Table 1. Baseline predictors of reduction of disease activity at 12 months from start of abatacept. Linear regression.

<table>
<thead>
<tr>
<th>Variables</th>
<th>B</th>
<th>95% CI</th>
<th>P-value</th>
<th>B</th>
<th>95% CI</th>
<th>P-value</th>
<th>B</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex</td>
<td>0.39</td>
<td>[0.13, 0.64]</td>
<td>0.003</td>
<td>0.43</td>
<td>[0.20, 0.66]</td>
<td>&lt;0.001</td>
<td>0.42</td>
<td>[0.19, 0.64]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age (per SD)</td>
<td>1.00</td>
<td>[0.004, 2.21]</td>
<td>0.058</td>
<td>1.04</td>
<td>[0.051, 1.94]</td>
<td>0.37</td>
<td>1.00</td>
<td>[0.032, 1.96]</td>
<td>0.54</td>
</tr>
<tr>
<td>HAQ (per SD)</td>
<td>-0.14</td>
<td>[-0.35, -0.037]</td>
<td>0.009</td>
<td>-0.11</td>
<td>[-0.35, -0.13]</td>
<td>&lt;0.001</td>
<td>N/A</td>
<td>[-0.13, 0.065]</td>
<td>0.54</td>
</tr>
<tr>
<td>VAS pain (per SD)</td>
<td>0.26</td>
<td>[0.15, 0.37]</td>
<td>&lt;0.001</td>
<td>-0.058</td>
<td>[-0.17, 0.054]</td>
<td>0.31</td>
<td>N/A</td>
<td>[-0.04, 0.033]</td>
<td>0.02</td>
</tr>
<tr>
<td>MTX</td>
<td>0.20</td>
<td>[0.013, 0.41]</td>
<td>0.066</td>
<td>0.17</td>
<td>[-0.36, 0.024]</td>
<td>0.087</td>
<td>-0.14</td>
<td>[-0.33, 0.043]</td>
<td>0.13</td>
</tr>
<tr>
<td>Prednisolone</td>
<td>-0.19</td>
<td>[-0.41, 0.017]</td>
<td>0.072</td>
<td>-0.17</td>
<td>[-0.42, -0.23]</td>
<td>&lt;0.001</td>
<td>-0.31</td>
<td>[-0.40, -0.21]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Male sex</td>
<td>-0.30</td>
<td>[-0.40, -0.20]</td>
<td>&lt;0.001</td>
<td>-0.32</td>
<td>[-0.41, -0.23]</td>
<td>&lt;0.001</td>
<td>-0.31</td>
<td>[-0.40, -0.21]</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

B=beta coefficient; N/A=not applicable; SD=standard deviation; CI=confidence interval. Bold text indicates significant associations. DAS28, Disease activity Score of 28 joints; RA, rheumatoid arthritis; HAQ, Health Assessment Questionnaire; VAS, visual analogue scale; MTX, methotrexate; bDMARD, biologic disease-modifying antirheumatic drug. Current treatment

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POS0630 COMPARISON OF THE EFFICACY AND SAFETY OF ORIGIONAL AND BIOSIMILAR ADALIMUMAB MOLECULES IN CHILDHOOD RHEUMATIC DISEASES

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Background: The TNF-α inhibitor adalimumab is a biological disease modifying anti-rheumatic drug (bDMARD) that has been used in different rheumatic diseases with a resistant course. ABP-501 is a biosimilar product (BP) of adalimumab, recently approved by the FDA and EMA. To our knowledge, there is no study assess the efficacy and safety of these two molecules on pediatric patients.

Objectives: We aimed to compare the efficacy and safety of the original and biosimilar adalimumab (ABP-501) molecules in childhood rheumatic diseases.

Methods: This non-interventional, retrospective, single-centre analysis carried out in Umraniye Training and Resarch Hospital, Pediatric Rheumatology Clinic, Istanbul, Turkey. The study group consisted of patients who were followed due to chronic rheumatic disease between January 1, 2016 and June 1, 2020, and received reference or biosimilar adalimumab therapy for at least three months. Demographic and clinical data of patients were collected at baseline, 3rd, 6th, and 12th months of treatment. Disease activity assessment was made with JADAS-27 in JIA patients, with SUN criteria in uveitis patients, and with Behçet's Disease Activity Index in BD patients. Efficacy and safety of treatments were compared between reference and biosimilar adalimumab groups.

Results: A total of 89 patients (65 with original and 24 with biosimilar molecule) treated with adalimumab, were included in the study. There were 45 female and 44 male in the study, and the median age at the initiation of the adalimumab was 166 months (min-max: 36-231). Of the 89 patients evaluated, the primary diagnoses of 62 were juvenile idiopathic arthritis, 13 were idiopathic uveitis, eight were Behçet's disease, three were Blau syndrome, two were chronic recurrent multifocal osteomyelitis and one was Vogt-Koyanagi-Harada syndrome. 63 of the patients were biologic-naive, and 13 were switched from etanercept, 11 from infliximab, and two from other bDMARDs. The median exposure time of adalimumab was 16 months (min-max:3-70) in RP and 14.5 months (min-max: 3-23) in BP. All patients had active disease before treatment. In the group treated with RP, inactive disease was achieved in 60%, 76.6% and 87.2% of the patients at the 3rd, 6th and 12th months, respectively. Also, inactive disease was achieved in 62.5%, 78.2% and 78.2% of the patients at the 3rd, 6th and 12th months in the group treated with BP, respectively. There was no statistically significant different in efficacy between the groups at the 3rd, 6th and 12th months (p=0.83, 0.07 and 0.32). Serious adverse events were seen in one patient in each groups (lymphoma in RP group, tuberculous meningitis in BP group). Non-serious adverse events were observed in eight patients (12.3%) in the RP group and in two patients (6.3%) in the BP group, without statistically significant different between groups (p=0.86).

Conclusion: No significant difference was observed between the biosimilar adalimumab ABP-501 and RP adalimumab in terms of efficacy and safety.

REFERENCES:

Disclosure of Interests: None declared

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POS0631 COMPARATIVE EFFICACY OF COMBINATION THERAPY WITH BIOLOGIC OR TARGET SYNTHETIC DRUGS FOR RHEUMATOID ARTHRITIS: A BAYESIAN NETWORK META-ANALYSIS

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Background: Biologic agents and small molecules have shown long term benefit when added in patients with active RA non-responders to conventional DMARDs treatment (1). In head-to-head trials only adalimumab was compared to other drugs in combination with methotrexate, with some evidence of superiority but no data on multiple comparisons have been reported (2). The availability of biosimilar agents led in clinical practice to prefer mainly the cheaper one, so the choice of the most effective treatment remains a clinical unmet need (3).

Objectives: To assess the relative efficacy of different therapeutic strategies for achieving ACR50 response at 24 weeks of treatment in patients with active RA, based on direct and indirect evidence using the WinBUGS 1.4 software (MRC Biostatistics Unit, Cambridge, UK).

Methods: We performed systematic reviews of MEDLINE, EMBASE, and Cochrane Library databases, searching for all published phase 3 Randomised Controlled Trials (RCTs) comparing adalimumab originator to its biosimilars, abatacept, baricitinib, certolizumab pegol, tofacitinib or upadacitinib, combined to MTX, in patients with active RA inadequate responders to previous conventional DMARDs. American College of Rheumatology (ACR) 50% response at 24 weeks of treatment had to be evaluated both in adalimumab branch and in examined drug branch. Bayesian fixed-effect network meta-analysis was performed to combine the direct and indirect evidence using the WinBUGS 1.4 software (MRC Biostatistics Unit, Cambridge, UK).

Results: Eleven RCTs evaluating 86’004 patients were included in the analysis, namely originator (1) and biosimilars (2) adalimumab, abatacept (3), baricitinib (4), certolizumab pegol (5), tofacitinib (6) and upadacitinib (7). Convergence was reached at n.100’000 iterations. Upadacitinib seems to be more effective than both originator and biosimilar adalimumab in achieving ACR 50 (OR 1.25 95%CI 1.01-1.55). In head-to-head trials only adalimumab was compared to other drugs in combination with methotrexate, with some evidence of superiority but no data on multiple comparisons have been reported (2). The availability of biosimilar agents led in clinical practice to prefer mainly the cheaper one, so the choice of the most effective treatment remains a clinical unmet need (3).

Figure 1. Caterpillar plot OR for ACR50 at 24 weeks (originator [1] and biosimilars [2] adalimumab; abatacept [3]; baricitinib [4]; certolizumab pegol [5]; tofacitinib [6]; upadacitinib [7]).
Conclusion: Although patients with active RA and inadequate response to MTX have different therapeutic combination of biologics or small molecules options, the best relative efficacy in terms of ACR50 response after 24 weeks of treatment is for upadacitinib 15 mg/day.

REFERENCES:

Disclosure of Interests: Fabio Cacciapaglia Speakers bureau: Roche, Pfizer, Eli Lilly, MSD, UCB, BMS, Abbvie, Vincenzo Venerito; None declared, Stefano Stano: None declared, Marco Fornano: None declared, Giuseppe Lopalco Speakers bureau: Celgene, BMS, Abbvie, Novartis, Florenzo Iannone Speakers bureau: Roche, Pfizer, Eli Lilly, MSD, UCB, Abbvie, Novartis, Celgene

Figure 1. The hospital separations and total drugs use patterns of RA in 1995-2014 in Western Australia.

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Disclosure of Interests: Khalid Almutairi: None declared, Johannes Nossent: Speaks at the speakers bureau of Celgene, BMS, Abbvie, Novartis, Florenzo Iannone; None declared, Marco Fornano: None declared, Giuseppe Lopalco: None declared, Stefano Stano: None declared, Stefano Venerito.

Background: Before using biological DMARDs, EULAR suggests the use of synthetic DMARDs (especially methotrexate) for RA and PsA [1-2].

Objectives: It was aimed to evaluate the differences of disease duration and csDMARDs till first bDMARD in RA and PsA patients.

Methods: HUR-BIO (Hacettepe University Biologic Registry) is a prospective, single center database of biological treatments since 2005 and to date 2070 RA and 520 PsA patients have been recorded. Demographic, clinical and laboratory data before bDMARDs of the patients were noted. When investigating the differences between groups, the effects of gender, age and disease duration were adjusted using two-way ANOVA and ANCOVA tests. The selection was made for the gender, age and for indifferece of the relevant groups by using propensity score matching.

Results: We included 481 RA, and 482 PsA age and gender matched patients in the study. Age, gender and disease duration information were given in the Table 1. 72.8% of the RA patients were RF or anti-CCP positive. Overall, 56.3, 100% of the RA, and PsA patients first biologic therapies were anti-TNFs, respectively. All RA patients started with csDMARDs before bDMARD treatments, whereas 450 of 482 (93.4%) PsA patients. Methotrexate was the anchor csDMARD for both diseases. RA patients more frequently used all csDMARDs included methotrexate, lefunomide, sulphasalazine hydroxychloroquine and corticosteroids as well. Median disease duration till bDMARD treatments in RA and PsA patients were 55 and 18.5 months respectively (p<0.001) (Table 1).

Table 1. Demographic characteristics and csDMARDs before first bDMARD

<table>
<thead>
<tr>
<th>RA (n=481)</th>
<th>PsA (n=482)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, n (%)</td>
<td>319 (66.3)</td>
<td>332 (68.9)</td>
</tr>
<tr>
<td>Age, years (means±SD)</td>
<td>50.7±12.1</td>
<td>50.7±12.1</td>
</tr>
<tr>
<td>Disease duration, years*</td>
<td>12.3 (6-16)</td>
<td>7 (3-12)</td>
</tr>
<tr>
<td>Symptom duration before diagnosis, years*</td>
<td>10 (0-1)</td>
<td>1 (0-4)</td>
</tr>
<tr>
<td>The period of time between diagnosis and bDMARD initiation, months*</td>
<td>55 (24-115)</td>
<td>18.5 (8-58)</td>
</tr>
<tr>
<td>The period of time between symptoms and bDMARD initiation, months*</td>
<td>70 (35-151)</td>
<td>48 (20-124)</td>
</tr>
</tbody>
</table>

Methotrexate

Everb n (%) | 400 (83.3) | 373 (77.5) | 0.015 |
| Just before bmDMARD initiation n (%) | 251 (52.2) | 230 (47.7) | 0.093 |

Hydroxychloroquine sulfate

Everb n (%) | 292 (60.8) | 170 (35.3) | 0.000* |
| Just before bmDMARD initiation n (%) | 262 (54.5) | 99 (20.5) | 0.000* |

Leflunomide

Everb n (%) | 237 (49.4) | 129 (26.8) | 0.000* |
| Just before bmDMARD initiation n (%) | 160 (33.3) | 96 (19.9) | 0.000* |

Sulfasalazine

Everb n (%) | 353 (73.5) | 265 (55.1) | 0.000* |
| Just before bmDMARD initiation n (%) | 156 (32.4) | 146 (30.3) | 0.259* |

Corticosteroids

Everb n (%) | 419 (87.3) | 281 (58.4) | 0.000* |
| Just before bmDMARD initiation n (%) | 335 (69.6) | 187 (38.8) | 0.000* |

Conclusion: According to HUR-BIO real life data, for inflammatory arthri- tis patients who started bDMARDs, the periods of time between diagnosis and bDMARDs were more reasonable (18 months) in PsA patients than RA patient’s periods which were approximately three times longer. RA patients were used much more and longer duration of csDMARDs. This explicit distinction may be explained by synthetic DMARDs on activity differences between the RA and PsA.

REFERENCES: