

AB0292

EFFICACY AND SAFETY OF TWO BIOSIMILAR ETANERCEPT AFTER THE SWITCH FROM THEIR CORRESPONDING ORIGINATOR IN THE TREATMENT OF PATIENTS WITH AUTOIMMUNE ARTHRITIS; A RETROSPECTIVE ANALYSIS IN A REAL LIFE SETTING

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Background: The available biosimilars of etanercept are as effective and well tolerated as their bio originator molecule in the naive treatment of chronic autoimmune arthritis. More data about the switching from the bio originator are needed.

Objectives: To compare the clinical outcomes of the treatment with etanercept biosimilars (SB4 and GP2015) naive and after the switch from their corresponding originator in patients affected by autoimmune arthritis in a real life setting

Methods: We retrospectively analyzed the baseline characteristics and the retention rate in a cohort of patients who received at least a course of etanercept (originator or biosimilar) in our Rheumatology Units from January 2000 to January 2020. We stratified the study population according to biosimilar use. Descriptive data are presented by medians (interquartile range [IQR]) for continuous data or as numbers (percentages) for categorical data. Drug survival distribution curves were computed by the Kaplan-Meier method and compared by a stratified log-rank test. A Cox proportional hazards regression analysis stratified by indication, drug, age, disease duration, sex, treatment line, biosimilar use and prescription year was performed. P values ≤ 0.05 were considered statistically significant.

Results: 477 patients (65% female, median age 56 [46-75] years, median disease duration 97 [40.25-178.75] months) treated with etanercept were included in the analysis. 257 (53.9%) were affected by rheumatoid arthritis, 139 (29.1%) by psoriatic arthritis, and 81 (17%) by axial spondylarthritis. 298 (62.5%) were treated with etanercept originator, 97 (20.3%) with SB4, and 82 (17.2%) with GP2015. Among the biosimilars 90/179 (50.3%) patients were naive to etanercept treatment. Among the 89 switchers we observed 8 treatment discontinuations: one due to surgical infection complication, three due to disease flare, two due to subjective worsening and one due to remission. The overall 6- and 12-month retentions rate were 92.8% and 80.2%. The 6- and 12-month retention rate for etanercept, SB4 and GP2015 were 92.7%, 93.4% and 90.2%, and 82%, 74.5% and 88.1% respectively, without significant differences among the three groups ($p=0.374$). Patients switching from originator to biosimilars showed and overall higher treatment survival when compared to naive (12-month retention rate 81.2% vs 70.8%, $p=0.036$). The Cox proportional hazard regression analysis highlighted that the only predictor significantly associated with an overall higher risk of treatment discontinuation was the year of prescription (HR 1.08, 95% CI 1.04 to 1.13; $p<0.0001$).

Conclusion: In our retrospective study etanercept originator and its biosimilars (SB4 and GP2015) showed the same effectiveness. Patients switching from originator to biosimilar showed a significant higher retention rate when compared to naive. The only predictor of treatment discontinuation highlighted by the Cox proportional hazard regression analysis was the year of treatment prescription.

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AB0293

FACTORS ASSOCIATED WITH INITIATION OF BIOLOGIC DISEASE-MODIFYING ANTIRHEUMATIC DRUGS IN MOROCCAN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Rheumatoid arthritis (RA) is a progressive autoimmune disorder of joints that is associated with high health care costs, yet guidance is lacking on how early to initiate biologic disease-modifying antirheumatic drugs (DMARDs). Few studies have examined the factors associated with the transition from non biologic DMARDs to biologic DMARDs in RA patients.

Objectives: to examine the association of patient's comorbidities with initiation of biologic DMARDs (disease-modifying antirheumatic drugs) in rheumatoid arthritis (RA).

Methods: cross-sectional study was designed on a cohort of RA patients. Socio-demographic, clinical data and comorbidities were collected. Logistic regression analysis was used to explore the impact of comorbidities on the initiation of

bDMARD. The statistical analysis was done by SPSS. 20, $p < 0.05$ was considered significant.

Results: among the 257 patients, 90.5% were females. Their mean age was 54.66 \pm 11.9 years. The most frequent comorbidities in our population were: high blood pressure (22.5%), diabetes (16.6%), history of heart disease (5.1%), history of neoplasia (2.4%) and nephropathies (2%). RA patients with comorbidities were more likely to initiate bDMARD: high blood pressure ($p = 0.003$ OR=2.36, 95% CI: 1.332- 4.181), history of heart disease ($p = 0.036$ OR=3.01, 95% CI: 1.073-8.468) and history of neoplasia ($p = 0.026$ OR= 5.07, 95% CI: 1.219- 21.110). In multiple regression models, high blood pressure was associated to the initiation of biologic agents ($p = 0.026$, OR= 2.07, 95% CI: 1.090-3.932).

Conclusion: the probability of initiating therapy with biologic agents in patients with RA is affected by different co-morbidities in our context specifically hypertension.

References:

- [1] Machado-Alba JE, et al. Time to and factors associated with initiation of biological therapy in patients with rheumatoid arthritis in Colombia. Rev Colomb Reumatol. 2018
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AB0294

PERSISTENCE WITH ABATACEPT VERSUS TUMOR NECROSIS FACTOR-INHIBITORS FOR RHEUMATOID ARTHRITIS COMPLICATED BY POSITIVE ANTI-CYCLIC CITRULLINATED PEPTIDE/RHEUMATOID FACTOR OR OTHER POOR PROGNOSTIC FACTORS

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Background: Rheumatoid arthritis (RA) treatment usually begins with a non-biologic disease-modifying antirheumatic drug (DMARD), followed by a biologic DMARD (including abatacept or tumor necrosis factor-inhibitors [TNFi]) in non-responsive patients.¹ Since, treatments are switched if disease activity does not improve, it is valuable to understand treatment persistence and switch patterns in RA patients with poor prognostic factors in a real-world setting.

Objectives: To assess 12-month treatment persistence in early-line abatacept versus TNFi treated patients with RA complicated by poor prognostic factors.

Methods: We performed a multi-center retrospective medical record review of adult RA patients with poor prognostic factors treated at 6 United States clinics. Patients were treated with abatacept or TNFi as the first biologic treatment at the clinic. Poor prognostic factors included positive anti-cyclic citrullinated peptide antibodies (ACPA+), positive rheumatoid factor antibodies (RF+), increased C-reactive protein levels, elevated erythrocyte sedimentation rate levels, or presence of joint erosions. TNFis included adalimumab, etanercept, infliximab (and their biosimilars), certolizumab pegol, or golimumab. Data were collected from first biologic treatment for ≥ 1 year. Patients with Crohn's disease, ankylosing spondylitis, ulcerative colitis, psoriatic arthritis, or anal fistula were excluded. Demographic, disease, and treatment information (start, stop, reason for discontinuation) was abstracted. Treatment persistence (continuation of index treatment with gap ≤ 60 days) at 12 months and time to discontinuation were reported. Multivariate logistic and Cox regressions were used to compare 12-month persistence and risk of discontinuation between abatacept and TNFi, controlling for demographic and clinical characteristics (age, sex, Charlson comorbidity index [CCI], RA duration), baseline utilization, and clinic. Findings among a subgroup of ACPA+ and/or RF+ patients are reported.

Results: Data on 265 patients (100 abatacept, 165 TNFi) were collected, including 163 ACPA+ and/or RF+ patients (55 abatacept, 108 TNFi). Overall, abatacept patients were older than TNFi patients (67.0 vs. 60.3 years, $p<0.001$), but there were no statistically significant differences in gender, comorbidities, or duration of treatment at the clinic. At 12 months, 83.0% of abatacept patients were persistent vs. 66.1% of TNFi patients ($p=0.003$). Persistence was similar among ACPA+ and/or RF+ patients (83.6% vs. 64.8%, $p=0.012$). Median time to discontinuation was 1,423 days for abatacept vs. 690 days for TNFi ($p=0.014$) (961 days vs. 581 days among ACPA+ and/or RF+ patients, $p=0.048$) (Figures 1,2). In the adjusted analysis, risk of all-cause discontinuation was statistically significantly higher among TNFi than abatacept patients (1.7 [95% CI: 1.1-2.6], $p=0.012$). The odds of TNFi patients being persistent at 12 months was 51% lower than abatacept patients, although not statistically significant

($p=0.071$). More TNFi than abatacept patients discontinued index treatment due to disease progression (27.3% vs. 12.0%, $p=0.003$). Adjusted analyses showed that TNFi patients had a statistically significantly higher risk of discontinuing index treatment due to disease progression (3.4 [95% CI: 1.6-7.2], $p=0.001$).

Conclusion: In a real-world setting, RA patients with ACPA or RF positivity or other poor prognostic factors are less likely to discontinue abatacept compared with TNFi and are more likely to be persistent on their early line treatment. This difference may be explained by the lower proportion of patients discontinuing abatacept due to disease progression.

References:

[1] Singh et al. *Arthritis Care Res.* 2012;64(5):625-639. doi:10.1002/acr.21641

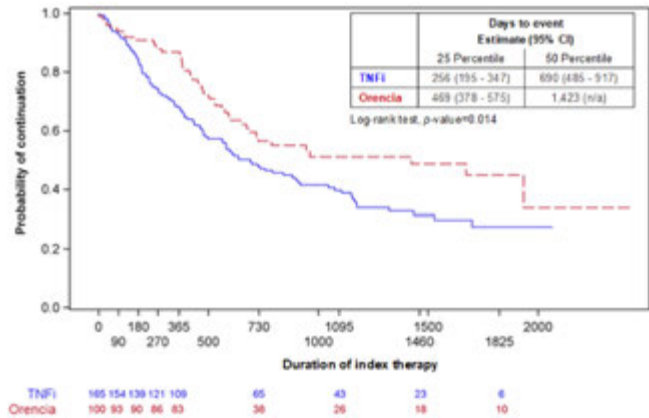


Figure 1. Time to discontinuation of index treatment among all patients (N=265)

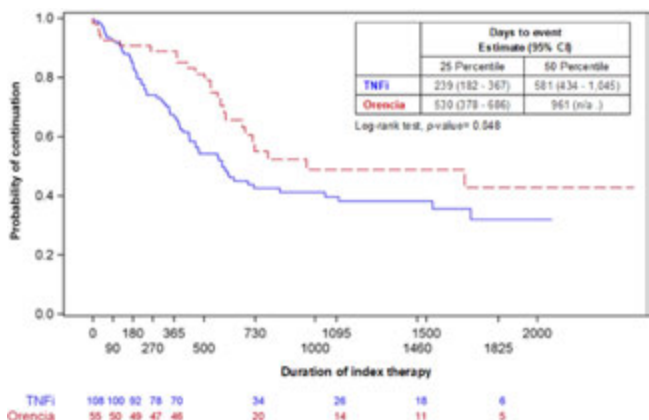


Figure 2. Time to discontinuation of index treatment among ACPA+ and/or RF+ patients (N=163)

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AB0295 CHANGE IN DISEASE ACTIVITY AND TREATMENT RESPONSE AFTER ABATACEPT TREATMENT FOR RHEUMATOID ARTHRITIS: REAL-WORLD EVIDENCE FROM THE UK

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Background: Patients with moderate to severe active rheumatoid arthritis (RA) may be treated with biological disease-modifying antirheumatic drugs (bDMARDs), such as abatacept, after treatment failure with conventional synthetic DMARDs (csDMARDs). Abatacept has shown equivalent efficiency with other targeted therapies for RA in clinical trials and network meta-analyses. However, there is limited real-world evidence on patient outcomes associated with abatacept treatment in UK routine clinical practice.

Objectives: To describe the clinical outcomes of RA patients treated with abatacept in UK real-world clinical practice.

Methods: A multi-centre, retrospective observational study was undertaken in RA patients treated with abatacept at any line of therapy (LOT). Data were extracted from medical records at four UK hospitals. Patients aged 18 years or older who received abatacept between 1 January 2013 and 31 December 2017 were included. The index date was the date of first bDMARD initiation, with follow-up from index date to latest RA clinic visit, death or 31 December 2017, whichever occurred first.

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 criteria¹⁻³.

Results: The study included 213 patients (mean age 55.2 years, 71.4% female, 7.0 years mean duration of RA at index date). Where ACPA and RF status were recorded, 66.1% of patients were anti-citrullinated protein antibodies (ACPA) and rheumatoid factor (RF) positive at index. Mean DAS28-ESR at index was 6.2 (SD 1.0) and 80.9% of patients were categorised with high disease activity. Irrespective of LOT, changes in DAS28-ESR (where recorded) from LOT initiation among patients treated with abatacept versus other bDMARDs were -1.59 vs -1.56 (LS mean (SE): -0.04; 95% CI: -0.45,0.38; $p=0.86$) at 6 months and -1.98 vs -1.42 (LS mean (SE): -0.56; 95% CI: -1.04,-0.07; $p=0.03$) at 12 months, respectively. Table 1 shows that compared with other bDMARDs, patients treated with abatacept at any LOT experienced good response to treatment at 6 months (22.8%, $n=21/92$ vs 15.9%, $n=24/151$) and 12 months (27.9%, $n=17/61$ vs 20.5%, $n=24/117$) according to EULAR criteria.

Table 1. Treatment response at 6 and 12 months after initiation of any LOT*

EULAR response	6 months		12 months	
	Abatacept, n = 92	Other bDMARDs, n = 151	Abatacept, n = 61	Other bDMARDs, n = 117
Good	21 (22.8%)	24 (15.9%)	17 (27.9%)	24 (20.5%)
Moderate	38 (41.3%)	60 (39.7%)	22 (36.1%)	40 (34.2%)
None	33 (35.9%)	67 (44.4%)	22 (36.1%)	53 (45.3%)

n = number of unique LOTs in which a patient has both a DAS28-ESR collected at initiation and 6 and/or 12 months (a patient may be included in this analysis multiple times)

Patients who received abatacept remained on treatment for significantly longer than patients who received other bDMARDs at LOT1 (median 53.4 vs 17.4 months; $p<0.01$) (Figure 1) and at LOT2 (median 40.1 vs 17.1 months; $p<0.01$).

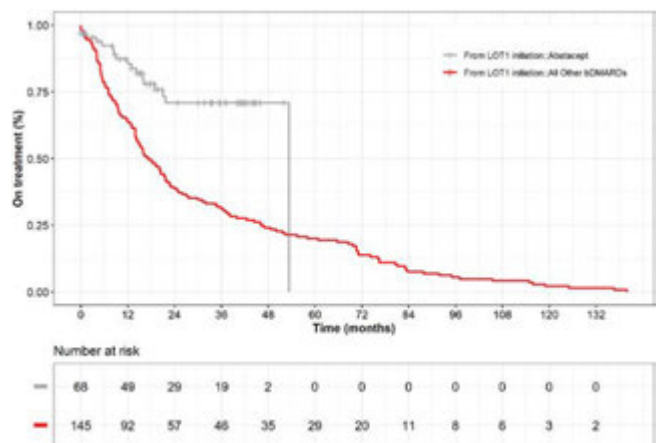


Figure 1. Time on treatment from first LOT initiation, abatacept versus other bDMARDs

Conclusion: RA patients who received bDMARDs, including abatacept, experienced reduced disease activity. These findings are comparable with those from a European, multicentre, observational study on patients receiving abatacept⁴.