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THU0099

DEVELOPMENT OF A NEW PATIENT-GENERATED OUTCOME MEASURE TO IDENTIFY DISEASE-SPECIFIC DISTRESS IN PEOPLE WITH RHEUMATOID ARTHRITIS

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Background: Rheumatoid Arthritis (RA) is a progressive inflammatory disease which causes pain, joint damage and disability. Patients with RA may experience psychological distress in addition to their physical symptoms. They may also experience disease-specific distress (DSD), which is related to the burden of living with their life-long illness. This phenomenon has been identified in patients with other long-term conditions, e.g. cancer, Irritable Bowel Disease, and Diabetes. In type 1 and 2 diabetes elevated DSD is associated with poorer clinical outcomes, and effective interventions can reduce diabetes distress. Patient involvement in the development of patient generated outcome measures (PGOM's) is important, as they may have different perspectives about their health condition that researchers and/or health care professionals may not have considered. Previous secondary data analysis of patient interviews has suggested that DSD does seem to exist in people with RA, as an entity distinct from other forms of psychological difficulties.

Objectives: The aim of this study was to develop a PGOM, based on previously reported domains of distress, to identify DSD in people with RA for use in clinical and research practice. The study aimed to involve patients in the development of the new outcome measure.

Methods: A three-phase qualitative study was conducted. In Phase 1 items were generated from secondary data analysis of patient interviews. In Phase 2, a focus group of people with RA were consulted with the aim to establish initial face and content validity of the measure and perform item reduction. In Phase 3, individual cognitive interviews (n=9) with people with RA were conducted to further establish face and content validity of the Scale, refine items if necessary and ensure the questionnaire 'made sense' to participants. A psychometrician was consulted to consider the development of the new Scale.

Results: In Phase 1, 44 items were initially created to form the Rheumatoid Arthritis Distress Scale (RADS). After Phase 2 and 3 focus group and cognitive interviews respectively, items were reduced from 44 to 39 and three additional supplementary questions were created, to include items such as time since diagnosis and disease activity. Dimensions were classified into five domains of RA distress. Overall participants reported the content of the RADS to be clear and relevant, and that DSD is a valid concept in RA, distinct from clinical depression or anxiety

Conclusion: DSD appears to be an important concept in RA. The 39-item RADS currently demonstrates acceptable face and content validity in this patient group. It may be beneficial to establish face and content validity in a more diverse patient sample before proceeding with further psychometric testing. The RADS may be a useful tool for healthcare professionals to identify DSD in patients with RA. Direct patient involvement and their commitment have been instrumental in the development of new outcome measures.

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THU0100

PHYSICAL FUNCTION IN RA PATIENTS IN REMISSION UNDERGOING TAPERING AND/OR STOPPING OF DMARDS

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Background: Several studies including our own RETRO study have shown that tapering or stopping disease modifying anti-rheumatic drugs (DMARDs) in rheumatoid arthritis (RA) patients in sustained remission is feasible (1-3). However, tapering/stopping bears the risk of decline in physical function as some patients may relapse and face increased disease activity.

Objectives: Here we analysed the impact of tapering or stopping DMARD treatment on the physical function of RA patients, who were randomized into continuation, tapering or stopping DMARD treatment in the RETRO study.

Methods: RETRO is a multicentre, parallel-group phase 3 trial in which RA patients in stable DAS-28-ESR remission were randomized to (i) DMARD tapering, (ii) stopping DMARDs after a 24-week-taper or (iii) control strategy that continued DMARDs.^{1,2,3} HAQ and DAS-28 scores were measured at 0, 3, 6, 9 and 12 months.^{1,2} Functional worsening was defined as a HAQ increase of ≥ 0.25 . We calculated incidences of functional worsening (per 100 person-months) in each treatment group with 95% Poisson confidence intervals and plotted event-free survival by treatment arm. The effect of treatment reduction strategy on functional worsening was assessed in a recurrent-event Cox regression model with control, taper or taper/stop group as the predictor.

Results: 201 patients were analysed. In 44 patients functional worsening was observed. Incidence (95%CI) of functional worsening was in the control 1.48 (0.77-2.59), taper 1.74 (0.95-2.92) and taper/stop arm 1.96 (1.16-3.10). The incidences suggest higher probability of functional worsening in tapering and/or stopping DMARDs, however at the end of study, functional worsening was similar among the groups (Figure). Thus, in comparison to the control group, hazard ratio (HR) (95%CI) for functional worsening was 1.21 (0.56 -2.62) in the taper arm and 1.32 (0.76-2.60) in the taper/stop arm.

Conclusion: Point estimates and survival curves show that functional decline after tapering or stopping DMARDs in RA patients with stable remission is small. Although the incidence figures suggest a trend these results do not reject with good certainty the null hypothesis of no worsening in functional status.

Abstract THU0100 – Figure 1.

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THU0101 TORQUE TENO VIRAL LOAD FOR MONITORING OF BIOLOGICAL THERAPIES IN RHEUMATOID ARTHRITIS

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Background: The apathogenic and highly prevalent Torque Teno Virus (TTV) is associated with the immunocompetence of its host and has been proposed for immunologic monitoring in solid organ transplantation.

Objectives: Herein we explore TTV levels in rheumatoid arthritis (RA) patients receiving biological disease-modifying anti-rheumatic drugs (bDMARDs) in the context of clinical response.

Methods: The BIOBIO study was designed to evaluate biomarkers for prediction of clinical response in patients with RA. Within this multicentre open-label trial, patients with insufficient response to MTX were randomized to TNFi (infliximab; INF), anti-IL-6 receptor (tocilizumab; TCZ), CTLA4-Ig (abatacept; ABA) or anti-CD20 (rituximab; RTX) in addition to MTX. TTV in peripheral blood samples was quantified at baseline and 3 months by RT-PCR.

Results: TTV was measured in 95 RA patients [INF (n=23), TCZ (n=22), ABA (n=27) or RTX (n=23)]. Median TTV levels at baseline were 4.2×10^4 c/ml with no difference between the treatment groups. After 3 months of treatment patients with INF (p=0.018), ABA (p=0.071) and RTX (p<0.001) showed an increase in TTV levels compared to baseline. There was no change in TTV in patients with TCZ, who were omitted from further analyses. TTV at 3 months after treatment was higher in patients achieving a SDAI85 response at month 6 (p=0.019). Levels of above 5.6×10^5 c/ml at month 3 showed a 67% specificity and 81% sensitivity for a SDAI85 response at month 6, corresponding to a positive likelihood ratio of 2.6

(95% CI: 1.6-4.1). Patients in the top tertile of month 3 TTV ($>7.8 \times 10^5$ c/ml) had lower SDAI, CDAI and DAS28 and higher SDAI85 response rates at month 6 (OR: 4.18, CI: 1.41-16.42; p=0.012). The highest non-response rates were found in patients within the lowest TTV tertile (Table A), and the highest remission rates were found in the highest TTV tertile (Table B). No patient below a TTV value of 2.7×10^4 c/ml at month 3 showed SDAI85 treatment response at month 6.

Conclusion: Our data suggest that TTV levels in patients with RA treated with INF, ABA or RTX at month 3 are associated with clinical responses at month 6, and thus may constitute a biomarker for therapeutic monitoring.

Abstract THU0101 –Table 1.

A	No response					Total
	SDAI50	SDAI70	SDAI85	SDAI85	SDAI85	
LTIV	43.8%	37.5%	18.8%	0.0%	100%	
MTTV	15.8%	42.1%	26.3%	15.8%	100%	
HTTV	27.3%	18.2%	18.2%	36.4%	100%	

B	Disease Activity States				Total
	HDA	MDA	LDA	REM	
LTIV	25.0%	31.3%	43.8%	0.0%	100%
MTTV	5.0%	35.0%	40.0%	20.0%	100%
HTTV	17.4%	26.1%	21.7%	34.8%	100%

Cross-tables: A – Left: depicting distribution of patients in different SDAI response categories at 6 months (non-overlapping) by tertiles of TTV at 3 months (LTIV: low tertile; MTTV: middle tertile; HTTV: high tertile). B – Right: depicting distribution of patients in different disease activity states at 6 months (HDA=high disease activity; MDA=moderate disease activity; LDA=low disease activity; REM=remission) by tertiles of TTV at 3 months

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THU0102 PATIENT DISEASE TRAJECTORIES IN BARICITINIB-TREATED PATIENTS WITH RHEUMATOID ARTHRITIS AND INADEQUATE RESPONSE TO METHOTREXATE

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Background: In RA-BEAM phase 3 study, baricitinib (bari) 4mg demonstrated clinical efficacy in patients (pts) with rheumatoid arthritis (RA) and an inadequate response to methotrexate. Bari, a selective Janus kinase 1/2 inhibitor, is approved for the treatment of moderate to severe active RA in adults in >50 countries. For improved treatment strategy, it is important to understand whether the pt population is composed of distinct pt groups with differing treatment responses and associated baseline characteristics.

Objectives: To identify different treatment trajectories, based on CDAI improvement, in bari 4mg treated pts over 52 weeks; and examine the associated clinical disease measures, structural damage score and baseline characteristics.

Methods: Growth Mixed Model (GMM), a novel latent class mixed model, was used to classify the longitudinal disease patterns instead of