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FRI0085

RETENTION RATE OF ADALIMUMAB AND ABP 501 IN THE TREATMENT OF A LARGE COHORT OF PATIENTS WITH INFLAMMATORY ARTHRITIS: A REAL LIFE RETROSPECTIVE ANALYSIS

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Background: The recent introduction of ABP 501, an adalimumab biosimilar, in treatment of rheumatic diseases was supported by a comprehensive comparability exercise with its originator. On the other hand observational studies comparing adalimumab and ABP 501 in inflammatory arthritis are still lacking.

Objectives: To compare the clinical outcomes of the treatment with adalimumab, both originator and biosimilar, in a large cohort of patients affected by autoimmune arthritis in a real life setting.

Methods: We retrospectively analysed the baseline characteristics and the retention rate in a cohort of patients who received at least a course of adalimumab (originator or biosimilar ABP 501) in eight Rheumatology Units from January 2003 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. P values ≤0.05 were considered statistically significant.

Results: 764 patients (53.4% female, median age 55 [44-65] years, median disease duration 60 [25-149] months) treated with adalimumab were included in the analysis. 308 (40.3%) were affected by rheumatoid arthritis, 244 (31.9%) by psoriatic arthritis, and 212 (27.7%) by axial spondylarthritis. 558 (73%) were treated with adalimumab originator and 206 (27%) with ABP 501. Among the biosimilars 60 (29.1%) patients were naïve to adalimumab treatment. The overall 6-month retentions rate was 93.1%. The 6-month retention rate for adalimumab and ABP 501 were 93.3% and 91.2% respectively, without significant differences between the groups (p=0.541). Patients switching from originator to biosimilar showed and overall higher treatment survival when compared to naïve (6-month retention rate 95% vs 90-4%), although it was not significant (p=0.179).

Conclusion: In our retrospective study adalimumab originator and its biosimilar ABP 501 showed the same effectiveness. Patients switching from originator to biosimilar showed an higher retention rate when compared to naïve.

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FRI0086

DISEASE ACTIVITY MEASURES AND OTHER POTENTIAL PREDICTORS OF SUCCESSFUL TNF INHIBITORS TAPERING IN RA PATIENTS

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Background: Biologic therapy (BT) resulted in a substantial improvement of outcomes in Rheumatoid Arthritis (RA). However, it is also associated with higher costs, adverse events and patient's request to dose reduction and drug holidays. Although clinical practice guidelines suggest consider tapering biologics after sustained remission, the optimal approach for de-escalation remains unknown.

Objectives: i) to identify potential features associated with long-term successful TNF inhibitors (TNFi) tapering (Tap) in RA patients (pts), including the possible predictive value of different disease activity measures (DAS28, SDAI, CDAI). ii) to describe long-term outcome in relation to dose reduction of BT.

Methods: Observational prospective study of 91 RA pts who started a first TNFi between 2000-2014 and in whom tapering (dose down-titrated or interval widen) was applied after achieving sustained remission/Low disease activity. Demographic, clinical and analytical data were collected at biologic initiation. Disease activity was measured using DAS28, SDAI and CDAI at de-escalation start and at 6 (6 m), 12 (12 m), 18 (18 m) and 24 months (24 m) follow-up. Tap failure (primary outcome) was defined as reinstatement of full dose, escalation to the previous dose level or discontinuation due to secondary inefficacy. Tap status (Tap failure/success) was also assessed at each studied time point. Mann-Whitney U test and Fisher's exact test were used to test statistical differences. Logistic regression analysis was used to identify predictors of tap failure at 12 and 24 m.

Results: Of the 91 cases included (mean age 53 ±12.5 years, 74% women), eleven (12%) experienced Tap failure at the 12 m mark. At 24 m, 18 pts (20%) failed to taper, while 74 (80%) succeeded. At 12 and 24 m no significant differences were found in baseline and pre-Tap characteristics between those who experienced tap failure and those who succeeded (Table 1). In the univariate analysis, at the 12 m mark, there were no factors related to tapering; however, at 24 m, a longer time from TNFi start to achievement of remission was identified as a predictor of Tap failure (OR=1.64, p=0.02); this feature remained associated with failed Tap at 24 m in the multivariate analysis (OR=1.75, p=0.02). Neither of the three disease activity indices measured at Tap initiation predicted long-term tap failure.

Conclusion: In our cohort of RA patients on tapered TNFi, time from TNFi start to achievement of remission seemed to determine successful tapering of biological treatment. However, disease activity scores measured at dose reduction initiation were not predictive of successful de-escalation strategies.

table

Baseline Characteristics	Pts who presented a tap failure at 24 m (n=18)	Pts who presented a successful tap at 24 m (n=73)	Total population (n=91)	P value
Age at TNFi start (years)	48.4 (13.2)	54 (12.1)	53 (12.5)	P=0.06
Sex (female) n (%)	13 (72)	54 (74)	67 (74)	P=1.00
Non smokers, n (%)	7 (41)	41 (58)	48 (54)	P=0.28
BMI, m (SD)	25.3 (4.8)	25.5 (4.2)	25.5 (4.3)	P=0.75
RF +, n (%)	15 (83)	59 (81)	74 (81)	P=1.00
CCP, + n (%)	13 (72)	58 (82)	71 (80)	P=0.51
Monotheapy, n (%)	3 (17)	8 (11)	11 (12)	P=0.45
Disease duration, m (SD)	8.8 (6.6)	10.2 (7.1)	9.9 (7)	P=0.36
DAS28 at TNFi start, m (SD)	4.7 (1.3)	4.7 (1.1)	4.7 (1.2)	P=0.71
CDAI at TNFi start, m (SD)	25.2 (23.5)	22.5 (12.3)	23.1 (15.1)	P=0.64
SDAI at TNFi start, m (SD)	23.4 (13.7)	22.1 (12.4)	22.3 (12.6)	P=0.9
Pre-Tap Characteristics:				
DAS28 at Tap initiation, m (SD)	2.3 (0.7)	2.4 (0.7)	2.4 (0.7)	P=0.83
CDAI at Tap initiation, m (SD)	3.6 (3)	3.5 (4.2)	3.5 (4)	P=0.47
SDAI at Tap initiation, m (SD)	4.4 (3)	3.8 (4.2)	3.9 (3.9)	P=0.17
Time from TNFi start to achievement of remission	1.9 (1.6)	1.1 (1)	1.3 (1.2)	P=0.08
Time from achievement of remission to tapering	2.2 (2.5)	2.5 (2.6)	2.4 (2.5)	P=0.46

m, mean; SD, standard deviation

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FRI0087

DURABILITY OF CERTOLIZUMAB PEGOL IN PATIENTS WITH RHEUMATOID ARTHRITIS OR PSORIASIS OVER THREE YEARS: AN ANALYSIS OF POOLED CLINICAL TRIAL DATA

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Background: Durability over time varies according to the safety, tolerability and efficacy of a drug.¹ However, durability may vary between patient (pt) subgroups,^{1,2} and physicians should consider pt characteristics when making treatment decisions. Certolizumab pegol (CZP) is an anti-tumour necrosis factor (anti-TNF) agent approved for the treatment of chronic inflammatory diseases, including rheumatoid arthritis (RA) and plaque psoriasis (PSO).³ However, little is known about the impact of pt baseline characteristics on long-term CZP durability.

Objectives: To investigate the durability of CZP and reasons for discontinuation over 3 years (yrs) in subgroups of pts with RA or PSO using pooled clinical trial data.

Methods: 27 RA and 3 PSO clinical trials were pooled for indication-specific analyses. Kaplan-Meier curves were calculated to estimate CZP durability for pt subgroups by age, gender, disease duration, prior anti-TNF use and geographic region. Reasons for CZP discontinuation were investigated.

Results: 6927 RA and 1112 PSO pts were included; mean ages were 53.0 yrs (standard deviation [SD]: 12.2 yrs) and 45.4 (13.0) yrs, respectively. 79.3% RA pts were female (of all patients, 19.4% were women of childbearing age [18–<45 yrs; WoCBA]) compared with 33.5% (15.2% WoCBA) in PSO. Mean disease durations were 6.4 (6.9) yrs for RA and 18.4 (12.3) yrs for PSO. 18.5% RA and 13.3% PSO pts had prior anti-TNF use. Maximum CZP exposure was ~8 yrs for

Table 1. CZP durability at 3 years,[a] by patient subgroup

% patients	RA	PSO
All	49.2	70.1
Age, yrs		
18–<45	52.1	66.3
45–<65	49.4	68.3
≥65	43.3	69.4
Gender		
Female	49.3	64.1
Male	48.2	69.2
WoCBA	51.1	62.0
Male aged 18–<45 yrs	56.5	68.3
Prior anti-TNF use		
Yes	49.3	60.1
No	49.6	68.5
Disease duration, yrs		
<1	43.2	39.6
1–<5	52.6	63.6
5–<10	51.4	64.4
≥10	48.7	69.7
Region		
Asia-Pacific	58.5	
Central Europe	61.5	78.8
Eastern Europe	54.2	
Latin America	57.1	
N America	36.6	53.9
W Europe	33.8	67.7
Rest of the world	66.3	

[a] For PSO, the 3 year analysis was calculated with Week 144 data. CZP: certolizumab pegol; N: North; PSO: psoriasis; RA: rheumatoid arthritis; TNF: tumour necrosis factor; W: Western; yrs: years.

RA and ~3 yrs for PSO. At 1 yr, 63.4% of RA pts remained on CZP vs 80.3% PSO pts, decreasing to 49.2% RA pts and 70.1% PSO pts at 3 yrs (Table 1). Reasons for discontinuation, at any time during the trials, included lack of efficacy (RA 13.5%; PSO 1.8%), adverse events (RA 11.9%; PSO 8.1%), consent withdrawn (RA 6.7%; PSO 6.7%), lost to follow-up (RA 1.8%; PSO 4.3%), protocol violation (RA 1.7%; PSO 0.3%) and other (RA 9.2%; PSO 8.7%). In RA pts, CZP durability was lower in the elderly and in pts with disease duration <1 yr. In PSO, durability was lower in pts with disease duration <1 yr or prior anti-TNF use. Durability was lower in WoCBA pts than male pts aged 18–<45 yrs for both indications. CZP durability was lower in Western Europe and North America compared to other regions.

Conclusion: Overall, CZP durability was similar to that reported for other anti-TNFs with some differences between indication and subgroups.¹ Factors influencing durability included age, disease duration and geographic region. Gender differences were observed in the 18–45 yrs age group, however, both male and female CZP durability was higher than in older RA pts.

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FRI0088

CHANGE IN SERUM BILIRUBIN SUGGESTS TREATMENT RESPONSE IN RHEUMATOID ARTHRITIS PATIENTS TREATED WITH MOLECULAR-TARGETED AGENTS

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Background: Bilirubin is an antioxidant with anti-inflammatory properties. In previous reports, serum bilirubin levels were correlated with disease activity of autoimmune diseases including rheumatoid arthritis (RA). Various molecular-targeted