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Treatment Regimens and Persistence in Colombian Patients Diagnosed with Rheumatologic Diseases after Failure of Conventional Disease-Modifying Antirheumatic Drugs.

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OBJECTIVE

- To describe the treatment regimens and persistence of use in Colombian patients diagnosed with rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS) or juvenile idiopathic arthritis (JIA) after failure of conventional disease-modifying antirheumatic drugs (csDMARDs).

METHODS

- Retrospective, descriptive, longitudinal study of patients with diagnosis of RA, PsA, AS, JIA follow-up in a center specialized in rheumatological diseases in Colombia.
- Patients were included using International Code Diseases (ICD-10): rheumatoid arthritis -RA- (M053, M058, M059, M060 and M069), psoriatic arthritis -PsA- (L400, L405, L409), ankylosing spondyloarthritis -AS- (M45X) in older than 18 years and juvenile idiopathic arthritis -JIA- (M082, M080, M084, M089) in younger than 18 years.
- Patients who started treatment with a first biological DMARD (bDMARD) or tofacitinib between February 1, 2016 and December 31, 2019 were included. Demographic, clinical characteristics, and treatments were collected.
- Patient data were obtained from the clinical records and the dispensing medication database.
- Follow-up ended when patients discontinued therapy or until 24 months of treatment.
- Descriptive analysis was carried out with frequencies and proportions for the qualitative variables, and measures of central tendency and dispersion for the quantitative variables.
- The Kaplan Meier method was used to determine the time in days from the index date to switch, interruption, discontinuation, and persistence time of bDMARDs or tofacitinib.

RESULTS

- Four hundred twenty-six patients were included, with a mean age of 50.2 years and 72.8% were women. The mean follow-up of 635.2 days.
- The most frequent diagnosis was RA (71.8%). 80.3% and 77.2% of patients had respectively received csDMARDs and glucocorticoids in the last six months (Table 1).
- The bDMARDs most frequently used at baseline were rituximab (31.2%), etanercept (23.0%), and adalimumab (14.6%). 80.3% continued to receive concomitant csDMARDs.
- Monotherapy with TNF-α inhibitors and non-TNF-α inhibitors was similar 18.4% and 20.5%, respectively.
- 48.8% (n=208) had no changes, interruptions or discontinuations of treatments during the follow-up. 12.9% were switched to other treatments (first change), which occurred on average at 390.6 days (95% CI: 342.7-438.6). 43.6% (n=24/55) changed from TNF-α inhibitors to non-TNF-α inhibitors, 30.9% (n=17) from non-TNF-α inhibitors to another medication belonging to non-TNF-α inhibitors, 21.8% (n=12) TNF-α inhibitors to other TNF-α inhibitors, and 3.6% (n=2) non-TNF-α inhibitors to TNF-α inhibitors. Only 1.4% (n=6) had a second change on average 538.5 days (95% CI: 440.0-637.0) from the index date (Table 1).
- 26.3% (n=112) of patients had interruptions of bDMARDs or tofacitinib and 6.6% had more than 1 interruption (Table 1). The first happened in mean 271.2 days (CI95% 242.4-300.1 days). The second was at 456.5 days (IC95% 408.9-504.1) and third was 617.5 (CI95% 610.6 – 624.4).
- Patients who received csDMARDs concomitantly were more likely to persist with biological therapy (OR:8.50; 95%CI: 32.49-210.73; p<0.001).

RESULTS (cont)

Table 1. Sociodemographic and pharmacological characteristics of a group of patients with inflammatory arthritis, Colombia

Variables	RA		AS		PsA		JIA		Total	
	n=306	%	n=77	%	n=35	%	n=8	%	n=426	%
Age, mean ± SD	52.8 ± 12.5		43.9 ± 14.2		50.4 ± 12.1		12.8 ± 2.3		50.2 ± 14.1	
Age, median (IQR)	53.5 (45.0-61.1)		42.2 (33.3-54.8)		49.8 (44.3-59.2)		12.8 (10.8-16.0)		51.4 (41.4-59.2)	
Female, n (%)	254	83.0	34	44.2	17	48.6	5	62.5	310	72.8
Year of the index date, n (%)										
2016	54	17.6	16	20.8	4	11.4	1	12.5	75	17.6
2017	58	19.0	16	20.8	7	20.0	3	37.5	84	19.7
2018	91	29.7	25	32.5	15	42.9	2	25.0	133	31.2
2019	103	33.7	20	26.0	9	25.7	2	25.0	134	31.5
csDMARDs: 6-month previous to baseline period	296	96.7	47	61.0	32	91.4	8	100.0	383	89.9
Methotrexate	200	65.4	15	19.5	24	68.6	6	75.0	245	57.5
Leflunomide	212	69.3	2	2.6	8	22.9	2	25.0	224	52.6
Sulfasalazine	90	29.4	37	48.1	6	17.1	1	12.5	134	31.5
Chloroquine	50	16.3	1	1.3	2	5.7	1	12.5	54	12.7
Hydroxychloroquine	25	8.2	0	0.0	0	0.0	0	0.0	25	5.9
Azathioprine	14	4.6	1	1.3	0	0.0	0	0.0	15	3.5
Cyclosporine	3	1.0	0	0.0	2	5.7	0	0.0	5	1.2
Corticosteroids: 6-month previous to baseline period	270	88.2	36	46.8	16	45.7	7	87.5	329	77.2
bDMARDs: Initial treatment										
TNF-α inhibitors	120	39.2	74	96.1	22	62.9	7	87.5	223	52.3
Non-TNF-α inhibitors	183	59.8	3	3.9	13	37.1	1	12.5	200	46.9
JAK inhibitors	3	1.0	0	0.0	0	0.0	0	0.0	3	0.7
csDMARDs: Concomitant treatment	266	86.9	43	55.8	25	71.4	8	100.0	342	80.3
Switch										
First switch	35	11.4	15	19.5	5	14.3	0	0.0	55	12.9
Second switch	4	1.3	1	1.3	1	2.9	0	0.0	6	1.4
Interruptions	65	21.2	34	44.2	11	31.4	2	25.0	112	26.3
Discontinuations	73	23.9	18	23.4	9	25.7	2	25.0	102	23.9

SD: Standard deviation; IQR: Interquartile Range; RA: Rheumatoid Arthritis; AS: Ankylosing Spondylitis; PsA: Psoriasic Arthritis; JIA: Juvenile Idiopathic Arthritis; csDMARDs: Conventional Disease-Modifying Antirheumatic Drugs; bDMARDs: biological Disease-Modifying Antirheumatic Drugs.

RESULTS (cont)

Figure 1. Sankey plot from the first treatment to first treatment switch prescribed during follow up.

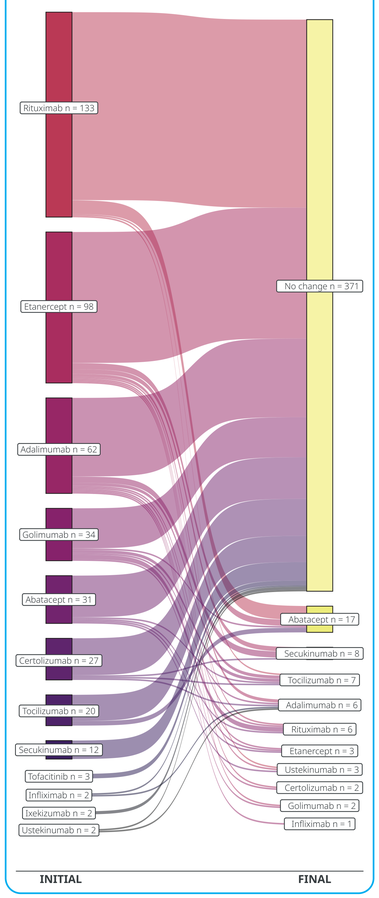
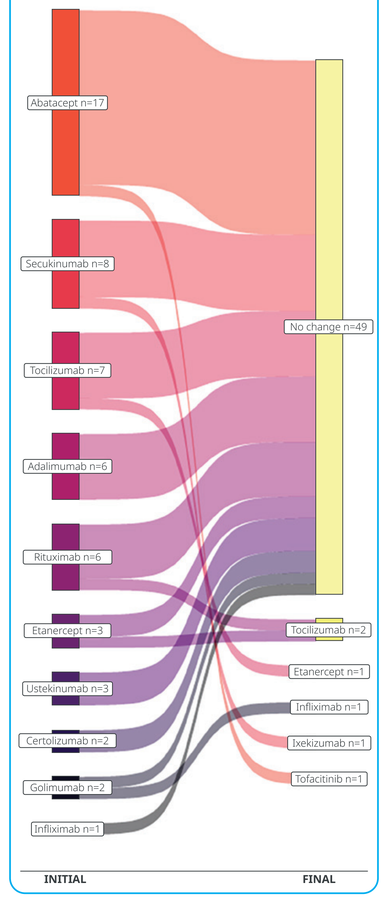


Figure 2. Sankey plot from the second switch in the patients during follow-up



CONCLUSION

- Patients who fail treatment with csDMARDs more frequently recieved rituximab, etanercept or adalimumab as advanced therapy.
- These patients underwent few medications switching after starting the first bDMARD during the approximately two years; however, a quarter interrupted or discontinued the therapy. Combination therapy with csDMARDs were more likely to persist with biological therapy.

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