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Real-world effectiveness of golimumab in adult patients with rheumatoid arthritis, psoriatic arthritis, and axial spondyloarthritis and an inadequate response to initial TNFi therapy in Greece: the GO-BEYOND prospective, observational study

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Abstract

The impact of golimumab (GLM) on remission or low disease activity (LDA) was evaluated in patients with moderate-to-severe rheumatoid arthritis (RA), progressive psoriatic arthritis (PsA), or severe axial spondyloarthritis (axSpA), who failed previous treatment for their rheumatic disease with one initial tumor necrosis factor α inhibitor (TNFi). This is a multicenter, prospective, real-world observational 18-month study, conducted in Greece. The primary endpoint, assessed at 6 months, included the proportion of patients attaining LDA and/or remission (Disease Activity Score for 28 joints based on C-reactive protein [DAS28-CRP] ≤ 3.2), minimal disease activity (MDA; MDA criteria), and moderate disease activity (Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] score 4–7), respectively. Other endpoints evaluated the persistence to GLM treatment and its impact on patients' work productivity (Work Productivity and Activity Impairment [WPAI] instrument) and quality of life (QoL; EuroQoL5 dimensions 3 levels [EQ-5D-3L] questionnaire). Descriptive statistics, the Wilcoxon signed-rank test, and Kaplan–Meier method were used for analyses. At 6 months, LDA was achieved by 46.4% of patients with RA, MDA by 57.1% of patients with PsA, and BASDAI 4–7 by 24.1% of patients with axSpA. For all study patients, persistence rates on GLM were high (85.1–93.7%) over 18 months; all WPAI domain scores and the EQ-5D-3L index score improved significantly ($p < 0.001$) from baseline to 18 months. GLM treatment was effective in patients with RA, PsA, or axSpA who had failed previous treatment with one TNFi and led to significant WPAI and QoL improvements. Persistence rates were high. Trial registration number and date of registration: As per the local regulations the study has been registered at the national registry for non-interventional studies https://www.dilon.sfee.gr/studiesp_d.php?meleti_id=MK8259-6995.

Keywords Golimumab · Rheumatoid arthritis · Psoriatic arthritis · Axial spondyloarthritis · Disease activity · Quality of life

Introduction

Chronic inflammatory rheumatic diseases, including rheumatoid arthritis (RA), psoriatic arthritis (PsA), and axial spondyloarthritis (axSpA), are frequently observed in clinical practice [1]. The main clinical manifestations of RA include pain in the joints and potential damage of bone and cartilage, as well as disability [2], PsA involves a diverse symptomatology and local inflammation pathways, including uveitis, dactylitis, osteitis, as well as skin and nail disease [3]. AxSpA is associated with chronic back pain and

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stiffness, primarily of the pelvis and the lower back, although any part of the spine can be involved [4]. These diseases are of predominant interest to rheumatologists due to their significant impact on the patient's quality of life (QoL) and their substantial burden for patients and society [5].

Significant advances have been achieved in the clinical outcomes of these diseases, based mainly on evolved treatment strategies and the availability of multiple effective therapies. The current treatment strategy paradigm is the treat-to-target concept in RA and PsA, aiming at disease remission or low disease activity (LDA) [6, 7], and the maximization of QoL in axSpA [8]. Furthermore, several disease-modifying antirheumatic drugs (DMARDs) with diverse modes of action are available (conventional synthetic [cs], biologic [b], and targeted synthetic DMARDs), allowing for a tailored approach for a specific patient. The bDMARDs comprise, among other agents, the tumor necrosis factor α inhibitors (TNFis) etanercept, infliximab, adalimumab, certolizumab pegol, and golimumab.

The use of TNFis in the treatment of autoimmune disorders has improved clinical outcomes. However, treatment failure with TNFis is a common occurrence in RA [9], PsA [10], and axSpA [11]. In RA, reasons for discontinuation mainly include lack of efficacy, followed by physician preference, safety, patient preference, and no access to treatment [12], while in PsA and axSpA, TNFi discontinuation/switching includes primarily inefficacy and lack of tolerability [13, 14]. As a result, persistence with TNFi treatment is negatively impacted. In RA, the median time to TNFi discontinuation was ~ 26 months [12], and the discontinuation of TNFi treatment was 59.5% in patients with an inadequate response to a previous DMARD and 74.1% in patients who had failed a first bDMARD [15]. In PsA and axSpA the approximate 1-year discontinuation rates in were 30% [16] and 15% [17], respectively. In general, physicians manage TNFi failure in all three indications by switching either to an alternative TNFi or to another class of targeted agent with a different mode of action [6–8].

Golimumab is a human monoclonal antibody that prevents the binding of tumor necrosis factor α to its receptors [18]. In the European Union, golimumab has been approved, among other indications, for the treatment of moderate-to-severe active RA (in combination with methotrexate), active and progressive PsA (alone or in combination with methotrexate), and axSpA [18]. Golimumab's safety and efficacy in RA, PsA, and axSpA have been demonstrated in several pivotal randomized clinical trials and their long-term extensions [19]. Golimumab has also been evaluated in these indications in several retrospective [20–22] and prospective [23–25] real-world studies, albeit that only two of these studies focused exclusively on patients who had failed treatment with one previous TNFi [20, 25]; thus, further real-world, prospective data, in patients with RA, PsA and axSpA who had failed one previous TNFi treatment would fill this gap in knowledge.

The present prospective study, GO-BEYOND, assessed primarily the effectiveness of golimumab in patients with RA, PsA, or axSpA who had failed one previous TNFi. Other study objectives included the patients' persistence to golimumab treatment, work productivity and activity impairment, and healthcare resource utilization (HCRU).

Methods

Study design and patient population

GO-BEYOND was a prospective, observational, 18-month study conducted in 21 rheumatologic sites (private practices and hospitals) in Greece, constituting a wide selection of centers throughout Greece. Participant enrolment lasted from 30 March 2018 to 28 June 2019, and the last patient visit occurred in 28 December 2022. Visits were scheduled at enrolment (baseline) and post-baseline at approximately 3, 6, 12, and 18 months per routine clinical care.

Treatment initiation with golimumab and any treatment changes during the observation period fell entirely into the responsibility of the treating physicians and were based on the approved therapeutic protocols. Golimumab was prescribed per label [18]. Briefly, across RA, PsA, and axSpA, the recommended golimumab dose is 50 mg monthly (given concomitantly with methotrexate in RA) or 100 mg monthly for patients with body weight > 100 kg who do not achieve an adequate clinical response after three to four 50 mg doses.

Eligible patients were 18 years of age or older, diagnosed with active moderate-to-severe RA, active and progressive PsA, or severe and active axSpA, as based on the physicians' assessment, who had failed previous treatment for their rheumatic disease with one initial TNFi, with or without methotrexate. Previous TNFi treatment failure was defined as loss of efficacy after ≥ 6 months of treatment (secondary failure) or intolerability or inconvenience after ≥ 3 months of treatment. The criteria for exclusion included: (i) previous treatment with non-TNFi bDMARDs or ≥ 1 TNFi; (ii) previous treatment with other biological therapeutics (including anakinra and abatacept); (iii) RA patients on bDMARD monotherapy who could not be switched to golimumab plus methotrexate or those with intolerance to methotrexate; (iv) any contraindication to the use of golimumab as per label or a clinically serious adverse reaction, opportunistic infection, or allergic reaction to the initial TNFi; and (v) history of lymphoproliferative disease, malignancy, or history of malignancy within the previous five years.

Table 1 Baseline characteristics and treatment history of patients with RA, PsA, and axSpA initiating treatment with golimumab

	All patients (N = 242)	Patients with RA (N = 117)	Patients with PsA (N = 63)	Patients with axSpA (N = 62)
Demographic characteristics				
Age, years	55.0 (46.0–65.0)	61.0 (52.0–70.0)	52.0 (43.0–60.0)	47.5 (41.0–57.0)
Female, n (%)	173 (71.5)	103 (88.0)	35 (55.6)	35 (56.5)
Nationality, n (%)				
Greek	234 (96.7)	111 (94.9)	62 (98.4)	61 (98.4)
Other	1 (1.6)			
Weight, kg	78.0 (67.0–88.0)	73 (66.0–85.0)	80.0 (70.0–89.0)	80.0 (65.0–90.0)
BMI, kg/m^2	27.7 (24.2–31.0)	27.7 (24.2–32.0)	27.8 (24.2–31.3)	26.8 (24.1–30.1)
Current smoker, n (%)	49 (20.2)	22 (18.8)	10 (15.9)	17 (27.4)
Clinical characteristics				
Duration of rheumatoid disease, years				
Median (Q1–Q3)	3.6 (2.1–7.1)	3.6 (2.2–7.2)	4.0 (2.1–7.7)	3.3 (1.8–6.6)
Mean (SD)	5.7 (6.1)	5.9 (6.2)	5.7 (5.3)	5.5 (6.9)
CRP, mg/L	7.0 (1.3–13.0)	4.6 (0.7–11.0)	10.0 (3.4–16.0)	7.0 (3.2–13.0)
ESR, mm/h	29.0 (16.0–40.0)	27.0 (17.0–42.0)	31.5 (20.0–40.0)	24.0 (15.0–38.0)
Anti-CCP, U/ml	11.0 (0.5–88.0)	45.0 (7.0–128.0)	1.0 (0.0–1.3)	0.4 (0.0–7.0)
DAS28-CRP	–	4.8 (4.5–5.3)	4.7 (4.36–5.1)	–
BSA, %	–	–	8.0 (3.0–10.0)	–
ASDAS score	–	–	–	3.5 (2.8–4.0)
BASDAI score	–	–	–	6.2 (4.7–6.9)
ASAS HI score	–	–	–	12.8 (11.0–15.9)
Previous treatment				
Treatment with one TNFi, n (%)				
Etanercept	82 (33.9)	47 (40.2)	20 (31.7)	15 (24.2)
Adalimumab	66 (27.3)	28 (23.9)	23 (36.5)	15 (24.2)
Infliximab	59 (24.4)	30 (25.6)	14 (22.2)	15 (24.2)
Certolizumab pegol	35 (14.5)	12 (10.3)	6 (9.5)	17 (27.4)
Treatment with methotrexate, n (%)	189 (78.1)	113 (96.6)	56 (88.9)	20 (32.3)
Duration of previous treatment, years				
TNFi	1.2 (0.6–2.6)	1.1 (0.5–2.5)	1.2 (0.6–2.5)	1.3 (0.6–2.8)
Methotrexate	1.4 (0.7–2.7)	1.8 (0.7–3.5)	1.0 (0.7–1.4)	1.8 (0.7–2.7)

Data are median (Q1–Q3) unless otherwise shown

Anti-CCP anti-citrullinated protein antibody, *ASDAS* ankylosing spondylitis disease activity score, *ASAS*, assessment of SpondyloArthritis international society, *axSpA* axial spondyloarthritis, *BASDAI* bath ankylosing spondylitis disease activity index, *BMI* body mass index, *BSA* body surface area, *CRP* C-reactive protein, *DAS28* disease activity score for 28 joints, *ESR* erythrocyte sedimentation rate, *HI* health index, *LDA* low disease activity, *MDA* minimal disease activity, *N* number of patients, *PsA* psoriatic arthritis, *Q1* first quartile, *Q3* third quartile, *RA* rheumatoid arthritis, *SD* standard deviation, *TNFi* tumor necrosis factor alpha inhibitor

Study endpoint measures

The primary endpoint was assessed at 6 months after golimumab initiation for all three disease groups and regarded the proportions of patients achieving: (i) LDA and/or remission (Disease Activity Score for 28 joints based on the high-sensitivity C-reactive protein [DAS28-CRP] < 3.2) in RA [26]; (ii) minimal disease activity (MDA; defined by the achievement of five of seven MDA criteria) in PsA [27] and (iii) moderate disease activity (Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] between 4 and 7 in AxSpA [28].

The major secondary endpoints were set per disease group. For the RA group, the endpoints included the proportion of patients achieving LDA and/or remission (DAS28-CRP < 3.2) at 3, 12, and 18 months, and the proportion of patients achieving remission (DAS28-CRP < 2.6) and good and moderate EULAR response [29] at each post-baseline visit. For the PsA group, the endpoints included the proportion of patients achieving MDA at 3, 12, and

18 months, and the proportion of patients achieving remission (DAS28-CRP < 2.6) and good and moderate EULAR response at each post-baseline visit. For the axSpA group, the endpoints included the proportions of patients achieving a BASDAI score of < 4, 4–7, and ≤ 7 at 3, 12, and 18 months; the proportions of patients achieving inactive disease defined as an Ankylosing Spondylitis Disease Activity Score [ASDAS] < 1.3) [30] and BASDAI 50 (defined as a 50% of improvement of the initial BASDAI) [31] at each post-baseline visit; and the description of the BASDAI, ASDAS, and the Assessment of SpondyloArthritis international Society (ASAS) Health index (HI) [32] scores at baseline and at each post-baseline visit.

Other secondary endpoints, assessed at each post-baseline visit, included persistence with golimumab treatment, the patients' work productivity and activity impairment (using the Work Productivity and Activity Impairment [WPAI] score) [33] the improvement in QoL (using the EuroQoL 5 dimensions 3 levels, EQ-5D-3L (https://euroqol.org/eq-5d-instruments/eq-5d-3l-about/), and the HCRU (using a patient diary).

Statistical analysis

A precision-based sample size calculation was performed for each cohort (RA, PsA, axSpA). Assuming a response rate of 30% at 6 months, a sample size of 102 RA, 57 PsA, and 57 axSpA patients would offer a maximum margin of error of ~ 10% in estimating the response rate per disease group (alpha = 10%). Additionally, assuming a drop-out rate of 10%, 113 RA, 63 PsA, and 63 axSpA patients were planned to be enrolled, i.e., a total of 239 patients. All prespecified analyses were performed in the overall eligible population, i.e., every eligible patient who gave informed consent and initiated golimumab treatment for RA, PsA, or axSpA, with available data for each endpoint (i.e., using the as-observed data). Analyses were mainly descriptive. Categorical data, including categories of continuous data, are presented in frequency tables. Continuous data are presented using the median value and 25 (Q1) and 75 (Q3) percent quartiles. Continuous variables were described by visit. Changes in continuous variables from baseline to each subsequent visit were assessed in subgroups of patients with

Table 2 Primary and selected major secondary endpoints for patients with RA, PsA, and axSpA during 18 months of treatment with golimumab

	3 months	6 months	12 months	18 months
Patients with RA				
Patients attending each visit, N	115	104	99	89
Patients with LDA and/or remission (DAS28-CRP ≤ 3.2)	35/108 (32.4)	***45/97 (46.4)***	50/91 (54.9)	59/76 (77.6)
Patients with remission (DAS28-CRP < 2.6)	16/108 (14.8)	34/97 (35.1)	39/91 (42.9)	37/76 (48.7)
Patients with good and moderate EULAR response	69/106 (65.1)	76/93 (81.7)	81/87 (93.1)	69/72 (95.8)
Patients with PsA				
Patients attending each visit, N	61	57	53	53
Patients with MDA	17/58 (29.3)	***32/56 (57.1)***	34/50 (68.0)	43/50 (86.0)
Patients with LDA and/or remission (DAS28-CRP ≤ 3.2)	21/53 (39.6)	34/48 (70.8)	33/42 (78.6)	26/30 (86.7)
Patients with remission (DAS28-CRP < 2.6)	12/53 (22.6)	31/48 (64.6)	28/42 (66.7)	17/30 (56.7)
Patients with good and moderate EULAR response[a]	41/51 (80.4)	43/46 (93.5)	41/41 (100.0)	29/29 (100.0)
Patients with axSpA				
Patients attending each visit, N	57	55	51	48
Patients with BASDAI score 4–7	24/56 (42.9)	***13/54 (24.1)***	5/51 (9.8)	2/47 (4.3)
Patients with BASDAI score < 4	28/56 (50.0)	40/54 (74.1)	46/51 (90.2)	43/47 (91.5)
Patients with BASDAI ≤ 7	52/56 (92.9)	53/54 (98.1)	51/51 (100.0)	45/47 (95.7)
Patients with BASDAI 50, n (%)	22/56 (39.3)	33/54 (61.1)	39/51 (76.5)	39/47 (83.0)
Patients with inactive disease activity (ASDAS < 1.3), n (%)	8/55 (14.5)	15/48 (31.3)	17/49 (34.7)	16/41 (39.0)

Data are n (%) unless otherwise shown. The primary study objective for each of the RA, PsA, and axSpA groups is shown in bold and italicized characters

This analysis included patients with paired assessments (i.e., patients with data available both at the respective visit and at baseline). Fractions of patients indicate the numbers of patients achieving each endpoint divided by the number of patients with available data per endpoint and per visit; percentages are calculated from this division

axSpA axial spondyloarthritis, *BASDAI* bath ankylosing spondylitis disease activity index, *CRP* C-reactive protein, *DAS28* disease activity score for 28 joints, *EULAR* European alliance of associations for rheumatology, *LDA* low disease activity, *MDA* minimal disease activity, *PsA* psoriatic arthritis, *RA* rheumatoid arthritis

[a]The numbers (and percentages) of patients achieving good and moderate EULAR response is the sum of the respective numbers (and proportions) of patients with good and moderate EULAR response separately

paired assessments (i.e., patients with assessments available at baseline and at the specific post-baseline timepoint). No formal hypothesis testing was performed; however, changes from baseline were also statistically assessed using the Wilcoxon signed-rank test to provide a more coherent evaluation of the results.

Patients' compliance was defined as the proportion of full doses taken over the total doses planned during the follow-up period. Persistence was defined as the duration of time from initiation to discontinuation of therapy. Persistence rates (i.e., patients remaining on golimumab treatment) at the post-baseline visits were estimated using the Kaplan–Meier method. All analyses were performed using SAS® version 9.4.

Results

Patient disposition and baseline characteristics

A total of 243 patients were enrolled, of whom one patient was excluded from the baseline analysis as he/she met the exclusion criterion of having received more than one previous TNFi. Of the remaining 242 patients, 117 (48.3%) had RA, 63 (26.0%) had PsA, and 62 (25.6%) had axSpA (Table 1). Compared to the PsA and axSpA groups, the RA group was older (ages, median: 52.0, 47.5, 61.0 years, respectively) and had a higher proportion of female patients (55.6%, 56.5%, 88.0%, respectively). The patients with extra-articular manifestations per disease group are shown in Supplementary Table 1. The disease duration was similar between the groups. All patients presented with active disease; the median (Q1–Q3) DAS28-CRP for the RA and PsA groups was 4.8 (4.5–5.3) and 4.7 (4.3–5.1), respectively, and the median (Q1–Q3) BASDAI score for the axSpA group was 6.2 (4.7–6.9). Before study entry, most patients with RA had received etanercept (47, 40.2%), and most patients with PsA had received adalimumab (23, 36.5%); almost equal numbers of patients with axSpA had received each of certolizumab pegol, etanercept, adalimumab, and infliximab. The median treatment period with previous TNFis ranged from 1.1 (RA) to 1.3 (axSpA) years. Almost all patients with RA and PsA had previously received methotrexate (96.6% and 88.9%, respectively), while the proportion of patients with axSpA who had received methotrexate was lower (32.3%).

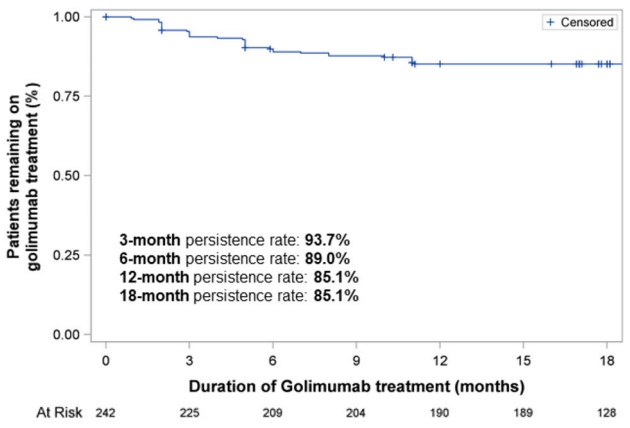

Fig. 1 Persistence rates with golimumab treatment through 18 months for all study patients

Evolution of disease activity measurements during the observation period

Of the 242 patients included in the analysis, 233 (96.3%), 216 (89.3%), 203 (83.9%), and 190 (78.5%) patients attended the 3-, 6-, 12- and 18-month visits, respectively. Fifty-two (21.5%) patients withdrew prematurely during the observation period, most frequently due to patient lost to follow-up (26/52 patients, 50.0%) and adverse events (17/52 patients, 32.7%).

Patients with RA

The median (Q1–Q3) DAS28-CRP values showed a continuous improvement (decrease) from baseline through 18 months (4.8 [4.5–5.3]) to 2.6 [1.7–3.1], respectively), with similar improvements being observed for the corresponding CRP and ESR measures (Supplementary Table 2). The difference in the DAS28-CRP, CRP, and ESR values between the baseline and each visit was significant ($p < 0.001$ for all comparisons; Supplementary Table 2). For the primary objective, the proportion of patients achieving LDA and/or remission (DAS28-CRP < 3.2) at 6 months was 46.4% (45/97) (Table 2); the respective proportions at three, 12, and 18 months were 32.4% (35/108), 54.9% (50/91), and 77.6% (59/76). The proportions of patients achieving remission (DAS28-CRP < 2.6) at three, six, 12, and 18 months were 14.8% (16/108), 35.1% (34/97), 42.9% (39/91), and 48.7% (37/76), respectively, and the combined proportions of patients with good and moderate EULAR response were 65.1% (69/106), 81.7% (76/93), 93.1% (81/87), and 95.8% (69/72), respectively (Table 2).

Patients with PsA

The median (Q1–Q3) DAS28-CRP values showed a continuous improvement (decrease) from baseline through 18 months (4.7 [4.3–5.1]) to 2.3 [1.6–2.9], respectively), as did the median (Q1–Q3) BSA (8.0 [3.0–10.0] to 0.0 [0.0–1.0]) (Supplementary Table 2); improvements in these measures were observed even after 3 months of treatment. Similar improvements from baseline to 18 months

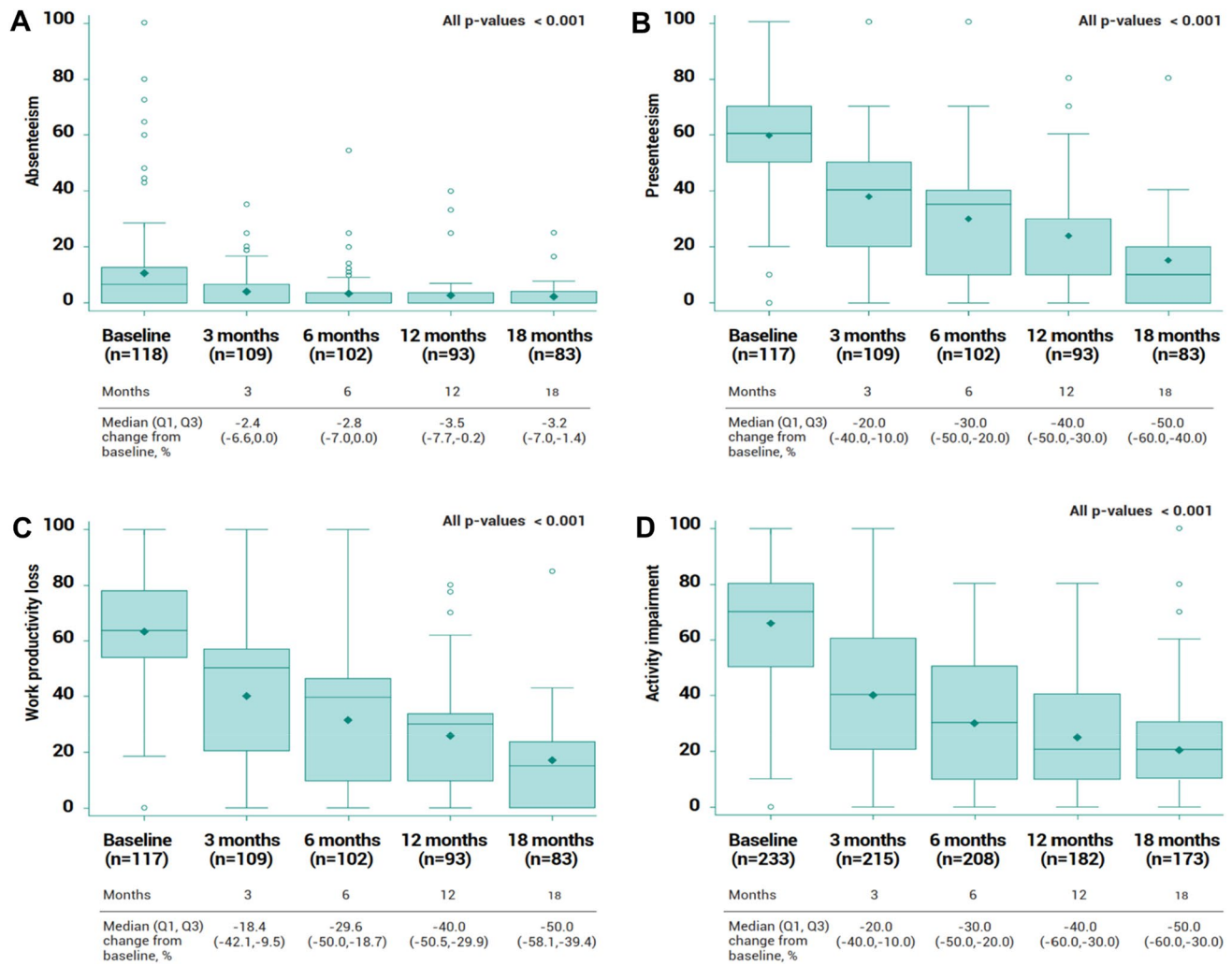

Fig. 2 Evolution of the WPAI domain scores for all patients during 18 months of treatment with golimumab, evaluating absenteeism (**A**), presenteeism (**B**), work productivity loss (**C**) and activity impairment (**D**). Data are patients (n) or median (Q1–Q3) change from baseline. For the post-baseline visits, data for patients with paired assessments (i.e., data available both at baseline and at the respective visit) are shown. The changes in values from baseline to each post-baseline visit were assessed with the Wilcoxon signed-rank test. *Q1* first quartile, *Q3* third quartile, *WPAI* work productivity and activity impairment

were observed for CRP and ESR (Supplementary Table 2). The difference in the DAS28-CRP, BSA, ESR, and CRP values between the baseline and each visit was significant ($p < 0.001$ for all comparisons; Supplementary Table 2). For the primary objective, the proportion of patients achieving MDA at 6 months was 57.1% (32/56; Table 2); the respective proportions at 3, 12, and 18 months were 29.3% (17/58), 68.0% (34/50), and 86.0% (43/50). The proportion of patients achieving remission (DAS28-CRP < 2.6) at 3, 6, 12, and 18 months was 22.6% (12/53), 64.6% (31/48), 66.7% (28/42), and 56.7% (17/30), respectively, and the combined proportions of patients with good and moderate EULAR response were 80.4% (41/51), 93.5% (43/46), 100.0% (41/41), and 100.0% (29/29), respectively (Table 2).

Patients with axSpA

The median (Q1–Q3) BASDAI values improved from baseline through 18 months (6.2 [4.7–6.9]) to 1.0 [0.6–2.5], respectively), as did the median (Q1–Q3) values for the ASDAS (3.5 [2.8–4.0] to 1.4 [1.0–1.7], respectively) and ASAS HI (12.8 [11.0–15.9] to 5.0 [3.2–8.5], respectively) scores (Supplementary Table 2); improvements in all three disease activity measures were observed already after 3 months of treatment. The difference in all the above measure values between the baseline and each post-baseline visit was significant ($p < 0.001$ for all comparisons; Supplementary Table 2). For the primary endpoint, the proportion of patients with BASDAI score 4–7 at 6 months was 24.1% (13/54; Table 2). The proportions of patients with

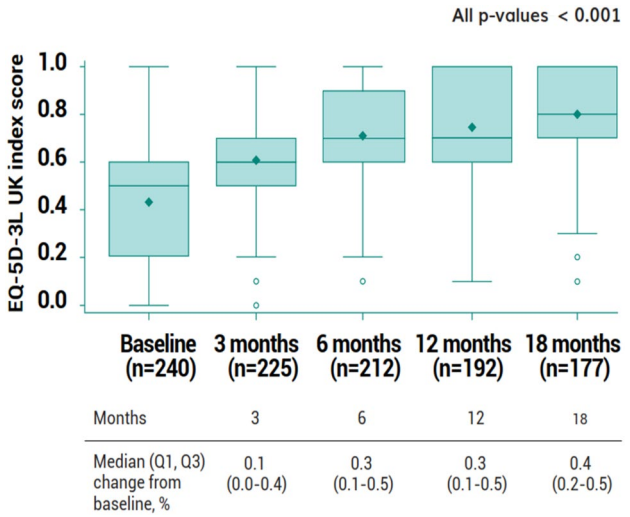

Fig. 3 Evolution of the EQ-5D-3L UK index score for all patients during 18 months of treatment with golimumab. Data are patients (n) or median (Q1–Q3) change from baseline. For the post-baseline visits data for patients with paired assessments (i.e., data available both at baseline and at the respective visit) are shown. The changes in values from baseline to each post-baseline visit were assessed with the Wilcoxon signed-rank test. *EQ-5D-3L* EuroQol 5 dimensions 3 levels, *Q1* first quartile, *Q3* third quartiles

BASDAI < 4 continuously increased from 3 to 18 months (50.0% [28/56] to 90.2% [46/51], respectively; Table 2). The proportions of patients achieving BASDAI 50 at 3, 6, 12, and 18 months were 39.3% (22/56), 61.1% (33/54), 76.5% (39/51), and 83.0% (39/47), respectively (Table 2).

Persistence with golimumab treatment

For the entire study population, a median (Q1–Q3) of 19.0 (18.0–19.0) injections per patient were administered during the observation period; six (2.5%) patients missed ≥ 1 golimumab dose. The median (Q1–Q3) compliance rate was 100.0% (100.0–100.0). For all patients, the persistence rates (95% CI) at 3, 6, 12, and 18 months were 93.7% (89.9–96.2), 89.0% (84.3–92.4), 85.1% (79.9–89.1), and 85.1% (79.9–89.1), respectively (Fig. 1). Treatment persistence rates were similar among the three disease groups (data not shown).

Assessment of work productivity and activity impairment and quality of life

For the entire study population, all median (Q1–Q3) WPAI domain scores continuously decreased (improved) from baseline through 18 months; the change in all domain scores from baseline to each visit was significant ($p < 0.001$ for all comparisons; Fig. 2A–D). Similarly, the median (Q1–Q3) EQ-5D-3L UK index score continuously increased (improved) from baseline through 18 months, and the changes from baseline to each visit were significant ($p < 0.001$ for all comparisons; Fig. 3). The above-mentioned changes in the WPAI domain scores and the EQ-5D-3L UK index score between baseline and each post-baseline visit were also observed at the disease group level ($p < 0.001$ for all comparisons; data not shown).

Disease-related healthcare resource utilization

During the 6 months before baseline, all patients (100.0%) had laboratory tests (Table 3); the total number of laboratory tests performed was 1071. During the same period, specialist consultations, hospitalizations, biopsies and/or imaging tests, and physiotherapies occurred in 34.3%, 9.5%, 24.8%, and 4.5% of all patients, respectively.

At each post-baseline visit, HCRU was mainly driven by laboratory tests and specialist consultations, with approximately 90.0% of patients reporting laboratory tests and approximately 20.0% reporting visits to specialists (Table 3). The HCRU remained stable and at the expected (as per clinical practice) level during the 18 months of observation. Notably, no hospitalizations were recorded during this time.

Discussion

Patients with RA, PsA, or axSpA and an inadequate response or intolerance to previous treatment with TNFi (or other bDMARDs) are routinely encountered in everyday clinical practice [12, 13, 20]; the management of these patients is challenging in terms of achieving and maintaining clinical response.

The present, real-world, prospective study focused exclusively on patients with RA, PsA, or axSpA who had previously failed treatment with one TNFi and primarily assessed the efficacy of second-line golimumab. Our study showed that by 6 months, the time of the primary endpoint assessment, 46.4% of patients with RA attained LDA and/or remission (DAS28-CRP < 3.2), 57.1% of patients with PsA attained MDA, and 24.1% of patients with axSpA achieved a BASDAI score of 4–7. Furthermore, by 18 months, which was the end of our observational period, 77.6% of patients with RA achieved LDA and/or remission, 86.7% of patients with PsA achieved MDA, and 91.5% of patients with axSpA achieved BASDAI < 4. Taken together, these outcomes indicate that golimumab is a reasonable second-line TNFi option for the treat-to-target strategy for these patients.

Although not directly comparable, our findings are generally aligned with those from previous real-world studies assessing the efficacy of golimumab in patients with autoimmune rheumatoid disorders. According to current

Table 3 Healthcare resource utilization for patients with RA, PsA, and axSpA during the 6 months before study entry and the 18 months of treatment with golimumab

	Patients, N	Patients with laboratory tests, n (%)	Number of laboratory tests	Patients with disease-related specialist visits, n (%)	Patients with hospitalization, n (%)	Patients with biopsies and/or imaging tests, n (%)	Patients with physiotherapies, n (%)
All patients							
Six-month period before study inclusion	242	242 (100.0)	1071	83 (34.3)	23 (9.5)	60 (24.8)	11 (4.5)
After study inclusion							
3 months[a]	233	221 (94.8)	648	44 (18.9)	0 (0.0)	2 (0.9)	2 (0.9)
6 months[a]	216	200 (92.6)	564	44 (20.4)	0 (0.0)	3 (1.4)	2 (0.9)
12 months[a]	203	185 (91.1)	559	39 (19.2)	0 (0.0)	2 (1.0)	0 (0.0)
18 months[a]	190	169 (88.9)	469	35 (18.4)	0 (0.0)	2 (1.1)	2 (1.1)
Six-month period before study inclusion[b]	216	216 (100.0)	962	80 (37.0)	20 (9.3)	57 (26.4)	11 (5.1)
Six-month period after study inclusion[b]	216	210 (97.2)	1163	49 (22.7)	0 (0.0)	4 (1.9)	3 (1.4)
Patients with RA							
Six-month period before study inclusion	117	117 (100.0)	534	37 (31.6)	10 (8.5)	21 (17.9)	5 (4.3)
After study inclusion							
3 months[a]	115	109 (94.8)	321	19 (16.5)	0 (0.0)	1 (0.9)	1 (0.9)
6 months[a]	104	98 (94.2)	284	21 (20.2)	0 (0.0)	2 (1.9)	1 (1.0)
12 months[a]	99	91 (91.9)	289	16 (16.2)	0 (0.0)	1 (1.0)	0 (0.0)
18 months[a]	89	81 (91.0)	244	15 (16.9)	0 (0.0)	1 (1.1)	1 (1.1)
Six-month period before study inclusion[b]	104	104 (100.0)	478	35 (33.7)	8 (7.7)	19 (18.3)	5 (4.8)
Six-month period after study inclusion[b]	104	101 (97.1)	580	22 (21.2)	0 (0.0)	2 (1.9)	2 (1.9)
Patients with PsA							
Six-month period before study inclusion	63	63 (100.0)	242	19 (30.2)	5 (7.9)	14 (22.2)	3 (4.8)
After study inclusion							
3 months[a]	61	58 (95.1)	159	12 (19.7)	0 (0.0)	1 (1.6)	0 (0.0)
6 months[a]	57	53 (93.0)	140	11 (19.3)	0 (0.0)	0 (0.0)	0 (0.0)
12 months[a]	53	46 (86.8)	124	11 (20.8)	0 (0.0)	1 (1.9)	0 (0.0)
18 months[a]	53	47 (88.7)	109	9 (17.0)	0 (0.0)	1 (1.9)	1 (1.9)
Six-month period before study inclusion[b]	57	57 (100.0)	218	19 (33.3)	4 (7.0)	14 (24.6)	3 (5.3)
Six-month period after study inclusion[b]	57	55 (96.5)	285	13 (22.8)	0 (0.0)	1 (1.8)	0 (0.0)

Table 3 (continued)

	Patients, N	Patients with laboratory tests, n (%)	Number of laboratory tests	Patients with disease-related specialist visits, n (%)	Patients with hospitalization, n (%)	Patients with biopsies and/or imaging tests, n (%)	Patients with physiotherapies, n (%)
Patients with axSpA							
Six-month period before study inclusion	62	62 (100.0)	295	27 (43.5)	8 (12.9)	25 (40.3)	3 (4.8)
After study inclusion							
3 months[a]	57	54 (94.7)	168	13 (22.8)	0 (0.0)	0 (0.0)	1 (1.8)
6 months[a]	55	49 (89.1)	140	12 (21.8)	0 (0.0)	1 (1.8)	1 (1.8)
12 months[a]	51	48 (94.1)	146	12 (23.5)	0 (0.0)	0 (0.0)	0 (0.0)
18 months[a]	48	41 (85.4)	116	11 (22.9)	0 (0.0)	0 (0.0)	0 (0.0)
Six-month period before study inclusion[b]	55	55 (100.0)	266	26 (47.3)	8 (14.6)	24 (43.6)	3 (5.5)
Six-month period after study inclusion[b]	55	54 (98.2)	298	14 (24.5)	0 (0.0)	1 (1.8)	1 (1.8)

Data are patients (N) or n (%)

Percentages of patients attending each visit are calculated using the number of patients in each time point (shown in the second column) as the denominator

AxSpA axial spondyloarthritis, *HCRU* healthcare resource utilization, *N* patients attending each visit, *n* number of patients with HCRU or numbers of tests performed, *PsA* psoriatic arthritis, *RA* rheumatoid arthritis

[a]Compared to the previous visit

[b]Among patients with data available in the six-month period before and after study inclusion (i.e., among patients who attended the 6-month visit)

knowledge, only two real-world prospective studies, the German GO-NICE [1] and the Italian GO-BEYOND [25] studies, assessed the proportion of patients with RA who achieved LDA and/or remission with golimumab at 6 months. The proportion of patients achieving LDA and/or remission was similar between our study and GO-NICE (46.4% and 49.2%, respectively), although the latter included both biological-experienced and biological-naïve patients. In contrast, the Italian GO-BEYOND study, which included only patients with an inadequate response to the first TNFi as our study, reported a higher proportion (68.0%) of patients achieving LDA and/or remission. The available data cannot explain this difference in LDA and/or remission rates between the current and the Italian GO-BEYOND studies, especially given that the RA populations in both studies had moderate disease (median DAS28-CRP 4.8 and 4.1, respectively); furthermore, the disease duration in the current study was numerically lower than that of the patients included in the Italian GO-BEYOND study (3.6 and 11 years, respectively), and it has been established that shorter RA duration is associated with better clinical outcomes with bDMARDs [34].

Regarding the patients with PsA, the rate of patients achieving MDA at 6 months was similar with the rate reported for golimumab-treated patients in a real-world, retrospective study conducted in Canada (57.1% and 53.9%, respectively) [35]; it is noted, however, that the latter study included both bDMARD-naïve patients and patients previously treated with one bDMARD. Finally, regarding the patients with axSpA, the current study showed that the median BASDAI score was reduced from 6.2 at baseline to $\leq$ 2.2 at 6 months and was sustained thereafter. A post hoc analysis of the previously-mentioned GO-NICE study [23] found that golimumab as a second-line biologic agent in patients with AS significantly reduced the mean BASDAI from 4.9 at baseline to 3.3, at 6 months.

In this study, high persistence rates with golimumab treatment (range 85.1%–93.7%) were observed over 18 months of observation, despite patients having already been treated with a previous TNFi. High 2-year persistence rates with treatment golimumab treatment were also observed in a

recent real-world retrospective study conducted in Italy in patients with autoimmune rheumatoid disorders who had previously failed treatment with one TNFi (RA: 61.4%; PsA: 72.5%; and spondyloarthritis: 80.0%) [21]. Similarly, high 1-year probability of persistence rates (80%) were reported in a recent real-world retrospective study conducted in Spain in patients with PsA and axSpA who discontinued treatment with an initial TNFi [20]. The high persistence rates to treatment with golimumab in patients who have failed one previous TNFi is an important finding of this and previous real-world studies that could inform rheumatologists when choosing between agents for such patients.

For all patients, components of the WPAI score (absenteeism, presenteeism, work productivity and activity impairment) and the EQ-5D-3L UK index scores were significantly reduced from baseline to 3, 6, 12, and 18 months ($p < 0.001$, all comparisons). Previously, the GO-ART [36] and the GO-NICE [37] studies reported that golimumab treatment in patients with RA, PsA, and AS improved all WPAI domain scores within 3 months and resulted in substantial improvements in the EQ-5D-3L domain scores within 6 months.

Lastly, HCRU measures overall decreased during the observation period compared to the 6 months before study entry. This decrease was noteworthy for hospitalizations, with no reported hospitalizations during the observation period.

Limitations should be considered when interpreting the study findings. Patient selection bias cannot be ruled out, as the choice of treatment with golimumab was based on the investigator's judgment. As the study was non-comparative, outcomes cannot be directly compared to other TNFi or DMARDs. The follow-up period of 18 months may limit the extrapolation of the results to the longer-term, given that RA, PsA, and axSpA are chronic conditions. The possibility of patient recall bias needs to be considered for patient-reported outcomes (e.g., QoL, WPAI) and HCRU. However, every effort was made to mitigate patient recall bias with the use of patient-reported outcomes with a short recall period and validated in the Greek language; also, a patient diary was used for prospectively recording HCRU data. The statistical accuracy in estimating study outcomes at each time point may have decreased due to patients lost to follow-up. Additionally, the study was not designed to test any formal hypotheses, and p-values were only presented to allow a more comprehensive evaluation of the findings; no adjustment for multiple comparisons was made.

Conclusions

This real-world, prospective study in patients with RA, PsA, and axSpA and a previous TNFi failure, showed that golimumab treatment over 18 months was efficacious in these challenging patients. This finding combined with the high persistence to golimumab treatment and the substantial improvements in work productivity, activity impairment, and QoL support the use of golimumab as a second line treatment option in these diseases.

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Data availability Data are available from the corresponding author upon reasonable request. There are circumstances that may prevent MSD Greece from sharing the requested data.

Code availability All data were analyzed using SAS v9.4 (SAS Institute, Cary, NC).

Declarations

Conflict of interest *Dr Prodromos Sidiropoulos* has received support for the present manuscript from MSD, in addition to research grants from Pfizer, Genesis, UCB, GSK, MSD, Abbvie, Novartis, Roche, Eli Lilly and Amgen. He has also received consultation payments from Pfizer, Abbvie and Eli Lilly, and honoraria from Pfizer, UCB, Abbvie, Novartis and Eli Lilly. He has received support for attending a Data Safety Monitoring Board or Advisory Board from Pfizer, Abbvie, Novartis and Eli Lilly. *Dr Dimitrios Vassilopoulos* has received support for the present manuscript from MSD. *Dr Periklis Vounotrypidis* has received support for the present manuscript from MSD, in addition to research grants from Abbvie, Genesis pharma and Novartis. *Dr Andreas Bounas* has received support for the present manuscript from MSD, in addition to grants or contracts from Abbvie, Amgen, Genesis, MSD, Novartis and Pfizer. He has also received honoraria from Abbvie, Aeonorasis, Amgen, Bausch Health, Faran, Genesis, GSK, Janssen, MSD, Novartis, Pfizer and UCB, as well as for participation on a Data Safety Monitoring Board or Advisory Board from Abbvie, Aeonorasis, Amgen, Bausch Health, Faran, Genesis, GSK, Janssen, MSD, Novartis, Pfizer and UCB. *Dr Anna Kandyli* has received consultation payments from Abbvie, Mylan and Genesis, as well as honoraria from Abbvie and Novartis. She has received support for attending meetings and/or travel from UCB, and for participating on a Data Safety Monitoring Board or Advisory Board from Genesis and Amgen. *Dr Gkikas Katsifis* has received honoraria from Abbvie, Aenorasis, Amgen, Janssen, Jenessis, Lilly, MSD, Novartis, Sobi, Roche, Pfizer and UCB. Also, the author has received support for attending meetings from Ab-

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Ethical approval The study was conducted in accordance with the EU Directive 2001/20/EC section for non-interventional studies and the applicable laws and regulations of Greece. All included patients provided written informed consent before study entry. The present study was performed in accordance with the Helsinki declaration of 1964, and its later amendments. The study was approved by the competent Institutional Review Boards (IRBs) of all participating hospital sites. Participation of private practice investigators was approved by the IRB of a participating hospital located in the same geographic region as the Private Practice. Specifically, the IRBs that reviewed and approved the study, and corresponding ethical review reference numbers include IRB of "Laiko" General Hospital (reference number: 6046/24-Apr-2018), IRB of "KAT" Regional General Hospital (reference number: 188/14-Jun-2018), IRB of Private Practice under "Laiko" General Hospital (reference number: 59/15-Feb-2018), IRB of University General Hospital of Heraklion, Crete (reference number: 17991/22-Nov-2018), IRB of "Olympion"Rehabilitation Center of Patras (reference number: 14-Mar-2018), IRB of Private Practice under University General Hospital of Ioannina (reference number: 5th/08-Apr-2018), IRB of Private Practice under European Interbalkan Medical Center (reference number 17-Jan-2018), IRB of Private Practice under European Interbalkan Medical Center (reference number 22-Jan-2019), IRB of "Attikon" University General Hospital (reference number 5th/29-May-2018), IRB of "Ag. Pavlos" of Thessaloniki (reference number: 123/08-Mar-2018), IRB of "Ippokrateio"General Hospital of Athens (reference number: 4552/19-Mar-2018), IRB of Naval Hospital of Athens (reference number: 3/18/02-Apr-2018).

Consent to participate All persons gave their informed consent prior to their inclusion in the study.

Consent to publish All participants provided consent for publication of the material collected in the context of this study in a non-identifiable manner.

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