Comorbidities (yes)	34.8%	46.5%	0.024
The only associated factors to a better response in patients ≥ 65 yr were: higher DAS28 score, lower HAQ score and bio-naïve ($p < 0.05$).			

Conclusions: The effectiveness of CZP among ≥ 65 yr only differed from their younger counterparts from DAS28 remission rate, with a lower percentage, and side-effects (higher percentage, with higher comorbidities percentage too). However, after one year of real-life data CZP seemed as both safety and effective enough as younger RA patients in real-life scenario.

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SAT0209 A COMPARATIVE REAL-WORLD UTILIZATION PATTERNS OF INNOVATOR AND BIOSIMILAR INFlixIMAB IN A TREATMENT NAÏVE AND SWITCH POPULATION FROM GERMANY: A PRESCRIPTION CLAIMS ANALYSIS

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Background: Data on treatment utilization patterns for innovator infliximab (IFX) and biosimilar infliximab (CT-P13) in IBD are scarce. Given low uptake of biosimilars in Canada to date, evaluation of treatment initiation and discontinuation was undertaken in a proxy country, Germany, which has similar demographic factors and neither have a mandated biosimilar switch policy.

Objectives: Retrospective prescription claims analysis comparing utilization patterns of innovator (IFX) and biosimilar (CT-P13) infliximab in treatment naïve population at 12 months and in patients continuing IFX vs switching to CT-P13 at 6 months.

Methods: QuintilesIMS™ longitudinal health insurance prescription data from Germany identified patients with an index claim of IFX or CT-P13 in all indications between Feb 2015-Oct 2016. Twelve-month post-drug initiation and 6-month post innovator-to-biosimilar switch retention analyses were conducted. All patients had sufficient claims history post-index and ≥ 2 claims of IFX or CT-P13 within the analysis period. Six-month analyses included: 1) matched analysis where each CT-P13 switch patient was matched to 5 IFX patients for IFX exposure prior to switch; 2) unmatched analysis where CT-P13 switch patients were compared to the first 6 months of the IFX treatment naïve population. Log-binomial regression analyses were conducted to determine the relative risk (RR) of being retained on treatment at 6 or 12 months adjusted for age, sex, biologic treatment history and prescriber specialty.

Results: 6,491 patients had a claim of IFX or CT-P13. Of these, 1,160 and 1,324 patients had follow up time for inclusion in the 12-month naïve and 6-month post-switch analyses, respectively. Only IFX to CT-P13 switch utilization ($n=101$) was investigated. The risk adjusted probability of being retained on treatment after 12 months was 23% greater in the IFX group than in the CT-P13 group (RR IFX=1.23, 95% Confidence Interval [CI]: 1.12–1.36, $p < 0.0001$). The probability of being retained was also greater in men, those who were bio-naïve and those prescribed drug by a rheumatologist. In the matched 6 months post-switch analysis the risk adjusted probability of being retained on treatment was 26% greater in the IFX maintenance group than in the CT-P13 switch group (RR IFX=1.26, 95%CI: 1.10–1.45, $p=0.0007$). The probability of being retained was also greater in those prescribed drug by a rheumatologist. Similar results were found in the unmatched analysis (RR IFX =1.32, 95%CI: 1.16–1.51, $p < 0.0001$), where the probability of being retained was also greater in men and in those who were bio-naïve.

Conclusions: The findings from Germany demonstrate significant differences in the real-world utilization patterns of patients treated with IFX or CT-P13 in all labelled indications. Limitations of this study include a heterogeneous population, disease severity and reasons for staying on treatment or switching could not be determined. Future analyses should capture clinical outcomes to better understand observed utilization patterns.

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SAT0210 TREATMENT RETENTION RATE OF BIOLOGICAL TREATMENT IN ELDERLY RHEUMATOID ARTHRITIS PATIENTS COMPARED WITH YOUNGER RHEUMATOID ARTHRITIS PATIENTS – A SINGLE CENTER COHORT STUDY -

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Background: Biological (BIO) therapy has become a standard therapy in the treatment of rheumatoid arthritis (RA) and long-term outcomes has increasingly evaluated. Elderly people has increased in Japan and 27.3% of whole people in Japan was 65 years of age or older in 2016. We reported treatment retention rate of BIO therapy in RA patients in EULAR2015 annual meeting as mixed data of elderly RA patients (ERA) and younger RA patients (YRA) ¹.

Objectives: This observational cohort study investigated the treatment retention rate in ERA compared with YRA.

Methods: Toyohashi RA Database (TRAD) was used. 330 RA patients who initiated any of BIO agents (infliximab, etanercept, adalimumab, tocilizumab, abatacept, golimumab, infliximab-BS) as first Bio in our institute from 2003 to 2016 were included in this study. Switching from one Bio agent to another was defined as continuation of Bio therapy in this study. Stopping of BIO therapy was defined as non-administration for longer than 3 months for any reasons other than remission and pregnancy related. We divided whole patients into two categories using age at initiation of BIO therapy such as YRA (64 years of age or younger) and ERA (65 years of age or older). ERA was further subdivided into two categories such as yERA (65–74 years of age) and oERA (75 years of age or older). We investigated patients' characteristics, treatment retention rate by Kaplan-Meier method and reasons of stopping BIO therapy and compared them between categories.

Results: Baseline characteristics at the initiation of BIO treatment: %female was 82.4%. Mean age was 58.1 years old (210 YRA, 98 yERA and 22 oERA). Mean RA duration was 10.9 years. % methotrexate (MTX) concomitant was 82.1% and mean used dose was 8.9 mg/weeks (MTX dose was restricted up to 8 mg/weeks until 2011 in Japan and 16 mg/w after 2011). % prednisolone (PSL) concomitant was 50.9%. % Bio monotherapy was 9.1%. Mean baseline DAS28-CRP and SDAI was 4.6 and 24.4, respectively. % high disease activity measured using DAS28 and SDAI at baseline was 44.4% and 42.2%, respectively (Fig1). Baseline disease activity were getting lower year by year. Continuation rate of BIO treatment in whole patients is 88.4% at 1 year, 82.0% at 3 years, 72.2% at 5 year and 57.1% at 10 years. There were significant differences in continuation rate of BIO treatment between YRA and ERA (Fig2), between YRA and yERA and between YRA and oERA, but not between yERA and oERA. Major reasons (over 10%) of stopping BIO therapy in YRA were infection other than respiratory system (15.7%), infection of respiratory systems (11.8%), ineffectiveness (11.8%) and malignancy (11.8%). Major reasons in ERA were infection of respiratory systems (21.3%) and infection other than respiratory systems (10.6%).

Figure 1 Continuation rate of biological therapy in whole patients

Figure 2 Continuation rate of biological therapy in YRA and ERA

YRA: younger RA patients, ERA: elderly RA patients

Conclusions: Although continuation rate of BIO treatment in ERA was inferior to that in YRA, that in yERA was not significantly different from that in oERA. Serious infection, especially in respiratory systems, was most frequent reason for stopping BIO therapy in ERA. These results suggested that BIO therapy in ERA demands close attention to infection and special strategies might need in the treatment of ERA people.

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SAT0211

IS THERE A POTENTIAL FOR THERAPEUTIC DRUG MONITORING OF SUBCUTANEOUS TOCILIZUMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS IN DAILY PRACTICE?

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Background: Tocilizumab (TCZ), is a humanized antibody that competitively inhibits membrane-bound and soluble IL-6 receptors. Subcutaneous (sc) TCZ might be a potential candidate for therapeutic drug monitoring (TDM) since a high variability in serum concentrations has been reported. Considering that TCZ concentrations above 1 µg/mL have been claimed to be sufficient for normalizing CRP production (1), there might be an overexposure in a substantial proportion of patients. We expect that patients can at least reduce to a dose aiming for a trough concentration of 5 µg/mL. Insights in serum concentrations of sc TCZ with clinical efficacy are lacking, but are necessary to reduce overexposure, potential dose-dependent adverse effects and at the same time reduce costs.

Objectives: To describe TCZ trough serum concentrations in patients with rheumatoid arthritis (RA) treated with sc TCZ.

Methods: Prospective study with consecutive RA patients starting treatment with sc TCZ between June 2015 to October 2017 who had previously failed treatment with at least two DMARDs, including MTX. TCZ was administered at a dose of 162 mg every week and patients were followed for 28 weeks. The study was conducted at the Amsterdam Rheumatology and Immunology Center | Reade. Serum trough samples were collected at baseline and at 4, 16, 28 weeks thereafter. An enzyme-linked immunosorbent assay (ELISA) was used for TCZ measurement. To analyze the concentration variability among patients at 28 weeks, a last observation carried forward approach was used.

Results: In total, 26 patients were included in the study and 94 TCZ serum concentrations were measured. Median and interquartile range (IQR) of the follow-up period was 28 (16-28) weeks and 54% of the patients accomplished week 28. Drug concentrations ranged from 0.2 to 63 µg/mL, with an overall median (IQR) of 26.0 (10.5-42.0) µg/mL. In the majority of patients, TCZ concentrations stabilized after 4 weeks of treatment. Variability in drug concentrations at 28 weeks is shown in figure 1. Median (IQR) TCZ serum concentrations at 28 weeks was 24.0 (6.4-43.0) µg/mL, 92% of the patients achieved a concentration above 1 µg/mL and 88% had a concentration > 5 µg/mL.

[TCZ] at 28 weeks with LOCF

Conclusions: The Interindividual variability among patients on sc TCZ is remarkably high. The majority of the patients achieved serum concentrations far above 5 µg/mL, suggesting overexposure in those patients. Therefore, TDM might be useful to optimize treatment, reduce (potential) side effects and achieve cost-effectiveness.

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Rheumatoid arthritis - non biologic treatment and small molecules

SAT0212

THE SAFETY AND TOLERABILITY OF INTRA-ARTICULAR INJECTION OF TOLEROGENIC DENDRITIC CELLS IN PATIENTS WITH RHEUMATOID ARTHRITIS: THE PRELIMINARY RESULTS

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Background: Dendritic cells (DCs) are known to contribute to the pathogenesis of rheumatoid arthritis (RA) through the presentation of cartilage glycoprotein, production of proinflammatory cytokines and activation of Th1/Th17 responses. Along with stimulating activity, DCs may exhibit suppressive functions via capacity to induce T cell apoptosis/anergy and to generate regulatory T cells. Since these DCs have potential to control autoreactive T-lymphocytes, utilization of tolerogenic DCs seems to be a promising immunotherapeutic tool to treat RA.

Objectives: The aim of our study is to evaluate the safety and tolerability of a single intra-articular injection (into the knee joint) of autologous monocyte-derived dendritic cells generated in the presence of IFN-α/GM-CSF and tolerized with Dexamethasone in RA patients.

Methods: DCs were generated by culturing blood monocytes for 5 days with GM-CSF and IFN-α in the presence dexamethasone, applied on third day. Azoximer bromide as maturation stimuli was added on fourth day. Ten RA patients with moderate and high disease activity and ultrasound-defined knee synovitis were recruited in this study. All patients fulfilled ACR/EULAR criteria (2010) and received methotrexate, leflunomide, sulfasalazine or their combination. The patients received intra-articular injections of 1*10⁶, 3*10⁶, 5*10⁶, 8*10⁶ DCs in knee joints. Safety was assessed by evaluation of adverse events (AE). Acceptability was assessed by questionnaire. DAS28 and HAQ were used for assessment of treatment efficiency. This trial registered on clinicaltrials.gov (ID: NCT03337165).