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AB0585 (2024)

REAL-WORLD EXPERIENCE OF RITUXIMAB BIOSIMILAR CT-P10, IN PATIENTS WITH RHEUMATOID ARTHRITIS FROM A TERTIARY CARE CENTER

Keywords: Real-world evidence, Biosimilar Pharmaceuticals, Biological DMARD

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Background: Rituximab is a chimeric monoclonal antibody to the CD20 antigen of B cells; it has been approved as a treatment for rheumatoid arthritis (RA) having good response in patients with failure to other treatments. The high cost of biological therapies is a major barrier, particularly in lower-income countries. For this reason, biosimilars are increasingly used, so real-world reporting of their use becomes important.

Objectives: Evaluate the efficacy and safety of rituximab biosimilar CT-P10 in the real-world, in patients with RA who had a previous use of innovative rituximab, and patients naive to the use of rituximab, in an outpatient rheumatology unit in Guatemala.

Methods: Cross-sectional study of patients with a diagnosis of RA fulfilling the 2010 ACR/EULAR criteria, who used rituximab biosimilar CT-P10 with dose infusion of 1000 mg at 0 and 15 days every 6 months, during the period from June 1, 2018, to June 31, 2019. Efficacy was evaluated by the change in disease activity by DAS 28, ESR, CRP, and functionality by HAQ – DI at 0,3,6 and 12 months. In naive patients, the percentage of achievement of ACR 20, 50, and 70 was measured.

Results: A total of 30 patients were included, of which 20 patients had received innovative rituximab and were switched to the use of biosimilar rituximab CT-P10, and 10 patients were naive to the use of rituximab. The mean age was 53 and 49 years; at least 95% of the patients had received 1 or more bDMARs previously; the treatment regimen used in 80% of the patients was in combination with cDMARDs, 95% of patients who were switched from innovator to biosimilar were in remission and 90% of Naive patients were in moderate and high activity **(Table 1).** Patients who switched from innovator to biosimilar had no change in the measurements of DAS 28, ESR, CRP, and HAQ-DI during follow-up with p value > 0.05 **(Figure 1**). Naive patients had a difference with a p-value for DAS 28: 0.00006, ESR: 0.017, CPR: 0.042 and HAQ-DI: 0.001, decreasing significantly after 3 months of follow-up **(Figure 1**), with a reach of ACR 20 of 100%, ACR50 of 80% and ACR70 of 20%, and 100% for the three measurements after 12 months of follow-up. Seven patients presented adverse events, three had a mild urinary tract infection, one had an upper respiratory tract infection, and three had an allergic reaction while receiving the infusion. Discontinuation occurred in three patients, one due to severe respiratory infection and two due to allergic reactions. Patients who presented adverse events were in the group of switched ones.

Table 1.

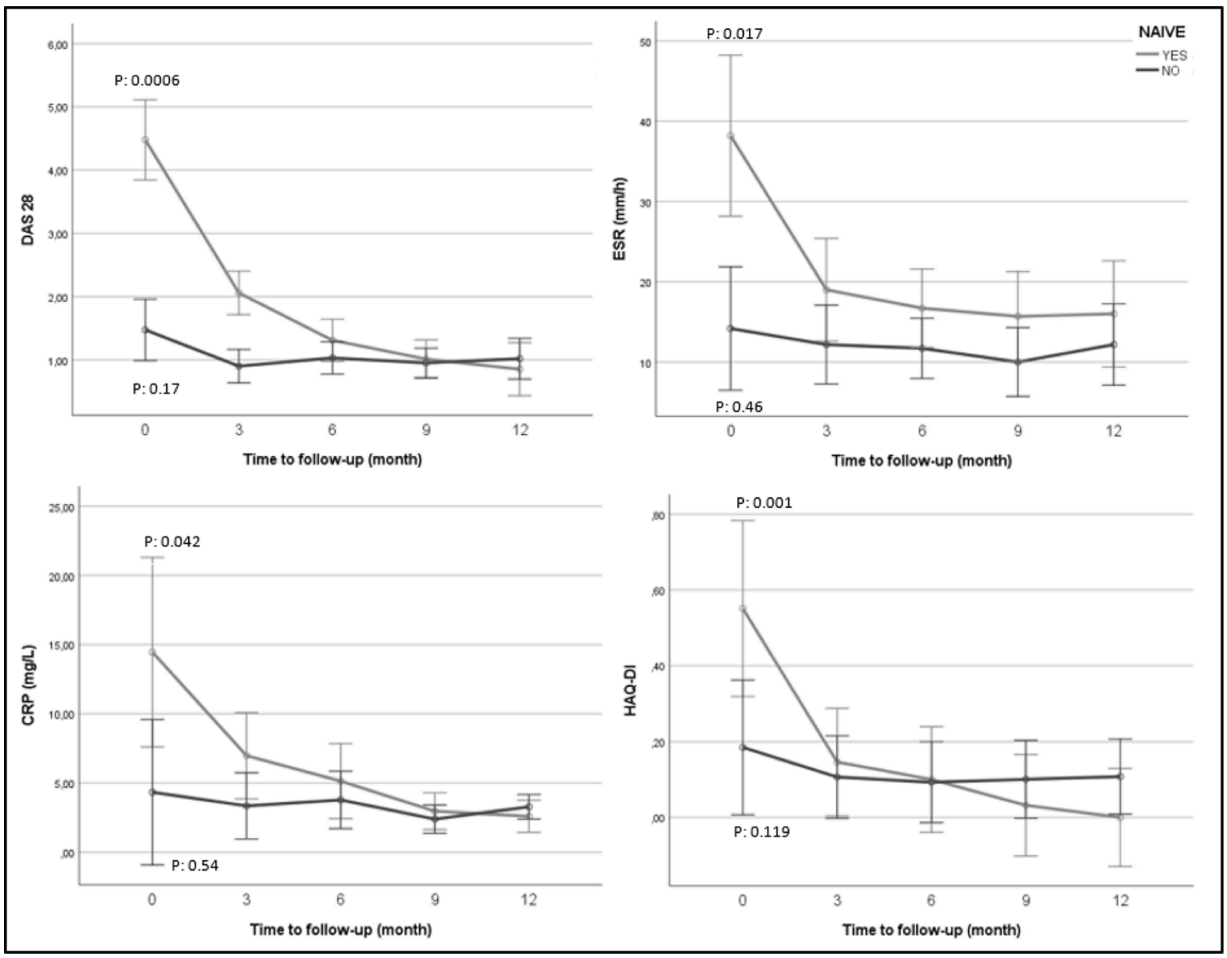
	Switched N: 20	**Naive N: 10**
Mean Age (±SD) *	53.8 (11.52)	49 (12.12)
Female n (%)	17 (75)	10 (100)
Mean RA disease duration (±SD) *	14.35 (8.93)	11.7 (9.31)

	Switched N: 20	Naive N: 10
ase n (%)	12 (60)	2 (20)
tDMARDs use n (%)	19 (95)	9 (90)
e beginning of follow-up		
8 (±SD)	1.35 (1.056)	4.47 (0.69)
Mean of ESR (±SD) **	13.3 (10.18)	38.2 (21.4)
Mean of CRP (±SD) **	4.15 (6.21)	14.45 (15.05)
Mean of HAQ DI (±SD)	0.16 (0.31)	0.55 (0.39)
Activity at the end of follow-up		
Mean DAS 28 (±SD)	1.01 (0.77)	0.85 (0.28)
Mean of ESR (±SD) **	12.18 (8.45)	16 (12.62)
Mean of CRP (±SD) **	3.27 (1.75)	3.27 (1.75)
Mean of HAQ DI (±SD)	0.107 (0.24)	0 (0)
AE ☥ summary n (%)		
AE	7 (35)	0 (0)
SAE	1 (5)	0 (0)
AE leading to discontinuation	3 (15)	0 (0)

* Time in Years; **ESR in mm/h CRP in mg/L.☥ Adverse events, SAE: Serious adverse events

Figure 1.

Mean Change from Baseline in DAS28, ESR, CRP and HAQ-DI. The p value reflects the difference from the beginning to the end of follow-up.



Conclusion: the use of biosimilar rituximab CT-P10 is effective and safe in our environment in naive patients and is compared to the response obtained with the use of innovative rituximab.

REFERENCES: NIL.

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ɔf Interests: None declared.

version:1.02

DOI: 10.1136/annrheumdis-2024-eular.2094

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Citation: , volume 83, supplement 1, year 2024, page 1575

Session: Rheumatoid arthritis *(Publication Only)*