Franck[4], Klas Nordlind[5]
[1]Department of Dermatology, Mälarsjukhuset, Eskilstuna, [2]Department of Medicine, Solna, Dermatology and Venereology Unit, Karolinska Institutet, [3]Department of Medicine, Gastroenterology and Hepatology Unit, Karolinska Institutet, [4]Department of Clinical Neuroscience, Division of Psychiatry, Karolinska Institutet, Stockholm, and Department of Medicine, Visby Hospital, Visby, [5]Department of Medicine, Solna, Dermatology and Venereology Unit, Karolinska Institutet, Stockholm, Sweden

Background: We have earlier in a limited cross-sectional study shown a correlation in females for alcohol consumption and extent

of psoriasis. There are few prospective studies on the relation of alcohol with the extent of psoriasis.
Objectives: The purpose of this prospective study was to further investigate how alcohol affects psoriasis in female patients.
Methods: Twenty-two female psoriasis patients with light to moderate psoriasis, with only local treatment and with a regular alcohol intake, were recruited. The study was run for three years, starting in 2014. We used Christmas and New Year, as intervention period, when the amount of alcohol is expected to exceed normal consumption. The total study period was 8 weeks. During the study period, the alcohol intake was measured by the patients filling a calendar, specifying the alcohol intake per day, moreover, the degree of severity of psoriasis, degree of pruritus, and of perceived stress, using a visual analog scale. In addition, the patients once a week determined Self-Administered Psoriasis Area and Severity Index (SAPASI).
Results: The alcohol intake, which was generally low to moderate, increased during Christmas and New Year, reaching its maximum during week 52 (Christmas week). There was a marginal increase in the extent of psoriasis, determined by SAPASI, during week 52. There was no correlation with alcohol intake nor pruritus. The level of perceived stress decreased shortly after week 52, and reached its lowest value during week 1, after that increasing.
Conclusion: Even if there is an increased alcohol consumption during Christmas and New Year, there is no evident worsening of psoriasis.

P013
PSORIASIS AND CANCER. RETROSPECTIVE STUDY IN THE PSORIASIS SECTOR OF THE DERMATOLOGY SERVICE AT RAMOS MEJIA HOSPITAL

Jennifer Kreimer, Alejandra Crespo, Elena Chaparro, Daniela Gonzalez, Veira Rosana, Kogan Nora

Introduction: Psoriasis is a chronic, systemic, immune-mediated inflammatory disease that compromises the skin, attachments, semi-mucosal, mucous membranes and joints. There are different clinical forms that can vary in the same patient at different times of life. It is accompanied by comorbidities that affect the quality and survival of patients. Within the comorbidities associated with psoriasis, malignancies constitute a prominent and controversial group. In the review of the current literature, there would be evidence of a relationship between psoriasis and cancer, given the existence of structural and molecular similarities between the two pathologies. Objectives: To assess the prevalence of cancer development in patients with psoriasis in our population.
Methods: A retrospective epidemiological analysis of the total population of 1969 patients with psoriasis is carried out, attended in the psoriasis sector of the dermatology service of Ramos Mejía Hospital in the period between January 2008 and January 2018.
Results: We identified 56 patients who presented coexistence of oncological pathology and psoriasis of different severity: 38 severe, 14 moderate and 4 mild. The population was divided equally between both sexes. Of these 56 patients, 61 tumors were detected (non-melanoma skin cancer, solid tumors and lymphomas). The oncological manifestations are the following: table 1.
Table 1. Oncological manifestations Oncological manifestations Tumor quantification Total % Cutaneous Squamous Cell Carcinoma 4 7% Basal Cell Carcinoma 12 20% Breast Cancer 9 15% Prostate Cancer 12 20% Thyroid Cancer 6 10% Endometrial Cancer 3 5% Lung Cancer 1 2% Colon Cancer 4 7% Lymphoma No Hodgkin 1 2% Cervical Cancer 2 3% Kidney Cancer 1 2% Multiple Myeloma 1 2% Testicular Cancer 2 3% Tumoral Micosis Fungoide 1 2% Acute Myeloid Leukemia 1 2% Bladder Cancer 1 2% TOTAL 61 100% The epidemiological analysis of this group of patients showed an incidence for all types of malignancies of 3.098% in this population. The diagnosis of psoriasis preceded the oncological diagnosis in 50 of the patients studied.
Conclusions: The incidence of cancer in the general population in Argentina, according to the Ministry of Health is 172.3–242.9 per 100,000 inhabitants. In our study population, we found an incidence of 3.098%, which would support the hypothesis of an increased risk of developing cancer in patients with psoriasis. The risk was identical in both sexes and directly proportional to the degree of severity of the psoriasis.
Reference:
Pouplard C, Brenaut E, et al. Risk of cancer in psoriasis: a systematic review and meta-analysis of epidemiological studies. JEADV 27 (Suppl. 3), 36–46, 2013Ramos Mejia, Service of Dermatology

P014
HEMATOLOGICAL DISORDERS IN THE PATIENT WITH PSORIATIC ARTHRITIS TREATED WITH METHOTREXATE AND TUMOR NECROSIS ALPHA (TNFALPHA) INHIBITOR

Renata Sokolik[1], Aleksandra Butrym[2], Grzegorz Mazur[2], Piotr Wiland[1]
[1]Department and Clinic of Rheumatology and Internal Medicine, [2]Department and Clinic of Internal and Occupational Diseases and Hypertension, Wroclaw Medical University, Wroclaw Poland

Introduction: Non-Hodgkin lymphomas are a heterogenous group of neoplastic disorders characterized by clonal limphoid cell proliferation. They rank sixth among the cancers in terms of the frequency of occurrence in adults. Waldenstrom macroglobulinemia is lymphoplasmic hyperplasia with excessive production of monoclonal M-protein. According to literature data, patients with psoriasis have more frequent lymphomas than healthy population. The real risk of lymphoproliferative disease in psoriatic arthritis patients has not yet been defined.
Objectives: The aim of the study was to describe a case of a patient with psoriatic arthritis and concurent monoclonal gammopathy, who did not respond to treatment with TNFalpha inhibitor in combination with methotrexate.
Methods: A 57 year old woman with psoriasis and psoriatic arthritis diagnosed in 2012 (presence of HLA B27 antigen, arthritis of the sacroiliac joints, peripheral arthritis) with monoclonal gammopathy of undeterminated significance, was treated with non-steroid anti-inflammatory drugs, methotrexate (20 mg once a week), folic acid 15 mg and inhibitor of TNFalpha.
At the beginning of biological therapy she presented with laboratory results: ESR 126, total protein 8 g/dl, abnormal IgM 11.6 g/l (normal range 0.4–2.3 g/l), IgG 2.25 g/l (normal range 7–16g/l), IgA 0.32 g/l (normal range 0.7–4 g/l). Immunofixation test revealed possitivity for IgM kappa monoclonal protein. There were no abnormalities in the bone marrow aspiration biopsy, no lymphadenopathy was observed. She complained of general weakness and polineuropathy. Analysis of spino-cerebral fluid showed type V of oligoclonal band.
Results: In 2017, after 2 years of TNFalpha inhibitor combined with methotrexate therapy, the diagnosis of Waldenstrom macroglobulinemia has been done. The patient presented with high ESR 103 and monoclonal IgM 33 g/l. Repeated aspiration bone marrow biopsy showed 3% of plasmocytes and 21% of lymphocytes.
Conclusions: The patient started standard RCD chemotherapy regimen (rituximab, cyclophosphamide, dexamethason) with good clinical response to therapy.

P015
THE RELATIONSHIP BETWEEN PSORIASIS, COMORBIDITIES, AND DEPRESSION ONSET: A NATIONWIDE OBSERVATIONAL CONTROL STUDY

Kirk Geale[1], Martin Henriksson[2], Jussi Jokinen[3], Marcus Schmitt-Egenolf[1]
[1]Dermatology, Department of Public Health and Clinical Medicine, Umeå

University, Umeå, [2]Department of Medical and Health Sciences, Linköping University, Linköping, [3]Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

Introduction: Psoriasis is a complex, systemic disease associated with comorbidities extending beyond the skin, often affecting psychological well-being which may manifest as clinical depression. Psoriasis can be viewed narrowly by focusing on the skin, or holistically to include associated comorbidities. To date, the complex interplay between psoriasis, comorbidities, and depression has not been adequately described, and an innovative approach is necessary to understand interrelationship between them.
Objectives: Calculate incidence rates of depression in psoriasis patients compared to the general population and subsequently explore the risk factors associated with depression onset. Determine the contributions of comorbidities compared to narrowly defined, psoriasis-only symptoms.
Methods: 96,666 psoriasis patients were matched to 15 controls and followed from psoriasis onset until incident depression diagnosis or censoring using population-based routine care data. Incidence of depression was calculated using Poisson regression models. Risk of depression onset using a narrow definition of psoriasis was compared to a holistic definition including all comorbidities using a Cox proportional hazards model, with additional adjustment for sociodemographic factors. Comorbidities were represented by ICD chapters with more than 5% correlation with psoriasis. Sensitivity analysis examined the role of psoriatic arthropathy, alternative depression definitions, and searched for unobserved confounding.
Results: Patients with psoriasis have a higher incidence of clinical depression than those without the disease. Holistically, psoriasis was associated with an increased risk of depression onset of 40% (HR = 1.404, $p < 0.001$), compared to 12% increase (HR = 1.115, $p < 0.001$) when narrowly defined. The proportional hazards assumption appeared to hold in each survival analysis. A substantial portion, but not all, of psoriasis patients' risk of depression onset was attributable to comorbidities, and sociodemographic factors did not appear to affect the estimates of association between depression and psoriasis. Major differences were found between antidepressant- and diagnosis-based definitions of depression, while inclusion of psoriatic arthropathy did not affect the results. No unmeasured confounding was identified.
Conclusions: Due to the elevated risk of depression in psoriasis patients, treating physicians should ensure patients' psychological well-being is addressed, especially in those presenting with additional risk factors, to break the cyclical relationship between depression and psoriasis and improve patients' quality of life. Contemporary, holistic management of psoriasis patients should encourage routine screening for depression.

P016

EFFICACY OF ADALIMUMAB PLUS METHOTREXATE IN PATIENTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS

Ghasem Rahmatpour Rokni, Mohamad Goldust
Mazandaran University of Medical Sciences

Background: Adalimumab, a high-affinity monoclonal antibody that selectively targets tumor necrosis factor alpha, is efficacious in treating moderate-to-severe plaque psoriasis. Currently there are some reports regarding drug resistance to adalimumab (1,2).
Objective: This study aimed at evaluating the efficacy of adalimumab plus methotrexate in patients with moderate to severe plaque psoriasis.
Methods: In this cross sectional study, 23 patients suffering from moderate to severe psoriasis were recruited. Patients received adalimumab 80 mg week 0, 1 and then 40 mg every 2 weeks and methotrexate up to 25 mg/week. The primary outcome measure was the difference in Psoriasis area and severity index (PASI-75) response after 12 weeks. The secondary outcomes included PASI 75 at week 6 (onset of action) and week 12, Investigator's Global Assessment (IGA), Patient Global Assessment, impact on quality of life (Skindex-17 and SF-36), Treatment Satisfaction Questionnaire of Medication, duration of remission, maintenance treatment and safety.
Results: In the study group, 86.9% (20 out of 23 patients) reached PASI-75 at week 12. The longitudinal analysis showed a PASI reduction of 6.42% per week. The onset of action was achieved in 65.2%. At week 12, IGA 'clear or almost clear' was observed in 91.3% ($p < 0{\cdot}01$). Skindex-17 symptom score was significant with combination therapy ($p < 0{\cdot}01$). Maintenance treatment achieved PASI 75 for 82.6% ($p < 0{\cdot}01$). Mild adverse events were reported in 79.5%.
Conclusion: Combination therapy of adalimumab plus methotrexate is a highly effective, well-tolerated, maintenance therapy in patients with moderate to severe plaque psoriasis.
References:
1. Mease P, Hall S, FitzGerald O et al. Tofacitinib or Adalimumab versus Placebo for Psoriatic Arthritis. N Engl J Med 2017 Oct 19. 377;1537-1550.
2. Papp K, Bachelez H, Costanzo A et al. Clinical similarity of biosimilar ABP 501 to adalimumab in the treatment of patients with moderate to severe plaque psoriasis: A randomized, double-blind, multicenter, phase III study. J Am Acad Dermatol 2017 Jun. 1976;1093-1102.

P018

ATTAINMENT OF REMISSION AND MINIMAL DISEASE ACTIVITY AFTER STARTING METHOTREXATE SUBCUTANEOUS THERAPY

Elena Loginova, Tatiana Korotaeva, Elena Gubar, Svetlana Glukhova, Eugeny Nasonov
Nasonova Research Institute of Rheumatology, Moscow

Introduction: Methotrexate (MTX) is the first-choice therapy in psoriatic arthritis (PsA). There is limited data concerning efficacy of early administration and rapidly dose escalation of MTX subcutaneous (s/c) in early (E) PsA patients (pts).
Objective: to study attainment of remission (REM) or minimal disease activity (MDA) after starting MTX s/c therapy in EPsA pts treated according to treat-to-target (T2T) strategy.
Methods: 77 (M-37/F-40) pts with active EPsA, according to the CASPAR criteria were included. Mean age 37.4±10.8 years (yrs.), PsA duration 11±10 months (mon.), psoriasis duration 86±96.1 mon., DAPSA 32.45±12.7. At baseline all pts started MTX s/c therapy. The dose of MTX s/c was escalated by 5 mg every 2 weeks from 10 mg/wk to appropriate dose 20–25 mg/wk according to the drug intolerance. If the patient did not achieve remission or MDA on MTX mono-therapy, biological (b)DMARDs was added. At baseline and every 3 mon. of study (till 24 mon.) all pts underwent assessment of PsA activity by DAPSA and MDA criteria (tender joint count ≤1, swollen joint count ≤1, PASI ≤1 or BSA ≤3, patient pain global assessment VAS ≤15, patient´s global disease activity VAS ≤20, HAQ ≤0.5, enthesitis count ≤1). The proportion of pts who achieved REM by DAPSA ≤4 and MDA (5 of 7 cutpoints), the timing of REM/MDA, the mean dose of MTX during the study were performed. M±SD, Me [Q75; Q50], (%), W-test were calculated. All $p < 0.05$ were considered to indicate statistical significance.
Results: 36 out of 77 pts (46.75%) did not achieve REM or MDA in MTX therapy within 7±5 mon. and bDMARDs were added. 5 out of 77 pts (6.5%) stopped MTX therapy due to intolerance within 6±2 mon. 36 out of 77 pts (46.75%) went on taking MTX-monotherapy. In 22 out of 36 pts, who had mean DAPSA 27.7±10.0 at baseline, data was available by the 24 mon. of study. At baseline median dose of MTX s/c was 15 [10;20], Min 10–Max 20 mg/wk. At the third mon. of study median dose of MTX s/c was escalated to 20 [20;20], Min 0–Max 25 mg/wk. After attainment of REM/MDA the dose of MTX was decreased. At the end of the study median dose of MTX s/c was 7.5 [0;15], Min 0–Max 20

mg/wk (fig.1). After starting MTX disease activity by DAPSA significantly decreased by the third mon. and maintained till the end of the study (fig.2). DAPSA-REM and MDA was reached within 9.7±7.7 and 13.7±7.6 mon. accordingly. By the 24 mon. of therapy stable REM by DAPSA and MDA was seen in 10 out of 22 pts (45.5%) and in 16 out of 22 pts (72.7%) accordingly.
Conclusions: In half of EPsA pts early administration of MTX s/c and rapidly dose escalation is effective and well tolerated. After achieving REM or MDA, a decrease of the dose of MTX is possible in most cases.

P019

SECUKINUMAB IN PREGNANCY: OUTCOMES IN PSORIASIS, PSORIATIC ARTHRITIS AND ANKYLOSING SPONDYLITIS FROM THE GLOBAL SAFETY DATABASE

Richard Warren[1], Kristian Reich[2], Richard Langley[3], Bruce Strober[4], Dafna Gladman[5], Atul Deodhar[6], Teresa Bachhuber[7], Weibin Bao[8], Evelyn Altemeyer[9], Samina Hussain[10], Jorge Safi[8]
[1]The Dermatology Centre, Salford Royal NHS Foundation Trust, The University of Manchester, UK, [2]Dermatologikum Berlin and Georg-August-University Gottingen, Germany, [3]Dalhousie University, Halifax NS, Canada, [4]University of Connecticut Health Center, Farmington, CT, USA and Probity Medical Research, Canada, [5]Toronto Western Hospital, Toronto, Canada, [6]Division of Arthritis & Rheumatic Diseases, Oregon Health & Science University, USA, [7]Novartis Pharma GmbH, Nuremberg, Germany, [8]Novartis Pharmaceuticals Corporation, East Hanover, USA, [9]Novartis Ireland Ltd, Dublin, Ireland, [10]Novartis Healthcare Pvt. Ltd, Hyderabad, India

Introduction: Secukinumab, a fully human monoclonal antibody selectively targeting IL-17A, is highly efficacious in the treatment of moderate to severe psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS), with sustained efficacy and favorable safety profile. Long term treatment with targeted therapies such as secukinumab may be necessary in women of childbearing age. Pre-clinical animal studies with secukinumab, which can cross the placenta, do not indicate harmful effects with respect to pregnancy, embryonic/fetal development, parturition or postnatal development, however only limited data has been reported on human pregnancies.
Objectives: Using the Novartis global safety database, we analyzed the outcome of pregnancies where there was maternal or paternal exposure to secukinumab.
Methods: The Novartis global safety database (covering all secukinumab indications and including clinical trial and post-marketing data) was searched for cases reporting pregnancy and neonatal topics. All pregnancies where there was either maternal or paternal exposure to secukinumab were included in the systematic, independently validated analysis. The cut-off date was 25th June, 2017.
Results: Of 292 pregnancies reported, 141 (48.3%) came from clinical trials, 79 (27.1%) were spontaneous reports and 72 (24.7%) were from post-marketing surveillance, with 238 cases of maternal and 54 cases of paternal exposure. 175 patients received secukinumab for psoriasis, 38 for PsA, 15 for AS and 62 for other/unknown indications. The majority of patients discontinued secukinumab in the first trimester of pregnancy; 18 did not discontinue. Of 153 cases where the outcome was known, there were 73 full term normal neonates and 37 elective terminations. Rates of spontaneous abortions were 30/292, 10.3% overall (30/153 known outcomes, 19.6%). These are in line with previously reported rates (15–20%) for the general population with maternal age of 30.6 (study mean). No still births (> 20 weeks) were reported. Three congenital abnormalities were reported following maternal and 1 paternal exposure, with no repeated pattern of abnormality. At data cut-off, 32 pregnancies were ongoing.
Conclusions: There was no evidence for increased rates of adverse pregnancy outcomes across indications with secukinumab in this review of the safety database. Given the limited exposure reported to date, the safe continuous use of secukinumab throughout pregnancy requires further research.

P020

IXEKIZUMAB IMPROVES IMPACT OF GENITAL PSORIASIS ON SEXUAL ACTIVITY: RESULTS FROM A PHASE 3B STUDY

Jennifer Clay Cather[1], Kim Meeuwis[2], Russel Burge[3], Alison Potts Bleakman[3], Chen-Yen Lin[3], Alice Gottlieb[4], Catriona Ryan[5]
[1]Modern Dermatology and Modern Research Associates, Dallas, TX, USA, [2]Radboud University Medical Center, Nijmegen, The Netherlands, [3]Eli Lilly and Company, Indianapolis, IN, USA, [4]Department of Dermatology, New York Medical College at Metropolitan Hospital, New York, NY, USA, [5]St. Vincent's University Hospital, Dublin, Ireland

Introduction: Genital psoriasis (GP) is often associated with impaired sexual health. Ixekizumab (IXE) is a high-affinity monoclonal antibody that selectively targets interleukin-17A.
Objective: To evaluate the effect of IXE on the impact of GP on sexual activity during 12 weeks of treatment compared to placebo (PBO) in patients with moderate-to-severe GP.
Methods: In this double-blind, placebo-controlled study, patients ($n = 149$) with moderate-to-severe GP were randomized (1:1) to receive PBO or 80 mg IXE every 2 weeks following an initial dose of PBO or 160 mg IXE. The impact of GP on sexual activity was measured by pre-specified patient-reported outcomes including the Genital Psoriasis Sexual Impact Scale (GPSIS), which is composed of the Sexual Activity Avoidance (Avoidance) and Impact of Sexual Activity on Genital Psoriasis Symptoms (Impact) subscales, the Sexual Frequency Questionnaire (SFQ) item 2, and the Dermatology Life Quality Index (DLQI) item 9. Of patients with a baseline SFQ item 2 score ≥2, the percentage of patients whose frequency of sexual activity was never (0) or rarely (1) limited by GP (SFQ item 2 0/1) was examined. Among patients with respective GPSIS subscale scores ≥3 at baseline, response was measured as the percentage of patients whose frequency of avoiding sexual activity was never (1) or rarely (2) impacted by GP (GPSIS-Avoidance 1/2) and whose GP symptom worsening after sexual activity was very low/none at all (1) or low (2) (GPSIS-Impact 1/2). DLQI item 9 response was measured as the percentage of patients with no (0) or a little (1) impairment of sexual activity. Treatment comparisons were made using a logistic regression model with missing values imputed by non-responder imputation.
Results: IXE treatment reduced the impact of GP on sexual activity at Week 12 versus PBO as assessed by SFQ item 2 0/1 (IXE 78.4%, PBO 21.4%; $p < 0.001$), GPSIS-Avoidance 1/2 (IXE 76.7%, PBO 25.7%; $p < 0.001$), and DLQI item 9 0/1 (IXE 92.0%, PBO 56.8%; $p < 0.001$). IXE was superior to PBO as early as Week 1 for SFQ item 2 0/1 ($p < 0.05$), Week 2 for DLQI item 9 0/1 ($p < 0.001$), and Week 4 for GPSIS-Avoidance 1/2 ($p < 0.01$). GPSIS-Impact 1/2 response rates suggested a trend of reduced impact of sexual activity on GP symptoms (IXE 85.7%, PBO 52.9%; $p = 0.062$).
Conclusions: During 12 weeks of treatment, IXE resulted in a rapid and significant decrease in the impact of GP on sexual activity, including how often GP limited sexual frequency among patients with moderate-to-severe GP.
Cather J, Meeuwis K, Burge R, Bleakman AP, Lin C-Y, Ryan C. Ixekizumab Provides Greater Improvement Versus Placebo on the Impact of Genital Psoriasis on Sexual Activity for Patients with Moderate-to-Severe Genital Psoriasis in a Randomized, Double-Blind Phase 3b Clinical Trial. American Academy of Dermatology-76th Annual Meeting 2018.

P021

DOSE OPTIMIZATION OF SECUKINUMAB IN SUBJECTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS: OPTIMISE STUDY

Kristian Reich[1], Lluis Puig[2], Jacek Szepietowski[3], Carle Paul[4],

Michael Rissler[5], Christian Sieder[6], Roberto Orsenigo[7], Kamel Chaouche-Teyara[5]

[1]SCIderm Research Institute Hamburg and Dermatologikum Berlin, Germany, [2]Department of Dermatology, Hospital de la Santa Creu I Sant Pau, Barcelona, Spain, [3]Department of Dermatology, Venereology and Allergology, Wroclaw Medical University, Wroclaw, Poland, [4]Department of Dermatology, Larrey University Hospital, Toulouse, France, [5]Novartis Pharma AG, Basel, Switzerland, [6]Novartis Pharma GmbH, Nuernberg, Germany, [7]Novartis Farma S.p.A, Origgio, Italy

Introduction: Secukinumab is a fully human monoclonal antibody that selectively neutralizes IL-17A, a key cytokine involved in the development of psoriasis. Heterogeneity in clinical response to targeted therapies such as secukinumab may be addressed by flexible dosing.

Objectives: To compare downtitration of PASI90 responders to 6-weekly and uptitration of PASI≥75 to <90 responders to two-weekly secukinumab dosing with standard 4-weekly dosing.

Methods: OPTIMISE was a randomized, multicenter, open-label, rater blinded Phase 3b study. 1647 subjects received secukinumab 300 mg at baseline, Weeks 1, 2, 3 and 4 then 4-weekly to Week 24. At Week 24, PASI90 responders were randomized to secukinumab 300 mg q4w ($n=644$) or q6w ($n=662$) to Week 52; PASI≥75 to <90 responders were randomized to secukinumab 300 mg q4w ($n=114$) or 2-weekly (q2w) ($n=92$) to Week 52. Groups were stratified by body weight (<90kg, ≥90kg).

Results: PASI90 response was maintained at Week 52 by 85.7% subjects with q4w dosing vs 74.9% with q6w dosing; OR 1.91 (95% CI 1.44, 2.55). The primary endpoint, non-inferiority of q6w vs q4w dosing in PASI90 responders, was not met. In PASI≥75 to <90 responders, 46.5% of subjects achieved PASI90 response by Week 52 with q4w dosing. PASI90 response at Week 52 was numerically higher for q2w compared to q4w dosing (56.5% vs. 46.5%), but this difference did not reach statistical significance ($p=0.1013$). This numerical benefit of q2w dosing was even higher in subjects weighing ≥ 90 kg ($n=49$; 57.1% vs. 39.6%; $p=0.1053$). No new or unexpected safety signals were observed.

Conclusions: Non-inferiority of q6w vs. q4w dosing cannot be claimed in maintaining PASI90 response achieved at Week 24. Around half of PASI≥75 to <90 responders at 24 weeks, can achieve PASI90 response with continued q4w dosing. Subjects with higher body weight may benefit from the q2w dosing.

P022

INHIBITION OF ANTI-TNF-ALPHA CYTOKINE IN THE TREATMENT OF PSORIASIS AND THE ANALYSIS OF INFECTIOUS COMPLICATIONS

Tatiana Péčová, Karolína Vorčáková[1], Marián Grendár[2], Juraj Péč[1]

[1]Department of Dermatovenereology, [2]Biomedical Center Martin, Jessenius Faculty of Medicine in Martin, Comenius University in Bratislava, Slovakia

Introduction: TNF-alpha cytokine plays an important role in the regulation of activation, proliferation, differentiation and apoptosis of the immune cells. It is an important therapeutical target in the treatment of chronic plaque psoriasis. From its other roles, it plays key part in formation and maintenance of granuloma through the increased fagocytic capacity of macrophages and eradication of intracellular pathogens, therefore its inhibitors pose a risk for granulomatous infections and reactivation of latent tuberculosis.

Objectives: The main focus was to assess the infectious complications of biologic anti-TNF-alpha treatment of chronic plaque psoriasis with focus on the tuberculosis and reactivation of its latent form. Moreover, the authors tried to establish possible risk factors on the reactivation of latent tuberculosis.

Methods: The authors analyzed the group of 190 patients from Middle-European population treated with TNF-alpha inhibitors, as compared to other biologics, for the occurence of infectious complications. Interferon-gamma release assay (IGRA) test was performed before the start of the treatment and then every year, in accordance with The Tuberculosis Network European Trials Group (TBNET) consensus. Statistical analysis was performed on the results.

Results: 3% of patients had permanently positive IGRA test (before and after beginning of the treatmet) and in 28% of patients treated by TNF inhibitors, conversion of IGRA test appeared with negative test before treatment and positive test after administration of biologics. No active tuberculosis was detected. The average time of IGRA conversion was 3 years after beginning of treatment. The only statistically significant predictor was age, with an increase of age by one year associated with the 5.8% increase of risk of IGRA conversion. Regarding other infectious complications, the most common infections in patients treated with biologics were respiratory and HPV infections. No severe infection leading to the permanent discontinuation of treatment was observed.

Conclusions: Treatment with TNF-alpha inhibitors was associated with statistically significant risk of IGRA test conversion. The only established predictor of risk was age of patient, with no influence of previous or concomittant systemic tretament. However, the limitation was size of group of patients. The most common infections were common respiratory infections and viral HPV infections.

References:

Andersen P, Munk ME, Polock JM et al. Specific immune-based diagnosis of tuberculosis. Lancet 2000; 356:1099-1104.

Bieber J, Kavanaugh A. Tuberculosis and opportunistic infections: relevance to biologic agents. Clin Exp Rheumatol. 2004; 22:126-133.

Doherty SD, Van Voorhees A, Lebwohl MG, et al. National Psoriasis Foundation consensus statement on screening for latent tuberculosis infection in patients with psoriasis treated with systemic and biologic agents. J Am Acad Dermatol 2008; 59:209-217.

Drago L, Nicola L, Signori V et al. Dynamic QuantiFERON response in psoriasis patients taking long-term biologic therapy. Dermatol Ther 2013; 3:73-81.

Hernandez C, Cetner AS, Jordan JE, et al. Tuberculosis in the age of biologic therapy. J Am Acad Dermatol 2008; 9:363-380.

Solovič I, Sester M, Gomez-Reino JJ, et al. The risk of tuberculosis related to tumour necrosis factor antagonist therapies: a TBNET consensus statement. Eur Respir J 2010; 36:1185-1206.

P023

TREATMENT USE AND SATISFACTION AMONG PATIENTS WITH PSORIASIS AND PSORIATIC ARTHRITIS IN SCANDINAVIA

Kåre Steinar Tveit[1], Albert Duvetorp[2], Mikkel Østergaard[3], Lone Skov[4], Kjersti Danielsen[5], Lars Iversen[6], Oliver Seifert[7]

[1]Haukeland University Hospital, Bergen, Norway, [2]Linköping University, Linköping, Sweden; Skånes Universitetssjukhus, Malmö, Sweden, [3]Copenhagen Center for Arthritis Research, Center for Rheumatology and Spine Diseases, Rigshospitalet, Glostrup, University of Copenhagen, Copenhagen, [4]Herlev and Gentofte Hospital, University of Copenhagen, Copenhagen, Denmark, [5]UiT The Arctic University of Norway, Tromsø, Norway; University Hospital of North Norway, Tromsø, Norway, [6]Aarhus University Hospital, Aarhus, Denmark, [7]Linköping University, Linköping, Sweden; Ryhov Hospital, Jönköping, Sweden

Introduction: Patients' perspectives on psoriasis (PsO) and psoriatic arthritis (PsA) treatment are important in establishing better approaches to their care.

Objectives: To assess treatment use and satisfaction among patients with PsO/PsA in Scandinavia.

Methods: NORPAPP was an on-line survey carried out in Nov/Dec 2015 using YouGov panels in Sweden, Denmark, and Norway. Adults with physician-diagnosed PsO or PsA ($n=1221$), answered questions about contact with the healthcare system, and treatment experience and satisfaction. Self-perceived disease severity was dichotomised to severe (responses of "quite severe", "very severe" or "extremely severe") and non-severe ("not particularly severe" or "not severe at all").

Results: Among respondents with PsO alone 38.9% had seen a dermatologist in the past year, and 10.7% had never seen a dermatologist; 60.9% of those with PsA±PsO had seen a rheumatologist in the past year; 14.3% had never seen a rheumatologist. Systemic treatments had been used by 14.6% of respondents with PsO alone and 58.5% with PsA±PsO. Respondents with self-perceived severe symptoms and patient organization members (POMs) were more likely than those with non-severe symptoms or non-members, to have discussed systemic treatments with their physician and to have used the treatments; however, 35.2% of respondents with self-perceived severe symptoms had never discussed systemic treatment with their physician. Asked about long-term health risks of systemic treatments, 18–44 year-olds and POMs were less likely to answer "don't know" than 45–74 year-olds (47.7%–49.1% vs 66.7%–72.9%) or non-members (26.1%–30.7% vs 66.8%–70.4%). Biologics had been used by 40.7% of POMs vs 6.9% of non-members, and 21.5% of 18–44 year-olds vs 8.1% of 45–74 year-olds. Among respondents using oral/injectable methotrexate 30.5% were dissatisfied, 60.2% citing side-effects as the reason; 22.9% of biologics users were dissatisfied, 28.9% citing lack of effect and 28.1% citing side-effects.
Conclusion: In Scandinavia POMs and young patients are more likely to receive systemic treatment. A high proportion of patients are dissatisfied with their treatment because of side effects.

P024

FIRST PATIENT-REPORTED INSIGHTS FROM A MULTINATIONAL, RETROSPECTIVE, CROSS-SECTIONAL STUDY OF REAL-WORLD EXPERIENCE OF PSORIASIS PATIENTS TREATED WITH APREMILAST IN CLINICAL DERMATOLOGY PRACTICE (APPRECIATE)

Matthias Augustin[1], Marc Alexander Radtke[1], Kilian Eyerich[2], Mona Ståhle[3], Christine Bundy[4], Myriam Cordey[5], Volker Koscielny[5], C. Elise Kleyn[6], Christopher EM Griffiths[6]
[1]Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf, Hamburg, [2]Department of Dermatology and Allergy, Technical University of Munich, Munich, Germany, [3]Department of Medicine, Karolinska Institute, Solna, Sweden, [4]School of Healthcare Sciences, College of Biomedical and Life Sciences, Cardiff University, Cardiff, UK, [5]Celgene International, Boudry, Switzerland, [6]Dermatology Centre, Salford Royal NHS Foundation Trust, University of Manchester, Manchester Academic Health Science Centre, Manchester, UK

Introduction: Patient (pt)-centered care is gaining traction in long-term disease management. We report on a multinational, retrospective, cross-sectional study in psoriasis pts treated with apremilast (APR), an oral phosphodiesterase 4 inhibitor, in a real-world clinical setting.
Objectives: The study aims to identify important pt needs and therapeutic benefits of APR.
Methods: Consecutive pts with chronic plaque psoriasis treated according to routine clinical practice who could be contacted 6±1 mo after APR initiation were enrolled. Medical chart review, standardized pt-reported outcome tools (PBI, TSQM-9), and pt/physician questionnaires were used. An interim analysis of the first 104 pts from 40 sites in Germany (42), UK (31), and Sweden (31) was performed using predefined descriptive statistics.
Results: 102 pt questionnaires were analyzed (98%). At 6±1 mo, 74 pts (71%) continued APR; 30 (29%) had discontinued APR (lack of efficacy [14%], safety/tolerability [11%], other [4%]). Assessment of pts' main needs from a therapy (quite/very important on the PBI) revealed the importance pts attributed to skin involvement (93% of responders), confidence in healing (92%), being itch free (85%), fewer side effects (84%), being able to lead a normal everyday life (83%), and needing less time for daily treatment (80%). Based on a clinically meaningful PBI score ≥1, 78% of pts achieved a benefit with APR after 6 mo. Mean (SD) PBI score was 2.2 (1.3) and increased to 2.5 (1.2) for pts on continued APR at 6 mo vs 1.6 (1.3) for pts who discontinued APR. Pts achieved benefit related to skin involvement (60%), confidence in healing (70%), itch (69%), side effects (60%), being able to lead a normal everyday life (72%), and needing less time for daily treatment (65%). Consistent with phase 3 studies, most frequently reported AEs were diarrhea (19.2%), nausea (16.4%), and headache (11.5%); 25% of pts reported weight loss (no change, 71%; gain, 4%).
Conclusions: This interim analysis indicates main pt needs from a therapy extend beyond skin improvement. Findings indicate APR may address diverse pt needs.
Prior Presentation: EADV 2017

P025

PHYSICIAN- AND PATIENT-REPORTED OUTCOMES WITH APREMILAST FOR PATIENTS WITH PLAQUE PSORIASIS DURING ROUTINE DERMATOLOGY CARE IN GERMANY: A SECOND INTERIM ANALYSIS

Kristian Reich[1], Stefanie Bomas[2], Bernhard Korge[3], Uwe Schwichtenberg[4], Hannah Mentz[5], Kathrin Groegel[5], Natalie Núnez Gómez[5]
[1]Dermatologikum Hamburg and SCIderm Research Institute, Hamburg, [2]Praxis Dr. med. S. Rotterdam, Gelsenkirchen-Feldmark, [3]Priv. Doz. Dr. med. Korge, Düren, [4]Derma Nord Hautarztpraxen Dr. med. Schwichtenberg, Bremen, [5]Celgene GmbH, Munich, Germany

Introduction: LAPIS-PSO is an ongoing, 52-week, prospective, multicenter, observational cohort study in real-world dermatology clinical settings in Germany.
Objectives: To present a 4-month interim analysis of patient (pt)-reported outcomes and efficacy assessments of apremilast (APR) among pts ($n = 294$; full analysis set [FAS], $n = 196$) who were continuing APR at 4 mo.
Methods: Physician- and pt-reported outcomes for QOL, treatment effectiveness, and treatment satisfaction were evaluated in pts with psoriasis vulgaris during long-term APR treatment. The primary endpoint at Visit 2 (~4 mo after baseline [BL]) is the proportion of pts who achieve DLQI score ≤5 or improvement from BL in DLQI score ≥5 points.
Results: At BL, mean (SD) age was 51.7 (13.20) years in the FAS; 90 pts (45.9%) were female. At APR initiation, 171 pts (87.3%) had Physician's Global Assessment of disease severity (PGA) ≥3 and 174 (89.2%) had Patient's Global Assessment of disease severity (PaGA) ≥3; mean psoriasis-involved BSA was 22.2%, mean pruritus VAS score was 56.6 mm, and mean DLQI score was 14.1. In all, 62.7% of pts had scalp PGA (ScPGA) ≥3; 42.5% had palmoplantar PGA (PPPGA) ≥3. Among pts continuing APR at 4 mo, 120/181 (66.3%) achieved DLQI score ≤5 or reduction by ≥5 points. Mean (SD) improvement in BSA was −9.5% (14.91) and mean (SD) percentage improvement in pruritus VAS score was −47.3% (32.29). A total of 32.1% of pts achieved PGA 0 (clear) or 1 (minimal); 32.6% achieved PaGA 0 or 1. NAPSI-50 was achieved by 62.4% (53/85) of pts. In all, 58.4% (87/149) of pts achieved ScPGA 0 or 1 and 69.0% (29/42) had PPPGA 0 or 1. AEs were consistent with the known safety profile of APR. Eighty pts (27.8%) reported ≥1 AE; 1 AE occurred in ≥5% of pts (diarrhea, $n = 21$ [7.3%]).
Conclusion: In routine clinical care in Germany, APR treatment outcomes for pts with psoriasis vulgaris, including difficult-to-treat locations such as the nails, scalp, palms, and soles, confirm the broad efficacy of APR observed in clinical trials.
Prior Presentation: AAD 2018

P026

IMPROVEMENTS IN WORK PRODUCTIVITY WITH UP TO 104 WEEKS OF APREMILAST MONOTHERAPY: RESULTS FROM A PHASE 3B, RANDOMIZED, CONTROLLED STUDY IN BIOLOGIC-NAIVE SUBJECTS WITH ACTIVE PSORIATIC ARTHRITIS

Philip J. Mease[1], Dafna D. Gladman[2], Eric K. Davenport[3], Xiaolei Zhou[3], Benoit Guerette[4], Lichen Teng[4], Satyin Kaura[4], Peter Nash[5]
[1]Swedish Medical Center and University of Washington School of Medicine, Seattle, WA, USA, [2]Krembil Research Institute, Toronto Western Hospital, Toronto, ON, Canada, [3]RTI Health Solutions, Research Triangle Park, NC, USA, [4]Celgene Corporation, Summit, NJ, USA, [5]University of Queensland, Brisbane, Australia

Introduction: PsA patients may have impaired functioning in home or work activities. The phase 3b ACTIVE study assessed efficacy of apremilast (APR) monotherapy in biologic-naive subjects with active PsA who may have had exposure to 1 conventional DMARD.
Objectives: Assess work productivity through Wk104.
Methods: Subjects were randomized (1:1) to APR 30 mg BID or placebo (PBO). Subjects whose SJC/TJC did not improve ≥10% at Wk16 were eligible for early escape. At Wk24, remaining PBO subjects switched to APR. Work productivity and activity impairment were assessed at baseline (BL) and Wk16 using the WPAI:PsA; WPAI:PsA Absenteeism, Presenteeism, Work Productivity Loss, and Activity Impairment subscale scores range from 0% to 100%; higher scores indicate greater impairment. Work-related subscales were assessed in employed subjects; activity impairment was assessed in all subjects. Correlations were examined at Wk16 between WPAI:PsA subscale and SF-36v2 domain scores (Physical Functioning [PF], Bodily Pain [Pain], and Vitality [VIT]) associations with ACR20 response. Work productivity improvement was assessed to Wk104.
Results: BL characteristics were similar between groups. At Wk16, APR improved work productivity and ability to carry out daily activities vs PBO, with greater mean improvements in overall Work Productivity Loss ($p = 0.001$) and Activity Impairment ($p < 0.001$). Estimated mean change in Absenteeism score was similar with APR vs PBO ($p = 0.679$). The Presenteeism score showed significant improvement with APR vs worsening with PBO (−10.8% vs 4.1%; $P = 0.002$). At Wk16, statistically significant correlations were observed between WPAI:PsA subscale (except Absenteeism) and SF-36v2 domain scores, as were associations with ACR20 response. In subjects randomized to APR at BL, Wk16 improvements were generally maintained to Wk104 in those continuing APR.
Conclusions: In biologic-naive subjects with PsA, APR contributed to overall improvement in work productivity at Wk16, which correlated with SF-36v2 PF, Pain, and VIT scores and was associated with ACR20 response; improvements in WPAI:PsA subscale scores were generally maintained to Wk104.
Prior Presentation: EULAR 2018

P027

EXAMINING DISEASE SEVERITY AND SYMPTOM IMPROVEMENT WITH PATIENT AND PHYSICIAN ASSESSMENTS: RESULTS FROM A PHASE IV ANALYSIS OF APREMILAST IN PATIENTS WITH MODERATE PLAQUE PSORIASIS

Mark Lebwohl[1], J. Mark Jackson[2], Jerry Bagel[3], Eugenia Levi[4], Jerry Weaver[4], Linda Stein Gold[5], Ali Alikhan[6], Seth Forman[7], Benjamin Lockshin[8], Kristina Callis Duffin[9]
[1]Icahn School of Medicine at Mount Sinai, New York, NY, [2]University of Louisville, Forefront Dermatology, Louisville, KY, [3]Psoriasis Treatment Center of Central New Jersey, East Windsor, NJ, [4]Celgene Corporation, Summit, NJ, [5]Henry Ford Health System, West Bloomfield, MI, [6]University of Cincinnati, Department of Dermatology, Cincinnati, OH, [7]Forward Clinical Trials, Tampa, FL, [8]DermAssociates, Rockville, MD, [9]University of Utah, Salt Lake City, UT, USA

Introduction: UNVEIL is the first study of apremilast in patients (pts) with moderate psoriasis (BSA 5%-10%) naive to biologic and systemic therapy.
Objectives: Improvements on physician and pt assessments over 52wks are described.
Methods: Pts with chronic moderate plaque psoriasis (BSA 5%-10%; sPGA = 3 [0–5 scale]) were randomized (2:1) to apremilast 30 mg BID (APR) or placebo (PBO) for 16wks. Pts continued APR (APR/APR) or switched from PBO to APR (PBO/APR) through Wk52 (open-label treatment). Physician assessments were product of sPGA and BSA (PGAxBSA), proportion of pts who achieved sPGA score 0 (clear) or 1 (almost clear) and PGAxBSA-75 (≥75% improvement from baseline [BL]). Pt assessments were Dermatology Life Quality Index (DLQI), pruritus VAS (0–100 mm), Treatment Satisfaction Questionnaire for Medication (TSQM), and Pt's Global Assessment (PtGA [0–4 scale]).
Results: In randomized pts (PBO $n = 73$; APR $n = 148$), mean BL BSA was 7.2%, PGAxBSA was 21.8, DLQI was 11.0, and pruritus VAS was 56.6mm. At Wk16, mean improvement in PGAxBSA was greater with APR vs PBO (−48.1% vs −10.2%; $P < 0.0001$); more pts achieved sPGA 0 or 1 and PGAxBSA-75 with APR vs PBO (30.4% vs 9.6% and 35.1% vs 12.3%). At Wk16 achievement of DLQI response (≥5-point decrease in pts with BL DLQI > 5) was greater with APR vs PBO (63.8% vs 34.5%), as were pruritus VAS response (improvement ≥20%: 62.8% vs 45.2%) and TSQM global satisfaction (63.2 vs 48.7) and effectiveness (57.3 vs 38.8). More pts had PtGA ≤1 with APR vs PBO (33.8% vs 20.5%). At Wk52, PGAxBSA changes were −42.2% (PBO/APR) and −55.5% (APR/APR); 45.3% (PBO/APR) and 42.1% (APR/APR) of pts achieved PGAxBSA-75, 35.9% (PBO/APR) and 33.1% (APR/APR) achieved sPGA response, 55.6% (PBO/APR) and 59.4% (APR/APR) achieved DLQI response, and 68.8% (PBO/APR) and 66.9% (APR/APR) achieved pruritus VAS response. TSQM global satisfaction (PBO/APR 59.2; APR/APR 59.9) and effectiveness (PBO/APR 57.7; APR/APR 54.1) were similar between groups at Wk52; 42.2% (PBO/APR) vs 37.2% (APR/APR) had PtGA ≤1.
Conclusion: Physician and pt assessments improved with APR up to 52wks in biologic- and systemic-naive pts with moderate psoriasis.
Prior Presentation: AAD 2018

P028

HEMOGLOBIN A1C AND WEIGHT CHANGES WITH APREMILAST IN PATIENTS WITH PSORIASIS AND PSORIATIC ARTHRITIS: POOLED LABORATORY ANALYSIS OF THE PHASE 3 ESTEEM AND PALACE TRIALS

Luis Puig[1], Neil Korman[2], Chiara Greggio[3], Joshua Cirulli[3], Lichen Teng[3], Vinod Chandran[4], Majed Khraishi[5], Nehal N. Mehta[6]
[1]Hospital de la Santa Creu i Sant Pau, Barcelona, Spain, [2]Case Western University and University Hospitals Cleveland Medical Center, Cleveland, OH, [3]Celgene Corporation, Summit, NJ, [4]University of Toronto and Krembil Research Institute, University Health Network, Toronto, ON, Canada, [5]Memorial University of Newfoundland, St. Johns, NL, Canada, [6]National Heart, Lung and Blood Institute, Bethesda, MD

Introduction: Psoriasis and psoriatic arthritis (PsA) are associated with high prevalence of obesity and metabolic syndrome. In phase 3 trials, apremilast, an oral PDE4 inhibitor, was efficacious in patients (pts) with moderate to severe plaque psoriasis (ESTEEM 1 and 2 [EST]) and active PsA (PALACE 1–3 [PAL]).
Objectives: To explore potential effects of apremilast on metabolic parameters, we assessed weight change and A1c in pts receiving placebo (PBO) or apremilast 30 mg twice daily (APR) in a pooled analysis of EST and PAL.

Methods: Mean A1c change and mean percent weight change at Wk16 were compared among pts with baseline (BL) A1c < 5.7%, 5.7% to 6.4% (prediabetes), and ≥6.5% (diabetes) and between pts reporting/not reporting concomitant insulin use. Spearman rank correlations between percent change from BL in weight and change in A1c at Wk16 were calculated; $p < 0.05$ was considered significant.
Results: In the pooled EST-PAL population, 2,242 pts (PBO $n = 913$; APR $n = 1,329$) received study medication at BL. In all, 230 pts had BL A1c ≥6.5%. At Wk16, A1c change in pts with BL A1c < 5.7% was 0.02 with PBO and 0.04 with APR. In pts with BL A1c 5.7% to 6.4%, small changes were observed (PBO −0.07; APR −0.12). Greatest A1c changes were in pts with BL A1c ≥6.5% (PBO −0.08; APR −0.31). At Wk16, mean weight change was 0.11% (PBO) and −1.32% (APR). In pts reporting and not reporting concomitant insulin use, mean weight change was 0.05% and 0.12% with PBO, respectively, and −1.83% and −1.31% with APR. Weight change in pts with BL A1c < 5.7%, 5.7% to 6.4%, and ≥6.5% was 0.02%, 0.26%, and 0.11% with PBO, respectively, and −1.24%, −1.35%, and −1.68% with APR. Correlations between changes in weight and A1c were generally low, with greater correlation in APR pts with higher BL A1c. Correlation was statistically significant in APR pts with BL A1c ≥6.5%.
Conclusion: With APR, decreases in weight and A1c were greater in pts with higher BL A1c. Pts receiving APR and insulin had weight loss despite the association between insulin use and weight gain. Future studies may be warranted to determine whether reductions in A1c with APR are independent of weight loss.
Prior presentation: AAD 2018

P029

CANADIAN HUMIRA POST-MARKETING OBSERVATIONAL EPIDEMIOLOGICAL STUDY ASSESSING THE EFFECTIVENESS OF ADALIMUMAB VS NON-BIOLOGIC DMARDS IN PSORIATIC ARTHRITIS (COMPLETE-PSA): 12-MONTH EFFECTIVENESS DATA

Majed Khraishi[1], Louis Bessette[2], Andrew Chow[3], Boulos Haraouil[4], Viktoria Pavlova[5], Jacqueline Stewart[6], Valencia Remple[7]
[1]Memorial University of Newfoundland, St. John's NL, [2]Laval University, Centre Hospitalier de l'Université Laval, Quebec QC, [3]University of Toronto ON, [4]Centre hospitalier de l'Université de Montréal, Montreal QC, [5]McMaster University, Hamilton ON, [6]University of British Columbia, Penticton BC, [7]AbbVie Corporation, Montreal QC, Canada

Background: Observational studies comparing the effectiveness of adalimumab (ADA) to non-biologic DMARDs (nbDMARD) in PsA patients failing prior treatment are scarce. COMPLETE-PSA is a Canadian observational study which assessed effectiveness of ADA and non-biological therapies (NSAIDs and DMARDs) among PsA patients failing previous therapy.
Objectives: To describe the baseline (BL) demographic and disease parameters and to compare 12-month real-life effectiveness of patients initiating nbDMARD or ADA.
Methods: Eligible patients eligible are anti-TNFα naïve adults, with active PsA requiring a treatment regimen change, per the treating physician's judgment. This analysis included patients enrolled during Jul/2011–Jun/2016. Outcome measures analyzed were: DAS28, SF-12, DLQI, presence of extra-articular manifestations (EAMs; enthesitis & dactylitis), psoriasis BSA, achievement of modified MDA (achievement of [i] 4/6 (MDA 1) and [ii] 5/6 following criteria (MDA 2): TJC ≤1, SJC ≤1, BSA ≤3%, pain VAS ≤15mm, PtGA ≤20 and HAQ ≤0.5), modified remission (SJC = 0, TJC = 0, absence of enthesitis and dactylitis, BSA ≤3% and HAQ ≤0.5), DAPSA LDA (≤14), and DAPSA remission (REM; ≤4). Analyses were conducted by initial group assignment (intent-to-treat approach).
Results: 406 patients were included (nbDMARD $n = 146$, ADA $n = 260$). BL demographics were comparable between treatment groups. However, patients initiating ADA were more likely to be unemployed (47.3% ADA vs 34.9% nbDMARD, $p = 0.015$), had higher DAS28 (4.8 vs 4.4, $p = 0.002$) and total DLQI score (6.1 vs 4.3, $p = 0.007$), and were more likely to have BSA≥3% (44.6% vs 35.0%, $p = 0.063$) and high DAPSA disease activity (50.8% vs 32.3%, $p = 0.015$). A higher proportion of nbDMARD patients had dactylitis (36.1% vs 25.3%, $p = 0.023$). No differences were observed between groups in enthesitis, overall EAMs, or QoL at BL. Following 12 months, mean adjusted DAS28 (2.6 vs 3.4, $p < 0.001$) and DLQI (2.2 vs 2.9, $p = 0.530$) scores, but not SF-12, were lower in the ADA group. Furthermore, even though statistical significance was not always met, ADA patients had lower DAPSA score ($p = 0.025$) (LDA/REM: 64.9% vs 58.6%; REM: 37.7% vs 17.1%), were more likely to be in modified remission (14.7% vs 9.7%, $p = 0.311$), and to have mMDA (mMDA 1: 15.6% vs 12.6%, $p = 0.529$; mMDA 2: 17% vs 11.5%, $p = 0.253$) and BSA < 3% (89.3% vs 83.9%, $p = 0.207$). Also, EAM prevalence decreased in both groups but was significantly lower in the ADA group (17.4% vs 35.8%, $p < 0.001$). Over time, 9.6% of ADA patients initiated another biologic and 32.2% of patients in the nbDMARD group initiated biologic treatment ($p < 0.001$).
Conclusions: PsA patients initiating ADA in Canadian routine clinical care have significantly greater BL disease severity compared with those initiating nbDMARDs. However, 12-month ADA treatment resulted in improved disease control and EAMs. DAPSA-REM evaluation seems more sensitive than mMDA in differentiating both populations.

P030

SECUKINUMAB EFFICACY IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: META-ANALYSIS OF 4 PHASE 3 TRIALS

Philip Mease[1], Bruce Kirkham[2], Peter Nash[3], Alejandro Balsa[4], Bernard Combe[5], Jürgen Rech[6], Ruvie Martin[7], Gregory Ligozio[7], Ken Abrams[7], Luminita Pricop[7]
[1]Swedish Medical Centre and University of Washington, Seattle, USA, [2]Guy's & St Thomas' NHS Foundation Trust, London, UK, [3]Department of Medicine, University of Queensland, Brisbane, Australia, [4]Hospital Universitario La Paz, Instituto de Investigación Sanitaria (IdiPAZ), Madrid, Spain, [5]Hôpital Lapeyronie, Université Montpellier 1, Montpellier, France, [6]Friedrich-Alexander-University Erlangen-Nürnberg (FAU), Monash University, Germany, [7]Novartis Pharmaceuticals Corporation, East Hanover, USA

Introduction: Secukinumab (SEC) has exhibited rapid, significant and sustained improvement in the signs and symptoms of psoriatic arthritis (PsA) in 4 Phase 3 studies.1–4
Objective: To report meta-analyzed efficacy results for SEC versus placebo at Week (Wk) 16 in PsA patients (pts) by prior TNF inhibitor (TNFi) use and with/without concomitant methotrexate (MTX) use from 4 Phase 3 studies: FUTURE 2,3,4,5.
Methods: A total of 2148 pts with active PsA were randomised in FUTURE 2, 3, 4 and 5 studies (397, 414, 341 and 996, respectively). Study designs were described elsewhere.1–4 Assessments included ACR20/50 by prior TNFi use (naïve/inadequate response or intolerance [-IR]) and with/without MTX use.
Results: Out of 2049 pts in analysis, 461, 572, 335, and 681 pts received SEC 300mg, 150mg, 150mg without load (NL) and placebo (PBO), respectively. ACR 20/50 responses were improved with SEC vs PBO at Wk 16 in both TNFi-naive/-IR pts and pts with/without concomitant MTX use (Table); improvements were also observed with SEC vs PBO for all other secondary endpoints.
Conclusions: SEC provided improvement in the signs and symptoms of active PsA regardless of previous TNFi therapy or concomitant MTX use. Higher response rates were observed in TNFi-naïve pts compared to TNFi-IR pts. SEC 300mg was associated with higher responses compared to 150mg in pts with TNFi-IR and no concomitant MTX use.

References:
1) J Rheumatol. 2017; 56(11):1993-03. 2) Rheumatology 2017;56:1993-03; 3) Arthritis Rheumatol. 2017;69 (s10); 4) PANLAR 2018, A718

Table: ACR20/50 responses at Week 16 by TNFi status and concomitant MTX use

	ACR20/50 Response [Treatment Effect vs. PBO at Week 16 (%)]		
Pts subgroup	SEC 300mg	SEC 150mg	SEC 150mg (NL)
TNFi naïve	34.6/30.1	31.6/25.1	34.5/22.6
TNFi-IR	29.3/18.1	24.5/14.7	17.8/8.3
With MTX	23.1/20.1	28.1/20.1	23.5/11.3
Without MTX	41.6/29.1	29.7/20.6	34.5/22.6

P031

IMPACT OF ADALIMUMAB VS. NON-BIOLOGIC TREATMENTS ON SKIN OUTCOMES OF PSORIATIC ARTHRITIS PATIENTS: REAL-WORLD DATA FROM THE COMPLETE STUDY

Majed Khraishi[1], Louis Bessette[2], Boulos Haraoui[3], Valencia Remple[4]

[1]Memorial University of Newfoundland, St. John's NL, [2]Laval University, Centre Hospitalier de l'Université Laval, Quebec, [3]Centre hospitalier de l'Université de Montréal, [4]AbbVie Corporation, Montreal, QC, Canada

Background: Previous studies have shown the efficacy of anti-TNFα agents in improving nail, skin and joint manifestations of psoriatic arthritis (PsA). However, real-world data on the comparative effectiveness of switching to or adding these agents vs. continuing non-biologic treatments in patients having failed prior non-biologic treatment are necessary to support the integration of treatment algorithms into routine care.

Objectives: The aim of this analysis was to compare the effect of adalimumab (ADA) vs. non-biologic treatments (nbDMARD: NSAIDs and DMARDs) on skin outcomes and patient reported outcomes following initial treatment failure. In addition, the impact of the extent of baseline skin disease on treatment outcomes was examined.

Methods: Patients eligible for COMPLETE PsA are anti-TNFα naïve adults, with active PsA who require change in their treatment regimen, per the judgment of the treating physician. In the current analysis patients enrolled between July/2011 – Jun/2016 who had available information on baseline psoriasis body surface area (BSA) were included. Outcome measures analyzed were: BSA, Dermatology Life Quality Index (DLQI), Short Form Health Survey (SF-12), and the Beck Depression Inventory (BDI). Analyses were conducted by initial group assignment (intent-to-treat approach).

Results: A total of 392 patients were included (ADA $n = 249$, nbDMARD $n = 143$). Baseline demographics and disease duration were comparable between treatment groups. However, patients initiating ADA were more likely to have BSA≥3% (44.6% vs. 35%, $p = 0.063$) and had higher DLQI (6.2 vs. 4.3, $p = 0.006$) scores. No differences were observed in SF-12 physical (PCS) and mental (MCS) component scores at baseline.

During treatment, BSA levels significantly improved in both groups but more patients achieved a BSA < 3% when treated with ADA vs. nbDMARD both at 6 months (89.7% vs. 80.2%, $p = 0.027$) and 12 months (89.0% vs. 83.7%, $p = 0.222$). Furthermore, upon adjusting for baseline scores, patients in the ADA group experienced greater improvements in DLQI ($\Delta LSM = -1.62$, $p = 0.004$), particularly in the daily activities, leisure, and work/school domains, and SF-12 PCS ($\Delta LSM = 0.36$, $p < 0.001$). These differences between groups in BSA levels and DLQI improvement were more profound among patients with BSA≥3% at baseline.

During follow-up, 9.2% of ADA patients initiated another biologic and 32.2% of patients in the nbDMARD group initiated biologic treatment ($p < 0.001$).

Conclusions: PsA patients starting ADA following initial failure of non-biologic treatment in Canadian routine clinical care experience greater benefits in skin outcomes and quality of life compared to switching to different non-biologic treatment. These benefits are particularly evident among patients with more severe skin disease at baseline.

P032

IXEKIZUMAB IMPROVES NAIL AND SKIN PSORIASIS THROUGH 52 WEEKS OF TREATMENT IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: RESULTS FROM TWO RANDOMIZED, DOUBLE-BLIND, PHASE 3, CLINICAL TRIALS (SPIRIT-P1 AND SPIRIT-P2)

Joseph F. Merola[1], Mitsumasha Kishimoto[2], David Adams[3], So Young Park[3], Diamant Thaçi[4]

[1]Department of Dermatology and Medicine, Division of Rheumatology, Harvard Medical School, Brigham and Women's Hospital, Boston, MA, USA, [2]Immuno-Rheumatology Center, St. Luke's International University, St. Luke's International Hospital, Tokyo, Japan, [3]Eli Lilly and Company, Indianapolis, IN, USA, [4]Comprehensive Center for Inflammation Medicine, University Hospital, Schleswig-Holstein Campus Luebeck, Luebeck, Germany

Introduction: Ixekizumab (IXE), a high-affinity monoclonal antibody that selectively targets interleukin-17A, is approved for treatment of patients (pts) with active psoriatic arthritis (PsA) and provides persistent efficacy through 52 weeks (wks) of treatment.

Objective: To evaluate the efficacy of IXE treatment over 52 wks on nail and skin psoriasis in biologic disease-modifying anti-rheumatic drug (bDMARD)-naïve and -experienced pts with active PsA.

Methods: Adult pts with active PsA were bDMARD-naïve (SPIRIT-P1) or -experienced (SPIRIT-P2, TNF inhibitor inadequate responders [TNFi-IR] or intolerant). Pts were randomized to IXE 80 mg every 2 (Q2W) or 4 wks (Q4W), placebo, or (in SPIRIT-P1) 40 mg adalimumab Q2W. Efficacy of IXE on nail and skin psoriasis in patients randomized to IXE was measured by the Nail Psoriasis Severity Index (NAPSI), Psoriasis Area and Severity Index (PASI), and static Physician Global Assessment (sPGA). Missing data were imputed using nonresponder imputation for categorical variables and modified baseline observation carried forward for continuous variables.

Results: IXE provided high clinical response in skin and nail psoriasis that persisted through 52 wks of treatment, regardless of IXE dosing or prior bDMARD use (Table).

	SPIRIT-P1 (bDMARD Naïve)		SPIRIT-P2 (TNFi-IR or Intolerant)	
	IXE Q4W $n = 107$	IXE Q2W $n = 103$	IXE Q4W $n = 122$	IXE Q2W $n = 123$
PASI 75[a]	52/73 (71.2)	45/59 (76.3)	41/68 (60.3)	37/68 (54.4)
PASI 90[a]	44/73 (60.3)	43/59 (72.9)	34/68 (50.0)	27/68 (39.7)
PASI 100[a]	37/73 (50.7)	37/59 (62.7)	27/68 (39.7)	24/68 (35.3)
sPGA 0/1[b]	39/52 (75.0)	29/41 (70.7)	37/60 (61.7)	41/62 (66.1)
sPGA 0[b]	29/52 (55.8)	23/41 (56.1)	26/60 (43.3)	27/62 (43.5)
NAPSI = 0[c]	30/69 (43.5)	28/74 (37.8)	41/89 (46.1)	24/74 (32.4)
NAPSI mean (SD) change from baselinec	-15.9 (18.3)	-20.0 (20.8)	-15.2 (19.7)	-14.4 (19.0)

Unless otherwise indicated, values are presented as: n/Nx (%), where Nx is [a]pts with baseline BSA≥3%, [b]pts with baseline sPGA≥3, or [c]pts with baseline fingernail psoriasis

Conclusions: In these two phase 3 clinical trials in patients with active PsA, ixekizumab provided persistent high clinical response for improvement or clearance of nail and skin psoriasis through 52 wks of treatment.

P034

IXEKIZUMAB MAKES THERAPEUTIC THRESHOLDS POSSIBLE IN ACTIVE PSORIATIC ARTHRITIS PATIENTS: RESULTS FROM SPIRIT TRIALS

Laura C Coates[1], M. Elaine Husni[2], Eric Lespessailles[3], Lisa Kerr[4], Gaia Gallo[4]

[1]University of Oxford, Leeds, UK, [2]Cleveland Clinic, Cleveland, OH, USA, [3]Université d'Orléans, Orléans, EA, France, [4]Eli Lilly and Company, Indianapolis, IN, USA

Introduction: Treatment goals in psoriatic arthritis (PsA) are moving toward attainment of absolute therapeutic thresholds rather than relative improvement.

Objective: To explore the effect of ixekizumab (IXE), an anti-IL-17A monoclonal antibody, as assessed by composite endpoints, up to 52 weeks (wks) for the SPIRIT-P1 and SPIRIT-P2 trials.

Methods: Data were analyzed from 2 double-blind, phase 3 trials investigating the efficacy and safety of IXE in active PsA patients (pts). For SPIRIT-1 [1] biologic disease-modifying antirheumatic drug-naïve pts were randomized to placebo (PBO, $n = 106$) or 80 mg IXE every 4 wks (Q4W, $n = 107$) or every 2 wks (Q2W, $n = 103$) post 160 mg starting dose. For SPIRIT-2 [2] (inadequate responders to tumor necrosis factor inhibitors [TNFi]) pts were randomized to PBO ($n = 118$) or 80 mg IXE Q4W ($n = 122$) or Q2W ($n = 123$) post 160 mg starting dose. Minimal disease activity (MDA), MDA very low disease activity (VLDA), Disease Activity in Psoriatic Arthritis (DAPSA) LDA, DAPSA remission, Psoriatic Arthritis Disease Activity Score (PASDAS) LDA, and PASDAS VLDA composite endpoints were evaluated. Imputation for categorical responses was non-responder imputation. Treatment comparisons (with placebo up to Wk 24) based on the intent-to-treat population were made using a logistic regression model. Data up to Wk52 are summarized.

Results: At Wk 24, percentage of pts achieving MDA (SPIRIT-P1 Q4W: 29.9; Q2W: 40.8; PBO: 15.1; SPIRIT-P2 Q4W: 27.9; Q2W: 31.9; PBO: 3.4), MDA VLDA (SPIRIT-P1 Q4W: 10.3; Q2W: 11.7; PBO: 0.9; SPIRIT-P2 Q4W: 12.3; IXEQ2W: 3.3; PBO: 0.8), DAPSA LDA (SPIRIT-P1 Q4W: 31.8; Q2W: 34.0; PBO: 17.9; SPIRIT-P2 Q4W: 25.4; Q2W: 27.6; PBO: 11.1), DAPSA remission (SPIRIT-P1 Q4W: 15.9; Q2W: 24.3; PBO: 4.7; SPIRIT-P2 Q4W: 14.8; Q2W: 7.3; PBO: 0.8), PASDAS LDA (SPIRIT-P1 Q4W: 42.1; Q2W: 50.5; PBO: 18.9; SPIRIT-P2 Q4W: 39.3; Q2W: 35.0; PBO: 6.8), and PASDAS VLDA (SPIRIT-P1 Q4W: 11.2; Q2W: 20.4; PBO: 1.9; SPIRIT-P2 Q4W: 13.1; Q2W: 7.3; PBO: 0.0) was greater with Q4W and Q2W versus placebo.

Similarly, at Wk 52 the response rates were either sustained or improved: MDA (SPIRIT-P1 Q4W: 39.3; Q2W: 36.9; SPIRIT-P2 Q4W: 34.4; Q2W: 23.6), MDA VLDA (SPIRIT-P1 Q4W: 14.0; Q2W: 15.5; SPIRIT-P2 Q4W: 12.3; Q2W: 6.5), DAPSA LDA (SPIRIT-P1 Q4W: 30.8; Q2W: 29.1; SPIRIT-P2 Q4W: 34.4; Q2W: 26.0), DAPSA remission (SPIRIT-P1 Q4W: 22.4; Q2W: 29.1; SPIRIT-P2 Q4W: 18.9; Q2W: 11.4), PASDAS LDA (SPIRIT-P1 Q4W: 43.0; Q2W: 50.5; SPIRIT-P2 Q4W: 45.1; Q2W: 30.9), and PASDAS VLDA (SPIRIT-P1 Q4W: 17.8; Q2W: 26.2; SPIRIT-P2 Q4W: 17.2; Q2W: 11.4).

Conclusions: Regardless of previous TNFi exposure, a higher proportion of IXE-treated pts achieved MDA and MDA VLDA, DAPSA LDA and DAPSA remission, and PASDAS LDA and PASDAS VLDA at Wk 24 versus placebo. At Wk 52, the extent of IXE clinical response sustained or further improved.

Reference:

1. Mease PJ et al. Ann Rheum Dis. 2017;76(1):79-87. 2. Nash P et al. Lancet. 2017;389(10086):2317-2327.

P035

THE MACROPHAGE MODULATOR MP1032 SHOWS SAFETY AND EFFICACY IN A HUMAN PHASE IIA STUDY FOR THE TREATMENT OF MODERATE-TO-SEVERE PLAQUE PSORIASIS

Petra Schulz, Astrid Kaiser, David Kosel, Sara Schumann, Wolfgang Brysch

MetrioPharm GmbH, Berlin, Germany

Introduction: MP1032 belongs to a new class of anti-inflammatory drugs that modulate the redox state of activated macrophages. MP1032 attenuates pro-inflammatory cytokine secretion *in vivo* and *in vitro* and has pronounced disease-modifying effects in various preclinical models.

Objectives: This randomized, double-blind, parallel, and placebo-controlled trial aimed to evaluate pharmacokinetics, safety, and efficacy of orally administered MP1032 in patients with moderate-to-severe plaque psoriasis.

Methods: Forty-six patients with chronic plaque psoriasis (PASI > 10; disease duration ≥ 6 months) were equally randomized to receive either 100 mg MP1032 or placebo by twice daily oral administration. The study design consisted of a 42 day treatment period with a follow-up of 28 days. Pharmacokinetic sampling occurred on day 1 at 15, 30, 60, and 120 min post-dose. Adverse events were coded according to the Medical Dictionary for Regulatory Activities. Efficacy parameters were assessed at screening and on day 1, 15, 29, 43, 57, and 71.

Results: Enrolled patients had an average age of 40 years (21–65 years) and a median baseline PASI of 13.6 (ranging from 10.1 to 40.8). Pharmacokinetic evaluation demonstrated that MP1032 was rapidly absorbed, reaching maximum plasma concentrations within 15 min after administration. Then, MP1032 plasma levels were quickly declining, indicating a fast elimination. Safety analysis did not reveal any clinically important safety issues. No serious adverse events or deaths were reported and the incidence of treatment emergent adverse events (TEAEs) between placebo and the MP1032 treatment group was comparable. The majority of TEAEs were mild to moderate in nature (mostly common cold, headache, and itching). Analysis of clinical laboratory data and vital signs did also not reveal any adverse effects of MP1032. After only six weeks of treatment, MP1032 led to a PASI reduction of about 25% in patients who entered the study with a PASI of 10–15. In contrast, placebo administration reduced the respective PASI only about 12%. During the four-week follow-up period, median PASI scores in the MP1032 group trended back upward while the placebo group remained unchanged, suggesting a positive therapeutic effect of MP1032. Since, patients with a lower basal PASI had greater improvements during therapy than those with higher scores, MP1032 seems to be a treatment option for patients with mainly moderate psoriasis.

Conclusion: After six weeks of treatment, there was a clinically relevant response in patients who entered the study with PASI scores of 10–15. Overall, MP1032 demonstrated an excellent safety profile and was well tolerated. Hence, redox modulation targeted at the innate immune response represents a promising new therapeutic mechanism for psoriasis and other chronic inflammatory diseases.

P036

SECUKINUMAB IMPROVES SIGNS AND SYMPTOMS OF PSORIATIC ARTHRITIS: RESULTS FROM A PHASE 3 STUDY, FUTURE 5

Philip J. Mease[1], D van der Heijde[2], R Landewé[3], S Mpofu[4], P Rahman[5], H Tahir[6], A Singhal[7], S Navarra[8], E Boettcher[8], X Zhu[10], A Readie[10], L Pricop[10], K Abrams[10]

[1]Swedish Medical Center and University of Washington, Seattle, WA, USA, [2]Leiden University Medical Center, Leiden, [3]University of Amsterdam and Atrium Medical Center, Amsterdam, the Netherlands, [4]Novartis, Pharma AG, Basel, Switzerland, [5]Memorial University, Newfoundland and Labrador, Canada, [6]Whipps, Cross Hospital, London, UK, [7]Southwest Rheumatology, Dallas, TX, USA, [8]Rheumazentrum Favoriten, Vienna, Austria, [9]University of Santo Tomas Hospital, Manila, Philippines, [10]Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA

Introduction/Objectives: Secukinumab (SEC), a fully human mAb to IL-17A, has shown efficacy in psoriatic arthritis (PsA). Here we present the primary results of FUTURE 5, assessing efficacy, including inhibition of radiographic progression of subcutaneous (sc) SEC 300 and 150mg in patients (pts) with PsA (1).

Methods: Pts ($n = 996$) with active PsA, were randomized (2:2:2:3) to sc SEC 300mg with loading dosage (LD; $n = 222$), 150mg with LD ($n = 220$), 150mg without LD ($n = 222$), or placebo (PBO; $n = 332$). All groups received SEC or PBO at baseline (BL), Weeks (Wks) 1, 2, 3, and 4, and then every 4 wks. Primary endpoint was ACR20 at Wk16. Key secondary endpoint was radiographic structural progression, as measured by modified total van der Heijde Sharp score (mTSS).

Results: SEC significantly improved ACR20 at Wk16 vs PBO

(Table). Radiographic progression (mTSS) was significantly inhibited at Wk24 in all SEC arms vs PBO (Table). A greater proportion of pts had no radiographic progression (change from BL in mTSS ≤0.5) with SEC vs PBO: 88% (300mg), 79% (150mg), 83% (150mg without LD), and 73% (PBO). Results for other secondary endpoints are shown in Table. No unexpected safety signals were reported.

Conclusions: Subcutaneous SEC 300 mg with LD and 150 mg with and without LD provided rapid and clinically significant improvements in the signs and symptoms of PsA and inhibited radiographic progression. Safety profile was consistent with that previously reported.

Reference:

1. Mease PJ, et al. Arthritis Rheumatol.2017;69(suppl 10).

Table

Wk 16 data(a)	300 mg	150 mg	150 mg without LD	PBO
ACR20(b)	62.6***	55.5***	59.5***	27.4
mTSS(c)	0.08*	0.17^	–0.09*	0.5
PASI 75/90(b,d)	70***/53.6***	60***/36.8***	58.1***/31.6***	12.3/9.3
HAQ-DI(c)	–0.6***	–0.4***	–0.5***	–0.2
Enthesitis resolution(b,e)	55.7**	54.6**	41.9	35.4
Dactylitis resolution(b,e)	65.9***	57.5**	56.3	32.3
DLQI(c,d)	–8.5***	–7.4***	–7.0***	–2.4
mNAPSI(c,f)	–9.2***	–9.3***	–7.7***	–2.5

***$P < 0.0001$; **$P < 0.001$; *$P < 0.01$; ^$P < 0.05$ un-adjusted P-values vs PBO. (a)Wk24 data for mTSS; (b)% responders; (c)mean change from BL; (d)Data from pts with BL psoriasis ≥3% body surface area; (e)Data from pts with dactylitis or enthesitis at BL; (f)Data from pts with nail psoriasis at BL

P037

INCIDENCE OF INFLAMMATORY BOWEL DISEASE IN PATIENTS TREATED WITH SECUKINUMAB: POOLED ANALYSIS OF 21 RANDOMISED CONTROLLED PHASE 3/4 CLINICAL TRIALS OF PSORIASIS, PSORIATIC ARTHRITIS, AND ANKYLOSING SPONDYLITIS

Stefan Schreiber[1], Jean-Frederic Colombel[2], Brian G Feagan[3], Kristian Reich[4], Atul Deodhar[5], Iain B McInnes[6], Brian Porter[7], Ayan Das Gupta[8], Luminita Pricop[7], Todd Fox[9]

[1]Department of Internal Medicine, University Hospital Schleswig-Holstein, Kiel, Germany, [2]Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York, USA, [3]Robarts Clinical Trials Inc., Department of Epidemiology and Biostatistics, Department of Medicine, Division of Gastroenterology, University of Western Ontario, London, Ontario, Canada, [4]Dermatologikum Hamburg and Georg-August-University, Göttingen, Germany, [5]Oregon Health & Science University, Portland, OR, USA, [6]Institute of Infection Immunity and Inflammation, University of Glasgow, Glasgow, UK, [7]Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA, [8]Novartis Healthcare Pvt. Ltd., Hyderabad, India, [9]Novartis Pharma AG, Basel, Switzerland

Introduction: Inflammatory bowel disease (IBD) including Crohn's disease (CD) and ulcerative colitis (UC) are common comorbidities associated with psoriasis, psoriatic arthritis (PsA), and ankylosing spondylitis (AS). Compared with the general population, epidemiological studies have shown that patients (pts) with psoriasis or PsA are at a 2–4-fold increased risk of developing CD and a 2–3-fold increased risk of developing UC.1–5 Additionally, in pts with AS, there is a 3–5-fold increased risk of IBD compared with the general population.6 Secukinumab is a fully human monoclonal antibody that neutralizes interleukin-17A and is approved for the treatment of psoriasis, PsA, and AS.

Objectives: To evaluate the incidence of IBD, CD, and UC in pts with psoriasis, PsA, or AS who received IL-17A-inhibition with secukinumab from 21 phase 3/4 clinical trials of secukinumab for psoriasis, PsA, or AS.

Methods: This analysis evaluated pooled data from fourteen phase 3 and one phase 4 psoriasis trials, three phase 3 PsA trials, and three phase 3 AS trials. Pts with a history of IBD, but not active ongoing IBD, were eligible for enrollment in these trials. Data from all pts that received at least one dose of secukinumab were included in this analysis. IBD reporting includes cases of CD, UC, and IBD not otherwise specified (NOS).

Results: A total of 7355 pts receiving secukinumab were assessed for the presence of IBD: 5181 with psoriasis, 1380 with PsA, and 794 with AS. Over the entire treatment period, the mean total exposure to secukinumab was 10,416.9 patient-years (pt-yrs) in pts with psoriasis, 3866.9 pt-yrs in pts with PsA, and 1943.1 pt-yrs in pts with AS. The exposure-adjusted incidence rate (EAIR) per 100 pt-yrs (95% confidence interval) of CD, UC, and IBD NOS in secukinumab-treated pts were 0.05 [0.02, 0.11], 0.13 [0.07, 0.23], and 0.01 [0.00, 0.05], respectively in the psoriasis studies; 0.08 [0.02, 0.23], 0.08 [0.02, 0.23], and 0.05 [0.01, 0.19], respectively in the PsA studies; and 0.4 [0.2, 0.8], 0.2 [0.1, 0.5], and 0.1 [0.0, 0.3], respectively in the AS studies. Additionally, the incidence of IBD, CD, and UC did not increase over time.

Conclusion: Pooled data from 21 studies indicated that the observed exposure- adjusted incidence rates of IBD, CD, and UC with secukinumab were low and did not increase over time in pts with moderate to severe plaque psoriasis, PsA, or AS.

References:

1. Augustin M, et al. Acta Derm Venereol. 2010;90(2):147-51
2. Cohen AD, et al. J Eur Acad Dermatol Venereol 2009;23:561-5.
3. Egeberg A, et al. Br J Dermatol. 2016;175(3):487-92. 4. Li WQ, et al. Ann Rheum Dis. 2013;72(7):1200-5.
4. Makredes M, et al. J Am Acad Dermatol. 2009;61(3):405-10.
5. Stolwijk C, et al. Ann Rheum Dis. 2015;74(7):1373-8; 6. Stolwijk C, et al. Ann Rheum Dis. 2015;74(7):1373-8.

P038

ANALYSIS OF THE POSITION OF THE FUMARIC ACID ESTERS IN CURRENT EUROPEAN PSORIASIS GUIDELINES

Cecilia Dietrich[1], Adria Gual[2], Laura Padulles[2]

[1]Dermatologikum Hamburg, Germany, [2]Almirall S.A., Barcelona, Spain

Introduction: Since 1994 a combination of fumaric acid esters (FAEs) (dimethylfumarate [DMF] plus three salts of monoethylfumarate [MEF]) has been approved in Germany for moderate-to-severe psoriasis, however is not widely licensed elsewhere. While a new formulation of DMF has been recently approved by the European Commission (June 2017) as monotherapy for adults with moderate-to-severe psoriasis, only UK (NICE) guidelines mention DMF to date.[1]

Method: Current treatment guidelines for plaque psoriasis in several European countries are reviewed to determine if these guidelines include therapy with FAEs and how these may guide the use of DMF monotherapy in the future.

Results: FAE status varies across Europe. Current European guidelines recommend FAEs for the initial and long-term treatment of psoriasis. These guidelines (based on consensus/expert opinion) also recommend a gradual increase in dose.[2] Country-specific guidelines vary in their individual recommendations. German guidelines endorse FAEs as 1st-line treatment for moderate-to-severe psoriasis, based on BSA > 10% or a PASI score of > 10, and recommend clinical assessments after 16–24 weeks of treatment.[3] UK guidelines approve FAEs only as a 2nd-line option for severe plaque psoriasis (PASI ≥10 or DLQI≥ 10),[1] whilst in the Netherlands FAEs are indicated only for initial treatment of moderate-to-severe disease.[4] Swiss guidelines also recommend the use of FAEs for moderate-to-severe psoriasis, but only in patients who are unresponsive to topical therapy.[5] In Sweden, FAEs can be considered as a 2nd-line treatment option.[6]

Other country-specific guidelines are less clear. While Spanish guidelines discuss FAEs as a slower-acting therapy requiring treatment goals to be set at week 16, no specific guidance on the use of FAEs is given.[7] Likewise, while Italian guidelines mention FAEs, they are not included in treatment recommendations as they are currently not licensed in Italy.[8] In contrast, there is no mention of FAEs in guidelines in Denmark, Portugal and Norway.

Conclusion: European guidelines recommend FAEs for both the

initial and long-term treatment of moderate-to-severe psoriasis. In Germany, FAEs have been licensed for >20 years and are commonly used as 1st-line therapy. In the rest of Europe, there is growing acceptance of FAEs as a systemic therapy option in moderate-to-severe disease. Guidelines continue to evolve as experience grows outside Germany, and will need to be updated to guide the use of the newly approved DMF monotherapy in future.

References:

1. NICE 2017. https://www.nice.org.uk/guidance/TA475
2. Nast A, et al. JEADV 2015;29:2277-94
3. Nast A, et al. 2017 https://bit.ly/2ESJhv3
4. Zweegers J, et al. 2014 https://bit.ly/2GtvwA2
5. Kolios AG, et al. Dermatol 2016. 232:385-406
6. Krogstad A. Psoriasis 2017 https://bit.ly/2F05vbh
7. Dauden E, et al. JEADV 2016;30 Suppl 2:1-18
8. Gisondi P, et al. JEADV 2017;31(5):774-790

P039

SECUKINUMAB PROVIDES RAPID AND SUSTAINED RESOLUTION OF ENTHESITIS IN PSORIATIC ARTHRITIS PATIENTS: POOLED ANALYSIS OF TWO PHASE 3 STUDIES, FUTURE 2 AND FUTURE 3

Laura C Coates[1], Dennis McGonagle[2], Georg Schett[3], Philip J Mease[4], Erhard Quebe-Fehling[5], Darren L Asquith[6], Lawrence Rasouliyan[7], Shephard Mpofu[5], Corine Gaillez[5]

[1]University of Oxford, Oxford, UK, [2]University of Leeds, Leeds, UK, [3]University of Erlangen-Nuremberg, Erlangen, Germany, [4]Swedish Medical Centre and University of Washington, Seattle, USA, [5]Novartis Pharma AG, Basel, Switzerland, [6]Novartis Pharmaceuticals UK Ltd., Camberley, UK, [7]RTI Health Solutions, Barcelona, Spain

Introduction: Enthesitis, one of the key features of psoriatic arthritis (PsA), shows chronicity in 50–70% of affected patients (pts).1 Secukinumab (SEC), a fully human monoclonal antibody that selectively neutralises IL-17A, provided significant and sustained improvement in the signs and symptoms of active PsA, with sustained resolution of enthesitis in Phase 3 studies.2,3

Objectives: To evaluate the effect of SEC on resolution of enthesitis count (EC; defined by Leeds Enthesitis Index) in PsA pts using pooled data from two Phase 3 studies, FUTURE 2 (NCT01752634) and FUTURE 3 (NCT01989468).

Methods: SEC and placebo (PBO) were administered weekly during the first 4 weeks (wks) followed by subcutaneous maintenance dosing every 4 weeks thereafter (PBO until Wk 16/24). The results are reported only for SEC 300 and 150 mg (approved doses). Pts with baseline (BL) enthesitis (BLE) or without BLE (No BLE) were included. Evaluation through Wk 104 included: time to first resolution of enthesitis (i.e. EC = 0); shift analysis of BL EC (1, 2 or 3–6) to full resolution (FR) and partial resolution (PR; reduction of EC) at Wks 24 and 104; and number of new enthesitis sites developed in No BLE pts. Data are as observed in the overall population; time to first resolution of enthesitis was analysed in the overall population and by prior use of tumour necrosis factor inhibitor (TNFi-naïve and -inadequate responders [IR]).

Results: A total of 466 pts had BLE with a mean EC of 3.1±1.6, and 246 pts had no BLE. Median days to resolution of EC in BLE pts for SEC 300, 150 mg and PBO groups were 57, 85 and 167 in overall population; 57, 85 and 120 in TNFi-naïve pts; and 92, 82 and 169 in TNFi-IR pts, respectively. In pts with BL EC = 1/2, 72%/61% (SEC 300 mg), 71%/66% (SEC 150 mg) and 45%/44% (PBO), respectively, achieved FR at Wk 24, with FR in SEC groups sustained or increased to 77%/81% (SEC 300 mg) and 75%/88% (SEC 150 mg) at Wk 104. In BL EC = 3–6, 81% (SEC 300 mg), 73% (SEC 150 mg) and 71% (PBO) of pts achieved FR and PR at Wk 24, with an increase of FR and PR to 88% (in both SEC 300 and 150 mg) at Wk 104. A total of 89% of pts with No BLE did not develop enthesitis by Wk 104.

Conclusions: Time to resolution of enthesitis was earlier with SEC than PBO in the overall population, with faster resolution observed in TNFi-naïve than TNFi-IR pts. Majority of SEC-treated pts with BL EC = 1/2 had FR by Wk 24, with further an improvement by Wk 104. In pts with BL EC = 3–6, greater improvement was observed with SEC 300 mg vs PBO in the proportion of pts with FR and PR of enthesitis at Wk 24; further improvements were observed in both SEC groups at Wk 104.

References:

1. Schett G, et al. Nat Rev Rheumatol. 2017;13:731–41.
2. Mease PJ, et al. N Engl J Med. 2015;373:1329–39.
3. McInnes IB, et al. Lancet 2015;386:1137–46.

P041

LONG-TERM SAFETY OF ADALIMUMAB (HUMIRA) IN ADULT PATIENTS FROM GLOBAL CLINICAL TRIALS ACROSS MULTIPLE INDICATIONS: AN UPDATED ANALYSIS IN 29,987 PATIENTS REPRESENTING 56,951 PATIENT-YEARS

Gerd R. Burmester[1], Remo Panaccione[2], Kenneth B. Gordon[3], James Rosenbaum[4], Dilek Arikan[5], Winnie L. Lau[5], Rita Tarzynski-Potempa[2]

[1]Charité - University Medicine Berlin, Berlin, Germany, [2]University of Calgary, Calgary, AB, Canada, [3]Medical College of Wisconsin, Milwaukee, WI, USA, [4]Oregon Health & Science University and Legacy Devers Eye Institute, Portland, OR, USA,[5]AbbVie Inc., North Chicago, IL, USA

Introduction: Adalimumab is an anti–tumor necrosis factor-α (TNF-α) agent indicated for the treatment of immune-mediated diseases. The long-term safety of adalimumab was previously reported in 23,458 patients representing up to 12 years of clinical trial exposure in rheumatoid arthritis (RA), juvenile idiopathic arthritis, ankylosing spondylitis (AS), psoriatic arthritis (PsA), plaque psoriasis (Ps), and Crohn's disease (CD).

Objectives: Here we report an updated analysis examining the long-term safety of adalimumab in adult patients with RA, AS, non-radiographic axial spondyloarthritis (nr-axSpA), peripheral SpA (pSpA), PsA, Ps, hidradenitis suppurativa (HS), CD, ulcerative colitis (UC), and non-infectious uveitis (UV).

Methods: Safety data from 78 clinical trials of adalimumab (RA, 33; AS, 5; nr-axSpA, 2; pSpA, 1; PsA, 3; Ps, 13; HS, 3; CD, 11; UC, 4; UV, 2; other, 1) were included in these analyses, including randomized controlled, open-label, and long-term extension studies conducted in Europe, North America, South America, Asia, Australia, New Zealand, and South Africa through December 31, 2016. Adalimumab postmarketing surveillance data were not included in this analysis. Safety assessments included all adverse events (AEs) and serious AEs (SAEs) that occurred after the first adalimumab study dose and up to 70 days (5 half-lives) after the last study dose.

Results: This analysis included 29,987 patients, representing 56,951 patient-years of exposure. The majority of adalimumab exposure was in RA studies (37,106 PYs). The most frequently reported SAE of interest was infection (highest incidences in CD: 6.9, UV: 4.1, RA: 3.9, and UC: 3.5). The overall standardized mortality ratio was 0.65, 95% CI [0.5, 0.74]. For most of the adalimumab populations (AS, PsA, Ps, UC, CD, and RA), the observed number of deaths was below what would be expected in an age- and sexadjusted population. For HS, nr-axSpA, pSpA, and UV studies, the small size of these trials precluded accurate assessment of the standardized mortality ratio, and the 95% CIs all included 1.0.

Conclusion: This analysis of data from clinical trials of adalimumab demonstrated an overall safety profile consistent with previous findings and with the TNF inhibitor class. No new safety signals or tolerability issues with adalimumab treatment were identified and, for most indications, the mortality rate was below what would be expected in an age- and sexadjusted population. Efficacy and safety data continue to support the well-established benefits of adalimumab for the approved indications.

Previously Published Arthritis Rheumatol. 2017; 69 (suppl 10).

P042

CLINICAL RESPONSE AFTER GUSELKUMAB TREATMENT AMONG ADALIMUMAB PASI 90 NON-RESPONDERS: RESULTS FROM THE VOYAGE 1 AND 2 TRIALS

Christopher Griffith[1], Marc Alexander Radtke[2], Sang Woong Youn[3], Robert Bissonnette[4], Michael Song[5], Yasmine Wasfi[5], Bruce Randazzo[5], Yin You[5], Yaung-Kaung Shen[5], Bruce Strober[6]

[1]Dermatology Centre, Salford Royal Hospital, University of Manchester, UK, [2]Universitaetsklinik Hamburg-Eppendorf, Hamburg, Germany, [3]Seoul National University College of Medicine, Bundang Hospital, Seongnam City, South Korea, [4]Innovaderm Research, Montreal, QC, Canada, [5]Janssen Research & Development, LLC, Spring House, PA, USA, [6]University of Connecticut Health Center, Farmington, Connecticut and Probity Medical Research, Waterloo, Ontario, Canada

*Objective:*To evaluate the levels of response to guselkumab (GUS) among adalimumab (ADA) PASI 90 non-responders in the VOYAGE 1 and VOYAGE 2 trials.

Materials/Methods: In VOYAGE 1 ($n = 837$), patients were randomized to GUS 100 mg at Weeks (Wks) 0/4/12, then every 8 wks; placebo (PBO) at Wks 0/4/12 followed by GUS 100 mg at Wks 16/20 and then every 8 wks; or ADA 80 mg at Wk 0, 40 mg at Wk 1, and 40 mg every 2 wks through Wk 47. In VOYAGE 2 ($n = 992$), patients were randomized to GUS 100 mg at Wks 0/4/12/20; PBO at Wks 0/4/12 then GUS 100 mg at Wks 16/20; or ADA 80 mg at Wk 0, 40 mg at W1, and then every 2 wks through Wk 23. ADA PASI 90 non-responders initiated GUS at Wk 52 (VOYAGE 1) or at Wk 28 (VOYAGE 2) and continued GUS treatment through Wk 100. Here we report PASI 100, PASI 90, IGA 0 (cleared) and IGA 0/1 (cleared/minimal disease), Dermatology Quality of Life Index (DLQI), and Psoriasis Symptom and Sign Diary (PSSD) outcomes among these ADA PASI 90 non-responders after initiating GUS treatment through Wk 100.

Results: In VOYAGE 1, among 138 ADA-treated PASI 90 non-responders who initiated GUS treatment at Wk 52, a PASI 90 response was achieved by 75.0% of patients at Wk 76, and 72.6% of patients at Wk 100. At Wk 100, 78.5% of patients achieved an IGA 0/1 response, 74.8% of patients reported a DLQI 0/1 score, 33.3% of patients reported a PSSD symptom score of 0, and 18.9% reported a PSSD sign score of 0. In VOYAGE 2, among 112 ADA-treated PASI 90 non-responders who initiated GUS at Wk 28, a PASI 90 response was achieved by 66.1% of patients at Wk 48 and 75.5% of patients at Wk 100. At Wk 100, 81.0% of patients achieved an IGA 0/1 response, 65.3% of patients reported a DLQI 0/1 score, 32.6% of patients reported a PSSD symptom score of 0, and patients 18.0% reported a PSSD sign score of 0.

Conclusions: Among ADA PASI 90 non-responders, GUS treatment provided robust levels of efficacy, which were maintained through Wk 100.

P043

CONSISTENCY OF RESPONSE BY WEIGHT ACROSS SUBGROUPS OF PATIENTS WITH PSORIASIS TREATED WITH GUSELKUMAB: RESULTS FROM THE VOYAGE 1 AND 2 TRIALS

Kim Papp[1], Jeffrey Crowley[2], Diana Rubel[3], Ian Landells[4], Michael Song[5], Yasmine Wasfi[5], Yin You[5], Yaung-Kaung Shen[5], Diamant Thaci[6]

[1]Clinical Research and Probity Research, Inc., Waterloo, Ontario, Canada, [2]Bakersfield Dermatology and Skin Cancer Medical Group, Bakersfield, CA, USA, [3]Woden Dermatology, Phillip ACT 2606, Australia, [4]Nexus Clinical Research, St. John's Newfoundland, CA, [5]Janssen Research & Development, LLC, Spring House, PA, USA, [6]Universitatsklinikum Schleswig-Holstein-Lubeck, Germany

*Objective:*To evaluate the consistency of response of guselkumab (GUS) across predetermined weight quartile subgroups of psoriasis patients.

Materials/Methods: In VOYAGE 1 ($n = 837$) and VOYAGE 2 ($n = 992$), patients were randomized to GUS 100 mg at Weeks 0/4/12/20; placebo (PBO) at Weeks 0/4/12 followed by GUS 100 mg at Weeks 16/20; or ADA 80 mg at Week 0, 40 mg at Week 1, and 40 mg every 2 weeks through Week 23. The co-primary endpoints were the proportions of GUS vs PBO patients achieving: 1) ≥90% improvement in PASI score (PASI 90), and 2) cleared/minimal disease (IGA 0/1) responses at Week 16. Response rates across endpoints were evaluated for predetermined subgroups by baseline weight quartiles.

Results: Pooled data from the two studies at Week 16 and Week 24 demonstrated that patients in the guselkumab group achieved substantially higher clinical responses compared with placebo at Week 16 and ADA at Week 24 across all quartiles of weight as cutoffs. At Week 16, for each quartile, defined by < 74.6, $\geq 74.6 - < 86.4$, $\geq 86.4 - < 100$, and ≥ 100 kg, the proportions of GUS patients with a PASI 90 response were 76.0%, 78.6%, 66.2%, and 65.2%, respectively and the proportions with an IGA 0/1 response were 89.1%, 88.6%, 78.7%, and 82.6%, respectively. The proportions of PBO patients with a PASI 90 response by these quartiles were 5.0%, 2.9%, 1.2%, and 0.9%, respectively and the proportions with an IGA 0/1 response were 11.6%, 10.5%, 4.9%, and 3.5%, respectively.

At Week 24, the proportions of GUS patients with a PASI 90 response by weight quartile were 79.7%, 81.1%, 75.1%, and 73.4%, respectively and the proportions with an IGA 0/1 response were 85.9%, 88.1%, 83.1%, and 78.3%, respectively. The proportions of ADA patients with a PASI 90 response by these quartiles were 62.4%, 66.0%, 52.7%, and 35.5%, respectively and the proportions with an IGA 0/1 response were 70.9%, 76.5%, 61.1%, and 45.2%, respectively.

Conclusions: The efficacy of GUS treatment was demonstrated across all predefined weight quartiles and high efficacy responses were observed in psoriasis patients without regard to weight.

P044

IMPACT OF CLINICAL SPECIALTY SETTING ON DISEASE MANAGEMENT IN PATIENTS WITH PSORIATIC ARTHRITIS

Wolf-Henning Boehncke[1], Rudolf Horváth[2], Ediz Dalkiliç[3], Sónia A. L. Lima[4], Masato Okada[5], Maja Hojnik[6], Fabiana Ganz[7], Ennio Lubrano[8]

[1]Geneva Univ. Hospitals and Univ. of Geneva, Geneva, Switzerland, [2]Univ. Hospital Motol, Prague, Czech Republic, [3]Uludağ Univ. Sch. of Med., Gorukle, Bursa, Turkey, [4]ABC Med. Sch., Santo André, Brazil, [5]St. Luke's International Hospital, Tokyo, Japan, [6]AbbVie, Ljubljana, Slovenia, [6]AbbVie AG, Baar, Switzerland, [8]Univ. of Molise, Campobasso, Italy

Introduction: Evidence suggests that timely and effective management can improve long-term outcomes in patients (pts) with psoriatic arthritis (PsA); however factors influencing treatment management decisions are not well understood.

*Objective:*To evaluate the association between the clinical specialty setting and time from inflammatory musculoskeletal symptom onset to PsA diagnosis and to different management steps in pts with a diagnosis of PsA.

Methods: LOOP is a large cross-sectional, multi-center, observational study conducted in 17 countries across Western and Eastern Europe, Latin America, and Asia. Adult pts (≥18 years) with a suspected or an established diagnosis of PsA routinely visiting a rheumatologist (rheum), dermatologist (derm) or non-rheum/non-derm site were eligible to participate in this study. Each enrolled patient in the study was assessed by both rheum and derm. Main endpoints assessed were time from inflammatory musculoskeletal symptom onset to PsA diagnosis, time from PsA diagnosis to first csDMARD and to first bDMARD, and time from first csDMARD to first bDMARD.

Results: Of the 1483 pts enrolled in this study, 1273 pts with a confirmed diagnosis of PsA were included in this analysis. A ma-

jority of pts were recruited by rheums (671, 52.7%), followed by derms (541, 42.5%), physiatrists (36, 2.8%), and other specialties (25, 2.0%). PsA was first suspected by a rheum in 726 (57.0%) pts and by a derm in 541 pts (42.5%). Pt demographics and disease characteristics were mostly comparable between rheum and derm settings. Disease activity was higher in PsA pts in derm setting compared with rheum setting. The mean time from symptom onset to PsA diagnosis was 24 months (mo) in rheum setting and 1 mo longer for derms. In rheum and derm settings, the mean time from PsA diagnosis to first csDMARD were 11 and 25 mo, respectively; whereas the mean time to first bDMARD were 52 and 55 mo, respectively. The mean time from first csDMARD to first bDMARD was 42 mo for rheums; while it was 3 months shorter for derms.
Conclusion: Although the duration from symptom onset to PsA diagnosis was similar between rheum and derm setting, there were differences in the timing of introduction of different DMARD classes. Notably, mean time to first csDMARD was significantly shorter in rheum setting. PsA pts in derm setting had significantly higher disease activity. These data lend further support to the need for rheum-derm collaborative approach to optimize management of pts with PsA.

P045

SPEED OF RESPONSE OF GUSELKUMAB COMPARED WITH ADALIMUMAB FOR THE TREATMENT OF MODERATE-TO-SEVERE PSORIASIS: RESULTS THROUGH WEEK 24 FROM THE PHASE 3, DOUBLE-BLINDED, PLACEBO- AND ACTIVE COMPARATOR-CONTROLLED VOYAGE 1 AND VOYAGE 2 TRIALS

Andrew Blauvelt[1], Stephen Tyring[2], Sandra Philipp[3], David Adam[4], Michael Song[5], Yasmine Wasfi[5], Yin You[6], Yaung-Kaung Shen[5], Jerry Bagel[6]

[1]Oregon Medical Research Center, Portland, OR, [2]Center for Clinical Studies, Webster, TX, USA, [3]Dermatology, Charité, Universitaetsmedizin Berlin, Berlin, Germany, [4]CCA Medical Research Corp. Ajax, ON, and Probity Medical Research, Waterloo, ON, Canada, [5]Janssen Research & Development, LLC, Spring House, PA, [6]Psoriasis Treatment Center of Central NJ, East Windsor, NJ, USA

Background: VOYAGE 1 and 2 were two phase 3 double-blinded, placebo/active comparator-controlled trials evaluating guselkumab (GUS), a fully human monoclonal antibody targeting interleukin (IL)-23, compared with adalimumab (ADA) in the treatment of patients with moderate-to-severe plaque psoriasis. Here, we report speed of response results based on Psoriasis Area and Severity Index (PASI) outcomes through Week 24 from pooled VOYAGE 1 and 2 data.
Methods: In VOYAGE 1 and 2, patients with plaque psoriasis were randomized at baseline to GUS 100 mg (Weeks 0 and 4, then every 8 weeks [q8w]; pooled $n = 825$), ADA (80 mg Week 0, 40 mg Week 1, then 40 mg every 2 weeks [q2w]; pooled $n = 582$), or placebo (Weeks 0, 4, and 12, then GUS 100 mg at Weeks 16 and 20; pooled $n = 422$). Efficacy was evaluated using PASI 75, PASI 90, and PASI 100 responses (patients achieving ≥75%, ≥90%, and 100% PASI improvement from baseline, respectively) through Week 24. Median time to achieve a response was defined as the time taken for ≥50% of the patients to ever achieve a response.
Results: Based on the pooled VOYAGE 1 and 2 data, median time to achieve a PASI 75 response was ≤8 weeks for both the GUS and ADA groups. However, median time to achieve a PASI 90 response was ≤12 weeks for GUS and ≤16 weeks for ADA. Median time to achieve a PASI 100 response was ≤24 weeks for GUS, but was not achieved for ADA. Median time to achieve any defined endpoint was not achieved for the placebo group.
Conclusions: Taken together, these results demonstrate that patients with moderate-to-severe psoriasis treated with GUS rapidly achieved high levels of response, and more efficiently and more quickly than with ADA.

P046

SAFETY OF CERTOLIZUMAB PEGOL OVER 48 WEEKS IN CHRONIC PLAQUE PSORIASIS PHASE 3 TRIALS

Andrew Blauvelt[1], Bruce Strober[2], Richard Langley[3], Daniel Burge[3], Lisa Pisenti[5], Mohamed Yassine[5], Sarah Kavanagh[6], Catherine Arendt[7], Robert Roller[6], Mark Lebwohl[8], Kristian Reich[9]

[1]Oregon Medical Research Center, Portland, OR, [2]University of Connecticut Health Center, Farmington, CT, USA, [3]Dalhousie University, Nova Scotia, Canada, [4]Demira, Inc., Menlo Park, CA, [5]UCB Pharma, Smyrna, GA, [6]UCB Pharma, Raleigh, NC, USA, [7]UCB Pharma, Brussels, Belgium, [8]Icahn School of Medicine at Mount Sinai, New York, NY, USA, [9]SCIderm Research Institute, Hamburg, and Dermatologikum Berlin, Germany

Introduction: The Fc-free, PEGylated, anti-tumor necrosis factor certolizumab pegol (CZP) has shown efficacy in chronic plaque psoriasis (PSO) over 48 weeks' treatment.[1,2]
Objectives: To report 48-week safety data for CZP in PSO.
Methods: Data were pooled from ongoing phase 3 trials of CZP in adults with PSO ($n = 962$): CIMPASI-1 (NCT02326298), CIMPASI-2 (NCT02326272), CIMPACT (NCT02346240). Patients (pts) had PSO ≥6 months (Psoriasis Area Severity Index ≥12, ≥10% body surface area affected, physician's global assessment ≥3/5) and were randomized to CZP 400 mg every 2 weeks (Q2W) or 200 mg Q2W (400 mg loading dose at Weeks 0/2/4), placebo (PBO) for 16 weeks, or etanercept for 12 weeks (CIMPACT only). We present data for pts receiving ≥1 CZP dose during initial and/or maintenance periods with up to 48 weeks' exposure as of 20Oct2016 (CIMPASI-1), 16Aug2016 (CIMPASI-2), 05Dec2016 (CIMPACT). Adverse events (AEs) were classified using MedDRAv18.1. Incidence rates (IR) are the incidence of new cases per 100 patient-years (PY).
Results: Total CZP exposure was 730PY. 709 pts (73.7%) experienced ≥1 AE; IRs were similar between pts receiving CZP 200 mg Q2W and 400 mg Q2W (Table 1). Rates of serious AEs were low, including infections and infestations (Table 1). There were 4 malignancies (1 anaplastic oligodendroglioma, 2 basal cell carcinoma, 1 keratoacanthoma), 1 congestive heart failure, 1 death (motor vehicle accident) and 1 case of primary progressive multiple sclerosis, all reported in patients receiving CZP 400 mg Q2W. AE IR did not increase with exposure duration, and at Week 16 was comparable for CZP and PBO pts (Table 2).
Conclusion: CZP safety was as expected for this therapeutic class in PSO and there were no new safety signals.
References:
1. Reich K, (2017). Skin,1;24; 2. Augustin M, (2017). Skin,1;s24

Table 1 AEs and Serious AEs to Week 48

IR/100 PY (95% CI)			
	All CZP ($n = 962$)	CZP 400 mg Q2W ($n = 627$)	CZP 200 mg Q2W ($n = 460$)
AEs	219.6 (203.7–236.4)	228.6 (207.8–250.9)	221.2 (197.6–246.7)
Serious AEs	9.1 (7.0–11.6)	10.1 (7.3–13.8)	7.6 (4.8–11.4)
Serious infections and infestations	1.5 (0.8–2.7)	1.9 (0.8–3.8)	1.0 (0.2–2.8)
Active tuberculosis	0.1 (0.0–0.8)	0.2 (0.0–1.3)	0

Table 2 AEs to Week 16

IR/100 PY (95% CI)				
	PBO ($n = 157$)	All CZP ($n = 692$)	CZP 400 mg Q2W ($n = 342$)	CZP 200 mg Q2W ($n = 350$)
AEs	342.6 (277.8–417.9)	319.1 (289.1–351.4)	348.3 (303.5–397.9)	292.1 (252.8–335.9)

P047

SECUKINUMAB PROVIDES SUSTAINED MINIMAL DISEASE ACTIVITY (MDA) AND REMISSION RELATED TO DISEASE ACTIVITY INDEX FOR PSORIATIC ARTHRITIS (DAPSA): 2-YEAR RESULTS FROM A PHASE 3 STUDY

Laura C Coates[1], Peter Nash[2], Tore Kristian Kvien[3], Laure Gossec[4], Philip J Mease[5], Lawrence Rasouliyan[6], Luminita Pricop[7], Corine Gaillez[8], Josef S Smolen[9]

[1]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK, [2]University of Queens-

land, Brisbane, Australia, [3]Diakonhjemmet Hospital, Oslo, Norway, [4]Pitié Salpêtrière Hospital, AP-HP, Paris, France, [5]Swedish Medical Centre and University of Washington, Seattle, USA, [6]RTI Health Solutions, Barcelona, Spain, [7]Novartis Pharmaceuticals Corp., East Hanover, USA, [8]Novartis Pharma AG, Basel, Switzerland, [9]Medical University of Vienna, Vienna, Austria

Introduction: DAPSA and MDA are validated composite indices used in psoriatic arthritis (PsA) to measure disease activity states (1).
Objectives: To assess the proportion of pts treated with secukinumab (SEC) reaching DAPSA remission (REM) or low disease activity (LDA) and those who reached either MDA or very low disease activity (VLDA) at Weeks (wks) 16 and 104 in the FUTURE 2 study (2).
Methods: DAPSA-REM, DAPSA-REM/LDA, MDA, and VLDA and their core components were assessed in the overall population and in pts stratified by prior anti-TNF use (TNF-Naïve/IR) and time since first PsA diagnosis (≤ 2/> 2 years) using as observed data.
Results: At Wk16, in the overall population, the proportion of pts treated with SEC 300/150 mg achieving remission was 14%/10% (DAPSA-REM) and 8%/6% (VLDA) and achieving LDA was 42%/44% (DAPSA-REM/LDA) and 28%/23% (MDA). A higher proportion of anti-TNF-naïve pts and pts with early diagnosis (≤ 2 years) treated with SEC achieved and sustained DAPSA-REM/LDA and MDA than in the overall population (Table). DAPSA-REM/LDA and MDA responses with SEC were sustained through Wk104.
Conclusions: In the overall population, a higher proportion of SEC treated pts at Wk16 achieved DAPSA-REM, VLDA, DAPSA-REM/LDA, and MDA than those treated with placebo with a greater number of pts achieving DAPSA-REM or LDA than VLDA or MDA, respectively. These responses were sustained through Wk104.
References:
1.Coates, Helliwell.Ann Rheum Dis 2016;75:640-43.
2.McInnes et al. Rheumatol.2017;56:1993-2003.

Table.

% Response		DAPSA-REM/ LDA TNF-Naïve/IR	MDA TNF-Naïve/IR	DAPSA-REM/ LDA ≤ 2/> 2 years	MDA ≤ 2/ > 2 years
Wk16	300 mg	52/22	34/15	52/40	43/23
Wk104	150 mg	54/27	32/8	42/45	21/24
	Placebo	23/10	14/3	17/19	7/12
	300 mg	75/46	49/25	63/66	33/43
	150 mg	62/33	37/10	46/57	20/33

Total number of pts providing data to the analysis: secukinumab 300 mg ($n = 100$), 150 mg ($n = 100$) and placebo ($n = 98$).

P048

PREDICTORS OF RESPONSE TO TILDRAKIZUMAB FOR MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS

Andrew Blauvelt[1], Kristian Reich[2], Kim A Papp[3], Stephen K Tyring[4], Rodney Sinclair[5], Diamant Thaçi[6], Melinda Gooderham[7], Qing Li[8], Nicole Cichanowitz, Carmen La Rosa[8]
[1]Oregon Medical Research Center, Portland, OR, USA, [2]SCIderm Research Institute and Dermatologikum Hamburg, Hamburg, Germany, [3]Probity Medical Research, Waterloo, ON, Canada, [4]Department of Dermatology, University of Texas, Houston, TX, USA, [5]University of Melbourne, Melbourne, VIC, Australia, [6]University of Lübeck, Lübeck, Germany, [7]Queens University, SKiN Centre for Dermatology and Probity Medical Research, Peterborough, and Queens University, Kingston, ON, Canada, [8]Merck & Co., Inc., Kenilworth, NJ, USA

Introduction: Efficacy of tildrakizumab (TIL), a high affinity, humanized, immunoglobulin G1κ monoclonal antibody against interleukin-23p19, has been evaluated for chronic plaque psoriasis (PsO) in 2 phase 3 randomized controlled trials.
Objective: The aim of our analysis was to determine predictors of response to TIL treatment in the 2 trials.
Methods: Patients (pts) with moderate to severe PsO were randomized in reSURFACE 1 (phase 3; NCT01722331) and reSURFACE 2 (phase 3; NCT01729754) [1]. In Part 1 (Week [W]1–W12), pts received subcutaneous TIL 200 mg, TIL 100 mg, or placebo (PBO) at W0 and W4. Pts receiving PBO in Part 1 were rerandomized to TIL 200 mg or 100 mg in Part 2 (W12–W28). For each trial, continuous variables of mean baseline Psoriasis Area and Severity Index (PASI), body mass index (BMI), Physician's Global Assessment (PGA), and PASI component for head region as well as dichotomous variables of baseline PASI > 20 or ≤ 20 and PASI 50 response or nonresponse at W8 were evaluated as predictors of response. Response was defined in this analysis as PASI 50 or PASI 90 at W12 and W28.
Results: None of the continuous variables appeared to be consistently predictive of PASI 50 or PASI 90 response, nor were baseline PASI > 20 or ≤ 20 definitive predictors of response. PASI 50 response vs nonresponse at W8 with TIL 200 mg appeared to be predictive of a PASI 50 response at W12 (percentage of patients±SD: 98%±0.9% vs 59%±6.1%, respectively, in reSURFACE 1, and 99%±0.8% vs 57%±5.7%, respectively, in reSURFACE 2) and of a PASI 90 response at W12 (47%±3.3% vs 0%±0%, respectively, in reSURFACE 1, and 50%±3.3% vs 5%±2.6%, respectively, in reSURFACE 2). The percentage of patients with PASI 50 response vs nonresponse at W8 with TIL 200 mg who achieved PASI 50 by W28 was 99%±0.6% vs 90%±3.8%, respectively, in reSURFACE 1, and 99%±0.8% vs 86%±4.0%, respectively, in reSURFACE 2; the percentage who achieved PASI 90 by W28 was 70%±3.1% vs 23%±5.4%, respectively, in reSURFACE 1, and 70%±3.1% vs 21%±4.7%, respectively, in reSURFACE 2. Similar trends in predictive responses were observed with TIL 100-mg treatment.
Conclusions: Achievement of PASI 50 by W8 was predictive of a PASI 50 and PASI 90 response at W12 and W28. Most of the patients who had not achieved PASI 50 by W8 were able to achieve a PASI 50 response by W28. Baseline PASI score, PGA, and BMI were not predictive of PASI 50 or PASI 90 response.
Reference:
1. Reich K, et al. Lancet. 2017;390:276–288.
Acknowledgements: The studies were funded by Merck Sharp & Dohme, Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.
Analyses were presented at the American Academy of Dermatology Annual Meeting, February 16–20, 2018, San Diego, CA, USA.

P049

LONG-TERM EFFICACY OF GUSELKUMAB TREATMENT AFTER DRUG WITHDRAWAL AND RETREATMENT IN PATIENTS WITH MODERATE-SEVERE PLAQUE PSORIASIS: RESULTS FROM VOYAGE 2

Kenneth Gordon[1], April Armstrong[2], Peter Foley[3], Yasmine Wasfi[4], Michael Song[4], Yaung-Kaung Shen[4], Shu Li[4], Ernesto J Muñoz-Elías[4], Bruce Randazzo[4], Kristian Reich[5]
[1]Medical College of Wisconsin, Milwaukee, WI, [2]University of Southern California, Los Angeles, CA, USA, [3]The University of Melbourne, St. Vincent's Hospital, Melbourne and Skin & Cancer Foundation Inc., Carlton, VIC, Australia, [4]Janssen Research & Development, LLC, [5]Dermatologikum Hamburg and SCIderm Research Institute, Hamburg, Germany

Objective: To report long-term efficacy of guselkumab (GUS) after drug withdrawal and retreatment in patients with moderate-severe psoriasis (PsO) in the Phase 3 VOYAGE 2 study.
Methods: At Wk28, patients initially randomized to GUS who achieved a PASI90 response were re-randomized to either PBO/withdrawal (with retreatment upon loss of ≥50% PASI improvement achieved at Wk28 or at Wk72 if retreatment criteria were not met) or continued GUS treatment through Wk72.
Results: Among 375 patients initially randomized to GUS who achieved a PASI90 response at Wk28, 182 were re-randomized to PBO/withdrawal and 193 to GUS/maintenance treatment. Efficacy for the continued GUS treatment group was maintained through Wk72, while responses for the withdrawal group diminished, with PASI90 responses of 86.0% vs 11.5% respectively at

Wk72. Among the 182 patients in the withdrawal arm, 117 were retreated with GUS prior to Wk72; 56 did not meet retreatment criteria and initiated retreatment at Wk72 per protocol. Of 173 patients retreated, 87.6% achieved PASI90 within 6 months of commencing retreatment. No new safety signals were observed with GUS withdrawal and retreatment through Wk100. Maintenance of PASI90 response after drug withdrawal was associated with continued suppression of IL-17A, IL-17F, & IL-22, while loss of response was associated with increased levels of these circulating cytokines.
Conclusion: Superior maintenance of high efficacy response rates was achieved with continuous GUS treatment vs withdrawal, and the majority of retreated patients achieved PASI90. Maintenance of PASI90 after drug withdrawal was associated with continued suppression of IL-17A, IL-17F, and IL-22.

P050

OUTCOMES ASSOCIATED WITH ACHIEVEMENT OF VARIOUS TREATMENT TARGETS IN PATIENTS WITH PSORIATIC ARTHRITIS RECEIVING ADALIMUMAB

Josef S. Smolen[1], Daniel Aletaha[1], Dafna D. Gladman[2], Ying Zhang[3], Fabiana Ganz[4]
[1]Medical University of Vienna, Vienna, Austria, [2]University of Toronto, Toronto Western Hospital, Toronto, Ontario, Canada, [3]AbbVie, Inc., North Chicago, IL, USA, [4]AbbVie, Inc., Baar, Switzerland

Background: Various instruments are currently used for disease activity and outcome assessment in psoriatic arthritis (PsA). Some measures attempt to incorporate the total spectrum of psoriatic disease manifestations [eg, minimal disease activity (MDA)] while others focus on arthritis assessments [eg, disease activity index for PsA (DAPSA)]. Whether in patients (pts) with PsA it is sufficient to primarily consider joint disease aspects remains unclear.
*Objective:*To compare DAPSA remission and low disease activity (LDA) with MDA and very low disease activity (VLDA) for the presence of residual abnormalities of the respective composing variables.
Methods: This post hoc analysis included pts with PsA receiving adalimumab (ADA) in one of two multicenter studies: ADEPT was a 24-week (wk), randomized, double-blind, placebo-controlled trial; ACCLAIM was a 12-wk, open-label study conducted in Canada in care settings that reflected usual practice. Frequencies of DAPSA remission/LDA and MDA/VLDA were summarized, and the individual PsA manifestations within these states were assessed. DAPSA was summed from the following continuous variables: swollen (66) and tender (68) joints, pt global assessment (PtGA, cm), pt pain (PP, cm), and C-reactive protein (CRP, mg/dL). DAPSA remission was defined as ≤4 and DAPSA LDA as >4 and ≤14. MDA criteria were as follows: ≤1 tender, ≤1 swollen joint, ≤1 entheseal point, PP ≤15mm, PtGA ≤20mm, HAQ ≤0.5, and PASI ≤3. MDA was calculated as fulfilling 5 of the 7 criteria, and VLDA calculated as fulfilling all 7 criteria. Data were as observed.
Results: Among 151 pts receiving ADA in ADEPT, 33 (22%) each achieved DAPSA remission and LDA at wk 24, and 20 (14%) and 11 (7%) achieved MDA and VLDA, respectively. Pts achieving DAPSA LDA appeared to mirror those in MDA, with the exception of experiencing numerically higher PP, PtGA, and PASI scores at wk 24. Pts in DAPSA LDA did experience numerically lower SJC when compared with the MDA achievers, and, like MDA achievers, displayed little residual enthesitis. Only VLDA, but not MDA, could match the stringency of DAPSA remission, a finding that was confirmed through analysis of the ACCLAIM cohort. However, VLDA allowed for numerically higher residual PP and PtGA levels when compared with DAPSA remission. Importantly, residual enthesitis did not differ among pts achieving DAPSA remission or VLDA. Irrespective of disease activity assessment, pts receiving ADA displayed little to no radiographic progression.
Conclusions: In the ADEPT and ACCLAIM cohorts, pts who achieved DAPSA remission or VLDA demonstrated similar outcomes with respect to the individual components of both scores, despite the omission of several of these within the DAPSA. Given the DAPSA's continuous nature, its use may offer a good alternative to fulfillment of the VLDA criteria, but these results require confirmation in different pt populations.
Previously published Ann Rheum Dis 2017.

P051

EFFICACY AND SAFETY OF IXEKIZUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: THREE YEAR RESULTS FROM A PHASE 3 STUDY (SPIRIT-P1)

Vinod Chandran[1], Roy Fleischmann[2], Eric Lespessailles[3], Philip Helliwell[4], Olivier Benichou[5], Janelle Erickson[5], Catherine Shuler[5]
[1]Krembil Research Institute, University of Toronto, Toronto, Canada, [2]Metroplex Clinical Research Center, Dallas, USA, [3]University Orléans, Orléans, France, [4]University of Leeds, UK, [5]Eli Lilly and Company, Indianapolis, USA

Introduction: Ixekizumab (IXE), an interleukin-17A antagonist, was superior to placebo (PBO) in improving the signs and symptoms of psoriatic arthritis (PsA) at Week 24 in biologic-naïve patients (pts).
*Objective:*To determine the efficacy and safety of IXE treatment up to 3 years in biologic-naïve pts with PsA. *Methods:* In the SPIRIT-P1 Phase 3 trial (NCT01695239), 210 pts were randomized to IXE (80 mg every 4 [Q4W] or 2 [Q2W] weeks), 101 pts to adalimumab (active reference arm), and 106 pts to PBO at Week 0. ADA and PBO patients were re-randomized to IXE at the end of the double-blind treatment period. Ad-hoc efficacy for all pts initially randomized to IXE (intent-to-treat [ITT]) is presented. Modified non-responder imputation (missing data considered non-response for pts discontinued due to lack of efficacy or adverse events [AEs]; multiple imputation for all other missing data) was applied to efficacy response outcomes. Ad hoc safety data, for all pts who received at least one IXE dose during the trial ($n = 386$), are presented as exposure-adjusted incidence rates (IRs; number of pts with events*100 /total pt years [PY]).
Results: Efficacy results are summarized for ITT IXE-treated pts (Table 1). Improvements in ACR (American College of Rheumatology) responses, enthesitis, dactylitis, PASI (Psoriasis Area and Severity Index), and NAPSI (Nail Psoriasis Severity Index) persisted up to 3 years. Safety assessments for all pts initially randomized to IXE or re-randomized to IXE during SPIRIT-P1 are summarized (Table 2). IRs of treatment-emergent AEs (TEAEs) were similar between IXE Q4W and Q2W treatment groups.

Table 1. Efficacy Outcome Measures at Week 156 (ITT IXE-Treated Population)

	IXE Q4W ($n = 107$)	IXE Q2W ($n = 103$)
ACR20	69%	62%
ACR50	51%	56%
ACR70	33%	44%
LEI = 0a	47%	40%
LDI-B = 0b	62%	69%
PASI75c	63%	69%
PASI90c	51%	65%
PASI100c	44%	61%
NAPSI = 0d	54%	57%

[a]Pts with Leeds Enthesitis Index (LEI) > 0 at baseline. [b]Pts with Leeds Dactylitis Index-Basic (LDI-B) > 0 at baseline. [c]Pts with psoriatic lesions ³3% of body surface area at baseline. [d]Pts with fingernail psoriasis at baseline.

Table 2.

	Total IXE Q4W ($n = 195$; Total PY = 450.4)	Total IXE Q2W ($n = 191$; Total PY = 442.1)
TEAEs	169 (37.5)	168 (38.0)
Serious AEs	38 (8.4)	23 (5.2)
Serious Infections	8 (1.8)	2 (0.5)
Discontinued due to AE	17 (3.8)	23 (5.2)
Death	1a (0.2)	0
Infections	111 (24.6)	112 (25.3)
Injection-Site Reactions	40 (8.9)	43 (9.7)
Hypersensitivities	10 (2.2)	21 (4.7)

n = pts with ≥1 designated AE. Data presented as n (IR). For safety analyses, baseline was defined as the time of the first IXE injection. Total PYs is the total time pts were in the treatment period following the first IXE injection. aPt experienced a cerebrocardiovascular accident.

Conclusion: In pts treated with IXE, improvements in the signs and symptoms of PsA persisted up to 3 years. The safety profile was consistent with previous studies of IXE.
Previously presented as Chandran et al. 2018 EULAR Congress. June 13-16th

P052
INCIDENCE OF SERIOUS GASTROINTESTINAL EVENTS AMONG TILDRAKIZUMAB-TREATED PATIENTS WITH PSORIASIS

Melinda Gooderham[1], Boni E Elewski[2], David M Pariser[3], Howard Sofen[4], Alan M Mendelsohn[5], Nicole Cichanowitz[6], Qing Li[6], Carmen La Rosa[6]
[1]Probity Medical Research, Waterloo, and Skin Centre for Dermatology, Peterborough, Canada, [2]Department of Dermatology, University of Alabama at Birmingham School of Medicine, Birmingham, [3]Eastern Virginia Medical School and Virginia Clinical Research, Inc., Norfolk, [4]Department of Medicine (Dermatology) UCLA, Los Angeles, [5]Sun Pharmaceutical Industries, Inc., Princeton, [6]Merck & Co., Inc., Kenilworth, USA

Introduction: Tildrakizumab is a high-affinity, humanized, immunoglobulin G1κ monoclonal antibody against interleukin-23p19 for the treatment of chronic plaque psoriasis.
Objectives: We evaluated gastrointestinal (GI) adverse events (AE) and, specifically, cases of inflammatory bowel disease (IBD; ie, Crohn's disease or ulcerative colitis) in the clinical development program for tildrakizumab.
Methods: Patients with moderate to severe plaque psoriasis were randomized in 3 large clinical trials: P05495 (phase 2; NCT01225731), reSURFACE 1 (phase 3; NCT01722331), and reSURFACE 2 (phase 3; NCT01729754) [1,2]. In this post hoc analysis, we sought to identify serious GI AEs and new-onset or exacerbation of pre-existing IBD from a pooled dataset of tildrakizumab-treated patients from these 3 trials, which followed patients up to 52 (reSURFACE 2) or 64 (reSURFACE 1) weeks. This analysis evaluated patients who received tildrakizumab 100 mg and 200 mg in P05495 and the reSURFACE trials.
Results: In this analysis, we pooled 1911 patients from the 3 trials who received either tildrakizumab 100 or 200 mg. There were no new cases of IBD reported; among 6 patients with a history of IBD randomized to tildrakizumab, none experienced an exacerbation. The numbers (rate per 100 patient-years) of patients with serious GI AEs in the pooled dataset were 8 (0.80) for tildrakizumab 100 mg and 4 (0.43) for tildrakizumab 200 mg. These serious GI AEs included abdominal pain, constipation, diverticulum, dyspepsia, gastritis, thrombosed hemorrhoids, esophageal polyp, pancreatitis (1 patient each) among patients treated with tildrakizumab 100 mg, and abdominal hernia, upper abdominal pain, acute pancreatitis, and salivary gland enlargement (1 patient each) among patients treated with tildrakizumab 200 mg.
Conclusion: In this post hoc analysis of patients from 3 large, randomized clinical trials, serious GI AEs were infrequent and there were no new cases of IBD or exacerbations of IBD.
Acknowledgements: The studies were funded by Merck Sharp & Dohme, Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.
Reference:
1. Papp K, et al. Br J Dermatol. 2015;173:930–939. 2. Reich K, et al. Lancet. 2017;390:276–288.

P053
DURABLE REDUCTION IN ABSOLUTE PASI WITH CERTOLIZUMAB PEGOL IN PATIENTS WITH CHRONIC PLAQUE PSORIASIS

Alice B Gottlieb[1], Andrew Blauvelt[2], Diamant Thaçi[3], Craig Leonardi[4], Yves Poulin[5], Luke Peterson[6], Catherine Arendt[7], Marion Boehnlein[8], Kristian Reich[9]
[1]Department of Dermatology, New York Medical College at Metropolitan Hospital, NY, NY, [2]Oregon Medical Research Center, Portland, OR, [3]University Hospital of Schleswig-Holstein Campus Lübeck, Lübeck, Germany, [4]Central Dermatology and Saint Louis University School of Medicine, St. Louis, MO, [5]Centre de Recherche Dermatologique du Québec Métropolitain, Québec, Canada, [6]UCB Pharma, Raleigh, NC, [7]UCB Pharma, Brussels, Belgium, [8]UCB Pharma, Monheim, [9]SCIderm Research Institute, Hamburg, and Dermatologikum Berlin, Germany

Introduction: Certolizumab pegol (CZP), an Fc-free, PEGylated, anti-tumor necrosis factor, has shown efficacy in chronic plaque psoriasis (PSO).[1,2]
Objectives: To assess the proportions of patients (pts) achieving selected PASI thresholds over 48 weeks of CZP treatment.
Methods: Data were pooled from CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326272), ongoing phase 3 trials in adults with moderate to severe PSO ≥6 months (Psoriasis Area Severity Index [PASI] ≥12, ≥10% body surface area affected, physician's global assessment ≥3/5). Pts were randomized 2:2:1 to CZP 400 mg every 2 weeks (Q2W), 200 mg Q2W (400 mg loading dose [LD] at Weeks 0/2/4), or placebo (PBO). Week 16 PASI 50 responders receiving CZP continued the same dose to Week 48. We present the proportions of patients reaching PASI ≤1, 2, 3 and 5 at Weeks 16 and 48. Responder rate estimates were calculated using a logistic regression model. Pts not achieving PASI 50 at Weeks 16/32/40/48 were subsequently classed as non-responders. Other missing data were imputed using multiple imputation (Markov Chain Monte Carlo method).
Results: At Week 0, 175, 186 and 100 pts were randomized to CZP 400 mg Q2W, CZP 200 mg Q2W, and PBO. Baseline mean PASI was comparable across CZP 400 mg Q2W/CZP 200 mg Q2W/PBO pts: 19.6 (SD:7.3)/19.2 (7.2)/18.6 (6.6). At Week 16, PASI ≤1 was achieved by 39.9% pts receiving CZP 400 mg Q2W and 36.2% CZP 200 mg pts, vs 2.6% PBO pts. Similarly, a higher proportion of CZP vs PBO pts achieved PASI ≤2, PASI ≤3 and PASI ≤5 (Table). In CZP-treated pts, PASI was maintained or further reduced to Week 48, with 48.2% CZP 400 mg Q2W pts and 39.9% CZP 200 mg Q2W pts achieving PASI ≤1 after 48 weeks' treatment (Table).
Conclusions: Higher proportions of CZP vs PBO pts met absolute PASI cut-offs over 16 weeks and response was maintained or further improved to Week 48. Although durability of response was observed with both doses, higher proportions of pts treated with CZP 400 mg Q2W than 200 mg Q2W were able to reach the most stringent cut-offs at Week 48.
Reference:
1. Reich K, (2017). Skin,1;s23; 2. Augustin M, (2017). Skin,1;s24
Table. Pts achieving absolute PASI cut-offs at Weeks 16 and 48

PASI	Week	PBO (*n* = 100) % (95% CI)	CZP 400 mg Q2W (*n* = 175) % (95% CI)	CZP 200 mg Q2Wa (*n* = 186) % (95% CI)
≤1	16	2.6% (0.0–6.2)	39.9% (29.3–50.4)	36.2% (26.5–45.9)
	48	-	48.2% (37.4–59.0)	39.9% (29.8–50.0)
≤2	16	3.3% (0.0–7.0)	54.5% (43.9–65.1)	46.7% (36.5–56.8)
	48	-	70.5% (60.2–80.8)	55.9% (44.6–67.3)
≤3	16	6.8% (1.0–12.5)	70.5% (59.3–81.6)	65.1% (53.4–76.7)
	48	-	75.2% (65.5–85.0)	63.7% (52.6–74.8)
≤5	16	12.2% (4.3–20.1)	83.0% (74.9–91.1)	77.6% (68.4–86.9)
	48	-	82.3% (74.4–90.3)	73.1% (63.4–82.7)

aPts received CZP 400 mg Q2W LD at Weeks 0/2/4. CI: Confidence interval.

P054
RELATIONSHIPS BETWEEN TILDRAKIZUMAB DOSE, EXPOSURE, EFFICACY AND SAFETY IN PSORIASIS PHASE 3 STUDIES

Bruce Strober[1], Howard Sofen[2], Paul Yamauchi[3], Alan Mendelsohn[4], Jeff Parno[4], Simon Lowry[4], Stephen Rozzo[4], Boni Elewski[5]
[1]UConn Health, University of Connecticut, Farmington, CT, USA; Probity Medical Research, Waterloo, ON, Canada, [2]Ronald Reagan UCLA Medical Center, Los Angeles, CA, [3]University of California at Los Angeles Medical Center, Santa Monica, CA, [4]Sun Pharmaceutical Industries, Inc., Princeton, NJ, [5]University of Alabama at Birmingham Hospital, Birmingham, AL, USA

Introduction: Tildrakizumab (TIL) is a high-affinity, humanized,

anti–interleukin-23p19 monoclonal antibody that demonstrated efficacy in phase 3 trials in moderate to severe chronic plaque psoriasis (reSURFACE 1 [NCT01722331] and 2 [NCT01729754]) [1].
*Objective:*Here we investigated the relationship between TIL serum concentration, and efficacy and safety outcomes, in reSURFACE 1 and 2.
Methods: Placebo or TIL 100 mg or 200 mg was administered at Weeks 0 and 4, then every 12 weeks. Endpoints included proportion of patients achieving 75% Psoriasis Area and Severity Index (PASI 75) improvement from baseline (PASI 75 responders). Pooled efficacy data for each dose from reSURFACE 1 and 2 were grouped into quartiles based on average (mean) serum TIL concentration during Weeks 0–12 (Cav12). Associations between median Cav12 for each quartile (Q) and TIL dose were analyzed for PASI 75 response at Week 12 and adverse events (AEs).
Results: TIL steady-state concentrations were achieved by Week 16 and were proportional to the dose administered. Median Cav12 (range) for TIL Q1–Q4, respectively, were 4.4 (2.1–5.2), 5.7 (5.2–6.4), 7.0 (6.4–7.8), and 8.7 (7.8–16.1) µg/mL for TIL 100 mg ($n = 616$) and 8.7 (4.2–10.4), 11.5 (10.4–12.5), 14.1 (12.5–15.5), and 17.3 (15.5–30.6) µg/mL for TIL 200 mg ($n = 622$). PASI responses were similar for corresponding quartiles across doses, with no relationship between serum concentration and patient response for Q1–Q3. Greater PASI 75 responses were associated with the highest Cav12 (Q4), particularly for TIL 100 mg where PASI 75 response rates (95% confidence intervals [CI]) were 58.4% (54.6, 62.3), 62.3% (58.4, 66.1), 59.2% (55.3, 63.1), and 73.7% (70.1, 77.0) for Q1–Q4, respectively. Corresponding PASI 75 rates (95% CIs) for patients receiving 200 mg were 52.9% (49.0, 56.8), 68.6% (64.9, 72.2), 64.5% (60.6, 68.1), and 74.8% (71.2, 78.0) over Q1–Q4. There were no associations between AE rates and serum concentrations, and incidence rates of any AE, any infections, serious infections, upper respiratory tract infections, malignancies, non-melanoma skin cancer, confirmed extended major cardiovascular events, and drug-related hypersensitivity for TIL-treated patients were similar to, or less than, for placebo-treated patients.
Conclusions: No relationship was apparent between TIL dose or Cav12 and PASI response, although the greatest response was seen for the highest serum concentration. Importantly, there were no associations between serum concentration and AE incidence.
Study sponsored by Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA; analyses funded by Sun Pharmaceutical Industries, Inc.
Reference:
1. Reich K, et al. Lancet. 2017;390:276–288.

P055

LONG-TERM SAFETY AND EFFICACY OF ADALIMUMAB FROM THE PHASE 3 RANDOMIZED, PLACEBO-CONTROLLED TRIAL IN PATIENTS WITH NAIL AND SKIN PSORIASIS

Jeff Crowley[1], Paolo Gisondi[2], Ziqian Geng[3], Ofelia Reyes Servin[3]
[1]Bakersfield Dermatology, Bakersfield, CA, USA, [2]University of Verona, Verona, Italy, [3]AbbVie Inc, North Chicago, IL, USA

Introduction: We evaluated long-term (up to 52 weeks) safety and efficacy of originator adalimumab every-other-week treatment (ADA eow) for fingernail psoriasis (Ps) in patients (pts) with moderate-to-severe Ps with substantial, clinically impactful, moderate-to-severe fingernail Ps.
Methods: In 26-week Period A, pts were randomized 1:1 to 40 mg ADA after initial 80 mg dose, or matching placebo (pbo). Period B (open-label, 26 weeks) entry criteria: completion of Period A, or ≥25% increase from baseline in affected body surface area (BSA) at week 16. At Period B entry (week 26), Period-A pbo pts received an initial blinded dose of 80 mg ADA; all received ADA eow from weeks 27 through 51. We analyzed all pts who received ADA throughout the 52 weeks. Efficacy is reported using multiple imputation (MI) for missing data, and as observed results.
Results: Of the 217 randomized pts, 203 received at ≥1 dose of ADA, 188 entered Period B, and 168 completed the trial. Of those receiving continuous ADA treatment through 52 weeks ($n = 109$), response rates (MI) for key efficacy outcomes at weeks 26 and 52, respectively, were as follows. ≥75% improvement from baseline in modified Nail Ps Severity Index (mNAPSI 75): 47.4% and 54.5%. Physician's Global Assessment of fingernail Ps of 0 (clear) or 1 (minimal) with ≥2 grades improvement from baseline (PGA-F 0/1): 51.1% and 55.6%. Mean change (improvement) from baseline in nail Ps pain (numerical rating scale [NRS]): 3.6 and 3.8. Mean change (improvement) from baseline in Nail Ps Physical Functioning Severity score (NPPFS): 3.4 and 3.9. Mean change (improvement) from baseline in Dermatology Life Quality Index score (DLQI): 9.1 and 9.0 ($n = 94$).
As observed response rates at weeks 26 and 52 respectively, were as follows. mNAPSI 75: 47/88 (53.4%) and 52/80 (65.0%). PGA-F 0/1: 48/88 (54.5%) and 49/80 (61.3%). Mean change (improvement) from baseline in nail Ps pain (NRS): 3.8 ($n = 92$) and 4.4 ($n = 80$). Mean change (improvement) from baseline in NPPFS: 3.9 ($n = 92$) and 4.4 ($n = 80$). Mean change (improvement) from baseline in DLQI: 9.3 ($n = 69$) and 9.7 ($n = 65$).
Adverse events (AEs) per 100 pt years (E/100PYs; in 140.3 PYs) were: any event, 352 (250.9), serious AEs, 21 (15.0); and serious infections, 9 (6.4). AE's were similar to those observed in phase 3 clinical trials of ADA for Ps.
Conclusion: ADA treatment of nail Ps across 52 weeks demonstrated short- and long-term efficacy. No new safety signals were identified in these pts receiving ≥1 dose of ADA.

P056

EIGHT-YEAR INTERIM RESULTS FROM THE ESPRIT 10-YEAR POSTMARKETING SURVEILLANCE REGISTRY OF ADALIMUMAB FOR MODERATE TO SEVERE PSORIASIS

Jashin J. Wu[1], William Abramovits[2], Francisco Kerdel[3], Dilek Arika[4], Dianlin Guo[4], Hartmut Kupper[5], Vera Kuehnl[5], Rakesh Singh[4], Alan Fleischer[4]
[1]Kaiser Permanente Los Angeles Medical Center, Los Angeles, [2]Division of Dermatology, Baylor University Medical Center, Dallas, [3]Florida Academic Dermatology Centers, Miami, [4]AbbVie Inc., North Chicago, USA, [5]AbbVie Deutschland GmbH & Co KG, Ludwigshafen, Germany

Introduction: ESPRIT is a 10-year (y) international prospective observational registry evaluating the long-term safety and effectiveness of originator adalimumab (ADA) in adult patients (pts) with moderate to severe chronic plaque psoriasis.
Objectives: To determine safety, effectiveness, and pt-reported outcomes (PROs) over an 8-y period from an interim analysis of data collected from the ESPRIT registry.
Methods: ESPRIT enrolled pts who were continuing ADA treatment from a current prescription or previous study participation, or initiating ADA ≤4 weeks of entering the registry. The All-Treated pt population (All-Rx) received at least 1 ADA dose in this registry. Pts were evaluated at 3 and 6 months (mos) post-enrollment, and then every 6 mos for up to 10 ys. This interim analysis includes data collected from 26 Sep 2008 through 30 Nov 2016. Incidence rates (IR) for all treatment-emergent adverse events (All-TEAEs) in All-Rx pts are reported as events per 100 pt-ys (E/100PY) of overall exposure to ADA. Physician's Global Assessment (PGA) and PROs (US only) were evaluated in as-observed population (pt numbers were small at 96 mos).
Results: For the 6045 All-Rx pts enrolled and dosed in ESPRIT, median duration of overall exposure to ADA was 3.9 ys. Registry discontinuation rate in All-Rx pts was 39.4%; with the most common reason being lost to follow up (18.2%). IR (E/100PY) for All-TEAEs was: overall 22.0; serious AEs 4.5; malignancies

1.1, serious infections 1.0; non-melanoma skin cancer 0.7; active TB < 0.1; and All-TEAEs leading to death 0.2. Standardized mortality ratio was 0.34 (95% CI, 0.25–0.46), indicating the observed number of deaths was below expected in an age-, sex- and country-matched population. PGA clear/minimal was achieved by 57.0%, 58.7%, 59.1%, 62.6%, 61.9%, 63.8%, 65.5%, and 45.0% of pts at 12, 24, 36, 48, 60, 72, 84, and 96 mos, respectively. In 4202 US pts, mean change from baseline in Dermatology Quality of Life Index, total work productivity impairment, and total activity impairment at 12-mo intervals were -3.1/-5.5/-8.3, -3.2/-5.4/-9.1, -3.3/-5.3/-8.4, -3.5/-5.6/-8.7, -3.9/-5.8/-9.3, -3.7/-6.3/-8.7, -5.1/-9.1/-11.4, and -5.9/-7.5/-13.8.

Conclusions: In this 8-y interim analysis, no new safety signals were observed and safety was consistent with the known safety profile of ADA. The number of TE deaths in the registry was below the expected rate. As-observed effectiveness of ADA and improvement from baseline in PROs were maintained through 96 mos.

P057

DURABILITY OF RESPONSE IN CERTOLIZUMAB PEGOL-TREATED PATIENTS OVER 48 WEEKS IN CIMPASI-1 & 2 TRIALS

Kristian Reich[1], Andrew Blauvelt[2], Diamant Thaçi3, Craig Leonardi[4], Yves Poulin[5], Luke Peterson[6], Catherine Arendt[7], Alice B Gottlieb[8]

[1]SCIderm Research Institute, Hamburg, and Dermatologikum Berlin, Germany, [2]Oregon Medical Research Center, Portland, USA, [3]University Hospital of Schleswig-Holstein Campus Lübeck, Lübeck, Germany, [4]Central Dermatology and Saint Louis University School of Medicine, St. Louis, USA, [5]Centre de Recherche Dermatologique du Québec Métropolitain, Québec, Canada, [6]UCB Pharma, Raleigh, USA, [7]UCB Pharma, Brussels, Belgium, [8]Department of Dermatology, New York Medical College at Metropolitan Hospital, NY, USA

Introduction: Certolizumab pegol (CZP), the only Fc-free, PEGylated, anti-tumor necrosis factor biologic, has shown clinical improvements and a safety profile consistent with the class in adults with chronic plaque psoriasis (PSO).[1,2,3]

Objectives: To assess durability to Week 48 of the initial Week 16 clinical response with CZP in PSO patients (pts) in two identical phase 3 trials.

Methods: Data were pooled from CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326272), ongoing CZP phase 3 trials in adults with PSO ≥6 months (Psoriasis Area Severity Index [PASI] ≥12, ≥10% body surface area affected, physician's global assessment [PGA] ≥3/5). Pts were randomized 2:2:1 to CZP 400 mg every two weeks (Q2W), 200 mg Q2W (400 mg loading dose [LD] at Weeks 0/2/4), or placebo (PBO). At Week 16, PASI 50 responders receiving CZP continued the same dose through the maintenance period to Week 48. PASI 50 non-responders at Weeks 32/40/48 were classed as non-responders at subsequent time points. These analyses do not include PBO pts or Week 16 PASI 50 non-responders. We report number needed to treat (NNT) to achieve PASI 75 at Week 16, and PASI 75 at Week 48 in pts who achieved PASI 75 at Week 16. Week 16 NNT, 95% confidence intervals (95% CI) and Week 48 PASI 75 responder rates were estimated using logistic regression in which missing data and patients withdrawn due to relapse (< PASI 50 during the maintenance period) were imputed using multiple imputation (Markov Chain Monte Carlo [MCMC] method). Sensitivity analyses on PASI 75 were conducted using non-responder imputation (NRI).

Results: At Week 16, NNT to achieve a PASI 75 response was 1.41 (95% CI: 1.26–1.60) for the CZP 400 mg Q2W dose group and 1.53 (1.35–1.77) for the CZP 200 mg Q2W dose group.

Of the pts randomized to CZP 400 mg Q2W and CZP 200 mg Q2W at Week 0 who entered the blinded maintenance phase, 132/149 and 130/150 achieved PASI 75, respectively. Out of Week 16 PASI 75 responders, 98.0% of patients treated with CZP 400 mg Q2W and 87.5% of patients treated with CZP 200 mq Q2W also reported a PASI 75 response at Week 48 (Table). Sensitivity analyses using NRI showed similar trends with both doses, and similar trends were seen in PASI 90 response rates.

Conclusions: These analyses show that patients in both CZP dose groups demonstrate durability of their initial Week 16 high-level response to Week 48, with greatest durability seen in the CZP 400 mg Q2W dose group (98.0% maintenance between Weeks 16 and 48).

Reference:

1. Blauvelt A (2018). Skin, 2:s16; 2. Reich K (2017). Skin,1;s23; 3. Augustin M (2017). Skin,1;s24

Table: Pts achieving PASI 75 at Week 48 among Week 16 PASI 75 responders pooled for CIMPASI-1 and CIMPASI-2

	CZP 400 mg Q2W	CZP 200 mg Q2Wa
Week 16 responders, n	132	130
Week 48 responders		
MCMC, % (95% CI)	98.0% (95.6–100)	87.5% (79.7–95.4)
NRI, % of Week 16 (n)	88.6% (117)	78.5% (102)

aPts received 400 mg CZP LD at Weeks 0/2/4.

P058

PRIMARY EFFICACY AND SAFETY OF ADALIMUMAB IN NAIL PSORIASIS FROM THE FIRST 26 WEEKS OF A PHASE-3, RANDOMIZED, PLACEBO-CONTROLLED TRIAL WITH SUBANALYSIS IN PATIENTS WITH AND WITHOUT PSORIATIC ARTHRITIS

Boni E. Elewski[1], Pheobe A. Rich[2], Frank Behrens[3], Gérard Guillet[4], Ziqian Geng[5], Ofelia Reyes Servin[5]

[1]University of Alabama at Birmingham, School of Medicine, Birmingham, AL, USA, [2]Oregon Health and Science University Hospital, Portland, OR, USA, [3]Goethe University Medical Center, Frankfurt, Germany, [4]Hopital La Miletrie, Service de Dermatologie, CHU Poitiers, France, [5]AbbVie Inc, North Chicago, IL, USA

Introduction: Psoriasis (Ps) disease burden for patients with psoriasis (Ps) and concomitant fingernail Ps plus psoriatic arthritis (PsA) is higher compared with patients with Ps alone.

Objective: We report safety and efficacy of originator adalimumab (ADA) in patients with fingernail Ps, and also for patients with or without concomitant PsA.

Methods: Results are reported from the double-blind PBO-controlled, Period A in which 217 patients with moderate to severe plaque Ps and fingernail Ps were included and randomized 1:1 to receive 40 mg ADA every other week (eow) from week 1 (initial 80mg dose at week 0), or matching PBO, for 26 weeks. The primary endpoints were the proportion of patients with ≥75% improvement in modified Nail Ps Severity Index (mNAPSI 75) and the proportion of patients with Physician's Global Assessment of Fingernail Psoriasis (PGA-F) of clear (0) or minimal (1) with ≥2-grade reduction from baseline (primary in US only; for regulatory purposes). Missing data were handled by multiple imputation. Safety was assessed using treatment-emergent adverse events (AEs).

Results: Of the 217 randomized patients (108 PBO, 109 ADA), 84.3% were male; mean age was 46.7 years; 188 (86.6%) completed 26 weeks of treatment or early escaped to Period B according to protocol. At baseline, 28.6% had PsA (29.6% PBO, 27.5% ADA) with mean duration 7.91 years [SD 8.314]. Total fingernail mNAPSI 75 was achieved by 0.5% PBO vs 61.5% ADA of patients with PsA and 4.6% PBO vs 40.9% ADA without PsA ($p < 0.001$ for both groups). PGA-F 0 or 1 with ≥2-grade reduction was achieved by 4.4% PBO vs 59.3% ADA with PsA and 7.9% PBO vs 44.9% ADA without PsA ($p < 0.001$ for both groups). Adverse

events (AEs) in Period A were reported by 55.6% PBO vs 56.9% ADA (with PsA: 56.3% PBO vs 56.7% ADA; without PsA: 55.3% PBO vs 57.0% ADA without PsA); serious AEs by 4.6% PBO vs 7.3% ADA (with PsA: 9.4% PBO vs 10.0% ADA; without PsA: 2.6% PBO vs 6.3% ADA).

Conclusions: The results demonstrated that in this population, ADA was more effective than PBO for the treatment of fingernail Ps, and significantly improved signs and symptoms, both overall and regardless of the presence or abscense of PsA; no new safety risks were identified with ADA eow treatment for 26 weeks.

Previously published J Am Acad Derm. 2017. 76(6 suppl 1): AB204.

P059

CERTOLIZUMAB PEGOL IS EFFECTIVE FOR CHRONIC PLAQUE PSORIASIS ACROSS PATIENT SUBGROUPS

Kristian Reich[1], Andrew Blauvelt[2], Diamant Thaçi[3], Craig Leonardi[4], Yves Poulin[5], Daniel Burge[6], Luke Peterson[7], Catherine Arendt[8], Alice B Gottlieb[9]

[1]SCIderm Research Institute, Hamburg, and Dermatologikum Berlin, Germany, [2]Oregon Medical Research Center, Portland, OR, USA, [3]University Hospital of Schleswig-Holstein Campus Lübeck, Lübeck, Germany, [4]Central Dermatology and Saint Louis University School of Medicine, St. Louis, MO, USA, [5]Centre de Recherche Dermatologique du Québec Métropolitain, Québec, Canada, [6]Demira, Inc., Menlo Park, CA, [7]UCB Pharma, Raleigh, NC, USA, [8]UCB Pharma, Brussels, Belgium, [9]Department of Dermatology, New York Medical College at Metropolitan Hospital, New York, NY, USA

Introduction: The Fc-free, PEGylated, anti-tumor necrosis factor certolizumab pegol (CZP) has shown efficacy in chronic plaque psoriasis (PSO). [1,2]

Objectives: To assess the efficacy of CZP to 48 weeks across patient (pt) demographic and baseline disease characteristic subgroups in phase 3 trials.

Methods: In this prespecified, pooled subgroup analysis, data were pooled from CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326272), ongoing phase 3 trials in adults with moderate to severe PSO ≥6 months (psoriasis area and severity index [PASI] ≥12, affected body surface area [BSA] ≥10%, physician's global assessment [PGA] ≥3/5). Pts were randomized 2:2:1 to CZP 400 mg every 2 weeks (Q2W), 200 mg Q2W (400 mg loading dose at Weeks 0/2/4), or placebo (PBO). At Week 16, PASI 50 responders receiving CZP continued the same dose through the maintenance period to Week 48. PASI 50 nonresponders at Weeks 32/40/48 were classed as nonresponders at subsequent time points. Subgroups included age, weight, body mass index (BMI), baseline PASI, BSA and PSO duration. PASI 75, PGA 0/1, and PASI 90 responder rates were summarized at Week 16 using a logistic regression model with multiple imputation (overall population) and descriptively at Week 48 based on nonresponse imputation (subgroups).

Results: 175/186/100 pts received CZP 400 mg Q2W/CZP 200 mg Q2W/PBO. Efficacy was observed across all subgroups for both CZP 400 mg Q2W and 200 mg Q2W, with higher Week 48 PASI 75 responder rates in CZP 400 mg Q2W vs CZP 200 mg Q2W treated pts (Table). Similar trends were observed for PGA 0/1 and PASI 90.

Conclusions: Treatment with either dose of CZP resulted in clinically meaningful improvements in signs and symptoms of PSO at Week 16 maintained at Week 48. Similar to the overall population, PASI 75, PGA 0/1, and PASI 90 responder rates were greater for CZP 400 mg Q2W versus 200 mg Q2W across most subgroups at Week 48.

References:

1. Reich K (2017). Skin,1;s23; 2. Augustin M (2017). Skin,1;s24

Table: Week 48 PASI 75 subgroup responder rates

	CZP 400 mg Q2W (*n* = 175		CZP 200 mg Q2W (*n* = 186)	
	N	PASI 75 responders n (%)	N	PASI 75 responders n (%)
Baseline demographics				
Weight (kg)				
≤74.00	40	32 (80.0)	32	23 (71.9)
> 74.00–≤85.00	36	28 (77.8)	35	24 (68.6)
> 85.00–≤95.40	36	26 (72.2)	34	23 (67.6)
> 95.40–≤109.00	28	18 (64.3)	45	26 (57.8)
> 109.00	35	24 (68.6)	40	21 (52.5)
BMI (kg/m²)				
≤25.44	37	30 (81.1)	35	25 (71.4)
> 25.44–≤28.68	39	36 (92.3)	33	25 (75.8)
> 28.68–≤31.92	39	26 (66.7)	32	20 (62.5)
> 31.92–≤37.16	25	16 (64.0)	48	30 (62.5)
> 37.16	35	20 (57.1)	38	17 (44.7)
Age (years)				
< 40	65	54 (83.1)	67	45 (67.2)
≥40– < 64	97	66 (68.0)	107	65 (60.7)
≥65	13	8 (61.5)	12	7 (58.3)
Baseline disease characteristics				
PSO duration (years, median)				
≤15.00	84	61 (72.6)	96	64 (66.7)
> 15.00	91	67 (73.6)	90	53 (58.9)
PASI (median)				
≤17.00	79	55 (69.6)	97	59 (60.8)
> 17.00	96	73 (76.0)	89	58 (65.2)
BSA (%, median)				
≤19.0	88	67 (76.1)	97	60 (61.9)
> 19.0	87	61 (70.1)	89	57 (64.0)

P060

DISCONTINUATION OF BIOLOGIC THERAPIES IN CHRONIC PLAQUE PSORIASIS: A RETROSPECTIVE COHORT

Susanne Gulliver, Wayne Gulliver, Shane Randell

NewLab Clinical Research

Introduction: Psoriasis is a chronic debilitating auto immune disease which manifests on the skin through red scaly plaques. Biologic treatment have been very successful in controlling moderate to severe psoriasis, however they are quite expensive and not all treatments work for all patients. This study looks to understand the demographics, treatment patterns, treatment failures, number of therapies and time to switching. A cohort of 459 patients treated with biologics was examined

Objectives: 1. To understand the demographics, treatment patterns, treatment failures, number of therapies and time to switching.
2. To decipher patterns in biologic use in order to prescribe more efficiently and optimize health care resources.

Methods: This was a retrospective cohort of all patients exposed to biologic or PD-4 inhibitors within a single Dermatologist's private practice. A simple summary of patient demographics including gender, treatment patterns, reasons and length of time before discontinuation was compiled. Reasons for discontinuation included lack of efficacy (primary or secondary), adverse events (AEs), patient choice or other.

Results: There were 189 females (41.2%) and 270 males (58.8%) with 914 incidences of biologic or PD-4 inhibitor treatment. The mean age was 53.48±12.6 and the mean treatment duration was 37.3 months±39.5 (approx. 3000 treatment years).

39.2% of patients (180) remained on the first biologic (range 0.5 to 15 years). The mean number of therapies was 1.99 (range 1–8), but increased to 2.63 if patients were not biologic naive.

More male patients stayed on their first biologic (74.2% in ustekinumab-treated patients and in the Apremilast group 32.3%).

Reasons for discontinuation: AEs (14.69%) and non-response (30%); highest rates were in etanercept (78.0%), and infliximab (75.4%); lowest rates was in etanercept 12.8% (14 of 109 patients), highest in infliximab 34.9%, (44 of 126 patients.

Conclusions: The most common cause for discontinuation of biologics was an AE and non-responsiveness (45.69%). Women

were more likely to discontinue therapy than men. Males were more likely to remain on the first biologic therapy. Adalimumab and ustekinumab had lowest rates of discontinuation. Etanercept, infliximab and apremilast had the highest.

References:
1. M. Esposito, et al. Survival rate of antitumour necrosis factor α treatments for psoriasis in routine dermatological practice: a multicentre observational study. Br J Dermatol (2013). [Online] http://onlinelibrary.wiley.com/doi/10.1111/bjd.12422/full.
2. R. Gniadecki et al. Comparison of long-term drug survival and safety of biologic agents in patients with psoriasis vulgaris. Br J Dermatology (2014). [Online] http://onlinelibrary.wiley.com/doi/10.1111/bjd.13343/full
3. A.A. Levin, A.B. Gottlieb, S.C. Au. A comparison of drug failure rates and reasons for discontinuation in biologics versus systemic therapies. Journal of Drugs in Dermatology (2014) [Online] http://europepmc.org/abstract/med/25007369
4. R.B. Warren, et al. Differential Drug Survival of Biologic therapies for the treatment of psoriasis a prospective Observational cohort Study from the British association of Dermatologists Biologic interventions register (BADBIR). J Invest Dermatol (2015). [Online] http://www.sciencedirect.com/science/article/pii/S0022202X15418494
5. J. Zweegers, et al. Body mass index predicts discontinuation due to ineffectiveness and female sex predicts discontinuation due to side-effects in patients with psoriasis treated with adalimumab, etanercept or ustekinumab in daily practice: a prospective, comparative, long-term drug-survival study from the BioCAPTURE registry. Br J Dermatol (2016) 175: 340–347. doi:10.1111/bjd.14552.

P061

INCIDENCE OF INFECTIONS IN CLINICAL TRIALS OF TILDRAKIZUMAB FOR MODERATE TO SEVERE PLAQUE PSORIASIS

Jeffrey Crowley[1], Craig Leonardi[2], Sheila Sturgill-Koszycki[3], Alan Menter[4], Alan Mendelsohn[3], Qing Li[4], Nicole Cichanowitz[5], Carmen La Rosa[5]

[1]Bakersfield Dermatology, Bakersfield, CA, [2]Central Dermatology, St Louis, MO, [3]Sun Pharmaceutical Industries, Inc., Princeton, NJ, [4]Division of Dermatology, Baylor Scott & White and Texas A&M College of Medicine, Dallas, TX, [5]Merck & Co., Inc., Kenilworth, NJ, USA

Introduction: Risk of infections is a concern with cytokine inhibitor treatments.

Objectives: This analysis assessed infections during phase 2 and 3 trials of tildrakizumab (TIL), a high-affinity, humanized, IgG1κ monoclonal antibody against IL-23p19 under development for moderate to severe chronic plaque psoriasis.

Methods: Patients (Pts) were randomized in P05495 (phase 2; NCT01225731), reSURFACE 1 (phase 3; NCT01722331), and reSURFACE 2 (phase 3; NCT01729754) [1,2]. In Part 1 (Week ([W]1–16) of P05495, pts received subcutaneous (SC) TIL 5, 25, 100, or 200 mg or placebo (PBO) at W0 and W4 and were rerandomized to various TIL doses in Part 2 (W16–52). In Part 1 (W1–12) of reSURFACE 1 and 2, pts received SC TIL 200 mg, TIL 100 mg, or PBO at W0 and W4. Pts were rerandomized in Part 2 (W12–28) and Part 3 (W28–64 or W28–52 in reSURFACE 1 and 2, respectively). Etanercept (ETN) 50 mg was an active control in Parts 1–2 of reSURFACE 2. Treatment-emergent adverse event data pools ($n = 2081$) for the PBO-controlled and full trial periods (52 weeks for P05495/reSURFACE 2; 64 weeks for reSURFACE 1) were analyzed. Severe infections met the regulatory definition of a serious adverse event or required intravenous antibiotics.

Results: In the PBO-controlled period, incidences of infections were comparable for TIL 100 mg and 200 mg (23% and 22%, respectively) and PBO (23%); all were comparable with ETN (24%). Incidences of severe infections were low for all treatment groups (range, 0.0%-0.3%; TIL $P \geq 0.6$ vs PBO). In the full trial period, exposure-adjusted rates (pts/100 pt-years) for infections with TIL 100 mg and 200 mg (48.9 and 52.6, respectively) were lower than with PBO and ETN (79.5 and 86.0, respectively). Exposure-adjusted rates for severe infections were 1.10, 1.61, 1.96, and 0.91 for TIL 100 mg, TIL 200 mg, ETN, and PBO, respectively. In all, 33 severe infections were identified (respiratory: TIL 100 mg, 4 events; TIL 200 mg, 2 events; ETN and PBO, 0 events; skin: TIL 100 mg, 3 events; TIL 200 mg, 6 events; ETN, 2 events; PBO, 3 events; gastrointestinal: TIL 100 mg, 4 events; TIL 200 mg, 5 events; ETN and PBO, 0 events; urinary tract: TIL 200 mg, 1 event; ETN, 1 event; TIL 100 mg and PBO, 0 events). One pt had bone tuberculosis (TIL 200 mg; original purified protein derivative test was negative); 1 sepsis event (TIL 200 mg) occurred months after ending TIL treatment.

Conclusion: Infection rates with TIL treatment were low and comparable to PBO and ETN during the PBO-controlled period. By W52/64, exposure-adjusted rates remained low for all groups.

Reference:
1. Papp K, et al. Br J Dermatol. 2015;173:930-939. 2. Reich K, et al. Lancet. 2017;390:276-288.

Acknowledgements: The studies were funded by Merck Sharp & Dohme, Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.
Analyses were presented at the American Academy of Dermatology Annual Meeting, February 16-20, 2018, San Diego, CA, USA.

P062

EFFICACY AND SAFETY OF RISANKIZUMAB: RESULTS FROM TWO DOUBLE-BLIND, PLACEBO- AND USTEKINUMAB-CONTROLLED, PHASE 3 TRIALS IN MODERATE-TO-SEVERE PLAQUE PSORIASIS

Kenneth B. Gordon[1], Bruce Strober[2], Mark Lebwohl[3], Matthias Augustin[4], Andrew Blauvelt[5], Yves Poulin[6], Kim A. Papp[7], Howard Sofen[8], Lluis Puig[9], Peter Foley[10], Mamitaro Ohtsuki[11], Mary Flack[12], Ziqian Geng[13], Yihua Gu[13], Joaquin M. Valdes[13], Elizabeth H.Z. Thompson[14], Hervé Bachelez[15]

[1]Medical College of Wisconsin, Milwaukee, Wisconsin, [2]University of Connecticut Health Center and Probity Medical Research, Farmington, CT, [3]Icahn School of Medicine at Mount Sinai, New York, NY, USA, [4]University Medical Center Hamburg-Eppendorf (UKE), Hamburg, Germany, [5]Oregon Medical Research Center, Portland, OR, USA, [6]Centre Dermatologique du Québec Métropolitain, Québec, QC, Canada, [7]K Papp Clinical Research and Probity Medical Research, Waterloo, ON, Canada, [8]University of California, Los Angeles, School of Medicine, Los Angeles, CA, USA, [9]Hospital de la Santa Creu i Sant Pau, Universitat Autònoma de Barcelona, Barcelona, Spain, [10]The University of Melbourne, Parkville, Skin & Cancer Foundation Inc, Carlton, and Probity Medical Research, Carlton, VIC, Australia, [11]Jichi Medical University, Shimotsuke, Japan, [12]Boehringer Ingelheim Pharmaceuticals Inc., Ridgefield, CT, [13]AbbVie Inc., North Chicago, IL, USA, [14]AbbVie Inc., Redwood City, CA, USA, [15]Saint-Louis Hospital, Sorbonne Paris Cité University Paris Diderot, Paris, France

Introduction: Interleukin-23 is a key cytokine in the development and maintenance of psoriatic lesions. Risankizumab is a humanized IgG1 monoclonal antibody that binds to IL-23's p19 subunit, selectively inhibiting this critical cytokine and its role in psoriatic inflammation.

Methods: UltIMMa-1 ($n = 506$) and UltIMMa-2 ($n = 491$) were replicate, randomized, double-blind, placebo- and active comparator-controlled studies that evaluated efficacy and safety of risankizumab in adult patients with moderate-to-severe plaque psoriasis. Patients were stratified by weight and prior TNFi-exposure and randomized 3:1:1 to receive 150 mg risankizumab, 45/90 mg ustekinumab (weight-based per label) or matching placebo. Patients were dosed at weeks 0, 4, 16, 28, and 40, with placebo crossover to risankizumab at week 16. Co-primary endpoints were PASI 90 and sPGA0/1 at week 16 versus placebo with comparisons between risankizumab and ustekinumab as ranked secondary endpoints. Missing data were imputed as non-response.

Results: All primary and ranked secondary endpoints were met for both trials ($p < 0.001$). At week 16 of UltIMMa-1&2 trials, risankizumab-treated patients achieved significantly higher PASI 90 (75.3%/74.8%) and sPGA0/1 (87.8%/83.7%) response rates versus placebo- (4.9%/2.0%; 7.8%/5.1%) or ustekinumab-treated

patients (42.0%/47.5%; 63.0%/61.6%). At week 52, risankizumab-treated patients achieved significantly higher response rates versus ustekinumab. In both trials, treatment-emergent adverse event (TEAE) rates were comparable across treatment groups throughout the study duration. The most frequently reported TEAE was upper respiratory tract infection.
Conclusion: Risankizumab was consistently superior to both placebo and ustekinumab in the treatment of moderate-to-severe plaque psoriasis. TEAE profiles were similar between risankizumab and ustekinumab, and there were no unexpected safety findings.

P063

EFFICACY AND SAFETY OF GUSELKUMAB ADMINISTERED WITH A NOVEL SELF-INJECTION DEVICE FOR THE TREATMENT OF MODERATE-TO-SEVERE PSORIASIS: RESULTS FROM THE PHASE III ORION SELF-DOSE STUDY THROUGH WEEK 16

Laura Ferris[1], Elyssa Ott[2], Gigi Jiang[2], H. Chih-Ho Hong[3], Wojciech Baran[4]
[1]University of Pittsburgh, Pittsburgh, PA, [2]Janssen Research & Development, LLC, Spring House, PA, [3]UBC Department of Dermatology and Skin Science, Vancouver, BC and Probity Medical Research, Surrey, [4]Department of Dermatology, Venereology and Allergology, Wroclaw Medical University, Wroclaw, Poland

*Objective:*To evaluate the efficacy and safety of guselkumab (GUS) administered using a novel, self-injection device in adult patients with moderate-severe plaque psoriasis (PsO).
Methods: ORION is a Phase 3, multicenter, randomized, double-blind, PBO-controlled study evaluating GUS administered using a self-SC injection device that delivers the contents of a pre-filled syringe. Patients of age≥18 years with moderate-severe PsO for at least 6 months, IGA score ≥3, PASI score ≥12, and BSA ≥10%, and were candidates for/or may have previously received systemic therapy or phototherapy, were eligible for the study. At baseline, 78 patients were randomized to PBO ($n = 16$) at wks 0, 4, and 12 with crossover to GUS 100mg at wks 16, 20, and28 or GUS ($n = 62$) at wks 0, 4, 12, 20, and 28. The co-primary endpoints were the proportions of patients achieving 1) an IGA score of cleared (0) or minimal (1) and 2) a PASI 90 response at wk16 (GUS vs PBO). Major secondary endpoints were the proportions of patients achieving an IGA score of 0 and a PASI 100 response at wk16. Results through wk16 are presented.
Results: Baseline demographics and PsO disease characteristics were generally similar between the PBO and GUS-treatment groups. At wk16, significantly higher proportions of GUS vs PBO patients achieved an IGA score of 0/1 (80.6% vs. 0.0%, $p < 0.001$) and a PASI 90 response (75.8% vs. 0.0%, $p < 0.001$). In addition, significantly higher proportions of GUS vs PBO patients achieved an IGA score of 0 (56.5% vs 0.0, $p < 0.001$) and a PASI 100 response (50.0% vs 0.0, $p < 0.001$) at wk16.
Through wk16, the proportions of patients with ≥1 AE were comparable between the treatment groups (GUS: 62.9%, PBO: 68.8%; respectively). Discontinuation rates due to AEs were 1.6% for GUS patients and 6.3% for PBO patients. Two patients in the GUS group had SAEs (1 chest discomfort and 1 atypical chest pain). There were no serious infections, malignancies, or deaths.
Conclusion: GUS administered using a novel self-injection device was efficacious and well-tolerated in patients with moderate-severe PsO. The efficacy and safety profile of GUS administered with this device was consistent with previously reported findings from the pivotal phase 3 studies in which GUS was administered using a different self-injection device.

P064

EFFICACY OF TILDRAKIZUMAB IN ETANERCEPT PARTIAL RESPONDERS OR NONRESPONDERS

Jeffrey Crowley[1], Kim A Papp[2], Chih-ho Hong[3], Jeff Parno[4], Alan M Mendelsohn[4], Qing Li[5], Nicole Cichanowitz[5], Carmen La Rosa[5]
[1]Bakersfield Dermatology, Bakersfield, CA, USA, [2]Probity Medical Research, Waterloo, ON, Canada, [3]University of British Columbia, Department of Dermatology and Skin Science and Probity Medical Research, Surrey, BC, Canada, [4]Sun Pharmaceutical Industries, Inc., Princeton, NJ, USA, [5]Merck & Co., Inc., Kenilworth, NJ, USA

Introduction: Etanercept (ETN) is an anti-tumor necrosis factor medication that was among the first biologics approved for psoriasis. Additional medications have been developed or are in development for psoriasis, and patients who do not adequately respond to ETN may benefit from these more recent biologics.
Objectives: To evaluate the efficacy of tildrakizumab (TIL), a high-affinity, humanized, anti-interleukin-23p19 antibody in patients (pts) with moderate to severe chronic plaque psoriasis who were partial responders (Psoriasis Area and Severity Index [PASI] ≥50– < 75) or nonresponders (PASI < 50) to ETN and were subsequently rerandomized to TIL in a phase 3 trial.
Methods: Pts with psoriasis (≥10% body surface area, Physician's Global Assessment [PGA] ≥3, and PASI score ≥12) participated in a 3-part, 52-week, randomized controlled trial (reSURFACE 2; NCT01729754) [1]. In Part 1 (Week [W]0–W12), pts were randomized to subcutaneous TIL 200 mg, TIL 100 mg, or placebo (PBO) administered at W0 and W4, or ETN 50 mg administered 2x/week. In Part 2 (W12–W28), TIL- and ETN-treated pts remained on the same treatment (TIL administered at W16; ETN 1x/week), whereas PBO-treated pts were rerandomized to TIL 100 or 200 mg. In Part 3 (W28–W52), ETN responders (PASI ≥75) were discontinued, partial and nonresponders were switched to TIL 200 mg (administered at W32, W36, W48). For this post hoc analysis, the percentages of pts (±SD) with PASI responses and PGA response (score of 0 [clear] or 1 [minimal] with at least a 2-grade score reduction from baseline) were determined at W52. Primary results from the trial have been previously reported.
Results: In all, 1090 pts were randomized. Of the 313 pts randomized to ETN, by W28 there were 83 partial responders and 39 nonresponders. At W52 (after 20 weeks of TIL treatment) for ETN partial responders, 75%±5%, 34%±5%, 15%±4%, and 58%±5% had achieved PASI 75, 90, 100, and PGA responses, respectively, with TIL 200-mg treatment. At W52 for ETN nonresponders, 54%±6%, 31%±5%, 10%±3%, and 56%±5% had achieved PASI 75, 90, 100, and PGA responses, respectively, with TIL 200-mg treatment. Adverse events were similar in pts switched from ETN to TIL at W28, compared with the pts who were maintained on TIL through W52.
Conclusions: A substantial portion of patients with moderate to severe chronic plaque psoriasis who were partial responders or nonresponders to ETN may respond after switching to treatment with TIL 200 mg. TIL may be a reasonable option for those who do not achieve adequate response to ETN.
Reference:
1. Reich K, et al. Lancet. 2017;390:276-288.
Acknowledgments: This study was funded by Merck Sharp & Dohme, Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.
Analyses were presented at the American Academy of Dermatology Annual Meeting, February 16–20, 2018, San Diego, CA, USA.

P065

EFFICACY OF TILDRAKIZUMAB IN MODERATE TO SEVERE PSORIASIS PATIENTS WITH PRIOR EXPOSURE TO APREMILAST

Kenneth Gordon[1], Kristian Reich[2], David Pariser[3], Alan Menter[4], Stephen Tyring[5], Howard Sofen[6], Stephen Rozzo[7], Jeffrey Parno[7], Qing Li[8], Carmen La Rosa[8]
[1]Medical College of Wisconsin, Milwaukee, WI, USA, [2]SCIderm Research Institute and Dermatologikum Hamburg, Hamburg, Germany, [3]Eastern Virginia Medical School and Virginia Clinical Research, Inc., Norfolk, VA, [4]Division of Dermatology, Baylor University Medical Center, Dallas, TX,

[5]Department of Dermatology, University of Texas, Houston, TX, [6]Department of Medicine (Dermatology) UCLA, Los Angeles, CA, [7]Sun Pharmaceutical Industries, Inc., Princeton, NJ, [8]Merck & Co., Inc., Kenilworth, NJ, USA

Introduction: Tildrakizumab (TIL) is a high-affinity, anti–interleukin-23p19 monoclonal antibody for the treatment of chronic plaque psoriasis.
Objectives: We assessed a subgroup of patients with chronic plaque psoriasis who reported prior treatment with apremilast (APT), a phosphodiesterase 4 inhibitor, to evaluate its potential influence on efficacy in 2 large phase 3 clinical studies of tildrakizumab.
Methods: The reSURFACE studies were 3-part, double-blind, randomized controlled studies in patients (≥18 years of age) with moderate to severe chronic plaque psoriasis [1]. TIL 100 and 200 mg were evaluated for 64 weeks (reSURFACE 1; NCT01722331) and 52 weeks (reSURFACE 2; NCT01729754). Part 1 (0–12 weeks) was placebo (PBO)-controlled, whereas Part 2 (12–28 weeks) rerandomized PBO patients to TIL. The washout period for discontinuation of APT before randomization in these studies was 4 weeks. In this post hoc analysis, we analyzed the efficacy responses to TIL in patients who reported prior exposure to APT. Physicians' Global Assessment (PGA) (0 or 1) and Psoriasis Area and Severity Index (PASI) 75, 90, and 100 responses were assessed at Weeks 12 and 28 in this cohort. One patient with missing data at Weeks 12 and 28 was considered to be a nonresponder at these visits. The TIL groups were pooled owing to the small numbers reporting prior APT exposure.
Results: The pooled reSURFACE 1 and 2 dataset includes 1238 patients randomized to TIL; of these, prior APT exposure was reported by 35 patients ($n = 21$ for 100 mg and $n = 14$ for 200 mg). In the overall pooled population of TIL-treated patients, PASI 75, PASI 90, PASI 100, and PGA (0.1) responses were achieved by 783 (63%), 450 (36%), 161 (13%), and 715 (58%) at Week 12 and 898 (73%), 647 (52%), 303 (25%), and 784 (63%) at Week 28, respectively. In the population of TIL-treated patients with prior APT exposure, PASI 75, PASI 90, PASI 100, and PGA (0.1) responses were achieved by 21 (60%), 9 (26%), 5 (14%), and 22 (63%) at Week 12 and 27 (77%), 16 (46%), 7 (20%), and 22 (63%) at Week 28, respectively. There were no discontinuations due to adverse events (AEs) among patients with prior APT exposure.
Conclusions: Efficacy responses with TIL were similar for the small sample of patients with prior exposure to APT and the overall pooled population from reSURFACE 1 and reSURFACE 2. These results were consistent with the notion that no adverse effect on efficacy or discontinuations due to AEs are expected when initiating treatment with TIL among patients with prior exposure to APT.
Reference:
1. Reich K, et al. Lancet. 2017;390:276–288.
Acknowledgements: The studies were funded by Merck Sharp & Dohme, Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.
Analyses were presented at the American Academy of Dermatology Annual Meeting, February 16–20, 2018, San Diego, CA, USA.

P066

RISANKIZUMAB EFFICACY/SAFETY IN MODERATE-TO-SEVERE PLAQUE PSORIASIS: 16-WEEK RESULTS FROM IMMHANCE

Andrew Blauvelt[1], Kim A. Papp[2], Melinda Gooderham[3], Richard G. Langley[4], Craig Leonardi[5], Jean-Philippe Lacour[6], Sandra Philipp[7], Stephen Tyring[8], Michael Bukhalo[9], Jashin J. Wu[10], Jerry Bagel[11], Ellen H. Frankel[12], David Pariser[13], Mary Flack[14], Joseph Scherer[14], Ziqian Geng[15], Yihua Gu[15], Anne Camez[16], Elizabeth H.Z. Thompson[17]

[1]Oregon Medical Research Center, Portland, OR, [2]K Papp Clinical Research and Probity Medical Research, Waterloo, [3]School of Medicine, Queen's University, Kingston, and Centre for Dermatology and Probity Medical Research, Peterborough, ON, [4]Dalhousie University, Halifax, NS, Canada, [5]St. Louis University, St. Louis, MO, USA, [6]Hôpital de l'Archet, University of Nice–Sophia Antipolis, Nice, France, [7]Charité Universitätsmedizin Berlin, Berlin, Germany, [8]University of Texas Health Science Center and Center for Clinical Studies, Houston, TX, [9]Altman Dermatology Associates, Arlington Heights, IL, [10]Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA, [11]Psoriasis Treatment Center of Central New Jersey, East Windsor, NJ, [12]RISkinDoc, Cranston, RI, [13]Eastern Virginia Medical School and Virginia Clinical Research Inc, Norfolk, VA, [14]Boehringer Ingelheim Pharmaceuticals Inc., Ridgefield, CT, [15]AbbVie Inc., North Chicago, IL, USA, [16]AbbVie Deutschland GmbH & Co KG, Ludwigshafen, Germany, [17]AbbVie Inc., Redwood City, CA, USA

Introduction: Interleukin-23 (IL-23), a key regulator of multiple effector cytokines (including IL-17, IL-22, and TNF), is thought to drive the development and maintenance of psoriatic lesions. Risankizumab is a potent humanized IgG1 monoclonal antibody that inhibits IL-23 by specifically binding its p19 subunit.
Objectives: To report efficacy and safety results of risankizumab from initial 16-week (wk) placebo (PBO)-controlled period of IMMhance trial in patients (pts) with moderate-to-severe chronic plaque psoriasis (PsO).
Methods: IMMhance (NCT02672852) is a phase 3 multicenter, randomized, double-blind, PBO-controlled trial, evaluating the efficacy and safety of risankizumab versus PBO in pts with moderate-to-severe chronic plaque PsO. The initial 16-wk PBO-controlled period (507 pts, stratified by weight and prior TNFi-exposure, randomized 4:1 to receive either risankizumab [150 mg at wks 0 and 4] or PBO) was followed by randomized withdrawal and subsequent re-treatment with risankizumab. Co-primary endpoints were PASI 90 and sPGA 0/1 responses at wk 16; missing data were imputed as non-responders.
Results: At baseline, the mean age and weight were 49.2 years and 92.0 kg, respectively; 70.2% of pts were male. A history of diagnosed or suspected psoriatic arthritis was reported in 34.7% of pts and prior TNFi therapy was reported in 36.5% of pts. Mean baseline PASI and BSA were 20.2 and 26.1%, respectively. At wk 16, all primary and ranked secondary endpoints were met ($p < 0.001$). At Wk 16, risankizumab -treated pts achieved significantly higher PASI 90 (73.2%) and sPGA 0/1 (83.5%) response rates versus PBO-treated pts (2.0%; 7.0%). Treatment-emergent adverse events (TEAEs) and serious AEs were reported in 45.5% and 2.0% of risankizumab-treated pts, respectively. Through 16 wks, there were no deaths, major adverse cardiovascular events, or cases of tuberculosis in risankizumab-treated pts.
Conclusions: Risankizumab was superior to PBO in the treatment of adult pts with moderate-to-severe plaque PsO. The safety profile was consistent with previously reported risankizumab trials with no new or unexpected safety findings.

P067

DISEASE SEVERITY AND EFFICACY INSIGHTS: PATIENT-LEVEL PASI SCORES IN TILDRAKIZUMAB PSORIASIS TRIALS

Kenneth Gordon[1], Jeffrey Crowley[3], Yves Poulin[3], Alan Mendelsohn[4], Jeff Parno[4], Stephen Rozzo[4], Charles Ellis[5]

[1]Medical College of Wisconsin, Milwaukee, WI, [2]Bakersfield Dermatology & Skin Cancer Medical Group, Bakersfield, USA, [3]Centre hospitalier de l'université Laval, Hôpital Hôtel-Dieu de Québec, Québec City, Canada, [4]Sun Pharmaceutical Industries, Inc., Princeton, [5]Department of Dermatology, University of Michigan Medical School, Ann Arbor, USA

Introduction: Tildrakizumab (TIL) is a high-affinity anti–IL-23p19 antibody that showed efficacy in 2 phase 3 chronic plaque psoriasis studies (reSURFACE 1 [NCT01722331] and 2 [NCT01729754]) [1]. Some dichotomous efficacy measures, eg, proportions of patients achieving a 75% Psoriasis Area and Severity Index (PASI) response, provide limited efficacy and disease severity information at a patient level. Analysis of patient-level PASI data could address these limitations.
*Objective:*To identify potential insights into efficacy assessment

and disease severity using a post hoc analysis of patient-level PASI data.

Methods: ReSURFACE 1 and 2 methods have been described previously [1]. Patients who participated in either TIL phase 3 study received TIL 100 mg or TIL 200 mg at Week (W)0 and W4, and every 12 weeks thereafter, or placebo (PBO) at W0 and W4 then TIL 100 mg or 200 mg at W12 and W16. PASI score distributions were analyzed using descriptive statistics.

Results: Numbers of patients and mean and median PASI scores are shown in the Table. By W4 (1 dose), 55% of patients in both TIL arms had PASI < 12, and would no longer meet clinical trial entry criteria. The percentage of patients with PASI < 12 increased during TIL treatment: 87% at W12, 93% at W28 (100 mg); 90% at W12, 97% at W28 (200 mg). At W12, 32% (TIL 100 mg), 29% (TIL 200 mg), and 2% (PBO) of patients had PASI ≤1.0. By W28, 48% (TIL 100 mg) and 52% (TIL 200 mg) of patients had PASI ≤1.0. Median PASI scores at W28 were 2.0 (TIL 100 mg) and 1.0 (TIL 200 mg).

Conclusions: These results suggest that PASI scores may provide additional information about disease severity, and resolution with treatment, that might not otherwise be available using dichotomous PASI assessments. Most TIL-treated patients had clinical improvement by W4, and ≈50% had nominal disease severity (PASI ≤1.0) by W28.

Reference:

1. Reich K, et al. Lancet. 2017;390:276–288.

Study sponsored by Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA; analyses funded by Sun Pharmaceutical Industries, Inc.

Table. PASI Scores

	TIL 100 mg (*n* = 616)	TIL 200 mg (*n* = 622)	PBO (*n* = 309)
W0			
Patients with PASI data, n	616	622	309
Mean (95% CI)	20.2 (19.6, 20.9)	20.3 (19.7, 20.9)	19.7 (18.8, 20.5)
Median (range)	18.0 (8.0–59.0)	18.0 (5.0–66.0)	18.0 (12.0–56.0)
W4			
Patients with PASI data, n	610	611	302
Mean (95% CI)	12.1 (11.5, 12.8)	12.0 (11.4, 12.6)	18.0 (17.0, 19.0)
Median (range)	11.0 (0.0–53.0)	11.0 (0.0–54.0)	16.0 (2.0–59.0)
PASI < 12, n (%)	337 (55)	335 (55)	60 (20)
PASI ≤1.0, n (%)	8 (1)	11 (2)	0 (0)
W12			
Patients with PASI data, n	598	602	288
Mean (95% CI)	5.2 (4.7, 5.7)	4.6 (4.2, 5.1)	16.6 (15.6, 17.7)
Median (range)	3.0 (0.0–38.0)	3.0 (0.0–36.0)	15.5 (0.0–57.0)
PASI < 12, n (%)	521 (87)	539 (90)	73 (25)
PASI ≤1.0, n (%)	189 (32)	175 (29)	5 (2)
W28			
Patients with PASI data, n	575	581	-
Mean (95% CI)	3.4 (3.0, 3.8)	2.7 (2.4, 3.0)	-
Median (range)	2.0 (0.0–26.0)	1.0 (0.0–24.0)	-
PASI < 12, n (%)	533 (93)	561 (97)	-
PASI ≤1.0, n (%)	278 (48)	303 (52)	-

P068

SUSTAINED AND IMPROVED EFFICACY OF TILDRAKIZUMAB FROM WEEK 28 TO WEEK 52 IN TREATING MODERATE-TO-SEVERE PLAQUE PSORIASIS

Boni Elewski[1], Alan Menter[2], Jeffrey Crowley[3], Stephen Tyring[4], Yang Zhao[5], Simon Lowry[5], Stephen Rozzo[5], Alan Mendelsohn[5], Jeffrey Parno[5], Kenneth Gordon[6]

[1]Department of Dermatology, The University of Alabama at Birmingham, Birmingham, Alabama, [2]Division of Dermatology, Baylor University Medical Center, Dallas, TX, [3]Bakersfield Dermatology, Bakersfield, CA, [4]Department of Dermatology, University of Texas Health Science Center, Houston, TX, [5]Sun Pharmaceuticals, Princeton, NJ, [6]Medical College of Wisconsin, Milwaukee, WI, USA

Introduction: Two phase-3, double-blind, randomized controlled trials (reSURFACE 1: NCT01722331; reSURFACE 2: NCT01729754) have demonstrated the efficacy and safety of tildrakizumab, a high affinity, humanized, IgG1 κ, anti-interleukin–23 monoclonal antibody, in the treatment of adult patients with moderate-to-severe plaque psoriasis over 28 weeks1.

*Objective:*This analysis evaluated whether the efficacy is sustained or improved from week 28 through week 52.

Methods: Both trials randomized adult patients with moderate-to-severe plaque psoriasis to receive tildrakizumab 100 mg or 200 mg at weeks 0, 4, then every 12 weeks. At week 28, patients with Psoriasis Area and Severity Index (PASI) response ≥50% were re-randomized, based on their week-28 PASI response, to receive the same, a higher or a lower dose of tildrakizumab or placebo (randomized withdrawal in reSURFACE 1 per the trial designs). The current analysis evaluated only patients treated with the same dose of tildrakizumab (100 mg or 200 mg) throughout the first 52 weeks. Four mutually exclusive groups were created based on week-28 PASI response: PASI 100, PASI 90–99, PASI 75–89 and PASI 50–74. PASI responses at week 52 (observed data) were analyzed for each week-28 PASI-response group.

Results: This analysis included 352 patients on tildrakizumab 100 mg (male: 69.9%; mean baseline age: 44.9 years) and 313 on tildrakizumab 200 mg (male: 67.1%; mean baseline age: 46.4 years). The proportions of patients achieving PASI 100, PASI 90–99, PASI 75–89 and PASI 50–74 at week 28 were 25.9%, 38.4%, 25.3% and 10.5% respectively for those on the 100 mg dose, and 24.6%, 24.3%, 19.5% and 31.6% respectively for those on the 200 mg dose. Among patients who achieved week-28 PASI≥90 with either dose of tildrakizumab, 88.9–89.4% maintained PASI≥90 at week 52. Overall, 91.1% patients on the 100 mg dose and 93.9% on the 200 mg dose with week-28 PASI≥75 maintained PASI≥75 at week 52. In addition, 39.3–40.4% of patients with week-28 PASI 75–89 remained PASI 75–89 at week 52 and 33.7%-41.0% improved to PASI≥90. Among patients with week-28 PASI 50–74, 20.2–29.7% achieved PASI≥90 and 52.5–64.9% achieved PASI≥75 at week 52. Overall, only 2.6% of patients on the 100 mg (9 out of 352) or 200 mg (8 out of 313) dose had week-52 PASI < 50.

Conclusions: Among patients with moderate-to-severe plaque psoriasis treated with tildrakizumab 100 or 200 mg at weeks 0, 4, then every 12 weeks, those who achieved week-28 PASI≥50 and continued on the same dose had sustained or improved efficacy from week 28 through week 52. The majority patients who achieved week-28 PASI≥75 or PASI≥90 maintained PASI≥75 or PASI≥90 at week 52. More than half of partial responders (PASI 50–74) at week 28 eventually achieved PASI≥75 and at least 1 in 5 achieved PASI≥90 at week 52.

Reference:

1. Reich K, Papp KA, Blauvelt A, et al. Tildrakizumab versus placebo or etanercept for chronic plaque psoriasis (reSURFACE 1 and reSURFACE 2): results from two randomised controlled, phase 3 trials. Lancet. 2017;390(10091):276-288.

This abstract was presented at 2018 Winter Clinical Dermatology Conference-Hawaii.

P070

BETTER SKIN CLEARANCE IS ASSOCIATED WITH IMPROVED QUALITY OF LIFE IN MODERATE-TO-SEVERE PSORIASIS PATIENTS TREATED WITH TILDRAKIZUMAB

Andrew Blauvelt[1], Stephen Tyring[2], Melinda Gooderham[3], John Koo[4], Yang Zhao[5], Simon Lowry[5], Stephen Rozzo[5], Alan Mendelsohn[5], Jeffrey Parno[5], Kristian Reich[6]

[1]Oregon Medical Research Center, Portland, OR, [2]Department of Dermatology, University of Texas Health Science Center, Houston, TX, [3]Skin Centre for Dermatology, Peterborough, ON, Canada, [4]Department of Dermatology, University of California at San Francisco, CA, [5]Sun Pharmaceuticals, Princeton, NJ, USA, [6]SCIderm Research Institute and Dermatologikum Hamburg, Hamburg, Germany

Introduction: Tildrakizumab, a high affinity, humanized, IgG1 κ, anti-interleukin–23 monoclonal antibody, has demonstrated effica-

cy and safety in patients with moderate-to-severe plaque psoriasis in two phase 3, double-blinded, randomized controlled trials (reSURFACE 1: NCT01722331; reSURFACE 2: NCT01729754)1.
*Objective:*The analysis examined the association between quality-of-life improvements and the degree of skin clearance in patients enrolled in the two phase 3 trials and treated with tildrakizumab 100 mg or 200 mg at weeks 0, 4, then every 12 weeks.
Methods: Both trials used a three-part design: Part 1 (weeks 0–12) was placebo-controlled; Part 2 (weeks 12–28) re-randomized placebo patients to receive tildrakizumab 100 or 200 mg; Part 3 (weeks 28–64, reSURFACE 1; weeks 28–52, reSURFACE 2) re-randomized patients from the tildrakizumab arms with Psoriasis Area and Severity Index (PASI) response ≥50 at week 28 to receive the same, a higher, or a lower dose of tildrakizumab, or placebo (randomized withdrawal in reSURFACE 1). The Dermatology Life Quality Index (DLQI) questionnaire was administered at weeks 0, 12, 28, 40, and 52. Tildrakizumab-treated patients were pooled from the two trials and classified into 5 mutually exclusive groups based on their week-28 PASI response: PASI < 50, PASI 50–74, PASI 75–89, PASI 90–99, and PASI 100. Baseline characteristics, the proportion of patients with DLQI 0/1, and mean DLQI changes from baseline were examined for each PASI response group.
Results: Overall, 575 patients on tildrakizumab 100 mg (male: 69.6%; mean baseline age: 45.6 years) and 581 on tildrakizumab 200 mg (male: 73.0%; mean baseline age: 45.9 years) were included. At week 28, 8.3%, 22.0%, 40.9%, 66.3%, and 86.5% (8.7%, 35.2%, 43.9%, 70.4%, and 85.9%) of patients with PASI < 50, 50–74, 75–89, 90–99, and 100 achieved DLQI 0/1 for those on 100 mg (200 mg), respectively. Patients with higher week-28 PASI response also had greater mean DLQI reductions from baseline at week 28 (100 mg: 5.7-13.4; 200 mg: 5.4–12.9). Similar patterns were observed among patients continuously treated with tildrakizumab 100 mg or 200 mg from baseline to week 52, with better PASI-response patients having greater proportions achieving DLQI 0/1 and greater DLQI reductions sustained from week 28 through week 52.
Conclusion: Tildrakizumab-treated patients with higher levels of PASI response also demonstrated better quality-of-life improvements. Achieving PASI 100 was not necessarily associated with achieving DLQI 0/1, therefore both efficacy and quality-of-life improvements need to be evaluated separately to provide a complete picture of treatment success.
Reference:
1. Reich K, Papp KA, Blauvelt A, et al. Tildrakizumab versus placebo or etanercept for chronic plaque psoriasis (reSURFACE 1 and reSURFACE 2): results from two randomised controlled, phase 3 trials. Lancet. 2017;390(10091):276-288.
This abstract has been accepted by 2018 EADV Spring Symposium.

P071

STATISTIC REVIEW OF PSORIASIS SYSTEMATIC THERAPIES IN NORTH GREECE

Konstantinos Efthimiadis, Florentina-Silvia Delli
State Clinical for Skin and Venereal Diseases Thessaloniki, Greece

Introduction: Psoriasis is a chronic disease that can have a significant effect on quality of life. Therefore, management of psoriasis involves both psychosocial and physical aspects of this disease, lately generally admitted as systemic. Numerous topical and systemic therapies are available for the treatment of the cutaneous manifestations of psoriasis. In our daily clinical practice, treatment modalities are chosen on the basis of disease severity estimated with PASI and DLQI, relevant comorbidities, and patient preference.
*Objective:*To assess the frequencies of each systemic drug, classical or biological, used for the treatment of mild, moderate to severe psoriasis in our hospital care unit from January 2016 since December 2016.
Methods: Moderate to severe psoriasis was defined by PASI > 10 and/or DLQI > 10 and/or any PASI in a patient with psoriatic arthritis.
Results: Most of our patients with mild to moderate psoriasis are using topical and classical therapies. A significant number of patients with severe psoriasis are using biological therapies and about a half of them were already used a classical or other biologic drug.
Conclusion: Despite the fact that new biological drugs are available for psoriasis treatment, it seems that the patients with mild psoriasis are still treating with topical products. At least as far as it concerns our Mediterranean country, it seems that our patients difficult accept the biological therapies as first choice line treatment.

P073

PHARMAKOVIGILANCE OF SYSTEMIC ANTIPSORITIC DRUGS: AN UPDATE FROM ROUTINE CARE

Christina Sorbe[1], Laura Kühl[1], Stephan Jeff Rustenbach[1], Ralph von Kiedrowski[2], Marc Alexander Radtke[1], Matthias Augustin[1]
[1]University Medical Center Hamburg-Eppendorf, [2]Dermatological office, Selters

Introduction & Objectives: The spectrum of antipsoriatic systemic therapies is constantly changing. The short-term efficacy and safety of the various therapies are demonstrated in controlled clinical studies. The German Psoriasis Registry PsoBest aims to gain long-term evidence of safety and effectiveness in routine care. Updated interim data of long-term safety of biological and non-biological treatment of psoriasis is presented.
Materials & Methods: The non-interventional German Psoriasis Registry PsoBest observes adult patients with moderate to severe psoriasis and/or psoriatic arthritis. Patients are registered at naïve systemic treatment start and are observed for 10 years in routine care. The registry aims to gain long-term evidence of safety and effectiveness of systemic antipsoriatic drugs. Data is collected in dermatological practices and walk-in clinics. Presented are standardised patient rates per 100 patient years (py) of exposure classified by system organ classes of MedDRA® (SOC, Medical Dictionary for Regulatory Activities).
Results: Until June 2017, 5,825 patients were registered and sufficient for analyses. They were predominantly male (58.8%), had a mean age of 47.7 years (SD 14.5) and 30.0% of patients suffered psoriatic arthritis. 4,729 patient years (py) were observed on biologic treatments and 6,583 py on other systemic treatments. For all cause death, malignancies and other serious adverse events (SAE), there were no significant differences between the treatment cohorts. Highest SAE rates were observed in the SOCs Surgical and medical procedures (3.5 and 2.6 patients/ 100 py on biologics and non-biologics, respectively), General disorders and administration site conditions (2.0 and 1.8 patients/ 100 py), Infections and infestations (1.6 and 1.1 patients/ 100 py) and Neoplasms (1.4 and 1.3 patients/ 100 py). Events from other SOCs were observed for less than 1 patient/ 100 py.
Non-serious adverse events (AE) within the SOCs Skin and subcutaneous tissue disorders, Renal and urinary disorders, Blood and lymphatic system disorders, Gastrointestinal disorders, Nervous system disorders, Vascular disorders as well as Investigations were less frequent in biologic treatment compared to non-biologics (2.2 vs. 5.3, 0.3 vs. 0.7, 0.4 vs. 2.3, 2.4 vs. 11.3, 1.3 vs. 2.7, 1.2 vs. 2.1 and 2.0 vs. 3.4 patients/ 100 py, respectively, $p \leq 0.05$). Non-serious infections were observed more often in biologics (7.0 vs. 4.8 0 patients/ 100 py, $p \leq 0.05$). For the lately authorized treatments secukinumab and apremilast 253 and 111 py were observed, for biosimilar treatment 5 py. They showed no deviations from the previously observed safety profile of other systemic therapies.
Conclusions: In the general, no increased risk of biological or non-biological treatments was observed. The specific differences in non-serious events will be evaluated in more detail in future

analyses. For robust data on recently authorised therapeutics, more observation time is needed, especially with a constantly changing spectrum of treatments.

P074

THE IMPACT OF PATIENT REQUESTS ON PSORIATIC ARTHRITIS TREATMENT

Lynn Price, Jennifer Robinson, Gianna Melendez
Spherix Global Insights

Introduction: As a result of direct to consumer advertising, patients frequently request well-known brands for the treatment of psoriatic arthritis, and these patients tend to be highly involved in their therapy decisions. Patient requests commonly relate to formulation preferences, and in an indication dominated by biologics administered either subcutaneously or intravenously, oral small molecules are in high demand.
Objectives: One of the objectives of this study was to gain further insight into patient requests as a main driver for switching to and from biologics/apremilast.
Methods: An independent market analytics firm collaborated with US rheumatologists ($n = 200$) to conduct a retrospective chart review of patients diagnosed with psoriatic arthritis (PsA) ($n = 1{,}008$), who had switched from one biologic therapy or apremilast to another in the prior twelve weeks. Rheumatologists were able to submit up to seven PsA patient charts. Data were collected in April 2017 and included clinical and non-clinical patient demographics, as well as physician demographics and attitudinal survey responses.
Results: PsA patients tend to be very involved when it comes to treatment decisions as 60 percent of patients had significant input or were the primary driver behind the recent decision to switch agents. Of those patient driven switches, only 36 percent of treating rheumatologists felt there was strong clinical rationale behind the switch; despite this, nearly half of rheumatologists state they tend to approve specific patient requests.
Two-thirds of collaborating rheumatologists believe patients would choose an oral agent over one that administered subcutaneously, thus switching to apremilast is particularly common when patients are involved in the decision. Patient requests were the primary driver behind 24 percent of all switches to apremilast, compared to just 12 percent when switching to a biologic. Furthermore, for rheumatologists who are not in favor of an "apremilast before biologics" treatment approach, patient requests are significantly more of a driver for the brand than those who have adopted an "apremilast before biologics" approach.
Conclusion: PsA patients are highly involved in the decision to initiate and switch biologic/apremilast therapies, and treating rheumatologists tend to be open to granting such requests, regardless of clinical rationale. When patient requests are a primary driver for switching, apremilast benefits the most; largely due to the oral formulation. With the new approval of the first JAK inhibitor and second oral option in the PsA market, tofacitinib will likely fill a gap for both physicians and patients by introducing a high efficacy oral option, warranting follow-up analysis on the evolution and impact of patient requests in PsA.

P075

THE RISK OF KC IN PSORIASIS PATIENTS RECEIVING BIOLOGICS COMPARED TO CONVENTIONAL SYSTEMIC THERAPIES

Kayleigh Mason
The University of Manchester, Manchester, UK

Introduction: Whether psoriasis patients exposed to biologic therapies have an elevated risk of keratinocyte carcinoma (KC), including basal cell carcinoma (BCC) or cutaneous squamous cell carcinoma (cSCC) remains uncertain.
Objective: The aim of the present study was to determine whether such patients were at higher risk of developing a KC compared to those on conventional therapy.
Methods: The British Association of Dermatologists Biologic Interventions Register (BADBIR), a pharmacovigilance register of psoriasis patients, explores the long-term safety of systemic therapies. Patients with chronic plaque psoriasis registering to BADBIR on their first biologic or a conventional therapy, who had at least one follow-up completed were included in analyses if they were of white ethnicity, Fitzpatrick skin types 1–4 and reported no previous cancers. Confounding factors included: age; sex; smoking; and previous exposure to acitretin, psoralen ultraviolet-A (PUVA), ciclosporin, and/or PUVA and ciclosporin. Propensity score-weighted Cox-proportional hazard models estimated the hazard ratio (HR) for developing a first KC or separately, first BCC or cSCC.
Results: In total, 5672 patients initiating biologic therapy and 3188 patients on conventional therapy who met the entry criteria were identified with 20558 and 7829 person-years of follow-up, respectively. During follow-up, 74 (1.3%) patients initiating a biologic therapy were diagnosed with their first KC (43 BCC; 34 cSCC first) and 22 (0.7%) patients receiving conventional therapy with their first KC (15 BCC; 10 cSCC first). No significant difference in risk was observed for developing a KC (adjusted HR 1.05; 95% CI 0.64, 1.73), BCC (0.84; 95% CI 0.45, 1.54) or cSCC (1.20; 95% CI 0.57, 2.50) on biologic compared to conventional therapy.
Conclusion: Biologic therapy does not appear to confer a higher risk of developing a first KC as compared to conventional therapy in psoriasis patients. These data will help inform clinical decision making in psoriasis patients at risk of KC in whom biologic or conventional therapy is being considered.
On behalf of the BADBIR Study Group, British Association of Dermatologists, London, UK

P076

PATIENT PERCEPTIONS OF PSORIASIS SEVERITY IN SWEDEN, NORWAY, AND DENMARK

Kjersti Danielsen[1], Albert Duvetorp[2], Lars Iversen[3], Mikkel Østergaard[4], Oliver Seifert[5], Kåre Steinar Tveit[6], Lone Skov[7]
[1]UiT The Arctic University of Norway, Tromsø, Norway; University Hospital of North Norway, Tromsø, Norway, [2]Linköping University, Linköping, Sweden; Skånes Universitetssjukhus, Malmö, Sweden, [3]Aarhus University Hospital, Aarhus, Denmark, [4]Copenhagen Center for Arthritis Research, Center for Rheumatology and Spine Diseases, Rigshospitalet, Glostrup, University of Copenhagen, Copenhagen, Denmark, [5]Linköping University, Linköping, Sweden; Ryhov Hospital, Jönköping, Sweden, [6]Haukeland University Hospital, Bergen, Norway, [7]Herlev and Gentofte Hospital, University of Copenhagen, Copenhagen, Denmark

Introduction: Optimal clinical management of psoriasis (PsO) and psoriatic arthritis (PsA) requires understanding of their impact on patients.
Objectives: NORPAPP aimed to evaluate disease prevalence and patient perceptions of severity in Sweden, Denmark, and Norway.
Methods: NORPAPP was an on-line survey carried out during November and December 2015 using YouGov panels in Sweden, Denmark, and Norway. The survey included 44 questions covering self-perceived disease severity/symptoms, quality of life, contact with the healthcare system, and treatment. The initial survey population was randomly selected using framing quotas based on population census data to ensure inclusion of a representative sample of adults (aged 18–74 years) from each country. Participants were asked if they had PsO or PsA and if it was physician diagnosed: those diagnosed by a physician were invited to participate in the full survey. Final survey data were weighted to match national sex and age distributions. Self-perceived disease severity was expressed by a 5-level score. Severity of PsO based on the % body surface area (BSA, mild ≤3%; moderate 4–9%; and severe

≥10%) was based on the respondent's estimate of palms of affected skin (1 palm = 1% BSA).
Results: Among 22,050 individuals questioned, reported prevalence of PsO and/or PsA was 9.7% (9.4% in Sweden, 9.2% in Denmark, and 11.9% in Norway); 1264 (5.7%) individuals reported physician diagnosis and 1221 of these completed the full survey. Among survey participants, 74.6% reported PsO alone, 10.3% PsA alone, and 15.1% both. There was a limited correlation between self-perceived disease severity and estimates of % BSA for PsO (Spearman's rho 0.42). Self-perceived PsO severity was related to the most common symptoms (itching and flaking/scales) but % BSA-based clinical severity was not. Respondents with PsA+PsO reported significantly worse self-perceived severity and % BSA of PsO than those with PsO alone. Overall, PsA symptoms were self-perceived to be more severe than PsO symptoms.
Conclusion: Patient perceptions of PsO severity differ from their estimates of %BSA and should be considered in the assessment and management of PsO.

P077
PATIENT EXPECTATIONS AND SATISFACTION IN PSORIASIS TREATMENT: A SURVEY FROM EUROPE AND CANADA

Jonathan Barker[1], Robert McKenzie[2], Daniel Saure[2], Stefan Wilhelm[2], Kunal Gulati[2], Ronald Vender[3]
[1]Guy's Hospital, St. John's Institute of Dermatology, London, UK, [2]Eli Lilly and Company, [3]Dermatrials Research INC, Hamilton, Ontario, Canada

Introduction: Psoriasis is a chronic immune-mediated disease that negatively affects the quality of life of patients.1 Despite recent advancements in treatment, patient expectations may differ from the treatment outcome, potentially leading to dissatisfaction.
Objective: To evaluate patient expectations on psoriasis treatment outcomes and to what extent these were met by the treatment.
Methods: Data were collected from patients with moderate-to-severe psoriasis with ≥ 3% skin involvement. Patients were included from 17 European countries and Canada through a structured, web-based interview in their local language. Patients were on topical, PUVA/phototherapy, conventional systemic or biological treatment. Descriptive statistical analyses were conducted.
Results: Overall, 1946 patients (mean [SD] age: 42 [13] years, 43% male) with psoriasis were surveyed between 6 July 2016 and 5 May 2017. The vast majority of patients currently on treatment reported reduced itchiness (69%), reduced flaking (62%), and clearer skin/skin that looked better generally (61%) as the main expectations of their treatment. In addition, these patients reported duration of effect (41%), extent of overall skin clearance (36%), and speed of onset (34%) as the main influences for changing their current treatment. Furthermore, patients were asked whether their achieved results matched with their initial treatment expectations. Patients reported that the convenience of dosing (68%) and administration method (68%) completely met, or even exceeded their initial expectations for the treatment. Conversely, expectations for reduced itchiness (62%), reduced flaking (62%), clearer skin/ skin that looked better generally (63%) were only partially met or not met at all. Approximately, two-third of patients were dissatisfied or only partially satisfied with the extent of their skin clearance and improvement in at least one specific area. Specifically, scalp (48%), legs (42%), and arms (41%) were the highest rated areas if asked for insufficient satisfaction for clearance.
Conclusion: Data from this international survey indicate that efficacy and maintenance of response are the patients' primary expectations of psoriasis treatment whereas, insufficient response to therapy in difficult-to-treat areas appears to be a major reason for patient dissatisfaction.
Reference:
1. Paul C, Bang B, Lebwohl M. Fixed combination calcipotriol plus betamethasone dipropionate aerosol foam in the treatment of psoriasis vulgaris: rationale for development and clinical profile. Expert Opin Pharmacother. 2017 Jan;18(1):115-121.
This survey was sponsored by Eli Lilly and Company, Indianapolis, USA.

P078
SOCIOECONOMIC DETERMINANTS OF PAEDIATRIC PSORIASIS

Jonathan Groot[1], Anne-Marie Nybo Andersen[2], Abdulfatah Adam[2], Tilde Elkjær Tind Nielsen[2,3], Christoffer Blegvad[3], Lone Skov[3]
[1]Department of Dermatology and Allergy, Herlev and Gentofte Hospital, University of Copenhagen, Hellerup, Denmark, [2]Section for Epidemiology, Department of Public Health, University of Copenhagen, Copenhagen, Department of Dermatology and Allergy, Herlev and Gentofte Hospital, University of Copenhagen, Hellerup, Denmark

Introduction: Psoriatic comorbidities have been shown to be inversely associated with socioeconomic position (SEP). We hypothesized that the social patterning of paediatric psoriasis would be similar to that observed for several psoriatic comorbidities, such as cardiovascular disease and type 2 diabetes mellitus.
Objectives: Our aim was to investigate whether maternal SEP is a determinant of paediatric psoriasis.
Methods: Data on paediatric psoriasis from 36,003 offspring of a national birth cohort were cross-linked with nation-wide registry data on maternal educational attainment, maternal labour market attachment and equivalised household income. We performed logistic regression analyses to test for associations between measures of maternal SEP and paediatric psoriasis. Cohort analyses were conducted, estimating the odds ratios (OR) and 95% confidence intervals (CI) of offspring psoriasis. We included maternal age at birth and maternal psoriasis as covariates in adjusted analyses.
Results: Maternal educational attainment and equivalised household income were inversely associated with offspring psoriasis. Offspring of mothers with a low educational attainment had an OR 1.62 (95% CI: 1.20–2.18; $p < 0.01$) of paediatric psoriasis, after adjusting for maternal psoriasis and age, compared to offspring of mothers with a medium educational attainment. Offspring of mothers in the highest quartile compared to mothers in the lowest quartile of equivalised maternal household income had an OR 0.59 (95% CI: 0.44–0.80; $p < 0.001$) of paediatric psoriasis, after adjusting for maternal psoriasis and age.
Conclusion: Lifetime prevalence of paediatric psoriasis was inversely associated with maternal SEP in our study population. Early life exposure to modifiable risk factors associated with SEP may play an important role in the development of paediatric psoriasis. Future studies are warranted to clarify the role of mediating factors.

P079
OBESITY AND THE RISK OF PSORIASIS: A KOREAN NATIONWIDE, POPULATION-BASED STUDY

Ju Hee Han[1], Kyung Do Han[2], Chul Hwan Bang[1], Young Min Park[1], Jun Young Lee[1], Yong Gyu Park[2], Ji Hyun Lee[1]
Department of Dermatology, Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Department of Biostatistics, College of Medicine, The Catholic University of Korea, Seoul, Korea

Introduction: Psoriasis is a T-helper-1 and -17 cell-mediated, chronic, inflammatory skin disease affecting approximately 1–3% of the general population. Psoriasis is currently considered as a chronic low-grade inflammatory condition that plays an active role in the development of the pathophysiologic phenomena responsible for metabolic syndrome and cardiovascular disease. Obesity, as a component of the metabolic syndrome, represents a major comorbidity and possibly contributes to reduced treatment response.
Objective: This nationwide, population-based study investigated the impact of body mass index (BMI) and waist circumference (WC) on the psoriasis in the Korean population.
Methods: We used the health check-up database, which is sub-

dataset of the Korean National Health Insurance Service database. Study population includes subjects who had undergone health screenings between January 2009 and December 2012. Patients who were diagnosed with psoriasis prior to the health screening or who were less than 20 years of age were excluded. This study investigated newly diagnosed patients with psoriasis (ICD-10 code, L40) by dermatologists among subjects during the follow-up period through the claim data.
Result: Total 22,633,536 subjects were included and psoriasis newly developed in 399,461 subjects. Mean BMI among newly developed psoriasis group (23.9±3.25) was higher than non-psoriasis group (23.68±3.27)($p < 0.0001$). Mean WC of newly developed psoriasis group (81.21±9.27) was higher than non-psoriasis group (79.99±9.26) ($p < 0.0001$). BMI showed J-shaped association with the risk of psoriasis. Subjects with BMI over 30 had higher risk of psoriasis (HR 1.118, 95% CI 1.1–1.137). The risk of psoriasis increased in proportion to WC. Subjects with WC over 105 cm showed highest risk of psoriasis (HR 1.305, 95% CI 1.261–1.349) after adjusting confounding factors including BMI. The risk of psoriasis increased most in the male group with normal weight, abdominal obesity (HR 1.175, 95% CI 1.15–1.2).
Conclusion: According to our study, the WC is more likely to affect the risk of psoriasis than obesity. Our study supports the association between abdominal obesity and psoriasis, which increases awareness of the role of abdominal obesity in the pathogenesis and comorbidities of psoriasis.

P080
CLINICAL CHARACTERIZATION OF PSORIATIC ARTHRITIS IN A MULTIDISCIPLINARY CARE MODEL OF PATIENTS WITH PSORIASIS

Dalila Alejandra Lopez-Rodriguez
Dermatologico Country

Introduction: Psoriatic arthritis (PsA) is an inflammatory arthropathy that occurs in patients with Psoriasis (PsO). The frequency of PsA in patients with PsO has been estimated between 10–40%. The presentation and clinical course are variable, therefore, it is necessary to understand the clinical behavior, severity and associated factors that condition functional impairment, disability and lost quality of life.
*Objective:*To describe the clinical features of the ApS, in a multidisciplinary PsO clinic.
Methods: Prospective study, August 2016-february 2018, patients attending to Multidisciplinary Clinic for psoriasis in Dermatologico Country were included.
Results: A total of 53 participants were included, finding a prevalence of psoriatic arthropathy of 58.5%.
The median age was 42 years and 71% were female. Patients with ApS have higher frequency of DM2, metabolic syndrome and hepatic steatosis. However, the differences are not statistically significant, which could be a result of the sample size. According to the activity of PsO the most frequent presentation was plaque psoriasis in 67.7%. Median PASI was 5.4 (1.5, 16.4). Axial presentation of ApS was observed in 51.6% and peripheral disease in 71%, enthesitis was found in 54.8% and dactylitis 16.1%. To determine the severity of PsA according DAS 28 score, we found 45.2% of patients presented severe activity. One hundred percent of the subjects with peripheral disease did not achieve low activity criteria of the disease measured by MDA. When calculating the tertiles of the HAQ instrument, it is possible to observe that 51.6% of patients presented severe deterioration in the quality of life. In the logistic regression model without adjustment, the presence of a severe DAS 28 is associated with an increase in the risk of deterioration in quality of life, with OR of 6.24 (1.74, 22.2). The presence of BMI > 27 is associated with an increase in the risk of deterioration in quality of life with OR of 6.53 (1.59, 26.8). When performing the adjusted multivariate model, the only variables that were associated with severe deterioration of quality of life were the presence of BMI > 27 and on the other side, pain, with BMI > 27 is the factor that mostly impairs the quality of life.
Conclusions: Prevalence of PsA in this series of patients with skin or nail psoriasis was 58.3%. The 45.2% of patients showed severe activity and 51.6% severe deterioration in their quality of life, that leads to disability and limitation performing daily activities. An early diagnosis provides the possibility of appropriate treatment to improve function, quality of life and decrease the progression and complications of the disease.

P081
TRIGGERING FACTORS IN CHILDHOOD PSORIASIS

Iveta Dencheva[1], Ivan Botev[2], Lyubka Miteva[1]
[1]Dermatology clinic "Persenk", [2]Department of Dermatology and Venereology, Medical University, Sofia, Bulgaria; Dermatology clinic "Persenk", Sofia, Bulgaria

Introduction: Psoriasis is a chronic multisystem, inflammatory disease that occurs at any age. It represents about 4% of all dermatosis observed in children. Approximately one third of all patients have onset of the disease under the age of 16. The most common triggering factors in children are stress, Koebner phenomenon, infections and seasonal change.
Objectives: The aim of this study was to assess the most common triggering and precipitating factors of psoriasis among Bulgarien children.
Materials and Methods: This study included 42 consecutively diagnosed children with psoriasis who presented in the Department of Dermatology and Venereology at Alexandrovska University Hospital, in Sofia, Bulgaria. The inclusion criteria were a clinical diagnosis of psoriasis and age under 18 years.
Results: A total of 42 children with psoriasis were examined, 18 (42.85%) males and 24 (57.15%) females. The most frequent factors precipitating psoriasis in our group of children were psychoemotional stress in 16 (38.09%) cases. Koebner`s phenomenon was observed in 3 (7.14%) patients. In only two (4.76%) children triggering factors associated with psoriasis were infections. In 17 (40.47%) cases aggravating factors could not be identified. The influence of the season on disease activity could be determined in 25 (59.52%) patients. All of them showed worsening in winter and improvement in summer.
Conclusion: The most frequent factors precipitating psoriasis in children revealed in this study, were stressful life events, Koebner phenomenon and infectious disease. Among patients who reported triggering factors, stress was the most common cause. The study showed that psoriasis in children relapses and worsens mainly in winter season.

P082
QUALITY OF CARE FOR PSORIASIS IN THE PAST 12 YEARS – RESULTS FROM A SERIES OF NATIONWIDE HEALTH CARE STUDIES IN GERMANY

Matthias Augustin
Institute for Health Services Research in Dermatology

Introduction: In Germany, the quality of health care for psoriasis was very critical in 2005. Most patients lacked of sufficient care and there was only a minor proportion receiving systemic drugs. In the mean time, there has been conducted a national psoriasis program in order to improve the quality of psoriasis care, including development of an evidence-based guideline, a consensus of treatment goals, the invention of a "culture of measurement" and consented national goals for psoriasis care. These measures were supported by the establishment of 30 regional psoriasis networks involving more than 800 dermatologists.
Objectives: (1) Presentation of the very recent results on the health care situation of patients with psoriasis vulgaris in dermatological

treatment in Germany 2016/17 (2) Comparison of health care quality indicators between the surveys 2004/05, 2007, 2013/14 and 2016/17.
Methods: Nationwide, non-interventional, cross-sectional studies. In each survey between 71 and 130 centers included patients and data from patients and dermatologists were obtained from a minimum of 1500 patients per survey. Quality of care indicators were severity of the psoriasis (PASI and proportion of patients with PASI > 20, indicating high severity), quality of life (DLQI and proportion of patients with DLQI > 10, indicating strong impairments in quality of life), previous systemic therapy and inpatient treatment in the last five years.
Results: Between January 2016 and December 2017 $n = 1827$ patients from 93 dermatological centers were included in the recent survey (mean age 51 years, 45.2% female). 7.5% had severe psoriasis (PASI > 20) compared to 9.2% in 2013/14, 11.6% in 2007 and 17.8% in 2004/05. The mean PASI was 7.3 compared to 8.1 in 2013/14, 10.1 in 2007 and 11.4 in 2005. The mean DLQI was 6.1 compared to 5.9 in 2013/14, 7.5 in 2007 and 8.6 in 2005. 21.4% reported a strongly impaired quality of life (DLQI > 10) compared to 21.3% in 2013/14, 28.2% in 2007 and 34.0% in 2005. 59.5% of all participants stated that they had received systemic therapy at least once within the last five years compared to 59.5% in 2013/14, 47.3% in 2007 and 32.9% in 2005. 18% received inpatient hospital treatment within the last five years at least once, compared to 20.1% in 2013/14, 20.1% in 2007 and 26.9% in 2005.
Conclusions: It can be assumed that health care quality for psoriasis patients in Germany has improved within the last 12 years.

P083
GLOBAL PSORIASIS ATLAS – WORK STREAM 2

Matthias Augustin, Nirohshah Suthakharan
University Medical Center Hamburg, Institute for Health Services Research in Dermatology and Nursing (IVDP)

Introduction: Psoriasis is a common, chronic and non-communicable skin disease with an immensely negative impact on people's lives. There is a lack of standardized case-definition or methodology leading to a wide variation in the prevalence estimate between 0.09% and 11.43%. To tackle this knowledge deficit and in response to the WHO Global report on Psoriasis (2016), the Global Psoriasis Atlas (GPA) will be a first-ever online leading epidemiological database on psoriasis. It will inform research, policy and health care provision worldwide. GPA provides a detailed disease prevalence and incidence as well as information on access to treatment, comorbidities and cost to society which will enable extensive comparisons between countries over time. Furthermore, it will provide accurate health data for decision makers, stakeholders and patients worldwide.
Objectives: The GPA includes two Work Streams (WS) Teams. WS1 is conducting extensive literature review on psoriasis. In this paper the WS2 is explaining the development of methodology to serve the framework for compiling the GPA data. Methods: Currently, data sources are being collected in two phases and for the selection of data sources an in-/exclusion criteria were developed and followed. Firstly, a global online survey on data source identification is being conducted in > 150 countries worldwide addressed to dermatologists and non-dermatologists. The questionnaire identifies local, regional and national data sources including registries, research institutes, projects, publications and other relevant sources supporting the GPA project. Secondly, Desk research on the same data sources is being conducted. Discussion on the following aspects: identification of non-published sources, integration of different sources, solving interpolation issues of hard-to-reach areas and creating database.
Results: Desk research has identified potential data sources from 199 countries which includes 194 ministries of health, 97 registries, 84 patient associations, 32 statistic institutes, 25 Public Health organizations, 230 research institutes (general/psoriasis specific), 13 claim data sources and 261 publications on psoriasis. The internal pilot for the global online surveys has been completed by an international expert team for further improvement. Currently, the surveys are being sent out to dermatologists and non-dermatologists. On a monthly base, both work streams are updating each other about their achievements and issues.
Conclusion: In the next steps of Work Stream 2, a database will be created in order to insert all identified data sources. Information from identified data sources will be used to contact (via email) the responsible persons to access this data. Additionally, survey responses will be analyzed and added in the database. This database will be updated regularly and extended to include comorbidities in future.

P084
GLOBAL BURDEN OF DISEASE: A SYSTEMATIC LITERATURE REVIEW ON DISABILITY WEIGHTS FOR SKIN DISEASES

Nirohshah Suthakharan, Matthias Augustin
University Medical Center Hamburg, Institute for Health Services Research in Dermatology and Nursing (IVDP)

Introduction: Skin diseases account for one of the most common human illnesses globally but in the recent Global Burden of Disease (GBD) study, psoriasis, for example, ranked 144 out of 174 conditions in the DALY rankings. Two components of DALY calculation are prevalence of the disease and disability weight factor. The derivation of disability weight (DW) factor depends on many factors which can lead to wide range of results. GBD methodology can significantly underestimate the skin disease burden.
Objective: To understand the currently used DWs of skin diseases in-depth and if these current records of DWs can be solely based on a survey that was conducted on the general population.
Methodology: A systematic literature review was performed to answer the research questions. Comprehensive search of eligible scientific and grey publication in English, from 2007 to 2017, were conducted in PubMed and EMBASE (Ovid). The studies included were based on 16 skin condition and other diseases indicating a re-estimation, alternative approach (also besides DALY) to DWs. 20 relevant studies were included and have been elaborated in the review based on a 'conceptual model of assessing DWs and its design choices' by Haagsma et al., 2014. The health state descriptions, panel composition, and valuation methods used to derive DWs in these studies is discussed in detail.
Results: There was scarce literature available for skin diseases in particular. DW value depends on and can vary with the panel composition: general public, health experts or patients. The health state description whether disease specific or generic, with or without label, describing the course of condition over a period or only temporarily, can all influence the panel members' decision. The valuation methods paired comparison, population health equivalence, visual analogue scale, standard gambling or person/time trade-off can alter the results to a great extent. The contextual differences across the countries can also make a difference in the calculation. The inclusion of certain skin conditions/health states under other medical specialties can be a major factor leading to underestimation of overall skin disease burden worldwide.

P085
MIR-499 POLYMORPHISM IS ASSOCIATED WITH SUSCEPTIBILITY TO PSORIATIC ARTHRITIS – PRELIMINARY STUDY

Renata Sokolik[1], Jerzy Świerkot[1], Milena Iwaszko[2], Mikołaj Kozłowski[1], Lucyna Korman[1], Piotr Wiland[1], Katarzyna Bogunia-Kubik[2]
[1]Department and Clinic of Rheumatology and Internal Medicine of Wroclaw Medical University, [2]Laboratory of Clinical Immunogenetics and

Pharmacogenetics, Hirszfeld Institute of Immunology and Experimental Therapy, Polish Academy of Sciences, Wroclaw, Poland

Introduction: Polymorphism within the miR-499 has been reported to be associated with susceptibility to rheumatoid arthritis (RA) in various populations.

Objectives: Our study aimed to find out whether similar association could be observed also in Polish population in both RA and psoriatic arthritis (PsA) patients.

Methods: For this purpose 359 individuals were studied, including 111 RA patients, 86 patients with PsA and 162 healthy blood donors that served as a control group. Genotyping for miR-499 rs3746444 T/C was performed using a LightSNiP assay.

Results: Distribution of the miRNA-499 alleles and genotypes was similar in RA patients and controls. Among RA patients those carrying the CC homozygous genotype presented with lower DAS28 at diagnosis (0.027) but higher CRP levels after 12 weeks of anti-TNF treatment ($p = 0.042$). Interestingly, the TT genotype (rs3746444) was overexpressed in patients with PsA as compared to controls (OR = 1.85, $p = 0.034$) but its frequency was not significantly different when compared to RA cases. This polymorphism was also not found to be associated with clinical parameters in PsA patients.

Conclusions: These results show that miR-499 rs3746444 T/C polymorphism may constitute a risk factor for psoriatic arthritis development.

P086

ASSOCIATION BETWEEN INFLAMMASOME-RELATED POLYMORPHISMS AND CLINICAL PHENOTYPES OF PSORIATIC ARTHRITIS

Kristina Juneblad, Gerd-Marie Alenius

Department of Public Health and Clinical Mediciine, Rheumatology, University Hospital, Umeå

Introduction: Psoriatic Arthritis (PsA) disease expression can vary from mild mono-/oligoarthritis to severe erosive polyarthritis comparable with Rheumatoid Arthritis (RA), with or without axial involvement, and manifestations such as dactylitis and enthesitis are common. Markers of systemic inflammation (ESR or CRP) are generally unhelpful as markers of disease severity since elevated in only 50% of cases.

In recent years, research on the interleukin 1β (IL1 β)–regulating protein complex, called the inflammasome, has shown interesting associations with various inflammatory diseases. E.g. for RA (1) and psoriasis (Pso) (2,3) associations with genetic polymorphisms in genes related to the inflammasome has been discovered. So far, no studies investigating genetic polymorphisms in inflammasome genes in patients with Psoriatic Arthritis (PsA) have been published.

Aim: To analyse different single nucleotide polymorphisms (SNP:s) in genes related to the inflammasome in relation to different disease phenotypes of Psoriatic Arthritis (PsA).

Methods: DNA from 771 PsA patients from Northern Sweden were analyzed for different single nucleotide polymorphisms (SNPs) in *NLRP3* (rs35829419 (*NLRP3*-Q750K), rs10733113, rs4353135), CARD8 (*CARD8*-C10X, rs 2043211) and *NLRP1* (rs8079034, rs878329) in relation to different phenotypes of PsA.

Results: A significant association was seen with *NLRP1* rs878329C and patients with axial involvement of disease. When different genotypes were compared, significantly higher frequency of genotype CC were detected in the subgroup with axial involvement of disease. In addition, *NLRP1* rs8079034T was significantly associated with prescription of a csDMARD. Also, the *NLRP3* rs10733113 showed association with the G-allele in patients with a skin disease with an early onset (Pso type1, onset < 40 years) and in the subgroup of PsA with destructive-/deforming disease significant association was found with the major allele, C, of NLRP3 Q705K rs35829419. (Table 1)

Conclusions: In the study, we found association with different phenotypes of PsA and different polymorphisms in inflammasome genes. The results could indicate a possible role of inflammasomes in different disease phenotypes of PsA and make further studies in the area of interest.

References:

1. Kastbom A, Verma D, Eriksson P et al. Rheumatol 2008;47:415-7.
2. Carlström M, Ekman AK, Petersson S et al. Exp Dermatol 2012;21:932-7.
3. Ekman AK, Verma D, Fredrikson M, Bivik C and Enerbäck C. Br J Dermatol 2014;171:1517-20.

Table 1. Genotype and allele frequencies in different PsA disease expressions[#]

		Genotype						
NLRP1 rs878329	*n*	G/G *n* (%)	G/C *n* (%)	C/C *n* (%)	C allele	χ^2	OR (95% CI)*	*p*-value
Axial disease	107	30 (28)	51 (48)	26 (24)	48%	4.44	1.37 (1.02–1.84)	0.035
Peripheral disease	539	184 (34)	275 (51)	80 (15)	41%			
NLRP3 Q705K rs35829419		C/C	C/A	A/A	C allele			
Destructive disease	314	282 (90)	32 (10)	0 (0)	95%	4.7	1.61 (1.05–2.57)	0.03
No destructive disease	360	304 (84)	54 (15)	2 (0.6)	92%			
NLRP3 rs10733113		G/G	G/A	A/A	G allele			
Pso type1	439	347 (79)	87 (20)	5 (1)	89%	7.4	1.58 (1.13–2.21)	0.007
Not Pso type1	210	149 (71)	53 (25)	8 (4)	84%			
NLRP1 rs8079034		C/C	C/T	T/T	T allele			
csDMARD ever	499	320 (64)	169 (32)	19 (4)	20%	9.1	1.63 (1.19–2.25)	0.003
Never csDMARD	216	164 (76)	47 (22)	5 (2)	13%			

*Calculated with χ^2 test comparing variant allele frequencies between patients and controls.
[#]Only significant association are shown.

P088

FREQUENCY OF INADEQUATE RESPONSE TO TREATMENT AMONG PSORIASIS PATIENTS ON FIRST-LINE BIOLOGICS

Anna Sheahan[1], Edward Lee[2], Lisa Pisenti[2], Mohamed Yassine[2], Robert Suruki[3]

[1]UCB Pharma, Raleigh, NC, [2]UCB Pharma, Smyrna, GA, [3]UCB Pharma, Raleigh, NC

Introduction: Studies describing the occurrence of inadequate response (IR) to biologic treatments in psoriasis (PSO) in the real-world setting are currently lacking. Thus an understanding of IR, due to the lack of treatment durability, persistence, or access, to 1st line biologics in PSO may help to identify and address unmet treatment needs.

Objectives: To assess the frequency of IR in the year after initiation of 1st line biologic treatment for PSO. IR was defined as biologic dose increase, biologic discontinuation, or add-on treatment.

Methods: Retrospective analysis of commercial US healthcare claims (2012–2016) was conducted. Patients initiating a biologic (PSO approved anti-TNF, secukinumab, ustekinumab, apremilast) with ≥ 1 year of database enrolment before and after biologic initiation (index date) who had a qualifying PSO ICD 9/10 code and no previous biologic exposure in the year prior to the index date were included. Patients experiencing any of the following were classified as experiencing an IR event: 1) ≥ 1 claim with a biologic dose > 110% of the label-recommended dose for ≥30 days, 2) cessation of 1st line biologic (> 2 months with no treatment) ('non-switch discontinuation'), 3) cessation of first line biologic followed by initiation of a new biologic within 2 months, or 4) addition of a corticosteroid, immunosuppressant, or biologic ('add-on treatment') with any days' supply overlap.

Results: Of the 13,995 patients meeting inclusion criteria, 9,520 (68.0%) experienced an IR event in the 12-month follow-up period (53.2% female; mean age: 46.2 yrs) and 4,475 (32.0%) did not experience an IR event (45.2% female; mean age: 46.9 yrs). The most frequently used 1st line biologics were adalimumab (42.5%) and etanercept (26.5%); the proportion of IR patients was 60.4% in adalimumab and 75.8% in etanercept. Among all IR patients,

non-switch discontinuation was experienced by 63.8% of patients, switch to another biologic by 15.1%, above label dosing by 11.5%, and add-on treatment by 9.7%. Overall, the mean time from initiation of 1st line treatment to IR event was 4.7 months, ranging from 4.3 months to add-on therapy and 5.7 months for patients switching to another biologic. Among patients switching to another biologic, 70.3% of patients were persistent on the new biologic after three months versus 54.0% after 6 months. The most frequent add-on therapies were immunosuppressive drugs (63.8%) followed by systemic corticosteroids (20.6%), and biologics (15.5%).
Conclusions: IR in 1st line PSO biologic treatment is common with non-switch discontinuation being the most frequent. This highlights an opportunity to optimize treatment options currently available and better understand patients' needs for successful therapy. Therapeutic options with improved durability may provide a clinically meaningful path to optimizing psoriasis management. Further analysis is necessary to identify underlying causes of IR and to guide more effective approaches to treatment.
Acknowledgements: This study was supported by UCB Pharma.

P089
BARRIERS OF GUIDELINE-COMPLIANT CARE FOR PSORIASIS IN GERMANY – RESULTS OF THE EUROPEAN STUDY PSOBARRIER

Matthias Augustin, Anna Langenbruch, Marc Radtke, Nicole Zander
University Medical Center Hamburg-Eppendorf

Introduction & Objectives: A series of nation-wide studies in Germany over the last years has focused on the quality of psoriasis care. It was found that a significant proportion of psoriasis patients is not treated according to the national guideline1. Similar underprovision of care has been identified in other countries as well, reflected by patients' dissatisfaction with the management of their disease2. This study aims to identify these barriers of guideline-compliant healthcare for psoriasis in Europe.
Materials & Methods: The study assesses barriers and quality of health care in a multi-centre, cross-sectional study design. Participating centres in five European countries (Denmark, Poland, Spain, United Kingdom, and Germany) aim to represent the range of dermatological health care-providing outpatient facilities of the respective country. The current analysis includes the data collected in Germany from January 2016 to May 2017.
Results: Data of $n = 497$ patients were analysed. Mean age was 49.7 years, 41.4% were female. Mean PASI was 7.2 ± 9.2, 20.9% had a PASI > 10. The mean DLQI was 6.2 ± 6.7. 27.0% were currently treated with systemics (excluding biologics), 22.3% with biologics. Since the diagnosis of psoriasis, the participants consulted on average 3.0 ± 2.3 different dermatologists (min 0/max 27) and had 3.5 ± 3.7 therapy changes. For 32.0% of the patients the time between the first skin changes and the first diagnosis of psoriasis was one year or longer. 7.6% stated that their health insurance turned down a therapy, treatment or referral that was recommended by a physician at least once.
Conclusions: The quite high numbers of consultations of different dermatologists, therapy changes and therapies turned down indicate that there might be barriers in psoriasis care. The generated data facilitate measures for an improved patient access to systemic drugs and biologics. The European comparison will allow for the first time the direct description of psoriasis care in a wide variety of European countries. The matching of patient-reported outcomes with data of the health care system and barriers from the physician's perspective is a novelty worldwide and the results will contribute to developing strategies to overcome these barriers.
References:
1 Augustin M, Schäfer I, Reich K, Glaeske G, Radtke MA. Systemic treatment with corticosteroids in psoriasis--health care provision far beyond the S3-guidelines. J Dtsch Dermatol Ges. 2011;9:833–38.
2 Dubertret L, Mrowietz U, Ranki A, van de Kerkhof, P C M, Chimenti S, Lotti T, et al. European patient perspectives on the impact of psoriasis: the EUROPSO patient membership survey. Br J Dermatol. 2006;155:729–36.

P090
INDIVIDUALISED THERAPY FOR PSORIASIS - CASE SERIES

Seema Mahesh[1], Viraj Shah[2], Mahesh Mallappa[1], George Vithoulkas[3]
[1]Centre For Classical Homeopathy, [2]Shah Homeopathic Clinic, [3]International Academy of Classical Homeopathy

Introduction: Psoriasis and its complications are still a challenge to clinicians. The autoimmune disorder though targeting the skin, involves the immune system as a whole. The inflammatory component in the pathogenesis of psoriasis has further established the role of aberrant immune system in the process [1, 2, 3].
Homeopathy addresses every individual's peculiar combination of genetic and epigenetic causative factors in the development of such auto immune diseases [4, 5]. Therefore it may be considered as a therapy where integrated approach is indicated.
Case series: 5 cases of psoriasis are presented, two of which were in erythrodermic state [one also with sepsis superimposed]. Through monitoring of blood markers and documenting on photos and videos the effect of individualised homeopathic therapy on psoriasis and its complications is demonstrated.
The theory of Levels of Health can explain the variety in the presentation of psoriasis and response to treatment in terms of the time taken and number of remedies required. The same theory also helps to assess the prognosis and comprehend the response to treatment [LOH]. With the help of the evidence of these cases we may formulate a larger study to ascertain the extent to which classical homeopathy may be employed in psoriasis.
Conclusions: These cases depict the potential for homeopathy in alleviating the suffering of patients with psoriasis if applied as individualised therapy and give grounds to further conduct controlled studies to confirm the role of homeopathy in psoriatic therapy.
References:
1. Boyd A, Menter A. Erythrodermic psoriasis. Journal of the American Academy of Dermatology. 1989;21(5):985-991.
2. Chandra A, Ray A, Senapati S, Chatterjee R. Genetic and epigenetic basis of psoriasis pathogenesis. Molecular Immunology. 2015;64(2):313-323.
3. Reich K. The concept of psoriasis as a systemic inflammation: implications for disease management. Journal of the European Academy of Dermatology and Venereology. 2012;26:3-11.
4. Vithoulkas G, Tiller W. The science of homeopathy. Athens: International Academy of Classical Homeopathy; 2009.
5. Vithoulkas G. Levels of health. Alonissos: International Academy of Classical Homeopathy; 2017.

P091
A UNIQUE CLINICAL CASE OF PSORIATIC ARTHRITIS AND RELAPSING POLYCHONDRITIS

Elena Gubar, Alla Godzenko, Tatiana Korotaeva
Nasonova Research Institute of Rheumatology, Moscow

Introduction: Relapsing polychondritis (RP) is a rare systemic autoimmune disorder affecting the cartilaginous structures of the body and resulting in their destruction. In the literature available we didn't find any references to RP occurring together with psoriatic arthritis (PsA).
*Objective:*to demonstrate a rare clinical case of RP and PsA.
Methods: Patient (pt) (female), 29 y.o., complained of pain, swelling, and hyperemia of both ears, pain in the joints, in heels and toes and pain in cervical spine. Scalp psoriasis (Ps) and Ps in the external ear canal occurred in April, 2017, nail Ps and dactilitis in October, 2017; in November, asymmetrical polyarthritis, pain in heels, pain and limitation of movement in cervical spine developed. Besides the pt noticed redness, swelling and pain in pinnas of both ears and impairment of hearing; conjunctivitis, stomatitis and subfebrile temperature developed.

At presentation: plaque Ps on the face and scalp, nail Ps, palmoplantar feet pustulosis (BSA–4%, PASI –2.1); both pinnas of the ears were swollen, painful and red; ear lobes were not involved. The pt suffered from conjunctivitis. The pt had asymmetrical polyarthritis, dactylitis, achillobursitis. Painful movements at cervical spine, rotation 30°-35°. ESR 54 mm/h, CRP 99 mg/l, RF negative, positive HLA B27, HLA B5 not detected. PET-CT imaging did not reveal any pathological changes besides bilateral auricular inflammation.
Results: PsA diagnosis was determined according to CASPAR criteria. RP diagnosis was based on the McAdams criteria. The diagnosis is definite when no less than three out of six criteria are present: bilateral auricular chondritis, nonerosive seronegative arthritis, nasal septum chondritis, ocular inflammation, respiratory tract chondritis, and cochlear disorder. Our pt had bilateral auricular chondritis, conjunctivitis, cochlear disorder. The diagnosis was confirmed by ear-auricles biopsy which showed perichondrial inflammation and granulocyte infiltration. The therapy delivered: methotrexate s/c 10 mg pw; Solu-Medrol i/v (750 mg cumulatively); methylprednisolone per os 16 mg per day. Within days, there was normalization of temperature, ear-auricle swelling, redness and pain had regressed; hearing was restored, conjunctivitis passed, the intensity of arthritises, dactylitis and spondylitis had decreased; the reduction in ESR, CRP was to 14 mm/h, to 7.0 mg/l accordingly.
Conclusion: As is known, when a pt has PsO, he is twice as likely to develop additional autoimmune diseases. It is of great importance to properly diagnose and treat cross autoimmune diseases. Early diagnosis (within 3 months) and adequate treatment resulted in rapidly decreased inflammatory process and in escaping nonreversible changes in cartilage tissues.

P092
SPINY FOLLICULAR HYPERKERATOSIS IN A PSORIASIS PATIENT TREATED WITH USTEKINUMAB

Antoanela Carija, Adela Markota Cagalj, Neira Puizina Ivic
University Hospital Centre Split

Introduction: We present a psoriasis patient developing asymptomatic white spiny follicular hyperkeratoses (SFH) after being treated with ustekinumab for 3 months.
Objectives: This type of eruption has been described under several names including spiny follicular keratoderma, hyperkeratotic spicules, filiform hyperkeratoses, parakeratotic horns, and follicular hyperkeratoses (1). Facial hyperkeratotic spicule eruption was reported in association with monoclonal gammopathy. Drug-induced filiform hyperkeratosis has been reported with cyclosporine, with BRAF inhibitors (vemurafenib), with acitretin and with vismodegib and sorafenib.
Methods: Our patient started ustekinumab treatment in June 2015. At the same time he was treated with metothrexate, folic acid, metformin and lisinopril/hydrochlorothiazide. Three months after ustekinumab introduction patient noticed growth of tiny skin projections located on the face, scalp, upper trunk and upper arms. Each spiny lesion was approximately 0.5 to 1 mm in diameter and up to 5 mm high. A biopsy of a white spiny keratotic projection showed orthokeratosis, achantosis and mild spongiosis in epidermis, inflammatory infiltrate in chorium and dilatated acrotrichiums. Condition resolved in several weeks without any treatment and without ustekinumab cessation.
Results: A similar condition viral-associated trichodysplasia (TS) was originally described in 1999 as a folliculocentric viral infection in a patient who was receiving cyclosporine after kidney and pancreas transplantation. Trichodysplasia spinulosa associated polyomavirus (TSPyV) was identified in TS lesions and shown to be the probable cause of this disease (2). Pathogenesis both of viral-associated TS and BRAF inhibitor-induced SFH is based on the paradoxical activation of MAPK (mitogen-activated protein kinase) pathway, which regulates a variety of cellular processes including cell division, differentiation and apoptosis.
Conclusions: Our patient developed SFH possibly due to use of ustekinumab, IL-12 and IL-23 inhibitor. The latter has a role in differentiation process of the skin (12), suggesting that inhibition of IL-23 might explain the imperfect keratinization process observed in SFH. Considering that in our patient drug was not stopped and the condition resolved in several weeks without any treatment, possible cause could be ustekinumab-induced immunosupression and consequent viral infection.
References:

1. Yanik ME, Erfan G, Albayrak H, et al. Acitretine-induced spiny follicular hyperkeratosis. Cutan Ocul Toxicol. 2016;35:165-167.
2. DeCrescenzo AJ, Philips EC, Wilkerson MG, et al. Trichodysplasia spinulosa: A rare complication of immunosuppression. JAAD Case Reports. 2016;2:307-309.

P093
COMBINATION THERAPY OF APREMILAST AND BIOLOGICAL PRODUCT IN A PATIENT WITH PSORIASIS

Koji Masuda, Fuminao Kanehisa, Norito Katoh
Department of dermatology, Kyoto Prefectural University of Medicine

Apremilast was approved in March 2017 in Japan for the treatment of psoriasis and psoriatic arthritis. Apremilast appears to have lower efficacy than biological product. However, its ease of administration as an oral agent coupled with a mild side effect profile makes it an attractive option for psoriasis treatment. While monotherapy with biological products is effective for many patients with psoriasis, some patients are not satisfied by the outcome. There are few data or reports about the safety and efficacy of apremilast in combination of biological product in the treatment of psoriasis.
We report a 46-year-old man with about a twenty-year history of plaque psoriasis and psoriatic arthritis who failed several therapies including topical therapy, phototherapy and etretinate. At the time of presentation, the patient was using secukinumab for 9 months, which had controlled his arthritis. However, the patient noted plaque remained mainly on his lower legs. Apremilast was added and up-titrated to 30 mg twice per day along with his secukinumab therapy. After two months of combination therapy, the patient's disease has improved and stabilized with only a few scattered erythematous mildly scaly plaques on his lower legs. The patient denied side effects of nausea, diarrhea or headache. Laboratory-work was within normal limits.
However, we also experienced two other cases who failed apremilast add on therapy to biological product because of efficacy or side effects. So, this method may be useful for uncontrolled patient for psoriasis, more studies are needed to determine the safety and efficacy of using these drugs together.

P094
PSORIASIS WORST-CASE SCENARIOS: A SERIES OF 3 CASE REPORTS

Elena Popa[1], Persa Ghitulescu[2], Patricia Cristodor[1], Caius Solovan[1]
[1]Department of Dermatology and Venereology, Clinical Emergency Municipal Hospital Timisoara; University of Medicine and Pharmacy "Victor Babes" Timisoara, Romania, [2]Department of Dermatology and Venereology, Clinical Emergency Municipal Hospital Timisoara

Introduction: Psoriasis is a chronic, immune, inflammatory disease, that can occur at any time and it is most common in the age group 50–69. The reported prevalence of psoriasis in countries ranges between 0.09% and 11.4%, making psoriasis a serious global problem.
Objectives: We present a series of 3 case reports that stand for some of the worst-case scenarios a Psoriasis patient could end up in.

We won't be insisting on the treatment nor the outcomes of these patients whereas the aim of this presentation is to emphasize the importance of patient's education, prevention, but also of an early and correct treatment.
Materials And Methods:
Case report no.1:
-Patient characteristics: 49-years-old white Caucasian male;
-Clinical presentation: widespread, confluent erythema of the skin, large scales, malaise, intense joint pain, shivers, oliguria, marked onychodystrophy of fingernails and toenails with an evolution of about 1 week;
-Physical examination: fever, tachycardia, generalized nontender adenopathy;
-Patients history: Psoriasis vulgaris and Psoriatic arthritis since 2003 treated with 8 months Methotrexate switched (due to digestive symptoms) to oral Acitretinum for about 2 months prior the current presentation;
-Possible cause of the flare-up: lack of compliance to treatment, but mostly because of disorderly lifestyle.
Case report no.2:
-Patient characteristics: 64-years-old white Caucasian male;
-Clinical presentation: widespread, confluent erythema of the skin, large scales, malaise, loss of appetite, marked onychodystrophy of fingernails and toenails with an evolution of about 2 weeks;
-Physical examination: fever, tachycardia;
-Patients history: Psoriasis vulgaris since 1992 treated with Adalimumb (discontinued after 2 years) and Methotrexate;
-Possible cause of the flare-up: voluntarily discontinuation of the treatment (Methotrexate) 3 weeks prior to current presentation.
Case report no.3:
-Patient characteristics: 38-years-old white Caucasian female;
-Clinical presentation: pustular lesions spread throughout an erythematous background intercalated with skin atrophies and subepidermal pseudocysts disseminated throughout the body, erythematous, scaly plaque on the scalp;
-Physical examination: vital signs within normal limits;
-Patients history: Pustular Psoriasis from the age of 7 treated with Prednisone, Acitretinum and topical steroids;
-Possible cause of the flare-up: voluntarily discontinuation of the treatment (Acitretinum) 7 months prior to current presentation (the patient wishes to conceive) and long-term use of potent topical steroids.
Results: All three cases were treated considering the Psoriasis type, clinical presentation and symptoms, each of them having a positive evolution during the hospitalization and follow-up visits.

P095
SUCCESSFUL SWITCHING TO BIOSIMILAR IN PSORIATIC PATIENT WITH SEVERE DRUG REACTION TO INFLIXIMAB. A CASE REPORT

Maria Politou[1], Maria Pompou[1], Dimitrios Rigopoulos[1], Nikolaos Fekkas[2], Anastasios Giannoukos[1]
[1]1st Department of Dermatology-Venereology "Andreas Syggros" Hospital, UOA, [2]Department of Dermatology-venereology, 401 Military Hospital, Greece

Introduction: Biosimilar medicines are drugs which are highly similar to other biological medicines already licensed and that do not have any clinically meaningful difference to the originator drug in structure, pharmacokinetics, quality, safety or efficacy.
Objectives: Many clinical and observational studies involving a switch between reference infliximab and its biosimilars have been conducted or are ongoing. Switching between reference biologics and biosimilars should be performed by the prescriber for clinical reasons such as optimizing efficacy or minimizing AES. Efficacy and clinical measures of safety were similar in the switched and not switched groups at studies end. Differences in the type of AES upon switching must also be considered. Because biosimilars are structurally distinct from innovator biologic, they may produce significantly different side effects. Although, data in the literature suggest that if a patient experience a severe allergic reaction to the originator drug it is most possible the same reaction to happen with the biosimilar this may not always be the case.
Methods/Results: We present a case of a 60 years old female patient with severe plaque psoriasis from 25 years treated with infliximab every eight weeks for the last five years with great therapeutic efficacy. During the last five infusions she presented mild reaction with itching and facial redness which was treated successfully with antihistamines without the need of interrupting the infusion. Patient was also administered pretreatment therapy with a three day course of corticosteroids to minimize these reactions. During the last infusion patient presented severe body rash and hypotension which led to the discontinuation of the infusion. Due to the great therapeutic response and because patient had undergone several therapies in the past which either hadn't tolerated or hadn't responded to, she was reluctant to change therapy so we decided to switch to a biosimilar. Patient is currently through the eight month of treatment with the biosimilar with no sign of reaction and with maintenance of the therapeutic response.
Conclusion: Biologics are much more complex than conventional chemical drugs because they are larger and have more complicated structures, so it is impossible to produce biosimilars that are identical to the originator drug. As a result, the therapeutic efficacy and safety of a biosimilar could vary from the originator because the end product is highly dependent on a proprietary manufacturing process that differs for each manufacturer. Our case suggests that we may try a switch between reference biologic and its biosimilar even when an allergic reaction to the originator drug had occurred, especially when we have a great therapeutic efficacy. However, more data is needed.

P096
SAFETY OF APREMILAST IN THE TREATMENT OF A PSORIASIS PATIENT WITH CHRONIC HEPATITIS B

Christina Fotiadou, Myrto Trakatelli, Despina Papathemeli, Elizabeth Lazaridou
Second Department of Dermatology-Venereology, Aristotle University Medical School

Introduction: The treatment of patients with moderate-to-severe psoriasis in an everyday clinical setting, sometimes, poses serious challenges. The presence of hepatitis B Virus Infection (HBV) in these patients complicates the therapeutic choices.
Objectives: We report the case of a female patient, 52 years old, suffering from moderate-to- severe plaque psoriasis and chronic hepatitis B.
Methods: She was referred to our outpatient psoriasis clinic with a Psoriasis Area and Severity Index (PASI) score of 13.2. The patient's condition has deteriorated the past year but she had not received any kind of systemic treatment. During our pre-treatment screening tests she was found HBsAg positive although the liver function tests were within normal rates. The HBV serological status of the patient (HBsAg, HBeAg, anti-HBc, anti-HBs and anti-HBe) was estimated. HBV DNA load was measured with the Polymerase Chain Reaction (PCR) method, in order to confirm that the disease was not active, and it was undetectable.
Results: At that point it was decided to treat the patient with Apremilast using the standard titration dosing schedule (10mg on day one and increasing the dose by 10 mg daily) until reaching the maintenance dose of 30mg twice daily on day 6. Antiviral treatment was not given to the patient but liver function tests were performed at a monthly basis and HBV load every three months during treatment. All these test from the baseline until last observation (12 months after) were within normal rates. The patient exhibited an amelioration of her condition from the beginning which was confirmed by the significant reduction of her PASI score

which reached PSI75 at week 12 and PASI90 at week 24. At the time of this writing, one year after the initiation of treatment, the patient remains almost clear from her psoriatic lesions. Apremilast was well-tolerated by the patient.
Conclusions: The treatment of moderate-to-severe psoriasis in the background of chronic HBV limits the therapeutic options due to the possibility of HBV reactivation when the psoriasis patient is treated with immunosuppressive or even immunomodulatory drugs. Apremilast is an oral small-molecule PDE-inhibitor, approved by the Food and Drug Administration for the treatment of moderate-to-severe- plaque psoriasis in 2014. It does not target any one cytokine but restores a balance of pro-inflammatory and anti-inflammatory mediators. The pharmacokinetics of Apremilast is not affected by hepatic impairment and the drug is not hepatotoxic. Moreover, it is not contraindicated in patients with active infection. To our knowledge, this is the first reported case of Apremilast psoriasis patient with chronic inactive Hepatitis B. It proved to be both safe and efficacious but large, well-organized studies are needed in order to confirm this conclusion.

P098

IL-22 INDUCES KERATINOCYTES HYPERPROLIFERATION IN PSORIASIS VIA MIR-21 AND MIR-31 UPREGULATION

Florence Abdallah
Centre de Biophysique Moléculaire, CNRS UPR4301, Orléans, France

Psoriasis is a chronic inflammatory skin disease that affects people of all ages with an estimated 3% prevalence worldwide. It manifests as thick red irritated skin lesions due to imbalanced keratinocytes hyperproliferation and differentiation caused mainly by increased activation of IL-22 pathway in keratinocytes. Emerging studies showed a specific psoriatic miRs signature where miR-21 and miR-31 are one of the most upregulated miRs. The latters act by favoring cellular proliferation and inflammation. Hence, re-conciliating the microRNAs and the immunopathogenic occasions responsible for psoriasis development can be a new approach for developing effective mechanism and target-based agents to treat psoriasis.
The common hyper-proliferation effect of IL-22, miR-21 and miR-31 prompted us to look after a potential interaction between these actors. The expression levels of those 2 microRNAs and that of their targets were evaluated both *in vitro* and *in vivo* studies in presence or absence of IL-22.
We first exploited different skin models to investigate a potential connection between IL-22 and miR-21 or miR-31. The qPCR analysis showed a significant increase in the relative expression (RE) of both miRs in the different models upon IL-22 stimulation during 24h compared to untreated cells. These observations indicate the implication of miR-21 and miR-31 in proliferation-differentiation processes in the different layers of the epidermis. We also examined the miR-21 target RE PTEN involved in cell growth and apoptosis control and the miR-31 target RE ppp6c involved in G1 to S phase transition restriction. In line with the upregulation of miR-21 and miR-31, IL-22 stimulation resulted in significant downregulation of both targets at the genomic and proteomic levels.
We next investigated the *in vivo* correlation between IL-22 and miR-21 or miR-31 respectively in the development of psoriatic lesion. We used the imiquimod-induced psoriasiform skin inflammation in Wild type and IL-22 deficient mice (known to be almost protected from IMQ). Mice displaying a less severe disease form had less miR-21 expression. By contrast, WT mice treated with IMQ exhibited significantly higher miR-21 RE than IL-22-/- mice. Furthermore, miR-31 expression in IL-22-/- mice was identical to miR-31 expression in WT control mice. These results suggest a direct correlation between IL-22 pathway and miR-31 epidermal expression. In line with these observations, the miR targets (PTEN and ppp6c) were contrariwise proportional to miRs expression confirming by that the specificity of the IL-22/miR-21 and IL-22/miR-31 correlation.
These findings identify IL-22 as a key regulator of miRs implicated in multiple signaling pathways that coordinate keratinocytes proliferation activity

P099

SERUM CONCENTRACION OF IFN-GAMMA IN PATIENTS WITH PSORIASIS: CORRELATION WITH CLINICAL TYPE AND SEVERITY OF DISEASE

Nermina Ovčina-Kurtović, Emina Kasumagić-Halilović, Jasmina Muhović
Dermatovenerology Department Clinical center University of Sarajevo, Bosnia and Herzegovina

Introduction: Psoriasis is a multifactorial chronic inflammatory disease. The etiopathogenesis of the disease is still unclear but there is evidence that many of cytokines released by keratinocytes and inflammatory leukocytes may contribute to the induction or persistence of the inflammatory process in psoriasis.
Objectives: The aim of the study was to evaluate serum concentrations of INF-gamma in patients with psoriasis and the healthy subjects and also to assess a possible association between IFN-gamma, clinical type and severity of disease.
Methods: The study included a total of 60 patients with psoriasis, both genders and all of ages. There were 20 healthy subjects in the control group. According to the clinical type of disease, patients with psoriasis were divided into four groups: psoriasis vulgaris, psoriasis pustulosa, psoriasis erythrodermica and psoriasis arthropatica. Blood samples were collected from all psoriasis patients and from healthy control subjects. Serum IFN-gamma levels were measured by an enzyme-linked immunosorbent assay (ELISA) technique. The severity of psoriasis vulgaris was assessed by Psoriasis Area and Severity Index (PASI) score.
Results: Of the total number of patients suffering from psoriasis 42 (70%) had psoriasis vulgaris. The second most frequent was psoriasis erythrodermica 9 (15%), while 6 (10%) patients had psoriasis pustulosa and 3 (5%) psoriasis arthropatica. The serum concentartion of IFN-gamma in patients with psoriasis was signifiicaly higher than that in the control group (1.91+1.79 pg/ml vs 0.91+0.38 pg/ml, respectively). Significantly elevated serum IFN-gamma concentrations were noticed in patients with psoriasis vulgaris (2.15+0.30 pg/ml), compared with patients suffering from psoriasis erythrodermica (1.57+0.68 pg/ml), psoriasis arthropatica (1.33+0.53 pg/ml), and in particular patients suffering from psoriasis pustulosa (1.08+0.21 pg/ml) who had the lowest mean serum concentration of IFN-gamma. There was no statistically significant difference between the mean values of IFN-gamma compared to the clinical type of psoriasis ($p > 0.05$). In the group of patients with psoriasis vulgaris 36 (85.71%) patients had mild form of disease with PASI < 50, and 6 (14.29%) patients had severe disease with PASI > 50. It was not found statistically significant correlation between IFN-gamma and PASI score.
Conclusions: The results of this study showed that psoriasis is associated with significant changes in serum concentracion of IFN-gamma. There was no statistically significant correlation between serum IFN-gamma concentracions, clinical type of psoriasis, and also severity of psoriasis vulgaris evaluated by PASI score.
References:
Baliwag J, Barnes DH, Johnston A. Cytokines in psoriasis. Cytokine 2015; 73 (2):342-350.
Takahashi H, Tsuji H, Hashimoto Y, Ishida-Yamamoto A, Iizuka H Serum cytokines and growth factor levels in Japanese patients with psoriasis, Clin Exp Dermatol 2010; 35:645-649.

P100

IMMUNOLOGICAL MEMORY EXISTS IN THE RECURRENT LESION AND NONRECURRENT SKIN AFTER REMISSION IN PSORIATIC PATIENTS

Zhu Shen
Institute of Dermatology and Venereology, Sichuan Academy of Medical Sciences & Sichuan Provincial People's Hospital

Introduction: Psoriasis usually recurs in previously affected areas, so a pathogenic memory has been proposed, but the nature of such site-specific recurrent memory is not completely known. Tissue-resident memory T (TRM) cells are non-recirculating memory T cells that persist long-term in epithelial tissues, including the skin. Because they can localize in the skin for many months, we speculate that TRM may contribute to recurrent pathology of psoriasis.
Objectives: The aim of the present study is to compare the differences of quantity proportion and secretion ability of cytokines of the TRM cells between recurrent and nonrecurrent lesions following remission, as well as to explicit the possible survival signal for these TRM cells in psoriatic lesion.
Methods: RNA-Seq, Gene Ontology and KEGG analysis, real-time PCR, flow cytometer analysis/sorting, cell stimulation assay, and western blot were used to explore the immunological memory.
Results: Compared with normal skin, there are common shared genes significantly upregulated (> 2 folds, $p < 0.001$) by recurrent and nonrecurrent lesions, including CD69. CD69 mRNA transcription level in nonrecurrent lesions after remission remains as high as in neighboring recurrent lesions. CD8+CD69+ TRM cells exist in both lesions, and they can secret almost same amount of IL-17A and IL-22 after stimulation. Levels of IL-15, secreted by keratinocytes in psoriasis epidermis, in nonrecurrent lesions remain as high as in neighboring recurrent lesions, and recombinant human IL-15 can induce CD69 on TRM cells.
Conclusions: Our preliminary study shows that CD8+CD69+ TRM cells persist in clinically resolved psoriatic lesions whether it recurs or not, and they can produce IL-17A and IL-22 with critical effect on psoriatic recurrence and development. Furthermore, we have indicated the IL-15 may play crucial role in the survival of CD8+CD69+ TRM cells in psoriatic lesions.
References:

1. Mueller SN, Mackay LK.Tissue-resident memory T cells: local specialists in immune defence. Nat Rev Immunol. 2016 Feb;16(2):79-89.
2. Clark RA. Resident memory T cells in human health and disease. Sci Transl Med. 2015 Jan 7;7(269):269rv1.
3. Park CO, KupperTS. The emerging role of resident memory T cells in protective immunity and inflammatory disease. Nat Med. 2015 Jul;21(7):688-97.
4. Cheuk S, Wikén M, Blomqvist L, Nylén S, Talme T, Ståhle M, EidsmoL. Epidermal Th22 and Tc17 cells form a localized disease memory in clinically healed psoriasis. J Immunol. 2014 Apr 1;192(7):3111-20.

P101

INVESTIGATING SYSTEMIC INFLAMMATION AS THE COMMON LINK BETWEEN DEPRESSION, PSORIASIS, AND PSORIATIC ARTHRITIS IN US VETERANS

Samar Gupta[1], Alicja Wasilewski[2]
University of Michigan[1], MI State[2]

Introduction: Psychosocial factors are important in the onset and/or exacerbation of psoriasis in 40% to 80% of cases. Psoriasis has been associated with suicide, and an increased prevalence of alcoholism and a range of personality characteristics.
A recent systematic meta-analysis of 98 eligible studies with a total of 401,703 psoriasis patients showed that patients with psoriasis were approximately one and a half times more likely to exhibit signs of depression compared with healthy controls. [1].
Emerging evidence suggests that depression, like psoriasis, is associated with systemic inflammation, and the systemic inflammatory profile of the two conditions show similar traits. Depression is considered to have a strong inflammatory component, similar to psoriasis, e.g. interleukin (IL)-2, IL-6, IL-12, and tumour necrosis factor (TNF)-α [2–5].
US Veteran population has increased incidence of mental health issue as compared to general population. making Veteran group a unique population that warrants investigation.
Objectives: Hypotheses - 1/ Veterans with concomitant depression and psoriasis/PsA may have elevated inflammatory markers like CRP, ESR, and SPEP. 2/ Depression may improve with the treatment of psoriasis/psoriatic arthritis without antidepressant use.
Methods: A 36-month retrospective chart review of 100 veterans with diagnosis of depression and psoriasis/psoriatic arthritis. Elevated inflammatory markers, including sedimentation rate, C-reactive protein (CRP) and serum protein electrophoresis (SPEP), as well as longitudinal disease course of depression (PHQ-8) and psoriasis/psoriatic arthritis (HAQ-DI); specifically disease activity, and depression symptoms will be assessed. We then aim to draw a correlation between disease activity and active depressive symptoms.
Results: to be available
Conclusions: to be available
References:

1. Dowlatshahi EA, et al. The prevalence and odds of depressive symptoms and clinical depression in psoriasis patients: a systematic review and meta-analysis. J Invest Dermatol 2014; 134: 1542–1551.
2. Allison DJ, Ditor DS. The common inflammatory etiology of depression and cognitive impairment: a therapeutic target. J Neuroinflammation 2014; 11: 151.
3. Dantzer R, et al. From inflammation to sickness and depression: when the immune system subjugates the brain. Nat Rev Neurosci 2008; 9: 46–56.
4. Han Q-Q, Yu J. Inflammation: a mechanism of depression? Neurosci Bull 2014; 30: 515–523.
5. Dowlati Y, et al. A meta-analysis of cytokines in major depression. Biol Psychiatry [Internet] 2010; 67: 446–457.

P102

THE IMMUNE-PHENOTYPE OF SMALL PLAQUE PSORIASIS

Touraj Khosravi-Hafshejani[1], Mehran Ghoreishi[2], Cristian Vera Kellet[3], Magdalena Martinka[4], Jan Dutz[1]
[1]Department of Undergraduate Medical Program, Faculty of Medicine, [2]Department of Dermatology, and Skin Science and [4]Department of Pathology and Laboratory Medicine, University of British Columbia, [3]Department of Dermatology, Pontifical Catholic University of Chile

Introduction: Small plaque psoriasis (SPP) is a subtype of psoriasis first described by Griffiths et al (2007). It resembles guttate psoriasis but lesions are larger, are chronic, and are not associated with streptococcal infection. We have observed SPP develop in four different population groups; patients under TNFα-inhibitor therapy, patients under immune checkpoint inhibitor (ICI) therapy, and patients with concurrent SLE or ANA positivity and psoriasis. Subtypes of psoriasis develop on a spectrum between autoimmune and auto-inflammatory responses and an interplay between three signalling pathways are involved in their distinct pathogenesis. Chronic plaque psoriasis lesions are on the autoimmune spectrum, dominated by a T-cell mediated TNFα/IL-23/IL-17/IL-22 axis. Pustular psoriasis is a neutrophilic infiltrative inflammatory skin disease resulting from dysregulation of the IL-36/IL-1 axis. Lastly, TNFα-inhibitor (TNFi) induced lesions have a SPP morphology and demonstrate increased expression of LL37 by keratinocytes, activated plasmacytoid dendritic cells and upregulated type-1 interferons (IFN). These lesions express fewer epidermal CD8 T cells.
Objectives: Our aim is to characterize the immune-phenotype of SPP in multiple clinical scenarios. We hypothesize that SPP develops as a result of increased expression of cytokines and antimicrobial peptides involved in the type-1 IFN pathway.
Methods: Skin biopsies were obtained from three patients with

TNFi-induced psoriasis, three patients with SLE and psoriasis, three patients with positive ANA and psoriasis, two patients with ICI-induced psoriasis and two patients with chronic plaque psoriasis as control. Immunohistochemistry was performed using antibodies against type-1 IFN induced MXA, LL37, IL-36 and CD8 T cells. The intensity and the area of positively stained samples were each graded from 0–4 and then multiplied to provide a final score.
Results: Small plaque lesions in various clinical scenarios had histologic changes consistent with psoriasis.. Immunohistochemical evaluation revealed an increased expression of MXA (TNFi = 14, SLE = 13.3, ANA = 11.3, ICI = 16 vs. control = 6, t-test $p < 0.05$), LL37 (TNFi = 10.8, SLE = 6, ANA = 9.7, ICI = 12 vs. control = 2, t-test $p < 0.05$) and IL-36 (TNFi = 10.5, SLE = 13.3, ANA = 11, ICI = 7, control = 0.25, t-test $p < 0.05$) in the keratinocytes of SPP patients. There was decreased CD8 T cell migration to the epidermis in SPP compared to control.
Conclusion: This is the first study to describe the immune-phenotype of SPP and to extend the phenotype observed in TNFi induced psoriasis to varying clinical scenarios. There was an increased expression of MXA, LL-37 and IL-36 as well as fewer epidermal CD8 T cells than in chronic plaque psoriasis consistent with the type-1 IFN pathway of psoriasis pathogenesis. This immune-phenotypic analysis may suggest tailored therapy for this form of psoriasis.

P104
SERUM GLUCOCORTICOID-INDUCIBLE KINASE-1(SGK1) LEVELS IN PATIENTS WITH PSORIATIC ARTHRITIS

Goksal Keskin[1], Ali Inal[2], Esra Dilek Keskin[3], Umit Olmez[1]
[1]Department of Immunology, Medical School of Ankara University, [2]Department of Immunology, Medical School of Baskent University, [3]Department of FTR, Medical School of Kırıkkale University

Introduction: Psoriatic arthritis (PsA) is an inflammatory rheumatic disorder that occurs in patients with psoriasis. The etiology of PsA is not well understood but evidence supports an interplay of genetic, immunologic, and environmental factors which promote pathological bone remodeling and joint damage in PsA. The glucocorticoid-inducible kinase-1(SGK1) is genomically upregulated by cell stress. However, excessive SGK1 expression and activity participates in the pathophysiology of several disorders, such as inflammation, autoimmune disease, fibrosis, hypertension, thrombosis and tumor growth.
Objectives: In this study, we analyzed the possible role of serum SGK-1 levels in the pathogenesis of psoriatic arthritis.
Methods: 56 patients with psoriasis (40 patients with psoriatic arthritis; 16 female, 24 male, mean age; 46.7 ± 6.5 years, mean disease duration 17.7 ± 4.3 years and 16 patients without arthritis; 8 female, 8 male, mean age; 43.2 ± 1.9 years, mean disease duration; 14.1 ± 3.9 years) and 19 healthy controls (11 female, 8 male; mean age 41.3 ± 4.7 years) were enrolled in this study. Oligoarthritis was the commonest clinical presentation (76.4 %). Dactylitis (73.4%) and enthesitis (48.1%) were frequent extra-articular features. All patients were negative for rheumatoid factor. HLA-B27 was negative in 14 patients. Serum SGK-1 levels were determined by ELISA.
Results: The mean serum SGK-1 levels were 58.4 ± 18.1 pg/ml in healthy controls, 163.7 ± 27.8 pg/ml in patients without arthritis and 443.9 ± 32.1 pg/ml in patients with arthritis. Serum SGK-1 levels were significantly high in patients with psoriasis compared with healthy controls ($p < 0.001$). Serum SGK-1 levels were significantly high in patients with psoriatic arthritis compared with in patients without psoriatic arthritis ($p < 0.001$).
Conclusions: The evidence is strong that immunological mechanisms are involved in the pathogenesis of psoriasis. In this study, we demonstrated that serum SGK-1 levels were significantly elevated in patients with psoriasis and psoriatic arthritis.

P105
DIFFERENTIAL NH2-TERMINAL AUTOANTIGEN TRIMMING MAY EXPLAIN EPISTASIS BETWEEN HLA-C*06:02 AND ERAP1 VARIANTS IN PSORIASIS RISK

Akiko Arakawa[1], Emma Reeves[2], Sigrid Vollmer[1], Yukiyasu Arakawa[1], Edd James[2], Jörg Prinz[1]
[1]Ludwig-Maximilian-University, [2]Southampton General Hospital

Introduction: NH2-terminal trimming by endoplasmic reticulum aminopeptidase 1 (ERAP1) generates the appropriate length of antigenic peptides for binding to and presentation by HLA-class I molecules. Genetic interaction between ERAP1 variants and HLA-class I alleles determines the genetic risk for various HLA-class I-associated inflammatory diseases. Epistasis between HLA-C*06:02 and ERAP1 variants affects also psoriasis risk but the mechanisms of these gene interactions remained unknown. Using a pathogenic Vα3S1/Vβ13S1-TCR from a psoriatic CD8+ T-cell clone we had shown that in psoriasis, HLA-C*06:02 mediates an autoimmune response against melanocytes through autoantigen presentation and we had identified a peptide from ADAMTS-like protein 5 (ADAMTSL5) as HLA-C*06:02-presented melanocyte autoantigen.
Objectives: To determine the role of ERAP1 variants in psoriasis pathogenesis.
Methods: We established ERAP1 knockout cells using CRISPR/Cas9 system. ERAP1 knockout cells transfected with plasmids coding for HLA-C*06:02, ERAP1 variants, and antigenic peptides were co-cultured with the TCR hybridoma to determine the levels of TCR ligation which reflect the generation of the antigenic ADAMTSL5 peptide and other Vα3S1/Vβ13S1-TCR ligands from precursors.
Results: Our data show that NH2-terminal trimming by ERPA1 is required to generate the actual antigenic ADAMTSL5 peptide from NH2-terminally elongated precursors. An ERAP1 variant protecting from psoriasis reduced the immunogenicity of the antigenic ADAMTSL5 peptide presumably through overtrimming and peptide destruction, whereas a psoriasis risk variant of ERAP1 highly kept the antigenicity of the autoantigen. This effect was specific for ADAMTSL5. Precursors of other Vα3S1/Vβ13S1-TCR self-ligands were not substrates of ERAP1.
Conclusions: Using a proven psoriatic autoantigen and a cognate psoriatic TCR, these experiments provide direct evidence that gene-gene interaction between ERAP1 and HLA-C*06:02 affects the risk for psoriasis through differential autoantigen trimming from precursors. These data furthermore propose a model where ERAP1 function essentially controls the autoantigenic potential of self-peptides in HLA-class I associated CD8+ T-cell mediated autoimmune diseases.

P106
ENVIRONMENTAL TRIGGERS OF AN HLA-C*06:02-RESTRICTED AUTOIMMUNE RESPONSE IN PSORIASIS

Secil Vural, Yukiyasu Arakawa, Adrian Galinski, Sigrid Vollmer, Akiko Arakawa, Jörg Prinz
Ludwig Maximilian University

Introduction: Psoriasis vulgaris is a multifactorial disease. While the major psoriasis risk gene HLA-C*06:02 accounts for up to 50% of disease onset, environmental factors are considered to contribute to approximately 30% of disease risk. Psoriatic skin inflammation is driven by an HLA-C*06:02-mediated autoimmune response against melanocytes. A pathogenic Vα3S1/Vβ13S1 T-cell receptor (TCR), which we had reconstituted from a lesional epidermal $CD8^+$ T-cell clone of an HLA-C*06:02–positive psoriasis patient in a mouse reporter hybridoma cell line, specifically reacts against melanocytes through HLA-C*06:02 restricted recognition of a psoriatic melanocyte autoantigen, ADAMTS-like protein 5 (ADAMTSL5). However, it is unknown whether and how environ-

mental factors may contribute to autoimmunity in psoriasis. TCRs are known to be polyspecific, recognizing multiple peptide ligands which share a conserved amino acid pattern specific for each TCR.
Objectives: To examine the potential role of environmental factors in the psoriatic autoimmune response.
Methods: We first determined the particular amino acid motif which is recognized by the psoriatic Vα3S1/Vβ13S1 TCR in the context of HLA-C*06:02. By homology searches using this conserved amino acid pattern, we selected 57 peptides from food, bacterial, fungal and viral pathogens and from the skin and intestinal microbiomes as candidate environmental antigens that may trigger the psoriatic autoimmune response. We cloned the peptides into expression plasmids, co-transfected them with HLA-C*06:02 into Cos7 cells and used them to stimulate the Vα3S1/Vβ13S1 TCR. TCR ligation was determined by GFP induction of TCR hybridoma in FACS analysis. We then stimulated blood lymphocytes with the candidate peptides that had ligated the Vα3S1/Vβ13S1 TCR. Lymphocyte activation was assessed by induction of activation markers and proliferation assays using thymidine incorporation.
Results: We identified a variety of peptides contained in proteins from food (wheat, coffee, apple, and spinach), microbiota of human skin or gut, and infectious pathogens including *Chlamydia trachomatis*, which ligated the psoriatic TCR in a polyspecific manner. Stimulation of blood lymphocytes with particular candidate antigens resulted in significant activation in psoriasis patients, as compared to healthy individuals. Interindividual-correlation analyses demonstrated cross-reactive immune responses between environmental antigens and the melanocyte autoantigen presented by HLA-C*06:02 in psoriasis patients. Among the candidate antigens, wheat peptides induced most robust lymphocyte activations in psoriasis patients. Moreover, psoriasis was significantly improved by wheat-free diet in several patients with lymphocytes responding to wheat, indicating potential pathogenic contribution of wheat antigens in psoriasis.
Conclusions: Our results provide unbiased evidence that several environmental antigens may trigger the melanocyte-specific autoimmune response in psoriasis. By identifying and avoiding those triggers at the molecular level which translate the genetic predisposition into disease manifestation, we may develop strategies to prevent disease onset and exacerbation.

P107

A SKEWED POOL OF RESIDENT T CELLS TRIGGERS DISEASE-ASSOCIATED TISSUE RESPONSES IN NEVER-LESIONAL PSORIASIS

Irène Gallais Sérézal[1], Elena Hoffer[1], Borislav Ignatov[1], Elisa Martini[1], Beatrice Zitti[2], Marcus Ehrström[3], Liv Eidsmo[1]
[1]Department of Medicine Solna, Karolinska Institutet, [2]Centre for Haematology and Regenerative Medicine, Department of Medicine, Karolinska Institutet, Karolinska University Hospital Huddinge, [3]Department of Reconstructive Plastic Surgery, Karolinska University Hospital Solna, Stockholm, Sweden

Background: Psoriasis lesions evolve as a result of cytokine driven interactions between intralesional immune cells and keratinocytes in genetically predisposed individuals. Skin resident T cells are implicated in maintenance and recurrence of psoriasis plaques but their composition and function in never-lesional psoriasis skin is less known.
*Objective:*Characterisation of T cell driven tissue responses and subsets of resident T cells in never-lesional psoriasis.
Methods: T cell driven tissue responses were assessed in explanted skin biopsies using Nanostring and Multiplex analysis. Epidermal and dermal T cells were characterised using flow cytometry in never-lesional skin from patients with mild disease.
Results: T cell activation induced epidermal psoriasiform- and type-1 interferon tissue responses in explants from never-lesional skin. Skin resident T cells were skewed with enrichment of epidermal IL-17 and IL-22 producing CD4+CCR6+ and CD8+CD103+CD49a- T cells and IFN-γ producing CD4 T cells in never-lesional skin compared to healthy skin. Keratinocytes from never-lesional psoriasis responded to IFN-γ activation with IFN-α secretion and MX1 upregulation and skin explants exposed to common fungal antigens produced the CCR6-attractant CCL20.
Conclusion: Resident T cells poised to induce psoriasiform tissue responses accumulate in never-lesional skin of psoriasis-afflicted individuals. Additionally our data suggest that microbial interplay with genetically predisposed keratinocytes may shape the local pool of resident T cells.
References:
Verma, D., Ekman, A.-K., Bivik Eding, C. & Enerbäck, C. Genome-Wide DNA Methylation Profiling Identifies Differential Methylation in Uninvolved Psoriatic Epidermis. J. Invest. Dermatol. (2017). doi:10.1016/j.jid.2017.11.036
Gudjonsson, J. E. et al. Global gene expression analysis reveals evidence for decreased lipid biosynthesis and increased innate immunity in uninvolved psoriatic skin. J. Invest. Dermatol. 129, 2795–2804 (2009).
Cheuk, S. et al. Epidermal Th22 and Tc17 Cells Form a Localized Disease Memory in Clinically Healed Psoriasis. J. Immunol. 192, 3111–3120 (2014).

P108

NAIL INVOLVEMENT IN PSORIASIS; IS IT A PREDICTOR OF PSORIATIC ARTHRITIS?

Omid Zargari[1], Ehsan Kazemnejad[2], Seyyede Zeinab Azimi[3]
[1]Department of Dermatology, Skin Research Center, Shahid Beheshti University of Medical Sciences, Tehran, [2]Department of Biostatistics, [3]Department of Dermatology, Guilan University of Medical Sciences, Rasht, Iran

Introduction: Psoriatic Arthritis (PsA) arises in an increased burden of psoriasis and impairments in both quality of life and functional capacity. The relationship between nail involvement and PsA in psoriasis is not fully characterized.
*Objective:*To evaluate the frequency and characteristics of nail involvement in psoriatic patients and to assess the relationship with joint involvement.
Methods: A total of 197 patients with moderate-to-severe psoriasis, were consecutively selected to participate in this cross-sectional study. The patients divided into two groups; with and without psoriatic arthritis.
Results: 69.5% of psoriatic (137 out of 197) patients had nail involvement. The most common nail abnormality was onycholysis, followed by pitting and oil drop. Nail changes were more common in patients with psoriatic arthritis (82.1% vs. 57.8%).
Limitations: Our study had certain limitations. One of them was lack of information about the subtypes of PsA. Also, we have not recorded the severity of nail involvements. Furthermore, previous medications may have interfered with the degree of nail changes in our patients.
Conclusion: Nail involvement is associated with PsA. Onycholysis, splinter hemorrhage, and oil drop were significantly more common in PsA group. In general, psoriatic patients with arthritis had the more severe disease.
References:
1. Klaassen KM, van de Kerkhof PC, Pasch MC. Nail psoriasis: a questionnaire-based survey. Br J Dermatol. 2013;169(2):314–319.
2. Langenbruch A, Radtke MA, Krensel M, Jacobi A, Reich K, Augustin M. Nail involvement as a predictor of concomitant psoriatic arthritis in patients with psoriasis. Br J Dermatol. 2014;171(5):1123–1128.

P109

ABSOLUTE AND RELATIVE PASI IMPROVEMENTS WITH IXEKIZUMAB TREATMENT: RESULTS AT WEEK 12 FROM IXORA-P

Kim Papp[1], Remus Ioan Orasan[2], Paula Polzer[3], Carsten Hennege[3], Radu Dumitru Nica[3], Stefan Wilhelm[3], Ulrich Mrowietz[4]

[1]Probity Medical Research, Waterloo, Ontario, Canada, [2]Human Physiology, Iuliu Hatieganu University of Medicine and Pharmacy, Romania, [3]Eli Lilly and Company, Indianapolis, Indiana, USA, [4]Department of Dermatology, University Medical Centre Schleswig-Holstein, Campus Kiel, Germany

Introduction and Objectives: Ixekizumab (IXE), an interleukin-17A antagonist, has shown superior efficacy in psoriasis compared to placebo,1 etanercept,1 and ustekinumab.2 This post hoc analysis intended to evaluate absolute and relative Psoriasis Area and Severity Index (PASI) improvements with IXE treatment in a phase 3 trial (IXORAP).
Methods: In IXORA-P, patients with moderate-to-severe psoriasis were randomized (2:1:1) to receive any of the 3 dosing regimens of IXE 80 mg: every 2 weeks (Q2W; $n = 611$), every 4 weeks (Q4W; $n = 310$), or Q4W/Q2W step-up ($n = 306$), for 52 weeks. Randomization was stratified by country and weight (< 80 kg, ≥80 to < 100 kg, or ≥100 kg). The percentage of patients achieving a 75%, 90% or 100% improvement from baseline in PASI (PASI 75, 90, and 100) was evaluated using logistic regression with dosing regimen, country, and baseline weight as factors. Fisher's exact test with nonresponder imputation was used to compare the response rates between treatment groups. Here, we present results at 12 weeks for Q2W (label dose) and Q4W groups; results from Q4W/Q2W group will be discussed separately.
Results: Mean (standard deviation) PASI score at baseline was 20.3 (8.25). Response rates were significantly higher ($p < 0.001$) for Q2W group compared to Q4W group across all cut-off points for absolute PASI: absolute PASI ≤1, 2, 3, and 5 response rates at Week 12 were 61.4%, 76.1%, 84.5%, and 89.4%, respectively, for Q2W group, and 49.7%, 64.5%, 72.6%, and 83.9%, respectively, for Q4W group. At Week 12, PASI 75 response rates in Q2W and Q4W groups were 89.2% and 83.2%, respectively ($p = 0.012$). For Q2W and Q4W groups, PASI 90 response rates were 75.3% and 63.2%, respectively ($p < 0.001$), and PASI 100 response rates were 46.0% and 32.6%, respectively ($p < 0.001$).
Conclusion: As reported in psoriasis registration trials, induction with IXE Q2W, the labeled dosing regimen, provides better clinical outcomes at Week 12.
References:
[1] Griffiths CE, Reich K, Lebwohl M, et al. Lancet 2015;386:541-51.
[2] Reich K, Pinter A, Lacour JP, et al. Br J Dermatol 2017;177(4):1014-23.

P110

PREVALENCE AND SEX DIFFERENCES OF PSORIATIC ARTHRITIS IN PATIENTS WITH SEVERE PLAQUE PSORIASIS.

Nadezhda Batkaeva[1], Tatiana Korotaeva[2], Edgem Batkaev[1]
[1]Peoples' Friendship University of Russia (RUDN University), [2]Research Institute of Rheumatology n. a. V. A. Nasonova

Background: Prevalence of psoriatic arthritis in patients with psoriasis has conflicting data in different population. But no study has been performed in Russian population of prevalence and sex differences of psoriatic arthritis in patients with severe plaque psoriasis.
Objectives: to evaluate the prevalence PsA in patients (pts) with PsO in a dermatological hospital cohort.
Methods: 890 pts (Male-516/Female-374) with severy plaque PsO, mean age 50.4±17.6 years, mean PsO duration 21.5±14.7, mean PASI 49.4±0.5 were included. 374 female were divided into groups by age. 113 young F. pts with age less than 49 years (mean age 36.1±11.0 years), 261 old F. pts with age more than 50 years (mean age 63.7±9.6 years). 516 male were divided into groups by age. 304 young M. pts with age less than 54 years (mean age 38.5±11.3 years), 212 old M. pts with age more than 55 years (mean age 38.5±11.3 years) were included. PsO and PsA pts were identify in hospital Database reporting and coding by International Statistical Classification of Disease and Related Health Problems (ICD-10) between 2010 - 2015 years. PSA was diagnosed after appointment with a rheumatologist and an X-ray examination. Diagnosis was carried out according to the criteria of CASPAR. M±m, t-test, x2, (%) were calculated. All $p < 0.05$ were considered to indicate statistical significance.
Results: 303 out of 890 pts (34.0%) had psoriatic arthritis (PsA). PsA pts were older then PsO pts without arthritis – 55.3±13.7 years and 50.4±17.6 years accordingly ($p < 0.001$). PsA was found significantly often in F. pts compare to M. pts – in 143 out of 374 pts (38.2%) and in 129 out of 516 pts (25.0%) accordingly ($p < 0.05$). PsA was found significantly often in F. pts over 50 years old (y.o.) compare to F. pts under 50 y.o. – in 134 out of 261 pts (51.3%) and in 9 out of 113 pts (7.9%) accordingly ($p < 0.05$). In old M. and young M. PsA was found in the same cases - in 58 out of 212 pts (27.3%) and in 71 out of 304 pts (23.3%) accordingly ($p > 0.05$).
Conclusions: PsA was detected in more than a third of patients with severe plaque psoriasis. PSA was found predominantly often in F. pts over 50 years of age with severe plaque psoriasis. Future investigation in this field is needed to determine the causes of high risks PSA in this age group.

P111

SKIN LESION SEVERITY IN EARLY AXIAL AND PERIPHERAL PSORIATIC ARTHRITIS PATIENTS

Elena Gubar, Elena Loginova, Svetlana Glukhova, Tatiana Korotaeva
Nasonova Research Institute of Rheumatology, Moscow

Introduction: Comparative analysis of skin lesion severity in early PsA patients with and without axial involvement hadn't been sufficiently studied.
*Objective:*to compare skin lesion severity of two early peripheral PsA patient populations – with and without axial involvement.
Methods: 95 patients (pts) (M/F–47 /48) with early PsA according to CASPAR criteria were included; all pts had peripheral arthritis for ≤2 years; no inflammatory back pain (IBP) pts were specially selected. Mean age 36.5±10.7 yrs, disease duration 12.2±10.3 mo, disease activity indexes DAS = 4.0±1.4, DAS28 = 4.2± 1.1, BASDAI = 4.5±1.6. Skin lesion severity was evaluated in terms of body surface area (BSA) affected and Psoriasis Area Severity Index (PASI). When BSA was ≥3%, PASI was calculated. PASI ≥11 indicates moderate and severe psoriasis.
All pts were evaluated for the presence of inflammatory back pain (IBP) by ASAS criteria. IBP was observed in 63 (66.3%) cases. Magnetic resonance imaging (MRI) of SIJs was performed in 79 pts, regardless of the presence of IBP, on Signa Ovation 0,35T. MRI results were evaluated by an independent reader. Bone marrow edema on MRI (STIR) was considered as active MRI sacroiliitis (MRI-SI). MRI-SI was detected in 28 of 79 (35.4%) examined cases. The examination also included X-ray of sacroiliac joints (SIJs) (pelvic radiographs). Radiographic sacroiliitis (R-SI) was considered according to New York criteria (unilateral grade≥3 or bilateral grade≥2). R-SI was found in 29 (30.5%) cases. Pts were split into two groups: those with axial involvement (axPsA), that is with IBP and/or MRI-SI and/or R-SI; and those without axial involvement (having only peripheral PsA [pPsA]). The axPsA group included 65 (68.4%) cases, the pPsA one 30 (31.6%) cases.
Results: skin lesions' severity was higher in the axPsA group than in the pPsA group: in axPsA pts BSA median was 3.0 [1.0 – 9.0] and in pPsA pts it was 1.0 [0.2 – 3.0] (p = 0.007); in the axPsA group PASI median was 15.6 [6.6 – 55.2] and in the pPsA group it was 6.0 [0.0 – 7.2] (p = 0.006).
Conclusion: Axial involvement in early PsA patients is associated with skin lesions' severity. These findings may have a positive impact on the selection of the best therapeutic strategy.

P112

GASTROINTESTINAL SYMPTOMS ARE COMMON IN U.S. PATIENTS WITH MODERATE-SEVERE PSORIASIS

Steven Feldman[1], Steve Fakharzadeh[2], Jill Abell[2], Timothy Hoops[2], Bhaskar Srivastava[2], Erik Muser[2], Danielle Dungee[2], Sean Quinn[2], Megan Leone Perkins[3], Michael Kappelman[4]

[1]Wake Forest School of Medicine, Winston-Salem, NC, [2]Janssen Scientific Affairs, LLC, Horsham PA, [3]HealthiVibe, LLC, Arlington, VA, [4]University of North Carolina, Chapel Hill, NC, USA

Background/Objective: Patients with moderate-to-severe plaque psoriasis (PsO) are at increased risk of developing inflammatory bowel disease (IBD). A survey was conducted to evaluate the prevalence of gastrointestinal symptoms in PsO patients.

Methods: An electronic survey was available to U.S. PsO patients with data collected from Jan-Feb. 2017. Patients with moderate-to-severe plaque PsO and healthy controls (HC), with common co-morbidities allowed in both groups qualified for inclusion in the survey. Psoriasis patients were further categorized as those without recent exposure to biologic therapy (PsO-) vs those with recent (within 4 months) biologic exposure (PsO+). GI symptoms and signs, including frequency and severity, were compared across groups. CalproQuest (CPQ) scores, which have recently been proposed as a tool to identify patients with elevated fecal calprotectin levels and increased risk for IBD, were also calculated. Patients with inflammatory bowel disease (IBD), inflammatory bowel syndrome (IBS), or other gastrointestinal (GI) diagnoses with symptoms that overlap with IBD were excluded.

Results: Overall, 915 patients with self-reported moderate-severe PsO and 1,411 healthy controls participated. Demographics were generally comparable between groups. GI symptoms and signs were significantly more prevalent in the PsO- and PsO+ groups vs the HC group, respectively: pain- 20.6% and 36.9% vs 10.5%; fullness/bloating- 37.2% and 48.4% vs 25.3%; and diarrhea (16.3% and 29.3% vs 12.2% (all p-values = 0.002 except diarrhea for PsO- vs HC, $p = 0.023$). Mucous and blood in the stool followed a similar pattern. A significantly greater percentage of PsO- and PsO+ patients had positive CPQ scores vs HCs, with the greatest percentage of positive CPQ scores in the PsO+ group.

Conclusion: GI symptoms and signs are common in patients with moderate-to-severe PsO, more so than in healthy controls. This suggests that physicians caring for patients with PsO may consider assessing for GI symptoms and signs, and monitoring for their progression with treatment of PsO to identify patients potentially at risk for developing IBD.

P113

SECUKINUMAB'S LONG-TERM SAFETY REMAINS FAVORABLE UP TO 5 YEARS OF TREATMENT

Christopher Griffiths[1], A. Blauvelt[2], K. Reich[3], C. Leonardi[4], N. Mehta[5], T. Tsai[6], R. You[7], P. Papanastasiou[8], M. Milutinovic[8], P. van de Kerkhof[9]

[1]Dermatology Centre, Salford Royal Hospital, University of Manchester, Manchester Academic Health Science Centre, Manchester, UK, [2]Oregon Medical Research Center, Portland, Oregon, USA, [3]Dermatologikum Berlin and Georg-August-University, Göttingen, Germany, [4]Saint Louis University Health Sciences Center, St. Louis, Missouri, [5]National Heart, Lung, and Blood Institute, Bethesda, Maryland, USA, [6]National Taiwan University Hospital, National Taiwan University College of Medicine, Taipei, Taiwan, [7]China Novartis Institutes for BioMedical Research, Shanghai, China, [8]Novartis Pharma AG, Basel, Switzerland, [9]Department of Dermatology, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands

Introduction and Objectives: Psoriasis is a condition typically requiring long-term treatment, thus longitudinal data establishing the safety of approved therapies are required. We report exposure adjusted incidence rates (IRs per 100 patient years) for treatment-emergent adverse events (AEs) per year of treatment from a pooled analysis of all secukinumab psoriasis trials to date (19 studies, 4,674 patients, 10,061 patient-years exposure; secukinumab exposure up to 5 years).

Methods: AE IRs were examined per year for subjects receiving secukinumab, and for 52 weeks only for those receiving etanercept (ETN), ustekinumab (UST), or placebo (PBO).

Results: Duration of exposure through 52 weeks of secukinumab treatment 300 mg, ETN 50 mg, UST 45/90 mg, and PBO was 1467.4, 296.9, 318.1, and 301 patient-years, respectively. Exposure duration through 2, 3, 4, and 5 years of secukinumab 300 mg treatment was 859.6, 423, 377.5, and 90 patient-years.

Over 52 weeks for secukinumab, ETN, UST, and PBO, respectively, exposure adjusted IRs were overall comparable across treatments: total AEs (275.6, 245.7, 252.2, 355.8); nasopharyngitis (28.4, 35.9, 31.2, 35.9); headache (12.6, 15, 14.6, 23.7); upper respiratory infections [URI] (9.1, 5.9, 9.9, 8.8); opportunistic infections (0.2, 0.3, 0.3, 0.3); *Candida* infections (4.7, 1.4, 1.6, 1.7); neutropenia (0.5, 1.4, 0, 0); major adverse cardiovascular events [MACE] (0.5, 0.3, 0.3, 1.3); Crohn's disease (0.1, 0, 0, 0); ulcerative colitis (0.1, 0.3, 0, 0); and malignant or unspecified tumors [excluding non-melanoma skin cancer [NMSC]] (0.4, 0.3, 0.3, 0.3).

Secukinumab 300 mg pooled safety remained favorable over time with no increases in AEs (exposure adjusted IRs for up to Year 1 to Year 5, respectively): total AEs (275.6, 168.1, 160.2, 111.9, 13.9); nasopharyngitis (28.4, 21.2, 24.1, 11.8, 3.4); headache (12.6, 5.4, 4.3, 4.9, 0); URI (9.1, 7.3, 6.1, 5.5, 0); opportunistic infections (0.2, 0.1, 0, 0, 0); *Candida* infections (4.7, 3.6, 1.9, 1.3, 1.1); neutropenia (0.5, 0.1, 0, 0, 0); MACE (0.5, 0.1, 0.5, 0, 0); Crohn's disease (0.1, 0, 0, 0, 0); ulcerative colitis (0.1, 0.4, 0.2, 0.3, 0); and malignant or unspecified tumors [excluding NMSC] (0.4, 0.4, 0.2, 0, 0).

Conclusions: This comprehensive pooled analysis supports the favorable long-term safety profile of secukinumab in patients with psoriasis; no new safety signals were identified for up to 5 years of treatment and secukinumab's safety profile was consistent with that established in a large phase 3 program.

Findings previously published at the AAD Annual Meeting, February 16–20, 2018, San-Diego, California.

P114

IMPACT OF IMPROVEMENT IN SKIN AND JOINT ON QUALITY OF LIFE IN ACTIVE PSORIATIC ARTHRITIS PATIENTS

Arthur Kavanaugh[1], Alice Gottlieb[2], Akimichi Morita[3], Joseph F Merola[4], Julie Birt[5], Chen-Yen Lin[5], Catherine L Shuler[5], Diamant Thaçi[6]

[1]University of California, San Diego, CA, [2]Department of Dermatology, New York Medical College at Metropolitan Hospital, New York, NY, USA, [3]Nagoya City University Medical School, Nagoya, Japan, [4]Harvard Medical School, Brigham and Women's Hospital, Boston, MA, [5]Eli Lilly and Company, Indianapolis, IN, USA, [6]University Hospital Schleswig Holstein Campus Luebeck, Ratzeburger Allee, Germany

Introduction: Psoriatic arthritis (PsA) is a chronic immune-mediated inflammatory disease affecting peripheral and axial joints. For patients with active psoriasis, the added burden of skin disease can further reduce health-related quality of life (HRQoL) of patients with joint disease.

Objective: To determine the contribution of joint and skin improvements in HRQoL of patients with active PsA during Phase 3 clinical trials investigating ixekizumab (IXE) treatment.

Methods: The double-blind Phase 3 trials (SPIRIT) investigated the treatment of IXE, a high-affinity monoclonal antibody selectively targeting interleukin-17A, for patients with active PsA. The integrated database of 2 SPIRIT trials consisted of biologic disease-modifying antirheumatic drug (DMARD)-naïve patients (SPIRIT-P1, NCT01695239) or inadequate responders to tumor necrosis factor (TNF)-inhibitors (SPIRIT-P2, NCT02349295). Patients were randomized to 80mg IXE every 4 weeks (Q4W,

$n = 229$) or 2 weeks (Q2W, $n = 226$) after a 160mg starting dose or placebo (PBO, $n = 224$). At baseline and Week 24, joint and skin diseases were measured by the Disease Activity index for PSoriatic Arthritis (DAPSA; calculated post-hoc) and Psoriasis Area and Severity Index (PASI), respectively. HRQoL was measured by EuroQoL 5 Dimensions Visual Analog Scale (EQ-5D VAS), Short Form-36 Health Survey (SF-36), and Work Productivity and Activity Impairment-Specific Health Problem (WPAI). The synergistic contribution of skin and joint improvements to HRQoL was modeled using smoothing spline method and depicted with response surface. Missing data were imputed using last observation carried forward.

Results: Of 679 PBO- and IXE-treated patients in the SPIRIT trials, 402 (65%) and 224 (36%) patients had ≥3% body surface area (BSA) and ≥10% BSA psoriasis at baseline, respectively. In these patients, we applied response surface modeling to investigate the relationship among DAPSA, PASI, and change from baseline in EQ-5D VAS at Week 24. The greatest improvement in EQ-5D VAS was associated with the largest percent improvements in both DAPSA and PASI together, rather than DAPSA or PASI alone. Similar observations, regardless of ≥3% or ≥10% BSA baseline psoriasis, were made in domains of SF-36 (General Health, Physical Functioning, Social Functioning, and Vitality; data not shown) and WPAI (Activity Impairment; data not shown).

Conclusion: For PsA patients with psoriasis, optimal improvements in patients' HRQoL, as measured by select domains of patient-reported outcomes, were dependent on successful treatment of both joint and skin symptoms.

Kavanaugh A, Gottlieb A, Morita A, Merola J, Birt J, Lin C-Y, Shuler CL, Thaci D. The Contribution of Skin and Joint Improvements to the Health-Related Quality of Life of Patients with Active Psoriatic Arthritis. Arthritis Rheumatol. 2017;69(Suppl 10).

P115

SECUKINUMAB SHOWS HIGH AND SUSTAINED EFFICACY IN SUBJECTS WITH MODERATE TO SEVERE PALMOPLANTAR PSORIASIS: 2.5-YEAR RESULTS FROM THE GESTURE STUDY

Alice B Gottlieb[1], John Sullivan[2], Alexey Kubanov[3], Ruquan You[4], Pascaline Regnault[5], Jennifer Frueh[5]

[1]Department of Dermatology, New York Medical College, Metropolitan Hospital, NY, USA, [2]Holdsworth House Medical Practice, Darlinghurst, Australia, [3]State Scientific Center of Dermatology, Venereology and Cosmetology, Moscow, Russia, [4]China Novartis Institutes for BioMedical Research, Shanghai, China, [5]Novartis Pharma AG, Basel, Switzerland

Introduction: Palmoplantar psoriasis (ppPsO) occurs in up to 40% of plaque psoriasis subjects and is often resistant to treatment. It is associated with pain, functional limitations, and greater impairment of health related quality of life compared with plaque psoriasis on other parts of the body (1). Secukinumab, a fully human monoclonal antibody which selectively neutralises IL-17A, has shown long lasting efficacy and safety in the complete spectrum of psoriasis manifestations, including nails, scalp, palms and soles and psoriatic arthritis.

Objectives: Here we report, the long-term follow-up efficacy and safety results from the GESTURE study, the first robust (2.5-year) data reported in subjects with moderate to severe ppPsO treated with secukinumab.

Methods: GESTURE is a double blind, randomised, placebo-controlled, parallel-group, multicentre phase 3b study to investigate safety and efficacy of secukinumab 150 and 300 mg s.c. in 205 subjects with moderate to severe ppPsO.

Results: As previously reported, after 16 weeks placebo-controlled treatment, the primary endpoint palmoplantar Investigator's Global Assessment (ppIGA) 0/1 and all secondary endpoints of this study were met, demonstrating superiority of secukinumab to placebo at week 16 (2). An interim analysis at week 80 established the continuation improvement of palmoplantar disease for all efficacy parameters. The effect was sustained through 2.5 years with 59.2% and 52.5% of subjects in secukinumab 300 and 150 mg groups, respectively [multiple imputation (MI)] achieving clear or almost clear palms and soles (ppIGA 0/1). Consistent with this observation, the mean palmoplantar Psoriasis Area and Severity Index % change from baseline reached –74.7% and –61.6% for secukinumab 300 and 150 mg, respectively, at 2.5 years (MI). The Dermatology Life Quality Index 0/1 response, was achieved in 45.5% vs. 23.9% of subjects for secukinumab 300 and 150 mg groups respectively (LOCF). Pain and function of palms and soles was markedly improved with secukinumab; as reflected by the Palmoplantar Quality of Life Instrument overall scores with 16.7% and 17.9% subjects experiencing no difficulty in hand and feet functionality in secukinumab 300 mg and 150 mg groups respectively (LOCF). The safety profile was consistent with that seen in secukinumab phase 3 trials. The most common adverse events across all treatment arms were nasopharyngitis, upper respiratory tract infection and headache.

Conclusions: GESTURE, the largest and longest duration randomised controlled trial to date, revealed that secukinumab provides a novel treatment option for the challenging and infrequently studied ppPsO population by providing a strong and sustained response through 2.5 years.

References:

1. Kumar B, et al. Acta Dermatol Venereol. 2002; 82:192–5.
2. Gottlieb A, et al. J Am Acad Dermatol. 2017; 76:70–80.

This investigation was sponsored by Novartis Pharma AG, Basel, Switzerland.

P116

SECUKINUMAB SHOWS HIGH AND SUSTAINED EFFICACY IN NAIL PSORIASIS: 2.5-YEAR TRANSFIGURE STUDY RESULTS

Kristian Reich[1], Petr Arenberger[2], Ulrich Mrowietz[3], Sasha Jazayeri[4], Matthias Augustin[5], Anne Parneix-Spake[6], Pascaline Regnault[7], Ruquan You[8], Jennifer Frueh[7]

[1]Dermatologikum Berlin and SCIderm Research Institute, Hamburg, Germany, [2]Department of Dermatology, Charles University, 3rd Faculty of Medicine, Prague, Czech Republic, [3]Psoriasis Center at the Department of Dermatology, University Medical Center Schleswig-Holstein, Kiel, Germany, [4]Alliance Dermatology and MOHS Center, Phoenix, USA, [5]Universität Hamburg, Hamburg, Germany, [6]Novartis Pharmaceuticals Corporation, East Hanover, USA, [7]Novartis Pharma AG, Basel, Switzerland, [8]China Novartis Institutes for BioMedical Research, Shanghai, China

Introduction: Nail psoriasis is associated with decreased finger mobility, functional impairment, pain and reduced quality of life (QoL) and is often challenging to treat. It correlates with more severe psoriatic disease and is an important predictor of psoriatic arthritis (PsA). Nails are affected in up to 50% of psoriasis patients, with a lifetime incidence as high as 90%[1]. Secukinumab, a fully human monoclonal antibody that selectively neutralises IL-17A, has shown long lasting efficacy and safety in the complete spectrum of psoriasis manifestations, including nails, scalp, palms and soles and psoriatic arthritis.

Objectives: Here, we report the long-term follow-up efficacy and safety results from the TRANSFIGURE study, the first robust (2.5-year) data reported in subjects with nail psoriasis treated with secukinumab.

Methods: TRANSFIGURE is a double blind, randomised, placebo-controlled, parallel group, multi-centre phase 3b study, to investigate safety and efficacy of secukinumab 150 and 300 mg s.c. in moderate to severe nail psoriasis, involving 198 subjects.

Results: As previously reported, at week 16 the primary endpoint NAPSI (NAil Psoriasis Severity Index) and all secondary endpoints of this study was met, demonstrating superiority of secukinumab to placebo after 16 weeks placebo-controlled treat-

ment[2]. An interim analysis at week 80 demonstrated the continuation of improvement in nail psoriasis for all efficacy parameters. The effect was sustained through 2.5 years with a large mean NAPSI improvement from baseline (BL) of −73.3% and −63.6% with secukinumab 300 and 150 mg, respectively (as observed). Secukinumab demonstrated sustained reductions (improvements) in total mean NAPPA (Nail Assessment in Psoriasis and Psoriatic Arthritis) QoL scores from BL to 2.5 years by −52.4% and −18.1%, and 70.2% and 71.0% of subjects achieved a weighted NAPPA-PBI (Patient Benefit Index) global score of ≥2 (at least moderate benefits) with secukinumab 300 and 150 mg, respectively (LOCF). Subjects showed considerable improvements in EQ-5D (EuroQOL 5-Dimension Health Status Questionnaire) compared with BL reporting decreased pain and discomfort. The safety profile was consistent with that observed in previous phase 3 trials of psoriasis and PsA.
Conclusions: TRANSFIGURE is the first large, randomised controlled trial to report long-term results in subjects with nail psoriasis. Secukinumab demonstrated strong sustainability of clinically meaningful efficacy, large QoL improvement and a favourable safety profile up to 2.5 years in this challenging form of psoriasis.
This investigation was sponsored by Novartis Pharma AG, Basel, Switzerland.
References:
Baran R. Dermatology. 2010; 221 Suppl 1:1–5.
Reich K. Ann Rheum Dis. 2016;75:603.

P117
THE OBESITY AND PREVALENCE PSORIATIC ARTHRITIS IN PATIENTS WITH PLAQUE PSORIASIS: DERMATOLOGICAL REAL-SETTING DATA

Maria Chamurlieva, Tatiana Korotaeva
N.A.Nasonova Research Institute of Rheumatology

Background: Psoriasis (PsO) is a chronic inflammatory disease, which can be associated with the obesity. A link between body mass index (BMI) and psoriatic arthritis (PsA) has been found recently. But there is limited data about this association in Russian population and from real-world data.
*Objective:*To study the incidence of PsA in PsO patients (pts) with/without obesity.
Methods: 103 pts (male-47/female-56) with different forms of plaque PsO, mean age 44±13.69 years (yrs.), mean PsO duration 10.7±10.2 yrs., mean PASI 15.39±12.51 were included. 61 out of 103 pts with PsO (59.2%) had psoriatic arthritis (PsA) by CASPAR criteria. In all pts BMI was calculated. If the BMI was more than 30 it was regarded as obesity. M±m, %, t-test were peformed. All $p < 0.05$ were considered to indicate statistical significance.
Results: The overweight in both groups of pts with PsO and PsA was not significantly different: in 30 pts without PsA and in 48 with PsA, 71.4% and 78.7% respectively. However, there was a significant difference in the frequency of PsA in the group of pts with a BMI = 30–35 (obesity 1 degree). Thus, it was more than 4 times higher the pts with PsA, compared with pts without PsA - 19 and 4 pts (31.2% vs. 9.5%) respectively ($p = 0.06$).
Conclusion: There is a higher incidence of PsA in PsO pts with obesity. It should be taken into account during choice of treatment and evaluation of efficiency of therapy in real-world dermatological setting. Russian population – based studies are needed.

P118
DIAGNOSIS OF PSORIATIC ARTHRITIS IN PATIENTS WITH MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS TREATED WITH SECUKINUMAB VS. OTHER TREATMENTS IN THE PURE REGISTRY: INDICATION OF SELECTION PREFERENCES AND UNDERDIAGNOSIS

Kim Papp[1], Melinda Gooderham[2], Jennifer Beecker[3], Charles Lynde[4], Isabelle Delorme[5], Ignacio Dei-Cas[6], Emmanouil Rampakakis[7], Lenka Rihakova[8], Shamiza Hussein[8], Antonio Vieira[8]
[1]K Papp Clinical Research and Probity Medical Research, Waterloo, ON, [2]SKiN Center for Dermatology, Queen's University and Probity Medical Research, Peterborough, ON, [3]University of Ottawa, Division of Dermatology, Ottawa, ON, [4]Lynde Institute for Dermatology, University of Toronto and Probity Medical Research, Markham, ON, [5]Dr. Isabelle Delorm Inc, Drummondville, QC, Canada, [6]Facultad de Medicina de la Universidad de Buenos Aires, Buenos Aires, Argentina, [7]JSS Medical, Saint-Laurent, QC, [8]Novartis Pharmaceuticals Canada Inc., Dorval, QC, Canada

Introduction: Secukinumab (SEC) is a fully human monoclonal antibody that selectively neutralizes IL-17A, a key cytokine involved in the development of psoriasis (PsO). SEC has shown long lasting efficacy and safety in the complete spectrum of PsO manifestations, including nails, scalp, palms and soles and psoriatic arthritis (PsA). PURE is an international registry of adult patients (pts) from Canada and Latin America with moderate to severe PsO treated with SEC vs other approved therapies (other Tx).
Objectives: To describe and compare the baseline demographic, disease, and clinical characteristics – specifically, the history of a PsA diagnosis among PsO pts treated with SEC vs other Tx.
Methods: Approximately 2,500 adult pts (1:1 ratio, SEC: other Tx) will be recruited. A decision regarding treatment must have been reached prior to enrollment. The independent-samples and Chi-square tests were used for continuous and categorical variables, respectively, for treatment group comparison.
Results: As of Nov 27, 2017, 1032 pts (397 SEC vs 635 other Tx) had been enrolled. Mean age (50.5 vs 49.4 years), time since diagnosis (18.5 vs 16.9 years), duration since symptom onset (20.5 vs 19 years), and race (78.6% vs 83.8% Caucasian) were comparable between groups. The percentage of females was lower in the SEC group (38.0%) vs other Tx (45.5%; $p = 0.037$). At baseline, the majority of SEC-treated pts (66.2%) were employed, and 23.7% vs 34.8% vs 34.3% had public vs private vs combined coverage, respectively. There was no difference between cohorts. A higher proportion of SEC pts had a history of PsA (23.2% vs 15.0%; $p = 0.001$) or diabetes (18.1% vs 13.4%; $p = 0.072$) compared to pts on other Tx. About 87.9% pts with PsA history and 34.1% pts without had a Psoriasis Epidemiology Screening Tool (PEST) score ≥3 at baseline; however, the diagnosis of PsA in these pts needs to be confirmed. In terms of prior PsO treatments, 52.4% vs 29.9% ($p < 0.001$) of SEC vs other Tx pts had been previously treated with methotrexate, and 50.6% vs 18.0% ($p < 0.001$) with a biologic. Prior to enrollment, 4.7%, 13.2% and 4.7% pts in the other Tx group received anti-IL-12/23, anti-TNF-α, and anti-IL-17A, respectively. Pts treated with SEC had a higher historical Psoriasis Area and Severity Index (PASI) score (16.5 vs 14.2; $p = 0.005$), baseline PASI (13.6 vs 12.0; $p = 0.001$) and Investigator's Global Assessment score (severe disease [score = 4]: 25.4% vs 20.1%) at enrollment compared to pts on other Tx.
Conclusions: Pts with moderate to severe PsO selected for treatment with SEC were more likely to have been previously exposed to another biologic, have comorbid PsA and had more severe skin disease, compared to pts treated with other Tx. A significant proportion of PsO pts may have their PsA undiagnosed in routine clinical care.
References:
Langley R, et al. NEJM 2014;371:326.
Armstrong AW, et al. J Clin Aesthet Dermatol 2016; S12-S16
McInnes IB, et al. Lancet 2015;386:1137 Mease PJ, et a

P119
EFFICACY AND SAFETY RESULTS OF GUSELKUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS OVER 56 WEEKS

Wolf Henning Boehncke[1], Alice Gottlieb[2], Atul Deodhar[3], Bin

Dong[4], Yuhua Wang[4], Yanli Zhuang[4], William Barchuk[5], Xie L. Xu[5], Elizabeth Hsia[4]
[1]Division of Dermatology and Venereology, Geneva University Hospital, and Department of Pathology and Immunology, University of Geneva, Geneva, Switzerland, [2]Department of Dermatology, New York Medical College at Metropolitan Hospital, New York, NY, [3]Oregon Health & Science University, Portland, OR, [4]Janssen Research & Development, LLC, Spring House, PA, [5]Janssen Research & Development, LLC, San Diego, CA, USA

*Introduction/Objective:*To evaluate the efficacy, safety & tolerability of guselkumab (GUS) in patients (pts) w/ PsA.
Methods: In this double-blind, PBO-controlled study, pts w/active PsA & ≥3% BSA of PsO despite treatment were randomized 2:1 to SC GUS 100mg or PBO at wks0, 4, & q8w thereafter through wk44. At wk16, pts w/ < 5% improvement from baseline (BL) in swollen & tender joint counts were eligible for early escape (EE) to open-label ustekinumab. At wk24, PBO pts crossed-over to GUS 100mg (PBO to GUS). The primary endpoint was ACR 20 at wk24. Major secondary endpoints were PASI 75 & ACR 50 responses, change from BL in HAQ-DI, & improvement in enthesitis (Leeds enthesitis index [LEI]) & dactylitis score (by a 0–3 scoring system) at wk24; & ACR 20 response at wk16. Through wk24, efficacy analyses were performed in a modified Intent-to-Treat (mITT) population. Pts who met treatment failure criteria, EE or had missing data at wk24 were considered non-responders for ACR/MDA endpoints at wk24. Efficacy post wk24 was evaluated in pts who did not EE & continued treatment at wk24 based on observed data.
Results: Of 149 pts (PBO:49, GUS:100), BL demographics & ACR component measures were generally similar between the 2 groups. 4 PBO & 9 GUS pts were previously exposed to anti-TNFα agents. At wk24, significantly more GUS pts achieved ACR 20 (58.0% vs 18.4%, $p < 0.001$), PASI 75 (78.6% vs 12.5%, $p < 0.001$), & ACR 50 (34.0% vs 10.2%, $p = 0.002$) responses vs PBO. At wk24, mean decrease in HAQ-DI score from BL (-0.42 vs. -0.06, $p < 0.001$), & median percent improvement in enthesitis (100% vs 33.33%, $p = 0.009$) & dactylitis (100% vs 33.33%, $p < 0.001$) scores (among pts w/ BL enthesitis and dactylitis) were significantly greater in GUS group vs. PBO. Significantly more GUS pts achieved ACR 20 at wk16 (60.0% vs 16.3%, $p < 0.001$) and MDA at wk24 (23.0% vs. 2.0%, $p = 0.001$) vs. PBO. Post wk24, efficacy improved in PBO to GUS crossover pts as expected and were well-maintained in GUS pts through wk56.
Through wk24, the frequencies of AEs & infections were comparable (AEs: PBO 32.7%; GUS 36.0%; infections: PBO: 20.4%; GUS: 16.0%). Post wk24, there was no disproportional increase in AE frequency or infections among GUS pts w/ longer exposure. Through wk56, there was 1 malignancy (basal cell carcinoma), 6 SAEs (myocardial infarction, osteoarthritis, pupils unequal, radius fracture, pneumonia, ulcerative keratitis), 2 pts discontinued treatment due to AEs, 1 grade 3 neutropenia, & 6 pts were positive for antibodies to GUS. No deaths occurred through wk56.
Conclusions: GUS demonstrated significant improvement on joint symptoms, physical function, PsO, enthesitis, dactylitis & quality of life; efficacy was well-maintained through wk56. GUS was well tolerated in this population after ~1 year of exposure.
Data has been previously presented at EULAR 2017 & ACR 2017

P120
TILDRAKIZUMAB EFFICACY OVER TIME BY WEEK 28 RESPONSE LEVELS IN TWO PHASE 3 CLINICAL TRIALS IN PATIENTS WITH CHRONIC PLAQUE PSORIASIS

Andrew Blauvelt[1], Howard Sofen[3], Kim Papp[3], Melinda Gooderham[4], Yang Zhao[5], Simon Lowry[5], Jeff Parno[5], Qing Li[6], Carmen La Rosa[6], Kristian Reich[7]
[1]Oregon Medical Research Center, Portland, OR, [2]Department of Medicine (Dermatology) UCLA, Los Angeles, CA, USA, [3]Probity Medical Research, Waterloo, ON, [4]Skin Centre for Dermatology, Peterborough, ON, Canada, [5]Sun Pharmaceuticals, Princeton, NJ, [6]Merck & Co., Inc., Kenilworth, NJ, USA, [7]SCIderm Research Institute and Dermatologikum Hamburg, Hamburg, Germany

Introduction: Tildrakizumab (TIL), a humanized, IgG1/κ monoclonal antibody for IL-23p19, recently demonstrated its efficacy in subjects with chronic plaque psoriasis in two, phase 3 clinical studies1.
*Objective:*In this analysis, we examined efficacy from baseline to week 52 among TIL patients achieving various Psoriasis Area and Severity Index (PASI) responses at week 28.
Methods: ReSURFACE 1 (NCT01722331) and reSURFACE 2 (NCT01729754) were double-blind, randomized controlled studies in subjects with moderate-to-severe chronic plaque psoriasis. Part 1 (0–12 weeks) was placebo controlled; Part 2 (12–28 weeks) re-randomized placebo patients to TIL; Part 3 (28–64 weeks, reSURFACE 1; 28–52 weeks, reSURFACE 2) re-randomized patients with ≥PASI 50 to continue or increase TIL dose or to placebo based on their PASI response at week 28. In this post-hoc pooled analysis, patients consistently on TIL 100 mg and 200 mg from baseline to week 52 were classified in 5 mutually exclusive groups based on their week-28 PASI response: PASI < 50, PASI 50–74, PASI 75–89, PASI 90–99, and PASI 100. Baseline characteristics and % PASI improvement from baseline up to week 52 (observed data) were examined for each group.
Results: This analysis included 575 (TIL 100 mg) and 581 (TIL 200 mg) patients; the proportions of patients with week-28 PASI 75/90/100 responses were 77%/54%/23% (TIL 100 mg) and 78%/58%/29% (TIL 200 mg). At week 28, 133 (23.1%), 175 (30.4%), 137 (23.8%), 82 (14.3%), and 48 (8.3%) TIL 100 mg patients and 170 (29.3%), 169 (29.1%), 114 (19.6%), 105 (18.1%), and 23 (4.0%) TIL 200mg achieved PASI 100, PASI 90–99, PASI 75–89, PASI 50–74, and PASI < 50, respectively. On average, PASI 100 patients were younger, lighter, and had shorter disease duration at baseline compared to other response groups. For TIL 100 mg, % PASI improvement was highest for PASI 100 and least for PASI < 50 patients on all visits up to week 28 (week 4: 53%, 46%, 38%, 30%, and 16%; week 28: 100%, 95%, 83%, 64%, and 33% for PASI 100, PASI 90–99, PASI 75–89, PASI 50–74, and PASI < 50 categories, respectively). Among patients achieving PASI > 50 at week 28 and continued up to 52 weeks, % PASI improvement maintained or improved from week 28 to week 52. Similar results were observed for TIL 200 mg as well as a subgroup analysis with bio-naive and bio-experienced patients respectively.
Conclusions: The majority of TIL 100 and 200 mg patients achieved PASI > 50 response at week 28, and PASI improvement was maintained from week 28 to week 52. Among patients achieving PASI > 90 at week 28, TIL 100 and 200 mg were associated with a rapid PASI improvement by week 4.
Reference:
1. Reich K, Papp KA, Blauvelt A, et al. Tildrakizumab versus placebo or etanercept for chronic plaque psoriasis (reSURFACE 1 and reSURFACE 2): results from two randomised controlled, phase 3 trials. Lancet. 2017;390(10091):276-288.
This abstract was presented at 2018 Annual Meeting of American Academy of Dermatology.Note: This abstract was presented at 2018 Annual Meeting of American Academy of Dermatology.

P122
POTENTIAL DISCONNECT: CO-MANAGEMENT OF PATIENTS WITH PSORIATIC ARTHRITIS BETWEEN RHEUMATOLOGISTS AND DERMATOLOGISTS

Lynn Price, Jennifer Robinson, Gianna Melendez
Spherix Global Insights

Introduction: On average, the majority of psoriasis (PSO) patients are diagnosed a year prior to a psoriatic arthritis (PsA) diagnosis, making the referral patterns and co-management between derma-

tologists and rheumatologists an important aspect to understanding the management of these diseases. Dermatologists represent an important referral-base for rheumatologists, accounting for over one-quarter of all new PsA patients. However, there are discrepancies between the specialists regarding the timing in which these referrals take place.
Objectives: One objective of the study was to gain further insight into rheumatologist and dermatologist co-management of patients with PsA.
Methods: An independent market analytics firm collaborated with US rheumatologists ($n = 101$) and US dermatologists ($n = 101$) to conduct analysis of both the PsA and PSO markets. Data were collected via an online survey fielded in November/December 2017 and included patient demographics, as well as physician demographics, and attitudinal survey responses.
Results: Rheumatologists indicate that 51 percent of referrals result from primary care physicians, 28 percent result from a dermatologist, and 13 percent are self-referred. The majority (73%) of PsA patients under the care of collaborating rheumatologists had previously been diagnosed with PSO prior to PsA. Dermatologists state that one-quarter of their patients with severe PSO also have PsA, with more than one-third of severe PSO patients also being co-managed with a rheumatologist. The majority of rheumatologists believe that dermatologists refer patients at the first sign of joint involvement and do not attempt to treat joint pain; however, 31 percent of dermatologists report they do not refer PSO patients to rheumatologists until patients have failed biologics or are not improving on their current systemic regimen, while an additional 35 percent report they refer only severe arthritis/patients with worsening disease. Furthermore, only 35 percent of dermatologists agree that they refer their PSO patients to a rheumatologists at the first sign of joint involvement.
At the time of dermatologist referral, rheumatologists state that two-thirds of referred patients are biologic/apremilast naïve, with only 6 percent having controlled PSO and joint pain. However, dermatologists state that 40 percent the patients that they referred to rheumatologists were treated with biologics and 15 percent of said referred patients were treated with apremilast. Indeed, 76 percent of dermatologists agree with the statement, "I *believe that starting my PSO patients earlier on biologic therapy will slow the development and progression of the arthritic component of the disease (PsA),*" while 57 percent of dermatologists agree *"I prefer to use biologics that are indicated in both PSO and PsA."*
Conclusion: With many patients diagnosed with both PSO and PsA, co-management between dermatologists and rheumatologists is common. While rheumatologists appear to be under the impression that they are receiving the majority of dermatologist-treated patients with PsA at the first sign of joint involvement, dermatologists largely report that they are managing and treating PsA patients. Furthermore, most dermatologists believe early aggressive use of biologic treatments will mitigate the development and/or progression of joint involvement, implying their willingness to manage their patients with PsA, particularly at early stages.

P123
THE USE OF TUMOR NECROSIS FACTOR INHIBITORS (TNF) IN THE SECOND-LINE BIOLOGIC/SMALL MOLECULE SETTING: A CROSS-SPECIALTY COMPARISON

Lynn Price, Jennifer Robinson, Gianna Melendez
Spherix Global Insights

TNF therapy has been the standard of care for adult patients diagnosed with autoimmune conditions, resulting in familiarity, comfort, and satisfaction among physicians. TNFs are typically used as a first-line biologic/small molecule in the treatment of psoriasis (PSO) and psoriatic arthritis (PsA). However, the adoption of agents with alternate mechanisms of action (AMOA) has increased in recent years across indications and the practice of sequential TNF prescribing after an initial TNF is less common. Though TNFs are still the preferred first-line agent, there are discrepancies between specialists on the use of AMOA agents in the second-line setting. This research sought to understand the extent to which AMOA agents are prescribed after an initial TNF, and how this varies across PSO and PsA.
An independent market analytics firm collaborated with US dermatologists ($n = 201$) and US rheumatologists ($n = 200$) to conduct a retrospective chart review of patients diagnosed with PSO ($n = 950$) and PsA ($n = 1{,}008$) who had switched from one biologic/apremilast to another agent in the prior 12 weeks. Physicians were able to submit up to 7 patient charts. PSO data was collected in September 2017 and PsA data was collected in April 2017.
Analysis of patients recently switched from one biologic/apremilast to a different brand revealed the majority of patients were treated with a TNF in the first-line biologic/small molecule setting, though this varies by indication. Rheumatologists prescribe first-line TNFs significantly more than dermatologists. 83% of PsA patients are prescribed TNFs first-line compared to just 69% of PSO patients. Furthermore, rheumatologists are significantly more likely to practice TNF-sequencing than dermatologists. Indeed, 44% of PsA patients treated with a first-line TNF were prescribed a second TNF, compared to 6% of PSO patients. Additionally, certain TNF brands have experienced recent declines in first line use, though this varies by indication as well. For rheumatologists, use of first-line etanercept has declined, 38% of PsA patients were initiated on etanercept at least 24 months prior to the study, compared to just 28% initiated on etanercept within 12 months of the study. For dermatologists, there were significantly more PSO patients initiated on etanercept in the first-line setting 24 months or more prior to the study compared to those initiated within 12 months of the study, (45% vs 31%.) This pattern also held true for adalimumab, where 42% of first-line PSO patients initiated more than 24 months prior to the study were prescribed adalimumab, a figure that drops to just 27% for patients initiated within 12 months.
Though the position of TNFs as first-line agents remains dominant, the treating specialist and indication influence how widespread and continuous TNF use is. Specifically, dermatologists are less likely to prescribe TNFs as first-line agents and are also significantly less likely to partake in the sequencing of TNFs in the first- and second-line setting than rheumatologists. The introduction of several agents in PSO reporting substantially higher rates of skin clearance compared to TNFs could potentially be the source of increased switching to AMOAs compared to other specialties; whereas superior efficacy of AMOA agents over TNFs in PsA may be less apparent.

P124
IMPACT OF GUSELKUMAB VERSUS PLACEBO AND ADALIMUMAB ON PATIENT REPORTED OUTCOMES IN PATIENTS WITH AND WITHOUT PSORIATIC ARTHRITIS IN VOYAGE 2

Luis Puig[1], Chenglong Han[2], Ron Vender[3], Michael Song[2], Yin You[2], Yaung-Kaung Shen[2], Peter Foley[4]
[1]Hospital de la Santa Creu i Sant Pau and Universitat Autònoma de Barcelona Medical School, Barcelona, Spain, [2]Janssen Research & Development, LLC, Spring House, PA, USA, [3]McMaster University, Hamilton, ON, Canada, [4]University of Melbourne, St. Vincent's Hospital, Melbourne and Skin & Cancer Foundation Inc., Carlton, Victoria, Australia

*Introduction/Objective:*VOYAGE 2 is a phase 3 double-blind, placebo/active comparator-controlled trial comparing guselkumab (GUS) with placebo (PBO) and adalimumab (ADA) in patients (pts) with moderate-to-severe PsO. The impact of treatment on patient-reported outcomes (PROs) was evaluated.
Methods: Pts were randomized to GUS 100mg (wks 0 & 4, then

q8wks), ADA (80 mg wk 0, 40 mg wk 1, then 40 mg q2 wks), or PBO (wks 0, 4, & 12, then GUS 100 mg wks 16 & 20). We evaluated PROs using the Work Limitations Questionnaire [WLQ; work productivity], the Hospital Anxiety & Depression Scale [HADS], and the Medical Outcomes Study 36-Item Short Form (SF-36; health related quality of life) at wk16 (GUS vs PBO) and wk24 (GUS vs ADA) in pts with and without PsA.

Results: In all, 18% of pts reported a history of PsA. At wk16, GUS pts had numerically greater improvements vs PBO in work productivity, anxiety and depression, and SF-36 PCS & MCS scores regardless of PsA status. The least square (LS) mean differences (95% CI; adjusted for baseline value) for GUS vs PBO for all PROs were generally similar between pts with and without PsA. At wk24, GUS pts had numerically greater improvements vs ADA in all PROs regardless of PsA status. The LS mean differences for GUS vs ADA were generally greater for pts with PsA vs pts without PsA (Table).

Conclusions: GUS showed better improvements in all PROs vs PBO at wk16 and vs ADA at wk24. Improvements vs PBO were similar regardless of PsA status, while improvements vs ADA were greater for pts with PsA.

Table: Summary of Change from Baseline in WLQ, HADS and SF-36 Scores from VOYAGE 2

	Week 16 GUS vs PBO				Week 24 GUS vs ADA			
	w/ PSA		w/out PSA		w/ PSA		w/out PSA	
	N, LSMean Diff (95% CI)	p-value	N, LSMean Diff (95% CI)	p-value	N, LSMean Diff (95% CI)	p-value	N, LSMean Diff (95% CI)	p-value
WLQ Physical Demands	86, -7.1 (-13.21, -0.92)	0.0249	446, -7.7 (-10.56, -4.88)	< 0.0001	79, -1.6 (-10.58, 7.29)	0.7152	445, -2.6 (-5.39, 0.28)	0.0769
WLQ Time Management	85, -6.6 (-15.35, 2.06)	0.1326	419, -7.0 (-10.31, -3.79)	< 0.0001	79, -4.3 (-14.40, 5.81)	0.3996	420, -0.6 (-3.46, 2.30)	0.6931
WLQ Mental-Interpersonal	83, -3.8 (-11.03, 3.35)	0.2913	439, -4.9 (-7.54, -2.35)	0.0002	78, -11.4 (-19.37, -3.34)	0.0061	436, -1.5 (-4.16, 1.11)	0.2569
WLQ Ouput Demands	84, -7.9 (-14.51, -1.21)	0.0211	440, -3.5 (-6.11, -0.88)	0.0089	79, -14.7 (-24.29, -5.17)	0.0030	437, -1.2 (-3.94, 1.62)	0.4136
Anxiety Score	135, -1.2 (-2.45, 0.04)	0.0584	608, -1.6 (-2.05, -1.07)	< 0.0001	133, -2.1 (-3.33, -0.83)	0.0012	608, -0.8 (-1.29, -0.28)	0.0025
Depression Score	135, -1.2 (-2.55, 0.06)	0.0611	608, -1.5 (-1.96, -0.98)	< 0.0001	133, -1.5 (-2.85, -0.09)	0.0374	608, -0.4 (-0.91, 0.10)	0.1158
SF-36 Physical Score	135, 5.7 (2.94, 8.43)	< 0.0001	607, 4.4 (3.31, 5.39)	< 0.0001	132, 2.9 (0.21, 5.57)	0.0346	608, 1.0 (-0.10, 2.04)	0.0753
SF-36 Mental Score	135, 4.5 (1.61, 7.48)	0.0026	607, 4.8 (3.53, 6.15)	< 0.0001	132, 3.2 (-0.12, 6.53)	0.0591	608, 1.8 (0.45, 3.15)	0.0092

N is the sample size across two groups.

P125

THE DERMATOLOGY LIFE QUALITY INDEX IN RUSSIAN PATIENTS WITH PSORIASIS AND PSORIATIC ARTHRITIS.

Nadezhda Batkaeva, Edgem Batkaev, Muslimat Gitinova
Peoples' Friendship University of Russia (RUDN University)

Introduction: The most severe form of psoriasis is psoriatic arthritis (PsA), which belongs to the seronegative spondyloarthritis group, characterized by chronic inflammation of the joints, spine, enthesis. The frequency of PsA in the population is 0.06–1.4%. PSA is comparable to rheumatoid arthritis (RA) in terms of progression, disability and quality of life (QOL) in patients.

Objectives: Compare the quality of life index of patients with severe forms of psoriasis (PsO) with psoriatic arthritis patients' index.

Methods: 120 (100%) patients suffering from PsO and PsA (Male-87/female - 33) were analyzed. 70 (54.2%) patients were diagnosed PsO, 50 (41.7%) were diagnosed PsA. The average age of patients with skin manifestations PsO was 54.0±14.2 years ($n = 70$). The average age of patients with PsA was 49.1±15.9 years ($n = 50$). The group of patients with PsA was older than the group PsO patients by age. PASI > 10. The quality of life was assessed using the Dermatology Life Quality Index (DLQI) questionnaire. The results were evaluated: from 0 to 1 score - cutaneous disease does not affect the patient's life, from 2 to 5 scores - the disease has a minor effect on the patient's life, from 6 to 10 scores - the disease has a moderate effect on the patient's life, from 11 to 20 scores - the disease has a very strong effect on the patient's life, from 21 to 30 scores - the disease has an extremely strong effect on the patient's life. Statistical processing of the data was carried out using the Excel analysis package. All $p < 0.05$ were considered to indicate statistical significance.

Results: 120 (100%) patients suffering from PsO were taken for analysis. The duration of PsO was: for more than 15 years - 25 people (35.7%), 10–15 years - 18 people (25.7%); 3–10 years - 15 people (21.4%), 1–3 years - 12 people (17.1%). The duration of PsA was: for more than 15 years – 5 people (10.0%), 10–15 years – 7 people (14.0%); 3–10 years – 20 people (40.0%), 1–3 years – 18 people (36.0%). Heredity was aggravated in 35 (29.1%) out of 120 patients. Comorbidity was presented in 112 (93.3%) out of 120 patients. Gastrointestinal and liver diseases were found in 48 (42.8%) out of 120 patients. Type 2 diabetes was observed in 45 (40.1%) out of 120 patients, cardiovascular diseases - in 100 (89.2%) out of 120 patients, diseases of the nervous system - in 59 (52.6%) out of 120 patients, and diseases of the urinary system - in 20 (17.8%) out of 120 patients.

The total score DLQI in the psoriasis group was 15.8±5.2. The score DLQI in PsO patients was 12.5±3.4 and in PsA patients was 20.4±3.7. The total score DLQI in PsO patients with comorbidity was 16.1±5.3.

Conclusions: The total score DLQI was significantly higher in patients with PsA compare to PsO patients. This result revealed the existence of an inferior quality of life for the PsO patients with comorbidity disease, compared with pts without comorbidity disease. The score of DLQI is affected the development and progress of the psoriasis and comorbidity pathology. Then higher DLQI value, the more it affects experience considerable physical and/or psychological discomfort, difficulties in social and professional adaptation, which subsequently cause significant distress and even social phobia. All these conditions psoriasis are interrelated by genetic and immunopathogenetic mechanisms. Thus, patients with psoriasis require an integrated approach and dynamic observation by dermatologists and doctors of related specialties.

P126

EFFECTS OF MINDFULNESS-BASED COGNITIVE THERAPY ON SELF-REPORTED PSORIASIS AND PSYCHOLOGICAL SYMPTOMS

Alan Maddock, David Hevey
School of Psychology, Trinity College Dublin

Introduction: Psoriasis can have a profound impact on a patient's life, with the prevalence of anxiety, depression, poor wellbeing and quality of life generally found to be high in psoriasis populations. Mindfulness based interventions have been shown to have positive impacts on anxiety, depression, wellbeing and quality of life in various populations.

Objectives: The aim of the present study was to investigate the effect of mindfulness-based cognitive therapy (MBCT) on psoriasis symptoms and psychological symptoms associated with psoriasis including anxiety, depression, reduced wellbeing and QoL. The study also aimed to investigate if MBCT significantly impacted the potential mediating variables of a new theory of mindfulness mechanisms the 'Clinically Modified Buddhist Psychological Model (CBPM)', these variables being acceptance, mindfulness, self-compassion, aversion, non-attachment, attention, rumination and worry.

Methods: 101 participants were randomly allocated to a treatment arm (MBCT) or a TAU arm. Participants were measured pre, post-treatment and after a 3-month follow up period. Data were analysed using intention-to-treat analysis and the ANCOVA method with baseline scores entered as covariates.
Results: There was a significant group×time (pre vs. post) interaction on all variables except QoL, indicating a significant reduction of each variable except QoL over time in the MBCT group, but not in the control group. When baseline variables were controlled for, the participants in the MBCT group achieved small statistically significant changes across all variables post intervention versus the TAU group.
Conclusions: The results suggest that MBCT may be a useful adjunct therapy for those suffering from psoriasis and the associated psychological symptoms relating to the condition. The results also indicate that each of the mechanisms outlined in the CBPM change significantly for patients who engage in the intervention.

P127

A MIXED METHODS STUDY EXPLORING THE IMPACT OF MINDFULNESS ON PSORIASIS, ANXIETY, DEPRESSION AND QOL

Alan Maddock, David Hevey
School of Psychology, Trinity College Dublin

Introduction: Psoriasis is a common condition with recognised psychological comorbidity. Psoriasis can have a profound impact on a patient's life, with the prevalence of anxiety, depression, poor wellbeing and quality of life generally found to be high in psoriasis populations. Based on Buddhist psychology, mindfulness based interventions have been shown to have positive impacts on anxiety, depression, wellbeing and quality of life in various populations.
Methods: Mixed methods explored the impact of a mindfulness based cognitive therapy (MBCT) intervention on 10 psoriasis patients using a Buddhist Psychological Model (BPM) as a theoretical framework to understand changes in these variables. Quantitative measures of acceptance, attention regulation, attachment, aversion, self-compassion, mindfulness, rumination, worry, wellbeing, anxiety, depression and psoriasis symptoms were completed pre and post intervention, and participants were interviewed about their experiences of MBCT.
Results: Statistically significant changes in attention, mindfulness, attachment, aversion, rumination, quality of life, anxiety and psoriasis were found. The qualitative data provided support for the BPM as a theoretical lens with which to understand the way in which mindfulness impacts on patient quality of life, anxiety and psoriasis symptoms.
Conclusions: This study gives support to the promising potential of mindfulness interventions being implemented by mental health care professionals with psoriasis patients.

P128

A LINK BETWEEN QUALITY OF PATIENT-PHYSICIAN COMMUNICATION AND PATIENT HEALTHCARE NEEDS IN PSA

A-M Orbai[1], L Coates[2], VF Azevedo[3], A Garg[4], A Majjhoo[5], CEM Griffiths[6], P Young[7], JC Cappelleri[8], J Moser[9], L Fallon[10]
[1]Johns Hopkins University School of Medicine, Baltimore, MD, USA, [2]University of Oxford, Oxford, UK, [3]Universidade Federal do Paraná, Curitiba, Brazil, [4]Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Hempstead, NY, [5]Shores Rheumatology, MI, USA, [6]University of Manchester, Manchester, UK, [7]Pfizer Inc, Collegeville, PA, [8]Pfizer Inc, Groton, CT, [9]The Harris Poll, Rochester, NY, USA, [10]Pfizer Canada, Montréal, QC, Canada

Introduction: Patient(pt)-physician(HCP) communication may influence symptom reporting and disease control.
Objectives: To evaluate psoriatic arthritis (PsA) symptoms, life impact and treatment satisfaction in pts who report good communication with their HCP vs suboptimal communication.
Methods: An online pt-based survey was conducted in the US from 2 Nov–1 Dec 2017. Pts had reported having PsA for >1 year, taken ≥1 synthetic(s) or biologic(b) DMARD for PsA. Pts reported overall health, PsA severity/symptoms/life impact, treatment satisfaction and communication experience. We evaluated differences by pt-HCP communication status.
Results: Overall, 301 pts with PsA responded, mean age 45 years, 61% female, 89% self-reported moderate/severe PsA. Current PsA treatments included bDMARD (52%), sDMARD (25%), combination b/sDMARD (15%). Overall, 256 (85%) of PsA pts were managed by a rheumatologist and 15% by a dermatologist. Of the 256, >40% reported suboptimal pt-HCP communication. Pts in the suboptimal vs good communication subgroups were typically younger, more likely to be Hispanic and reported greater life impact and lower satisfaction with pt-HCP communication (Table).

Table. Pts with PsA managed by rheumatologist ($n = 256$)

	"I worry that if I ask too many questions my healthcare professional will see me as a difficult patient and it will affect the quality of care I receive"		"I often tell my healthcare professional I am fine when I am really experiencing symptoms"	
	Agree $n = 105$ (41%) %	Disagree $n = 151$ (59%) %	Agree $n = 118$ (46%) %	Disagree $n = 138$ (54%) %
Mean age (years)	41.9	46.8*	41.6	47.5*
White	66	73	58	80*
Hispanic	20	15	26*	9
Black	10	7	11	7
Symptoms in past 12 months	85	90	86	
Joint pain	83	84	84	89
Skin/nail symptoms	74	79	72	83
Stiffness	70	72	75	82
Joint swelling				68
Moderate PsA	70*	55	58	64
Severe PsA	23	32	33	25
Reported impact on	76*	59	78*	56
-emotional well being	69*	56	69*	54
-work productivity	67*	48	66*	46
-romance/intimacy	40*	24	42*	21
-decision to start family	35*	17	36*	15
-education				
Very satisfied with HCP communication	43	75*	52	71*
Very satisfied with treatment	29	45*	36	40
Stopped taking treatment	22*	8	19*	9

*$p < 0.05$

Conclusions: Pts who reported suboptimal communication with their HCP may have greater healthcare needs for their PsA vs other pts.

P129

PSORIASIS PATIENTS POINT OF VIEW: WHAT ARE WE MISSING WHEN MANAGING THEM?

Elena Popa[1], Alexandra Brahas[2], Caius Solovan[1]
[1]Department of Dermatology and Venereology, Clinical Emergency City Hospital Timisoara; University of Medicine and Pharmacy "Victor Babes" Timisoara, Romania, [2]University of Medicine and Pharmacy "Victor Babes" Timisoara, Romania

Introduction: Psoriasis is a skin disease that can occur at any time and it is most common in the age group 50–69. The reported prevalence of Psoriasis in countries ranges between 0.09% and 11.4%, making it a serious global problem.
Psoriasis affects the quality of life and it is associated with many comorbidities such as depression, diabetes, cardiovascular disease and psoriatic arthritis.
To evaluate the severity and the efficiency of the treatment applied to patients with Psoriasis, in practice it is used PASI (Psoriasis Area and Severity Index). The value may vary, for example, in this study, PASI 75 represents the percentage (or number) of patients that have achieved a 75% or more reduction in their PASI score in 12 weeks from baseline.
Objectives: Aim of this study is to gain a better perspective on the Psoriasis patient's point of view when seeking a physician's

help, therefore, to try and minimize the gaps that exist when managing them.
Methods: This study was based on a custom questionnaire which included 14 questions for each patient. The responses were gathered from 20 patients (and it is still ongoing) diagnosed in our Department of Dermatology and Venereology Timisoara, each in different stages of disease. All the answers are confidential and anonymous. An informed consent was signed prior to any taken actions. To achieve meaningful results, we asked patients to be honest and to present the situation in a real way. The most important question on the questionnaire was "Which of the three options represents the PASI score you would like to achieve? 50/75/90?". In addition to this question, we provided the patients with three pictures each of them showing a different PASI score, so they can choose the proper answer much easier.
Results: 80% of the patients chose PASI 90, 15% chose PASI 75 and only 5% chose PASI 50.
In addition to this, the gender distribution showed us that 100% of the female patients chose PASI 90, proving how important appearance is for them, and how much of a weight it is for them to have disease that is in the limelight. On the other hand, the male patients were divided into three groups. 69% said that the efficiency of the therapy is very good, choosing PASI 90. Only 23% of male patients consider PASI 75 satisfying and the last 8% represents PASI 50.
Conclusions: Psoriasis is a chronic inflammatory disease, which is intensively studied at the cellular and molecular level. What is considered a good response to a treatment is sometimes different from the perception of a patient vs. a physician, therefore we must always keep a balance between aiming high (and maybe risking to over-treat some patients) and meeting the patient's expectations.

P130

THE IMPACT OF PSORIASIS AND PSORIATIC ARTHRITIS ON QUALITY OF LIFE AND CAREER IN SCANDINAVIA

Albert Duvetorp[1], Mikkel Østergaard[2], Lone Skov[3], Oliver Seifert[4], Kåre Steinar Tveit[5], Kjersti Danielsen[6], Lars Iversen[7]
[1]Skånes Universitetssjukhus, Malmö, Sweden; Linköping University, Linköping, Sweden, [2]Copenhagen Center for Arthritis Research, Center for Rheumatology and Spine Diseases, Rigshospitalet, Glostrup, University of Copenhagen Copenhagen, [3]Herlev and Gentofte Hospital, University of Copenhagen, Denmark, [4]Linköping University, Linköping, Sweden; Ryhov Hospital, Jönköping, Sweden, [5]Haukeland University Hospital, Bergen, [6]UiT The Arctic University of Norway; University Hospital of North Norway, Tromsø, Norway, [7]Aarhus University Hospital, Aarhus, Denmark

Introduction: Patients' perspectives on the effects of psoriasis (PsO) and psoriatic arthritis (PsA) on health-related quality of life (HRQoL) are important in establishing better approaches to their care and treatment.
Objectives: To better understand the impact of PsO and PsA on daily life, education and work in Scandinavian countries.
Methods: The NORdic PAtient survey of PsOriasis and Psoriatic arthritis (NORPAPP) was an on-line survey carried out in Nov/Dec 2015 using YouGov panels in Sweden, Denmark, and Norway. Adults (18–74 years old), with physician-diagnosed PsO or PsA ($n = 1221$), answered questions about the impact of disease on 10 aspects of daily activity/mood and on work/education; 5-point Likert scale responses were dichotomised into "no/minor impact" (1–3 or "don't know") and "strong impact" (4–5).
Results: For the 10 aspects of activity/mood a "strong impact" was reported for ≥4, 1–3 or 0 aspects by 22.8%, 24.2%, and 61.9% of respondents with PsO alone and 44.5%, 63.0%, and 27.0% of those with PsA±PsO. The most commonly reported strong impacts were limitations on dress (22.6%), sleep disorders (16.3%) and depression and/or anxiety (16.2%) for respondents with PsO alone; and, daily routine (45.1%), leisure/sports (44.0%), sleeping disorders (44.5%), and limitations on clothing (41.8%) for respondents with PsA±PsO. Regarding the impacts on work/career or education since development of symptoms, 6.4% of respondents with PsO alone and 30.3% of those with PsA±PsO reported a strong negative impact. Of the 82.2% of respondents who were working or studying, frequency of absences in the previous 12 months were significantly higher (Bonferroni corrected z-tests, total $\alpha = 0.05$) among those who: had PsA±PsO vs PsO alone; perceived their symptoms to be severe vs non-severe; used systemic vs only topical treatments; were aged 18–44 years vs 45–74; were members of patient groups vs non-members; saw a dermatologist or rheumatologist at least annually vs those who did not.
Conclusion: PsO has a profound impact on the HRQoL and career/education of individuals with these conditions in Scandinavia. The impact is greater among individuals with PsA±PsO.

P131

QUALITY OF LIFE OF PATIENTS WITH PSORIASIS IN KHARTOUM DERMATOLOGY HOSPITAL, DECEMBER 2017

Hind Madani
University of Khartoum- faculty of medicine

Introduction: Psoriasis is a common chronic non-contagious skin disease, affecting 1–3% of the world population. Defects in the immune regulation and the control of inflammation are thought to play major roles. Quality of life (QOL) is increasingly recognized as an important outcome measure in dermatology. Psoriasis although it doesn't affect the survival it has a great impact on quality of life of patients, and has a strong effect on social relations, psychological status, daily activities and thought to be associated with depression.
Objectives: The aim of this study was to determine the impact of psoriasis on the quality of life(QOL) of the patients in Khartoum dermatology hospital, 2017.
Methods: Descriptive case series study, hospital based survey conducted among 70 participants from psoriasis patients aged above 18 years in Khartoum dermatology hospital, through self-administered standard questionnaire, which was developed after extensive literature reviewing, comprised of Socio-demographic data, psoriasis life stress inventory(PLSI), psoriasis disability index(PDI) and depression assessment.
Results: 64.3% of the participants have a high psoriasis-related stress (PLSI) and 35.7% have a low psoriasis-related stress. 21.4% of the participants have a very large disability in daily activities (PDI), 37.1% have a large disability, 24.3% have a moderate disability, 14.3% have a mild disability and 2.9% have no disability at all.7.1% of the participants have a moderately severe depression, 15.7% have a moderate depression, 35.7% have a mild depression, 41.4% have none or minimal depression and none of the participants has a severe depression.
Conclusion: the study concluded that psoriasis has impacts on the quality of life, causing high stress and high disability in daily activities with variable degrees of depression.
Key words: psoriasis, QOL, PLSI, PDI, depression.
References:
1. El-Moselhy EA, Atlam SA, Mohammed AS, Hassan HM, Ebrahim AM (2015) Psychosocial Impact and Quality of Life among Adult Egyptian with Psoriasis. Dermatol Case Rep 1: 104. 2. Abbas Darjani N. Quality of Life in Psoriatic Patients: A Study Using the Short Form-36 [Internet]. PubMed Central (PMC). 2017 [cited 30 March 2017]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4192777/
3. Finlay AY, Coles EC. The effect of severe psoriasis on the quality of life of 369 patients. Br J Dermatol\1995;132:236-44. CrossRef PubMed WebofScience GoogleScholar
4. Tang M, Chang C, Chan L, Heng A. Quality of life and cost of illness in patients with psoriasis in Malaysia: a multicenterr study. 2018
5. Langley R. Psoriasis: epidemiology, clinical features, and quality of life. Annals of the Rheumatic Diseases. 2005;64(suppl_2):ii18-ii23.

P132

MIRIKIZUMAB SIGNIFICANTLY IMPROVES SELF-REPORTED DISEASE SEVERITY AND GENERAL HEALTH STATUS IN PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS

Melinda Gooderham[1], Paul Klekotka[2], Emily Edson Heredia[2], Joanne Li[2], Baojin Zhu[2], Jiaying Guo[2], Jerry Bagel[3]

[1]SKiN Centre for Dermatology, [2]Eli Lilly & Company, [3]Windsor Dermatology

Introduction: In a randomized, placebo-controlled, phase 2 trial (NCT02899988), mirikizumab met its primary efficacy endpoint at Week 16.1

Objective: To determine if mirikizumab improves patient-reported disease severity and general health status in psoriasis patients at Week 16.

Methods: Adults with moderate-to-severe psoriasis were randomized 1:1:1:1 to receive placebo ($n = 52$), mirikizumab 30 mg ($n = 51$), 100 mg ($n = 51$), or 300 mg ($n = 51$) at Weeks 0 and 8. At baseline and Weeks 2, 4, 8, 12, and 16, patients completed the Patient Global Assessment of psoriasis (PtGA) (0 = clear, 5 = severe). At baseline and Week 16, patients completed the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36; [range 0–100]) which measures 8 general health status domains that can be scored as mental component and physical component summaries. For continuous measures, comparisons were made by a mixed-effects for repeated measures model (PtGA) or an analysis of covariance model (SF-36). Comparisons of categorical efficacy variables were conducted by logistic regression analysis with non-responder imputation (NRI).

Results: At Week 16, mirikizumab-treated patients reported greater improvements in psoriasis severity and aspects of physical functioning versus placebo (Table).

Conclusion: Mirikizumab treatment at various doses significantly improved psoriatic disease severity and physical health status.

Reference:

1. Reich K et al. Programme and abstracts of Psoriasis from Gene to Clinic; Nov. 30-Dec. 2, 2017; Abstract FC31.

Table. Patient-Reported Outcomes (Week 16)

		Mirikizumab		
	Placebo $n = 51$	30 mg $n = 48$	100 mg $n = 51$	300 mg $n = 51$
PtGA, least squares mean(SE)	0.4 (0.16)	2.2 (0.16)***	2.9 (0.16)***	2.8 (0.16)***
Change from Baseline in SF-36 Domains, LSM (SE)				
Physical functioning	2.8 (1.9)	7.2 (2.0)	8.2 (1.9)*	7.2 (2.0)
Role-physical	1.2 (2.4)	11.4 (2.5)**	11.5 (2.5)**	12.3 (2.5)**
Bodily pain	5.7 (2.8)	17.6 (2.9)**	19.2 (2.9)***	18.9 (2.9)**
General health	1.4 (1.9)	5.8 (2.0)	3.2 (1.9)	5.4 (1.9)
Vitality	1.0 (2.0)	6.9 (2.1)*	4.7 (2.0)	6.2 (2.0)
Social functioning	-0.2 (2.4)	10.5 (2.4)**	13.4 (2.4)***	8.2 (2.4)*
Role-emotional	1.3 (2.0)	5.2 (2.1)	6.1 (2.0)	6.0 (2.0)
Mental health	1.7 (1.8)	5.5 (1.8)	6.6 (1.8)	3.2 (1.8)
≥2.5 point improvement in SF-36 MCS, % (NRI)	36.5	37.3	45.1	33.3
≥2.5 point improvement in SF-36 PCS, % (NRI)	42.3	52.9	56.9	62.7*

MCS, mental component summary; PtGa, Patient Global Assessment; PCS, physical component summary; SE, standard error; SF-36, 36-Item Short Form Health Survey.
*$p < .05$ vs placebo; **$p < .01$ vs placebo; ***$p < .001$ vs placebo.

P133

EFFECT OF TILDRAKIZUMAB ON PERSONAL RELATIONSHIPS IN PATIENTS WITH MODERATE-TO-SEVERE CHRONIC PLAQUE PSORIASIS

Kim Papp[1], Alexa Kimball[2], Andrew Blauvelt[3], Kristian Reich[4], Melinda Gooderham[5], Stephen Tyring[6], Rodney Sinclair[7], Diamant Thaci[8], Yang Zhao[9], Nicole Cichanowitz[10], Qing Li[10], Carmen La Rosa[10]

[1]K Papp Clinical Research and Probity Medical Research, Waterloo, Ontario, Canada, [2]Harvard Medical School, Boston, MA, [3]Oregon Medical Research Center, Portland, OR, USA, [4]ScIderm Research Institute and Dermatologikum Hamburg, Hamburg, Germany, [5]SKiN Centre for Dermatology and Probity Medical Research, Peterborough, and Queen's University, Kingston, Ontario, Canada, [6]Department of Dermatology, University of Texas, Houston, TX, USA, [7]University of Melbourne, Melbourne, VIC, Australia, [8]University of Lübeck, Lübeck, Germany, [9]Sun Pharmaceutical Industries, Inc., Princeton, NJ, [10]Merck & Co., Inc., Kenilworth, NJ, USA

Introduction: The negative impact of psoriasis extends beyond the patient, affecting his/her social interactions and the quality of life of cohabitants. Furthermore, patients with psoriasis often experience sexual difficulties because of their disease.

Objective: This analysis examined the effect of treatment with tildrakizumab (TIL) on personal relationships of patients with moderate-to-severe chronic plaque psoriasis.

Methods: Patients in two phase 3 trials reSURFACE 1 (NCT01722331) and reSURFACE 2 (NCT01729754) were randomized to subcutaneous TIL 200 mg, 100 mg, or placebo (PBO) and received treatment at weeks 0 and 4. PBO patients were re-randomized at week 12 to either TIL 200 mg or 100 mg. Etanercept (ETN) 50 mg (semiweekly until week 12 then weekly until week 28) was also a treatment arm in reSURFACE 2. Data on personal relationships were collected at weeks 12 and 28 from the Dermatology Life Quality Index (DLQI) questionnaire question 8 (Q8) "Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives" and question 9 (Q9) "Over the last week, how much has your skin caused any sexual difficulties". Each question was scored on a scale of 0 (not affected at all) to 3 (very much affected). The data were pooled from reSURFACE 1 and 2.

Results: In all, 1,820 patients had DLQI data. All patients reported a negative effect for Q8 and Q9 at baseline. At week 12, the proportion of patients with no negative effect (score of 0) on personal relationships (Q8 and Q9) was higher for TIL 200 mg, TIL 100 mg, and ETN than for PBO (76%, 72%, and 64% vs. 39%, respectively). A similar trend was observed for individual questions Q8 and Q9. At week 28, more patients on TIL 200 mg and TIL 100 mg reported no negative effect on personal relationships than those on ETN (85% and 77% vs. 66%; respectively). More patients on TIL 200 mg and TIL 100 mg reported no negative effect than those on ETN for Q8 (89% and 81% vs. 70%; respectively) and for Q9 (89% and 84% vs. 75%, respectively).

Conclusions: TIL had a beneficial effect on psoriasis-related personal relationship problems and sexual difficulties, compared to placebo and ETN.

This abstract was presented at 2018 Annual Meeting of American Academy of Dermatology.

P134

PRURITUS SEVERITY ASSESSMENT AND CORRELATION WITH BASELINE CHARACTERISTICS OF PATIENTS WITH PSORIASIS VULGARIS: AN EXPLORATORY ANALYSIS OF THE PHASE IIIB, PSORITUS STUDY

Sonja Ständer[1], Sabine Steinke[1], Matthias Augustin[2], Dieter Metze[1], Karin Loser[1], Daniel Baeumer[3], Thomas Luger[4]

[1]Department of Dermatology and Competence Center Chronic Pruritus and [4]Department of Dermatology, University hospital Münster, Münster, [2]Institute for Health Services Research in Dermatology and Nursing, Hamburg, and [3]Novartis Pharma, Nuernberg, Germany

Introduction: Chronic pruritus lasts for at least 6 weeks and is a most common symptom in patients with psoriasis. Pruritus is a highly prevalent and troublesome symptom and has a negative impact upon patients' health-related quality of life (QoL). The ItchyQoL is a pruritus-specific QoL questionnaire that can be applied to patients with pruritus independent of the underlying disease.

Objective: To assess the impact of pruritus on QoL in patients with psoriasis by an exploratory analysis of baseline characteristics of subjects from the PSORITUS study.

Methods: PSORITUS was an exploratory, randomized, double-blind, placebo-controlled 16-week drug withdrawal study with a 16-week open-label run-in phase, to assess the kinetics of psoriasis symptoms, pruritus intensity, and lesional biomarkers. Subjects

≥18 years of age with chronic moderate-to-severe psoriasis at least 6 months prior to baseline, with a Psoriasis Area and Severity Index (PASI) score > 10 at baseline, and pruritus intensity ≥30 on a 100-point Visual Analogue Scale (VAS, the worst itching within a recall period of 24 hours), were included. In an exploratory baseline analysis, correlation coefficients were calculated between ItchyQoL outputs and individual baseline characteristics based on Spearman's (r) and Kendall rank correlations (t). A multiple linear regression model was performed to assess the effect of exploratory variables correlating with the ItchyQoL score and achieving statistical significance (p-value < 0.05).
Results: The study included 130 subjects with psoriasis. The subjects had a mean age of 46.8 years (standard deviation [SD], 12.30) and majority (71.5%) were in the age group of 35–64 years. The mean (SD) time since first diagnosis of psoriasis and psoriatic arthritis (PsA) was 19.5 (13.81) and 17.2 (18.30) years, respectively; 13.8% of subjects had PsA. The mean (SD) baseline PASI, patient benefit index (PBI), and ItchyQoL score was 23.9 (10.85), 84.2 (24.17), and 78.7 (17.42) respectively, indicating severe disease activity and pruritus. The baseline ItchyQoL score showed moderate correlation with baseline VAS scores for average and worst pruritus (r: 0.542 [95% CI: 0.41, 0.65] and 0.547 [95% CI: 0.41, 0.66]; t: 0.381 [95% CI: 0.22, 0.52] and 0.383, 95% CI: 0.23, 0.52]) and a strong correlation with baseline dermatology life quality index (DLQI) scores (r: 0.803 [95% CI: 0.73, 0.86]; t: 0.622 [95% CI: 0.50, 0.72]. Furthermore the multiple linear regression analysis showed substantial dependency of QoL measured by ItchyQoL for VAS (average pruritus last 24 h), duration of psoriasis and health-related patient needs as measured by patient benefit index.
Conclusions: ItchyQoL assessment demonstrated that subjects with psoriasis are highly burdened by pruritus and show severely impaired quality of life. The correlation between pruritus intensity, ItchyQoL- and DLQI questionnaire results suggests the need for routine assessment of pruritus in clinical practice.

P135
QUALITY OF LIFE AND PSYCHOSOCIAL IMPLICATIONS IN PATIENTS WITH PSORIASIS

Anargyros Kouris[1], Eftychia Platsidaki[1], Alexandros Katoulis[2], Vasiliki Markanton[1], Christos Christodoulou[2], Evangelos Balaskas[1], Georgios Kontochristopoulos[1]
[1]Andreas Sygros Skin Hospital, [2]Attikon University Hospital, Athens, Greece

Introduction: Psoriasis is a common, long-term skin disease that affects approximately 1.5–3% of the population. The burden of living with psoriasis is equivalent to or greater than that seen in other long-term conditions, such as cardiac failure and chronic lung disease. The stigma provoked by the disease, often lead to the discontinuation of daily activities and social withdrawal. Nevertheless, these effects of psoriasis are seldom recognized and often undertreated.
Objectives: The aim of the study is to evaluate the quality of life, anxiety and depression, self-esteem and loneliness in patients with psoriasis.
Methods: Ninety-eight patients with psoriasis were enrolled in the study. The quality of life, depression and anxiety, loneliness and self-esteem of the patient were assessed using the Dermatology Life Quality Index, Hospital Anxiety and Depression Scale, the UCLA loneliness Scale (UCLA-Version 3) and Rosenberg's Self-esteem Scale, respectively.
Results: The Dermatology Quality of Life Index score among psoriasis patients was 13.52±4.58. They had statistically significantly higher scores according to the Hospital Anxiety and Depression Scale -anxiety subscale ($p = 0.031$)-compared with healthy volunteers. Moreover, a statistically significant difference was found between the two groups concerning the UCLA-scale ($p = 0.032$) and RSES-scale ($p < 0.0001$). Female patients presented with lower self-esteem than male patients.

P136
SWEDISH PSORIATIC PATIENTS' PERSPECTIVE OF THEIR DISEASE. RESULTS FROM AN OBSERVATIONAL PATIENT SURVEY

Charlotta Enerbäck[1], Sofie Fors[2], Anna-Karin Dahlborn[2]
[1]Department of Dermatology, Linköping University Hospital, Linköping, Sweden, [2]Novartis

Introduction: A global patient survey was adapted and implemented in Sweden, in order to explore and understand the patients' view on their disease, as well as the personal and emotional impact of their psoriasis. The focus of the survey was the patient's perception of the possibility to achieve clear skin, and how having clear skin could affect their quality of life. A publication based on earlier data is under review.
Methods: The Swedish "Clear about Psoriasis" survey was conducted from June 16 2017 to August 8 2017. Recruitment was made via online panels and patient organizations. Validated methods were used to assess severity of disease and health-related quality of life. The survey consisted of multiple-choice questions, no definition of clear skin was given, and spontaneous feelings/perceptions were reported. Respondents (≥18 years old) were required to have current plaque psoriasis, for which they had received a medical diagnosis and should not have participated in an online survey about psoriasis in the preceding four weeks. The analysis included only patients with moderate-to-severe plaque psoriasis, defined as a Psoriasis Area Severity Index (PASI) score ≥10, or a PASI score 5.0–9.9 with plaques in visible and/or in sensitive areas, such as the face and genitals.
Results: In total, 54 patient responses were completed and analyzed. Mean age was 45 years and 80% were female. The average self-assessed PASI score was 16.0, 26% had PASI 5.0–9.9, 74% PASI > 10 and 54% reported to have psoriatic arthritis. Current treatment allowed 44% of patients to achieve clear or almost clear skin. Clear or almost clear skin was believed to be achievable by 30% of the patients. Of patients reaching clear or almost clear skin, 71% had talked to their physician about their aim for clear skin. Among patients who have not achieved clear or almost clear skin, 47% had spoken to their physician about their aim. 57% of the patients were satisfied with their current treatment. The most important reasons for treatment satisfaction were less itching (81%), and the achievement of less pain and soreness (55%). Not achieving clear skin was the major reason for dissatisfaction. Discrimination or humiliation has been experienced by 98%. About 69% have been asked if they are contagious. Relationships were affected and 52% avoided to have sex. Worklife was affected by 65% of the respondents. For 58% of patients it took more than 5 years to get a treatment that resulted in clear or almost clear skin. During the last 6 months, 24% of employed patients had taken at least one day off work due to their disease whilst 5% took more than 14 days.
Conclusions: This survey shows that a majority of patients do not believe achieving clear or almost clear skin is possible and they are not comfortable to talk to their physician about it. Furthermore, patients encounter a stigmatizing environment. Better treatment as well as improved patient information is needed.
Novartis is grateful to Psoriasisförbundet for facilitating the survey.

P137
IXEKIZUMAB PROVIDES GREATER CUMULATIVE BENEFITS VERSUS USTEKINUMAB OVER 24 WEEKS FOR PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS IN A RANDOMIZED, DOUBLE-BLIND PHASE 3B CLINICAL TRIAL

Andrew Blauvelt[1], Mark Lomaga[2], Russel Burge[3], Baojin Zhu[3], Carsten Henneges[3], Wei Shen[3], David Shrom[3], Martin Dossenbach[3], Andreas Pinter[4]
[1]Oregon Medical Research Center, [2]DermEdge Research, [3]Eli Lilly and Company, [4]University Hospital Frankfurt

Introduction: Ixekizumab, a high-affinity monoclonal antibody that selectively targets IL-17A, was shown to be superior to ustekinumab, an IL-12/23 inhibitor, with respect to skin clearance and quality of life up to 24 wks in patients with moderate-to-severe psoriasis in IXORA-S1.
Objectives: The objective of this analysis was to compare the cumulative benefits of ixekizumab versus ustekinumab at 12 and 24 weeks of treatment in IXORA-S, with respect to skin clearance, itching, health-related quality of life (HRQoL), and pain.
Methods: In the IXORA-S trial, patients were randomized (1:1) to receive either IXE (160-mg starting dose, then 80-mg every 2 wks for 12 wks followed by 80-mg every 4 wks; $n = 136$) or UST (45–mg/90-mg weight-based dosing per label; $n = 166$) through 52 wks. Data at week 12 and week 24 were used in this post-hoc analysis. At wks 2, 4, and every 4 wks thereafter, clinical benefits were measured using percentage improvements in Psoriasis Area and Severity Index (PASI 75/90/100); the Itch Numeric Rating Scale (NRS; 0 = no itch, 10 = worst itch imaginable); and Skin Pain VAS (0 = no pain, 100 = maximum pain). Health-related quality of life (HRQoL) benefit was measured at wks 2, 4, 12, and 24 using the Dermatology Life Quality Index (DLQI) [DLQI score = 0.1 indicates no effect on patient's life]. Total benefits - PASI 75/90/100; itch NRS = 0; DLQI = 0.1; Pain VAS 0 – were used to determine the area-under-the-curve (AUC) of responders for each outcome at 12 and 24 weeks. Missing values were imputed using non-responder imputation (NRI). AUC results, capturing the rapid and sustained treatment response, were normalized as a percentage of maximum possible (0–100%) AUC. The clinical benefit ratios between IXE vs UST were calculated for each outcome to show relative cumulative benefit.
Results: At 12 wks, the normalized cumulative clinical benefit with IXE vs UST, respectively, was 58.2% and 32.9% (PASI75); 36.7% and 15.6% (PASI90); 14.2% and 4.0% (PASI100); 25.3% and 14.3% (itch); 36.0% and 23.7% (pain); and 44.9% and 25.2% (DLQI). Cumulative clinical benefits at week 24 for IXE and UST, respectively, were 74.3% and 54.3% (PASI75), 58.1% and 32.3% (PASI90), 29.0% and 12.2% (PASI100); 33.5% and 22.1% (itch); 42.7% and 30.6% (pain); and 54.3% and 37.0% (DLQI). At 12 wks, clinical benefit ratios (IXE/UST) for PASI 75/90/100 were 1.77, 2.36, and 3.52; 1.51 for pain; and 1.78 for both itch and DLQI. At 24 wks, the ratios were 1.37, 1.80, 2.38 (PASI 75/90/100), 1.52 (itch), 1.39 (pain) and 1.47 (DLQI).
Conclusions: Cumulative benefits measured by PASI, itch, pain, and DLQI responders were greater for IXE vs. UST following 12 and 24 wks of treatment. Long-term cumulative benefits will be addressed upon publication of Week 52 results from the IXORA-S trial.
Reference:
Reich K, et al. Br J Dermatol. 2017;177(4):1014-1023.
Previously presented at AAD, San Diego, CA; February 16 – 20, 2018.

P138

COACH@HOME: A SUPPORT PROGRAM FOR PATIENTS TREATED WITH CERTOLIZUMAB PEGOL

Nicolai Böhme[1], Ann-Dörthe Holst[2], Friedrich Dybowski[3], Christoph Volberg[4], Hans-Georg Pott[5], Udo Lendl[6]
[1]Healthcare at Home Deutschland GmbH, Weinheim, [2]Rheumapraxis, Ludwigslust, [3]Rheumapraxis Ruhr, Herne, [4]Rheumatologie in Neuss, Neuss, [5]Rheumatologikum Hannover, Hannover, [6]UCB Pharma GmbH, Monheim am Rhein, Germany

Introduction: Coach@home (c@h) is a German support program for certolizumab pegol (CZP)-treated patients (pts) with rheumatic diseases, including psoriatic arthritis (PsA). Eight coaching calls are offered over one year, scheduled around critical milestones on the therapeutic journey. These are made by trained nurses, who offer support and information about both the pt's disease and its treatment with CZP.
Objectives: To assess the baseline characteristics of PsA pts subscribed to c@h, and the level of pt satisfaction with the program across indications (Sep 2017 data cut).
Methods: c@h was launched in Jun 2014, and is available to pts who are prescribed CZP according to the local product label. Pts must be CZP-naïve when subscribed to the program, and pt consent is required prior to subscription by the treating physician. There are no additional criteria for enrolment, although the program must be recommended to the pt by the treating physician. Pt satisfaction across indications (PsA, rheumatoid arthritis and axial spondyloarthritis) was measured at program completion or discontinuation using the net promoter score (NPS), which has previously been used for this purpose.1 The NPS is derived by asking pts to state the likelihood that they would recommend c@h to others (on a 0–10 scale). Rankings of 9–10 are considered 'promoters', 7–8 'passives', and 0–6 'detractors'. Subtracting the percentage of detractors from that of promoters yields the NPS.
Results: A cumulative total of 136 PsA pts had been registered to c@h by Sep 2017. Mean age at baseline was 52 years; the majority were female (69%). Prior biological DMARD exposure was 24%. The most common topics discussed on calls were treatment adherence (290 calls), CZP maintenance dose (284 calls) and syringe disposal (201 calls). The average length per call was 15.7 min (SD: 5.33) at the end of Week 0 (total: 135 calls), and 14.6 min (SD: 6.59) at the end of Week 52 (45 calls).
Across indications, a cumulative total of 272/655 pts had either completed the coaching period ($n = 70$) or discontinued ($n = 202$) by 28 Sep 2017, of whom 106 rated the program. Of these, 87.5% gave promoter scores, 10.4% passive, and 3.8% detractor, yielding an NPS of 83.7. The program was still ongoing at the time of this data cut.
Conclusions: c@h offers support and guidance to CZP-treated pts in Germany. Feedback from pts willing to provide a rating (39%) indicates a high level of satisfaction with the program.
References:
1. Hamilton DF. Bone Joint J 2014;96-B(5):622–8.
Acknowledgements: c@h is performed by Healthcare@home Deutschland GmbH, funded by UCB Pharma, led by Elke Zeise and managed by Karen Thiel and Manh Dan Nguyen. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this program. Editorial services were provided by Costello Medical.

P139

A COMPREHENSIVE SURVEY ASSESSING THE FAMILY PLANNING NEEDS OF WOMEN WITH PSORIASIS

Mark Lebwohl[1], Abby S Van Voorhees[2], Michael Siegel[3], Lindsey Shankle[3], Lisa Pisenti[4], Mohamed Yassine[4]
[1]Icahn School of Medicine at Mount Sinai, New York, NY, [2]Eastern Virginia Medical School, Norfolk, VA, [3]National Psoriasis Foundation, Portland, OR, [4]UCB Pharma, Smyrna, GA, USA

Introduction: Psoriasis (PS) in women often overlaps with their peak reproductive years. Data on the family planning (FP) experience of patients (pts) are therefore needed to optimize PS management.
Objectives: To report the results of a survey evaluating the FP needs of women with PS.
Methods: Women of childbearing potential (WoCP; aged 18–45) diagnosed with PS (including pts with psoriatic arthritis), were recruited to complete a 96-question web-based survey on SurveyGizmo®. The survey included questions on pts' experience, concerns and educational needs, and was disseminated using e-blasts (the National Psoriasis Foundation, Advance E-News, and TalkPsoriasis.org mailing lists) and social media (Facebook and Twitter). Responses were collected Dec 2017–Feb 2018.
Results: Of 141 pts completing the survey, 91 (65%) were planning to conceive (PTC), and 66 (47%) had experienced pregnancy (EP) within the last 5 years. Prescribed systemic medications were

being used by 40% of pts PTC and 12% of pts who had EP. Only 41% pts who had EP informed the healthcare provider (HCP) treating their PS of their pregnancy right away, while 21% did not notify them at all.
While PTC, most pts who had not EP (88%), sought FP advice from the internet; only 21% had consulted the HCP treating their PS, compared to 55% of pts who had EP. Of the 96 pts who discussed FP with the HCP treating their PS, just 7% said this was initiated by the HCP. Pts PTC were most influenced by their personal network (e.g. family), but of pts who had EP, 41% said the HCP treating their PS was one of the most influential types of support in their FP decisions. Pts reported wanting information on the impact of PS and treatments on their baby, the heritability of PS, and flare management during pregnancy. During pregnancy, 65% pts who had EP stopped treatment (of any type), 79% of whom did so out of fear of harming their baby. In 40% cases where pts had stopped all and any treatment for PSO, the decision was initiated by the pt, and in 47%, by their PS treatment provider. Of pts who stopped treatment, 44% experienced a worsening in the severity of their PS, yet most pts do/did not have a plan for flare management during pregnancy (PTC: 69%; EP: 65%). Many pts stopping all treatment had not been advised on restarting treatment post-partum (PTC: 42%; EP: 23%).
Conclusions: Many WoCP with PS take systemic medications but many do not discuss FP with their PS treatment provider, and if they do, the discussion is rarely initiated by the HCP. PS treatment providers should prioritize discussing FP, and plan treatment around and during pregnancy. The educational needs of WoCP with PS include the impact of treatment on their baby, flare management during pregnancy, and restarting treatment post-partum.
Acknowledgements: This study was funded by UCB Pharma. The survey was conducted by the National Psoriasis Foundation. We thank the patients who contributed to this study. Editorial services were provided by Costello Medical.

P140
THE PSYCHOSOCIAL IMPACT OF PSORIASIS: DIFFERENTIAL EXPERIENCES OF MEN AND WOMEN IN EARLY ADULTHOOD

Caitriona Ryan[1], Carl Vandeloo[2], Duncan Munro[3], Alvaro Arjona[1]
[1]Blackrock Clinic, Dublin, Ireland and University College, Dublin, Ireland, [2]UCB Pharma, Brussels, Belgium, [3]Cello Health, London, UK

Introduction: Plaque psoriasis (PSO) can have a profound impact on patients' (pts') psychosocial wellbeing, leading to self-consciousness, embarrassment, depression, social isolation and stigmatization. However, little is known of how the impact of disease differs between genders.
*Objective:*To evaluate differences in the psychosocial impact of PSO on quality of life in men and women in early adulthood.
Methods: Pts aged ≥18 in the US, Canada, France, Germany and Italy without a diagnosis of psoriatic arthritis were invited to complete a postal survey (Oct 2016–Jan 2017), in the ratio 3:1 as being treated with advanced therapy (biologic/apremilast), or eligible for but not yet receiving advanced therapy. Answers were given on 5- or 7-point Likert Scale. Percentages shown are proportions of pts responding using either of the two responses indicating greatest impact of disease. Data are presented for pts in early adulthood (18–45 years),[1] stratified by gender.
Results: 63 women and 73 men completed the survey; mean age was 35 and 36 years, respectively, mean age at diagnosis was 28 for both genders. Disease distribution was similar between genders, although women reported more severe disease affecting their arms and males reported more severe scalp disease. Whilst physical impacts of disease were similar (≤2 pts reported severe problems with walking, washing/dressing, carrying out housework/family/leisure activities or daily work), a higher proportion of women (14% vs 4%) reported severe/extreme pain or discomfort. Both genders were more concerned by appearance (women: 73%, men: 63%) than pain (women: 43%, men: 34%).
A higher proportion of women than men were concerned by their appearance (73% vs 63%), reported a greater impact on their choice of clothing (37% vs 21%), and always/usually tried to cover their skin (27% vs 16%). Similarly, psychosocial effects of disease tended to be greater in women: 16% women vs 8% men reported severe/extreme anxiety or depression; 29% women vs 18% men suffered sexually/in achieving intimacy. Similar proportions had suffered at work (women: 11%, men: 16%), while a higher proportion of women (6%) than men (3%) struggled to live their lives as they did prior to their diagnosis. These findings have been corroborated by ethnography studies.
Conclusion: Despite similar clinical manifestations of PSO, women in early adulthood tended to report a greater impact of their disease on their lives, both physically, in terms of pain, and psychosocially, in terms of effects on relationships and impact on their daily lives. Physician awareness of such gender differences in the impact of the disease on patients' lives would encourage a more holistic approach to discussing treatment options with their patients.
Reference:
1. A Conception of Adult Development. Daniel J. Levinson. 1986. American Psychologist vol. 41, No. 1, 3-13

P141
CERTOLIZUMAB PEGOL IMPROVES PATIENT-REPORTED OUTCOMES IN CHRONIC PLAQUE PSORIASIS OVER 1 YEAR

Diamant Thaçi[1], Alice B Gottlieb[2], Kristian Reich[3], Jerry Bagel[4], Luke Peterson[5], Oana Purcaru[6], Jolanta Węgłowska[7]
[1]University Hospital of Schleswig-Holstein Campus Lübeck, Lübeck, Germany, [2]Department of Dermatology, New York Medical College at Metropolitan Hospital, NY, NY, [3]SCIderm Research Institute, Hamburg, and Dermatologikum Berlin, Germany, [4]Psoriasis Treatment Center of Central New Jersey, East Windsor, NJ, [5]UCB Pharma, Raleigh, NC, USA, [6]UCB Pharma, Brussels, Belgium, [7]Niepubliczny Zakład Opieki Zdrowotnej multiMedica, Wrocław, Poland

Introduction: Certolizumab pegol (CZP) is an Fc-free, PEGylated, anti-TNF biologic. Here we present patient (pt)-reported quality of life (QoL), work productivity and social activities over 48 weeks of CZP treatment.
Materials/Methods: Data were pooled from CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326272) phase 3 trials of adults with PSO ≥6 months (psoriasis area and severity index [PASI] ≥12, affected body surface area [BSA] ≥10%, physician's global assessment [PGA] ≥3/5). Pts were randomized to CZP 400 mg every 2 weeks (Q2W), CZP 200 mg Q2W (following 400 mg loading dose at Weeks 0, 2, 4), or placebo (PBO) Q2W for 16 weeks. Week 16 CZP-treated PASI 50 responders continued initial blinded treatment to Week 48 (PBO-treated PASI 50 responders are not included). PASI 50 non-responders at Weeks 32, 40 and 48 were discontinued.
Mean change from baseline (CFB) in Dermatology Life Quality Index (DLQI), rates for DLQI minimally clinically important difference (MCID; ≥4-point improvement) and DLQI remission (score of 0/1), and CFB in Work Productivity and Activity Impairment (WPAI) PSO-specific at Weeks 16 and 48 were assessed. Negative CFB for DLQI and WPAI signifies improvement. CFB DLQI analyses used last observation carried forward (LOCF) imputation for missing data, DLQI MCID and remission analyses used non-responder imputation, WPAI analyses used last observation carried forward imputation at Week 16 and observed data at Week 48.
Results: At Week 16, CZP pts showed greater improvements in DLQI vs PBO, and higher proportions achieved DLQI MCID and DLQI remission (Table). Improvements were maintained to Week 48 in CZP-treated pts who continued treatment (Table). Improve-

ments in work productivity and reductions in activity impairment were seen with both CZP doses vs PBO; and were maintained to Week 48 in patients remaining in the trial. (Table).

Conclusions: Treatment with CZP was associated with improvements in QoL, work productivity and social activities vs PBO at Week 16, which was maintained to Week 48 in patients remaining in the trials.

Table. Improvements in DLQI and WPAI at Weeks 16 and 48

	PBO (n = 100)	CZP 400 mg Q2W (n = 175)		CZP 200 mg Q2W (n = 186)	
Week 16 DLQI	Week 16	Week 48	Week 16	Week 48	
Mean CFB (SD)	-3.1 (6.7)	-9.8 (7.0)	-10.3 (7.5)	-10.0 (8.2)	-9.7 (8.4)
MCID, n (%)	41 (41.0)	135 (77.5)	121 (69.1)	131 (70.4)	113 (60.8)
DLQI 0/1, n (%)	7 (7.0)	84 (48.0)	90 (51.4)	87 (46.8)	78 (41.9)
WPAI Domains, mean change from baseline (SD)					
Absenteeism	2.9 (22.1)	4.7 (22.7)	-0.1 (17.5) [n = 96]	0.7 (21.7)	2.6 (15.6) [n = 89]
Presenteeism	0.7 (21.8)	-12.9 (25.2)	-17.0 (26.1) [n = 96]	-9.6 (25.3)	-9.9 (27.1) [n = 89]
Work productivity loss	4.8 (28.5)	-9.0 (32.7)	-16.4 (28.9) [n = 96]	-9.0 (31.5)	-8.0 (30.1) [n = 89]
Activity impairment	-1.5 (25.3)	-23.9 (28.3)	-28.6 (28.9) [n = 129]	-21.0 (31.9)	-23.9 (29.4) [n = 132]

P142

TRANSLATING WHO RESOLUTION INTO THE PUBLIC: THE GERMAN PROGRAM AGAINST STIGMATIZATION OF PEOPLE WITH CHRONIC VISIBLE SKIN DISEASES

Matthias Augustin[1], Claudia Luck-Sikorski[2], Rachel Sommer[1], Janine Topp[1], Ines Schaefer[1], Marc Radtke[1], Sophie Schlette[3], Natascha Weinberger[4], Regina Spreckelsen[5], Anja Hilbert[6], Alexander Zink[7], Dagmar Wilsmann-Theis[8], Eckardt Breitbart[9], Ulrich Mrowietz[10]

[1]University Medical Center Hamburg-Eppendorf, [2]University Gera, [3]BVDD, [4]University of Leipzig, [5]University Hospital Kiel, [6]University Medical Center Leipzig, [7]University Munich, [8]University Bonn, [9]Dermatology Breitbart, [10]University Kiel

Introduction: The WHO resolution 2014 raised fundamental demands for the health care system to increase the awareness for patients with chronic skin diseases such as psoriasis, including its fight against stigmatization. Single member states were encouraged to take action on all levels, including public awareness campaigns. After a period of refusal, the German ministry of health approved a project submitted by German dermatologists, patient groups and further experts to develop interventions against stigmatization.

Objectives- Aim of investigation: The project aims to develop and evaluate public interventions against stigmatization of people with visible skin diseases.

Methods: The project consist of three phases. Within a one-year period current research will be processed through a systematic literature search; recommendations for intervention formats will be derived. The consecutive 18 months involve the development of defined intervention formats. The interventions are supposed to focus on locations of stigma and encounters of stigmatizing with stigmatized persons.

Results: The application has been approved and is funded by the German ministry of health for a period of three years throughout the years 2018 to 2021. The project group consists of 25 dermatology-, science- and patient-experts who work in operative groups in order to develop the content and the intervention format. In doing so, different levels of the stigmatization process, namely stereotypes, prejudice, discrimination are considered as important aspects and will be accounted for in the development of the intervention. First results of the literature review imply that people with visible skin disease such as psoriasis are affected by stigmatization in several dimensions and strategies for reducing the stigma are required.

Conclusion: Following the WHO resolution, this project is an example for successful project initiation of an interdisciplinary team to develop and implement an intervention against stigmatization. First outcomes will be a comprehensive review of papers derived from the systematic literature search in May 2018.

P143

THE GLOBAL RESEARCH ON THE IMPACT OF DERMATOLOGICAL DISEASES (GRIDD)

Matthias Augustin[1], Nirohshah Suthakharan[1], Christine Janus[2], Jennifer Austin[2], Christine Bundy[3], Rachael Pattinson[3]

[1]University Medical Center Hamburg, Institute for Health Services Research in Dermatology and Nursing (IVDP), [2]International Alliance of Dermatology Patient Organisations – IADPO, [3]University of Cardiff

Introduction: The Global Research on the Impact of Dermatological Diseases (GRIDD) project will be the first global patient-initiated and patient-led impact research study in dermatology. By including the patient perspective stringently into the burden metrics, this will be the first program to systematically challenge the current Global Burden of Disease concept, which markedly underestimates the patient burden of skin diseases.

*Objective:*The objective of the GRIDD research project is to develop a comprehensive measure of the impact of living with skin diseases instruments by country, regionally and worldwide. The global instrument, developed with patient organisations, will capture patient experiences, including the extent of disease impact and burden for patients and their families, for generic (i.e. all dermatological diseases) and specific dermatological disease including psoriasis assessment worldwide.

Materials + Methods: Development of the comprehensive measure of impact of disease will be based on a novel methodology with several phases. Phase 1 will systematically review existing measures of the life impact of skin diseases and conduct a patient-centered item identification exercise. Phase 2 will be informed by Phase 1 data and will focus on instrument development: develop the wording for items (i.e. impact categories) and appropriate item scaling. This measure will describe the impact on life which may include economic; psychological and social impacts. Phase 3 describes the acquisition of real world data to further test the validity and acceptability of the new measure. Lastly, phase 4 and 5 include dissemination and launch of data, the new measure and an implementation strategy to increase uptake of the measure.

Results: GRIDD has assembled a scientific advisory board representing different regions worldwide. Currently, we are collaborating with over 100 patient associations in 32 countries worldwide, with more than 26 disease areas. Industry funding has been secured from five different companies for the first phase and a portion of phase 2. The GRIDD research team, including researcher from the University Medical Center in Hamburg and University of Cardiff, met in 2017 to start phases 1 and 2. The systematic literature review on "Existing patient-centred outcome measures currently used in dermatology" is currently underway.

Conclusion: This novel patient-centric methodology will complement existing concepts of evaluating patient perspective in dermatology. GRIDD will provide an extended patient view for better decision making in dermatology on a global and country level. It supports local, regional and international attempts to create awareness, better position psoriasis and other skin diseases and encourage decision-makers and stakeholders to include dermatological diseases in their policies.

P144

TREATMENT OF NAIL PSORIASIS WITH DIFFERENT PULSE DURATIONS OF PULSED DYE LASER

Mohamad Goldust[1], Homan Alipour[2]

[1]Mazandaran University of Medical Sciences, [2]Tabriz University of Medical Sciences

Background: There are different treatment modalities for nail psoriasis but the treatment of choice is still controversial. Laser

therapy opened new windows for treatment of nail psoriasis (1,2).
*Objective:*The aim of this study was to evaluate the efficacy of different pulse durations in the treatment of nail psoriasis with the 595-nm PDL to determine the optimal pulse duration.
Methods: In this clinical trial study, 120 patients with bilateral fingernail psoriasis were evaluated. PDL was applied on the proximal and lateral nailfolds based on random assignment. 240 nails were treated with 6-millisecond pulse duration and 9 J/cm(2) whereas 240 nails were treated with 0.45-millisecond pulse duration and 6 J/cm(2). Nail Psoriasis Severity Index (NAPSI) was used to assess the clinical outcome from pretreatment and posttreatment photographs.
Results: After 6 months of first treatment, there was a significant reduction in overall NAPSI, nail matrix NAPSI, and nail bed NAPSI scores from baseline in both groups; however, no significant difference was found between the two pulse duration groups. Side effects were mild including transient petechiae and hyperpigmentation.
Conclusion: PDL was found to be an effective and well-tolerated option in the treatment of nail psoriasis. This study demonstrated that both the longer 6-millisecond and shorter 0.45-millisecond pulses of PDL (595 nm) have been clinically proven to be effective for the treatment of nail matrix and nail bed psoriasis.
References:
1. Al-Mutairi N, Nour T, Al-Rqobah D. Onychomycosis in patients of nail psoriasis on biologic therapy: a randomized, prospective open label study comparing Etanercept, Infliximab and Adalimumab. Expert Opin Biol Ther 2013;13(5):625-629.
2. Radtke MA, Beikert FC, Augustin M. Nail psoriasis - a treatment challenge. J Dtsch Dermatol Ges 2013;11(3):203-219.

P145
NEUTROPENIA IN A PSORIASIS PATIENT: SECUKINUMAB OR MICRONUTRIENT DEFICIENCY?
Maruska Marovt, Katarina Trcko, Pij B. Marko
University Medical Centre Maribor, Maribor, Slovenia

We report a case of severe neutropenia in a psoriasis patient, which developed three months after discontinuation of secukinumab. She had gastric bypass surgery a few years ago and was intermittently treated due to iron deficiency anemia. According to the suggested approach to the adult with unexplained neutropenia (1) a range of diagnostic tests were performed and no abnormalities were noticed. Neutropenia still persists, however the patient hasn't had any complications. Neutropenia was reported infrequently in subjects with moderate to severe psoriasis receiving secukinumab in a pooled analysis of 10 phase II and III clinical studies (2). Most were grades 1 or 2. Grade 3 neutropenia was uncommon and not associated with serious infections, and no grade 4 neutropenia was recorded. Deficiencies of dietary vitamins and minerals typically cause neutropenia in association with other cytopenias. Patients who have undergone bariatric surgery require lifelong vitamin and mineral supplementation. Severe neutropenia in our patient could be due to combination of secukinumab and micronutrient deficiency, however exact etiology remains unclear.
Berliner N (2018). Approach to the adult with unexplained neutropenia. In Newburger P (Ed.), UpToDate. Retrieved February 19, 2018, from https://www.uptodate.com/contents/approach-to-the-adult-with-unexplained-neutropenia
Van de Kerkhof PC, Griffiths CE, Reich K, Leonardi CL, Blauvelt A, Tsai TF, et al. Secukinumab long-term safety experience: A pooled analysis of 10 phase II and III clinical studies in patients with moderate to severe plaque psoriasis. J Am Acad Dermatol 2016 Jul;75(1):83-98.e4.

P146
ESTABLISHMENT OF A PSORIATIC SKIN MODEL FOR A-IRRADIATION
Julia Wiedemann[1], Valeria Grünebaum[1], Claudius Witzler[1], Maximilian Dornhecker[1], Sylvie Lerchl, Claudia Fournier[1,2]
[1]GSI Helmholtzzentrum für Schwerionenforschung, Darmstadt, Germany, [2]University of Applied Sciences, Darmstadt, Germany

Introduction: Psoriasis is on the indication list for therapy in radon galleries (1). Radon is a radioactive noble gas evaporating from rocks. It is absorbed through skin or lung epithelium during inhalation. Radon decays in the tissue under emission of α-particles. The estimated dose received during a radon therapy is in the order of 1.2 mSv which corresponds to the annual background irradiation caused by radon. Chronic inflammatory diseases such as rheumatoid arthritis are treated with radon and pain reduction and improvement of mobility are reported (2). Positive effects are also reported for psoriasis, but sparely documented. However, for both diseases the mechanisms underlying the clinical benefit are unknown.
Objectives: To investigate effects of radon treatment we have established a cellular model for psoriasis which can be used for irradiation with α-particles. The requirements in using α-particles are specific due to their short range.
Methods: Special rings stringed with a 2 µm oxygen plasma treated boPET foil are used to facilitate α-irradiation and growth of NHEK (normal human epidermal keratinocytes). Cells were cultured in rings or culture dishes for 24 hours and induced with IL-17, IL-22 and TNF-α. Supernatants and cells for protein and mRNA extraction were collected 24 hours after induction. ELISA, qPCR and Western Blot analysis was performed.
Results: We could show that it is possible to culture primary keratinocytes on plasma treated boPET foil with a similar morphology to cells cultured in cell culture dishes. Furthermore, the selected cytokines are able to significantly induce psoriasis-related markers like IL-19 and BDEF2 on mRNA level and the release of the cytokine IL-6. Testing if culturing of NHEK on the treated boPET foil alone has an inflammatory effect revealed no significant differences in the expression or release of markers compared to cells cultured in cell culture dishes.
Conclusion: We conclude that the plasma treated boPET foil is a promising tool for a setup, which enables α-irradiation of monolayer cell cultures. The induction of a psoriasis-like phenotype with cytokines leads to an enhancement of relevant markers.
References:
Gasteiner Kur- Reha- und Heilstollen-Betriebsges.m.b.H. www.gasteiner-heilstollen.com
Cucu et al; Front Immunol. 2017; 8: 882.; doi: 10.3389/fimmu.2017.00882
This work is supported by the Forschungsinstitut Bad Gastein (FOI-15/08-031WIE), EURADON, the Radon Gallery of Bad Gastein and GREWIS (02NUK017A)

P147
THE HISTORY OF PSORIASIS
Selma Poparic
Dermatology Department University Clinical Center of Sarajevo

Many ancient texts, including the Bible, mention people afflicted with diseases and symptoms very much like psoriasis. Ancient Egyptians wrote about a salve made with various herbs that would be spread on the skin, after which the afflicted person would be instructed to sit in the sun to bring relief to symptoms that seem to point to psoriasis. The Arabian physicians perhaps first distinguished psoriasis from other skin diseases already in the 8th century A.D., but the first written description of psoriasis appears during the Roman Empire in the 1st century AD in the books of A. Cornelius Celsus » De re medica libri octo». Galen (131–201 AD) of Pergamon, physician of some Roman imperators, was the first who used the term psoriasis, but only for an itchy, scaly eruption of the eyelids and scrotum, that was probably seborrheic dermatitis. Unfortunately, little was known about the origin of the disease for hundreds of years, in the darkness of the Middle Age - a period of stagnation, and many psoriasis sufferers were thought at the time to have leprosy. Because so little was known about contraction

and treatment, psoriasis patients were often separated from the general population for fear of them contaminating others. People with psoriasis – thousands in medieval Europe – were forced to warn others of their arrival by ringing a clapper.
It wasn't until the early 1800's that psoriasis was determined to be a condition separate from leprosy. In the cultural movement of Renaissance some authors mentioned the diseases psora and lepra in their books. In the 18th century hospitals or dispensaries were opened only for treatment of skin or venereal diseases giving to the physicians the opportunity to study more cases of skin diseases and psoriasis as well, while the end of the 19th century psoriatic micro morphology was already described. In 20th century many authors studied the genetic alteration, and today there is undisputed evidence that the disease is multifactorial.
Psoriasis, as a common disease, has a significant socio-economic impact on the individual and on the society. Last decades numerous immunological researches accumulate evidence of presence of alteration of the innate and adaptive immune response in psoriatic patients. This imply a primary disregulation of the immune system and permitts a better understanding and new insight in the pathogenesis and as well new possibilities in the management of psoriasis. This article shows a retrospective view of development of our knowledge on psoriasis through history.

P148
COMORBIDITIES AND TREATMENTS IN PATIENTS WITH INVERSE PSORIASIS

Mia Schneeweiss, Joseph Merola
Brigham and Women's Hospital

Introduction: Inverse (intertriginous) psoriasis is an underdiagnosed, often untreated phenotype of psoriasis (PsO) with a high burden of illness. Inverse PsO may occur in up to 23% of subjects with psoriasis, higher than previously reported.
Objectives: To characterize the frequency of inverse PsO and patient characteristics and their treatment in a large commercial insurance claims database.
Methods: We used longitudinal claims data from commercially insured patients in the US between 10/2015 and 12/2016 to identify adults with a diagnosis of flexural psoriasis (ICD-10-CM: L40.8, "other psoriasis" which is "recommended to be used for flexural PsO") associated with an outpatient or inpatient encounter. A 180-day enrollment period was required before the first diagnosis of AD. Among those diagnosed we computed the risk of initiating immunomodulating medications during the following 6 months. All analyses were conducted using the Aetion Evidence Platform.
Results: Of 1.5million patients with at least one code for PsO, after excluding patients with concomitant other autoimmune conditions, we identified 5,310 patients with an ICD-10 code of L40.8 used for inverse PsO (4/1,000) with a median age of 52 years and an equal gender distribution. Half of the patients were 41–60 years old.
Of those, 0.3% generalized pustular, 0.5% guttate, and 0.2% pustulosis palmaris et plantaris. Prevalent comorbidities included depression (7%), anxiety (6.5%), and cardiovascular conditions (5%). 20% received antidepressants. Within 180 days after the diagnosis of flexural PsO, 81% were using high-potency topical corticosteroids, 66% phototherapy, 8.6% calcipotriene, 5.6% ustekinumab, 7.2% methotrexate, 7.3% adalimumab, 3.3% etanercept, 1.3% acitretin, 0.8% infliximab, 0.9% Cyclosporine, 0.1% Sulfasalazine, 0.02% topical tacrolimus, 0.5% topical pimecrolimus.
In patients 60+, 83% used high-potency topical corticosteroids, 7.8% phototherapy, 8.8% calcipotriene, 3.1% ustekinumab, 6.9% methotrexate, 4.8% adalimumab, 2.9% etanercept, 1.5% acitretin, 0.5% infliximab, 0.9% Cyclosporine, 0.6% topical pimecrolimus.
Limitations: Although the ICD-10-CM code L40.8 is recommended for flexural PsO, its sensitivity/specificity for validating cases of flexural PsO has not been established, it may not encompass all aspects of inverse/intertiginous disease and the code may be highly underutilized.
Conclusions: Using the code ICD-10-CM L40.8, which is recommended to be used for inverse "flexural" PsO leads to lower prevalence estimates of inverse PsO than previously reported; this underscores the known underreporting and underdiagnosis of this condition. Among those patients diagnosed and coded, most received topical corticosteroids and/or phototherapy, others received calcipotriene, ustekinumab, methotrexate, adalimumab, etanercept, and acitretin. Further work is needed to understand how best to capture inverse (intertriginous) / flexural psoriasis for clinical research work.

P150
DEVELOPMENT OF THE "PSO SLEEPY-Q" AND THE "PSA SLEEPY-Q": TWO QUESTIONNAIRES TO CHARACTERIZE SLEEP IN PATIENTS WITH PSORIATIC DISEASE

Lourdes Perez-Chada
Harvard Medical School - Brigham and Women's Hospital

Introduction: Substantial evidence suggests that psoriasis (PsO) and psoriatic arthritis (PsA) are independently associated with sleep disturbance, which may result in serious health consequences including cardiovascular events and mortality. However, the validity of the sleep measures used in these studies is unknown as they have not been validated in patients with psoriatic disease or included psoriatic patients during their development process. There is a need for validated disease-specific Patient-Reported Outcome Measures (PROMs) to accurately characterize sleep in this population and to measure the effect of psoriatic therapies on sleep disturbance.
Objectives: This study aimed to develop and establish the content validity of 2 new sleep PROMs: the "PsO Sleepy-Q" and the "PsA Sleepy-Q".
Methods: Following FDA PROM-development guidance, our study: (*i*) hypothesized a conceptual framework and identified domains through literature review and patient semi-structured interviews using a saturation model ($n = 30$); (*ii*) rated domains for importance by patients ($n = 42$) and an international expert panel including dermatologists, rheumatologists and sleep experts ($n = 45$); (*iii*) selected final domains based of the patients' preference; (*iv*) generated item pools and the preliminary versions of the instruments.
Results: Psoriatic patients reported that sleep maintenance, adequacy, quantity and quality were the most important aspects of disordered sleep. Regarding causes of disturbed sleep: itch, skin and joint pain, stiffness, taking care of psoriatic lesions before bedtime, worsening of psoriatic symptoms at night, feeling uncomfortable in bed due to PsA and sleep apneawere the most outstanding factors selected. Finally, patients reported that disturbed sleep may increase psoriatic signs and symptomsas well as fatigue, cognitive impairment and psychological stress. Overall, patients with PsA expressed a higher burden of sleep disturbance compared to patients with PsO. Preliminary versions of the "PsO Sleepy-Q" and "PsA Sleepy-Q" including 18 and 24 items, respectively, were created. These questionnaires intend to measure the degree of sleep disturbance, the potential causes of sleep disturbance and the impairment related to sleep disturbance.
Conclusion: This study establishes the content validity of the "PsO Sleepy-Q" and "PsA Sleepy-Q", two patient-derived PROMs to characterize sleep in patients with psoriatic disease in research and clinical settings. These questionnaires will undergo cognitive debriefing and further psychometric testing to define the final instrument forms.

P151

UNSTABLE FORMS OF PSORIASIS – INDICATOR OF AN INTERMEDIATE STATE OF SYSTEMIC DISEASE

Florentina-Silvia Delli

State Hospital for Skin and Venereal Diseases - Hippokratia General Hospital, Thessaloniki, Greece

Introduction: Erytrodermic psoriasis, inverse psoriasis and generalized pustular psoriasis are considered three particular clinical forms of psoriasis.

Objectives: We present two clinical cases in which it is discussed the possibility of considering these clinical pictures as a manifestation of the immunological switch of psoriasis from an organ-target (skin or joint) disease, to a systemic form of psoriasis.

Methods: A 22-year-old-man with erythodermic psoriasis and a history of inverse psoriasis since childhood was successfully treated with 60 mg acitretin, until the diagnosis of psoriatic arthritis at the age of 26. The presence of arthritis determined us to change the therapy. Secukinumab at the classic therapeutic scheme is keeping the patient's skin clean of psoriatic lesions, except from the armpits, and without any arthritic symptoms. A 75-year-old-woman with psoriatic arthritis and hyperkeratotic palms and soles nonspecific lesions, under infliximab therapy presented generalized pustular psoriasis. After 3 months of acitretin 40mg and etanercept at the classic dose, the patient remains free of any symptoms.

Conclusions: The majority of psoriasis studies focus on chronic plaque psoriasis. We sustain the opinion that the above unstable forms of psoriasis, usually impossible to diagnose by other specialities than Dermatology, should be consider the main step in multidisciplinary approach of psoriasis as a systemic disease.

References:

1.Kivelevitch D et al. Pharmacotheraputic approaches for treating psoriasis in difficult-to treat areas. ExpertOpinPharmacother 2018 April; 19(6); 561-575

2.Sano S et al. Guselkumab, a human interleukin-23 monoclonal antibody in Japanise patients with generalized pustular psoriasis: efficacy and safety analyses of a 52-week, phase 3, multicentre, open-label study. JDermatol 2018 May; 45(5): 529-539

3.Cafaro G, McInnes IB. Psoriatic arthritis: tissue-directed inflammation? ClinRheumatol 2018 Apr; 37(4): 859-868.

P152

COULD BIOLOGICAL AGENTS FOSTER SUICIDE THROUGH ITS POTENTIAL ANTIDEPRESSANT MECHANISM? A PSYCHODERMATOLOGICAL APPROACH

Estela M Malatesta

Dermatologist and Psychiatrist, Doctor. Arturo Ameghino Mental Health Centre, Buenos Aires, Argentina. President of ADEPSI, Academy of Dermatology and Psychiatry

Introduction: Depression and Psoriasis are associated in up to 60% of the cases, with an increased risk of attempted and completed suicide in patients with severe forms of the disease. Bipolar Disorder is a biological condition that affects between 2 and 5% of the population, being an important cause of disability in the world. In spite of this, Bipolar Disorder is often underdiagnosed as Unipolar Depression, which increases the possibility of prescribing errors, as it occurs when administering only antidepressant agents without accompanying them with mood stabilizers, fostering the appearance of episodes of inverse polarity (SWITCHING) which, in turn, raises the risk of suicide.

Objectives: The "Cytokine Hypothesis" as a cause of depression suggests the association between the immune system and depression through the induction of the indolamine 2, 3- dioxygenase enzyme. The objectives of the poster are:

• To raise the need for new studies to confirm this hypothesis as well as the antidepressant effect of biological agents and their potential ability to cause a shift into mania.

• To deepen the criteria for patient selection for both scientific and therapeutic protocols.

Methods: This poster reviews the literature for evidence that while biological agents could improve the mood of patients with psoriasis treated with these drugs, this same favourable antidepressant effect on humor may trigger a switch of mood into mania, favouring attempted and completed suicide in undiagnosed bipolar patients treated for psoriasis with IL17-TNF alpha cytokine blockers.

Results: Evidence gathered so far suggests that common inflammatory processes could underpin both bipolar and psoriasis. The current literature is lacking of longitudinal and mechanistic studies, as well as comparison studies to explore the magnitude of this relation.

Conclusion: Considering both bipolar disorder and psoriasis as a multi-system disorder should help us understand the common physiopathology of this comorbidity so as not to see them as separated disorders. Consequently, it is vital to emphasize the importance of the initial psychiatric evaluation for a correct psychiatric/ clinical diagnosis for patients with Psoriasis to be both admitted to a strict control protocol and treated with biological agents.

P153

TREATING THE PAIN, NOT THE PROBLEM? RESULTS FROM A SWEDISH ONLINE SURVEY ON PSORIATIC ARTHRITIS AND PSORIASIS WITH JOINT PAIN

T Norgren, B Bohannan

Psoriasisförbundet, Stockholm, Sweden

Introduction: Psoriatic arthritis (PsA) is a chronic inflammatory disease associated with psoriasis, that can cause pain, swelling and, if untreated, severe joint destruction and disability. The knowledge about PsA among both the public and healthcare providers is limited, leading to both underdiagnosis and undertreatment. To raise awareness of PsA and gather relevant data, the Swedish Psoriasis Association (Psoriasisförbundet) and the Swedish Rheumatism Association (Reumatikerförbundet) initiated an educational awareness campaign on a well-visited online health information platform, which also featured a survey on healthcare experiences and Quality of Life.

Objectives: The purpose of the survey was to identify gaps or discrepancies in the healthcare provided for individuals diagnosed with PsA and for individuals with psoriasis and joint pain consistent with a PsA diagnosis, as well as understanding the impact on QoL for both groups.

Methods: The survey consisted of two questionnaires, one for individuals diagnosed with PsA, group A, and one for individuals diagnosed with psoriasis who have joint pain consistent with a PsA diagnosis (using CASPAR criteria as reference), group B. The survey was open from April 6 2017 to March 31 2018. The total number of respondents in group A was 5 201, and in group B 11 272. It was not mandatory to answer all questions in the survey. One section of the survey focussed on prescribed medication, to specifically identify discrepancies in the treatment of the diagnosed (A) and undiagnosed (B) groups. Limitations: self-reported diagnosis, possible to take survey multiple times using different devices.

Results: In response to the question "Which medication has been prescribed for your joint pain during the past year?" 23.91% of group B (214 of 895) answered that they had been prescribed opioid pain medication for their joint pain. In group A only 4.61% of the respondents (73 out of 1 582) were prescribed opioid pain medication for their PsA.

Conclusions: The results show a large discrepancy between the groups in the prescription of opioid pain medication. The results suggest that individuals with psoriasis that have joint pain consistent with a PsA diagnosis are being over-prescribed potentially addictive pain medication rather than receiving treatment for their underlying condition or inflammatory symptoms apart from pain.

As early diagnosis and effective treatment is vital to slow down disease progression, individuals with psoriasis as well as healthcare providers need to be educated on symptoms and diagnosis criteria of PsA to prevent undertreatment or treatment that may even be harmful.

Disclosure: Project platform and consultancy services were provided by health portal company Netdoktor. The project received funding from Novartis.

P154

AN INTERNATIONAL DELPHI SURVEY TO DEFINE SCREENING FOR PSORIATIC ARTHRITIS AND MEASUREMENT OF PSORIATIC ARTHRITIS SYMPTOMS IN PSORIASIS CLINICAL TRIALS

Lourdes Perez Chada
Harvard Medical School-Brigham and Women's Hospital

Introduction: The International Dermatology Outcome Measures (IDEOM) group was established to standardize patient-centered outcome measures to improve the assessment of treatment response and disease course in dermatology. To define the measurement set for psoriasis, IDEOM has initially defined a set of domains to be measured in all psoriasis clinical trials representing a "Core Domain Set". "Psoriatic arthritis (PsA) Symptoms" is part of this set.
Objectives: To achieve consensus on whether patients enrolling in a psoriasis clinical trial should first be screened for PsA and then with which measure their PsA symptoms should be assessed.
Methods: Following the OMERACT (Outcome Measures in Rheumatology) Filter 2.0, the COSMIN guidelines, and based upon the feedback from a consensus meeting held at the IDEOM 2017 Annual Meeting, we conducted an international, multidisciplinary and multi-stakeholder on-line Delphi survey. The survey was organized into 3 parts in which participants were asked to (1) vote on the role of PsA screening in psoriasis trials, (2) vote on the quality (measurement properties) of 4 patient-reported instruments: Patient Global (PG)-arthritis associated to a pain assessment tool, PG-Psoriatic Arthritis (PG-PsA) associated to a pain assessment tool, Routine Assessment of Patient Index Data-3 (RAPID3), and Psoriatic Arthritis Impact of Disease 9 (PsAID9), and (3) rank these instruments in order of importance. Additionally, respondents were invited to provide feedback on the survey.
Results: A total of $n = 293$, $n = 233$ and $n = 218$ subjects completed the PsA screening, instrument quality assessment, and ranking sections of the survey, respectively. The group was comprised of rheumatologists (44.5%), dermatologists (26%), patients (7.5%), industry partners (8.9%), dermatologist-rheumatologists (5.1%), and patient association representatives (3.4%). Results showed that 90%of participants agreed that all patients enrolling in a psoriasis trial should be screened for PsA. Regarding the quality of the instruments, only the PsAID9reached the pre-specified endpoint of $> 70\%$ with agreement that the instrument has good-to-excellent validity, feasibility, reliability and responsiveness; $< 15\%$ agreed that the quality of the instrument is poor or that there is not enough information to make an informed decision. In the ranking exercise, PsAID9 was the first choice(voted by 48% of respondents) and RAPID3 represented an acceptable alternative second choice (voted by 33% of respondents).
Conclusion: In this Delphi study, most participants agreed that all psoriasis trial participants should be screened for PsA. Regarding the measurement set for "PsA Symptoms", PsAID9 was selected as the most appropriate measure, while RAPID3 could be an acceptable alternative to PsAID9. This will be followed by a workshop at the IDEOM and GRAPPA 2018 annual meetings to review discussion points as well as any need for a second Delphi round.

P155

THE IMPACT OF A DIAGNOSIS ON THE PATIENTS' PERCEPTION OF TREATMENT AND CARE. RESULTS FROM AN ONLINE SURVEY ON PSORIATIC ARTHRITIS AND PSORIASIS WITH JOINT PAIN

T Norgren, B Bohannan
Psoriasisförbundet, Stockholm, Sweden

Introduction: Psoriatic arthritis (PsA) is a chronic inflammatory joint disease that, if untreated, can cause joint destruction and disability. The knowledge about PsA among both public and healthcare providers is limited, leading to underdiagnosis and undertreatment. To raise awareness of PsA and gather relevant data, the Swedish Psoriasis Association and the Swedish Rheumatism Association initiated a web-based educational campaign which also featured a survey on healthcare experiences and Quality of Life.
Objectives: The purpose of the survey was to identify the gaps in the healthcare provided for individuals diagnosed with PsA and individuals with psoriasis and joint pain consistent with a PsA diagnosis, as well as understanding the impact on QoL for both groups.
Method: The survey consisted of two questionnaires, one for individuals diagnosed with PsA, group A, and one for individuals diagnosed with psoriasis who have joint pain consistent with a PsA diagnosis (using CASPAR criteria), group B. The survey was open from April 6 2017 to March 31 2018. One section of the survey focussed on time to diagnosis and perception of healthcare. Limitations: self-reported diagnosis, possible to take survey multiple times using different devices.
Results: Both groups had seen multiple doctors for their joint pain. In group A 60% ($n = 1\,132$) had seen > 4 doctors, with 11% reporting having seen > 10. In group B 52.5% ($n = 824$) had seen > 4 doctors, with 8% having seen > 10. In group A nearly 51% ($n = 1\,211$) reported having had joint pain/symptoms for at least 1 year before receiving a diagnosis, with 12% waiting > 10 years. In group B 91% ($n = 1\,872$) reported having had joint pain/symptoms for at least 1 year, with 35% at > 10 years.
Perception of healthcare differed greatly between the groups. In group A over half ($n = 1\,273$) reported that their perception of healthcare improved or improved greatly after receiving their PsA diagnosis. In group B nearly 78% ($n = 1\,227$) reported being dissatisfied or very dissatisfied with the care they receive.
Conclusions: The results show that the group with a PsA diagnosis have a much more positive perception of the treatment and care they receive than the group without a diagnosis. Interestingly, in another part of the survey group B reported their psoriasis having a low to medium impact on their lives, indicating that their psoriasis may be mild enough to be treated in a primary care setting only. In the past few years there have been extensive efforts put into educating Swedish dermatologists on recognizing early signs of PsA, but steps should also be taken to raise awareness of psoriasis-associated joint pain among general practitioners to ensure timely referral to specialist care.

Disclosure: Project platform and consultancy services were provided by health portal company Netdoktor. The project received funding from Novartis.

Index