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SAT0109

ULTRASONIC EVALUATION OF JOINT INVOLVEMENT IN ESTABLISHED RA: ACTIVE SYNOVITIS PREDICTS SUSTAINED TREATMENT CHANGES IN SUSPECTED BIOLOGIC FAILURE

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Background: EULAR guidelines recommend treatment of rheumatoid arthritis (RA) targeted to remission.¹ Biologic switching should be considered where there is at least moderate disease activity (DAS28 >3.2). The role of ultrasound (US) in guiding treatment is perhaps less clear. D'Agostino et al have proposed a novel algorithm based on current best evidence.²

Objectives: We present a case series of 30 RA patients with perceived biologic failure. By applying the algorithm to this group of patients we reviewed the impact of musculoskeletal ultrasound findings on treatment changes when compared to DAS28 assessment alone.

Methods: All patients had US of the Backhaus 7 joints on the most affected side, and any additional symptomatic joints. A global OMERACT-EULAR synovitis score (GLOESS) was calculated for each patient.³ DAS28 was calculated at the time of US, and clinician opinion to continue or switch biologic was documented pre and post US. Patient notes were reviewed at 6 months to assess whether treatment changes were sustained.

Results: 26 patients had DAS28 >3.2. Of these, 10 were found to have GLOESS >6 and subsequently switched biologic therapy. 4 patients had DAS28 <3.2, despite clinical suspicion of persistent inflammatory disease. Of these patients, 2 were found to have GLOESS >6, and subsequently switched to an alternative biologic. At 6 months 20/24 patient's management remained consistent with previous US findings, 2 patients escalated treatment despite a previously negative US, 1 patient declined escalation (although US showed synovitis), 1 patient switched due to intolerance and 6 were lost to follow-up.

Table 1. Proposed treatment outcome (switch biologics) in symptomatic patients based on clinician opinion, DAS28 and US findings

	Clinician opinion pre-US	DAS28 at time of US	Clinician opinion post-US
Switch Biologics	23	26 (DAS28 >3.2)	12 (GLOESS>6) ^a
Don't Switch Biologics	7	4 (DAS28 <3.2)	18 (GLOESS<6)
Total	30	30	30
P value			<0.01^b, <0.01^c

^a 1 patient GLOESS <6 with severe tenosynovitis ^b Fisher's Exact test ^c Chi squared

Conclusions: US significantly reduced the need to switch treatment in this cohort of patients compared with DAS28. Longitudinal follow up supports the validity of US to determine those with active disease whilst on a biologic. The use of US may prevent over-treatment, and subsequently reduce morbidity and financial cost. Further work is needed to evaluate the clinical impact and cost effectiveness of routine US prior considering a change in biologic therapy.

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SAT0110

TRAJECTORIES OF FUNCTIONAL DISABILITY IN PATIENTS WITH EARLY INFLAMMATORY POLYARTHRITIS AND MODERATE DISEASE ACTIVITY: RESULTS FROM THE EARLY RHEUMATOID ARTHRITIS NETWORK AND NORFOLK ARTHRITIS REGISTER

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Background: A large group of patients with inflammatory polyarthritis (IP), and its subset rheumatoid arthritis (RA), have moderate disease activity, despite disease modifying therapy. Identifying patients with moderate disease who are likely to have subsequent high disability may prompt different treatment strategies for these patients.

Objectives: To identify common trajectories of disability progression in patients with moderate disease in two large prospective observational studies.

Methods: The Early Rheumatoid Arthritis Network (ERAN) recruited 1236 patients with RA (<36 months symptoms) from 23 centres in England from 2002-11. The Norfolk Arthritis Register (NOAR) recruited 1054 IP patients (<24 months symptoms) from Norfolk, England, from 2000-8. At baseline and subsequent follow-ups, functional disability was assessed using the Health Assessment Questionnaire (HAQ). Included patients scored ≥3.2 and <5.1 on the Disease Activity Score (DAS28) at either baseline, year 1 or year 2, and had previously received csDMARDs (N_{ERAN}=605; N_{NOAR}=407). Latent class growth models (LCGMs) were used to identify HAQ trajectories independently in each cohort. Age, sex, fulfilment of ACR RA criteria, symptom duration, DMARDs at baseline, and baseline

DAS28 were included as predictors of trajectory group membership using multinomial logistic regression.

Results: Baseline characteristics of the cohorts were similar (ERAN vs NOAR: mean age = 57 vs 56 years; female = 70% vs 69%; met ACR criteria = 88% vs 77%; mean DAS28 = 4.7 vs 4.2). For both cohorts, LCGM analysis indicated 4 subgroups provided best fit (Bayesian Information Criterion), with similar shaped trajectories (figure 1). Multinomial logistic regression indicated that older age (ERAN & NOAR, $p < 0.005$), female gender (ERAN & NOAR, $p < 0.01$), meeting ACR criteria (NOAR only, $p < 0.05$), use of DMARD (ERAN & NOAR, $p < 0.01$), and baseline DAS28 (ERAN & NOAR, $p < 0.005$) were related to an increased likelihood of being in a subgroup with higher disability (vs. lowest disability subgroup).

Conclusions: Four disability trajectories were observed in both the ERAN and NOAR cohort of patients with moderate disease activity. Patients on a worse trajectory who may benefit from more intensive treatment could potentially be identified earlier in the disease the group of patients with moderate disease activity.

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SAT0111 EFFICACY OF TOFACITINIB IN PATIENTS WITH MODERATE TO SEVERE RHEUMATOID ARTHRITIS BY BASELINE C-REACTIVE PROTEIN LEVELS AND ERYTHROCYTE SEDIMENTATION RATES

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Background: C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) levels are serum markers of inflammation in rheumatoid arthritis (RA). Tofacitinib is an oral JAK inhibitor for the treatment of RA.

Objectives: To investigate the impact of baseline (BL) inflammation severity, measured by CRP and ESR levels, on tofacitinib efficacy and safety.

Methods: Data were analysed from tofacitinib studies in patients (pts) with RA and prior inadequate response (IR) to conventional synthetic (cs) or biologic (b) DMARDs, who initiated tofacitinib 5 or 10 mg BID as monotherapy or with csDMARDs, mainly methotrexate. Data were pooled from 4 Phase 2 trials (NCT00413660; NCT00550446; NCT00603512; NCT00687193) and 5 Phase 3

randomised, double-blind, placebo-controlled trials (ORAL Scan [NCT00847613]; ORAL Solo [NCT00814307]; ORAL Sync [NCT00856544]; ORAL Standard [NCT00853385]; ORAL Step [NCT00960440]). Analyses were stratified by BL CRP and ESR levels (tertiles) separately. Efficacy analyses at Month 6 (M6) included ACR20/50/70 response rates and changes from BL in CDAL, DAS28-4 (ESR) and SDAI. Summary/descriptive statistics were provided. Adverse events (AEs) to M6 were summarised. Results were not adjusted for multiplicity.

Results: A total of 2161 pts were included in the csDMARD-IR group (grp) and 512 pts in the bDMARD-IR grp. Pt BL characteristics were generally similar between grps and across CRP and ESR tertiles, except that a numerically higher proportion of csDMARD-IR pts were Asian and RA disease duration was numerically shorter for csDMARD-IR pts vs bDMARD-IR pts. In both dose grps, ACR20/50/70 response rates at M6 were generally numerically higher in the highest BL CRP grp for csDMARD-IR and bDMARD-IR pts (figure 1). Generally, a trend for greater improvement from BL in disease activity at M6 was observed with higher BL CRP. Trends across endpoints were less clear when stratified by BL ESR (data not shown). Proportions of pts with AEs, serious AEs, serious infections and discontinuations due to AEs to M6 were generally similar regardless of BL CRP or ESR.

Figure 1. ACR20/50/70 response rates at Month 6 for tofacitinib 5 and 10 mg BID by baseline CRP concentrations (mg/L) in A) csDMARD-IR and B) bDMARD-IR pts

Conclusions: While efficacy outcomes in csDMARD-IR and bDMARD-IR pts with RA were improved after 6 months with tofacitinib 5 and 10 mg BID across all BL CRP/ESR tertiles, this post hoc analysis suggests that ACR response rates and disease activity improvements may be numerically greater in the highest BL CRP tertile, especially in bDMARD-IR RA pts. This trend was less clear with BL ESR. The tofacitinib safety profile was generally similar regardless of BL CRP or ESR, although changes in selected laboratory parameters have previously been associated with BL CRP following tofacitinib treatment.¹ These results suggest that subsets of pts with particularly good responses to therapy may be identified, but need further investigation.

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