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.

REFERENCES:

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Disclosure of Interest: None declared


AB0952
HIGH PREVALENCE OF INFLAMMATORY AND NON-INFLAMMATORY LIVER AND GASTROINTESTINAL DISEASES IN YOUNG PATIENTS WITH PSORIATIC ARTHRITIS: A HOSPITAL-BASED STUDY

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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 GI 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, VAS 1.21±0.28.

Results: 229 (159 M. only) were found in 1 out of 159 (0.62%) pts. Diseases of oesophagus, stomach and duodenum (K20–K23) were found in 96 out of 229 pts (42%). All of them 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 meaning (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 3 (4) 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 shown as Anti-TNF treatments were stopped due to inefficacy in 43/1023 (20.5%) outpatient visit during the follow-up period. The results of anti-TNF stopped and continuing patients; ΔPsAID-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.

Disclosure of Interest: None declared


AB0953
PSAID-12 CAN BE USED TO DETERMINE THE ANTI-TNF TREATMENT DECISION IN THE PSORIATIC ARTHRITIS REGISTRY

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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 inefficacy 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 meaning (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 3 (4) 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 shown as Anti-TNF treatments were stopped due to inefficacy in 43/1023 (20.5%) outpatient visit during the follow-up period. The results of anti-TNF stopped and continuing patients; ΔPsAID-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.

Disclosure of Interest: None declared

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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

<table>
<thead>
<tr>
<th>Proximal Nail Fold Thickness (mm)</th>
<th>Nail Bed Thickness (mm)</th>
<th>Proximal Nail Fold + Nail Bed (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psoriasis (n=25)</td>
<td>1.23±0.07</td>
<td>1.33±0.10</td>
</tr>
<tr>
<td>Psoriatic arthritis (n=35)</td>
<td>1.33±0.05</td>
<td>1.25±0.10</td>
</tr>
<tr>
<td>Psoriasis or psoriatic arthritis with nail psoriasis (n=41)</td>
<td>1.34±0.04</td>
<td>1.36±0.06</td>
</tr>
<tr>
<td>Psoriasis or psoriatic arthritis without nail psoriasis (n=19)</td>
<td>1.18±0.07</td>
<td>1.11±0.45</td>
</tr>
<tr>
<td>Rheumatoid arthritis (n=23)</td>
<td>1.14±0.07</td>
<td>1.14±0.10</td>
</tr>
<tr>
<td>Ulcerative colitis (n=28)</td>
<td>1.21±0.08</td>
<td>1.22±0.03</td>
</tr>
<tr>
<td>Crohn’s disease (n=13)</td>
<td>1.11±0.25</td>
<td>1.14±0.26</td>
</tr>
</tbody>
</table>

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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A RANDOMISED, DOUBLE-BLIND TRIAL COMPARING THE EFFICACY, SAFETY AND IMMUNOGENICITY OF MSB11022 VS.adalimumab biosimilar of adalimumab ORIGINATOR IN PATIENTS WITH MILD-TO-SEVERE PLACAE PSORIASIS

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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 II trial [2].

Objectives: To examine efficacy from baseline to week 52 of TIL patients achieving Psoriasis Area and Severity Index (PASI) 75 responses at week 26.

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 ± 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 – 2.23 – 2.98]). PGA and QoL scores were comparable between treatment groups. The incidence of treatment-emergent adverse events (TEAEs)/serious TEAEs was 51.3/6.6% for MSB11022 and 53.2/2.7% for adalimumab originator. Immunogenicity profiles 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.

REFERENCES:
