

Conclusions: ILD is a serious complication in RA with a significantly increased mortality compared with a large matched cohort of RA comparisons without ILD.

Disclosure of Interest: None declared

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FRI0175 USING SMARTPHONES TO IMPROVE REMOTE MONITORING OF RHEUMATOID ARTHRITIS: COMPLETENESS OF PATIENTS' SYMPTOM REPORTS

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Background: Clinical decisions about management of rheumatoid arthritis (RA) happen at intermittent clinic visits. In the absence of objective measures of disease severity between visits, understanding fluctuating disease severity largely relies on patients' symptom reports, and thus on patients' recall, eloquence, stoicism and willingness to discuss symptoms.

The Remote Monitoring of Rheumatoid Arthritis (REMORA) study aims to improve monitoring of disease severity in RA. Patients, clinicians and researchers co-designed a smartphone app to enable RA patients to report daily symptoms in between clinic visits with data integrated into the electronic health record. The data presented here were collected as part of the REMORA feasibility evaluation. **Objectives:** To evaluate the completeness of patient-reported symptom data submitted through the REMORA smartphone app over three months.

Methods: We invited 23 RA patients treated at the outpatient clinic of Salford Royal Foundation Trust (UK) to record their symptoms for three months using the REMORA smartphone app. Participants received notifications to record: daily scores for the seven items of the RA Impact of Disease score, as well as morning stiffness on a scale from 0 to 10; weekly scores for thirteen items on 28 tender and swollen joint self-assessments, global assessment, impact on work and activity, and flare occurrence; and monthly scores for the Health Assessment Questionnaire (HAQ) 20-item disability scale. We calculated the time that participants were in the study as the number of days between the first and last day of submitting daily scores. We then explored patterns of data entry, as well as entry completeness.

Results: Twenty patients accepted the invitation to participate. Eight (40%) were male, all but one were white British, and their mean age was 56.9±11.1 years. The median number of days in the study was 82 (interquartile range [IQR], 80 to 82). While being in the study, participants submitted daily scores on almost all days (median, 91% of days; IQR, 78 to 95), with four doing this on <60% of study days. Across participants, almost all of 1325 daily entries were complete, with only nine (<1%) having missing values for up to two individual items. Participants submitted weekly scores for a median of 11 out of 13 weeks (IQR, 10 to 12). Of all 213 weekly entries, fifteen (7%) had missing values, but never more than two. Lastly, 8/20 participants provided monthly HAQ scores only once, while a further 9/20 and 3/20 participants did this for two and all three months, respectively. No monthly entries had any missing values.

Conclusions: Our feasibility study showed that smartphones have the potential to support collection of daily patient reports of symptoms with high levels of completeness over three months. Lengthier monthly question sets were less likely to be completed compared to briefer daily and weekly ones. Future steps include exploring methods for adapting data entry frequency to (fluctuations in) disease severity in order to support sustained symptom reports over longer time periods and in a wider group of patients.

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FRI0176 CORRELATION BETWEEN DISEASE ACTIVITY AND MENTAL HEALTH IN CHINESE PATIENTS WITH RHEUMATOID ARTHRITIS-ASSESSMENT WITH SMART SYSTEM OF DISEASE MANAGEMENT (SSDM) MOBILE TOOLS

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Background: Rheumatoid arthritis (RA) patients can cause joint swelling and

tenderness, and affect the patient's mental health. Previous studies showed that 13–47% of RA patients suffered from anxiety and/or depression. Hospital anxiety and depression scale (HADS) is usually used to evaluate patients' mental health, which consists of 14 items divided into an anxiety subscale (HADS-A) and a depression subscale (HADS-D). Disease activity score in 28 joints (DAS28) is one of the most used tool to assess RA patients' disease activity. Both HADS and DAS28 assessments were commonly led by health professionals with paper questionnaire. This study applies the mobile platform of Smart System of Disease Management (SSDM) for evaluating DAS28 and HADS by RA patients.

Objectives: The purpose of this study is to describe the morbidity of mental comorbidity in Chinese patients with RA and analyze the potential association among DAS28 and HADS.

Methods: SSDM is a mobile application includes physicians' and patients' interfaces. The patient's terminal system includes self-assessment (DAS28, HADS), lab test results and medication management. After data entry, patients can synchronize data to the mobile terminal of their authorized rheumatologist. A cohort study was conducted with patients who were diagnosed with RA in tertiary hospital across China. All participants self-assessed both DAS28 and HADS with SSDM at least one time. Descriptive statistics were performed for patient and disease characteristics, assuming normality for DAS28 distribution and the level of disease activity was analyzed using Pearson's statistics. One-way analysis of variance was employed to explore for difference between sub-groups. Bivariate correlation and linear logistic analysis were employed to explore for potential correlation between DAS28 and HADS.

Results: From June 2016 to January 2017, 230 patients (male 66, female 164) from 12 hospitals performed 311 times HADS and 517 times DAS28 self-assessment. The mean (±SD) age was 34.17±13.11 (11–71) years, with the median disease duration of 24.70 (0–572) months. As the standard of HADS score higher than 10, 31% and 37% patients could be diagnosed as anxiety and depression respectively. According to the DAS28 assessment results, the proportion of patients with remission, low disease activity, moderate activity and high activity were 18%, 19%, 46% and 18% respectively. Bivariate correlation showed that DAS28 was positively correlated with HADS, $p < 0.001$. Both HADS-A and HADS-D showed linear regression association with DAS28 score, the regression equation as "HADS-A = 5.962 + 0.435*DAS28" and "HADS-D = 6.379 + 0.694*DAS28" respectively, $p < 0.001$.

Conclusions: DAS28 was positively correlated with HADS. SSDM is an effective mobile interface to serve for RA patients performing self-management of both disease activity and mental health as well as to supply physicians with valuable data.

Disclosure of Interest: None declared

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FRI0177 THE UNDERRATED PREVALENCE OF DEPRESSION IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Significant evidence in the scholarly literature suggests that depression is a common comorbidity among patients with rheumatoid arthritis (RA) (1) Comorbid depression in RA patients is especially troublesome because it often goes unrecognized and untreated (2) often because rheumatologists and their patients seldom communicate about depression (3). In addition, evidence of depression in RA patients is limited in Asia studies.

Objectives: To determine the prevalence of depression among patients with RA and explore the relationships between depression and an array of variables.

Methods: Cross-sectional online survey (n=500) of RA patients including the Patient Health Questionnaire [PHQ-9] (4) to measure the presence and severity of depressive symptoms were performed. The survey contained patient demographic, clinical characteristics such as functional impairment as assessed using the Japanese version of the Stanford Health Assessment Questionnaire (J-HAQ score), and the participant's current medical treatment. Ordered logistic regression was used to identify the determinants of depression conditions among survey respondents.

Results: The mean age of the 500 patients with RA was 54.3 years old and 67% were female. While only 25 (5%) of the population studied had been officially diagnosed with depression, 176 (35%) had PHQ-9 scores indicating depression was present. Comorbidity conditions, except for migraine and heart conditions, were not different between patients with depression and those without. Logistic regression analysis revealed a negative correlation between the prevalence of depression and younger age with odds ratio (OR) of 0.96 (95% confidence interval (CI); 0.93–0.98), higher education (OR, 0.60; 95% CI, 0.36–0.98 for a bachelor's degree or higher) and an income level of 0.8–1.6 million yen (OR, 0.45; 95% CI, 0.22–0.91). Positive correlations with depression was found in RA patients with high J-HAQ score (OR, 1.99; 95% CI, 1.47–2.71). Patients treated with biologic monotherapy were significantly less likely to have depression compared to those treated with non-biologic anti-rheumatic drugs (OR, 0.36; 95% CI, 0.17–0.75).

Conclusions: It is a potential risk of under-diagnosis and under-reporting of Depression in patients with RARA patients are more likely to experience depression if they are younger, have greater functional impairment, or whose treatment regimen includes pain medications without biologic drugs.

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Rheumatoid arthritis - anti-TNF therapy

FRI0178 RITUXIMAB IS EFFECTIVE IN THE TREATMENT OF RHEUMATOID ARTHRITIS REGARDLESS OF BODY MASS INDEX

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Background: High body mass index (BMI) is known to be associated with inadequate clinical response to anti-TNF agents in rheumatoid arthritis (RA) patients.¹ However, there are limited data on the effect of high BMI on the response to rituximab in RA patients, who showed an inadequate response or intolerance to anti-TNF agents.
Objectives: To investigate the impact of BMI on clinical response in the post-hoc analysis of randomized controlled trial that demonstrated clinical equivalence between a biosimilar of rituximab, CT-P10 and innovator rituximab, RTX² (NCT02149121).
Methods: A total of 332 patients who received two courses of either CT-P10 or RTX were included in this analysis. Patients were classified into 3 groups; normal weight (<25kg/m²), overweight (≥25 kg/m² ~<30 kg/m²) and obesity (≥30 kg/m²) as per WHO BMI category. Improvement in disease activity by the Disease Activity Score using C-reactive protein (DAS28-CRP), remission (≤2.6), low disease activity rate (LDA, ≤3.2) and ACR response at Week 24 (Week 24 of 1st course) and Week 48 (Week 24 of 2nd course) and duration of sustained LDA (from the first LDA observed to the last LDA observed up to Week 48) were analysed by BMI categories in the each and combined group of CT-P10 and RTX.
Results: In the pooled group of CT-P10 and RTX, the mean weights were 59 kg in normal weight, 73kg in overweight and 91kg in obesity. All other baseline characteristics were comparable among BMI groups including baseline disease activity based on DAS28; Moderate disease activity, 22.3% vs. 22.8% vs. 25.7%, respectively; High disease activity, 77.7% vs. 77.2% vs. 74.3%, respectively. There was no statistical difference among BMI groups in terms of DAS28 change from baseline and ACR 20/50/70 response (Table). No particular trend was observed in remission and LDA rate by DAS28 at Week 24 and Week 48 among BMI groups (Figure). Mean duration of sustained LDA (months) were also comparable

Table 1. DAS28, ACR responses by BMI subgroups

| Parameter | Visit | Normal (N=148) | Over weight (N=114) | Obesity (N=70) |
|------------------|----------|----------------|---------------------|----------------|
| DAS28, mean (SD) | Baseline | 5.88 (0.95) | 5.81 (0.89) | 5.69 (0.78) |
| | Week 24* | -2.43 (1.12) | -2.13 (1.19) | -2.39 (0.99) |
| | Week 48* | -2.76 (1.31) | -2.47 (1.32) | -2.74 (1.01) |
| ACR20, n (%) | Week 24 | 122 (82.4%) | 86 (75.4%) | 56 (80.0%) |
| | Week 48 | 119 (80.4%) | 88 (77.2%) | 60 (85.7%) |
| ACR50, n (%) | Week 24 | 80 (54.1%) | 56 (49.1%) | 39 (55.7%) |
| | Week 48 | 76 (51.4%) | 62 (54.4%) | 43 (61.4%) |
| ACR70, n (%) | Week 24 | 51 (34.5%) | 33 (28.9%) | 21 (30.0%) |
| | Week 48 | 47 (31.8%) | 36 (31.6%) | 26 (37.1%) |

*Change from baseline.

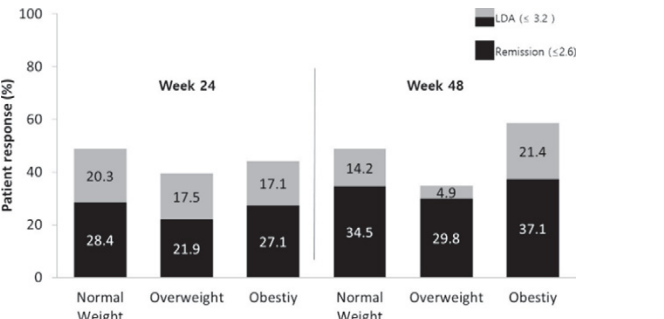


Figure 1. Remission and LDA by DAS28 by BMI group.

among the groups (4.5 vs. 4.7 vs. 5.0, respectively). Additionally, similar trends in all analyses were observed in each treatment group; CT-P10 and RTX.
Conclusions: The BMI does not affect the clinical response in RA patients with rituximab treatment. Therefore, this result supports that rituximab could be a reasonable therapeutic option for obese RA patients with inadequate response to anti-TNF agents.
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FRI0179 MINIMAL TO NO TRANSFER OF CERTOLIZUMAB PEGOL INTO BREAST MILK: RESULTS FROM CRADLE, A PROSPECTIVE, POSTMARKETING, MULTICENTER, PHARMACOKINETIC STUDY

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Background: Women with active chronic rheumatic inflammatory conditions (RA, PsA, AxSpA) often face uncertainty regarding the safety of the use of biologics during breastfeeding.¹ Limited and non-validated data exist on the potential transfer of anti-TNFs into breast milk.² CRADLE (NCT02154425) was the first sponsored study to evaluate certolizumab pegol (CZP) concentrations in breast milk, and to estimate the Average Daily Infant Dose (ADID) of maternal CZP.
Objectives: To determine the concentration of CZP in breast milk and calculate the ADID of maternal CZP.
Methods: CRADLE was a pharmacokinetic study of lactating mothers (≥6 weeks postpartum) receiving commercial CZP. Decision to treat with CZP and breastfeed was independent of study participation. At steady state (≥3 CZP doses), breast milk samples were collected on Days 0, 2, 4, 6, 8, 10, 12, 14 (±28) from each mother across 1 dosing period. CZP was detected using a highly sensitive, CZP-specific electrochemiluminescence immunoassay validated in milk (lower limit of quantification [LLOQ]=0.032 µg/mL; 10-fold lower than previous assays). CZP stability in milk was confirmed.
Results: 18 CZP-treated mothers were screened: 17 entered the sampling period; 16 on CZP 200 mg Q2W; 1 on CZP 400 mg Q4W (7 RA; 5 SpA; 5 CD; Table A). Samples from 4/17 mothers had no measurable CZP in breast milk; 13/17 had quantifiable levels for at least 1 time point (highest concentration: 0.076 µg/mL; Table B). Estimated ADID ranged 0–0.0104 mg/kg/day; median Relative Infant Dose (RID; calculated post hoc³): 0.15%. Infants of CZP-exposed mothers had a

Table A: Baseline characteristics of mothers and infants

| Mean (SD), unless otherwise stated | All mothers (N=18) [a] |
|--|------------------------|
| Age, years | 33.7 (4.2) |
| Weight, kg | 68.9 (9.6) |
| BMI, kg/m ² | 23.6 (3.0) |
| Indication for CZP treatment, n [b] | |
| Rheumatoid arthritis | 7 |
| Psoriatic arthritis | 3 |
| Axial spondyloarthritis/ankylosing spondylitis | 2 |
| Crohn's disease | 5 |
| Infant age at mother's first sample, n (%) | All infants (N=17) |
| ≤6 months | 13 (76.5) |
| >6 months–≤12 months | 2 (11.8) |
| >12 months–≤18 months | 2 (11.8) |

[a] Includes 1 screen failure; [b] n=17.

Table B: Concentrations of CZP (µg/mL) in breast milk

| Mother no. | 0 | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 28 |
|------------|-------|-------|-------|-------|-------|-------|-------|-------|----|
| 5 | 0.056 | 0.069 | 0.074 | 0.076 | 0.076 | 0.069 | 0.069 | 0.06 | – |
| 1 | 0.067 | 0.061 | 0.066 | 0.065 | 0.062 | 0.056 | 0.052 | 0.041 | – |
| 9 | 0.039 | 0.04 | 0.047 | 0.045 | 0.042 | 0.043 | 0.038 | 0.035 | – |
| 3 | BLO | 0.032 | 0.049 | 0.053 | 0.037 | 0.037 | 0.033 | 0.033 | – |
| 16 | 0.04 | 0.033 | 0.036 | 0.037 | 0.043 | BLO | BLO | BLO | – |
| 11 | BLO | BLO | 0.051 | 0.038 | 0.042 | BLO | 0.033 | BLO | – |
| 2 | BLO | BLO | 0.035 | 0.037 | 0.041 | BLO | 0.043 | BLO | – |
| 15 | BLO | BLO | 0.041 | 0.034 | 0.033 | BLO | 0.037 | BLO | – |
| 10 | BLO | BLO | BLO | 0.033 | 0.042 | 0.042 | BLO | BLO | – |
| 8 | BLO | BLO | 0.035 | 0.034 | 0.043 | BLO | BLO | BLO | – |
| 12 | BLO | BLO | 0.034 | 0.037 | 0.033 | BLO | BLO | BLO | – |
| 6 | BLO | BLO | 0.044 | 0.048 | BLO | BLO | BLO | BLO | – |
| 7 | BLO | BLO | BLO | BLO | BLO | 0.035 | BLO | BLO | – |
| 4 | BLO | BLO | BLO | BLO | BLO | BLO | BLO | BLO | – |
| 13 | BLO | BLO | BLO | BLO | BLO | BLO | BLO | BLO | – |
| 14 | BLO | BLO | BLO | BLO | BLO | BLO | BLO | BLO | – |
| 17 | BLO | BLO | BLO | BLO | BLO | BLO | BLO | BLO | – |

BLO: below the lower limit of quantification; LLOQ: lower limit of quantification.

Less than 3xLLOQ (<0.096 µg/mL)
Less than 2xLLOQ (<0.064 µg/mL)
BLO (<0.032 µg/mL)
CZP plasma C_{trough} from the RAPID2 study: 15.7 µg/mL