DURABLE CLINICALLY-MEANINGFUL IMPROVEMENTS IN HEALTH-RELATED QUALITY OF LIFE, FATIGUE, PAIN, AND WORK PRODUCTIVITY AMONG PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS TREATED WITH RISANKIZUMAB AT WEEK 100

Keywords: Psoriatic arthritis, Patient reported outcomes


Psoriatic arthritis, Patient reported outcomes

Keywords:

Table 1. Percentage of patients who achieved MCIDs at Week 24 and maintained MCIDs at Weeks 52 and 100

<table>
<thead>
<tr>
<th>Week 52</th>
<th>Week 100</th>
<th>Week 100</th>
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</thead>
<tbody>
<tr>
<td>RZB</td>
<td>PBO to RZB</td>
<td>RZB</td>
</tr>
<tr>
<td>FACIT-Fatigue</td>
<td>220 (84.6)</td>
<td>155 (79.9)</td>
</tr>
<tr>
<td>SF-36 PCS</td>
<td>275 (86.6)</td>
<td>205 (84.5)</td>
</tr>
<tr>
<td>BASDAI**</td>
<td>46 (90.2)</td>
<td>36 (90.0)</td>
</tr>
<tr>
<td>Morning stiffness</td>
<td>50 (94.3)</td>
<td>47 (92.2)</td>
</tr>
<tr>
<td>WPAI</td>
<td>73 (85.9)</td>
<td>76 (84.2)</td>
</tr>
<tr>
<td>Activity Impairment</td>
<td>78 (89.7)</td>
<td>73 (92.0)</td>
</tr>
</tbody>
</table>

**Table 1.** Percentage of patients who achieved MCIDs at Week 24 and maintained MCIDs at Weeks 52 and 100

**Results:** In the KEEPsAKE 1 and 2 trials, patients were randomised 1:1 to receive RZB 150 mg or PBO in the 24-week double-blind period. During the open-label maintenance period, all patients received RZB 150 mg. This analysis evaluated observed cases of RZB-treated patients who achieved minimal clinically important differences (MCIDs) in PROs at Week 24. Results are presented as the percentage of patients, of those who achieved MCIDs at Week 24, who maintained MCIDs in PROs from Week 52 to Week 100. MCIDs included a ≥10-point decrease in Patient’s Global Assessment (PGA), ≥10-point decrease in Pain, ≥30-point decrease in Health Assessment Questionnaire – Disability Index (HAQ-DI), ≥4-point decrease in Functional Assessment of Chronic Illness Therapy (FACIT) – Fatigue, ≥2.5-point increase in 36-Item Short Form Survey (SF-36) physical component summary (PCS), ≥1-point decrease in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), ≥1-point decrease in morning stiffness, and ≥20% reduction in Work Productivity and Activity Impairment Questionnaire (WPAI). Presenteeism, ≥15% in Work Productivity Loss, and ≥20% in Activity Impairment.

**Conclusion:** In KEEPsAKE 1 and 2 trials, the majority of RZB-treated patients with PsA who achieved MCID in PROs at Week 24 maintained responses through Week 100. Achieving MCIDs at Week 24 is associated with sustained and clinically meaningful changes in HRQoL.
Background: Major adverse cardiovascular events (MACE) are some of the numerous comorbidities associated with psoriasis (PsO) and psoriatic arthritis (PsA). Previous studies addressed the contribution of sufficient anti-inflammatory therapy for PsO and PsA in decreasing MACE incidence [1,2].

Objectives: Assessing the risk of developing MACE in patients with pre-existing PsO treated with different treatment regimens; topical treatment, conventional disease-modifying anti-rheumatic drugs (cDMARDs), and biologic disease-modifying anti-rheumatic drugs (bDMARDs) which had not previously studied sufficiently on real-world data.

Methods: We conducted a retrospective exploratory study with real-world data using the databases of the third largest Israeli health maintenance organization, ‘Meuhedet’ which covers approximately 1,300,000 subjects. All patients of ‘Muehedat’ diagnosed with PsO from January 2000 until January 2020 were included in the analysis. Overall, 61,003 patients with PsO were detected. In addition, each PsO patient was paired with four control subjects by gender, age, and ethnicity (general, Arabic, or Orthodox). We defined PsO and PsA according to physicians’ diagnoses. MACE included patients with either cerebral vascular accident (CVA), ischemic heart disease (IHD), or peripheral artery disease (PVD). The date of the MACE incident was defined by the first occurrence of one of the diagnoses. We classified the patients diagnosed with PsA into a separate group; thus, patients were categorized according to their diagnosis (control, PsO or PsA). Furthermore, we analyzed the patients by the most advanced treatment prescribed to the patient; sub-grouped 1 - topical therapy, sub-grouped 2 - cDMARDs (methotrexate or sulfasalazine), sub-grouped 3 - bDMARDs (anti-TNF, anti-IL17, or anti-IL12/23 agents) (Table 1). The Incident cases of MACE were analyzed according to the different lines of therapy mentioned above. In addition, Time-dependent Cox proportional hazard models were used to evaluate the adjusted risk of developing MACE by treatment group.

Results: 287,392 patients were included after exclusion by the defined criteria, contributing a total of 2,997,001 patient-years. Adjusted Cox proportional hazards regression analysis showed that the risk of developing MACE in PsO patients treated with topical treatment and those treated with cDMARDs was significantly higher in comparison to controls (Topical, HR: 1.1, CI: 1.02 - 1.1, p-value: <0.001; cDMARDs, HR: 1.2, CI: 1.0 - 1.5, p-value: 0.03). Yet, the risk of developing MACE in PsO patients treated with bDMARDs was not significantly different compared to controls (HR: 1.1, CI: 0.82 - 1.5, p-value: 0.55). On the contrary, the risk of developing MACE in all treatment groups of PsA patients was found to be significantly higher in comparison to controls (Topical, HR: 1.6, CI: 1.45 - 1.7, p-value: <0.001; cDMARDs, HR: 1.4, CI: 1.2 - 1.6, p-value: <0.001, bDMARDs, HR: 1.6, CI: 1.35 - 1.8, p-value: <0.001) (Figure 1). This analysis was adjusted to gender, body mass index (BMI), age of PsO diagnosis, lifetime diagnosis of diabetes mellitus type 2 (DM2), dyslipidemia, hypertension (HTN), and chronic heart failure (CHF); notably, male gender, higher BMI, older age, DM2, dyslipidemia, HTN, and CHF were all associated with a greater risk of developing MACE.

Conclusion: Despite that the psoriasis and arthritis severity is higher in patients treated with bDMARDs treatment compared to those treated with cDMARDs and topical treatment alone, bDMARDs have a protective effect on the risk of developing PsA.

REFERENCES:

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POS1526

TREATMENT EFFECTS OF IXEKIZUMAB AND ADALIMUMAB AT THE INDIVIDUAL DIGIT LEVEL WITH NAIL AND DISTAL INTERPHALANGEAL JOINT INVOLVEMENT IN PATIENTS WITH PSORIATIC ARTHRITIS

Keywords: Psoriatic arthritis, Clinical trials, bDMARD


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REFERENCES:

Background: The prevalence of nail disease in patients with psoriatic arthritis (PsA) ranges between 41% and 87% [1]. Psoriatic nail disease is intimately linked to adjacent distal interphalangeal joint (DIP) disease, and it is important to ascertain whether DIP-nail complex behaves differently under different biological therapies.

Objectives: The aim of this analysis was to comparatively assess the effect of ixekizumab (IXE) and adalimumab (ADA) at the individual digit level in improving nail and joint disease, in patients with PsA and concomitant nail involvement.

Methods: This post hoc analysis included patients from SPIRIT-H2H (NCT02151551) treated with either IXE or ADA who had baseline nail disease (NAPSI total score >0) and DIP involvement in at least one simultaneous digit, with either tenderness, swelling or both, at the individual digit level for each hand. Proportions of patients having a NAPSI total score >0 and proportions of patients having DIP involvement (tenderness or swelling) were evaluated at baseline and Week 24; post-baseline assessments were compared between treatment arms using Fisher’s exact test.

Results: Of the intent-to-treat population of SPIRIT-H2H (N=566), 354 patients had a NAPSI total score >0 and DIP involvement (swelling or tenderness) in at least 1 digit simultaneously at baseline (IXE, N=186 and ADA, N=168). Of these patients, significantly fewer IXE- vs. ADA-treated patients had a NAPSI total score of ≥ 0 at Week 24 (p<0.05 for 8/10 digits; Table 1) and numerically fewer IXE- vs. ADA-treated patients had DIP involvement at Week 24 across all 10 digits (p<0.05 for 4/10 digits; Table 1). Numerically fewer IXE- vs. ADA-treated patients had joint tenderness at Week 24. A similar pattern of improvement was seen out to Week 52 (Table 1).

Conclusion: In this analysis, in patients from SPIRIT-H2H with psoriatic arthritis who had nail involvement and DIP involvement at baseline, patients treated with IXE had less nail involvement, less DIP involvement and less tenderness compared to those treated with ADA at Week 24.

REFERENCE:

Figure 1.