In general, patients identified problematic gaps in SoCs more frequently than rheumatologists did. These findings can help to evaluate quality of care and to work towards improvement of care for RA patients in Europe.

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OP0308

QUALITY OF CARE PREDICTS OUTCOME IN SYSTEMIC LUPUS ERYTHEMATOSUS – CROSS SECTIONAL ANALYSIS OF A GERMAN LONG-TERM STUDY (LULA COHORT, 2011–2015)

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Background: Systemic lupus erythematosus (SLE) is a chronic disease, which is still associated with significant morbidity and mortality¹. Recommendations for the management of SLE patients exist²⁻⁵, but information on its implementation and the resulting impact on long-term outcome remain unclear.

Objectives: Our aim was to study the quality of SLE medical care in Germany to understand gaps and to analyze the association to long-term outcome parameters.

Methods: In the LuLa-study information on demographics, clinical and medical care parameters are assessed annually by self-reported questionnaires among a representative sample of SLE patients in Germany (LuLa cohort, n=572). In 2013 additional questions on the management of care, as mentioned in current guidelines and recommendations, were surveyed. Ten items predicting a good clinical care (quality measures) were evaluated and an overall score with a minimum of 0 points and a maximum of 10 points was calculated. The ten items are taking antimalarials, osteoporosis protection at a dose above 7.5mg prednisolone equivalent per day or taking ≤ 7.5mg per day, vaccination, blood pressure, fat metabolism counseling, urine examination and blood test once a year, treatment of comorbidity fat metabolism disorder, osteoporosis and hypertension. Health related quality of life (Short Form Survey, SF-12/36), damage (Brief Index of Lupus Damage, BILD) and disease activity (Systemic Lupus Activity Questionnaire, SLAQ) were chosen as relevant proxies for long-term outcome.

Using linear regression, we examined the relationship between the quality measures and outcome parameters, adjusted for age, disease duration and gender.

Results: 65.5% of the patients consulted a rheumatologist as a main contact for their disease. On average 6.1 points of the 10 quality measures were met (SD 1.7). The fulfillment of these quality measures varied between 22.8% (fat metabolism counseling) and 97.6% (osteoporosis protection at a dose above 7.5mg prednisolone equivalent per day or ≤ 7.5mg per day). Fulfilling more clinical care items in 2013 was predictive for high disease-related quality of life (SF-36, p=0.004), low progress in disease-related damage (BILD, p=0.048) and low disease activity (SLAQ, p=0.046) in the subsequent years.

Conclusion: Our study illustrates a strong link between the quality of care and important SLE outcome parameters: quality of life, disease-related damage and disease activity assessed by a self-reported questionnaire. Consistent considerations of these care parameters, which are recommended in several management guidelines, yield a positive effect on outcome. An interdisciplinary approach with general practitioners and other specialists is certainly beneficial and warranted. German Clinical Trial Register, www.germanctr.de, DRKS00011052

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OP0309

OPTIMIZATION OF FLARE MANAGEMENT IN PATIENTS WITH RHEUMATOID ARTHRITIS: RESULTS OF A RANDOMIZED CONTROLLED TRIAL

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Background: Flares in rheumatoid arthritis (RA) are common [1]. The shortage of readily available specialized care may hinder early detection and timely management of RA flares. Engaging non-physician rheumatology providers in care of RA flares may be beneficial.

Objectives: To evaluate the effect of a nurse-led flare management intervention versus usual care between rheumatology visits on flare occurrence and RA disease activity in patients with RA.

Methods: Patients with established RA (2010 ACR criteria) were randomized to the intervention versus usual care. The Flare Assessment in Rheumatoid Arthritis (FLARE-RA) questionnaire was administered monthly during the 24-month follow-up to all patients in the intervention arm to assess flare status. The results of the FLARE-RA questionnaire and patient's response to the question "Are you currently in a flare of your RA?" were recorded. Telephone nurse-led counseling or a visit with a mid-level rheumatology provider within 7 days of detection of flare was offered to patients in the intervention arm who indicated they were in flare. Patients in the usual care arm were followed by their rheumatology providers according to standards of care. OMERACT9 definition of flare was used to compare flare occurrence between the study arms. All patients completed satisfaction surveys at baseline and at the end of the follow-up.

Results: 150 patients with RA were randomized to intervention (n=75) versus usual care (n=75). At baseline, the majority of patients in the intervention arm (51%) and in the usual care (60%, p=0.32) were interested in expedited appointments with a rheumatology provider if in RA flare. There were no differences between the study arms at baseline in age, sex, tender joint counts, pain intensity, patient and physician global assessments, C-reactive protein levels, DAS28-CRP, CDAI, or SDAI. Despite randomization, patients in the intervention arm had lower swollen joint counts (1.1±2.7 vs 2.4, p=0.003) and Health Assessment Questionnaire (HAQ) score (0.6±0.6 vs 0.9±0.6, p=0.005) than those in the usual care arm. The number of patients in the intervention arm who completed the FLARE-RA questionnaires at baseline, 6, 12, 18, and 24 months was 75, 37, 27, 13, and 23, respectively. Patients in the intervention arm completed a median of 8.5 (range 1–24) questionnaires. RA flare was reported on 122 (19%) of these questionnaires; average FLARE-RA score: 2.57. Patients agreed to have an expedited clinic visit with a rheumatology provider during 39 (32%) of flares. The majority of patients preferred to self-manage their flare (76, 62%) or receive nursing advice over the phone 7 (6%). There were no differences in DAS28-CRP, CDAI, SDAI, anti-rheumatic treatment change by rheumatology provider, RA flare by OMERACT9 definition, or remission by CDAI between the study arms over 24-month follow-up. At the end of the study, a higher proportion of patients in the intervention arm (44%) versus the usual care arm (21%, p=0.04) reported positive effect of participation in the study on the management of RA flares.

Conclusion: The majority of patients expressed interest in expedited rheumatology appointments for their RA flares on their baseline patient-satisfaction survey. However, during the study, patients in the intervention arm largely preferred self-management and/or over-the-phone counseling. The nurse-led flare

management intervention had no major effect on RA disease activity metrics over the 24-month follow-up. However, patients in the intervention arm reported a positive effect of the intervention. More studies are needed to further understand patient preferences for optimal RA flare management and to design interventions to meaningfully address these preferences.

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OP0310

IMPLEMENTATION OF TNF-BIOSIMILARS (INFLIXIMAB AND ETANERCEPT) IN DANISH DEPARTMENTS OF RHEUMATOLOGY

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Background: The use of expensive biological drugs in rheumatology is rapidly increasing and has led to substantial increases in drug expenditures. A considerable reduction of drug costs is possible by using biosimilars as soon as they become available and carrying out non-medical shifts to biosimilars (i.e. switching a patient well treated on a biooriginator to the biosimilar). Research on biosimilars has focused on interchangeability and safety outcomes, but little focus has been on nationwide implementation and the direct economic consequences on drug expenses.

In Denmark, TNF-inhibitors are solely given in an in-hospital setting and bought through national tenders. The Danish in-hospital organization includes Regional Drug and Therapeutics Committees that ensures regional implementation of treatment guidelines and close collaboration between hospital pharmacies and regional clinical pharmacologists. Furthermore, the implementation of TNF-inhibitor biosimilars was preceded by careful preparations from among others a newly established national biosimilar task force.

Objectives: The aim of this study was to describe the implementation of the two first TNF-inhibitor biosimilars (infliximab and etanercept) in Danish departments of rheumatology.

Methods: Monthly data on drug sales to Danish rheumatology departments were used to assess the biosimilar uptake rate and subsequent changes in the drug expenditures during the implementation in Denmark.

Results: Shifts to biosimilars were begun within a few months following end of biooriginator patent, vertical lines in the figure. Use of the infliximab biosimilar was begun in April 2015, and in August 2015 biosimilar uptake was 92.9% of total infliximab use. Similarly use of etanercept biosimilar was begun in April 2016, and in June 2016 the biosimilar uptake was 91.6% of total etanercept use. In January 2015 the total use in Defined Daily Doses (DDD) were 42.4 thousand DDD's for infliximab and 37.3 thousand DDD's for etanercept. The use increased steadily and was in January 2018 138.4 thousand DDD's for infliximab and 62.1 thousand DDD's for etanercept (equivalent to increases of 226.6% and 66.8%). The increases in DDD's were not reflected in total drug costs due to the shift to biosimilars. The total drug cost for infliximab in January 2015 was 6.7 million DKK but was reduced to 5.4 million DKK in January 2018 (-19.4%). A corresponding cost reduction was seen for etanercept (11.3 million DKK in January 2015, 8.1 million DKK in January 2018, -28.7%).

Conclusion: Danish departments of rheumatology experienced a fast and near-complete switch of infliximab and etanercept biooriginators to biosimilars. At the same time the use of the drugs increased substantially, but due to large price reductions the total drug cost decreased despite the increasing use. We believe that a thorough preparation and an organizational setting supporting the implementation was crucial for the successful implementation. The Danish structure, with its national tendering, probably contributed to the substantial drug discounts obtained. The implementation will be used for future biosimilars in Denmark.

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OP0311

RETROSPECTIVE ANALYSIS OF PRESCRIPTION DYNAMICS OF ETANERCEPT AFTER INTRODUCTION OF BIOSIMILARS BASED ON NORWEGIAN PRESCRIPTION DATABASE. AN INTERIM ANALYSIS

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Background: In Norway, several high quality data registries are available that can be used to generate "real life" data. All individuals living in Norway are given a unique ID number which makes it possible to trace individuals. The Norwegian Prescription Database (NorPD) is one of the central public registers that are available for research purposes. All prescriptions being collected by individuals are recorded, including reimbursement code, dispensing date, name and dose of the prescribed drug. Following loss of exclusivity of some biologics, biosimilars are competing in the Norwegian tender.

Objectives: Both efficacy, bio-chemical features and patient satisfaction with biosimilars have been debated since they were introduced to replace originator. However, there is only sparse evidence as to how many patients were switched and how many are switched back to the originator so large, registry based studies are warranted.

Therefore, our aim was to follow all patients on originator receiving maintenance treatment (drug prescription being collected and registered in NorPD) after biosimilar entry (BE) in order to retrospectively describe the pattern of switch and monitor dynamics, assumed to be economically motivated from patients stable on originator to biosimilars or other preferred drug.

Methods: We included all patients on etanercept maintenance treatment for 9 months prior to BE with maximum gap of 4 months from previous prescription retrieval. Switch was defined as discontinuation of use for at least 4 consecutive months.

Prescription data scans from NorPD started March 2016 (BE) and data scans were performed every 3 months during the first 6 months of this project and every 6 months for 2 years. Final data extraction will be performed within July 2019. This abstract covers the interim analysis and the time period from 9 months prior to BE and 18 months thereafter.

Results: We have identified 8149 individuals on biologics prescribed in Norway. Of those, 4799 collected at least two prescriptions of etanercept before BE and are included in further analyses. The proportion of originator etanercept users declined sharply after biosimilar entry as expected for the first three months after BE and kept decreasing for the consecutive 9 months, however it changed little thereafter.

A great majority of former etanercept users was switched to SB4 (70.5%) and continued with this medication, however some switched back to etanercept or other