



# USE OF MONOTHERAPY ANTI-TNF AGENTS IN ANKYLOSING SPONDYLITIS PATIENTS FROM THE RHUMADATA® REGISTRY: 8-YEAR COMPARATIVE EFFECTIVENESS OF ADALIMUMAB, ETANERCEPT AND INFlixIMAB

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## INTRODUCTION

Anti-TNF agents namely adalimumab (ADA), etanercept (ETA) and infliximab (INF) are approved for the treatment of signs and symptoms of ankylosing spondylitis. Their efficacy has been demonstrated in randomized controlled trials against placebo. They have also been shown effective in the treatment of extra-articular features such as enthesitis, inflammatory bowel entities such as Crohn's disease and ulcerative colitis and uveitis. Antibodies and soluble receptors may have a different efficacy profile.

## OBJECTIVES

To assess the retention rates of adalimumab (ADA), etanercept (ETA) and infliximab (INF) in patients diagnosed with ankylosing spondylitis (AS) and to compare patient reported response over time.

## METHODS

Data of AS patients who had been prescribed adalimumab (ADA), etanercept (ETA) or infliximab (INF) in monotherapy on or after January 1<sup>st</sup> 2004 was extracted. Baseline demographics included age, gender, disease duration, HAQ-DI, fatigue and pain visual analog scale evaluations (VAS), morning stiffness, BASDAI, BASFI, ASDAS and HLA-B27. Eight-year drug retention rates were estimated and compared using Kaplan-Meier survival estimates. BASDAI improvement over time was assessed using proportional hazard model adjusted for age and disease duration at TNF initiation. Other differential measures of effectiveness were tested using general linear models (GLM). For these analyses, patients with baseline BASDAI of 4 or more were included. Statistical analysis was performed using SAS version 9.3. RHUMADATA® is a clinical database and registry used in daily clinical practice at the IRM, CORQ and the CREQ.

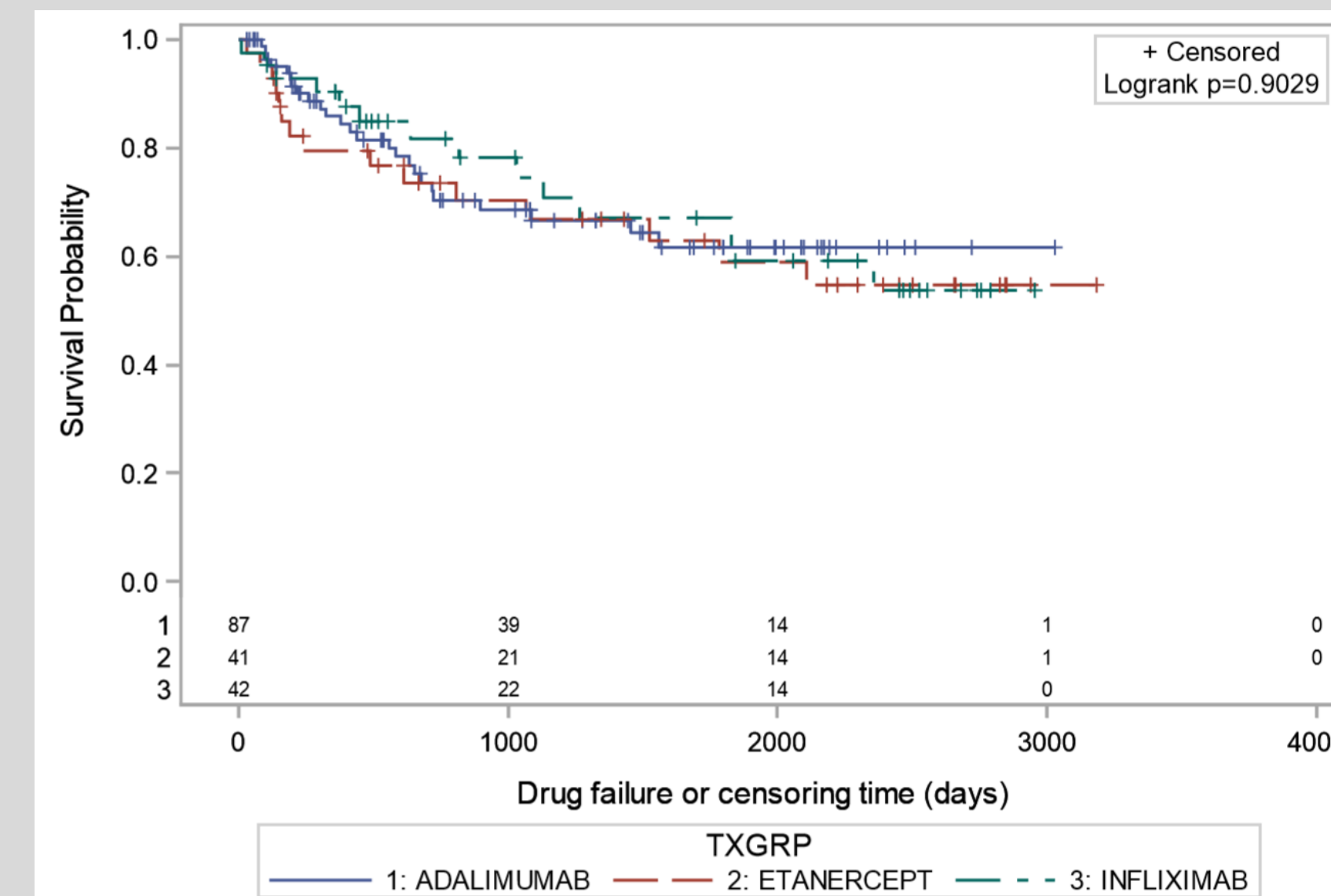
## BASELINE CHARACTERISTICS

Characteristics*	ADA	ETA	INF	ALL	p
N	87	41	42	170	
Age (years)	39.0 (11.6)	46.7 (11.8)	43.8 (9.7)	42.0 (11.6)	0.001
Disease duration (years)	5.2 (7.3)	9.8 (12.6)	8.2 (10.0)	7.0 (9.6)	0.0291
Gender (%women)	34%	17%	36%	31%	ns
HLA-B27 (% +)	84%	75%	57%	78%	ns
BASDAI	6.0 (2.2)	6.5 (1.6)	6.3 (2.4)	6.2 (2.1)	ns
ASDAS(ESR)	2.1 (1.6)	2.2 (1.5)	1.5 (1.7)	2.0 (1.6)	ns
ASDAS(CRP)	2.3 (1.7)	2.3 (1.6)	1.6 (1.8)	2.1 (1.7)	ns
BASFI	5.3 (2.5)	6.3 (1.9)	5.4 (2.3)	5.6 (2.3)	ns

## TIME TO EVENT ANALYSIS (BASDAI<2)

Characteristics*	ADA	ETA	INF
N	43	18	14
Age	39.7 (12.5)	48.0 (10.4)	44.6 (7.9)
Disease duration	5.5 (6.9)	11.3 (13.7)	5.6 (9.1)
BASDAI at baseline	6.6 (1.5)	6.2 (1.5)	6.5 (1.5)
Minimum BASDAI	2.2 (1.8)	2.4 (2.1)	1.9 (2.3)
Maximum percentage decrease in BASDAI	-65%	-62%	-68%
Time to maximum decrease in BASDAI (months)	15.7 (15.8)	15.9 (19.9)	25.5 (22.3)
Time to reach a BASDAI of 2 (months)	9.6 (8.4)	19.0 (23.3)	15.6 (18.2)
Percent reaching a BASDAI of 2	42%	61%	64%

\* Data are presented as means (SD), unless stated otherwise.



## RESULTS

Data from 170 patients diagnoses with AS was extracted and no significant differences in baseline characteristics were observed between treatment groups except for age and disease duration. The 8-year retention rate of ADA, ETA and INF were 62%, 55% and 54% respectively and were not statistically different (Log-Rank p=0.90). Seventy-five patients were used to analyse time required to reach a BASDAI of 2 and compare rates of response. At baseline, mean BASDAI for ADA, ETA and INF were respectively 6.6, 6.2, 6.5. The adjusted hazard ratio for reaching a BASDAI of two was found to be 0.77 (95% CI = [0.32, 1.87]) and 0.92 (95% CI = [0.40, 2.14]) when comparing ETA and INF to ADA respectively. Overall 42%, 61% and 64% of ADA, ETA and INF patients reached a target BASDAI of 2 in average adjusted times of 9.6, 19.0 and 15.6 months (p-value=0.31).

## CONCLUSIONS

Monotherapy adalimumab, etanercept and infliximab in AS patients show similar 8-years retention rates and similar improvement in BASDAI. They all represent good options for the treatment of AS in monotherapy.

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	Hazard ratio	95% Hazard ratio confidence limits	
ETA vs ADA	0.77	0.32	1.87
INF vs ADA	0.92	0.40	2.14
Age	1.02	0.99	1.06
Disease duration	0.98	0.94	1.03