Table 1. Description of psychiatric symptoms registered in the database for TNF- α inhibitors

Characteristics	Patients (Total = 71)
Major psychiatric symptoms:	11 (15%)
– Manic episode	8 (11%)
– Acute psychosis	3 (4%)
Minor psychiatric symptoms:	60 (85%)
– Anxiety/Nervousness	10 (14%)/6 (8%)
– Insomnia or decreased need for sleep	31 (44%)
– Psychomotor agitation/Aggressiveness	6 (8%)/8 (11%)
– Hallucinations	7 (10%)
– Libido exacerbation	2 (3%)
– Euphoria, grandiosity	4 (6%)
– Derealization, depersonalization	3 (4%)
Psychiatric side effect improved:	45 (63%)
– TNF- α Inhibitors withdrawn	32 (45%)
– TNF- α Inhibitors not withdrawn	9 (13%)
– Missing data	4 (6%)
Psychiatric side effect did not improved:	16 (22%)
– TNF- α Inhibitors withdrawn	8 (11%)
– TNF- α Inhibitors not withdrawn	4 (6%)
– Missing data	3 (4%)
Missing data improved/not improved	10 (14%)

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SAT0145 INFLUENCE OF BODY MASS INDEX (BMI) ON THE DISEASE INFLAMMATORY ACTIVITY AND TREATMENT RESPONSE IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: The use of biological therapy (BT) in rheumatoid arthritis (RA) has supposes a very important change in the disease's treatment and prognosis. Drugs like Anti-TNF α have proven unquestionable effectiveness. However, the lack or loss of such effectiveness over time raises the dilemma of what factors may influence it. There are studies that suggest the influence of BMI on the efficacy of these drugs and therefore on the control of the disease.

Objectives: To determine the influence of BMI on disease activity and response to treatment with infliximab (ifx) in patients with RA.

Methods: A retrospective observational study of a population of 76 patients with RA who received infliximab treatment, in a standard guideline of 3 mg/kg, in our service between 2000 and 2016 inclusive. The BMI was classified for some sub-studies in four categories: low (<18.5), normal (=18.5- <25), overweight (=25- <30) and obesity (=30). Disease activity was determined by DAS28 at three times: at baseline, at 6 months and at the year of infliximab treatment; Response to treatment was assessed by deltaDAS28 and EULAR response at 6 months and 1 year of treatment. The EULAR response was classified into two categories: "yes" (DeltaDAS28 > 1.2, or > 0.6 and DAS28 < 5.1) and "no" (DeltaDAS28 < .6, or < 5.1). First, activity and response rates to treatment were compared in these four groups over the three periods. A regression analysis was then performed for BMI and both activity and response to treatment.

Results: Characteristics of the 76 patients included in the study when initiating IFX therapy were: 66 (86.8%) were women, median (range) age 54 (21–83) years, 77% RF+, 81% ACPA+, disease duration 10.8 (1.0–39.0) years, 59% with concomitant methotrexate and 55% with other DMARDs. Median (range) BMI was 25.5 (16.7–40.2) kg/m². According to BMI, patients with underweight, normal, overweight and obesity were 0 (0.0%), 41 (53.9%), 22 (28.9%) and 13 (17.2%), respectively. The association between BMI and disease activity (median DAS28 (p25-p75)) is shown in Table 1:

Table 1

	Normal	Overweight	Obesity
DAS28 bas	5,63 (4–84–6,30)	5,44 (4,45–6,73)	6,25 (4,42–7,07)
DAS28 6m	3,90 (2,89–5,12)	3,97 (3,32–5,43)	4,80 (3,35–5,72)
DAS28 1y	3,91 (2,89–5,01)	3,69 (2,97–5,29)	4,48 (2,70–5,87)

The association between BMI and treatment response (median deltaDAS28 (p25-p75) and EULAR response (%)) is shown in Table 2:

Table 2

	Normal	Overweight	Obesity	p
Δ DAS28				
Δ DAS28 0–6m	1,72 (0,84–2,77)	1,39 (0,38–2,49)	0,77 (0,40–1,59)	0,2
Δ DAS28 0–1y	1,56 (0,81–2,74)	1,77 (0,92–2,92)	1,20 (0,73–1,90)	0,2
EULAR response 6m	70,7	68,2	30,8	0,065
EULAR response 1y	61,0	54,5	61,5	0,065

In the longitudinal analysis, a trending but not statistically significant relationship between adjusted BMI and DAS28 was observed at six month and at one year of treatment onset: β : 0,051; 95% CI (-0,06 to 0,109) and β : 0,037; 95% CI (-0,022 to 0,097)

Conclusions: BMI seems to influence, in a non significantly manner, in disease activity and in treatment response in RA treated with infliximab. Obesity BMI values are associated with increased activity and a lower response to this treatment than lower BMI values.

Disclosure of Interest: None declared

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SAT0146 RANDOMISED DOUBLE-BLIND STUDY SHOWS COMPARABLE LONG-TERM EFFICACY AND SAFETY BETWEEN RITUXIMAB BIOSIMILAR CT-P10 AND INNOVATOR RITUXIMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS: 48-WEEK RESULTS

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Background: In phase 1 trials (NCT01534884 and NCT01873443), pharmacokinetic equivalence of CT-P10, biosimilar of rituximab, to innovator rituximab (RTX) was demonstrated. In the phase 3 study, equivalence of PK and efficacy up to week 24 were achieved between CT-P10 and RTX (US and EU sourced)^{1,2}.

Objectives: To investigate the long-term efficacy, pharmacodynamics, immunogenicity and safety of CT-P10 up to week 48.

Methods: Patients with rheumatoid arthritis were randomly assigned to CT-P10, US-RTX or EU-RTX, in combination with MTX. The patients received 2 treatment courses at Week 0 and 24, each consisting of 2 infusions of 1000mg study drug at 2-week interval.

Results: A total of 372 patients were randomised, and 330 patients completed the 2nd course treatment. DAS28 scores through Week 48 were comparable between CT-P10 and US/EU-RTX (Figure), as well as the proportion of ACR responses at Week 48 between the CT-P10 and combined rituximab groups; 81.3% and 79.8% for ACR 20, 55.4% and 53.9% for ACR50, and 31.7% and 33.7% for ACR 70, respectively.

Figure 1. Efficacy Results – DAS28.

B-cell depletion was comparable from after the 1st infusion and up to Week 48. Number (%) of patients with positive anti-drug antibodies in the CT-P10, US-RTX, and EU-RTX was 7 (4.9), 13 (9.4), and 5 (8.6), respectively at Week 48. The safety profile was also similar across groups (Table).

Table 1. Summary of Safety Profile [n (%)]

	CT-P10 (N=161)	US-RTX (N=151)	EU-RTX (N=60)	Reference Products (US-RTX + EU-RTX) (N=211)
AE	122 (75.8)	96 (63.6)	37 (61.7)	133 (63.0)
Serious Adverse Event	13 (8.1)	14 (9.3)	2 (3.3)	16 (7.6)
Infection	61 (37.9)	53 (35.1)	17 (28.3)	70 (33.2)
Serious infection	2 (1.2)	3 (2.0)	0	3 (1.4)
Infusion related reaction (IRR)*	33 (20.5)	12 (7.9)	13 (21.7)	25 (11.8)
Malignancy	0	2 (1.3)	1 (1.7)	3 (1.4)
Progressive multifocal leukoencephalopathy	0	0	0	0

*None of IRR were serious or led to study drug discontinuation.