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POS0019
PREDICTORS OF SUSTAINED 6 MONTHS REMISSION AND FLARE IN PATIENTS WITH POLYMALGIA RHEUMATICA

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Background: Polymyalgia rheumatica (PMR) is a typical inflammatory disease of the elderly. The mainstay of treatment is usage of oral glucocorticoids (GC) usually leading to a dramatic response. However, long-term treatment is often required. In some instances, remission cannot be achieved and disease flares can occur. To date, few papers investigated the predictive factors of response to GC therapy suggesting a role for weight, elevated plasma viscosity and C-reactive protein (CRP). Moreover, there are no data on predictor factors of disease flares after 6 months of sustained remission.

Objectives: To evaluate the factors predictive of sustained 6 months remission and of flare in patients with PMR.

Methods: We evaluated clinical data from 137 PMR patients treated with GC for more than 6 months between September 2002 and June 2020. Patients were evaluated at baseline, re-evaluated at 1 month and after 3 months and then at least every 3 months. We analyzed the differences between patients who achieved remission within 6 months of diagnosis, who maintained it for at least 6 months, and patients who did not. Remission was defined as 1) the absence of clinical symptoms, 2) <7.5 mm/day of prednisone equivalents and 3) negativity of ESR and CRP. Patients treated with methylprednisolone were excluded from the analysis.

Results: Among the 137 patients (baseline F68: M69, mean age ± SD 74.5±6.6 years, mean ESR ± SD 49.9±27.7 mm/h, mean CRP ± SD 6.1±11.4 mg/dl), 57 achieved remission at 6 months (41.6%), and after this period, another 47 went into remission for a total of 104 patients (75.9%). The months required to achieve remission averaged 6.4 ± 3. No differences were observed between patients who achieved remission and patients who did not regarding age, sex, CRP, starting dose of GC, anti-CCP and rheumatoid factor. The ESR at baseline was higher in patients who achieved remission and did not experience flare. There were no significant differences in any analyzed parameters between patients who experienced flares and those who did not, including ESR and CRP values at baseline. Patients who achieved complete remission are less likely to develop flare. True remission should coincide with the discontinuation of steroid treatment; in fact, the maintenance of steroid therapy, even at low doses, is predictive of the development of flare.

REFERENCES:

Time to normalization of ESR and flare (months)

POS0020
EFFICACY AND SAFETY OF SECUKINUMAB IN PATIENTS WITH ROTATOR CUFF TENDINOPATHY: A 24-WEEK, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE II PROOF-OF-CONCEPT TRIAL

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Background: Rotator cuff tendinopathy (RC TP) is a multifactorial condition and one of the most common causes of musculoskeletal burden. Current standard of care (SoC) is limited to pain relief with NSAIDs and physiotherapy. Recent evidence indicates that IL-17A-expressing tendon-resident immune cells are present in human overuse tendinopathy, and IL-17A levels are increased in early human tendinopathic tissue samples [1, 2]. Secukinumab (SEC) is a fully human, monoclonal antibody that binds to and neutralises IL-17A.

Objectives: To evaluate the efficacy and safety of SEC in patients with active overuse RC TP refractory to oral NSAIDs/acetaminophen, physiotherapy or corticosteroid injections.

Methods: 96 patients with symptomatic RC TP with no or <50% rupture were randomly assigned to receive seven subcutaneous injections of SEC 300 mg or placebo (PBO) at baseline and Weeks 1, 2 and 3, followed by every 4 weeks starting at Week 4. The primary endpoint was change from baseline in the Western Ontario Rotator Cuff (WORC) index score at Week 14 for SEC vs PBO (two-sided p<0.1). Secondary endpoints included, visual analogue scale (VAS) pain score, Disability of Arm, Shoulder and Hand Questionnaire (QuickDASH) score,

Figure 1.

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American Shoulder and Elbow Surgeons Shoulder Evaluation Form (ASES), EQ-SD-5L score and patient global assessment (PGA) score. All endpoints were assessed through 24 weeks.

**Results:** Clinical improvement in both SEC and PBO groups on top of SoC treatment was observed, with no statistically significant difference demonstrated in the full study population on physical symptoms and function (Table 1). Similar results were observed in the secondary endpoints with marked improvement in both groups over time. Exploratory post-hoc analyses in a subgroup of 39% of the study subjects with non-acute, moderate to severe disease, SEC provided significant and clinically relevant improvements vs PBO through Week 24 in total WORC score (overall treatment difference: 19.2, p < 0.01) and pain (VAS, overall treatment difference: 15, p = 0.02) with early effect observed after two weeks (Figure 1). A favourable treatment effect in the more severe subgroup was demonstrated in other patient-reported outcomes. No serious adverse events were reported.

**Conclusion:** Although SEC did not demonstrate a significant benefit vs PBO in the overall patient population with active overuse RC TP, SEC did provide benefit in the subpopulation with non-acute, moderate to severe disease. Larger clinical trials of SEC in this area are warranted.

**REFERENCES:**


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**Table 1. Change from baseline in the SEC versus PBO groups in WORC index and pain (VAS)**

<table>
<thead>
<tr>
<th>Visit</th>
<th>SEC 300 mg</th>
<th>PBO</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total treated population N=96</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WORC Index percentage score (0 worst - 100 best)a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 29</td>
<td>22.35</td>
<td>19.49</td>
<td>0.45</td>
</tr>
<tr>
<td>Day 99</td>
<td>37.00</td>
<td>37.77</td>
<td>0.87</td>
</tr>
<tr>
<td>Day 169</td>
<td>43.41</td>
<td>40.97</td>
<td>0.64</td>
</tr>
<tr>
<td>Pain (VAS, 0 best - 100 worst)b</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 29</td>
<td>−26.04</td>
<td>−23.13</td>
<td>0.57</td>
</tr>
<tr>
<td>Day 99</td>
<td>−46.11</td>
<td>−40.56</td>
<td>0.28</td>
</tr>
<tr>
<td>Day 169</td>
<td>−52.23</td>
<td>−50.74</td>
<td>0.78</td>
</tr>
<tr>
<td><strong>Post-hoc population</strong> N=37</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WORC Index percentage score (0 worst - 100 best)a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 29</td>
<td>30.09</td>
<td>10.84</td>
<td>0.002</td>
</tr>
<tr>
<td>Day 99</td>
<td>48.26</td>
<td>31.83</td>
<td>0.048</td>
</tr>
<tr>
<td>Day 169</td>
<td>55.98</td>
<td>35.24</td>
<td>0.028</td>
</tr>
<tr>
<td>Pain (VAS, 0 best - 100 worst)b</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 29</td>
<td>−29.20</td>
<td>−14.85</td>
<td>0.125</td>
</tr>
<tr>
<td>Day 99</td>
<td>−51.48</td>
<td>−35.37</td>
<td>0.045</td>
</tr>
<tr>
<td>Day 169</td>
<td>−57.01</td>
<td>−46.64</td>
<td>0.217</td>
</tr>
</tbody>
</table>

**Day 1: SEC 42.47, PBO 40.47; SEC 67.04, PBO 64.85; SEC 35.93, PBO 32.90; SEC 71.72, PBO 67.58.** Day 1 values are given as absolute values to describe baseline WORC/Pain status.

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**Epidemiology: Big Questions - Big studies**

**POS0021 INTERMETATARSAL BURSITIS, A NOVEL FEATURE OF JUXTA-ARTICULAR INFLAMMATION IN EARLY RHEUMATOID ARTHRITIS: RESULTS FROM A LONGITUDINAL MRI-STUDY**

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**Background:** Rheumatoid arthritis (RA) is characterised by inflammation of the synovial lining. In addition to synovitis, the tendon sheaths of small hand and foot joints are also frequently inflamed. This results in tenosynovitis, which is often missed at clinical evaluation in early RA but visible on imaging, such as MRI. A third anatomical structure surrounded by a synovial lining is formed by the intermetatarsal bursae (IMB) and is frequently inflamed. The aim of this study was to investigate the volume of IMB using MRI in early RA.

**Objectives:** To determine whether the paratendon bursitis in the forefoot (intermetatarsal bursitis, IMB) is related to the overuse tendinopathy and if it is associated with dermal and inflammatory markers.

**Methods:** A total of 37 patients with early RA (Most recent disease duration 2-6 months) were included. MRI was performed on the forefoot (T2W, T1W, Fat-Suppressed T1W, PDW, DCE-T1W, PdW, 3D T1W, 3D Fat-Suppressed T1W) and measurements of IMB volume were performed on a dedicated workstation. Results were compared with healthy controls.

**Results:** IMB volume was significantly higher in early RA patients compared to controls. A significant correlation was found between IMB volume and inflammatory markers (CRP, ESR).

**Conclusion:** IMB is a novel feature of early RA and should be further investigated in larger studies.

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**Figure 1. Post-hoc analysis of function (WORC) in the treatment groups in non-acute, moderate to severe subpopulation.**

**Legend:**

(A) Full arrows: IMB; Dotted arrow: tenosynovitis; Arrowhead: synovitis.

(B) *p* signifies the association of change in averaged IMB size with change in total RAMRIS-inflammation between 0–12 months, estimated using GEEs. IMB-decrease was statistically significantly associated with total RAMRIS-inflammation decrease at the 0.05 level.

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