Psoriatic arthritis and its management: it’s more than just synovitis...

**Table 1. Baseline Demographics**

<table>
<thead>
<tr>
<th>Characteristics, mean (SD)</th>
<th>ADA+MTX</th>
<th>Escalated MTX</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=123</td>
<td>n=122</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>64 (52.0)</td>
<td>59 (48.4)</td>
</tr>
<tr>
<td>Age, y</td>
<td>54.4 (12.2)</td>
<td>48.8 (12.7)</td>
</tr>
<tr>
<td>BSA &gt;3%, n (%)</td>
<td>74 (60.2)</td>
<td>78 (63.9)</td>
</tr>
<tr>
<td>Pt pain</td>
<td>63.7 (19.5)</td>
<td>62.3 (20.9)</td>
</tr>
<tr>
<td>PtGA</td>
<td>65.0 (19.9)</td>
<td>62.9 (20.9)</td>
</tr>
<tr>
<td>HAQ-DI</td>
<td>1.2 (0.6)</td>
<td>1.2 (0.7)</td>
</tr>
<tr>
<td>LEI + plantar count</td>
<td>3.5 (2.1)</td>
<td>3.5 (2.1)</td>
</tr>
</tbody>
</table>

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**Figure 1. Study Design**

**Figure 2. MDA (A) and Secondary (B) Endpoints at Week 16**

**ADALIMUMAB INTRODUCTION VERSUS METHOTREXATE DOSE ESCALATION IN PATIENTS WITH INADEQUATELY CONTROLLED PSORIASIC ARTHRITIS: RESULTS FROM RANDOMIZED PHASE 4 CONTROL STUDY**

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Background: Methotrexate (MTX) is often used as first-line therapy for patients (pts) with psoriatic arthritis (PsA) despite limited efficacy and data on appropriate dosage. Minimal Disease Activity (MDA) is suggested as an adequate treat-to-target outcome. Biological disease-modifying anti-rheumatic drugs (bDMARDs) have demonstrated improved outcomes (including MDA rates) over MTX. However, more data are needed to define the optimal timing of bDMARD initiation and characterize efficacy of MTX dose escalation, to achieve optimal outcomes.

Objectives: To compare achievement of MDA by adding adalimumab (ADA) vs escalating MTX dose in PsA pts with inadequate disease control after initial MTX therapy.

Methods: The open-label, 2-part CONTROL study enrolled bDMARD-naive adult pts with active PsA (not in ADA at screening and ≤3 tender and ≤3 swollen joints) despite MTX 15 mg every wk (ew) for ≥4 wks. Pts were randomized to ADA 40 mg every wk + MTX 15 mg (ADA+MTX) or escalated MTX to 20–25 mg ew or highest tolerable dose during 16-wk part 1 (Fig 1). The primary endpoint was achievement of MDA, defined as fulfilling ≥5 of the 7 criteria: tender joint count ≤20, swollen joint count ≤6, Psoriatic Area Severity Index (PASI) ≤1, Psoriasis Area Body Surface Area (BSA) ≤3%, Pt’s global Assessment of psoriasis activity (PtGA) ≤15, Pt’s Visual Analogue Scale (VAS) ≤100, Pt’s Global Assessment of disease activity (PtGA) VAS ≤20, Health Assessment Questionnaire Disability Index (HAQ-DI) ≤0.5 and tender entheseal points (0–8) ≤1. Key secondary efficacy endpoints were achievement of ACR20 and PASI75 and change from baseline in HAQ-DI and Leeds Enthesitis Index (LEI) at wk 16.

Results: Overall, 246 pts were randomized; 245 received treatment (ADA+MTX, n=123; escalated MTX, n=122); 117 (95%) pts and 110 (90%) pts, respectively, completed part 1. Baseline characteristics were similar between groups (Table). During part 1, the average dose of MTX was 21.8 mg/ew (55% on oral MTX) in the escalated MTX group. Significantly higher proportion of pts in ADA+MTX (42%) vs escalated MTX (13%) group achieved MDA at wk 16 (non-responder imputation [NRI]; difference [95% CI] 28% [18%–39%]; P <0.001; Fig 2). Observed case analysis confirmed the NRI analysis. Lower ADA MDA rates at wk 16 were observed in the escalated MTX arm regardless of prior MTX duration (Fig 2). Significant improvements in key secondary endpoints were also observed with ADA+MTX vs escalated MTX (all P<0.05; Fig 2). In part 1, the proportion of patients with adverse events was similar between groups (ADA+MTX, 62% vs escalated MTX, 57%); no opportunistic infections, tuberculosis, malignancies, or deaths were reported during part 1.

Conclusion: A significantly higher proportion of pts achieved MDA at wk 16 after introducing ADA compared with escalating MTX dose; higher rates were observed regardless of prior MTX duration. Significantly higher responses in musculoskeletal, skin, and quality of life measures were observed with ADA+MTX vs escalated MTX. No new safety signals with ADA were identified in this pt population.

Background: We have previously reported that the presence of musculoskeletal pain in psoriasis patients is associated with a higher risk of developing psoriatic arthritis (PsA) (1). Furthermore, a subset of psoriasis patients shows evidence for structural enthesal lesions (SEL) in their hand joints (2), sometimes also referred to as “Deep Koebner Phenomenon”, which are highly specific for psoriatic disease and virtually absent in healthy controls, rheumatoid arthritis and hand osteoarthritis patients (2-4). However, it remains unclear whether SEL alone or in combination with musculoskeletal pain are associated with the development of PsA.

Objectives: To test whether the presence of SEL in psoriasis patients increases the risk for progression to PsA and how this is related to the presence of musculoskeletal pain.

Methods: Psoriasis patients without evidence of PsA were enrolled in a prospective cohort study between 2011 and 2018. All patients underwent baseline assessment of SEL in their 2nd and 3rd MCP joints by high-resolution peripheral quantitative computed tomography (HR-pQCT). The risk of PsA development associated with SEL and arthralgia was explored using survival analyses and multivariable Cox regression models.

Results: 114 psoriasis patients (72 men/42 women) with a mean (SD) follow-up duration of 28.2 (17.7) months were included, 24 of whom developed PsA (9.7 /100 patient-years, 95%CI 6.2 to 14.5) during the observation period. Patients with SEL (N=41) were at higher risk of developing PsA compared to patients without such lesions (21.4/100 patient-years, 95%CI 12.5 to 35.4, HR 5.10, 95%CI 1.53 to 16.99, p=0.008) (Kaplan Meier plot A). Furthermore, while patients without arthralgia and without SEL had a very low progression rate to PsA (1/29; 3.4%), patients with arthralgia but no SEL showed higher progression (5/33; 15.2%), which was in line with previous observations (1) (Kaplan Meier plot B). Presence of SEL further enhanced the risk for progression to PsA both in the absence (6/16; 37.5%) and presence (6/14; 42.8%) of arthralgia with the highest progression rate in those subjects with both arthralgia and SEL (p<0.001 by log rank test for trend) (Kaplan Meier plot B).

Conclusion: Presence of SEL is associated with an increased risk of developing PsA in patients with psoriasis. If used together with pain, SEL allow defining subsets of psoriasis patients with very low and very high risk to develop PsA.

References:

Figure 1. Prevalence of (A) PsA Disease Manifestations and (B) Other Manifestations With Axial Disease in the Overall Population

A

Axial disease

Investigator-defined PsA

Other manifestations with PsA

B

Axial disease definition

Manifestation, n (%) Investigator-Defined PsA (n = 291) Patients With Elevated Spine Symptoms (n = 863)

Enthesitis

154 (53.8)

311 (36.0)

Dactylitis

39 (10.0)

112 (13.0)

Peripheral arthritis

266 (68.5)

673 (78.0)

Nail

105 (49.5)

392 (45.4)

Skin

273 (68.8)

651 (75.4)

The heat map represents the frequency of any 2 domain combinations by the range of blue shades, with the darkest blue color specifying the highest frequency and the lightest blue specifying the lowest frequency of combinations.