

AB0365

**EFFICACY OF TOCILIZUMAB FOR CORTICOSTEROID AND METHOTREXATE SPARING IN RHEUMATOID ARTHRITIS**

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**Background:** Successful management of rheumatoid arthritis (RA) depends on the early administration of DMARDs and biologic DMARDs. The biologic agent tocilizumab, an interleukin-6 receptor inhibitor, has been used for the management of RA.

**Objectives:** The aim was to describe a cohort of RA patients treated with tocilizumab and the effect of this treatment on the other DMARDs used, namely methotrexate and corticosteroids.

**Methods:** In a cohort of 80 patients with rheumatoid arthritis the biologic agent tocilizumab was administered in combination with methotrexate administered sc and 10 mg prednisolone. Within this cohort, 26 patients were on tocilizumab administered iv 8 mg/kg/4wks (maximum dose 800 mg) and 54 were on tocilizumab administered sc 162mg/wk. As corticosteroid administration is characterized by adverse effects, such as osteoporosis and diabetes mellitus, in the course of the disease, in all patients an effort was made to reduce and, if possible, withdraw corticosteroids. An effort was also made to reduce methotrexate dosage. After a year, prednisolone was either significantly reduced or withdrawn. The final dosage of prednisolone was either 2.5-5 mg or complete withdrawal. The successful reduction of methotrexate dosing schedule was also achieved. The final methotrexate dose was either 12.5 mg sc or complete withdrawal. After a period of 52 weeks in this cohort 42 of 80 patients (52.5%) were on monotherapy with tocilizumab.

**Results:** In a cohort of 80 patients with RA the administrations of tocilizumab, either iv or sc, proved safe and effective. Remission or low disease activity of RA was achieved. Corticosteroid dosage was reduced. Methotrexate dosage was also reduced. After 52 weeks within the group of RA patients on treatment with tocilizumab, in 42 complete withdrawal of corticosteroids and methotrexate proved feasible. Patients on tocilizumab monotherapy remained in remission.

**Conclusion:** It appears that tocilizumab is safe and effective for the treatment of RA. Tocilizumab treatment may permit withdrawal of both corticosteroids and methotrexate in patients with RA. The management of active RA initially with low dose corticosteroids in combination with methotrexate sc and, in the case of failure to achieve remission, with the addition of the biologic agent tocilizumab had as a result either significant corticosteroid reduction or complete withdrawal and reduction of methotrexate dosage, the disease remaining in remission.

**Disclosure of Interests:** None declared

**DOI:** 10.1136/annrheumdis-2019-eular.8171

020 infusions (600mg No 2) in combination with DMARDs and glucocorticoids; 17 pts achieved a good/moderate EULAR response at week 24. Laboratory biomarkers were assessed at baseline and weeks 12 and 24 after the first infusion of RTX. ESR (mm/hr) (Westergren method); serum concentrations of CRP (mg/L), IgM RF (IU/ml) (laser nephelometry); anti-CCP2 (U/ml), IgA RF (U/ml), anti-MCV (U/ml) (ELISA kits); cytokine profile (xMAP technology) were assessed

**Results:** RTX and BCD-020 induced decreases in ESR, levels of CRP, IgMRF, IgARF, anti-MCV at week 12 and 24, p<0.05 (tabl.1). At week 24 - 20% of IgMRF positive pts at baseline (in the first group) and 10% of IgMRF positive pts (in the second group) turned negative. Levels of anti-CCP2 did not reduced. At week 24 - 7% of anti-CCP2 positive pts at baseline (in the first group) and 15% of anti-CCP2 positive pts (in the second group) turned negative. Depletion of CD19+B-cells was achieved at week 12 in all patients (absolute number 0), with an increase in the level of B cells at week 24, tabl.1. The immunoglobulin level decreased at week 24, but remained normal. In the first group RTX induced reduction in proinflammatory (IL-1b, IL-2, IL-6, IL-12, IL-15, IFN-γ, TNF-α), anti-inflammatory cytokines (IL-1Ra, IL-5, IL-9, IL-10, IL-13), growth factors (IL-7, GM-CSF, FGF-basic) and chemokines (MC-1) at week 24 (fig.1). In the second group BCD-020 induced reduction in IL-1b, IL-1Ra, IL-2, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-12, IL-13, IL-15, IL-17, Eotaxin, G-CSF, IFN-γ, IP-10, MC-1, MIP-1β, TNF-α, VEGF at week 24 p<0.05, fig.1.

Table 1

Parameter	Week	RTX group (n=34)	BCD-020 group (n=46)
ESR, mm/hr	0	56(1-63)	45(9-60.0)
	12	28(12-46)*	28(9-38.0)*
	24	23(12-35)**	21(7-32.0)**
	52	13(4.3-46.2)	13.3(8.9-45.2)
CRP mg/l	0	30.1(3.3-38.9)**	49.0(2-113.9)**
	12	6.9(0.2-12.7)*	6.9(0.2-13.9)*
	24	1.9(0.2-10.9)	2(0.2-10.9)
	52	1.5(0.2-10.9)	1.5(0.2-10.9)
IgM RF IU/ml	0	152.1(11.1-121.7)**	187.2(14.1-101.0)**
	12	43.5(10.8-44.8)*	54.1(10.3-129.0)**
	24	22.4(1.6-60.0)	23.8(10.4-107.0)**
	52	24.8(9.8-134.7)**	16.8(7.9-43.0)*
IgA RF U/ml	0	100.0(8.3-60.0)	113.7(10.3-104.0)
	12	100.0(4.2-100.0)	71.7(12.4-161.6)
	24	100(2.3-100)	61.3(10.1-103.7)
	52	57.9(1.5-100.0)	25.2(1.2-100.0)
anti-MCV U/ml	0	358.1(71.9-961.7)**	310.5(61.9-946.6)**
	12	218.6(66.4-623.7)*	133.8(11.7-102.8)
	24	7.8(1.4-12.8)	9.2(7.1-11.7)
	52	6.0(0.0-60.0)	6.0(0.0-60.0)
CD19+ B cells, %	0	0.110(0.1-0.600)	0.200(0.01-1.700)
	12	0.14(0.0-0.418)	0.19(0.0-0.413)
	24	0.13(0.1-0.710)	0.19(0.1-0.710)
	52	0.13(0.1-0.710)	0.19(0.1-0.710)
IgG, g/l	0	14.8(10.4-18.3)	13.9(9.3-14.1)
	12	12.1(1.1-14.7)	12.9(11.1-14.7)
	24	12.1(1.1-14.7)	12.9(11.1-14.7)
	52	12.1(1.1-14.7)	12.9(11.1-14.7)
IgA, g/l	0	2.8(1.5-2.7)	3.3(0.9-3.7)
	12	2.8(1.5-2.7)	3.3(0.9-3.7)
	24	2.8(1.5-2.7)	3.3(0.9-3.7)
	52	2.8(1.5-2.7)	3.3(0.9-3.7)

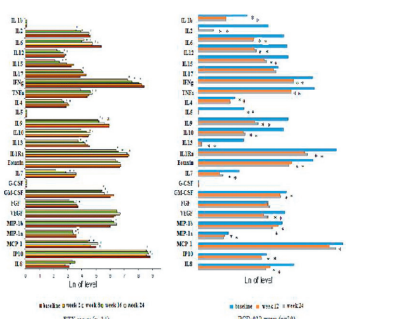


Figure 1

**Conclusion:** RTM biosimilar (BCD-020) has a similar effect on inflammatory and immunological biomarkers to the original RTM. BCD-020 therapy induced a rapid and significant improvement in ESR, levels of CRP, IgM/IgARF, anti-MCV, proinflammatory, anti-inflammatory cytokines, growth factors, chemokines levels and CD19+B cells depletion in RA pts

**Disclosure of Interests:** Anastasia Avdeeva: None declared, Maria Cherkasova: None declared, Alexander Artyuhov: None declared, Eh. Dashinimaev: None declared, D. Kusevich: None declared, Alexander Lila Speakers bureau: Pfizer, Inc., MSD, Novartis, AbbVie Inc., Celgene Corporation, Biocad, Janssen, UCB, Inc., Evgeny Nasonov: None declared  
**DOI:** 10.1136/annrheumdis-2019-eular.2748

AB0366

**COMPARISON OF THE EFFECT OF RITUXIMAB (ROCHE) AND RITUXIMAB BIOSIMILAR – BCD-020 (BIOCAD) ON INFLAMMATORY AND IMMUNOLOGICAL BIOMARKERS IN PATIENTS WITH RHEUMATOID ARTHRITIS**

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**Background:** BCD-020 (BIOCAD) is the first Russian rituximab (RTX) biosimilar which was approved for medical use in rheumatoid arthritis (RA) patients in Russia and some CIS countries

**Objectives:** To evaluate the changes in acute phase reactants, autoantibodies, immunoglobulins, cytokine profile and CD19+B lymphocytes in patients (pts) with RA during RTX and RTX biosimilar therapy

**Methods:** The study included 54 RA patients (pts), divided into two groups. The first group included 34 pts with RA (31 women, mean age 49(42-64), mean disease duration 66(36-132) months, mean DAS 28 6.2 (5.5-6.8)) who received two infusions of RTX - 35% at a dose of 500 mg, 65% of the dose of 1000 mg every two weeks in combination with DMARDs and glucocorticoids; 33 pts achieved a good/moderate EULAR response at week 24. The second group - 20 pts with RA (18 woman, mean age 61.5(54-66.5) years, mean disease duration 39.5(20-84) months, mean DAS 28 5.6(4.9-6.8)) who received two intravenous BCD-

AB0367

**REASONS FOR DISCONTINUATION OF BIOLOGICAL DRUG AND TARGETED SYNTHETIC DRUGS AMONG PATIENTS WITH INFLAMMATORY ARTHRITIS IN THE UNITED ARAB EMIRATES (UAE)**

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**Background:** In routine clinical care of Rheumatoid arthritis (RA) Spondyloarthritis(SPA) and Psoriatic arthritis (PSA) there is a high rate of discontinuation of biologic disease-modifying antirheumatic drugs (bDMARDs) and targeted synthetic disease-modifying antirheumatic drugs (tsDMARDs) due to loss of efficacy, side effects or lack of adherence. This can impact on the ability to achieve low disease activity.

**Objectives:** To evaluate the use of bDMARDs and tsDMARDs and analyze the reasons for discontinuation of these drugs and to compare them to our standard DMARD Methotrexate.

**Methods:** In this retrospective cohort analysis we included consecutive patients aged ≥ 18 years with RA/SPA/PSA attending 2 Rheumatology clinics in the UAE from August- December 2019. Statistical analysis was performed using STATA version 13 and R-studio. Continuous data were