

Characteristics of patients with difficult-to-treat rheumatoid arthritis in real life: data from the BIOBADASER registry.

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Fernando Montero¹, Pablo Rodríguez-Merlos¹, Lucía Otero-Varela², Francisco Javier Manero Ruiz³, Paloma Vela-Casasempere⁴, Cristina Campos Fernández⁵, Sara Manrique Arija⁶, Carlos Rodríguez-Lozano⁷, Olga Martínez González⁸, Jerusalem Calvo Gutierrez⁹, Jose Campos Esteban¹⁰, Diana Sueiro Delgado¹¹, Fernando Sánchez-Alonso², Isabel Castrejon¹

¹ Gregorio Marañón General University Hospital, Madrid, Spain; ² Spanish Society of Rheumatology Research Unit, Madrid, Spain; ³ Miguel Servet University Hospital, Spain; ⁴ General University Hospital of Alicante, Alacant, Spain; ⁵ Hospital General Universitario de Valencia, València, Spain; ⁶ Hospital Regional Universitario de Málaga, Málaga, Spain; ⁷ University Hospital of Gran Canaria Dr. Negrín, Rheumatology, Las Palmas de Gran Canaria, Spain; ⁸ Salamanca University Hospital, Salamanca, Spain; ⁹ University Hospital Reina Sofía, Murcia, Spain; ¹⁰ Puerta de Hierro Majadahonda University Hospital, Majadahonda, Spain; ¹¹ Complejo Hospitalario Universitario de Ourense - CHUO, Ourense, Spain.

Objective

To determine the **prevalence of difficult-to-treat rheumatoid arthritis (D2TRA)** in a multicenter national registry (BIOBADASER) and to investigate the influence of the initial successive lines of treatment (LoT) in the development of D2TRA.

Methods

- Longitudinal and prospective cohort study.
- Data extracted from BIOBADASER (a **multicenter national registry** of adverse events of biologics and targeted therapies in rheumatic diseases).
- Patients were classified as **refractory** if failure to at least 2 biologics or targeted synthetic disease modifying antirheumatic drugs (b/tsDMARDs) with different mechanisms of action (MoA). Patients were further classified as **D2TRA** if they had refractory RA and presented **moderate to high disease activity according to DAS 28-ESR at their last visit**.
- The comparator group (Non-D2TRA) included patients with refractory RA but low disease activity/remission.
- Demographics, comorbidities and clinical data just prior to starting the first bDMARD were collected and activity data was recorded in the latest visit.

Results

- 3852 patients with RA were included in the analysis. 1612 (42%) had refractory RA and 348 (9%) D2TRA.
- No differences were found between D2TRA and non-D2TRA in clinical variables except for age, being patients with D2TRA significantly older.
- The use of JAKi as their first or second LoT was more frequent in patients with non-D2TRA, although no statistical significance was reached.

Table 1. Demographic and clinical characteristics of the 3 populations

	Refractory RA (n= 892)	D2TRA (n=348)	Non-D2TRA (n=544)	p-value
Age (years), mean ± SD	63.1 (12.8)	64.2 (12.8)	62.5 (12.8)	0.047
Sex (female), n (%)	712 (79.8)	286 (82.18)	426 (78.31)	0.160
FR positivity, n (%)	159 (22.3)	51 (18.3)	108 (24.8)	0.104
aCCP positivity, n (%)	523 (73.6)	207 (74.29)	316 (73.29)	0.108
Smoking habit, n (%)				0.88
Smoker	565 (63.3)	219 (62.93)	346 (63.6)	
Non smoker	159 (17.8)	68 (19.54)	91 (16.73)	
Former smoker	129 (14.5)	47 (13.51)	82 (15.07)	
Charlson Index, mean ± SD	0.3 ± 0.8	0.4 ± 0.8	0.3 ± 0.8	0.215
DAS28-ESR, mean ± SD	2.1 ± 0.7	4.3 ± 0.9	3.0 ± 0.8	<0.001
Concomitant csDMARD, n (%)	470 (52.7)	194 (55.8)	276 (50.7)	0.144
Time to first b/tsDMARD (years)	6.6 (7.1)	6.9 (7.3)	6.5 (7.0)	0.374

Table 2. Therapeutic characteristics in the 3 populations

	Refractory RA (n= 892)	D2TRA (n=348)	Non-D2TRA (n=544)	p-value
Lines of treatment				0.145
TNFi -> other bDMARD	583 (65.4)	233 (67.0)	350 (64.3)	
TNFi -> JAKi	138 (15.5)	46 (13.2)	92 (16.9)	
Other bDMARD -> TNFi	75 (8.4)	34 (9.8)	41 (7.5)	
Other bDMARD -> JAKi	23 (2.6)	8 (2.3)	15 (2.8)	
JAKi -> TNFi	15 (1.7)	2 (0.6)	13 (2.4)	
JAKi -> other bDMARD	8 (0.9)	5 (1.4)	3 (0.69)	
other bDMARD-> other bDMARD	50 (5.6)	20 (5.8)	30 (5.5)	

Conclusions

- Around 40% of patients were classified as refractory RA in our registry but only 9% as D2T-RA.
- Earlier treatment with JAKi was more frequent in the non-D2TRA group.
- Further research should analyse the influence of LoT on the development of D2TRA.