SAT0056 RHEUMATOID ARTHRITIS MAGNETIC RESONANCE IMAGING SCORE (RAMRIS) CAN PREDICT DAS-28 THERAPY RESPONSE AFTER 6 MONTHS: RESULTS OF THE GERMAN ARTHROMARK COHORT

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Background: Remission is the ultimate goal in rheumatoid arthritis (RA). The absence of rheumatoid factors (RF) and /or anti-citrullinated protein (CCP) antibodies, no bone erosions on conventional x-rays, the presence of low disease activity, and early therapeutic intervention are established good prognostic markers. Magnetic resonance imaging (MRI) is a well evaluated imaging technic and is increasingly used in daily practice. In this study, we prospectively investigated the prognostic performance of high-field MRI and serological biomarkers 6 months after initiation of methotrexate in patients with early RA (eRA)

Objectives: To evaluate the value of high-resolution MRI of the hand as a prognostic marker for EULAR-response and remission after 6 month of MTX therapy in early RA patients

Methods: Prospective cohort study on the ArthroMark cohort using 3T MRI of the hand at baseline (V0) before initiating an MTX-therapy in eRA patients, after 3 months (V3) and after six months (V6). 28 patients (Ø 56.8 years) with RF and/or CCP positive RA and a disease duration <6 months (mean16.3 weeks) fulfilling the 2010 ACR/EULAR criteria were examined. EULAR core set of variables were recorded: patient's global assessment of overall disease activity; number of tender and swollen joints, ESR and CRP. The following biomarkers were assessed by ELISA: Dkk-1, Osteoprotegerin, IL-22, MMP-3, TNF-Alpha and Neuropeptide-Y. Remission was defined as DAS28 <2.6 according to the ACR/EULAR remission criteria. MRI-scans were analysed by using OMERACT RA-MRI scoring system (RAMRIS). To adjust for intrapersonal correlation, we calculated generalized linear mixed models with time being recognized as a confounder in pretests.

Results: A low RAMRIS subscore for erosions (p=0.019) or total RAMRIS score predicted response at V3 (p=0.03). No significant results were found for the other imaging markers assessed for response prediction at either V3 or V6. Concerning remission, low levels of RANKL at baseline were significantly associated with EULAR remission at V6 (p=0.033). The other markers assessed did not show significant results at either V3 or V6.

In multivariate analyses, response was predicted more accurately with the inclusion of either RAMRIS (p value LR-test =0.035), RAMRIS synovitis subscore at MCP-2 (p-value LR-test =0.035) or a combination of the two (p-value LR-test =0.042). Remission was more accurately predicted when RANKL was considered with low RANKL improving the chance of remission. In contrast to response-prediction, MRI did not significantly add to the prediction model for remission.

Conclusions: Low RAMRIS scores or RAMRIS synovitis subscores at MCP-2 were predictive for therapy response after 6 months in our generalized mixed model. Baseline RANKL was able to significantly predict remission. Our data suggests that MRI and/or biomarkers may aid response prediction and facilitate patient selection for intensified therapy in the future.

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SAT0057 PROSPECTIVE OBSERVATIONAL REAL-LIFE STUDY (STRATEGE) SHOWS THE EFFICACY OF TREAT-TO-TARGET STRATEGY AND METHOTREXATE MONOTHERAPY OPTIMIZATION IN PATIENTS WITH ESTABLISHED RHEUMATOID ARTHRITIS

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Background: Current guidelines consider MTX as initial gold standard treatment for patients (pts) with RA. They also propose various strategies for MTX inadequate responders, among which the most frequent are optimization of MTX therapy (alone or in combination with csDMARDs or bDMARDs).

Objectives: The objective of the trial was to explore the strategies applied in daily practice in RA pts with inadequate response to MTX.

Methods: STRATEGE was a prospective, observational, multicenter study. Main inclusion criteria were: confirmed RA (ACR 1987 or ACR/EULAR 2010 criteria) and treatment by MTX monotherapy with clinical, structural, functional and/or therapeutic evolution leading to therapeutic management modification. Data were obtained at 2 time-points: baseline and 6-month follow-up.

Results: Between Sept 2014 and July 2015, 176 rheumatologists, at 90% with private practice, included 854 pts, 801 of which composed the analyzable baseline set. Pts baseline characteristics were [mean (SD)]: age: 57.4 (13.7) yrs; RA duration: 5.3 (6.7) yrs; DAS28: 4.0 (1.1), with the following distribution: <2.6 for 10%, >3.2 for 74% and >5.1 for 16%; HAQ: 1.1 (0.84); and extra-articular features and erosive disease for respectively 10.5% and 39.9% of pts. All pts were receiving MTX monotherapy, orally for 67.6% and at mean (SD) dose of 14.2 (4.1) mg/wk for oral and 16.6 (3.8) mg/wk for parenteral administration. Concomitant treatment included corticosteroids for 45.8% of pts, at a mean (SD) dose of 8.2 (6.3) mg/d, and folic acid for 90.0%. After the inclusion visit, MTX prescription has been identically maintained (dose and route) for 28.1% of pts, interrupted for 1.9% and modified for 70.0%. Changes included dose increasing for 50.2%, dose tapering for 1.8% and a route modification for 21.4% (88.2% oral -> parenteral). After inclusion visit, MTX oral versus (vs) parenteral balance was respectively 49.8% at mean (SD) dose 16.2 (4.0) mg/wk vs 45.8%, 18.0 (3.9) mg/wk. Biologic treatment was initiated for 14.6%, in association with MTX for 95.7%. Other csDMARD treatment was initiated for 1.2% in monotherapy and for 3.6% in association with MTX. The reasons for treatment modification were mainly active RA (72.0%), worsening of clinical and biologic parameters (31.4%), radiographic progression (14.5%), remission not achieved (12.4%), steroid dependence (11.3%), and MTX intolerance 5.0%. Six-month follow-up results show that all the active treatment strategies were significantly and equally successful in improving disease activity (Table).

Table 1

	N	DAS28 Baseline	DAS28 (M6)	D DAS28	*p*
MTX unchanged (Ref.)	126	3.4 (1.3)	2.5 (1.0)*	-0.8 (1.2)	–
MTX optimization	519	4.0 (1.0)	2.9 (1.2)*	-1.1 (1.3)	0.10
bDMARDs	117	4.6 (1.1)	3.2 (1.1)*	-1.4 (1.3)	0.22
csDMARDs	39	4.3 (1.2)	3.1 (1.3)*	-1.3 (1.4)	0.37

Data presented: mean (SD). *$p<0.0001$ (M6 *vs* baseline), ANCOVA, adjusted for DAS28 at baseline.

Conclusions: Consistently with all current guidelines, results of the large prospective observational study STRATEGE reveal an important place held by initial MTX treatment optimization before initiation of a biotherapy and emphasize the importance of treat-to-target strategy.

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SAT0058 EFFECTS OF BARICITINIB ON PATIENTS WHO STOP METHOTREXATE MONOTHERAPY AND SWITCH TO BARICITINIB MONOTHERAPY

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Background: Baricitinib (bari) is a reversible oral Janus kinase (JAK) inhibitor with selectivity for JAK1/JAK2 in development for treatment of patients (pts) with active rheumatoid arthritis (RA). In the 52-week (wk) Phase 3 RA-BEGIN study of MTX-naïve pts, there were 3 arms: bari 4 mg once daily (QD), methotrexate (MTX) up to 20 mg weekly (QW), and the combination of bari plus MTX (bari+MTX). Nonresponders were rescued from week 24 onwards by receiving bari+MTX, regardless of original treatment. Bari monotherapy showed superior efficacy compared to MTX monotherapy and similar clinical efficacy to bari+MTX.

Objectives: Efficacy and safety were evaluated in pts from RA-BEGIN who switched from MTX or bari+MTX therapy to bari monotherapy upon entering the long-term extension (LTE) study (RA-BEYOND).

Methods: In RA-BEGIN, 588 pts were randomised 4:3:4 to MTX, bari monotherapy 4 mg, or bari+MTX. At Wk 52, pts could enter the LTE; all pts received bari 4 mg monotherapy. MTX could be added in the LTE by investigator decision. Seventy-seven percent of pts (451/588) enrolled in the LTE, of whom 423 had not been rescued in RA-BEGIN. This post hoc analysis evaluated clinical efficacy of pts who continued bari monotherapy compared to those in whom MTX was added within the first 24 wks of the LTE.

Results: Of these 423 pts, 200 (47%) remained on monotherapy at Wk 24 of the LTE and 223 pts started on MTX before wk 24. Most (193) had initiated MTX within 4 wks of starting the LTE study, evenly balanced from the 3 original arms of RA-BEGIN. Across study arms, pts who had MTX added in the LTE had worse disease control upon entry and during the LTE. Through 24 wks, statistically significant improvement in disease state was observed in the MTX-to-bari group regardless of whether or not MTX was added back. In the bari-to-bari monotherapy group, the addition of MTX led to lowered disease activity, which was statistically significant. No statistically significant changes in disease activity were observed in the pts who were switched from bari+MTX to bari monotherapy regardless of additional MTX therapy (Table 1). Exposure-adjusted incidence rates for total treatment-emergent adverse events, including non-serious infections, were lowest in the MTX-to-bari group. Clinically significant or consistent differences in SIE,