Comparing Drug Survival for Biosimilar SB4 Etanercept in Rheumatoid Arthritis Both Etanercept naïve and Non-Medical Switch Patients with Etanercept Reference Drug in a Norwegian Out-patient Clinic. Preliminary Results from a Multi-Center Study

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Background: In Norway encouraged by the health authorities non-medical switch from reference drug to biosimilar drug has been performed in most patients on biologic reference drugs with biosimilar drugs available, including etanercept. There is a need for real life data understanding the effect of biosimilar drugs when these drugs are introduced in clinical practice.

Objectives: To explore drug survival for biosimilar SB4 etanercept in RA patients, both etanercept naïve and non-medical switch patients, and compare with the etanercept reference drug.

Methods: Preliminary 2 years drug survival data from one center in a 5 center study in Norway exploring drug survival for etanercept reference drug and biosimilar etanercept SB4 is presented. At this outpatient clinic RA patients as part of standard clinical care has been monitored systematically since 2003. Drug survival for SB4 etanercept, both the etanercept naïve and the non-medical SB4 switch group, was compared with patients treated with the etanercept reference drug in the period 2003-2018. Baseline demographic, clinical and treatment data were retrieved and analyzed.

Preliminary 2 years drug survival data were used to explore 2 years drug survival. Survival differences between groups were tested using Bremsenhoff statistics.

Results: At the outpatient clinic the number of RA patients treated with etanercept reference drug was 356, the number of patients treated with SB4 with no previous etanercept was 36 and the patients with a non-medical switch from reference drug to biosimilar drug was 84.

In the table below baseline demographics and disease measures are shown for the etanercept reference group, the non-medical SB4 switch group and the SB4 naïve to etanercept group. Data in table are presented as percentage for group variables and as mean with standard deviation (SD) for continuous variables.

<table>
<thead>
<tr>
<th>Etanercept reference (n=356)</th>
<th>SB4 non-medical switch (n=84)</th>
<th>SB4 etanercept naïve (n=36)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>63.7 (15.4)</td>
<td>62.2 (11.6)</td>
</tr>
<tr>
<td>Females</td>
<td>71.1%</td>
<td>69.0%</td>
</tr>
<tr>
<td>Disease duration, years</td>
<td>12.6 (10.3)</td>
<td>18.3 (11.2)</td>
</tr>
<tr>
<td>Anti-CCP positive</td>
<td>75.4%</td>
<td>75.0%</td>
</tr>
<tr>
<td>DAS28</td>
<td>4.8 (1.4)</td>
<td>2.8 (1.3)</td>
</tr>
<tr>
<td>ESR mm/hr</td>
<td>29.5 (21.5)</td>
<td>17.6 (13.7)</td>
</tr>
<tr>
<td>CRP mg/l</td>
<td>20.3 (23.1)</td>
<td>5.0 (6.5)</td>
</tr>
<tr>
<td>Pain (VAS 0-100)</td>
<td>53.1 (27.0)</td>
<td>30.2 (25.3)</td>
</tr>
<tr>
<td>Fatigue (VAS 0-100)</td>
<td>53.4 (30.6)</td>
<td>34.4 (33.4)</td>
</tr>
<tr>
<td>MHAQ 0.78 (0.56)</td>
<td>0.51 (0.61)</td>
<td>0.71 (0.44)</td>
</tr>
</tbody>
</table>

Mean (95%CI) drug survival for the non-medical SB4 switch group was 1.53 (1.38-1.68) years, for the SB4 group with no previous etanercept 1.23 (0.95-1.51) years and for etanercept reference group 1.38 (1.31-1.46) years. A statistically significant difference (p<0.02) was found between the groups except between etanercept reference group and the etanercept SB4 group without prior etanercept (p=0.23). The percentage of RA patients starting with etanercept as first biologic drug was for etanercept reference 64.6% and for biosimilar etanercept SB4 36.1%. In the figure below Kaplan-Meier drug survival curves are shown.

Conclusions: To the best of our knowledge this is the first data showing that drug survival of an etanercept biosimilar drug after a non-medical...
EFFECTS OF BIOLOGICAL DISEASE-MODIFYING ANTI-RHEUMATIC DRUG TREATMENT ON PHYSICAL ACTIVITY, MUSCLE POWER, AGILITY AND INHIBITION OF FALL IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Disclosure of Interests: None declared


Background: It has been demonstrated that biological DMARDs (bDMARDs) treatment rapidly improved sign and symptom in patients with rheumatoid arthritis (RA). This study investigated the efficacy of bDMARDs on physical function such as muscle power and agility.

Methods: Periodic evaluation of physical function by the staffs in rehabilitation center in our institute has been performed in addition to routine rheumatology evaluation (SDAI, biomarkers, mHAQ) in RA patient initiated their first bDMARDs treatment from Oct. 2015 to Feb. 2018. 47 cases was registered in total. Evaluation of physical function included evaluation of muscle power (grasping power [GP] and knee extension power [KEP]), agility (Time up and go test [TUG] and 10m walking time [10mW]) and questionnaire using mHAQ, portable fall risk index [2] and the 25-questions geriatric locomotive function scale (locomo25) [3] at baseline (initiation of bDMARDs), 1month, 3months, 6months and 12months. Disease activity of RA (SDAI, CRP, MMP3) was evaluated at same time point. Although rapid improvement of composite measures or biomarkers is important in the treatment of RA, primary important goal of treatment is improvement of long term health-related quality of life (HR-QOL) [1]. HR-QOL is based on physical function such as muscle power and agility.

Objectives: This study investigated the efficacy of bDMARDs on physical function and fall risk in patients with RA.

Results: Baseline patients characteristics was as follow (n=17): mean age 59.1 years old, RA duration 13.7 years. Mean SDAI 19.6, mean CRP 1.9mg/dl. Used bDMARDs were tocilizumab in 5 cases, golimumab in 4 cases, etanercept in 3 cases, abatacept in 3 case, certolizumab in one case and infliximab-biosimilar in one case. Date is presents as mean values at baseline-1-3-6-12 months below. SDAI and CRP were significantly improved on and after one month (SDAI: 19.6-9.6-8.6-8.5-7.5, CRP [mg/dl]: 1.9-0.3-0.3-0.3-0.8). GP and knee extension power significantly improved on and after one months except KEP at 3 months (GP [kg]: 12.3-14.1-15.9-16.9-17.4, KEP [N/kg]: 2.6-3.1-3.1-3.4-4.3). TUG at 10mW significantly improved on and after one months except TUG at 3months and 10mW at 3 months (TUG [s]: 9.3-8.0-8.2-7.3-7.4, 10mW[s]: 8.3-7.7-7.5-6.9-6.8). mHAQ significantly improved on and from 6 months (0.46-0.33-0.19-0.20-0.12). locomo25 significantly improved on and from 1 month (31.7-20.6-18.5-16.7-15.0). Portable fall risk index significantly improved at only 12 months (8.8-8.6-7.8-7.8-6.8).

Conclusion: Signs and symptoms of RA were rapidly improved after the initiation of bDMARDs treatment and improvement of physical function was also rapidly improved. The changes from baseline and one month were more drastic in composite measure or biomarker of inflammation than that in muscle power and agility in respect with p-values. Inhibition of fall were achieved 12 months after bDMARDs initiation. These results suggested that physiotherapy might play an important role in RA patients treated with bDMARDs to gain more rapid improvement of physical function.

REFERENCES

Disclosure of Interests: None declared


SAT0148 IMMUNOGLOBULIN A LEVELS IN ADDITION TO RHEUMATOID FACTOR PREDICTS REMISSION ACHIEVEMENT WITH ABATACEPT IN PATIENTS WITH EARLY RHEUMATOID ARTHRITIS

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Methods: We retrospectively reviewed consecutive patients with RA who started ABT from 2010 through 2018 in Keio University Hospital. We defined early ABT use as the initiation of ABT within two years from diagnosis without radiographic progression in hand X rays, and stratified the patients into the early ABT users and the late ABT users. Baseline characteristics were compared between patients who achieved CDAI remission achievement at 6 months and those who did not in both groups.

Results: One hundred and seven RA patients who were treated with ABT with baseline information available were enrolled in the study. Among them, 15 patients were classified into the early ABT users and 92 were the late ABT users, and the remission rates at 6 months were 40% and 24%, respectively. In the early ABT users, patients who achieved CDAI remission at 6 months showed significantly higher IgA levels than those who did not achieve remission (390 mg/dl vs 279 mg/dl, P<0.04, respectively). The difference in IgA disappeared in the late ABT users (332 mg/dl vs 313 mg/dl, P=0.60, respectively). Principal component analysis revealed that in the early ABT users, patients who...