Association between DAS28 CRP and anti-CarP Ab
Also while 39 of 71 (54.9%) anti-CarP Ab positive RA cases had joint deformities and 23 of 71 (32.4%) of anti-CarP Ab positive cases had extra articular involvement and were statistically significant, 27 of 71 anti-CarP Ab positive cases showed joint erosions in X-ray but was not statistically significant.
In comparison, only extra articular involvement showed a statistical significance in ACCP positive patients whereas joint deformities and joint erosions on X-rays showed no correlation to ACCP.

### Conclusion
Anti-Carp antibody positivity is indicative of increased disease activity (DAS28-CRP score), joint deformities and extra articular involvement in RA patients. Aside from its presence demonstrated early in the course of RA through other studies, its ability in diagnosing RA cases in otherwise seronegative (RF and ACCP negative) population and the high sensitivity, specificity and diagnostic accuracy exhibited paves the way for its routine use as a diagnostic tool in conjunction with RF and ACCP for diagnosing RA and predicting disease outcome.

### References

### Disclosure of Interests
None declared
DOI: 10.1136/annrheumdis-2020-eular.5420

---

**THU0114**

**CERTOLIZUMAB PEGOL IN PATIENTS WITH RHEUMATOID ARTHRITIS: POOLED EFFICACY ANALYSIS OF PHASE 3 CLINICAL TRIALS ACROSS BASELINE RHEUMATOID FACTOR QUARTILES**

V. Tanaka1, Z. Li2, N. Inanc3, R. Xavier4, N. Till5, C. Cara6, C. Saadoun6, T. Takeuchi7. 1University of Occupational and Environmental Health, First Department of Internal Medicine, Kitakyushu, Japan; 2Peking University People’s Hospital, Department of Rheumatology & Immunology, Beijing, China; 3Marmara University School of Medicine, Division of Rheumatology, Istanbul, Turkey; 4Federal University of Rio Grande do Sul, Rheumatology Service, Porto Alegre, Brazil; 5UCB Pharma, Brussels, Belgium; 6Keio University, Division of Rheumatology, Tokyo, Japan

**Background:** The presence of rheumatoid factor (RF) in patients (pts) with rheumatoid arthritis (RA) is associated with higher disease activity, and is regarded as a risk factor for more aggressive RA. Most studies on anti-tumour necrosis factor (TNF) monoclonal antibodies such as infliximab, etanercept and adalimumab have shown better response in pts with negative versus positive and low versus high baseline RF titres. 2,3 Certolizumab pegol (CZP), a PEGylated, Fc-free antibody, has shown rapid and sustained reduction in signs and symptoms of RA patients.

**Objectives:**Certolizumab pegol (CZP), a PEGylated, Fc-free antibody, has shown rapid and sustained reduction in signs and symptoms of RA patients.

**Methods:**We conducted a post-hoc, pooled analysis of 12,326 pts with active RA enrolled in 12 phase 3 trials of CZP and infliximab (IFX). The analysis was performed across baseline RF (0, 1, 2 or ≥3) and ACP (0, 1, 2 or ≥3) quartiles.

**Results:**We pooled the data from 12 phase 3 trials of CZP and IFX. 10,996 pts had evaluable RF and ACP data. Cochrane’s Q test indicated heterogeneity across trials (p < 0.001). Meta-analysis showed significant differences between quartiles for baseline RF and ACP (p < 0.001) in the pooled analysis. The heterogeneity across trials was explained by clinicaland methodological differences.

**Conclusion:**We conducted a post-hoc analysis of data from 12 phase 3 trials of CZP and IFX. The analysis was performed in a large pool of pts with active RA to assess the differences in efficacy across baseline RF and ACP quartiles. CZP showed significant differences between quartiles for baseline RF and ACP, but the heterogeneity across trials was explained by clinical and methodological differences.
The efficacy of CZP in pts with different baseline RF levels has not been studied. Objectives: To assess the efficacy of CZP, as measured by Disease Activity Score 28-erythrocyte sedimentation rate (DAS28[ESR]), in pts with active RA across baseline RF levels.

Methods: In this post-hoc analysis, data were pooled from four clinical trials of CZP in RA: two global trials (RAPID 1, NCT00152386 and RAPID 2, NCT00175877), a Japanese trial (J-RAPID, NCT00791999) and a Chinese trial (RAPID-C, NCT02016158). Pts ≥18 years with active RA for ≥6 months (defined by ACR 1987 criteria), who received MTX for ≥6 months (≥3 months for RAPID-C) prior to baseline, were randomised 1:1 to receive placebo (PBO) every two weeks (Q2W)/CZP 400 mg Q2W/CZP 200 mg Q2W (CZP 400 mg at Weeks [Wks] 0/2/4) plus MTX for at least 24 Wks. Complete study design and pt characteristics were reported previously. Here we include only pts who received CZP 200 mg Q2W (CZP 400 mg at Wks 0/2/4). RF titers were measured by validated assays in local hospital laboratories. Pts were stratified into quartiles based on pooled baseline RF levels: ≤25.0, <78.5, ≤207.0 and ≥207.0 IU/mL. DAS28[ESR] categories were adopted to stratify pts: remission (REM), DAS28[ESR] ≤2.6; low disease activity (LDA), DAS28[ESR] ≤3.2. Missing values were imputed using last observation carried forward.

Results: Data were pooled from 1,017 and 504 pts in the CZP 200 mg Q2W and PBO Q2W groups, respectively. At baseline, mean (SD) DAS28[ESR] was similar with PBO vs CZP across RF quartiles (6.5 [9.0] – 7.0 [9.0] vs 6.6 [9.0] – 7.0 [9.0]). Compared with the PBO group, numerically higher DAS28[ESR] REM and LDA rates were observed for CZP 200 mg Q2W group at Wk 24 across RF quartiles (Figure 1). DAS28[ESR] REM and LDA responder rates increased to Wk 24 in pts treated with CZP. In general, LDA and REM rates were similar across RF quartiles at all timepoints (Figure 2).

Conclusion: Over 24 Wks of treatment, trends showed steady efficacy of CZP across baseline RF quartiles in pts with active RA. In this pooled post-hoc analysis, efficacy of CZP appeared to be consistent and independent of RF levels; observed efficacy may be related to the unique molecular structure of CZP. CZP treatment in association with MTX may be a feasible option in pts with RA regardless of baseline RF status.

References:

Acknowledgments: This study was funded by UCB Pharma. Editorial services were provided by Costello Medical, Singapore.

THU0115

THE VALUE OF KL-6 AS A PREDICTIVE FACTOR OF ACUTE EXACERBATION IN PATIENTS WITH RHEUMATOID ARTHRITIS-ASSOCIATED INTERSTITIAL LUNG DISEASE.

N. Tanaka1, K. Nishimura1, D. Waki1, K. Kadoba1, T. Yoshida1, H. Murabe1, T. Yokota1, T. Kurashiki Central Hospital, Department of Endocrinology and Rheumatology, Okayama, Japan

Background: Acute exacerbation (AE) is a life-threatening complication in connective tissue disease (CTD) associated interstitial lung disease (ILD) (CTD-ILD), including rheumatoid arthritis (RA). Although several risk factors for AE in CTD-ILD have been suggested, these are inconsistent. Krebs von den Lungen-6 (KL-6) is reported as a useful blood marker to detect severe CTD-ILD and RA-ILD, and serum KL-6 levels are significantly higher in patients with AE than in those without AE in RA-ILD patients [1]. However, the predictive value of KL-6 for AE in CTD-ILD or RA-ILD has not been completely confirmed.

Objectives: To investigate the predictive factors for AE including initial serum KL-6 levels at RA-ILD onset and sequential changes of KL-6. We also examined the causal relationship between AE and mortality of RA-ILD patients.

Methods: We retrospectively reviewed 115 patients with RA-ILD treated in our hospital between 2005 and 2019. Suspected drug-induced pneumonia cases or patients with other coexisting CTD were excluded. Cox regression analyses were used for univariate analysis to detect predictors of AE. Overall survival rate, respiratory-related deaths-free survival rate and AE-free survival rate were analyzed using the Kaplan-Meier method. P < 0.05 was considered statistically significant.

Results: Among 115 patients, 29 patients (25.2%) developed AE and 32 patients (27.8%) died. The median follow-up period (IQR) was 57 (25.9–91.5) months, 57.4% were female and the mean age at RA-ILD onset was 72.2 ± 7.9 years old throughout the whole cohort. Among the AE group, methotrexate (MTX), tumor necrosis factor a inhibitor (TNFi) and non TNFi biological-OMARDs were used at AE onset in 10.0%, 0.0%, and 3.6% of patients, respectively. There was a significant difference of serum KL-6 levels at AE onset between AE group and non-AE group (1081.9 ± 624.7 vs 556.1 ± 285.6 U/mL, p < 0.001). Initial serum KL-6 levels at RA-ILD onset in AE group were higher than those in non-AE group, without a significant difference (648.9 ± 325.7 vs 523.7 ± 276.8 U/mL, p = 0.050). The optimal cut-off level of initial serum KL-6 to predict AE was 551 ± 523.7 U/mL according to ROC analysis. In univariate analysis, the following factors were significantly associated with AE; usual interstitial pneumonia (UIP) pattern on HRCT at AE onset (Hazard Ratio [HR]: 2.18, 95%


https://ard.bmj.com/ on May 29, 2021 by guest. Protected by copyright.