ETANERCEPT HAS A BETTER RETENTION RATE AT 10 YEARS THAN ADALIMUMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS. RESULTS FROM RHUMADATA® A REAL LIFE CLINICAL DATABASE AND REGISTRY.

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BACKGROUND/PURPOSE

Very few studies have compare different agents used in the treatment of rheumatoid arthritis (RA) over the very long term, up to 10 years. The vast majority of them have duration of less than 3 to 4 years, are open-label, have selection entry criteria, and compare outcome measures such as DAS score, DAS improvement, HAQ improvement and so on. Rhumadata, a real life database and registry, enrolling all patients in a given center for whom a specific diagnosis such as RA has been posed, give a unique opportunity to compare retention rates in a large population of patients and analyse variables as predictors of retention. Our objectives is to compare the retention rate of adalimumab and etanercept after DMARDs failure in a population of RA patients and identify potential predictors of retention rate.

METHODS

Data of RA patients who had been prescribed either etanercept (ETA) or adalimumab (ADA) as first biologic agent on or after January 1st 2002 was extracted. The data included age and gender, disease characteristics, clinical variables, patient and physician specific assessments, laboratory measures and composite assessment of disease activity (DAS28-ESR, SDAI and CDAI). All patients were followed until they discontinued their treatment or June 2, 2015, the date at which the data was extracted from Rhumadata®. Secondary diagnoses and comorbidities established at or before the administration of the biologic agents were coded using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes. Infections occurring while on treatment, biologic status (ongoing or stopped) and the reasons for biologic cessation were also extracted. The 10-year drug retention rates were estimated and compared using Kaplan-Meier survival estimates and potential predictors were identified using univariate proportional hazard regression models. Statistical analysis was performed using SAS version 9.4.

RESULTS

The data from 548 RA patients (184 prescribed ADA and 364 etanercept) as first biologic agent were extracted from the RHUMADATA® clinical registry and database. The patients were mostly women (74.5%) and had an average age of 53.3(SD=12.8). The patients had an average disease duration of 7.1 years (SD=8.0) and provided 2327.3 person-years of observation. The 10-year retention rates of ADA and ETA were estimated at 27.2% (SD=3.9%) and 35.0% (SD=3.1%) respectively and an overall significant difference in retention rate was observed (log-rank p -value = 0.0031). Univariate proportional hazard models identified the biologic used (HR (ADA vs ETA) = 1.402, 95% CI: 1.120 to 1.755) and fatigue-VAS (HR (per unit increase in fatigue-VAS) = 1.402, 95% CI: 1.120 to 1.755) as significant predictors of retention (alpha=0.05). Concurrent use of nbDMARDs did not however reach statistical significance (HR (combination vs mono therapy) = 1.157, 95% CI: 0.842 to 1.591).

BASELINE CHARACTERISTICS

Table 1. Characteristics of patients treated with adalimumab and etanercept as first biologic agent.

	Adalimumab n=184	Etanercept n=364	All n=548
Age (years)*	52.3 (12.7)	53.8 (12.9)	53.3 (12.8)
Women, n (%)	132 (71.7%)	276 (75.8%)	408 (74.5%)
Disease Duration (years)	5.3 (6.7)	8.0 (8.4)	7.1 (8.0)
Person-years of treatment, total	658.9	1668.5	2327.3
Person-years of treatment	3.6 (3.3)	4.6 (3.8)	4.2 (3.7)
Number of previously used DMARDs	2.3 (0.9)	2.6 (1.1)	2.5 (1.0)
Number of concurrently used DMARDs	1.4 (0.7)	1.2 (0.8)	1.3 (0.7)
No DMARDs used	*18 (9.8%)*	*61 (16.8%)*	*79 (14.4%)*
Methotrexate	*141 (76.6%)*	*215 (59.1%)*	*356 (65.0%)*
Hydroxychloroquine sulfate	*79 (42.9%)*	*156 (42.9%)*	*235 (42.9%)*
Leflunomide	*19 (10.3%)*	*40 (11.0%)*	*59 (10.8%)*
Sulfasalazine	*13 (7.1%)*	*25 (6.9%)*	*38 (6.9%)*
Other	*7 (3.8%)*	*10 (2.7%)*	*17 (3.1%)*
Concurrent use of corticosteroids	52 (28.3%)	152 (41.8%)	204 (37.2%)
Duration of morning stiffness (min)	57.2 (188.4)	63.4 (160.8)	61.2 (170.7)
HAQ-DI, range 0-3	1.3 (0.6)	1.3 (0.7)	1.3 (0.7)
Fatigue VAS, range 0-10	3.8 (3.3)	3.9 (3.6)	3.9 (3.5)
Pain VAS, range 0-10	4.5 (3.2)	4.5 (3.4)	4.5 (3.4)
CRP (mg/L)	14.4 (27.9)	13.8 (23.5)	14.0 (25.0)
ESR (mm/hr)	21.8 (16.5)	24.5 (23.0)	23.6 (21.1)
RF positive (%)	66.7%	67.2%	67.0%
Anti-CCP positive (%)	61.2%	64.3%	63.2%
Tender joint count (TJC), range 0-28	6.8 (6.8)	7.5 (6.7)	7.0 (6.8)
Swollen joint count (SJC), range 0-28	7.7 (5.9)	7.7 (6.1)	7.7 (5.9)
Physician global VAS, range 0-10	4.3 (2.3)	4.8 (1.9)	4.6 (2.1)
Patient global VAS, range 0-10	4.2 (2.9)	4.1 (3.2)	4.1 (3.1)
Clinical disease activity index (CDAI), range 0-76	20.9 (13.0)	21.5 (14.2)	21.0 (13.2)

* Results are expressed as means and standard deviation unless mentioned otherwise.

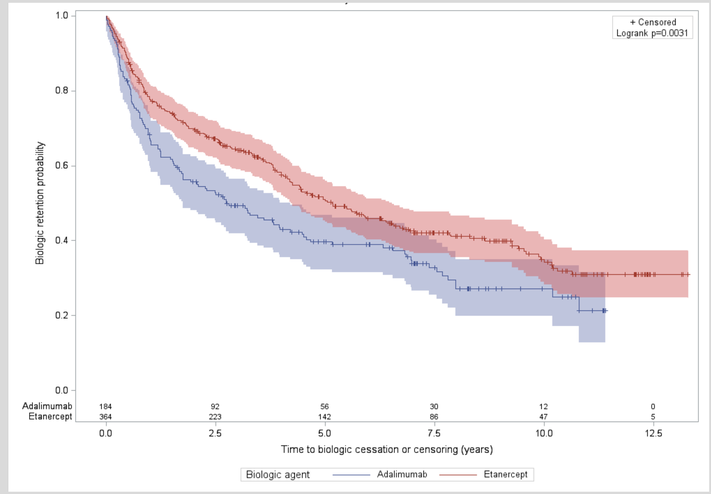

Figure 1. Retention probability of adalimumab and etanercept as first biologic agents.

CONCLUSIONS

After 10 years of continuous exposure to the first biologic in a population of RA patients, etanercept offers a clinically small but statistically significant advantage over adalimumab.

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