spondyloarthritis, axSPA) and infliximab trough levels, and the occurrence of adverse events.
**Results:** 260 patients fulfilled the inclusion criteria: 182 patients followed-up in Rheumatology (131 with axSPA, 31 with RA, and 20 with other inflammatory rheumatic diseases), 64 in Gastroenterology and 14 in Internal Medicine.
The retention rate at the time of the third biosimilar infusion was 82% (149/182 patients), which was lower than the rate observed in patients with inflammatory bowel diseases or uveitis followed-up in Gastroenterology and Internal Medicine, respectively (71/78 patients, 91%).
Between baseline and the last visit (mean follow-up: 34±4.5 weeks), 48/182 (26%) patients, including 36 patients with axSPA, discontinued biosimilar infliximab, mainly due to experienced inefficacy (n=47). No clinical or biological factors were associated with biosimilar discontinuation.
One infusion reaction led to treatment discontinuation. No serious adverse events occurred. 43 patients restarted innovator infliximab, 2 patients switched to etanercept, 1 to abatacept and 2 maintained biological-free.
In RA patients, the mean DAS28-CRP remained stable from baseline to the last visit: 3.38±1.16 to 3.08±1.08 (p=0.217). In axSpA patients, the mean BASDAI increased from 2.94±2.20 to 3.18±2.21 (p=0.046) and the mean ASDAS increased from 1.79±0.90 to 1.99±1.08 (p=0.022). In RA and axSPA, mean CRP levels at baseline (5.95±6.06 and 5.98±11.14 mg/l respectively) and the last visit (6.52±11.32 and 5.03±8.26 mg/l respectively) were not statistically different (p=0.289 and p=0.271, respectively).
Mean infliximab trough levels were similar in patients with RA (3.70±5.36 vs. 3.21±4.35 μg/ml, p=0.551) and AxSPA (5.88±5.82 vs. 5.70±5.42 μg/ml, p=0.617) during follow-up.
**Conclusions:** In the majority of patients, innovator infliximab can be switched to biosimilar infliximab without changes in efficacy and safety during 34 weeks follow-up. However, 26% of patients discontinued biosimilar infliximab, mainly those with AxSPA due to a subjective increase in BASDAI or ASDAS scores, possibly explained by suggestion or attribution effects rather than pharmacological differences.
**Disclosure of Interest:** None declared
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## SAT0164 ASSOCIATION BETWEEN FLARE AND RADIOGRAPHIC PROGRESSION IN PATIENTS WITH RHEUMATOID ARTHRITIS

J.S. Smolen[1], H. Jones[2], E. Mahgoub[2], R. Pedersen[2], L. Marshall[2]. *[1]Medical University of Vienna, Vienna, Austria; [2]Pfizer, Collegeville, United States*

**Background:** Biologic therapy has improved RA management, enabling some patients to achieve remission. Many clinicians decrease the biologic dose for patients in low disease activity (LDA) or remission. However, it is unclear which patients may flare and if flare contributes to radiographic progression.
**Objectives:** To assess whether patients who flared had a higher incidence of radiographic progression, and to compare patients with and without flares.
**Methods:** PRESERVE (ClinicalTrials.gov: NCT00565409) was a 2-period trial in patients with moderate RA despite MTX. Period 1 was open-label, single treatment induction with etanercept (ETN) 50mg+MTX weekly (QW) for 36 wks. Patients in LDA or remission (disease activity score for 28 joints [DAS28] $\leq$3.2) during wks 12 to 36 continued to Period 2, the randomized, double-blind phase to evaluate maintenance of LDA/remission. Patients were randomized to ETN 50mg+MTX QW, ETN 25mg+MTX QW, or placebo+MTX QW to wk 88. This post hoc analysis evaluated flare and radiographic progression at wk 88. Flare was defined 2 ways: 1) loss of LDA with/without DAS28 change of 0.6; and 2) relapse (DAS28$>$5.1 or DAS28$>$3.2 at $\geq$2 time points). Radiographic progression was evaluated according to 4 levels of stringency: 1) minimally clinically important difference (modified total Sharp score [mTSS] change $\geq$5); 2) smallest detectable difference (mTSS change $\geq$2.3); 3) mTSS change $\geq$0.5; and 4) mTSS change $>$0. Baseline (BL) characteristics were compared for patients with vs without flare, defined as loss of LDA and DAS28 change of 0.6. Analysis of covariance and chi-square test compared continuous and categorical outcomes, respectively.
**Results:** Age, race, BMI, and disease duration did not differ significantly for flare vs non-flare, total N=531. BL DAS28 was higher for flare vs non-flare: mean (SD) 4.37 (0.45) vs 4.27 (0.45), $p$=0.046. Other BL disease characteristics were similar between groups. With flare defined as relapse, significantly more flare than non-flare patients showed all 4 degrees of radiographic progression (table). With flare defined as LDA loss with/without DAS28 change of 0.6, radiographic progression did not differ significantly between groups, but numerically more patients with flare progressed. This was the trend for all treatments; the numbers were too small to analyze. Numerically more placebo patients progressed, regardless of flare status or progression category (data not shown).

Table. Radiographic progression at week 88

| Outcome | Flare Patients | Non-flare Patients | P-value* |
|---|---|---|---|
| Flare defined as loss of LDA and DAS28 change of 0.6 | | | |
| mTSS $>$0 | 43/271 (15.9) | 31/260 (11.9) | 0.2109 |
| mTSS $\geq$0.5 | 38/271 (14.0) | 24/260 (9.2) | 0.1045 |
| mTSS $\geq$2.3 | 20/271 (7.4) | 10/260 (3.8) | 0.0914 |
| mTSS $\geq$5.0 | 9/271 (3.3) | 2/260 (0.8) | 0.0633 |
| Flare defined as loss of LDA | | | |
| mTSS $>$0 | 44/280 (15.7) | 30/251 (12.0) | 0.2586 |
| mTSS $\geq$0.5 | 39/280 (13.9) | 23/251 (9.2) | 0.1043 |
| mTSS $\geq$2.3 | 20/280 (7.1) | 10/251 (4.0) | 0.1338 |
| mTSS $\geq$5.0 | 9/280 (3.2) | 2/251 (0.8) | 0.0670 |
| Flare defined as relapse | | | |
| mTSS $>$0 | 35/181 (19.3) | 39/350 (11.1) | 0.0119 |
| mTSS $\geq$0.5 | 31/181 (17.1) | 31/350 (8.9) | 0.0065 |
| mTSS $\geq$2.3 | 19/181 (10.5) | 11/350 (3.1) | 0.0011 |
| mTSS $\geq$5.0 | 9/181 (5.0) | 2/350 (0.6) | 0.0015 |

*Fisher's exact test. Overall treatment group. Values are n/N (%).

**Conclusions:** Using relapse as a rigorous definition of flare, radiographic progression occurs in significantly more flare than non-flare patients, demonstrating that it is a consequence of flare following biologic withdrawal.
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## SAT0165 REAL-WORLD UTILIZATION OF CONCOMITANT MEDICATIONS IN PATIENTS INITIATING ETANERCEPT: A RETROSPECTIVE COHORT STUDY OF CANADIAN CLAIMS-LEVEL DATA

M. Khraishi[1], Y. Zhang[2], J. Ivanovic[2], B. Millson[2], M.-J. Brabant[2], E. Singh[3], J. Woolcott[4], H. Jones[3]. *[1]Faculty of Medicine, Memorial University of Newfoundland, St. Johns; [2]Health Access & Outcomes, QuintilesIMS, Kanata, Canada; [3]Inflammation and Immunology, Global Medical Affairs, Pfizer Inc., Collegeville, United States; [4]Health Economics and Outcomes Research, Pfizer Inc., Kirkland, Canada*

**Background:** Methotrexate (MTX) and prednisone (pred) are immune suppressants frequently used to treat immune-mediated inflammatory diseases (IMIDs). Etanercept is a soluble TNF receptor (humanized protein) indicated for the treatment of IMIDs, including rheumatoid arthritis (RA), psoriatic arthritis (PsA), psoriasis (PsO), and ankylosing spondylitis (AS). Limited information exists on how MTX or pred use changes in patients who initiate etanercept in real-world settings.
**Objectives:** To evaluate whether initiation of etanercept impacts use of co-therapy with MTX or pred in Canadian patients with IMIDs.
**Methods:** A retrospective cohort study was conducted using claims-level data from QuintilesIMS Private Drug Plan database, Ontario Public Drug Plan database, and Quebec Public Drug Plan database. Bio-naïve patients initiating etanercept between 07/2013 and 06/2015, were identified and their claims made for MTX or pred were analyzed. Patients' utilization of MTX or pred was calculated as average weekly dose in mg, and then compared in the 6-months pre versus 12-months post initiation of etanercept using a paired t-test. Differences in the presence of concomitant medications pre and post-etanercept were also examined using a paired t-test.
**Results:** The study captured 3,745 etanercept patients (61% female, 77% aged between 18 and 65, 84% rheumatic diseases, and 15% PsO) across Canada in the selection period. Of selected patients, 33% used MTX (n=1,244) and 14% (n=523) used pred pre and post initiation of etanercept. In concomitant MTX patients, the average weekly dose dispensed was 25.2mg in the 6 months prior to initiation of etanercept, and 25.0mg in the 12 months following the first claim of etanercept ($p$=0.7493). In concomitant prednisone patients, the average weekly dose dispensed reduced from 123mg pre-etanercept to 108mg post-etanercept initiation ($p$=0.2316). 19% of patients stopped MTX (n=287) use post-etanercept initiation, compared to 36% who stopped pred use (n=289).
**Conclusions:** In this real-world setting, approximately 1/5 of patients stopped or reduced co-therapy of MTX; and 1/3 of patients stopped or reduced co-therapy of pred following initiation of etanercept; however, those patients who remained on co-therapy showed non-significant changes in their average consumption. Further research is needed to understand the impact on overall patient outcomes and safety.
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## SAT0166 MARKERS OF RESPONSE TO INFLIXIMAB IN RHEUMATOID ARTHRITIS – THE PLACE OF ANTINUCLEAR ANTIBODY AND NUCLEASE SERUM ACTIVITY

M. Volkava[1], A. Kundzer[1], I. Generalov[2], D. Petrovich[1]. *[1]Cardiology and Rheumatology, BelMAPGE, Minsk; [2]Clinical Microbiology, VSMU, Vitebsk, Belarus*

**Background:** It is important to study new potential markers of response to treatment in rheumatoid arthritis (RA), because up to 40% patients don't achieve