AB0907 TREATMENT PATTERNS IN PSORIATIC ARTHRITIS IN US AND EUROPE: RESULTS FROM A REAL-WORLD INTERNATIONAL SURVEY

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Background: With the availability of a greater range of Psoriatic Arthritis (PsA) treatment options, it is increasingly necessary to understand their use and impact on disease control in real-world practice.

Objectives: To assess treatment patterns and their impact on clinical outcomes among PsA patients currently receiving conventional/targeted synthetic disease-modifying anti-rheumatic drugs (cs/tsDMARD) or biologic DMARD (bDMARD).

Methods: A point in time survey was conducted in 2015 across the US, France, Germany, Italy, Spain and UK. Patients had physician-confirmed PsA and had to be receiving their current cs/tsDMARD (bio naive) or bDMARD (1st or 2nd line) for >6 months. Physicians provided information on demographics, treatment history, disease severity, clinical measures included body surface area (BSA), joint count, flare/remission status. Student t-tests, Pearson

Results: 519 physicians (331 rheums, 188 derms) provided data for 2467 PsA patients, clinical status and treatment outcomes. They had more affected joints but were less likely to flare vs cs/tsDMARD. These patients had more symptoms, more affected joints and more likely to flare vs 1st-line bDMARD. Patients receiving cs/tsDMARDs had a worse clinical profile than those on 1st-line bDMARD in all areas other than joint count. Patients on 2nd-line bDMARD had more symptoms, more affected joints and more likely to flare vs 1st-line bDMARD. They had more affected joints but were less likely to flare vs cs/tsDMARD. These findings were directionally similar in the EU and US (table 1). BSA was higher for cs/tsDMARD patients than for any bDMARD patients.

Table 1

<table>
<thead>
<tr>
<th>Current cs/tsDMARD (n=438)</th>
<th>Current 1st Line DMARD (n=820)</th>
<th>Current 2nd Line DMARD (n=205)</th>
<th>Current 2nd Line DMARD vs 1st Line (n=205)</th>
<th>Current 2nd Line DMARD vs cs/tsDMARD (n=820)</th>
<th>Current 2nd Line DMARD vs cs/tsDMARD (n=820)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean No. of PsA Symptoms</td>
<td>1.7</td>
<td>1.4</td>
<td>&lt;0.001</td>
<td>1.9</td>
<td>0.378</td>
</tr>
<tr>
<td>Mean No. of Joints Affected</td>
<td>3.2</td>
<td>3.3</td>
<td>0.531</td>
<td>4.0</td>
<td>&lt;0.001</td>
</tr>
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<td>0.531</td>
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<td>Mean No. of Joints</td>
<td>6.7%</td>
<td>3.4%</td>
<td>0.032</td>
<td>5.4%</td>
<td>&lt;0.001</td>
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<td>Mean No. of Joints</td>
<td>60.5%</td>
<td>39.5%</td>
<td>&lt;0.001</td>
<td>45.9%</td>
<td>&lt;0.001</td>
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<td>60.5%</td>
<td>39.5%</td>
<td>&lt;0.001</td>
<td>45.9%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mean BSA Remission</td>
<td>11.4%</td>
<td>7.8%</td>
<td>&lt;0.001</td>
<td>8.6%</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Conclusions: Only 39%-60% of patients were considered by physicians as in remission, revealing a considerable unmet need in both the EU and US in patients treated with cs/tsDMARDs and bDMARDs. Further research is needed to identify patients on cs/tsDMARDs who may be a candidate for advanced therapy and to recognise patients who might fail on bDMARD who therefore may benefit from a different therapeutic alternative.


AB0908 ABILITY OF THE REDUCTIVE X-RAY SCORE FOR PSORIATIC ARTHRITIS (REXSPA) TO DETECT CHANGE IN AN OBSERVATIONAL COHORT OF PATIENTS WITH PSA

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Background: The measurement of radiographic joint damage is important in characterising disease severity, progression, and prognosis in psoriatic arthritis (PsA). Existing radiographic measures are time-consuming to perform, leading to limited data collection from existing longitudinal observational studies.

Objectives: We have previously proposed a Reductive X-ray Score for Psoriatic Arthritis (ReXSPA) as more feasible method, and in this study set out to examine the sensitivity of ReXSPA in a new cohort of patients.

Methods: A retrospective sample of 28 patients who had hand and foot radiographs at 3 time points (5 years before [T1], at the time of [T2], and 5 years post [T3]) commencement of anti-TNF treatment were taken from the Bath longitudinal PsA cohort. Radiographs were scored for erosion, joint space narrowing and proliferation to calculate the Sharp-van der Heijde modified method (VDH) and ReXSPA scores. A sample of 9 radiographs were scored by all assessors (WT, AA and AA) to determine inter- and intra-rater reliability using intra-class correlation coefficients (ICC). Sensitivity to change was determined from timepoint T1 to T2 using the Standardised Response Mean (SRM) and Smallest Detectable Change (SDC).

Results: The patients’ mean age (SD) at T1 was 61 years (13.4), the mean disease duration was 11.2 years (11.14). Patients were followed up for a mean (SD) of 10.2 years (2.76). Overall inter- and intra-rater reliability for ReXSPA and VDH were 0.80 and >0.92 and 0.91 and >0.90 respectively. The median (IQR) of ReXSPA score was 8.5 (1–14), 12.5 (5–20) and 14.5 (8–36) at T1, T2, and T3 respectively. The percentage SDC was 0.91 for the ReXSPA method and 0.77 for the VDH method, and the SMDs were 0.92 and 0.87 respectively (table 1), demonstrating the sensitivity of both methods in detecting change. There was a trend towards slowing in radiographic progression following the initiation of TNF-inhibitors, but ReXSPA was less sensitive compared to the VDH and was not able to detect a significant change in the rate of progression post-TNF inhibition (p 0.08) (Graphic 1).

Table 1

<table>
<thead>
<tr>
<th>Method</th>
<th>Mean Change</th>
<th>SD of change</th>
<th>SEM</th>
<th>SRM</th>
<th>SDC</th>
<th>SDC% as of total score</th>
</tr>
</thead>
<tbody>
<tr>
<td>VDH</td>
<td>22.11</td>
<td>19.14</td>
<td>3.62</td>
<td>0.87</td>
<td>4.09</td>
<td>0.77</td>
</tr>
<tr>
<td>Erosion</td>
<td>7.29</td>
<td>10.62</td>
<td>2.01</td>
<td>1.46</td>
<td>2.27</td>
<td>0.71</td>
</tr>
<tr>
<td>JSN</td>
<td>16.96</td>
<td>15.17</td>
<td>2.87</td>
<td>0.89</td>
<td>3.24</td>
<td>1.56</td>
</tr>
<tr>
<td>ReXSPA</td>
<td>10.9</td>
<td>10.0</td>
<td>1.89</td>
<td>0.92</td>
<td>2.14</td>
<td>0.91</td>
</tr>
<tr>
<td>Erosion</td>
<td>3.21</td>
<td>5.31</td>
<td>1.00</td>
<td>1.65</td>
<td>1.13</td>
<td>1.03</td>
</tr>
<tr>
<td>JSN</td>
<td>6.36</td>
<td>5.11</td>
<td>0.97</td>
<td>0.80</td>
<td>1.09</td>
<td>1.24</td>
</tr>
<tr>
<td>Proliferation</td>
<td>0.96</td>
<td>2.32</td>
<td>0.44</td>
<td>2.40</td>
<td>0.50</td>
<td>1.39</td>
</tr>
</tbody>
</table>

Conclusions: Only 39%-60% of patients were considered by physicians as in remission, revealing a considerable unmet need in both the EU and US in patients treated with cs/tsDMARDs and bDMARDs. Further research is needed to identify patients on cs/tsDMARDs who may be a candidate for advanced therapy and to recognise patients who might fail on bDMARD who therefore may benefit from a different therapeutic alternative.


Abstract AB0908 – Table 1. Sensitivity to change of each scoring method

Sharp-van der Heijde modified method (VDH), Standard deviation (SD), Standard error of mean (SEM), Standardised response mean (SRM), Smallest detectable change (SDC).
Objectives: To evaluate the effectiveness and safety of Certolizumab Pegol (CZP) in a real in PsA patients.

Methods: Multicentric cohort of PsA patients treated with CZP according routine clinical practice. Study approved by local Ethics Committee. Maximum time of observation was 12 months. Effectiveness variables: SJC, TJC, PtGA (Patient Global Assessment) and DAS28-CRP. Safety variables: discontinuation rate.

Results: 262 patients with PsA were included: 43.5% male, mean (SD) age 49.9 (11.9) years, mean (Q1-Q3) disease duration 6.9 (1.9–9.3) years, 14.9% of patients HLAB27 positive, mean (SD) IMC (kg/m2) 26.9 (4.7), never smokers 70.3%. Extra-articular manifestations ever: Psoriasis (90%); PASI>10 40.9%, enthesitis (44.4%), dactylitis (41.9%), nail disease (32%), inflammatory bowel diseases (4.9%). 37.3% of the PsA patients had bone erosions and 3% arthritis mutilans. 48.9 patients received 1 prior csDMARD and 52.1% at least 2 csDMARD. Prior bDMARD: 28.4% none; 38.1% 1, 33.5%>2. 29.6% of PsA patients received CZP in monotherapy. Mean time on treatment with CZP 10 months.

Conclusions: The RexSPA is a reliable and sensitive alternate scoring method for the detection of radiographic progression in an observational cohort of patients with PsA, but not as sensitive to change as the VDH method.

REFERENCE:

Disclosure of Interest: None declared

CERTOLIZUMAB PEGOL’S EFFECTIVENESS, RETENTION RATE AND SAFETY IN PSORIATIC ARTHRITIS. ROUTINE CLINICAL PRACTICE DATA


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Background: Certolizumab pegol (CZP) is the only antiTNF pegylated without Fc fragment in monotherapy. Mean time on treatment with CZP 10 months. Prior bDMARD: 28.4% none; 38.1% 1, 33.5%>2. 29.6% of PsA patients received CZP in monotherapy. Mean time on treatment with CZP 10 months.

Conclusions: The RexSPA is a reliable and sensitive alternate scoring method for the detection of radiographic progression in an observational cohort of patients with PsA, but not as sensitive to change as the VDH method.

REFERENCE:

Disclosure of Interest: None declared

Abstract AB0909 – Figure 1. C2P retention rate and biologics exposure (n° of previous biologics)

Statistically significant differences in SJC, TJC and DAS28-CRP were observed at the last visit comparing with baseline (table 1). Percentage of patients with enthesitis at baseline (25.4%) decrease to 9.5% at the last visit; 73.2% of the patients had a resolution of the enthesitis (MASES=0). The percentage of patients with dactylitis at baseline (29.1%) decrease to 8.6% in the last visit; 82.5% of these patients had a resolution of the dactylitis. Statistically significant reduction of patients with nail disease was observed from 30.6% to 16.4%. According to Kaplan-Meier analysis, the drug survival of CZP was 78.2%, and no differences were observed in patients who received CZP as first/second biologic or after more than 1 failure to other biologicals agents (Figure1).

262 patients were included in the safety analysis, 21.8% withdrawn treatment: 12.6% due to lack of effectiveness, 5.3% due to intolerance and 3.8% other reasons.

Abstract AB0909 – Table 1. Effectiveness

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Last visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAS28; mean (SD)</td>
<td>4.6 (0.9)</td>
<td>3.8 (1.0)*</td>
</tr>
<tr>
<td>TJC; mean (SD)</td>
<td>7.2 (5.1)</td>
<td>4.0 (4.0)*</td>
</tr>
<tr>
<td>SJC; mean (SD)</td>
<td>5.0 (3.7)</td>
<td>2.8 (2.8)*</td>
</tr>
<tr>
<td>PtGA; mean (SD)</td>
<td>6.9 (1.7)</td>
<td>4.3 (2.0)</td>
</tr>
</tbody>
</table>

*p<0.001, Wilcoxon’s test

Conclusions: In this study of routine clinical practice CZP was effective in patients with PsA, with a significant decrease in DAS28-CRP and the percentage of patients with enthesitis and dactylitis. The retention rate of certolizumab pegol was not affected by the number of previous biological treatments.


Abstract AB0909 – Figure 1. Cumulative probability plot demonstrating ReXSPA progression pre- and post- TNF inhibition
LONG-TERM GOLIMUMAB RETENTION RATE IN PATIENTS WITH PSORIATIC ARTHRITIS. IS CONCOMITANT DMARD IMPORTANT?
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Methods: Prospective monocentric cohort of PsA patients treated with golimumab according to clinical practice. Study was approved by local Ethics Commit-tee. Demographic and clinical variables were analysed with Cox proportional hazard regression model.

Results: 48 patients were included, 20/48 (41.7%) oligoarticular, 19/48 (39.6%) polyarticular and 9/48 (18.7%) with peripheral and axial PsA. The baseline characteristics of the patients are shown in table 1.

Table 1. Baseline demographic and clinical characteristics of the patients.

| Age (mean (SD)-years) | 48.3 (11.1) |
| Female gender (%)      | 25 (52.1%)  |
| Concomitant DMARD (%)  | 24 (50%)    |

Disclosure of Interest:
None declared

Follow-up time was 89.25 patients-year. Mean survival time was 40.3 months (95% CI: 32.0–48.5). Age, mean evolution time and previous biological use were significant in the univariate analysis. Concomitant sDMARD had no influence on golimumab retention rate (HR: 1.3; 95% CI: 0.5–3.2; p=0.6). Figure 1. When golimumab was used as first or second biologic treatment, it had a better retention rate than when it was used as third or fourth, but did not reach statistical significance (HR: 2.3; IC 95%: 0.8–6.2; p=0.1). 18/48 patients (37.5%) withdrew golimumab treatment. 13/18 (72.2%) due to lack of efficacy, 1/18 (0.6%) due to adverse events and 4/18 (22.2%) due to other reasons.

CONCLUSIONS:
Real-world Golimumab retention rate in patients with PsA was good and did not depend on concomitant treatment with sDMARD. When used as first or second biologic, Golimumab retention rate tended to be better.

Disclosure of Interest: None declared


THE RELATIONSHIP BETWEEN NEUROPATHIC PAIN AND DISEASE ACTIVITY, SLEEP, FATIGUE, QUALITY OF LIFE IN PATIENTS WITH PSORIATIC ARTHRITIS
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Background: Neuropathic pain (NP) is composed of several abnormal sensations, including burning, prickling hyperalgesia and allodynia. NP is a common problem in rheumatic diseases such as rheumatoid arthritis and ankylosing spon-dylitis due to inflammatory processes. Previous studies showed that NP in other rheumatic diseases had a negative influence on sleep and quality of life.1, 2

Objectives: To examine the relation of neuropathic pain symptoms in Psoriatic Arthritis (PsA) with demographic, clinical and functional parameters.

Methods: PsA patients according to CASPAR criteria were recruited into the study. Demographic and clinical parameters were noted. PainDETECT measurement tool was used for evaluation of NP. Physical examination such as manual muscle testing and sensory examination for hyperalgesia and allodynia was performed (pinprick and light touch test). Disease Activity Score-28 (DAS-28) was noted for disease activity. Associations of NP with quality of life, sleep and fatigue were analysed by filling out Psoriatic Quality of Life (PsAQoL), Pittsburgh Sleep Quality Index (PSQI), Multidimensional Assessment of Fatigue (MAF). PainDETECT scores were categorised as no NP (<12 points), ambiguous NP (13–18 points), probable NP (>19 points). Group analysis was performed with Independent-Samples Kruskal-Wallis test. Spearman correlation coefficient (rho) was used for correlations between functional parameters. p<0.05 was accepted as significant.

Results: Forty eight PsA patients (31 female, 17 male) with a mean age 50.4 years (SD:10.0) and mean disease duration 92.2 months (SD: 90.2) were recruited into the study. The number of patients with ambiguous NP was 6 patients (4 female, 2 male) and probable NP was 12 patients (10 female, 2 male). The mean scores of PSQI, PsAQoL and MAF were significantly higher in patients with NP (p<0.05). There was no difference in mean scores of DAS-28 and disease duration among groups. The correlations between PainDETECT and other functional parameters were found moderate-strong as PSQI (rho=0.43, p=0.002), MAF (rho=0.44, p=0.002), PsAQoL (rho=0.66, p=0.0005). Also, the probability of NP existence increased with the age (rho=0.40, p=0.01). There was no significant correlation between and clinical parameters such as disease duration and DAS-28 (p>0.05).

Conclusions: These findings suggest that a substantial number of PsA patients suffering from NP. The neuropathic pain symptoms are found to be associated with worse self-reported quality of life and sleep disturbances. It is important to consider the existence of NP in the assessment and treatment process of PsA.

REFERENCES:

Disclosure of Interest: None declared


TWO-YEAR EFFICACY AND SAFETY OF GUSELKUMAB FOR TREATMENT OF MODERATE-TO-SEVERE PSORIASIS: PHASE 3 VOYAGE 1 TRIAL
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Background: Guselkumab (GUS) is an interleukin-23 inhibitor recently approved in the US for treatment of moderate-to-severe psoriasis.

Objectives: Efficacy and safety data for up to 100 wks of GUS treatment are reported.

Methods: In the VOYAGE 1 Phase 3, randomised, double-blind, placebo/active comparator-controlled trial, 837 patients were randomised at baseline to placebo (PBO) at wks0/4/12 then GUS 100 mg at wks16/20 and qw (n=174); GUS at wks0/4/12, and qw (n=329); or adalimumab (ADA) 80 mg at wk 0, 40 mg at wk1, and qw2 through wk47 then GUS at wks52 and qw (n=334). Efficacy was assessed using nonresponder imputation through wk48 and treatment failure rules from wks52–100.

Results: Among patients randomised to GUS, or PBO—GUS at wk16, efficacy (PASI, Psoriasis Area and Severity Index; PGA, Investigator’s Global Assessment) was maintained from wks52–100 with continuous GUS treatment. Among those