antagonist, tocilizumab (TCZ), on NT-proBNP levels and systolic heart function is yet to be obtained.

**Objectives:** Access the effect of 12 months TCZ therapy on NT-proBNP levels, transthoracic echocardiography results and analyze the association between congestive heart disease progression and RA activity.

**Methods:** 37 RA patients (pts) (31F/6M); median age 56,5 ± 8,4 years; disease duration 48 ± 6,7 years; 32 pts were treated with TCZ as monotherapy (2.32 ± 1,57 mg/kg). NT-proBNP levels decreased (100,95 ± 57,9 to 90,46 ± 33,6 pg/ml) along with elevation of LVEF (60,75 ± 6,5% to 62,5 ± 7,3%), p = 0,001. Increase of E/A (0,97 ± 0,8 to 1,17 ± 0,7) to 1,42 ± 0,42 correlated with decrease of NT-proBNP level (r = -0,63 ± 0,036). Raise of LVEF over 12 months correlated with decrease of RA activity according to SDAI scale (r = -0,670 ± 0,05). No significant relationship between NT-proBNP levels, LVEF, E/A and other scales measuring RA activity was found. Clinically all patients had improvement in evaluation of their health and no signs of CHD or RVD progression were found.

**Conclusion:** Use of TCZ in patients with active RA showed none to positive influence on heart condition, specifically, lowering NT-proBNP levels, improving LVEF and reducing clinical signs of LVD.

**References:**

**Disclosure of Interests:** None declared

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Background: Anti-Direct Antibodies (ADA) to adalimumab increase drug clearance in rheumatoid arthritis (RA).

Objectives: To study the ability of drug concentration or estimated clearance to identify ADA to adalimumab.

Methods: Adalimumab concentration was measured with a validated ELISA. ADA was measured using a capture ELISA (Theradiag®) and the Meso scale discovery (MSD) platform. Using a bayesian PK model, adalimumab clearance was estimated at 1, 3, 6 and 12 months. Predictions for ADA presence were calculated, and the correlation between ADA and adalimumab clearance was analysed.

Results: We analyzed 108 samples from 53 RA patients. Serum concentrations and clearance estimates showed good prediction performance for ADA presence (Table 1). There was a correlation between adalimumab clearance and ADA (Figure 1).

Table 1. Immunogenicity prediction of adalimumab, using trough concentration or estimated clearance

<table>
<thead>
<tr>
<th>Time of visit</th>
<th>ADA method</th>
<th>Adalimumab trough concentration</th>
<th>Adalimumab estimated clearance</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>AUC ROC</td>
<td>p-value</td>
</tr>
<tr>
<td>Month 1</td>
<td>THER</td>
<td>.55</td>
<td>.6411</td>
</tr>
<tr>
<td></td>
<td>MSD</td>
<td>.65</td>
<td>.0821</td>
</tr>
<tr>
<td>Month 3</td>
<td>THER</td>
<td>.89</td>
<td>.0006</td>
</tr>
<tr>
<td></td>
<td>MSD</td>
<td>.73</td>
<td>.0096</td>
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<tr>
<td>Month 6</td>
<td>THER</td>
<td>.95</td>
<td>.0035</td>
</tr>
<tr>
<td></td>
<td>MSD</td>
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<td>Month 12</td>
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<td></td>
<td>MSD</td>
<td>.88</td>
<td>.0002</td>
</tr>
</tbody>
</table>

Conclusion: Adalimumab concentration and clearance should be considered as reliable predictors for ADA presence in RA patients.

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Figure 1. correlation between adalimumab estimated clearance and ADA as provided by the Meso scale discovery (MSD) platform.

**Figure 1.** THE PROPER STUDY: RESULTS OF THE FIRST INTERIM ANALYSIS OF A PAN-EU REAL-WORLD STUDY OF SBS BIOSIMILAR FOLLOWING TRANSITION FROM REFERENCE ADALIMUMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS, AXIAL SPONDYLOARTHRITIS OR PSORIATIC ARTHRITIS


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Background: SBS, a biosimilar to reference adalimumab (ADA), received EU marketing authorisation in August 2017, based on the totality of evidence from pre-clinical and clinical Phase I and III studies that demonstrated bioequivalence, similar efficacy, and comparable safety and immunogenicity to the reference. There are few published data on the transition from reference to biosimilar ADA outside the controlled, randomised, clinical trial setting.

Objectives: To evaluate candidate predictors of persistence on SBS in EU patients across multiple indications.

Methods: This ongoing observational study will enrol approximately 1200 subjects with rheumatoid arthritis (RA), axial spondyloarthritis (axSpA) or psoriatic arthritis (PsA), who initiated SBS as part of routine clinical practice following a minimum of 16 weeks’ treatment with reference ADA, at clinics in Belgium, Germany, Ireland, Italy, Spain and the UK. Data are captured from clinic records retrospectively for the 24 weeks prior to transition, and prospectively and/or retrospectively for 48 weeks following transition. The primary objective is to evaluate candidate predictors of persistence, and primary outcome measures include baseline clinical characteristics, disease activity scores, clinical management and patient satisfaction over time. This interim analysis provides an overview of baseline characteristics for subjects enrolled and followed up by the data extract date of 20th December 2019.

Results: Of the 123 patients included in this interim analysis, 43 suffer from RA, 42 from axSpA and 38 from PsA.