Conclusion: In patients with D2T RA, TNFi were discontinued more often due to their ineffectiveness (93.3%; compared with C: p<0.0001). This inefficacy was more often secondary (56.7%; compared with C: p=0.01). In the structure of secondary inefficacy, the variant of its development after a break in reception for administrative reasons prevailed (52.9%; compared with C: p=0.02). The incidence of adverse reactions in both groups was comparable.

Disclosure of Interests: None declared


AB0347

TREATMENT RESPONSE WITH ABATACEPT PLUS METHOTREXATE TREATMENT FOR RHEUMATOID ARTHRITIS: REAL-WORLD EVIDENCE FROM THE UK

E. Choy1, S. Henning2,3, M. Brazill4, K. Pollock2, L. Groves5, D. Sugrue6, J. Houghton1,2,4, Cardiff University, CREATE Centre, Cardiff University School of Medicine, Cardiff, United Kingdom; 2Raynaud Educate, Portsmouth, United Kingdom; 3Bristol-Myers Squibb Pharmaceuticals Limited, Middlesex, United Kingdom; 4Health Economics and Outcomes Research Ltd, Cardiff, United Kingdom

Background: A previous real-world study has reported the characteristics, treatment patterns and clinical outcomes of patients with rheumatoid arthritis (RA) who received abatacept in UK clinical practice. However, many of the eligible population received abatacept monotherapy rather than as indicated. A subgroup analysis of patients treated with abatacept in combination with methotrexate (ABA + MTX) was therefore undertaken to explore the treatment effect in this specific patient population.

Objectives: Present a subgroup analysis describing the clinical outcomes of patients with RA treated with ABA + MTX in UK real-world clinical practice.

Methods: A multi-centre, retrospective observational study was undertaken in patients with RA treated with abatacept at any line of therapy between 1 January 2013 and 31 December 2017, across four UK centres. Data were collected from patient medical records from index date, defined as the date of first abatacept initiation, to most recent RA clinic visit, death or end of study (31 December 2017). Clinical outcomes (disease activity and response to treatment) were measured using the 28-joint Disease Activity Score based on erythrocyte sedimentation rate (DAS28-ESR) and European League Against Rheumatism (EULAR) response criteria. Patients that received abatacept outside indication (i.e., without receiving abatacept as indicated) were retrospectively excluded from the analyses dataset. Statistical analyses for the ABA + MTX subgroup were repeated in line with the methodology previously reported.

Results: This subgroup analysis included 133 patients, of 213 patients included in the original study, with RA that received ABA + MTX (mean age 54.6 years, 77.4% female, 7.5 years mean duration of RA at index date). At index date, 64.8% of patients were positive for both anti-citrullinated protein antibodies (ACPA) and rheumatoid factor (RF), where data were available. In total, 77.8% of patients were categorised with high disease activity at index, with mean DAS28-ESR of 6.2 (SD 1.1).

Irrespective of line of treatment (LOT), patients tended to have a more favourable distribution of good/moderate/no EULAR response when receiving ABA + MTX (31.8%/34.1%/34.1%; n=44) compared with receipt of other bDMARDs (12.7%/36.4%/50.9%; n=55) at 6 months. Similarly, a favourable distribution of good/moderate/no EULAR response in favour of those receiving ABA + MTX compared with other bDMARDs was observed at 12 months (30.6%/41.7%/27.8% versus 20.0%/35.0%/45.0%, respectively).

Patients receiving ABA + MTX remained on treatment for significantly longer than patients in receipt of other bDMARDs as first LOT (median time on treatment 53.4 vs 18.1 months; p<0.01). A similar trend was observed at second LOT, although differences were not statistically significant (median time on treatment 40.1 vs 19.7 months; p=0.08).

Conclusion: Patients who received treatment with any bDMARDs, including ABA + MTX, experienced reduced disease activity. However, those receiving ABA + MTX persisted with treatment significantly longer than when receiving other bDMARDs.

REFERENCES:


Acknowledgements: This analysis was supported by Bristol-Myers Squibb.

Disclosure of Interests: Ernest Choy Speakers bureau: Abbvie, Amgen, Bristol-Myers Squibb, Chugai Pharma, Eli Lilly, Galapagos, Gilead, Janssen, Novartis, Pfizer, Regeneron, Roche, Sanofi, and UCB, Consultant of: Abbvie, Amgen, Biogen, Bioncon, Chugai Pharma, Eli Lilly, Gilead, Janssen, Merck Serono, Novartis, Pfizer, Regeneron, Roche, R-Pharm and Sanofi, Grant/research support from: Bio-Cancer, Biogen, Novartis, Pfizer, Roche, Sanofi and UCB, Sadie Henning Shareholder of: Bristol Myers Squibb, Employee of: Yes, Bristol Myers Squibb, Marie Marie Shareholder of: Bristol Myers Squibb, Employee of: Currently an employee of Bristol Myers Squibb, Kevin Pollock Shareholder of: Yes - Bristol Myers Squibb, Speakers bureau: Yes - Merck Sharp & Dohme and Glaxo Smith Kline, Consultant of: Yes - Merck Sharp & Dohme, Employee of: Yes – currently employed by Bristol Myers Squibb, Lara Groves Grant/research support from: I am an employee of Health Economics and Outcomes Research Ltd., Cardiff, UK, who received fees from Bristol Myers Squibb in relation to this study, Daniel Sugrue Grant/research support from: I am an employee of Health Economics and Outcomes Research Ltd., Cardiff, UK, who received fees from Bristol Myers Squibb in relation to this study, John Houghton Grant/research support from: I am an employee of Health Economics and Outcomes Research Ltd., Cardiff, UK, who received fees from Bristol Myers Squibb in relation to this study


AB0348

THE PROPER STUDY: A 48-WEEK ANALYSIS OF A PAN-EU REAL-WORLD STUDY OF SB5 BIOSIMILAR FOLLOWING TRANSITION FROM REFERENCE ADALIMUMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS, AXIAL SPONDYLOARTHRITIS OR PSORIATIC ARTHRITIS

U. Müllen-Ladner1, K. Gaffney1, D. Jadon1, M. Matucci-Cerinic1,2, E. Charno Carmonna3, U. Freundensprung1, J. Addison1, Kerckhoff-Klinik, Rheumatology Unit, Bad Nauheim, Germany; 1Norfolk and Norwich University Hospitals NHS Foundation Trust, Rheumatology Unit, Norwich, United Kingdom; 2Cambridge University Hospitals NHS Foundation Trust, Rheumatology Unit, Cambridge, United Kingdom; 3University of Florence, Rheumatology Unit, Firenze, Italy; 4Hospital San Raffaele, UNIRAN, Milan, Italy; 5Hospital General de Mérida, Rheumatology Unit, Mérida, Spain; 6Biogen International GmbH, Evidence Analytics, Baar

Table 1. Patient clinical characteristics, SB5 dose, flare

<table>
<thead>
<tr>
<th>RA (N=207)</th>
<th>axSpA (N=127)</th>
<th>PsA (N=162)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at SB5 initiation (years), mean (SD); IQR</td>
<td>60.1 (11.8)</td>
<td>53.0, 68.0</td>
</tr>
<tr>
<td>Duration of disease (years), mean (SD); IQR</td>
<td>13.3 (11.4)</td>
<td>5.0, 19.5</td>
</tr>
<tr>
<td>Women</td>
<td>n%</td>
<td>n%</td>
</tr>
<tr>
<td>150</td>
<td>72.5</td>
<td>40</td>
</tr>
<tr>
<td>Patients receiving SB5 40mg Q2W</td>
<td>152</td>
<td>73.4</td>
</tr>
<tr>
<td>Baseline</td>
<td>132</td>
<td>72.5</td>
</tr>
<tr>
<td>Week 48</td>
<td>132</td>
<td>72.5</td>
</tr>
<tr>
<td>Episodes of Flare</td>
<td>0</td>
<td>187</td>
</tr>
<tr>
<td>1</td>
<td>20</td>
<td>9.7</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>How was Flare diagnosed</td>
<td>Disease score</td>
<td>11</td>
</tr>
<tr>
<td>Patient-reported symptoms</td>
<td>19</td>
<td>95.0</td>
</tr>
<tr>
<td>Secondary Loss of Response</td>
<td>3</td>
<td>15.0</td>
</tr>
<tr>
<td>Action taken for Flare</td>
<td>Biologic therapy dose adjusted</td>
<td>4</td>
</tr>
<tr>
<td>Non-biologic therapy dose adjusted</td>
<td>8</td>
<td>40.0</td>
</tr>
<tr>
<td>Clinical investigation</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Other*</td>
<td>9</td>
<td>45.0</td>
</tr>
</tbody>
</table>

*Includes cessation of therapy, prescription of corticosteroids, physical exercise, no action IQR, interquartile range; SD, standard deviation; Q2W once-two-weekly.

Disclosure of Interests: None declared

Background: SBS, a biosimilar to reference adalimumab (ADL), received EU marketing authorisation in 2017, based on pre-clinical and clinical phase I and III studies that demonstrated bioequivalence and comparable efficacy, safety and immunogenicity to ADL.

Objectives: The real-world study PROPER is designed to provide insights into outcomes of the transition from ADL to SBS outside the randomised, controlled, clinical trial setting.

Methods: Under an umbrella design, 1000 patients with immune-mediated inflammatory disease were enrolled at centres in Belgium, Germany, Ireland, Italy, Spain and the UK, and followed for 48 weeks post-transition. Eligible patients with a diagnosis of rheumatoid arthritis (RA), axial spondyloarthropathy (axSpA), psoriatic arthritis (PsA), ulcerative colitis or Crohn’s disease had been transitioned to SBS as part of routine treatment following a minimum of 16 weeks’ treatment with ADL. Data were captured from patient charts retrospectively for 24 weeks prior to and prospectively and/or retrospectively up to 48 weeks after SBS initiation. This analysis of the rheumatology cohort reports clinical characteristics, disease scores, persistence on SBS, clinical management and safety up to the close date of November 30th, 2021.

Results: Of the 496 patients included in this analysis, the majority were enrolled in UK (n=174), Germany (n=145) and Spain (n=73); Italy, Ireland and Belgium enrolled 45, 44 and 15 patients respectively. At study close, 487 patients had completed 48 weeks of follow-up; 397 of those remained on SBS throughout.

Methotrexate was received as concomitant therapy by 37% of patients and 20% had received a biologic therapy prior to reference ADL. Most patients (89.3% of RA, 92.1% of axSpA, 97.3% of PsA) transitioned to SBS at the same dose regimen received for ADL.

Clinical characteristics, SBS dose and flare are detailed in Table 1, disease scores in Figure 1.

Figure 1. Disease scores (paired patients), mean (95% CI)

Fifteen patients each experienced one unrelated Serious Adverse Event (SAE); 2 in the axSpA cohort [tachycardia, intracranial haemorrhage]; 6 in the PsA cohort [myocardial infarct (2), breast carcinoma, COVID-19, gallbladder calculus, dyspepsia]; 7 in the RA cohort [facial numbness, depression, COVID-19, pneumonia, oesophageal varices, pericarditis, coronary occlusion]. Two patients reported SAEs considered causally related to SBS: Herpes zoster and pneumonia (RA cohort), and ALS with worsening (PsA cohort).

Conclusion: This analysis of a large, contemporary cohort of EU patients with established RA, axSpA or PsA shows treatment effectiveness maintained at 48 weeks after switching from ADL to SBS, with most patients continuing on SBS Q2W throughout. Episodes of flare were uncommon, and the importance of patient-reported symptoms in recognition of flare is evident. No new safety signals were observed.

Acknowledgements: Statistical services were provided by FGK Clinical Research GmbH, Munich, Germany. Data management services were provided by Worldwide Clinical Trial, Research Triangle Park, NC, USA; Funding was provided by Biogen International GmbH.

Disclosure of Interests: Ulf Müller-Ladner Consultant of: Biogen, Grant/ research support from: Biogen, Karl Gaffney Speakers bureau: Novartis, UCB, AbbVie, Lilly, Consultant of: Novartis, UCB, AbbVie, Lilly, Pfizer, Grant/ research support from: NAAS, AbbVie, Pfizer, UCB, Novartis, Lilly, Cellgene, Celltrion, Janssen, Gilead, Biogen, Deepak Jadon Consultant of: AbbVie, Cellgene, Eli Lilly, Gilead, Janssen, MSD, Novartis, Oxford University Press, Pfizer, Roche, Sandox, UCB, Grant/research support from: AbbVie, Cellgene, Eli Lilly, Gilead, Janssen, MSD, Novartis, Oxford University Press, Pfizer, Roche, Sandox, UCB, Marco Maturacci-Cerinich Consultant of: Chemomab, Biogen, Pfizer, Lilly, Behring, Janssen, MSD, Eugenio Chaminizo Carmona Speakers bureau: Abbvie, Amgen, Biogen, BMS, Cellgene, Eli Lilly, Fresenius-Kabi, Galapagos, Janssen, MSD, Novartis, Pfizer, and UCB; Consultant of: Abbvie, Amgen, Biogen, BMS, Cellgene, Eli Lilly, Fresenius-Kabi, Galapagos, Janssens, MSD, Novartis, Pfizer, and UCB; Ulrich Freudsprung Shareholder of: Mayhold stock in Biogen, Employee of: Biogen, Janet Addison Shareholder of: Mayhold stock in Biogen, Employee of: Biogen, May


AB0349 ANALYSIS EFFICACY OF ABATACEPT TREATMENT IN BIOLOGIC-NAIVE AND BIOLOGIC-EXPERIENCED PATIENTS.

M. Borisova1, G. Lukina1,2, S. Yakov1, E. Lukichkina3, D. Karatsev3, A. Novikova2, E. Alexandrova2, E. Aronova3, S. Glukhova1, E. Nasonov1,4,4, V.A. Nasonova Research Institute of Rheumatology, Laboratory of Monitoring Safety of Antirheumatic Treatment, Moscow, Russian Federation; A.S. Loginov Moscow Clinical Scientific Center, Department of Rheumatology, Moscow, Russian Federation; Moscow Regional Research and Clinical Institute (MONIKI), Department of Rheumatology, Moscow, Russian Federation; 3. V.A. Nasonova Research Institute of Rheumatology, Scientific Director, Moscow, Russian Federation; 4. M. Sechenov First Moscow State Medical University, Department of Rheumatology, Moscow, Russian Federation

Background: Despite the high efficacy of rheumatoid arthritis (RA) therapy, in routine clinical practice, clinicians face questions about the choice of a second biologic, as well as the possibility of biologics monotherapy. Therefore, the specialties of biologics use in these categories of patients are of great clinical interest. This work is devoted to the study of the effectiveness of abatacept (ABA) therapy in biologic-naïve and biologic-experienced patients and in the subgroup of ABA monotherapy.

Objectives: To evaluate the effectiveness of ABA therapy between biologic-naïve and patients who had experienced an inadequate response to biologic agents and in the subgroup of ABA monotherapy.

Methods: We prospectively enrolled and followed 91 patients with high RA activity (SDAI=28±13.4, CDAI=25±12) and an inadequate response of conventional synthetic DMARDs (mainly methotrexate, 70.3%) and biologics (mainly TNFα blockers, 93%) were included in the study. Most of the patients were middle-aged (49±13.5), positive for RF (72.5%) and ACCP (77%) with moderate functional impairment - 1.4 (0.9-2). Patients were divided into two groups: biologic-naïve (48.4%, n=44) and biologic-experienced patients (51.6%, n=47). 18% (n=17) of patients had a history of an inadequate response of 2 or more biologics. The ABA monotherapy group (13%, n=12) was assessed separately by ABA-experienced therapy. ABA were administered IV, 10 mg/kg according to the standard scheme. The evaluation of the effectiveness of the therapy was carried out according to the EULAR/ACR 2011 criteria using the intention-to-treat approach and SDAI, CDAI and the functional state using the HAQ.

Results: ABA led to a significant (p<0.05) decrease in RA activity after 3 months of ABA therapy in all groups. After 6 months of treatment, there was a tendency towards an increase in the number of patients who achieved remission and low RA activity in the group of biologic-naïve patients, which continued to 12 months of therapy. So, after 6 months and 12 months in the group of biologic-naïve patients, the frequency of remission and low disease activity was 71% (n=25) and 76% (n=19) by SDAI, 75.6% (n=28) and 61.5% (n=24) by CDAI, respectively. Whereas, in the group of biologic-experienced patients - SDAI - 61.8% (n=21) and 69.2% (n=18), CDAI - 64.8% (n=22) and 77.8% (n=21), respectively. However, these differences didn’t reach significance. Similar results were obtained according to the EULAR criteria: after 12 months of treatment, the percentage of patients with a good response in both groups did not differ, 38% (n=14) in biologic-naïve and 38.4% (n=15) in biologic-experienced patients. ABA significantly improved functional status of patients, after 12 months the median HAQ of biologic-naïve and biologic-experienced patients were 0.7 (0.2–0.8) and 1.18 (0.7–1.6), respectively. More biologic-naïve patients achieved functional remission by HAQ after 6 and 12 months compared with biologic-experienced patients: 67% (n=23) vs. 33% (n=17), 62.5% (n=11) vs. 37.5% (n=9), respectively, but these differences didn’t reach significance. In the ABA monotherapy group after 6 months treatment, a good response by EULAR criteria was achieved in 10% (n=1) patients, while in the group of ABA+csDMARDs therapy in 43.5%, p=0.04. After 12 months the trend towards a more pronounced response in the combination therapy group persisted (11%, n=1 and 42%, n=8, respectively), but no significant differences were obtained.

Conclusion: Abatacept has shown significant improvement clinical and functional status in all studied groups. There were no significant differences in response to ABA therapy between biologic-naïve and biologic-experienced patients. ABA monotherapy were significantly worse compared with the combination therapy of ABA and csDMARDs after 6 months. After 12th month observation, this tendency continued, but no significant differences were achieved. This is probably due to the small number of patients on ABA monotherapy and, as a result, to the insufficient statistical representativeness of the sample.

Disclosure of Interests: None Declared.