Abstract AB0951 – Table 1. The thickness of proximal nail fold, nail bed and proximal nail fold + nail bed in patients with psoriasis, psoriatic arthritis and other rheumatic disease

	proximal nail fold (mm)	nail bed (mm)	proximal nail fold + nail bed (mm)
Psoriasis (n=25)	1.23±0.27	1.33 ±0.47	2.55±0.58
Psoriatic arthritis (n=35)	1.33±0.35	1.25 ±0.38	2.58±0.56
Psoriasis or psoriatic arthritis with nail psoriasis (n=41)	1.34±0.34	1.36 ±0.45	2.68±0.62
Psoriasis or psoriatic arthritis without nail psoriasis (n=19)	1.18±0.27	1.11 ±0.29	2.30±0.41
Rheumatoid arthritis (n=23)	1.14±0.27	1.14 ±0.33	2.27±0.46
Ulcerative colitis (n=28)	1.21±0.28	1.22 ±0.33	2.43±0.49
Crohn's disease (n=13)	1.11±0.25	1.14 ±0.37	2.25±0.49

Conclusions: Soft tissue thickness around the nail in patients with PsO and PsA was compared with other rheumatic diseases by ultrasonographic assessment. In patients with PsO and PsA with nail psoriasis, soft tissue swelling around nail was observed.

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AB0952

HIGH PREVALENCE OF INFLAMMATORY AND NON-INFLAMMATORY LIVER AND GASTROINTESTINAL DISEASES IN YOUNG PATIENTS WITH PSORIATIC ARTHRITIS: A HOSPITAL-BASED STUDY

N. Batkaeva¹, E. Batkaev², T. Korotava³. ¹Dermatology, Peoples' Friendship University of Russia (RUDN University); ²Dermatology, Peoples' Friendship University of Russia (RUDN University); ³Research Institute of Rheumatology n. a. V. A. Nasonova, Moscow, Russian Federation

Background: Psoriatic arthritis (PsA) is associated with numerous comorbidities, including gastrointestinal (GI) and liver diseases (LD). But there is limited data about the prevalence of these disorders among patients (pts) with PsA and severe psoriasis (PsO) in Russian population.

Objectives: to evaluate the prevalence of LD and GIT comorbidity in a hospital-based cohort of PsA pts.

Methods: 417 (304 Male (M.)/113 Female (F.)) PsA pts, according the CASPAR criteria, mean age 38.5±11.3/36.1±11.0 years (yrs) accordingly, PASI 49.4±0.56, PsA duration 6.6±7.4 years were included. PsA pts with all GIT and LD, including Diseases of oesophagus, stomach and duodenum (K20–K31), Disorders of gallbladder, biliary tract and pancreas (K80–K87), Alcoholic and toxic liver disease (K70–K77) (LD), Viral hepatitis (B15–B19) (VH), non-infectious enteritis and colitis (K55–K63) NEC) were identify in the hospital Database and coding by International Statistical Classification of Disease and Related Health Problems (ICD-10) between 2010–2015 years. M±m, t-test, (%) were calculated. All p<0.05 were considered to indicate statistical significance.

Results: 229 (159 – M./70 – F.) out of 417 pts (54.9%) had LD and GIT disorders. Gallbladder, biliary tract and pancreas disease coding as K80–K87 were found in significantly more cases in F. compare to M. pts – in 26 out of 70 pts (37.4%) and in 31 out of 159 pts (19.4%) accordingly (p<0.05). NEC coding as K55–K63 was found in M. only – in 1 out of 159 (0.62%) pts. Diseases of oesophagus, stomach and duodenum coding as K20–K31 were found in 96 out of 229 pts (42%). All of the alcoholic, toxic and viral liver disease were found in 75 out of 229 pts (32.75%). LD coding as K70–K77 were found in 33 out of 75 pts (44%). VH coding

as B15–B19 were found in 42 out of 75 pts (56%). No significantly gender differences were found in those group of pts.

Conclusions: GIT and LD were found in more than half of young pts with PsA and severe PsO. That information should be taken in account during the choice of safety therapy in this group of pts.

Disclosure of Interest: None declared

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AB0953

PSAID-12 CAN BE USED TO DETERMINE THE ANTI-TNF TREATMENT DECISION IN THE PSORIATIC ARTHRITIS REGISTRY

U. Kalyoncu, S. Kiraz, S. Apras Bilgen, O. Karadag, A. Akdogan, L. Kilic, A. Erden, B. Armagan, A. Sari, I. Ertenli. *Hacettepe University, Department of Internal Medicine, Division of Rheumatology, Ankara, Turkey*

Background: Psoriatic Arthritis Impact of Disease (PsAID-12) score has 12 questions and each question has its own weight. PsAID-12 is developed to be used in daily practice. However, in the daily practice, there has been no information on the utilisation of determining the response of the biological DMARD treatment.

Objectives: The assessment of utilisation of PsAID-12 for PsA patients on determination of the efficiency and inefficiency of anti-TNF treatment in a biological registry.

Methods: In this study patients were taken from Hacettepe University biological database (HUR-BIO). Since January 2013 PsAID-12 score was built in HUR-BIO database. PsAID-12 score was known for 116 patients before starting off the first anti-TNF treatment and 88 patients whose PsAID-12 score was 4 and above were included in the enquiry. Overall, 70 PsA patients included to analysis. Demographic data before anti-TNF treatment of PsA patients were noted. The decision of continuation, stopping or switching to another anti-TNF drugs were performed by both clinicians and the patients agreement. According to baseline evaluation, decrease of 20 mm and above on pain-VAS score and PGA, improvement of 0.22 unit and above on HAQ-DI score, or decrease of 1.2 unit and above on DAS-28 score were considered favourable to the anti-TNF treatment. Stopping or switching the anti-TNF treatments due to inefficiency was definitely a negative response. Pain-VAS score being under 15 mm or below, global-VAS score being 20 mm and below, HAQ-DI score being 0.5 and below, DAS-28 score being 2.6 and below were determined as targeted goals. Changes were analysed comparing to baseline level in PsAID-12 score, in compliance with the favourable and unfavourable responses to Anti-TNF treatments. In determining the response of the treatment, standardised response mean (SRM) was used.

Results: Seventy (78.6% female) patients were analysed, mean age was 45.5 (12.0). Mean follow-up duration was 18.3 (12.6) months, and total of 213 clinical visits were performed, median 3rd control visits were done. At baseline, the mean (SD) DAS-28 4.07 (1.22), HAQ-DI 0.86 (0.53), pain-VAS 6.9 (2.1), PGA-VAS 6.4 (1.7), and PsAID-12 6.6 (1.5) were as follows. Anti-TNF treatments were stopped due to inefficacy in 43/210 (20.5%) outpatient visit during the follow-up period. The results of anti-TNF stopped and continuing patients; Δ PsAID-12 were 0.38 (1.71), and 3.12 (2.14), respectively and PsAID-12 baseline/control visits 0.96 (0.29) vs 0.50 (0.33), respectively. Level of favourable response and achieving to goal according to ΔPsAID-12 and PsAID-12 Baseline/control visit were shown table 1. On the follow up visits, among measured parameters one of the highest SRM was detected in PsAID-12; PsAID-12 (1.10), DAS-28 (1.14), PGA (0.88), Pain (0.85), and HAQ-DI (0.51), respectively.

Abstract AB0953 – Table 1. Goals and responses of Anti-TNF treatment

Level of favorable response to anti-TNF treatments	of		ΔPsAID-12		PsAID-12 Baseline/control
			Yes	No	
		Δ Pain ≥ 20 mm	Yes n=136	3.4 (1.9)	0.47 (0.33)
			No n=77	1.1 (1.9)	0.81 (0.34)
		Δ PGA ≥ 20 mm	Yes n=133	3.4 (2.1)	0.45 (0.33)
			No n=80	1.2 (2.0)	0.84 (0.31)
		Δ HAQ-DI ≥ 0.22	Yes n=110	3.5 (2.0)	0.44 (0.29)
			No n=103	1.6 (2.1)	0.74 (0.38)
		Δ DAS-28 ≥ 1.2	Yes n=122	3.5 (2.1)	0.44 (0.31)
			No n=70	1.2 (1.8)	0.80 (0.32)
		Pain ≤ 15 mm	Yes n=57	4.3 (2.1)	0.28 (0.32)
			No n=156	1.9 (2.1)	0.71 (0.32)
		PGA ≤ 20 mm	Yes n=68	4.2 (2.1)	0.28 (0.29)
			No n=145	1.8 (2.0)	0.74 (0.32)
		HAQ-DI ≤ 0.5	Yes n=136	3.5 (2.1)	0.43 (0.32)
			No n=77	0.9 (1.7)	0.89 (0.28)
		DAS-28 < 2.6	Yes n=118	3.1 (2.3)	0.48 (0.35)
			No n=85	1.7 (2.2)	0.75 (0.36)

Conclusions: Having 3.5 unit or 50% decrease in the PsAID-12 score indicates a favourable response to anti-TNF treatment, 4 unit or 70% decrease indicates level

of targeted response. PsAID-12 appears to be an effective composite index for retaining the response of the treatment in biological registry.

Disclosure of Interest: None declared

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AB0954

A RANDOMISED, DOUBLE-BLIND TRIAL COMPARING THE EFFICACY, SAFETY AND IMMUNOGENICITY OF MSB11022, A PROPOSED BIOSIMILAR OF ADALIMUMAB, VERSUS ADALIMUMAB ORIGINATOR IN PATIENTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS

J. Hercogová¹, K.A. Papp², C.J. Edwards³, V. Chyrok^{4,*}, T. Halady⁴, M. Ullmann⁴, P. Vlachos⁵. ¹Charles University, Prague, Czech Republic, ²Probit Medical Research Inc, Waterloo, ON, Canada, ³University of Southampton, Southampton, UK, ⁴Fresenius Kabi, Aubonne, ⁵Cytel, Geneva, Switzerland

Background: Adalimumab is a fully human anti-TNF mAb, indicated for the treatment of multiple inflammatory disorders. MSB11022 is a proposed adalimumab biosimilar that has shown analytical similarity [1] and bioequivalence to US-licensed and EU-approved adalimumab originator, as well as comparable safety, tolerability and immunogenicity in a phase I trial [2].

Objectives: The aims of this multicentre, double-blind, parallel-group, 52-week phase III study (AURIEL-PsO, NCT02660580) were to demonstrate equivalence in efficacy (Psoriasis Area and Severity Index [PASI] 75) and to compare the safety and immunogenicity of MSB11022 vs. adalimumab originator in patients with moderate-to-severe chronic plaque psoriasis. This study was designed in-line with the biosimilar regulatory framework as part of the totality of evidence to confirm similarity and rationale for extrapolation.

Methods: A total of 443 eligible patients (391 evaluable, including 43 with psoriatic arthritis) from 69 sites in 12 countries were randomised 1:1 and treated with MSB11022 (n=202) or adalimumab originator (n=189) (80 mg subcutaneously [SC] on day 1; 40 mg SC every other week from weeks 2–14). The primary endpoint was PASI 75 at week 16; equivalence was established if the 95% confidence interval (CI) for the treatment difference was within ±18%. Secondary endpoints included % change from baseline in PASI (equivalence confirmed if 95% CI within ±15%), Physician Global Assessment (PGA), quality of life (QoL), immunogenicity and safety. Interim results at week 16 are presented.

Results: Patient baseline characteristics were comparable between MSB11022 and adalimumab originator groups: mean age 44.8 vs. 42.4 years, male 66.8% vs. 68.3%, mean PASI score 20.7 vs. 21.2, respectively. PASI 75 scores were 89.6% for MSB11022 and 91.5% for adalimumab originator (difference -1.9% [95% CI -7.82–4.16]). Mean % change from baseline in PASI was -90.6% for MSB11022 and -91.7% for adalimumab originator (difference -1.0% [95% CI -1.23–2.98]). PGA and QoL scores were comparable between treatment groups. The incidence of treatment-emergent adverse events (TEAEs)/serious TEAEs was 51.1/3.6% for MSB11022 and 53.2/2.7% for adalimumab originator. Immunogenicity profiles of MSB11022 and adalimumab originator were also similar and consistent.

Conclusions: Week 16 results of this phase III confirmatory study demonstrated equivalent efficacy and similar safety and immunogenicity profiles for MSB11022 vs. adalimumab originator at 16 weeks in patients with moderate-to-severe chronic psoriasis.

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AB0955

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

A. Blauvelt¹, H. Sofen², K. Papp³, M. Gooderham⁴, Y. Zhao⁵, S. Lowry⁵, A. Mendelsohn⁶, J. Pardo⁵, Q. Li⁶, C.L. Rosa⁶, K. Reich⁷. ¹Oregon Medical Research Center, Portland; ²Medicine, University of California at Los Angeles, Los Angeles, USA; ³Probit Medical Research, Waterloo; ⁴Skin Centre for Dermatology, Peterborough, Canada; ⁵Sun Pharmaceuticals, Princeton; ⁶Merck and Co., Inc., Kenilworth, USA; ⁷SCIderm Research Institute and Dermatologikum, Hamburg, Germany

Background: Tildrakizumab (TIL), a high affinity, humanised, IgG1/κ monoclonal antibody for IL-23p19, recently demonstrated efficacy in patients with chronic plaque psoriasis in two, phase 3 clinical trials.

Objectives: To examine 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, randomised controlled trials in subjects with moderate-to-severe chronic plaque psoriasis¹. Part 1 (0–12 weeks) was placebo controlled; Part 2 (12–28 weeks) re-randomised placebo patients to TIL; Part 3 (28–64 weeks, reSURFACE 1; 28–52 weeks, reSURFACE 2) patients with ≥PASI 50 were re-randomised to continue or increase TIL dose or to placebo based on response at week 28. In this post-hoc pooled analysis, patients 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 overall pooled 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 200 mg 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 for 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 remained consistent or improved from week 28 to week 52. Similar results were observed for TIL 200 mg as well as subgroup analysis with bio-naïve 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 rapid improvement by week 4.

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