



# COMPARATIVE 10-YEAR RETENTION RATE OF ADALIMUMAB USED IN MONOTHERAPY AND COMBINATION THERAPY IN RHEUMATOID ARTHRITIS (RA) PATIENTS FROM THE RHUMADATA CLINICAL DATABASE AND REGISTRY.

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## BACKGROUND/PURPOSE

The recent publication of the CONCERTO trial comparing the use of adalimumab in monotherapy versus in association with methotrexate (MTX) at dose varying from 2.5 to 20 mg weekly increased the awareness of the importance of anti-drug antibody in lowering the efficacy of adalimumab in patients with RA. Rhumadata®, a real life clinical database and registry, gives a unique opportunity to compare the two strategies over 10 years of treatment. Our objective is to evaluate the impact the combination of MTX over monotherapy on long term retention rate of adalimumab in a population of patients with RA.

## METHODS

Data of RA patients who had been prescribed adalimumab in any intention on or after January 1st 2002 was extracted. The data included age and gender, disease characteristics, clinical variables, patient and physician specific assessments, and laboratory measures. The clinical disease activity index (CDAI) was calculated using a readily available formula. 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 on or prior to 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. Statistical analysis was performed using SAS version 9.4.

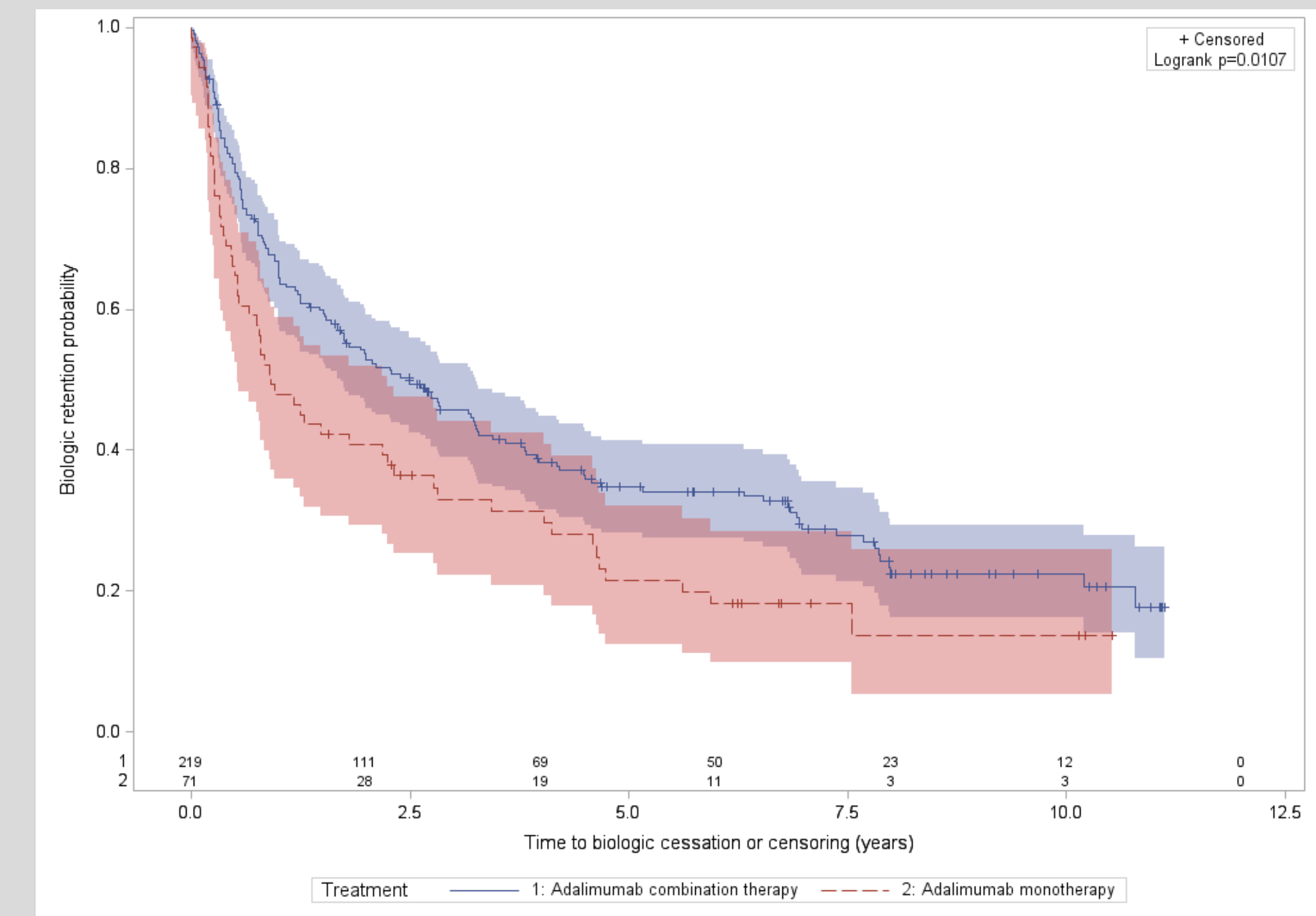
## RESULTS

The data from 290 patients prescribed adalimumab (219 in combination therapy and 71 in monotherapy, Table 1) in any intention were extracted from the RHUMADATA® clinical registry and database. The patients were mostly women (73.1%) and had an average age of 52.6(SD=12.8). The patients had an average disease duration of 7.4 years (SD=7.6) and were exposed to adalimumab for an average of 3.0 years (SD=3.1) providing 883.3 person-years of treatment. The most commonly reported comorbidities were “Diseases of The Circulatory System” and “Endocrine, Nutritional and Metabolic Diseases, and Immunity Disorders”. Approximately 50% of patients in both groups stopped ADA due to inefficacy. Patients prescribed MTX received an average daily dose of 15.4 mg (SD=6.1). The 10-year retention rates of ADA used in mono and combination therapy were estimated at 13.6% (SD=5.4%) and 22.4% (SD=3.4%) respectively and an overall significant difference in retention rate was observed, Figure 1.

## BASELINE CHARACTERISTICS

**Table 1. Characteristics of patients treated with adalimumab.**

	Combination Therapy n=219	Monotherapy n=71	All n=290
<b>Age (years)</b>	52.2 (12.7)	53.5 (12.9)	52.6 (12.8)
<b>Women, n (%)</b>	154 (70.3%)	58 (81.7%)	212 (73.1%)
<b>Disease Duration (years)</b>	6.5 (7.0)	10.3 (8.5)	7.4 (7.6)
<b>Person-years of treatment</b>	3.3 (3.2)	2.4 (2.8)	3.0 (3.1)
<b>Number of previously used biologics</b>	1.2 (0.4)	2.4 (1.1)	1.5 (0.8)
<b>Number of previously used DMARDs</b>	2.4 (0.9)	1.4 (1.7)	2.2 (1.2)
<b>Number of concurrently used DMARDs</b>	1.5 (0.5)	0.0 (0.0)	1.1 (0.8)
<b>No DMARDs used</b>	0 (0.0%)	71 (100.0%)	28 (9.7%)
<b>Methotrexate</b>	184 (84.0%)	0 (0.0%)	117 (40.3%)
<b>Hydroxychloroquine sulfate</b>	95 (43.4%)	0 (0.0%)	96 (33.1%)
<b>Leflunomide</b>	25 (11.4%)	0 (0.0%)	13 (4.5%)
<b>Sulfasalazine</b>	17 (7.8%)	0 (0.0%)	11 (3.8%)
<b>Other</b>	3 (1.4%)	0 (0.0%)	5 (2.6%)
<b>Use of corticosteroids</b>	62 (28.3%)	35 (49.3%)	97 (33.4%)
<b>Duration of morning stiffness (min)</b>	82.2 (245.3)	99.6 (227.2)	86.7 (240.3)
<b>HAQ-DI, range 0-3</b>	1.3 (0.7)	1.5 (0.7)	1.3 (0.7)
<b>Fatigue VAS, range 0-10</b>	4.0 (3.5)	5.2 (3.5)	4.3 (3.5)
<b>Pain VAS, range 0-10</b>	4.6 (3.3)	5.7 (3.0)	4.9 (3.3)
<b>CRP (mg/L)</b>	16.6 (30.5)	14.7 (22.1)	16.1 (28.6)
<b>ESR (mm/hr)</b>	21.9 (17.2)	26.9 (20.9)	23.2 (18.3)
<b>RF positive (%)</b>	66.2%	68.7%	66.8%
<b>Anti-CCP positive (%)</b>	60.1%	61.4%	60.4%
<b>Physician global VAS, range 0-10</b>	4.2 (2.3)	3.7 (2.3)	4.1 (2.3)
<b>Patient global VAS, range 0-10</b>	4.2 (3.0)	5.1 (3.2)	4.4 (3.1)
<b>Clinical disease activity index (CDAI), range 0-76</b>	20.9 (13.0)	21.5 (14.2)	21.0 (13.2)



**Figure 1. Retention probability of adalimumab in monotherapy and combination therapy.**

## CONCLUSIONS

Using adalimumab in combination with methotrexate improves significantly its retention rate in patients suffering of RA.

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