

# Clinical effectiveness of golimumab:

## interim analysis of the observational study of patients with ulcerative colitis on golimumab in the Swedish National Quality Registry for IBD – GO-SWIBREG

C. Eriksson<sup>1</sup>, D. Bergemalm<sup>1\*</sup>, L. Vigren<sup>2</sup>, L. Nilsson<sup>3</sup>, I. Visuri<sup>1</sup>, H. Hjortswang<sup>4</sup>, R. Udumyan<sup>5</sup>, S. Almer<sup>6</sup>, M. Seddighzadeh<sup>7</sup>, E. Hertervig<sup>8</sup>, P. Karlén<sup>3</sup>, H. Strid<sup>9</sup>, J. Halfvarson<sup>1</sup>, The GO-SWIBREG study group

<sup>1</sup>Örebro University, Department of Gastroenterology, Faculty of Medicine and Health, Sweden, <sup>2</sup>Hospital of Trelleborg, Department of Medicine, Division of Gastroenterology, Sweden, <sup>3</sup>Danderyd Hospital, Department of Internal Medicine, Stockholm, Sweden, <sup>4</sup>Linköping University, Department of Gastroenterology and Department of Clinical and Experimental Medicine, Sweden, <sup>5</sup>Örebro University, Department of Clinical Epidemiology and Biostatistics, Faculty of Medicine and Health, Sweden, <sup>6</sup>Karolinska Institute, Department of Medicine, Gastrocentrum, Stockholm, Sweden, <sup>7</sup>Merck Sharp and Dohme, Stockholm, Sweden, <sup>8</sup>Skåne University Hospital, Department of Gastroenterology, Lund, Sweden, <sup>9</sup>Södra Älvsborgs Hospital, Department of Internal Medicine, Borås, Sweden

### Background

Clinical trials may not appropriately reflect everyday clinical practice. Therefore, we aimed to assess the clinical effectiveness of golimumab in a real world cohort.

### Methods

This is a prospective, multi-centre cohort study. Eligible patients had an established diagnosis of ulcerative colitis, moderate-to-severe disease activity, defined as a Mayo endoscopic subscore  $\geq 2$  and initiated golimumab from 1/6/2014.

Clinical characteristics, treatment, clinical, biochemical, endoscopic activity and quality of life measures were recorded at baseline and prospectively, using an electronic Case Record Form, integrated with the Swedish National Quality Registry for IBD (SWIBREG).

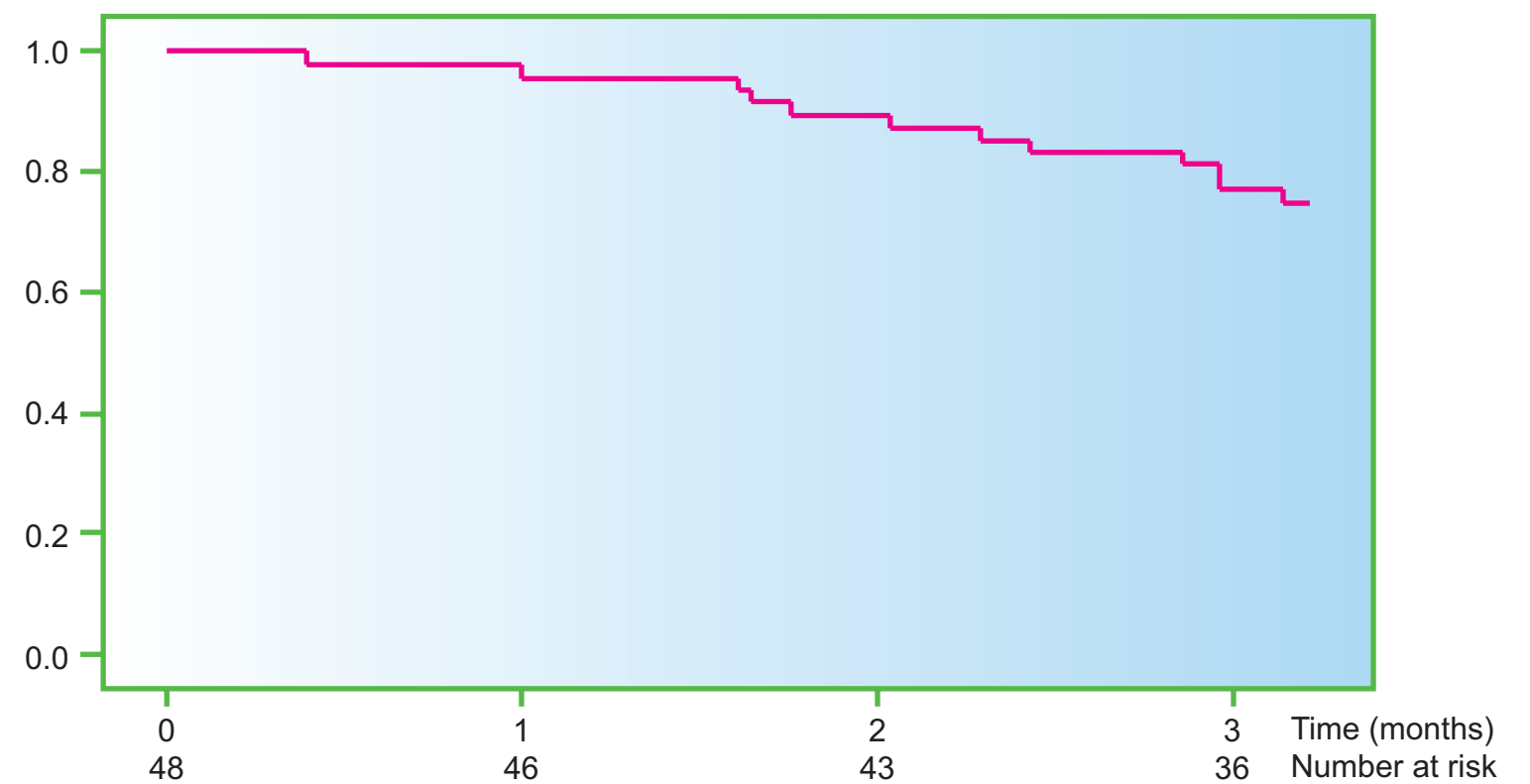
Primary objective was clinical effectiveness at 12 weeks and 52 weeks, i.e. clinical response (defined as a decrease in Mayo score by  $\geq 3$  points or 30% from baseline) and remission (defined as a score of  $\leq 2$  with no individual subscores  $> 1$ ). Differences between baseline and follow-up were assessed by Wilcoxon-signed rank test. Data from the 12 week induction part are presented.

### Results

50 patients were included, by 15/09/2017. At study entry, 24/50 (48%) were on concomitant treatment with immunomodulators, 16/50 (32%) on oral corticosteroids and 27/50 (54%) on 5-ASA. In total, 35/50 (70%) had previously been exposed to at least one TNF-antagonist (table 1). At 12 weeks, 37/50 (74%) were still on treatment with golimumab (figure 1).

Of the patients continuing golimumab until week 12, 8 (22%) were in clinical remission and 13 (35%) had a clinical response. The median Mayo score decreased from 7 (6-10) at baseline to 5 (1-8) at 12 weeks ( $p < 0.01$ ). Consistently, median faecal calprotectin decreased from 710 (275-1850)  $\mu\text{g/g}$  to 390 (45-870)  $\mu\text{g/g}$  ( $p = 0.02$ ). Quality of life improved in golimumab treated patients, with a significant reduction of the overall short health scale (SHS) score ( $p = 0.04$ ).

**Figure 1.** Kaplan–Meier analysis of survival on drug for patients with moderate to severe ulcerative colitis treated with golimumab.



**Table 1.** Baseline clinical and demographical characteristics of patients with ulcerative colitis

Median age yr. (IQR)	41 (28-53)
Sex female no. (%)	25 (50)
Median disease duration yr. (IQR)	5 (2-11)
Current smoker no. (%)	2 (4)
Extent –no. (%)	
Proctitis (E1)	5 (10)
Left-sided colitis (E2)	19 (38)
Extensive colitis (E3)	25 (50)
Unknown	1 (2)
Previous medications – no. (%)	
5-aminosalicylates	49 (98)
Corticosteroids	48 (96)
Immunomodulators	46 (92)
Anti-TNF therapy	35 (70)
Reason for termination of last anti-TNF no. (%)	
Primary non response	5 (14)
Secondary loss of response	18 (51)
Intolerance	9 (26)
Other reason	3 (9)

### Conclusions

This cohort of golimumab treated patients represents a treatment-refractory group. Improvements in clinical and inflammatory activity as well as in quality of life can be achieved already at 12 weeks.