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Four-years retention rate of golimumab administered after discontinuation of non-TNF inhibitors in patients with inflammatory rheumatic diseases

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Abstract

Background In patients with rheumatic diseases, the use of biological (b) or targeted synthetic (ts) disease-modifying antirheumatic drugs (DMARDs) after discontinuation of tumor necrosis factor inhibitors (TNFi) is known to be effective. However, data on the use of TNFi after discontinuation of non-TNFi bDMARDs or tsDMARDs (non-TNFi) are scarce. This study assessed the 4-years golimumab retention in patients with rheumatic diseases when used after discontinuation of non-TNFi.

Methods Adults with rheumatoid arthritis (RA; n = 72), psoriatic arthritis (PsA; n = 30) or axial spondyloarthritis (axSpA; n = 23) who initiated golimumab after discontinuation of non-TNFi from the Spanish registry of biological drugs (BIOBADASER) were analyzed retrospectively. The retention rate (drug survival or persistence) of golimumab up to 4 years was evaluated.

Results The golimumab retention rate was 60.7% (51.4–68.8) at year 1, 45.9% (36.0–55.2) at year 2, 39.9% (29.8–49.7) at year 3 and 33.4% (23.0–44.2) at year 4. Retention rates did not differ significantly whether golimumab was used as second, third, or fourth/subsequent line of therapy (p log-rank = 0.462). Golimumab retention rates were higher in axSpA or PsA patients than in RA patients (p log-rank = 0.002). When golimumab was administered as third or fourth/subsequent line, the 4-years retention rate after discontinuation of non-TNFi was similar to that after discontinuation of TNFi.

Conclusion In patients who discontinued non-TNFi, most of whom received golimumab as third/subsequent line of therapy, one-third of patients remained on golimumab at year 4. Retention rates were higher in patients with axSpA and PsA than in those with RA.

Keywords Axial spondyloarthritis, Golimumab, Medication retention, Psoriatic arthritis, Rheumatoid arthritis

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Background

Disease-modifying antirheumatic drugs (DMARDs) are a cornerstone of the treatment of patients with inflammatory rheumatic diseases. Available DMARDs include conventional synthetic, biological (b) and targeted synthetic (ts) DMARDs. The bDMARD group includes the well-established group of tumor necrosis factor inhibitors (TNFi) as well as non-TNFi drugs that target interleukins, T cells or B cells instead [1].

The European Alliance of Associations for Rheumatology (EULAR) recommends that patients with rheumatoid arthritis (RA) should receive conventional synthetic DMARDs initially, with the subsequent addition of either a bDMARD or a tsDMARD if treatment targets are not achieved in patients with poor prognostic factors [2]. For psoriatic arthritis (PsA), bDMARDs are recommended for patients with peripheral arthritis and an inadequate response to conventional synthetic DMARDs, and tsDMARDs are recommended in the event of an inadequate response to conventional synthetic DMARDs and bDMARDs (or when a bDMARD is not appropriate) [3]. In patients with axial spondyloarthritis (axSpA), bDMARDs are recommended for those with persistent high disease activity despite treatment with non-steroidal anti-inflammatory drugs [4].

TNFi are often the first bDMARD prescribed; however, in practice, some patients will be prescribed non-TNFi bDMARDs or even tsDMARDs first. In the event of failure of a bDMARD or tsDMARD in patients with RA, EULAR recommends using another drug from either class [2]. In patients with PsA who have an inadequate response to a bDMARD, a switch to another bDMARD or to a tsDMARD is suggested [3]. With regard to specific switches, the EULAR RA guideline indicates that after failure of TNFi therapy, another TNFi or a drug with a different mechanism of action can be tried [2]. However, there is no clear guidance on what to do after discontinuing non-TNFi bDMARDS or tsDMARDs.

Whilst the use of non-TNFi bDMARDs or tsDMARDs after discontinuation of TNFi has been shown to be effective [5–9], data on the opposite scenario (i.e., use of TNFi after discontinuation of non-TNFi bDMARDs or tsDMARDs) are scarce. Available studies have involved patients with RA and reported retention rates for periods of up to 2 years after switching from a non-TNFi bDMARD to a TNFi [10–14].

In this study, a prespecified retrospective analysis of the BIOBADASER registry, we assessed the probability of retention (persistence or drug survival) of the TNFi golimumab for up to 4 years in patients with rheumatic diseases (RA, axSpA, PsA) when used after discontinuation of non-TNFi bDMARDs or tsDMARDs.

Methods

Patient selection

All adults with RA, PsA or axSpA who had initiated golimumab after discontinuation of non-TNFi bDMARDs or tsDMARDs were identified from the BIOBADASER registry. BIOBADASER is the Spanish registry of biological drugs, promoted by the Spanish Agency of Medicines (https://www.aemps.gob.es/en/home.htm) and the Spanish Society of Rheumatology (https://www.ser.es/), and involves investigators from 28 university hospitals within the Spanish public healthcare system. Patients are enrolled when they start treatment with a bDMARD or tsDMARD and are followed up prospectively for data collection whilst they are treated with any of these therapies [15]. The registry started in February 2000 and is currently active. The current analysis was retrospective, based on data available in the registry, and patients retaining golimumab were censored on the last visit before the current analysis date (December 2021). To allow retention rates of patients who initiated golimumab after discontinuation of a non-TNFi bDMARD or a tsDMARD to be compared with golimumab initiated after discontinuation of another TNFi, the latter cohort was also identified from the same database.

The registry and its derived studies were approved by participating Clinical Research Ethic Committees. Informed consent, which includes analyses like that presented herein, is signed by all patients prior to inclusion in BIOBADASER.

Outcomes

The primary objective of this non-interventional study was to assess the 4-years retention rate (drug survival or persistence) of golimumab treatment when it had been initiated following discontinuation of a non-TNFi bDMARD or a tsDMARD. Secondary objectives were to assess the probability of retention of golimumab treatment by indication (RA, axSpA or PsA) and by line of therapy (second, third or fourth/later biological therapy). In addition, retention rates of patients who initiated golimumab after discontinuation of a non-TNFi bDMARD or a tsDMARD were compared with those of golimumab initiated after discontinuation of another TNFi, according to golimumab line of therapy.

Statistical analysis

Descriptive statistics are presented as means (standard deviation), medians (interquartile ranges), or percentages. Golimumab retention rates were assessed using Kaplan–Meier survival analysis. Patients retaining golimumab at the time of data analysis were right censored. Patients were considered to have discontinued golimumab if they had stopped golimumab permanently,

or if they had temporarily discontinued it for a period longer than 90 days (grace period). Differences in the retention rates between the different indications, lines of therapy and previous therapy were assessed with the log-rank test. A Cox regression analysis was used to adjust retention rates by the different variables studied. Statistical analyses were conducted using Stata v13.1.

Results

A total of 125 patients with RA (n = 72), axSpA (n = 23), or PsA (n = 30) initiated golimumab after discontinuation of non-TNFi bDMARDs or tsDMARDs. In 26 patients (20.8%), golimumab was initiated as second line therapy (i.e., after discontinuation of a first-line non-TNFi bDMARD or a first-line tsDMARD). In 29 patients (23.2%), it was initiated as third-line therapy (i.e., after discontinuation of two therapies, the second being a non-TNFi bDMARD or a tsDMARD, whatever the first had been, TNFi or non-TNFi), and in 70 patients (56.0%) it was fourth/subsequent line of therapy (i.e., initiated after discontinuation of three or more therapies, the third/subsequent of them a non-TNFi bDMARD or a tsDMARD, whatever the first and the second/subsequent had been).

Table 1 displays the main characteristics of the patients and the non-TNFi bDMARD/tsDMARDs that were discontinued before initiating golimumab. The median disease duration was 10.0 (IQR 6.5–17.4) years, and 68.0% were women. Among patients with RA, the most common previously discontinued therapies were abatacept, tocilizumab, tofacitinib and baricitinib, whilst in PsA they were secukinumab, ustekinumab and apremilast. In axSpA, secukinumab was the most frequently discontinued drug, accounting for all but two discontinuations.

The overall retention rate of golimumab was 60.7% (95% CI 51.4–68.8) at year 1 (number at risk: 64), 45.9% (36.0–55.2) at year 2 (number at risk: 37), 39.9% (29.8–49.7) at year 3 (number at risk: 23) and 33.4% (23.0–44.2) at year 4 (number at risk: 13). There were no significant differences in retention rates over 4 years whether golimumab was used as the second, third, or fourth/subsequent line of therapy (p log-rank = 0.462; Fig. 1, Table 2). Golimumab retention rates were higher in axSpA or PsA patients than in RA patients (p log-rank = 0.002, Fig. 2). In RA, the retention rates were 51.5% (year 1), 35.0% (year 2), 26.3% (year 3) and 19.7% (year 4). In contrast, retention rates in axSpA were 91.3% (year 1), 75.2% (year

Table 1 Main characteristics of patients at golimumab initiation

	All (n = 125)	RA (n = 72)	Axial SpA (n = 23)	PsA (n = 30)
Mean age, years (SD)	55.9 (13.5)	61.5 (12.2)	50.8 (12.7)	46.7 (10.3)
Gender, n (%)				
Male	40 (32.0)	10 (13.9)	16 (69.6)	14 (46.7)
Female	85 (68.0)	62 (86.1)	7 (30.4)	16 (53.3)
Median disease duration, years (IQR)	10.0 (6.5–17.4)	10.6 (7.6–18.6)	10.4 (5.7–44.0)	8.7 (4.6–10.9)
Order (line) of golimumab therapy, n (%)				
Second	26 (20.8)	15 (20.8)	2 (8.7)	9 (30.0)
Third	29 (23.2)	14 (19.4)	9 (39.1)	6 (20.0)
Fourth/subsequent	70 (56.0)	43 (59.7)	12 (52.2)	15 (50.0)
Previous non-TNFi therapy, n (%)				
Biological non-TNFi				
Abatacept	23 (18.4)	22 (30.6)	1 (4.4)	0 (0.00)
Rituximab	7 (5.6)	6 (8.3)	0 (0.0)	1 (3.3)
Tocilizumab	17 (13.6)	16 (22.2)	0 (0.0)	1 (3.3)
Sarilumab	4 (3.2)	4 (5.6)	0 (0.0)	0 (0.0)
Secukinumab	34 (27.2)	0 (0.00)	21 (91.3)	13 (43.3)
Ixekizumab	3 (2.4)	0 (0.0)	0 (0.0)	3 (10.0)
Ustekinumab	7 (5.6)	0 (0.00)	1 (4.4)	6 (20.0)
Targeted synthetic disease modifying antirheumatic drugs				
Apremilast	6 (4.8)	0 (0.0)	0 (0.0)	6 (20.0)
Baricitinib	10 (8.0)	10 (13.9)	0 (0.0)	0 (0.0)
Tofacitinib	14 (11.2)	14 (19.4)	0 (0.0)	0 (0.0)
TNFi previous to non-TNFi, n (%)*	42 (42.4)	17 (29.8)	16 (76.2)	9 (42.9)

IQR interquartile range, *PsA* psoriatic arthritis, *RA* rheumatoid arthritis, *SD* standard deviation, *SpA* spondylarthritis, *TNFi* tumor necrosis factor inhibitor

*Percentages calculated over 99 patients who had initiated golimumab in the third/subsequent line of therapy. Represents patients who had discontinued a TNFi prior to starting non-TNFi therapy (All, n = 99; RA, n = 57; axial SpA, n = 21; PsA, n = 21)

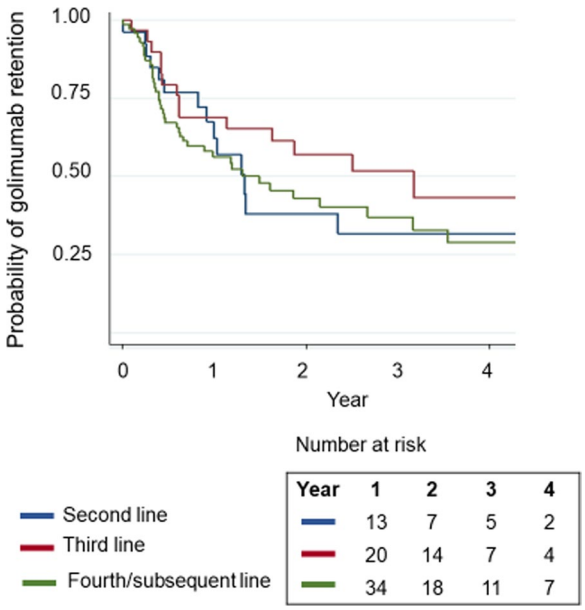

Fig. 1 Probability of golimumab retention after discontinuation of non-TNFi biologicals or tsDMARDs by line of therapy

2), 68.4% (year 3), and 58.6% (year 4), and in PsA rates were 58.5% (year 1) and 48.5% (years 2, 3 and 4). In the Cox regression model (Table 2), female gender was associated with a higher risk of discontinuation, as well as the use of golimumab as the fourth/subsequent line of therapy compared to use in the second line. Compared to RA, axial SpA and PsA were associated with longer retention (HR for discontinuation = 0.61 and 0.58 versus RA respectively).

The characteristics of patients who started golimumab after discontinuation of another TNFi are displayed in the Additional File 1: Table S1. When compared, by line of therapy, with this population (n = 475 and 509 cycles of golimumab), the 4-years retention rate of golimumab after non-TNFi bDMARDs/tsDMARDs was numerically, but not significantly, lower in second line (31.6% vs. 48.4%, *p* log-rank = 0.119), but similar when used as third (43.1% vs 44.4%, *p* log-rank = 0.838) or fourth/subsequent (28.7% vs 33.5%, *p* log-rank = 0.554) lines of therapy (Table 3). After adjustment by gender, indication and line of therapy, there were no differences in retention rates between use of golimumab after non-TNFi bDMARDs/tsDMARDs compared to use after TNFi (HR for discontinuation = 1.07 (0.79–1.45), *p* = 0.643).

Discussion

To the best of our knowledge, this is the first study showing 4-years retention rates for a TNFi initiated after discontinuation of non-TNFi bDMARDs or tsDMARD in patients with inflammatory rheumatic diseases. Overall, one-third of patients remained on golimumab after 4 years, with higher retention rates in axSpA or PsA patients. The results extend those from our previous analysis of the BIOBADASER database which reported 2-years retention rates after discontinuation of non-TNFi bDMARDs/tsDMARDs [14]. That analysis found a 2-years retention rate of 47.7%, which is similar to the rate of 45.9% in the current analysis.

A few other retrospective observational studies have evaluated retention of non-TNFi biological drugs compared with TNFi in RA patients switching to a new bDMARD after failure of a non-TNFi. These studies all involved RA patients and evaluated retention for periods up to 2 years. The largest study, an analysis of five Nordic registries, found that among 620 RA patients who started a second bDMARD (TNFi or non-TNFi) after failure of a first-line non-TNFi bDMARD (rituximab, abatacept or tocilizumab), 69% and 56% remained on the second agent after 6 months and 1 year respectively, with no significant difference between drugs [16]. At 6 months, less than one-third of recipients of a second non-TNFi agent remained on treatment and had low disease activity/remission, compared with 40% of those who received a TNFi. In contrast, an analysis of the Italian GISEA registry found that among 278 RA patients who were switched to another bDMARD after failure of a first-line non-TNFi bDMARD (rituximab, abatacept or tocilizumab), the 2-years retention rate was higher among patients who received another non-TNFi as second-line therapy compared with those who received a TNFi (63.5% versus 33.4%, $p < 0.001$) [13]. Three other studies in RA have also described inconsistent results [10–12]. The 72 patients

Table 2 Cox-regression analysis: hazard ratios for discontinuation of golimumab

	Hazard ratio	95% Confidence interval	P
Gender (women vs men)	1.47	1.15–1.87	0.002
Axial SpA vs RA	0.61	0.46–0.81	0.001
PsA versus RA	0.58	0.43–0.77	< 0.001
Third versus second biological drug	1.09	0.84–1.42	0.507
Fourth or further versus second biological drug	1.35	1.02–1.78	0.034

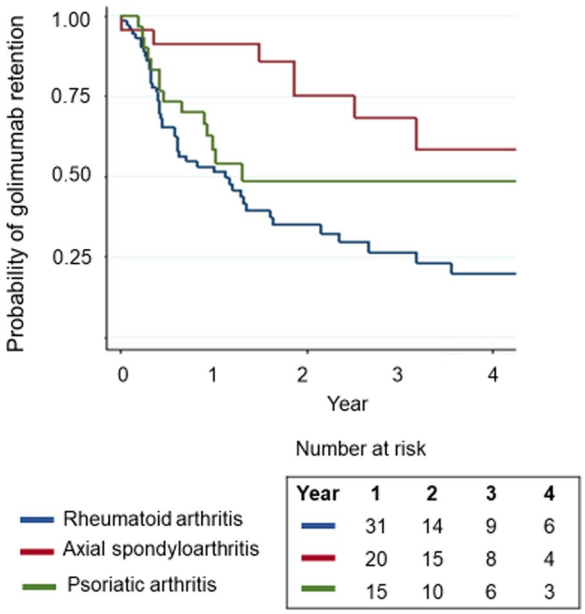

Fig. 2 Probability of golimumab retention after discontinuation of non-TNFi biologicals or tsDMARDs by indication

with RA in our study show a retention rate of golimumab of 51.5% at year 1 and 35.0% at year 2, but the sample comprised only 15 patients (20.8%) after failure of a first-line non-TNFi bDMARD, and most of them (close to 60%) were fourth/subsequent lines. For this reason, and for the fact that the studies do not provide information on specific TNFi (only as a group), comparison with the Nordic registries and GISEA registry, or with specific TNFi, is difficult. Overall, our data suggest that golimumab retention rates are at least as good as other TNFi in this context, but lower than when golimumab is used as first biological agent. We previously reported retention rates of golimumab as first-line biological drug in RA of 75.3% at year 1, 54.7% at year 2 and 50.0% at year 3 [14], and higher retention rates in SpA (85.6%, 81.6% and 71.4%) and PsA (83.3%, 73.0% and 67.6%) at year 1, 2 and 3, respectively.

Our study adds useful information to the existing evidence by including a wider scope of indications and a longer follow-up. Besides, in contrast to others, the current study involved a difficult-to-treat population that had experienced failure to several lines of therapy; most patients received golimumab as their third or further line of treatment, with half of them receiving it as their fourth/subsequent line of therapy. The retention rate did not differ significantly between golimumab used as second, third or fourth/subsequent line. Whilst real-world studies have produced conflicting results, they generally agreed that golimumab retention rates decreased when used as second or later line of therapy compared to use in first line [17, 18].

Retention rates were higher in patients with axSpA and PsA than in patients with RA in the current study. This is in alignment with results from the overall BIOBADASER cohort of all patients who had ever initiated golimumab,

Table 3 Golimumab retention rates after discontinuation of non-TNFi versus after discontinuation of TNFi, by line of therapy

	Golimumab after discontinuation of non-TNFi ($n=125$)		Golimumab after discontinuation of TNFi ($n=509$)		*p* log-rank
	n	Retention rate (95% confidence interval)	n	Retention rate (95% confidence interval)	
Second line	26		279		
Year 1	13	62.1 (39.3–78.5)	185	70.5 (64.7–75.5)	0.119
Year 2	7	38.0 (16.9–59.0)	139	59.1 (52.8–64.7)	
Year 3	5	31.6 (12.3–53.1)	112	55.0 (48.7–60.9)	
Year 4	2	31.6 (12.3–53.1)	81	48.4 (41.9–54.7)	
Third line	29		139		
Year 1	20	69.0 (48.8–82.5)	80	66.1 (57.5–73.4)	0.838
Year 2	14	56.9 (36.4–73.0)	65	59.0 (49.9–66.9)	
Year 3	7	51.7 (31.0–68.9)	48	50.0 (40.7–58.6)	
Year 4	4	43.1 (21.0–63.5)	33	44.4 (35.0–53.4)	
Fourth/subsequent line	70		91		
Year 1	34	56.2 (43.6–67.1)	46	57.5 (46.5–67.0)	0.554
Year 2	18	43.0 (29.8–55.4)	34	46.9 (35.9–57.1)	
Year 3	11	36.9 (23.6–50.3)	25	43.6 (32.6–54.1)	
Year 4	7	28.7 (15.3–43.6)	16	33.5 (22.5–44.9)	

TNFi tumor necrosis factor inhibitor

which also found that the retention period was shorter in RA patients [18]. Other studies have reported greater persistence of golimumab in patients with axSpA compared with RA or PsA [17, 19], whereas a systematic review found some evidence of lower persistence among axSpA patients, although it noted that several studies found no difference according to indication [20]. A recent analysis of data from the Korean College of Rheumatology Biologics registry showed that, for > 1000 patients with ankylosing spondylitis who were treated with TNFi, the overall TNFi discontinuation rate was 24.2% and the drug retention rate was higher for golimumab than for other TNFi [21].

The current study included an analysis of patients who started golimumab after discontinuation of another TNFi. Of note, it was found that when golimumab was administered as third or fourth/subsequent line of therapy, the 4-years retention rate after discontinuation of non-TNFi bDMARDs/tsDMARDs was similar to the retention rate after discontinuation of a TNFi. Overall, the results of this study suggest that when a bDMARD (either TNFi or non-TNFi) or a tsDMARD needs to be discontinued, golimumab provides an effective alternative with durable persistence on treatment.

This analysis of BIOBADASER is limited by its retrospective, non-comparative, observational design. The sample comprised a disproportionately high number of RA patients and fourth/subsequent lines of therapy. The standards of therapy for RA, axSpA and PsA are different and the role of TNFi, and specifically of golimumab, can vary from patient to patient. The outcomes have been provided for each indication and by line of therapy, which led to relatively small sample sizes in some cases. Nonetheless, the study provides useful information from real-world clinical practice. Given the wide range of therapies now available for the treatment of patients with rheumatic diseases, there will be an increasing number of patients who need to switch from non-TNFi bDMARDs and tsDMARDs to alternative treatments. The findings of this study may help to inform the management of this population.

Conclusion

We present, for the first time, 4-years retention rates for golimumab in patients with rheumatic diseases who had discontinued non-TNFi bDMARDs or tsDMARDs, most of whom received golimumab as third/subsequent line of therapy. In this difficult-to-treat population, the golimumab retention rate was almost 50% at year 2 and one-third of patients remained on golimumab at year 4. Retention rates were higher in patients with SpA and PsA, with retention rates about 50% at year 4, than in those with RA.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s42358-023-00296-1.

Additional file1. **Table S1**: Main characteristics of patients who have initiated golimumab after discontinuation of a TNFi, at golimumab initiation.

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Author contributions
All authors contributed to the study conception, design, data collection and analysis of the results. The first draft of the manuscript was written by LCC and DSM and all other authors commented on the manuscript. All authors approved the final version. Professional medical writing assistance was provided by KC and DPF, PhD, ISMPP CMPP™, Content Ed Net, with funding from MSD Spain. All authors read and approved the final manuscript.

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Availability of data and materials
The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Ethical approval and consent to participate
The study was performed in accordance with Good Pharmacoepidemiology Practice standards and the principles of the Declaration of Helsinki. The registry and its derived studies were approved by participating Clinical Research Ethic Committees. Informed consent, which includes analyses like that presented herein, is signed by all patients prior to inclusion in BIOBADASER.

Consent for publication
Not Applicable.

Competing interests
Manuel Pombo-Suárez: consulting honorarium from Janssen, MSD and Sanofi; lectures for Janssen, MSD and Novartis. Daniel Seoane-Mato: no conflict of interest. Federico Díaz-González: no conflict of interest. Fernando Sánchez-Alonso: no conflict of interest. Marta Sánchez-Jareño: full-time employee at MSD, Spain. Luis Cea-Calvo: full-time employee at MSD, Spain. Isabel Castrejón: no conflict of interest.

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