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Background: Biologic and Target Synthetic disease-modifying antirheumatic drugs (BTSs) have caused a paradigm shift in the treatment of patients with inflammatory joint disorders, e.g., rheumatoid arthritis (RA), where remission is now attainable [1]. The high cost of BTSs has caused restrictions on use and prescription, contributing to inequality of care worldwide [2]. An annual tender system was introduced in 2008 in Norway to reduce the costs of these drugs [3].
Objectives: Explore changes in drug costs for BTSs for RA patients treated at Norwegian rheumatology outpatient clinics between 2010 and 2019.
Methods: The project BioRheuma (BIOlogic treatment of patients suffering from inflammatory RHEUMAtic disorders in Norway) aimed to monitor patients treated with BTSs while using a designed computer program. Anonymized data files from the ten participating centers were merged and analyzed (EXCEL and SPSS). For each year in the ten-year period, the annual total cost for BTSs and mean BTS cost for treatment of one patient was calculated for all current BTSs users, for all those who started BTSs, and for patients starting naïve to BTSs. The cost was calculated based on price offers given at the annual tender process for the different years.
Results: The number of registered RA patients in the databases increased from 4909 in 2010 to 9335 in 2019. Simultaneously, the number of patients treated with BTSs increased from 1959 (39.9%) in 2010 to 4209 (45.1%) in 2019. The total treatment expenditure of these BTS treated patients was lowest in 2010 with 226 million Norwegian Kroner (NOK), highest in 2014 (350 million NOK) treating 3448 patients, and second-lowest in 2019 (255 million NOK).
The number of BTSs used for each year (Figure 1) is shown for all current users, all who started new BTSs treatment, and those starting BTSs naïve to BTSs. The same figure also reports the average cost of treating one RA patient with BTSs in these three groups. For the current users of BTSs, when the number of treated patients during follow-up doubled, the mean cost to treat one patient with BTSs was reduced by approximately 50% (decreasing from 115497 NOK in 2010 to 60701 NOK in 2019). The number of patients starting on BTSs approximately doubled, while keeping a steady small increase for the naïve patients to BTSs (382 in 2010 to 405 in 2019). The average starting treatment cost decreased from 114549 NOK in 2010 to 37384 NOK in 2019, and from 114987 NOK in 2010 to 28249 NOK in 2019, for patients starting on BTSs and for patients naïve to BTSs, respectively.

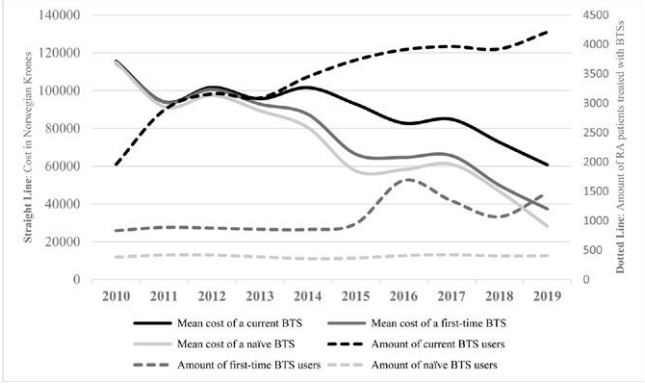

Figure 1. A ten-year overview of treating RA patient with BTSs

Conclusion: Our data shows that the average annual costs of treating a Norwegian RA patient on a current BTS, with a national tender system, were reduced by approximately 50% over the ten years 2010-19. For patients starting on a BTS, the average annual cost was reduced by approximately 75%. The consequence for the payers is that treatment can be offered at a lower price, and thus costly drugs may become more available for patients. We believe that mechanisms like the Norwegian tender system enforced upon the commercial pharmaceutical market improve competition and increase availability and use of costly drugs.

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OP0239 PSYCHOMETRIC EVALUATION OF FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY-FATIGUE IN PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

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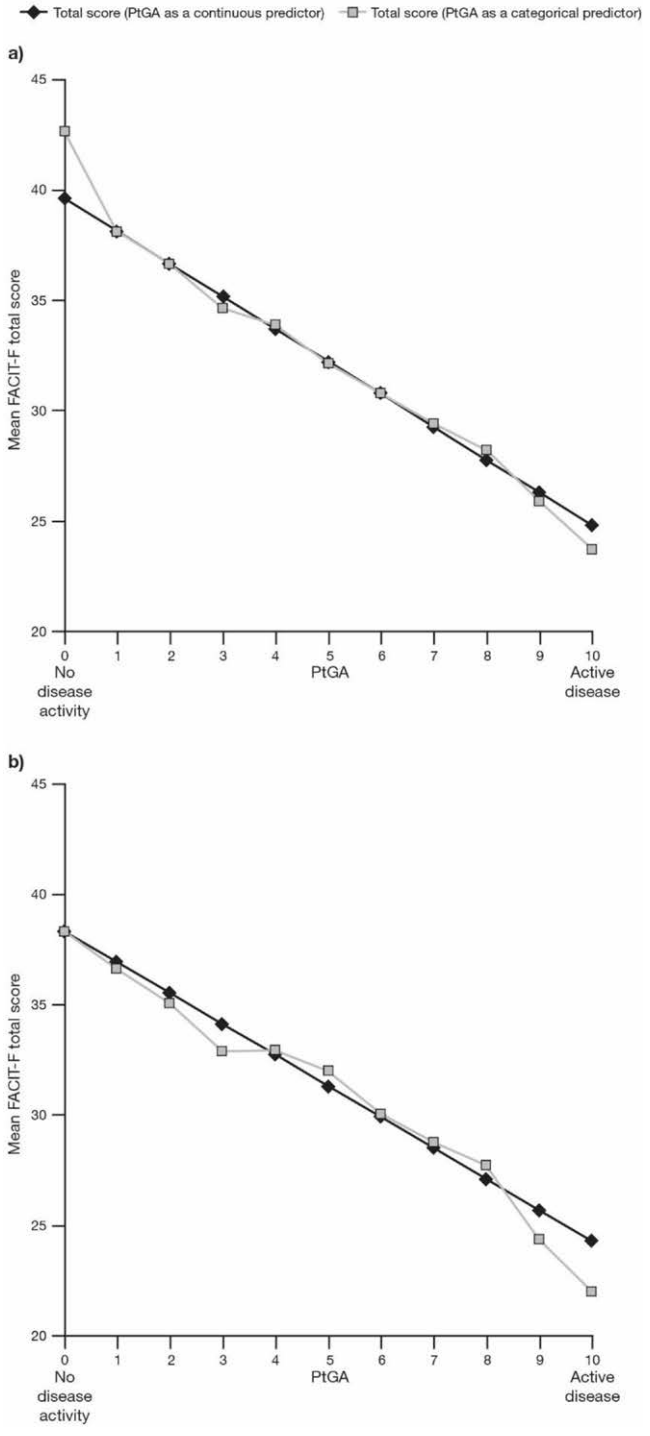
Background: Due to its impact on their health-related quality of life (QoL), fatigue is considered a core domain of disease assessment in patients (pts) with ankylosing spondylitis (AS). Psychometric data analyses in pts with rheumatoid and psoriatic arthritis have previously demonstrated that the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) is a reliable and valid measure in these pt populations,[1,2] but there are limited data supporting the psychometric validity and reliability of the FACIT-F scale in adult pts with active AS.
Objectives: To further evaluate the psychometric properties of the FACIT-F scale in adult pts with active AS.
Methods: This post hoc analysis used data from the Phase (P)2 (NCT01786668, Study 1) and P3 (NCT03502616, Study 2) studies of tofacitinib in pts with active AS. Second-order confirmatory analysis (CFA) evaluated the measurement model of FACIT-F with two domains (Experience and Impact) and the total score at baseline (BL) and the studies' respective primary analysis time points, Week (W)12 (Study 1) or W16 (Study 2). At the same time points, internal consistency reliability was examined by Cronbach's Coefficient alpha (α), and convergent validity was assessed through correlations of FACIT-F domain and total scores with a set of pt-reported outcomes (PROs): Pt Global Assessment of Disease Activity (PtGA), total back pain/nocturnal spinal pain due to AS, Short Form-36 Health Survey (SF-36v2), Bath AS Functional Index, Bath AS Disease Activity Index and ASQoL. Test-retest reliability was assessed by calculating Intraclass Correlation Coefficients (ICCs). The known-groups validity assessment was derived from an anchor-based repeated measures longitudinal model, with PtGA scores as the anchor (PtGA represented pt state from 'no disease activity' to 'very active disease' [PtGA=0 and 10, respectively]), and FACIT-F domain/total scores as the outcome. Estimations of ability to detect change and meaningful within-pt change (MWPC) were derived from anchor-based repeated measures longitudinal models, with change from BL in PtGA scores as the anchor and change from BL in FACIT-F domain/total scores as the outcome.
Results: The CFA model fit the data well (Bentler's Comparative Index ≥0.92 at BL, W12 [Study 1] and W16 [Study 2]), supporting the measurement model of the FACIT-F scale in pts with AS. Across time points in each study, the FACIT-F domain and total scores demonstrated excellent internal consistency (Cronbach's Coefficient α ≥0.88), and correlations between FACIT-F domain/total scores, and all PROs assessed generally exceeded 0.40. Generally, in both studies, the largest correlations (0.62–0.85) were between FACIT-F domain/total scores and the SF-36v2 vitality domain score and ASQoL. Test-retest reliability was acceptable for all FACIT-F domain/total scores (ICC ranged from 0.75–0.89 in both studies). An approximately linear relationship was observed between FACIT-F total scores and PtGA scores in both studies (Figure), as well as for Experience and Impact domain scores. The differences in FACIT-F domain/total scores were large and statistically significant between 'no disease activity' and 'very active disease' pt groups (standardised effect size ≥1.17), supporting known-groups validity. Ability to detect change was evidenced by an approximately linear relationship between changes in PtGA and FACIT-F domain/total scores in both studies; when pts experienced a change in PtGA, values for FACIT-F domain/total scores changed

accordingly. Conservatively, MWPC was estimated as 6.3 for FACIT-F total score, and 2.8 and 3.6 for FACIT-F Experience and Impact domain scores, respectively.

Figure. Relationship between FACIT-F total score and PtGA in a) Study 1 and b) Study 2



Conclusion: This quantitative analysis of data from two clinical studies of tofacitinib demonstrates the validity and reliability of the FACIT-F scale in adult pts with active AS. Therefore, these findings support the use of FACIT-F in AS studies.

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OP0240

EPIDEMIOLOGY, PREDICTORS OF MORTALITY AND ROLE OF PROPHYLAXIS FOR PNEUMOCYSTITIS JIROVECI PNEUMONIA AMONG RHEUMATIC PATIENTS: A TERRITORY-WIDE STUDY

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Background: *Pneumocystis jiroveci* pneumonia (PJP) is an opportunistic infection affecting immunocompromised individuals. Due to its high mortality, PJP prophylaxis is commonly recommended for many immunocompromising conditions. However, evidence regarding the burden and role of prophylaxis in PJP among rheumatic patients remains limited. There is lack of consensus for when and for whom to initiate prophylaxis. Delineating the epidemiology, predictors of mortality and efficacy of prophylaxis in PJP among rheumatic patients is urgently needed.

Objectives: To delineate the epidemiology of PJP, identify predictors of mortality and evaluate the usefulness of prophylaxis in rheumatology patients.

Methods: We performed a big-data cohort study based on the territory-wide healthcare database of the Hong Kong Hospital Authority. All patients with a diagnosis of anti-neutrophil cytoplasmic antibody-associated vasculitis (AAV), immune-mediated myositis (IMM), rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), systemic sclerosis (SSc), or spondyloarthritis (SpA) between 2015-2019 were included. PJP were identified based on physician diagnosis and/or positive microbiological results from deep respiratory tract specimens. Prophylaxis was defined as prescription of a prophylactic dose of co-trimoxazole for at least 2 weeks and/or inhaled pentamidine. Prevalence of PJP, prophylaxis and mortality among rheumatic patients were calculated. Demographics, blood parameters and immunosuppressants use was also collected for multivariate analysis. Number needed to treat (NNT) analysis was performed based on absolute risk reduction of PJP in patients with and without prior PJP prophylaxis.

Results: A total of 21,587 unique rheumatic patients were analysed (54% RA, 25% SLE, 13% SpA, 5% IMM, 2% AAV and 1% SSc). Between 2015-2019, 1141 (5.3%) patients were prescribed PJP prophylaxis and 48 (0.2%) developed PJP. None of those patients who developed PJP had received prophylaxis prior to infection. The risk of PJP was highest among SSc (1.8%), AAV (1.4%) and IMM (0.7%) patients, with NNT of SSc 36, AAV 48 and IMM 114. Within these disease entities, the majority of PJP occurred at prednisolone dose of 15mg/day (P15) or above (100% in SSc and IIM, 66.7% in AAV). Overall, PJP was associated with a mortality-rate of 39.6%. Glucocorticoid dose (daily prednisolone dose equivalent 29.1±23.5mg vs 11.4±7.2mg, P<0.01) and lymphopenia ($0.44x10^9$/L vs $0.90x10^9$/L, P= 0.04) at PJP diagnosis were associated with PJP mortality in rheumatic patients.

Conclusion: PJP is an uncommon but important infection in rheumatic patients associated with significant mortality. PJP prophylaxis is effective and should be considered in patients with SSc, AAV and IMM, especially in those receiving a steroid dose above P15.

Disclosure of Interests: None declared

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