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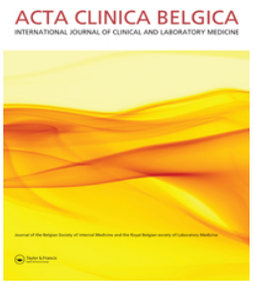

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Original Paper

Efficacy of golimumab in Belgian patients with active rheumatoid arthritis despite treatment with non-biologic disease-modifying anti-rheumatic drugs: sub-analysis of the GO-MORE study

Patrick Durez[1], Marie Vanthuyne[2], Muhammad S. Soyfoo[3], Ilse Hoffman[4], Michel Malaise[5], Piet Geusens[6]

[1]Rheumatology Department, Cliniques Universitaires Saint-Luc & Pôle de Pathologies Rhumatismales, Institut de Recherche Expérimentale et Clinique, Université Catholique de Louvain, Brussels, Belgium, [2]Rheumatology Department, Université Catholique de Louvain, Cliniques Universitaires Saint-Luc, Bruxelles, Belgium, [3]Service de Rhumatologie, ULB Hopital Erasme, Brussels, Belgium, [4]Dienst reumatologie, GZA, Sint-Augustinus, Wilrijk, Belgium, [5]CHU Sart Tilman, Service de Rhumatologie, Liège, Belgium, [6]UH & MUMC & ReumaClinic, Genk, Belgium

Objectives: The GO-MORE trial (NCT00975130) was a phase 3 study in 40 countries evaluating the efficacy and safety of golimumab as add-on therapy in biologic-naïve adults with active rheumatoid arthritis despite stable treatment with disease-modifying anti-rheumatic drugs. To inform local practice in Belgium and examine the role of baseline disease activity in treatment response, we compared the efficacy of golimumab in the Belgian subpopulation and the rest of the world.
Methods: Baseline disease activity and six-month efficacy rates in the GO-MORE trial were compared for the Belgian subpopulation and the rest of the world by *t*-tests and chi-squared tests.
Results: Except for functional impairment, all measures of baseline disease activity were significantly lower ($p < 0.0001$) in the Belgian population ($n = 123$) than in the rest of the world ($n = 3157$). At month six, the rate of good/moderate EULAR response was similar in Belgium and the rest of the world (78.9% vs. 82.2%; $p = 0.34$), but remission rates were higher in Belgium according to the DAS28-ESR (43.1% vs. 23.2%; $p < 0.0001$) and Simplified Disease Activity Index (22.0% vs. 13.8%; $p = 0.01$). Rates of low DAS28-ESR disease activity were also higher in Belgium (54.5% vs. 36.8%; $p < 0.0001$). Within the Belgian subpopulation, efficacy measures were not significantly different between patients with moderate ($n = 73$) and high baseline activity ($n = 49$). Rates of functional impairment at month six did not differ between the two populations.
Conclusion: In the Belgian population of the GO-MORE trial, baseline disease activity was lower and six-month remission rates were higher than in the rest of the world.

Keywords: Rheumatoid arthritis, Golimumab, Anti-rheumatic agents, Biological products

Introduction

Achieving and maintaining remission or low disease activity and, therefore, preventing worsening of structural damage and disability, are the current objectives in treating rheumatoid arthritis (RA).[1,2] Current first-line treatments include disease-modifying anti-rheumatic drugs (DMARDs), especially methotrexate. When treatment with DMARDs alone fails, anti-tumor necrosis factor (TNF) biologics are used in combination with DMARDs.

Correspondence to: Patrick Durez, Rheumatology Department, Cliniques Universitaires Saint-Luc & Pôle de Pathologies Rhumatismales, Institut de Recherche Expérimentale et Clinique, Université Catholique de Louvain, Brussels, Belgium. Email: patrick.durez@uclouvain.be

Golimumab is a fully human monoclonal antibody against TNF that has the advantage of being self-administered subcutaneously once per month.[3] Clinical trials have shown that golimumab is effective for treating RA not only in patients who have experienced methotrexate failure but also in patients naïve to methotrexate[4,5] and patients previously treated with anti-TNF biologics.[6] When used in combination with methotrexate, golimumab improves a variety of outcome measures, including disease activity index, patient-reported outcomes, and structural damage.[7]

The GO-MORE study (NCT00975130), completed in 2011,[8] evaluated the efficacy and safety of golimumab

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as an add-on therapy in biologic-naïve adults with active RA in a real-life clinical setting. GO-MORE was an open-label, multinational, multicenter, and prospective phase 3 trial that included patients who had active RA despite stable DMARD treatment for at least one month. In the first part of the trial, patients received subcutaneous golimumab 50 mg once monthly for six months as an add-on to the DMARDs they were already receiving. In the second part, patients who had a good or moderate response at the end of the first part but did not achieve remission were randomized 1:1 to continue subcutaneous golimumab treatment or to receive a combination of intravenous and subcutaneous golimumab. At the end of the first part (month six), 82% of the patients had achieved a good or moderate response according to the European League Against Rheumatism (EULAR) criteria and 24% had achieved clinical remission. In the second part, remission rates were similar for subcutaneous injection and for the combination of subcutaneous injection and intravenous infusion.

The GO-MORE trial included a large, heterogeneous population of 3280 patients from 475 centers in 40 countries.[8] The study therefore provided information relevant to daily clinical practice over a wide geographic area, where concomitant treatments, treatment histories, and demographic characteristics can vary substantially. Because this variability can influence some outcomes, an analysis by country can help inform local practice. Here, we describe a sub-analysis on the efficacy of golimumab in Belgian patients in the GO-MORE study.

Materials and methods

The objective of this analysis was to compare the baseline patient characteristics and the efficacy of monthly subcutaneous golimumab 50 mg between Belgian patients and the patients in the rest of the world in the GO-MORE trial. The GO-MORE study was an open-label, multinational, multicenter, and prospective phase 3 trial (NCT00975130) performed in 475 centers in 40 countries and composed of two parts.[8] GO-MORE was approved by the appropriate research ethics committees and was conducted in accordance with the Declaration of Helsinki and standards of good clinical research practice, and all included patients provided written informed consent. Only the first part is included in the current analysis because insufficient patient numbers ($n = 9$) were available for the second part.

Part 1 of the GO-MORE trial included adults with a diagnosis of RA according to the 1987 revised American College of Rheumatology (ACR) criteria who had active disease (28-joint disease activity score calculated using the erythrocyte sedimentation rate [DAS28-ESR] ≥ 3.2) despite DMARD treatment. Patients had to have used at least one DMARD at a stable dose for at least one month and had to have been able to maintain the dose during the trial. Patients received subcutaneous golimumab 50 mg administered by an autoinjector device once monthly for six months. The patients were allowed to continue the following DMARDs: methotrexate, sulfasalazine, hydroxychloroquine, chloroquine, chloroquine phosphate, leflunomide, gold salts, azathioprine, and cyclosporine. The primary efficacy assessment was the proportion of patients who achieved a good or moderate EULAR response at the end of month six (DAS28-ESR improvement > 1.2 from any baseline score or improvement of 0.6–1.2 from a baseline score ≤ 5.1).[9] Secondary efficacy assessments included the DAS28 calculated with the erythrocyte sedimentation rate (DAS28-ESR),[10] Simplified Disease Activity Index (SDAI),[11] and the Health Assessment Questionnaire-Disability Index (HAQ-DI).[12] Further details of the GO-MORE study design and conduct are provided elsewhere.[8]

Statistical analysis

Efficacy (EULAR response, remission rate, HAQ-DI) was compared between Belgium and the rest of the world population using *t*-tests for mean values and chi-squared tests for percentages. Proportions of patients attaining DAS28-ESR low disease activity (score ≤ 3.2), DAS28-ESR remission (score < 2.6), SDAI remission (score ≤ 3.3), and minimal functional impairment (HAQ-DI ≤ 0.5) were calculated. A p-value < 0.05 was considered statistically significant. Results are presented as means ± standard deviation.

Results

Patients and baseline characteristics

The Belgian subpopulation of the GO-MORE trial included 123 biologic-naïve patients with active RA. The population for the rest of the world included 3157 patients. Belgian patients were on average 51.4 ± 13.7 years of age, mostly (79.7%) women, and the average disease duration was 6.3 ± 6.9 years. Sex, age, and disease duration were similar between the Belgium subpopulation and the rest of the world (Table 1). Methotrexate dose was similar in the Belgian subpopulation and the rest of the world (Supplemental Figure 1) and the proportion of patients taking glucocorticoids was identical in the two populations (63.4%), but the number of failed DMARDs tended to be lower in the Belgian subpopulation than the rest of the world (Supplemental Figure 2). Except for HAQ-DI, all measures of disease activity indicated significantly lower disease activity at baseline in the Belgian population than in the rest of the world. For example, according to the DAS28-ESR, the proportion with high disease activity was 40.2% for Belgian patients vs. 80.1% for the rest of the world.

Efficacy in the Belgian subpopulation and comparison with the rest of the world

At the end of part 1 of the GO-MORE trial (month six), the response rate in the Belgian subpopulation was 78.9% according to the EULAR DAS28-ESR (Table

Table 1 Baseline patient characteristics for the Belgian subpopulation and the rest of the world in the GO-MORE study

		Belgian subpopulation	Rest of the world	
Characteristic	**Statistic**	***N* = 123**	***N* = 3157**	***p*-value**
Female	*n* (%)	98 (79.7)	2618 (82.9)	0.35[a]
Age (*y*)	Mean ± SD [range]	51.4 ± 13.7 [18–82]	52.3 ± 12.8 [18–88]	0.45[b]
Disease duration (*y*)	MEAN ± SD	6.3 ± 6.9	7.7 ± 7.9	0.0532[b]
Baseline disease activity				
TJC28	Mean ± SD	9.2 ± 6.4	13.1 ± 6.8	<0.0001[b]
SJC28	Mean ± SD	5.3 ± 4.2	9.8 ± 5.5	<0.0001[b]
CRP (mg/L)	Mean ± SD	10.7 ± 17.2	14.6 ± 20.5	0.0405[b]
ESR (mm/h)	Mean ± SD	21.1 ± 17.0	35.4 ± 24.7	<0.0001[b]
DAS28-ESR	Mean ± SD	4.97 ± 0.98	6.01 ± 1.08	<0.0001[b]
DAS28-ESR range[a]				<0.0001[a]
Moderate (3.2–5.1)	*n* (%)	73 (59.8)	625 (19.9)	
High (>5.1)	*n* (%)	49 (40.2)	2523 (80.1)	
DAS28-CRP	Mean ± SD	4.69 ± 0.93	5.44 ± 0.99	<0.0001[b]
HAQ-DI[b]	Mean ± SD	1.4 ± 0.7	1.4 ± 0.7	0.19[b]

Note: *p*-values were calculated by Chi-squared test[a] or *t*-test[b].Abbreviations: CRP, C-reactive protein; DAS28-CRP, 28-joint disease activity score based on the C-reactive protein concentration; DAS28-ESR, 28-joint disease activity score based on the erythrocyte sedimentation rate; ESR, erythrocyte sedimentation rate; HAQ-DI, Health assessment questionnaire-disability index; SJC28, 28-joint swollen joint count; SD, standard deviation; TJC28, 28-joint tender joint count.
[a]DAS28-ESR categories were not available for one patient in the Belgium subpopulation and nine patients in the rest of the world.
[b]HAQ-DI results were not available for three patients in the rest of the world subpopulation.

Table 2 Comparison of response rates in the Belgian subpopulation and the rest of the world at the end of part 1 of the GO-MORE study (month six)

	Belgian subpopulation	Rest of the world	
	***N* = 123**	***N* = 3157**	
Measure	*n* (%)	*n* (%)	*p*-value
DAS28-ESR good/moderate EULAR response[a]	97 (78.9)	2595 (82.2)	0.34
DAS28-ESR low disease activity[b]	67 (54.5)	1161 (36.8)	<0.0001
DAS28-ESR remission[c]	53 (43.1)	731 (23.2)	<0.0001
SDAI remission[d]	27 (22.0)	437 (13.8)	0.01
Minimal or no functional impairment[e]	50 (40.7)	1176 (37.3)	0.44

Note: *p*-values were determined by Chi-squared test.
Abbreviations: DAS28-ESR, 28-joint disease activity score based on the erythrocyte sedimentation rate; EULAR, European League Against Rheumatism; SDAI, simplified disease activity index.
[a]DAS28-ESR improvement > 1.2 from any baseline score or improvement of 0.6–1.2 from a baseline score ≤ 5.1.
[b]DAS28-ESR score ≤ 3.2.
[c]DAS28-ESR score < 2.6.
[d]SDAI ≤ 3.3.
[e]HAQ-DI ≤ 0.

2). This was similar to the response rate for the rest of the world (82.2%) ($p = 0.34$). However, remission rates were higher in the Belgian subpopulation than in the rest of the world according to the DAS28-ESR (43.1% vs. 23.2%; $p < 0.0001$) and SDAI (22.0% vs. 13.8%; $p = 0.01$). These differences in remission rates between the Belgian patients and the rest of the world could be detected as early as two months after initiation of golimumab treatment (Fig. 1(a)–(d)). Rates of low DAS28-ESR disease activity were also significantly higher in Belgian patients than in the rest of the world (54.5% vs. 36.8%; $p < 0.0001$) (Table 2).

Within the Belgian subpopulation, the rate of EULAR DAS28-ESR good/moderate response did not differ significantly between patients with moderate ($n = 73$) and high baseline activity ($n = 49$) ($p = 0.49$) (Table 3). The rates of DAS28-ESR low disease activity ($p = 0.58$), DAS28-ESR remission ($p = 0.14$), SDAI remission ($p = 1.00$), and the presence of minimal or no functional impairment according to the HAQ-DI ($p = 0.46$) within the Belgian subpopulation also did not differ according to baseline disease activity.

Discussion

The GO-MORE trial confirmed the efficacy of golimumab in RA patients refractory to DMARDs.[8] The current analysis showed that disease activity at baseline was moderate in most Belgian patients and, on average, lower than in the rest of the world. This is probably due to several factors, including earlier diagnosis, earlier treatment with DMARDs, and tighter control of disease activity in Belgium than in many other countries. After six months, 79% of Belgian patients responded to subcutaneous golimumab 50 mg once monthly as an add-on to DMARDs. This was similar to the response rate of 82% for the rest of the world. However, rates of remission were 40–60% higher in Belgium than in the rest of the world according to DAS28-ESR and SDAI. These differences could be detected at the first assessment two months after the initiation of golimumab treatment and, therefore, after a single subcutaneous injection.

We initially suspected that the difference in remission rates between the Belgian population and the rest of the world was related to the lower baseline disease activity in the Belgian patients. For example, only 40% of Belgian patients had high disease activity, much lower than the rate (80%) in the rest of the world. However, within the Belgian subpopulation, the rate of remission did not significantly differ according to disease

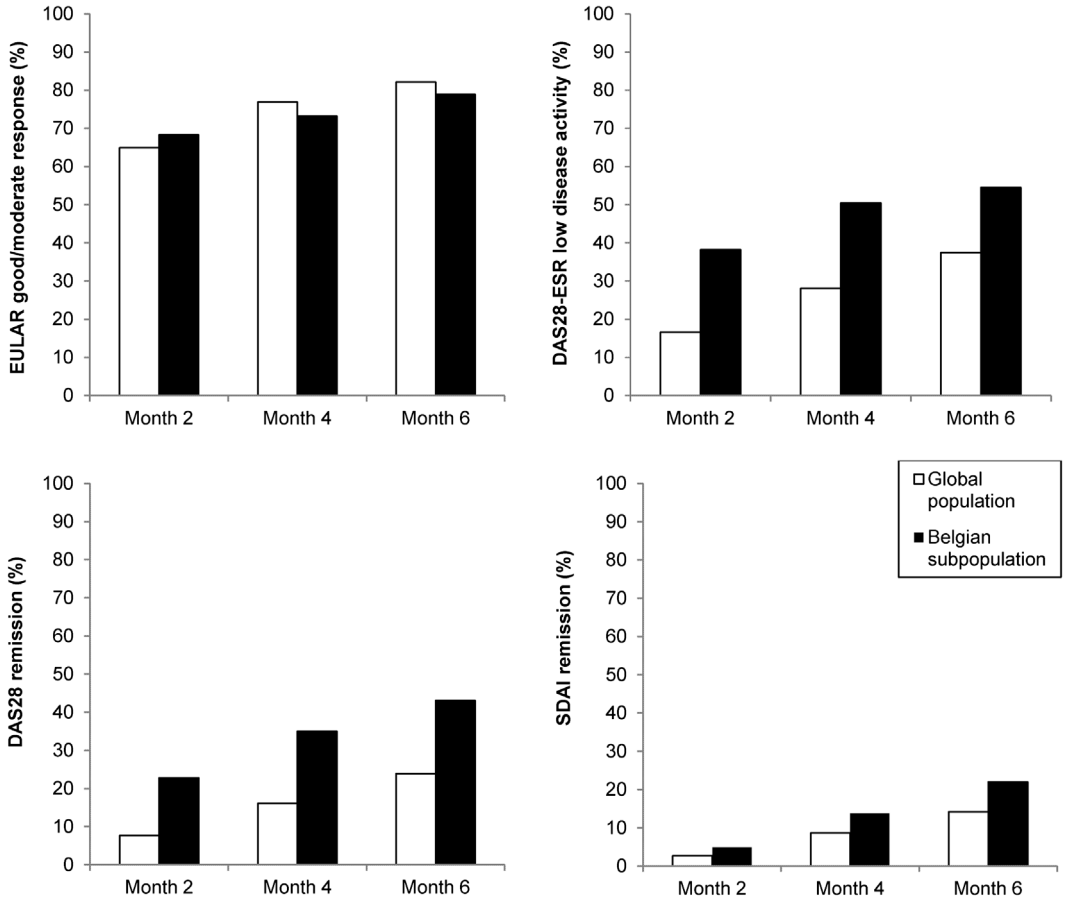

Figure 1 Efficacy in the Belgian subpopulation and the rest of the world within part 1 of the GO-MORE study. (A) Proportion of patients attaining a EULAR good/moderate response at months two, four, and six. A good/moderate EULAR response was defined as a DAS28-ESR improvement > 1.2 from any baseline score or an improvement of 0.6–1.2 from a baseline score ≤ 5.1. (B) Proportion of patients with DAS28-ESR low disease activity (DAS28-ESR score ≤ 3.2) at months two, four, and six. (C) Proportion of patients attaining DAS28-ESR remission (DAS28-ESR score < 2.6) at two, four, and six months. (D) Proportion of patients attaining SDAI remission (SDAI ≤ 3.3) at months two, four, and six. Abbreviations: DAS28-ESR, 28-joint disease activity score based on erythrocyte sedimentation rate; EULAR, European League Against Rheumatism; SDAI, Simplified Disease Activity Index.

Table 3 Response rates within the Belgian subpopulation (N = 123) at the end of part 1 of the GO-MORE study (month six) according to baseline disease activity

	Moderate disease activity at baseline[a]	High disease activity at baseline[b]	
	***N* = 73**	***N* = 49**	
Measure	*n* (%)	*n* (%)	*p*-value
DAS28-ESR good/moderate EULAR response[c]	56 (76.7)	41 (83.7)	0.49
DAS28-ESR low disease activity[d]	42 (57.5)	25 (51.0)	0.58
DAS28-ESR remission[e]	36 (49.3)	17 (34.7)	0.14
SDAI remission[f]	16 (21.9)	11 (22.4)	1.00
Minimal or no functional impairment[g]	32 (43.8)	18 (36.7)	0.46

Note: *p*-values were determined by Fisher's exact test.Abbreviations: DAS28-ESR, 28-joint disease activity score based on the erythrocyte sedimentation rate; EULAR, European League Against Rheumatism; HAQ-DI, Health assessment questionnaire-disability index; SDAI, simplified disease activity index.

[a]DAS28-ESR = 3.2–5.1.

[b]DAS28-ESR > 5.1.

[c]DAS28-ESR improvement > 1.2 from any baseline score or improvement of 0.6–1.2 from a baseline score ≤ 5.1.

[d]DAS28-ESR score ≤ 3.2.

[e]DAS28-ESR score < 2.6.

[f]SDAI ≤ 3.3.

[g]HAQ-DI ≤ 0.

activity at baseline, suggesting that the higher rate in the Belgian population was unrelated to lower baseline disease activity.

The differences in remission rates could also not be due to differences in disease duration because they were similar between the Belgian population and the rest of the world.

Instead, differences in access to or quality of care might have been the most important determinant. At baseline, the Belgian patients had, on average, lower disease activity than the rest of the world, suggesting better disease control. This can explain the relatively high response and remission rates in other wealthy countries such as Spain.[7] In fact, several studies have shown that living in countries with higher wealth is associated with lower RA disease activity.[13–15] This might be due, in part, to differences in types of concomitant therapies used, but the results from the global GO-MORE population did not reveal an effect of DMARD type or concomitant corticosteroid use on RA disease activity.[8] Better quality of care might also lead to higher patient expectations and therefore better responses to treatment. In fact, in the global GO-MORE population, patients with more positive expectations had higher remission rates, greater improvements in function, and better quality of life than patients with lower expectations.[16] Another possible explanation is a difference in radiological damage, although this was not evaluated during the GO-MORE trial.

This analysis of the Belgian subpopulation allowed us to specifically examine the effect of subcutaneous golimumab 50 mg once monthly as an add-on to DMARD treatment in Belgian clinical practice. Due to the low baseline disease activity in this population, this analysis also allowed us to explore how baseline disease activity affects response. Admittedly, the Belgian subpopulation included only 123 patients, but this probably should have been sufficient to detect any differences according to baseline activity. Our results indicate that differences in response to RA treatments according to baseline activity or subpopulation are more likely due to differences in the access to and quality of care. Our results also highlight the utility of performing efficacy studies across a wide range of countries and regions followed by subanalyses to determine clinical efficacy in selected local care environments.

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Supplemental data

Supplemental data for this article can be accessed at http://dx.doi.org/10.1080/17843286.2017.1314079

Contributors

PD analyzed the data, wrote the article in whole/part, and revised the article. MV, IH, MM, and PG collected and analyzed the data.

Conflict of interest

P.D. declares participation in speakers' bureaus for Bristol-Myers Squibb, Samsung, Pfizer, UCB, Mundipharma, Hospira, and Eli Lilly. I.H. has received honoraria from MSD-Belgium for speaking. All other authors report no declarations of interest.

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