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IMPACT OF METHOTREXATE ON DISEASE PATTERN IN ACTIVE PSORIATIC ARTHRITIS PATIENTS ELIGIBLE FOR A RANDOMIZED CLINICAL TRIAL WITH USTEKINUMAB: COMPARATIVE BASELINE DATA FROM MULTICENTRE INVESTIGATOR-INITIATED MUST TRIAL

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Background: Methotrexate (MTX) is a csDMARD treatment that is initiated as first-line therapy (after NSAID) in active psoriatic arthritis (PsA). Randomized clinical trials mostly require treatment failure or intolerance of csDMARD/MTX therapy before initiation of a biological treatment. We designed an investigator-initiated (IIT) randomised blinded study comparing PsA patients starting open label Ustekinumab (UST) combined with blinded MTX or placebo (PLC). Patients are stratified regarding their previous MTX therapy (continuation or discontinuation of MTX (MTX-pre-treated patients – group A) or newly initiate MTX or continue without MTX (MTX-naïve patients – group B).

Objectives: To determine disease characteristics of patients with active psoriatic arthritis regarding their skin and musculoskeletal manifestations in dependence of their MTX treatment status.

Methods: A total of 186 patients with active PsA (defined as TJC ≥ 4 , SJC ≥ 4 (68/66 joint count) and DAS28 ≥ 3.2) were screened for eligibility. At baseline (BL) 173 patients starting open label UST were randomised to receive either MTX or PLC. At Screening (SCR) and BL, demographic data, PsA and PsO disease activity (joint count (TJC/SJC), enthesitis (LEI), dactylitis (number of digits), PASI, BSA, mtNAPSI), previous medication as well as quality of life (QoL) and function (documented as PRO using DLQI, HAQ and subjects assessment of pain as visual analogue scale (VAS) was documented.

Results: Our preliminary blinded data export comprised all documented and released data for SCR and BL until Mid-January 2020 - in total 154 randomized patients. Thereof, 78 patients were randomized in group A and 76 in group B. BL characteristics were well balanced between groups (mean age A: 50.7 years vs. 46.4 in B, BMI 29 vs. 29.6 in B). More male were included in B (72% vs. 50 %). In median, patients in A had a disease duration of 2.9 y whereas duration in B was in median 0.3 y. More patients in A had failed previous biological therapy (17 to 6 in

B), discontinued due to intolerability or ineffectiveness as allowed for study inclusion. Mean DAS28 was 4.5 (moderate disease activity) for both groups and mean values for SGA, PGA were comparable (SGA: 59.1 vs 54.9 PGA: 61.4 vs. 55.6) reflecting comparable disease activity in peripheral arthritis. Mean LEI was comparable in both groups (A: 1.3 vs B: 1.1). Mean number of digits with dactylitis were slightly higher in B (0.8) than in A (0.2). Overall HAQ showed no differences (1.0 in B vs. 0.8 in A – missing data 45 and 29 resp.) and pain VAS did not differ between groups (A: 54.9mm vs. 56.6mm in B). PASI and NAPSI were higher in B at BL than in group A (PASI: 7.2 vs. 3.3, mtNAPSI 5.0 vs. 3.0) and PRO showed a higher skin disease burden experienced by MTX-naïve patients prior randomization: in DLQI more patients on MTX experience “no effect” of their skin disease on QoL (22% vs. 7%) whereas more MTX naïve patients see a “moderate” “large” to “extreme large effect” of their disease on QoL (16%, 11%, 5% in B vs. 10%, 8%, 3% in A).

Conclusion: Our results give important information about comparability of patient population on MTX or without MTX therapy eligible for biological trials. Despite a comparable disease activity in peripheral arthritis scores, skin disease activity was increased in patients without MTX compared to MTX treated patients. Number of affected digits in dactylitis was lower with MTX, whereas its impact on enthesitis seems to be neglectable.

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CARTILAGE DEGRADATION IN PSORIATIC ARTHRITIS IS ASSOCIATED WITH INCREASED SYNOVIAL PERFUSION AS DETECTED BY MAGNETIC RESONANCE IMAGING

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Background: Even though cartilage loss is a known feature of psoriatic arthritis (PsA), research is sparse on its role in the pathogenesis of PsA and its potential use for disease detection and monitoring. Using delayed gadolinium-enhanced magnetic resonance imaging of cartilage (dGEMRIC) and dynamic contrast-enhanced MRI (DCE MRI), research has shown that early cartilage loss is strongly associated with synovial inflammation in rheumatoid arthritis (RA). The aim of this study was to determine if acute inflammation is associated with early cartilage loss in small finger joints of patients with PsA.

Objectives: Is local perfusion in PsA patients measured by dynamic MRI associated to local cartilage loss?

Methods: Metacarpophalangeal (MCP), proximal interphalangeal (PIP), and distal interphalangeal (DIP) joints of 17 patients with active PsA were evaluated by high-resolution 3 Tesla dGEMRIC and DCE MRI using a dedicated 16-channel hand coil. Semi-quantitative and quantitative perfusion parameters were calculated. Images were analyzed by two independent raters for dGEMRIC indices, PsA MRI scores (PsAMRIS), total cartilage thickness (TCT), and joint space width (JSW).

Results: We found significant negative correlations between perfusion parameters (except K_{ep}) and dGEMRIC indices, with the highest value at the MCP joints (K_{trans} : $\tau = -0.54$, $p = 0.01$; K_{ep} : $\tau = -0.02$, $p = 0.90$; IAUC: $\tau = -0.51$, $p = 0.015$; Initial Slope: $\tau = -0.54$, $p = 0.01$; Peak: $\tau = -0.67$, $p = 0.002$). Heterogeneous correlations were detected between perfusion parameters and both, total PsAMRIS and PsAMRIS synovitis sub-scores. No significant correlation was seen between any perfusion parameter and JSW and/or TCT.

Conclusion: As examined by DCE MRI and dGEMRIC, there is a significant association between early cartilage loss and acute synovial inflammation in small finger joints of PsA patients.