ARTÍCULO ORIGINAL

Real-world effectiveness and safety of golimumab in ulcerative colitis: multicenter experience from Chile

Efectividad y seguridad en mundo real del uso de golimumab en colitis ulcerativa: experiencia multicéntrica de Chile

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ABSTRACT

Objectives: Evidence on golimumab for ulcerative colitis (UC) is scarce in Latin America. We aimed to assess the real-world effectiveness and safety of golimumab in a multicenter Chilean cohort. **Materials and methods:** We conducted a retrospective, observational study including adult patients with moderate-to-severe UC treated with golimumab under the Chilean government coverage program (July 2019-August 2023). Clinical, biomarker, endoscopic, and histological outcomes were evaluated at weeks 16 and 52. Dose optimization strategies and adverse events (AEs) were recorded. **Results:** Seventy-nine patients were included (69.6% women; median disease duration 8 years). Most were anti-TNF naïve (94%). At week 16.81% achieved symptomatic remission, 77% biomarker remission, 35% endoscopic remission, and 38% histological remission. At week 52, 43 patients remained on treatment; of these, 93% achieved symptomatic remission, 98% biomarker remission, 63% endoscopic remission, and 42% histological remission. Dose optimization was required in 62% of patients, and early optimization was associated with higher remission stability. Kaplan-Meier analysis showed 75% clinical remission at 24 months. Adverse events were infrequent, with no colectomies reported. **Conclusions:** In this first Chilean and Latin American multicenter real-world study, golimumab proved effective and safe for moderate UC, achieving high rates of clinical and biomarker remission, particularly with early dose optimization. Despite newer biologics and small molecules, golimumab remains a valid therapeutic option in regions with limited access.
Keywords: *Colitis, Ulcerative; golimumab; real-world evidence; Latin America; Biological Products (source: MeSH NLM).*

RESUMEN

Objetivos: La evidencia sobre golimumab en colitis ulcerosa (CU) en Latinoamérica es limitada. Nuestro objetivo fue evaluar la efectividad y seguridad de golimumab en práctica clínica real en una cohorte multicéntrica chilena. **Materiales y métodos:** Se realizó un estudio retrospectivo y observacional que incluyó pacientes adultos con CU moderada a grave tratados con golimumab bajo el programa de cobertura estatal chileno entre julio de 2019 y agosto de 2023. Se evaluaron desenlaces clínicos, biomarcadores, endoscópicos e histológicos a las semanas 16 y 52. Además, se registraron estrategias de optimización de dosis y eventos adversos (EA). **Resultados:** Se incluyeron 79 pacientes (69,6% mujeres; mediana de duración de la enfermedad: 8 años). La mayoría eran naïve a anti-TNF (94%). A la semana 16, el 81% alcanzó remisión sintomática, el 77% remisión de biomarcadores, el 35% remisión endoscópica y el 38% remisión histológica. A la semana 52, 43 pacientes permanecían en tratamiento; de ellos, el 93% alcanzó remisión sintomática, el 98% remisión de biomarcadores, el 63% remisión endoscópica y el 42% remisión histológica. La optimización de dosis fue necesaria en el 62% de los pacientes, y la optimización precoz se asoció con una mayor estabilidad de la remisión. El análisis de Kaplan-Meier mostró una tasa de remisión clínica del 75% a los 24 meses. Los EA fueron infrecuentes y no se reportaron colectomías. **Conclusiones:** En este primer estudio multicéntrico chileno y latinoamericano en vida real, golimumab demostró ser efectivo y seguro para el tratamiento de la CU moderada a severa, alcanzando altas tasas de remisión clínica y de biomarcadores, especialmente con optimización temprana de dosis. A pesar de la disponibilidad de nuevos biológicos y moléculas pequeñas, golimumab continúa siendo una opción terapéutica válida en regiones con acceso limitado a terapias avanzadas.
Palabras clave: *Colitis Ulcerosa; Enfermedades del Sistema Inmune; América Latina; Productos Biológicos (fuente: DeCS BIREME).*

INTRODUCTION

Ulcerative colitis (UC) is a chronic immunologically mediated condition characterized by recurrent flares and remissions. Its incidence and prevalence of UC have been rising in Latin America [1,2], reflecting the epidemiological transition previously observed in developed countries [3]. In Chile, hospital-based studies indicate a growing number of UC cases and related hospitalizations, though nationwide epidemiological data remain scarce [4,5].

Treatment goals in UC include steroid-free clinical remission, mucosal healing, preservation of gastrointestinal function, and prevention of hospitalizations, colectomy, and disability-ultimately improving quality of life. Conventional therapies such as mesalamine, corticosteroids, and thiopurines often fail to achieve or maintain remission, necessitating biologics or small molecules [6-10].

Golimumab, a fully human monoclonal antibody targeting TNF-α, has demonstrated efficacy in the PURSUIT trials [11-13]. Real-world evidence from Europe and Asia has confirmed its effectiveness and safety, though its use has declined with the introduction of newer therapies [14-28]. In Chile, golimumab remains widely used due to government financial coverage under the "Ley Ricarte Soto" program.

This study aimed to evaluate the real-world effectiveness, safety, and optimization of golimumab in UC patients across two Chilean referral centers.

MATERIALS AND METHODS

Study design and setting

We conducted a retrospective, observational cohort study of UC patients treated with golimumab at Clinica Universidad de los Andes and Hospital San Juan de Dios, Santiago, Chile, between July 1, 2019, to August 31, 2024.

Inclusion criteria

Inclusion criteria were: Age ≥18 years; confirmed UC diagnosis by endoscopic and histological criteria; failure or intolerance to thiopurines.

Exclusion criteria were lack of follow-up within 16 weeks or incomplete records.

Treatment, follow up and monitoring

Golimumab was administered subcutaneously (200 mg week 0, 100 mg week 2, then 50/100 mg every 4 weeks, weight-based). Optimization to 100 mg every 2 weeks was permitted.

Although this was a retrospective study, all patients were managed according to a predefined local protocol for biologic therapies, which ensured strict and systematic follow-up. Visits were scheduled at weeks 4, 12, 16, 24, and 52, with additional evaluations if flares occurred. Fecal calprotectin (FC) was measured at baseline, week 12, and every 4 months thereafter. Colonoscopy was routinely scheduled within 6 months of induction and repeated as clinically indicated, based on FC results and disease activity.

Outcomes

Primary: Symptomatic remission (partial Mayo <3, no variable >1) confirmed by PROs [7,8,29].

Secondary: Biomarker remission (FC <250 µg/g), endoscopic remission (MES=0, UCEIS<1), histological remission (Geboes<2 or Nancy=0), disease clearance (combined) [30].

Dose optimization outcomes, adverse events (AEs), and treatment persistence were recorded.

Lastly, treatment discontinuation was tracked, including cases of primary non-response (failure to achieve an initial therapeutic effect) and secondary loss of response (decline in efficacy over time) [31].

Statistical analysis

Continuous variables were described using means/medians, categorical variables as proportions. Associations were assessed with χ^2 tests and relative risk (RR). Treatment persistence was estimated using Kaplan–Meier survival curves, compared with log-rank tests.

The primary outcome was clinical remission at week 52, defined according to clinical criteria (partial Mayo score). For multivariable analysis, a binary variable was constructed (remission vs no remission).

Multivariable analysis was performed to identify factors independently associated with clinical remission at week 52. Adjusted risk ratios (RR) and 95% confidence intervals (CI) were estimated using generalized linear models (GLM) with a log link and Poisson distribution with robust variance.

The following covariates were included a priori based on clinical relevance: sex, age (<40 years), disease duration (<10 years), disease extent (extensive vs non-extensive), time on golimumab (≤12 months vs >12 months), and treatment optimization.

All variables were entered simultaneously into the model. Given the sample size, the analysis was considered exploratory, and no automated variable selection procedures were applied.

A two-sided *p* value <0.05 was considered statistically significant. Statistical analyses were performed using SPSS v.29 (IBM Corp., Armonk, NY, USA) and Stata 15.1.

Ethical considerations

Approved by Ethics Committees of Universidad de los Andes (CEC2022079) and Hospital San Juan de Dios

(RENº06656/2023), adhering to the ethical guidelines of the 1975 Helsinki Declaration. Informed consent was obtained from all patients for inclusion in this protocol.

RESULTS

Patient characteristics

Of 82 screened patients, 3 were reclassified as Crohn's disease and excluded. Seventy-nine UC patients (69.6% women, median disease duration 8 years) were analyzed. Mean age at diagnosis was 42 years. Ninety-four percent were anti-TNF naïve. Baseline characteristics are shown in Table 1 and flowchart in Figure 1.

Table 1. Baseline clinical characteristics of patients with ulcerative colitis.

Outcomes (n=79)	Number
Disease duration (n, %)	
< 10 years	49 (62.1)
≥ 10 years	30 (37.9)
Disease extension area (n, %)	
Proctitis	3 (3.79)
Left side	29 (36.7)
Extensive (include Bipolar)	47 (59.5)
Treatments (n, %)	
Prior use of anti TNF-α	5 (6.33)
Reasons for using Golimumab	
AE to immunomodulators	24 (30.4)
Immunorefractoriness	50 (63.3)
Infliximab AE	1 (1.26)
Access issue	3 (3.79)
Primary no response to Infliximab	1 (1.26)
Golimumab Starting dose (n, %)	
50 mg / 4 weeks	59 (74.7)
100 mg / 4 weeks	20 (25.3)
Optimized therapy (n, %)	49 (62.02)
Golimumab Maintenance dose (n, %)	
50 mg / 4 weeks	20 (25.3)
100 mg / 4 weeks	43 (54.4)
100 mg/ 2 weeks	16 (20.3)
Total Scores and Biomarkers (median, range)	
Mayo Endoscopy Score (MES)	2 (2-3)
Partial Mayo Score (pMS)	4 (3 - 5)
Fecal Calprotectin before Golimumab (µg/g) n=71*	600 (369-800)

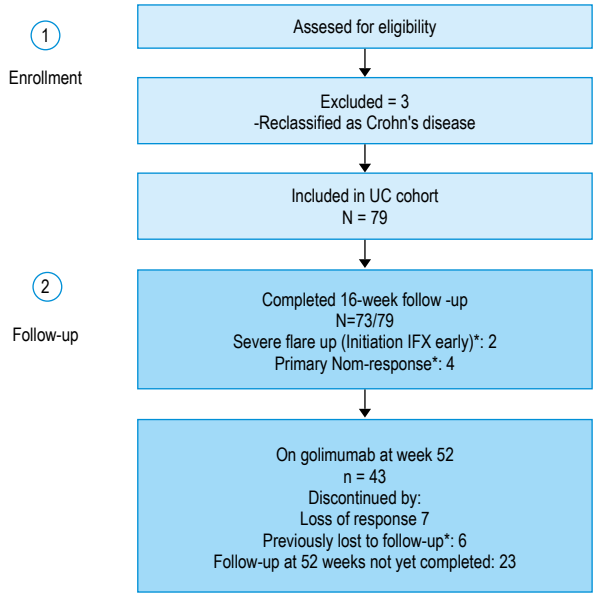

Figure 1. Patient flowchart.

Dose optimization

Therapy was optimized in 49 patients (62%): 25.3% required 100 mg every 2 weeks, and 54.4% remained on 100 mg every 4 weeks. Optimization occurred before week 12 in 61.2% due to inadequate symptomatic response. Median FC before optimization was significantly higher than in non-optimized patients (418 vs 80 µg/g; $p<0.05$).

Short-term outcomes

At week 16, 92% of patients remained on golimumab. Symptomatic remission was achieved in 81%, biomarker remission in 77%, endoscopic remission in 35%, and histological remission in 38% (Table 2).

Long-term outcomes

At week 52, 43 patients (54.4%) remained on treatment. Remission rates were 93% for symptomatic, 98% for biomarker, 63% for endoscopic, and 42% for histological remission (Table 2)

Table 2. Clinical outcomes with golimumab during induction and maintenance in ulcerative colitis.

Outcome	Week 16 (n=79)	Week 52 (n=43)
Patients remaining on golimumab	92%	54.4%
Symptomatic remission	81%	93%
Biomarker remission	77%	98%
Endoscopic remission	35%	63%
Histological remission	38%	42%

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Table 3. Effect of Golimumab on clinical, endoscopic, histological and biomarker activity at 52 weeks of treatment, adjusted for sex, age, duration and extent of disease, treatment time and optimization of therapy.

	Activity at week 52											
Outcomes	**Clinical**			**Endoscopic**			**Histological**			**Biomarker**		
	RR	**CI 95%**	**p value**	**RR**	**CI 95%**	**p value**	**RR**	**CI 95%**	**p value**	**RR**	**CI 95%**	**p value**
Sex, Female	0.87	[0.33-2.28]	0.78	1.60	[0.53-4.86]	0.38	1.35	[0.76-2.40]	0.25	1.06	[0.35-3.30]	0.91
Age, <40 years	1.30	[0.52-3.23]	0.58	1.60	[0.63-4.05]	0.31	1.31	[0.83-2.05]	0.23	1.52	[0.60-3.86]	0.38
Disease duration[a]	1.68	[0.59-4.81]	0.32	1.79	[0.59-5.47]	0.27	0.82	[0.54-1.26]	0.39	0.79	[0.31-1.98]	0.61
Time of Golimumab[b]	3.27	[1.24-8.64]	0.011	3.45	[0.35-33.86]	0.26	1.15	[0.73-1.81]	0.56	5.66	[2.03-15.79]	0.001
Optimized therapy	0.92	[0.36-2.32]	0.86	1.60	[0.53-4.86]	0.38	2.41	[1.04-5.58]	0.006	2.27	[0.57-9.09]	0.21
Disease Extension[c]	1.87	[0.65-5.36]	0.23	4.55	[0.67-30.99]	0.05	0.96	[0.60-1.53]	0.87	0.92	[0.35-2.40]	0.87

RR: Risk ratio; CI 95%: confidence interval; * p < 0.05. (a) Disease duration: < 10 years; (b) Time of Golimumab ≤12 months; (c) Disease Extension: extensive

Effect of golimumab optimization

Patients who underwent golimumab optimization achieved higher remission rates compared with those who were not optimized: clinical remission 90% vs 72%, biomarker remission 100% vs 68%, endoscopic remission 65% vs 50%, and histological remission 45% vs 35% (Figure 2).

Seven patients (8.9%) experienced secondary loss of response; all were switched to another anti-TNF.

Analysis of the relative risk

When assessing the relative risks for disease activity at 52 weeks in patients receiving Golimumab, it appears that the duration prior to starting Golimumab may represent a risk factor for clinical activity, with an RR of 3.27, p=0.011 (95% CI: 1.24-8.64), and fecal calprotectin levels (RR = 5.66; 95% CI [2.03 - 15.79]; p = 0.001). Additionally, the extent of the disease could be associated with endoscopic activity, with an RR of 4.55 (95% CI: 0.67-30.99), see Table 3.

In multivariable analysis, golimumab treatment duration ≤12 months was associated with a lower likelihood of clinical remission at week 52 (adjusted RR 0.74; 95% CI 0.56-0.98; p=0.036). No significant associations were observed for sex, age, disease duration, treatment optimization, or disease extent, see Table 4.

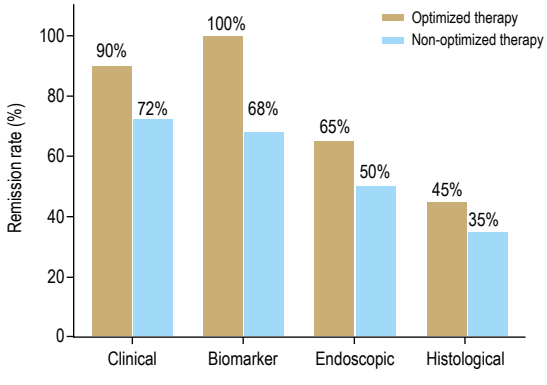

Figure 2. Effect of golimumab optimization on remission rates at week 52. Remission rates for clinical, biomarker, endoscopic, and histological outcomes at week 52 in patients who received optimized versus non-optimized golimumab therapy. Optimization was associated with higher remission across all outcomes.

Survival analysis

Kaplan-Meier-estimated remission was 94.7% at 6 months, declining to 75.2% at 24 months, and stabilizing at 70.7% at 30 months (Figure 3a). Patients who underwent golimumab optimization maintained more stable remission compared with those without optimization (Figure 3b).

Safety

Nine patients experienced exacerbations; two were primary non-responders requiring early hospitalization, seven had secondary loss of response. No colectomies were reported. Adverse events were rare and mild.

Table 4. Multivariable analysis of factors associated with clinical remission at week 52.

Variable	Adjusted RR	95% CI	*p* value
Female sex	0.98	0.75–1.27	0.855
Age <40 years	0.94	0.74–1.18	0.572
Disease duration <10 years	0.93	0.76–1.15	0.504
Golimumab treatment duration ≤12 months	0.74	0.56–0.98	0.036
Optimized therapy	1.02	0.80–1.30	0.870
Extensive disease	0.89	0.71–1.13	0.352

RR: risk ratio; **CI:** confidence interval.
Adjusted risk ratios were estimated using a generalized linear model with log link and Poisson distribution with robust variance. The outcome was clinical remission at week 52.

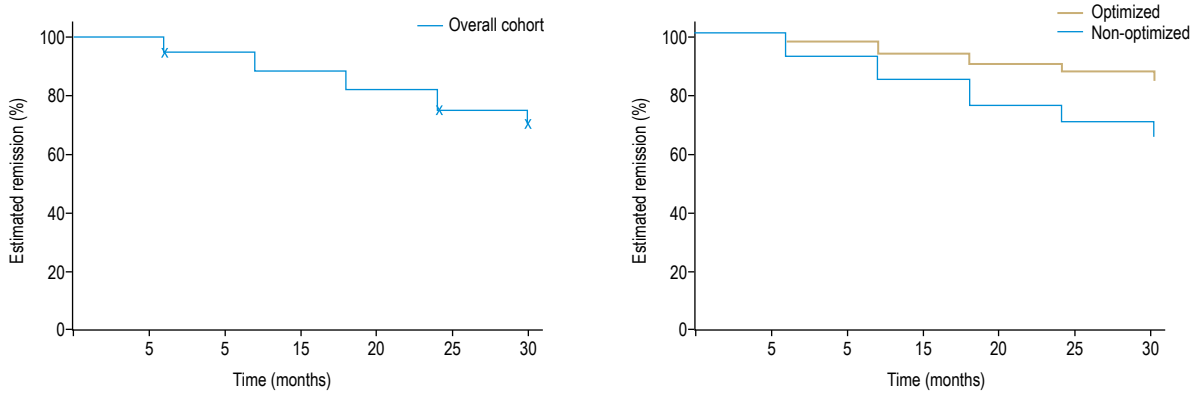

Figure 3. Kaplan-Meier-estimated remission with golimumab in ulcerative colitis. (**a**) Overall cohort: Kaplan-Meier-estimated remission was 94.7% at 6 months, 75.2% at 24 months, and 70.7% at 30 months. (**b**) Stratified analysis according to therapy optimization: optimized patients maintained more stable long-term remission compared with non-optimized patients.

DISCUSSION

In this first Chilean multicenter cohort, golimumab demonstrated substantial effectiveness and safety in the management of moderate-to-severe UC under real-world conditions. High rates of symptomatic and biomarker remission were achieved, particularly among anti-TNF–naïve patients, and early dose optimization proved crucial for sustaining remission over time.

Our findings are consistent with those reported in European and Asian cohorts, although the notably high proportion of biologic-naïve patients in our study (94%) [32-34], may partly explain the higher remission rates observed. In this context, early dose optimization mereged as a critical factor to maintaining long-term disease control, in line with previous reports such as Taxonera *et al.* [33], who showed early optimization improved long-term outcomes.

In a multivariable análisis, time on golimumab was the main factor associated with outcomes at week 52. Patients with shorter treatment duration (≤12 months) were more likely to have ongoing disease activity and less likely to achieve clinical remission. This finding is clinically plausible, as sustained exposure to biologic therapy is often required to achieve durable disease control and mucosal healing in UC. Notably, baseline demographic and disease-related characteristics were not significantly associated with outcomes, suggesting that treatment duration may be a more relevant determinant of long-term response in this cohort.

Given the relatively small sample size and the observational design, these results should be interpreted as exploratory. However, they provide relevant real-world evidence supporting the importance of sustained biologic therapy in achieving long-term remission.

Beyond clinical outcomes, our findings also highlight the disparities in therapeutic access across regions. While golimumab is being replaced by newer biologics and small molecules in many countries [35,36], it continues to be a relevant therapeutic option in Chile, where government coverage policies make it widely available. This underscores how treatment strategies may differ depending on local health systems and access constraints, yet still yield meaningful clinical benefit. In resource-limited or geographically distant settings, therapies considered "less current" elsewhere may remain highly effective and represent the most practical option for patients.

Safety findings mirrored those of large post-marketing studies, with mostly mild infections and no colectomies. The absence of severe AEs supports golimumab's tolerability [37].

Limitations include retrospective design, data from only two centers, lack of therapeutic drug monitoring, and attrition at 52 weeks. Nevertheless, strengths include comprehensive assessment (clinical, biomarker, endoscopic, histological) and real-world applicability under government coverage.

Golimumab should therefore be viewed not only as a historically validated biologic, but also as a therapy with ongoing real-world value in countries where disparities in availability shape clinical practice [37]. These data reinforce the importance of generating local evidence to inform treatment decisions and to advocate for equitable access to effective therapies across different healthcare systems.

Golimumab was early optimizated, as soon as clinical response is not achieved.

In conclusion, golimumab remains a valid therapeutic option for UC, particularly in resource-constrained settings. These findings highlight the importance of early dose optimization and support the continued inclusion of golimumab in treatment strategies in Latin America.

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