Retention rates for Etanercept: comparing the original with a biosimilar

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Conclusions

We found higher retention rates for bionaive patients starting the biosimilar SB4 compared to those starting the originator oETN. Whereas both treatments were equally effective, patients treated with oETN had more injection site reactions. We cannot rule out selection bias since there is practice variation in the usage of biosimilars in Germany (regional quota systems). In addition, patients receiving either oETN or SB4 were not entirely comparable (e.g. more comorbidities on oETN).

Background & Objectives

Since the first approval of a biosimilar in 2015, the number of biosimilars used for the treatment of rheumatoid arthritis (RA) has been increasing. Until now, there are just a few analyses investigating retention rates of biosimilars and the respective originators in daily rheumatologic care.

Our objective was to compare treatment survival on the etanercept originator (oETN) to the biosimilar SB4 using real-world data.

Patients & Methods

The prospectively followed cohort of the German register RABBIT (Rheumatoid Arthritis: Observation of biologic therapy) continuously includes RA patients with a new start of a DMARD after at least one csDMARD failure. We used data gathered from January 2015 until December 2017 and restricted to patients enrolled with either oETN (originator) or biosimilar (SB4). Treatment discontinuation during the first six months was investigated in patients that were biologic naive prior to enrollment. Drug survival rates were analyzed using Kaplan-Meier curves.

Results

Overall, 283 patients were included in the register starting SB4 and 369 with oETN. Patients of the two groups did not differ substantially in disease characteristics (table 1). But more patients starting oETN had three or more baseline comorbidities, and less patients had ever smoked.

Table 1: Baseline characteristics of patients enrolled with etanercept (oETN or SB4).

	oETN (originator) n=369	SB4 (biosimilar) n=283
Age in years	58.1 ± 13.1	58.6 ± 12.5
Female patients	266 (72.1%)	204 (72.1%)
Disease duration in years	9.0 ± 9.1	8.0 ± 7.3
Autoantibody positivity (rheumatoid factor or anti-CCP)	241 (66.9%)	192 (68.1%)
DAS28-ESR	5.1 ± 1.2	4.9 ± 1.2
C-reactive protein in mg/l	13.8 ± 19.7	14.9 ± 18.8
% of full physical function	64.5 ± 23.1	66.2 (22.9)
Prior DMARD therapies		
No. of csDMARD failures	2.1 ± 1.0	2.0 ± 0.9
No. of bDMARD failures	0.2 ± 0.6	0.2 ± 0.5
Bionaive patients	317 (85.9%)	250 (88.3%)
Therapy with glucocorticoids	299 (81.0%)	299 (83.0%)
Daily dosage in mg/d	3.8 (4.6)	4.4 (6.8)
Baseline comorbidities		
None	53 (14.4%)	54 (19.1%)
1-2	141 (38.2%)	117 (41.3%)
≥ 3	175 (47.4%)	112 (39.6%)
Smoking, ever	198 (53.7%)	182 (64.3%)

Numbers are given as mean ± standard deviation, or frequency (percentage).

Another 259 patients who had already been enrolled in RABBIT switched to SB4 during follow up. Before SB4 treatment start, 21% were bionairve and had received csDMARDs or no drug therapy, 40% had been treated with oETN, and 39% with another biologic. Patients switching to SB4 during follow-up are not further considered in this analyses.

Treatment discontinuation

Table 2: Etanercept discontinuation within 180 days and reasons.

	oETN (originator) n=317	SB4 (biosimilar) n=250
Treatment stop		
within 90 days	54 (17%)	20 (8%)
between day 90 and 180	46 (15%)	14 (6%)
Reasons for discontinuation*		
Adverse events	49 (46%)	20 (56%)
Loss of response	31 (29%)	9 (25%)
Remission	2 (2%)	1 (3%)
Non-compliance	10 (9%)	4 (11%)
Pregnancy	4 (4%)	0
Treatment costs	10 (9%)	1 (3%)

Out of all bionaive patients that had started etanercept (n=317 oETN, n=250 SB4), 100 patients (32%) stopped oETN and 34 patients (14%) stopped SB4 treatment within 6 months (table 2).

Etanercept was most frequently discontinued due to adverse events and loss of response/ineffectiveness. The most common cause for discontinuation due to adverse events were skin reactions at the injection site in 49% (24 of 49) of oETN and 35% (7 of 20) of SB4 patients.

** Multiple reasons could be given (percentages refer to all answers =100%)*

Etanercept retention rates

Kaplan-Meier curves of bionaive patients show higher retention rates over 6 months for SB4 than for oETN. Adjusting the curves for disease duration and comorbidities had no significant influence on the results (data not shown).

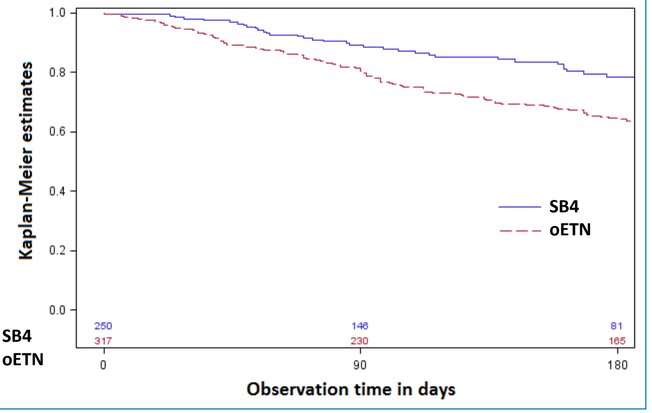

Figure: Treatment continuation in patients enrolled with SB4 or oETN who were bionaive until enrollment.

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