

Early Symptomatic Response to Guselkumab in Inflammatory Bowel Disease: First Real-world Data From the German GORGEIOUS Study

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Background



Guselkumab (GUS)

- Fully human, dual-acting monoclonal antibody that selectively inhibits interleukin (IL)-23 by targeting its p19 subunit and binds to CD64 on IL-23-producing inflammatory monocytes¹.
- Approved by EMA and FDA for treatment of moderate-to-severe Crohn's disease (CD) and ulcerative colitis (UC).



Early symptomatic improvement is clinically meaningful for patients with CD and UC². While GUS has demonstrated efficacy in clinical trials, real-world evidence, particularly on early response with GUS, is limited^{3,4}.



GORGEIOUS (NCT07102368) is an exploratory multicenter, prospective, observational study designed to evaluate effectiveness, safety, and patient-reported outcomes of GUS in clinical routine practice in Germany for up to two years.

Objective



In this first interim analysis, we assessed early symptomatic response in patients with CD or UC using daily diary data from the first 28 days following the first GUS dose.

Methods

- Since August 2025, the ongoing GORGEIOUS study has been collecting physician-documented and patient-reported data from patients with CD or UC initiating GUS in routine clinical care according to the approved label across 65 sites in Germany.
- This interim analysis reports diary data from patients who completed the 28-day assessment period, reflecting early symptom changes following the first induction dose of GUS administered on day 0 (d0).
- Following abstract acceptance, an updated data cut (10 Jul 2026) was performed to increase the evaluable patient population and to enable a more robust assessment of early response outcomes; findings remained consistent with those from the initial dataset.
- Patients completed a daily symptom diary via a smartphone app during the first 28 days of treatment. Assessed symptoms included: *stool frequency, soft/liquid stools, nightly stools, bowel urgency, rectal bleeding, and abdominal pain* in the last 24 hrs.
- Results are presented descriptively and stratified by disease cohort (CD and UC).
- Further analyses will be performed as follow-up data accrues.

Results

Study population and baseline characteristics

- Baseline characteristics reflect real-world inflammatory bowel disease (IBD) population (**Table 1**) and suggest that treatment decisions were influenced by factors beyond symptom burden, such as persistent inflammatory activity or prior treatment failure. Most patients (~70%) were advanced drug therapy (ADT)-experienced.

Daily symptomatic response

- Following one induction dose of GUS, rapid, consistent, and clinically relevant improvements were observed across all 6 symptom dimensions in both indications.
- For most symptomatic endpoints, patients reported clinically meaningful improvements within the first week, with benefits sustained or continuing to improve through d28.
- Stool frequency (Fig. 1a & 1b):** In CD, mean stool frequency decreased from 3.7 at d1 to 2.9 at d7 and further to 2.7 at d28. In UC, mean reported stools decreased from 6.9 at d1 to 5.1 at d7 and 4.2 at d28.
- Nightly stools (Fig. 2a & 2b):** Nightly stools, a key driver of sleep interruption, were reported by 28.1% and 52.2% of patients, respectively, with CD and UC at d1. By d28, the proportion had lowered to 13.0% in CD and 29.1% in UC, corresponding to relative reductions of 53.7% and 44.3%, respectively.
- Bowel urgency (Fig. 3a & 3b):** At d1, bowel urgency was reported by the majority of patients in both cohorts. In CD, rate decreased from 54.8% to 41.2% by d28 (a 24.8% relative reduction); in UC, from 77.0% to 47.7% (a 38.1% relative reduction).
- Rectal bleeding (Fig. 4a & 4b):** Moderate or severe rectal bleeding was infrequent in CD, decreasing from 4.2% at d1 to 2.1% at d28. In UC, where rectal bleeding was predominantly reported, the proportion decreased from 29.0% at d1 to 11.8% at d28, representing a relative reduction of 58.9%.
- Abdominal pain (Fig. 5a and 5b):** Both CD and UC cohorts reported reductions of abdominal pain, with more prominent relief in UC, where the proportion of patients with no or mild pain increased from 66.7% at d1 to 86.5% at d28.



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Key Takeaways

- ✓ GORGEIOUS is the largest real-world study of patients treated with GUS in IBD to date. Its population reflects patients typically seen in routine clinical practice in Germany, with long disease duration and heterogeneous treatment histories.
- ✓ Daily patient-reported symptom diary entries capture symptom relief information, without recall bias.
- ✓ For most symptomatic endpoints, clinically meaningful improvements were already evident within the first week following a single dose of GUS, with a substantial proportion of the overall 28-day improvement achieved by days 6–8 and modest additional gains thereafter.
- ✓ Reductions in nocturnal stools and abdominal pain particularly highlight the relevance for patients' quality of life.
- ✓ No new safety signals were identified through week 4.
- ✓ These interim findings provide the first real-world evidence of early symptomatic response to GUS in routine clinical practice in Germany.

Baseline characteristics of the 389 GORGEIOUS patients in this 1st interim analysis, by CD and UC cohorts

Table 1. Baseline Characteristics	CD Cohort N=236	UC Cohort N=153
Gender – Female	51.3%	52.9%
Age, years; median (Q1/ Q3)	37 (29/51.5)	38 (27/50)
Disease duration ≤2 years / >2 years	21.2% / 78.8%	25.5% / 74.5%
CD Location ^{a,b} , available N	202	
L1 – terminal ileum	33.1%	NA
L2 – colon	17.4%	NA
L3 – ileocolonic	42.0%	NA
L4 – upper gastrointestinal	15.3%	NA
CD Disease behaviour ^{a,b} , available N	202	
B1 – non-stricturing, non-penetrating	49.6%	NA
B2 – stricturing	30.9%	NA
B3 – penetrating	12.3%	NA
P – perianal	8.9%	NA
UC Extent of disease ^a , available N		148
E1 – Proctitis	NA	17.6%
E2 – Left sided colitis	NA	35.8%
E3 – Pancolitis	NA	46.6%
UC Severity of disease ^a , available N		149
S0 – asymptomatic / S1 – mild	NA	1.3% / 8.7%
S2 – moderate / S3 – severe	NA	63.8% / 26.2%
Disease activity status, available N	182	121
Remission or inactive disease	HBI 0-4: 35.7%	PMS 0-2: 13.2%
Mild disease	HBI 5-7: 31.9%	PMS 3-4: 28.1%
Moderate disease	HBI 8-16: 32.8%	PMS 5-6: 32.2%
Severe disease	HBI >16: 0.0%	PMS 7-9: 26.4%
Abnormal endoscopic activity, available N	164	106
CD: moderate/severe or SES-CD score ≥7; UC: MES ≥2	61.6%	76.4%
Number of previous ADT		
0	23.3%	28.8%
1 / 2	37.7% / 21.2%	32.0% / 24.2%
3 / 4	11.0% / 6.8%	7.2% / 7.8%
Corticosteroid use at baseline		
Yes	32.2%	49.0%
Laboratory inflammatory parameters		
Available N	181	132
CRP >5 mg/L	54.7%	45.5%
Available N	100	75
tCAL >250 µg/g	58.0%	64.0%

Data is presented as percent unless specified otherwise. Cohort specific variables are marked as NA. All assessments have only been documented if assessed during local clinical routine. *Montreal classification. ^aMultiple answers possible. CRP=C-reactive protein, tCAL=fecal calprotectin, HBI=Harvey Bradshaw Index, PMS=spatial Mayo score.

Stool frequency within the first 4 weeks of GUS

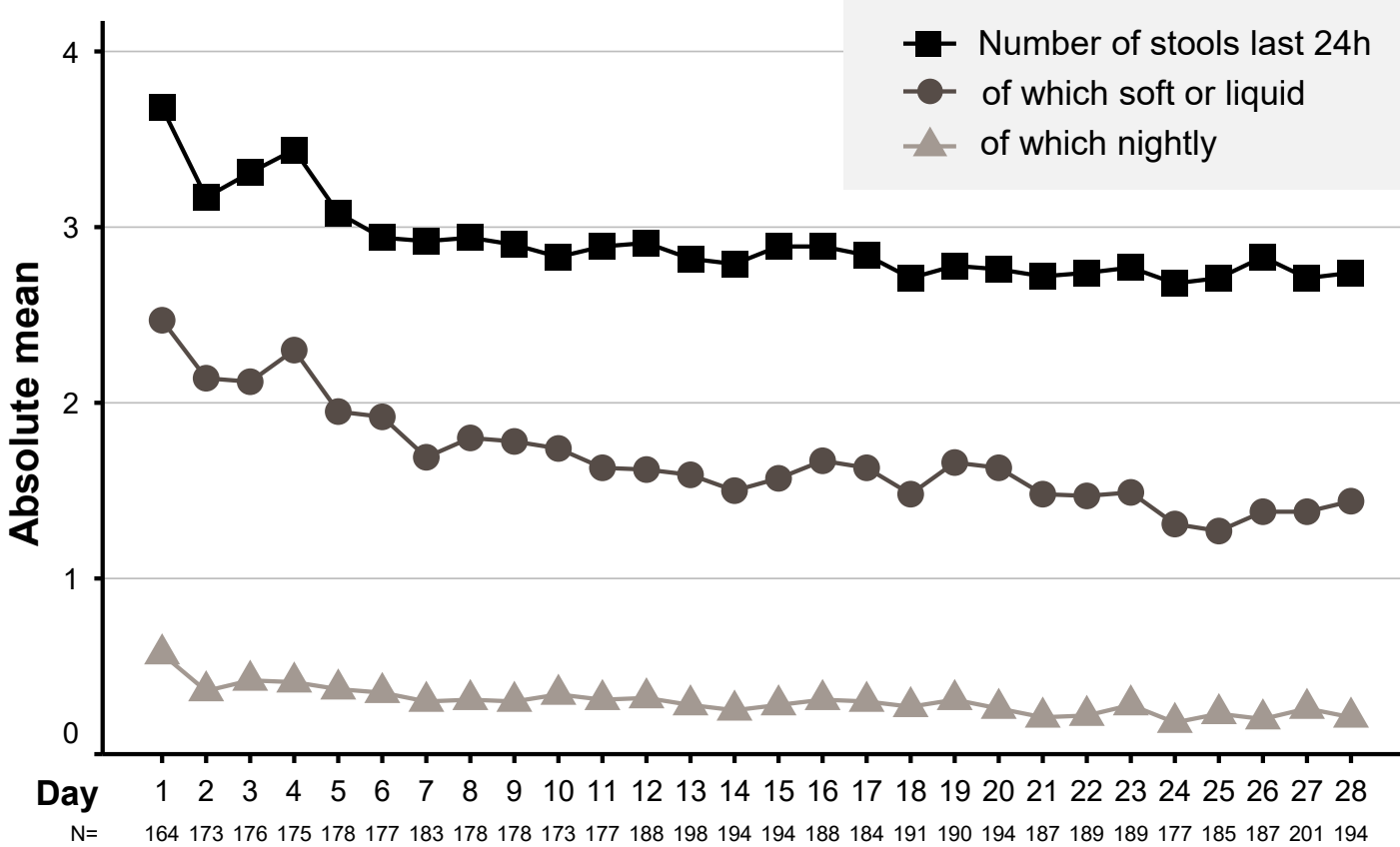


Fig. 1a. In patients with CD, the stools frequency mean decreased from 3.7 to 2.7, of soft or liquid stools from 2.5 to 1.4, from d1 to d28, respectively.

Nightly stools within the first 4 weeks of GUS

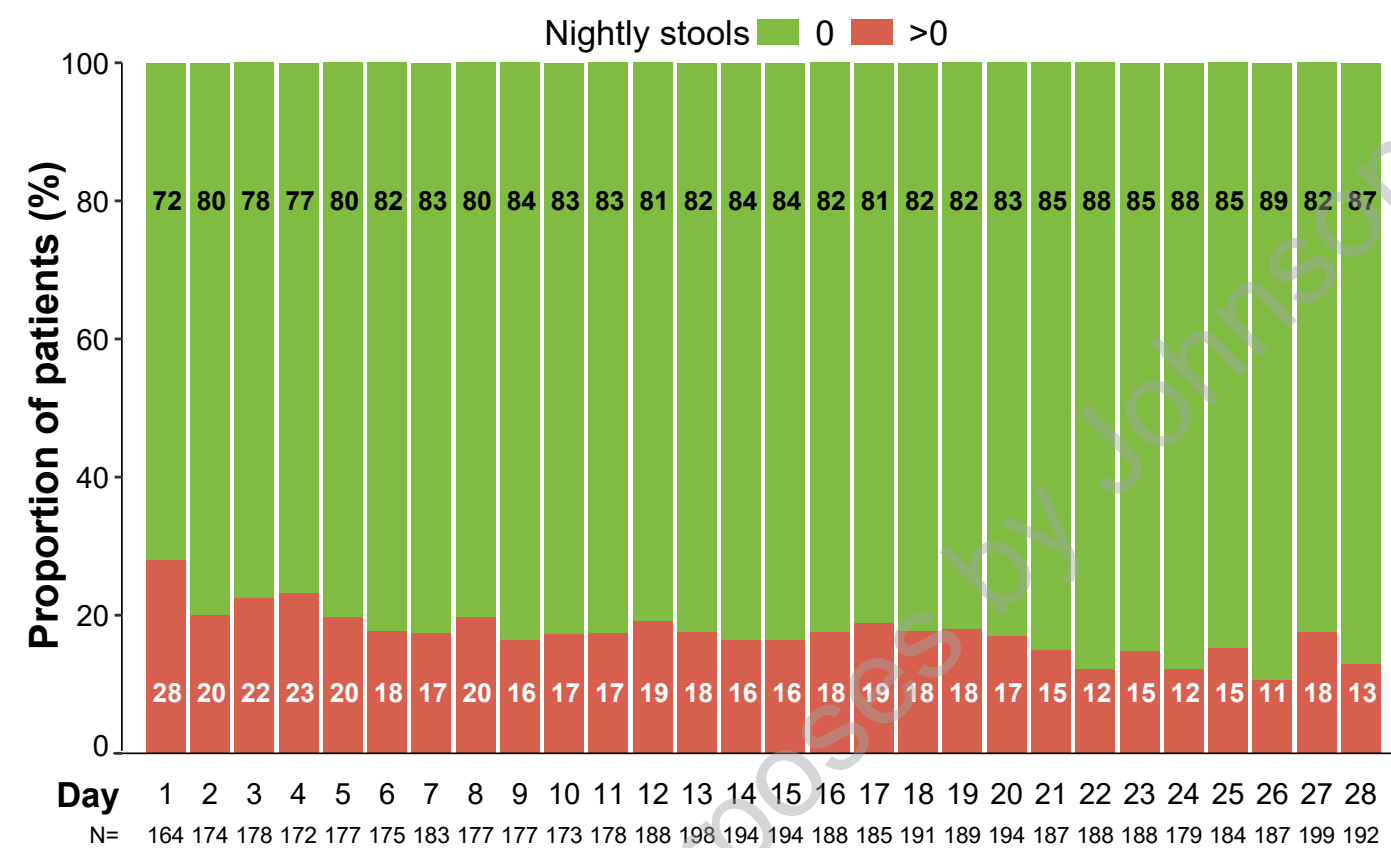


Fig. 2a. The number of patients with CD with nightly stools decreased by 53.7% during 28 days after the initial dose

Bowel urgency within the first 4 weeks of GUS

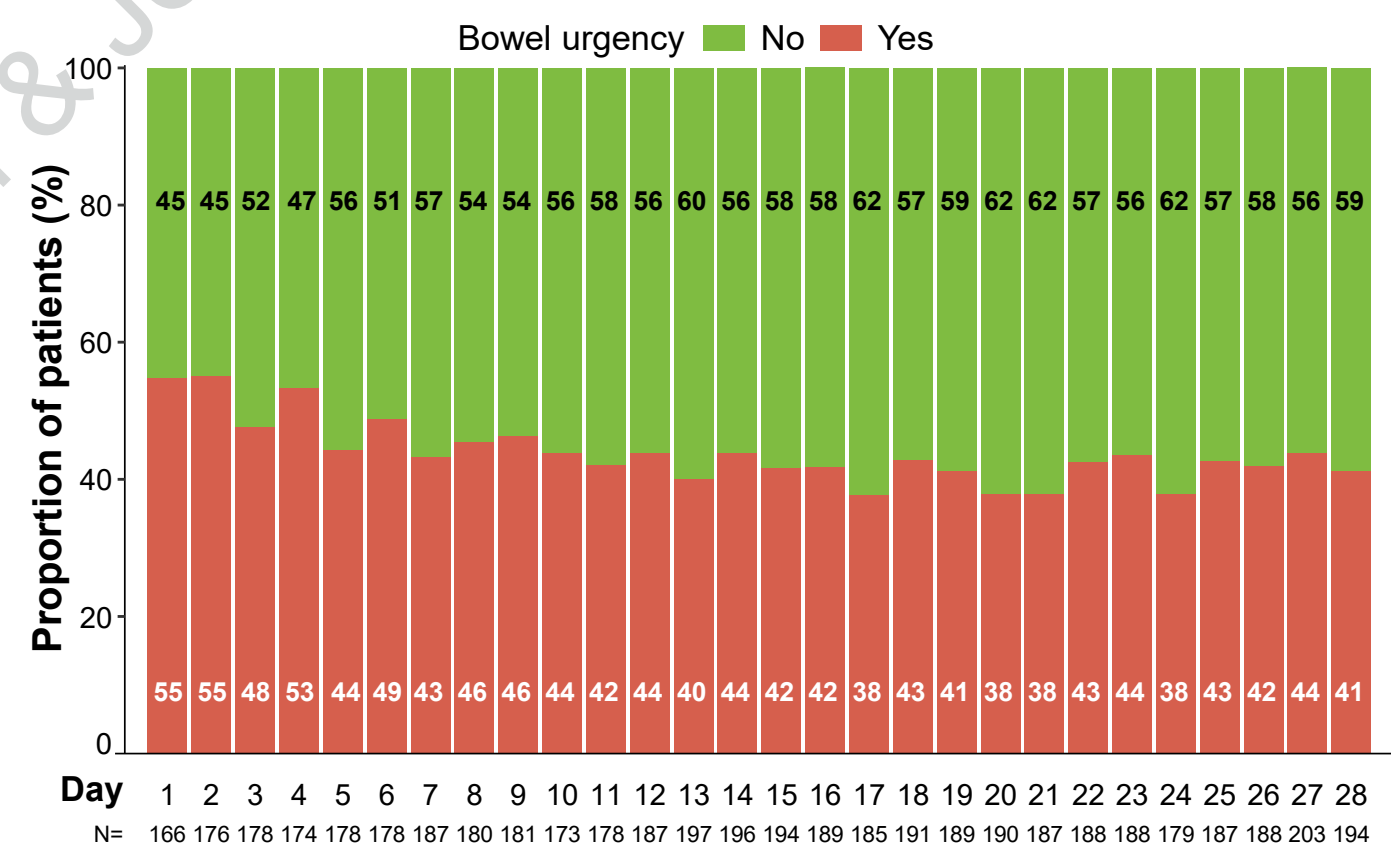


Fig. 3a. During 28 days after the first dose of GUS, the number of patients with CD with bowel urgency decreased by 24.8%.

Rectal bleeding within the first 4 weeks of GUS

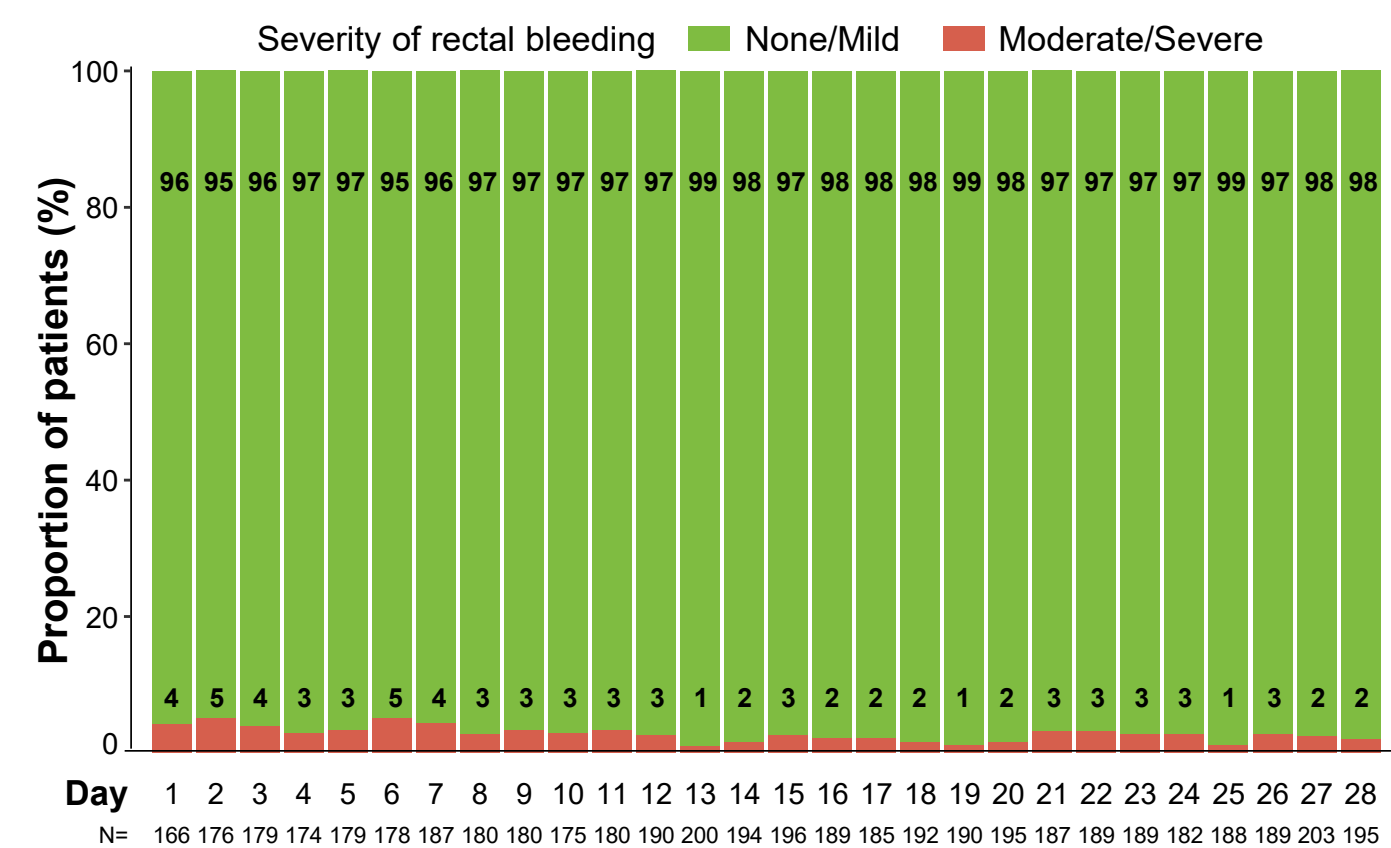


Fig. 4a. 4.2% of patients with CD had moderate or severe rectal bleeding at d1, which was reduced to 2.1% at d28.

Abdominal pain within the first 4 weeks of GUS

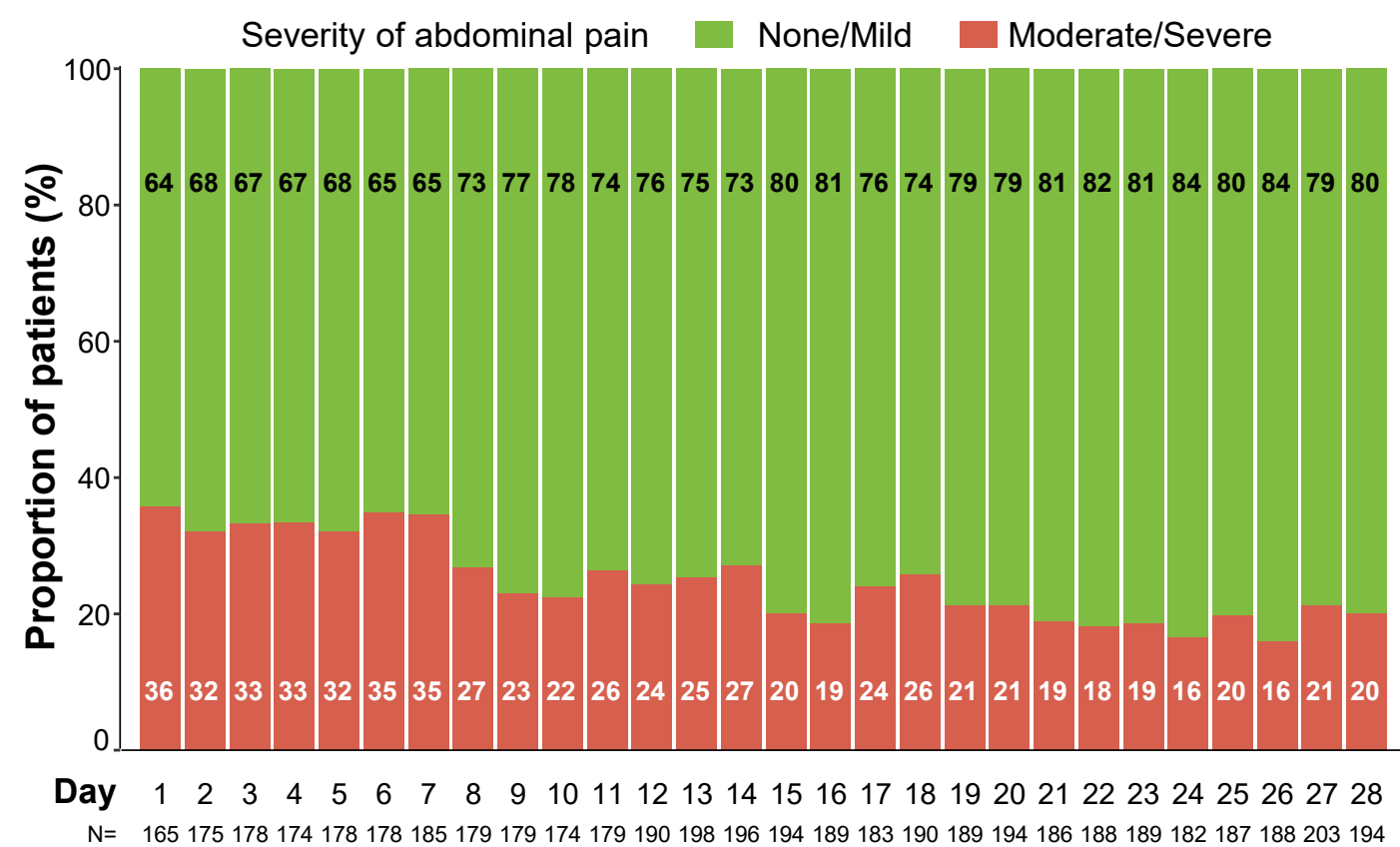


Fig. 5a. Moderate or severe abdominal pain was reported by 35.8% at d1 and by 20.1% of patients with CD at d28, a relative reduction of 43.9%.

ULCERATIVE COLITIS COHORT

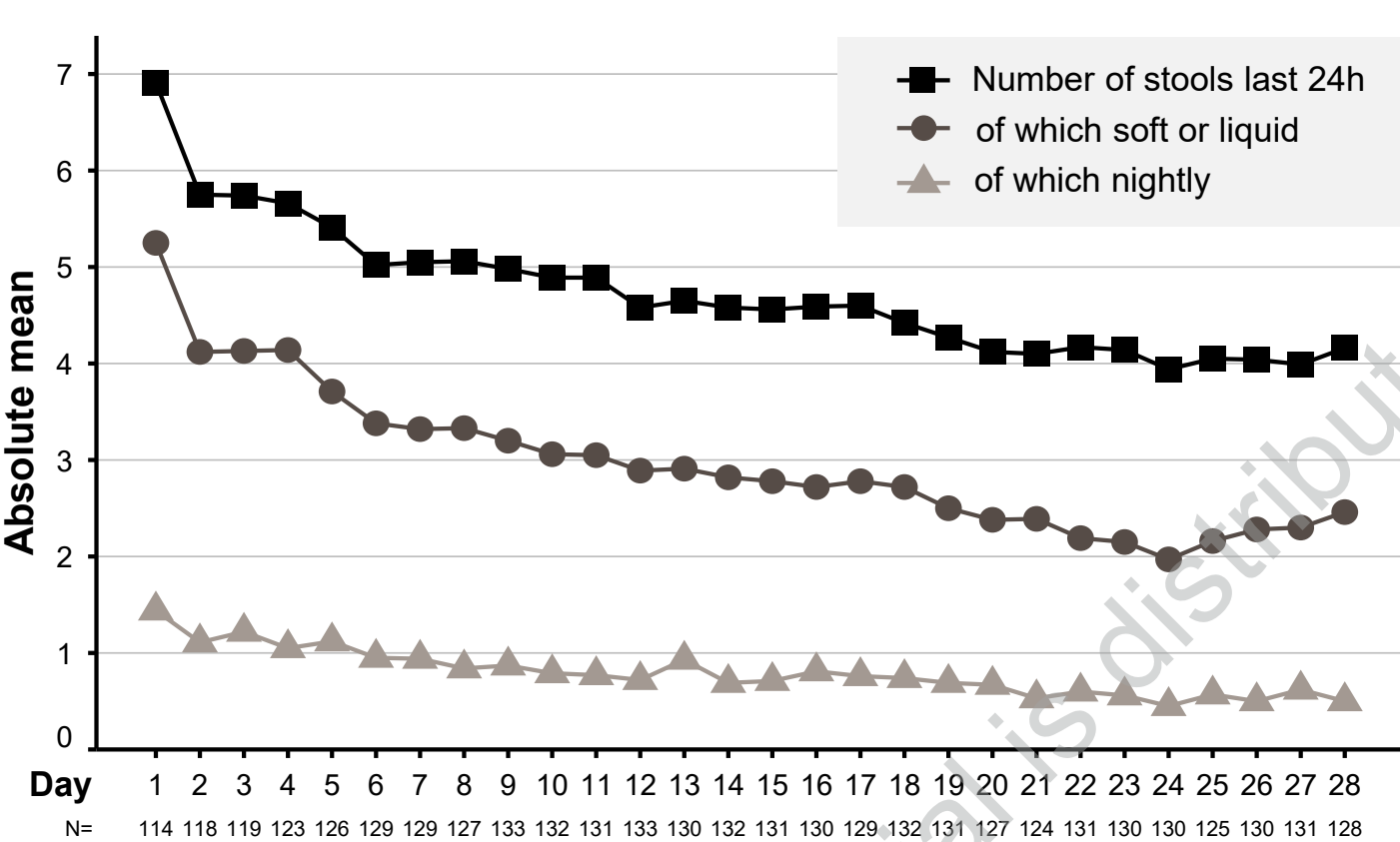


Fig. 1b. In patients with UC, the stool frequency mean decreased from 6.9 (d1) to 4.2 (d28). Soft or liquid stools were decreased from 5.3 (d1) to 2.5 (d28).

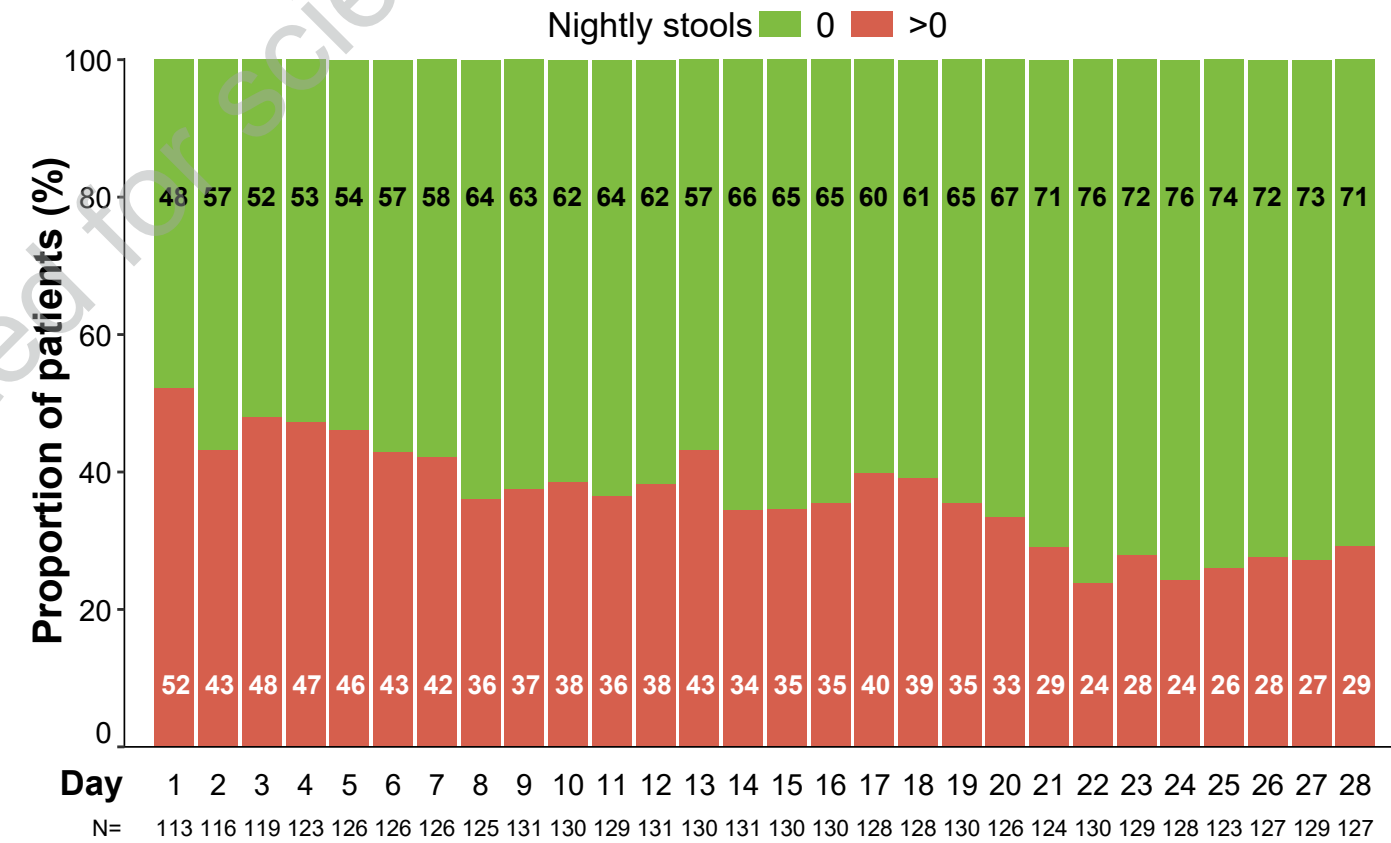


Fig. 2b. Among patients with UC who reported nightly stools, the first induction dose of GUS decreased the frequency by 44.3% by d28.

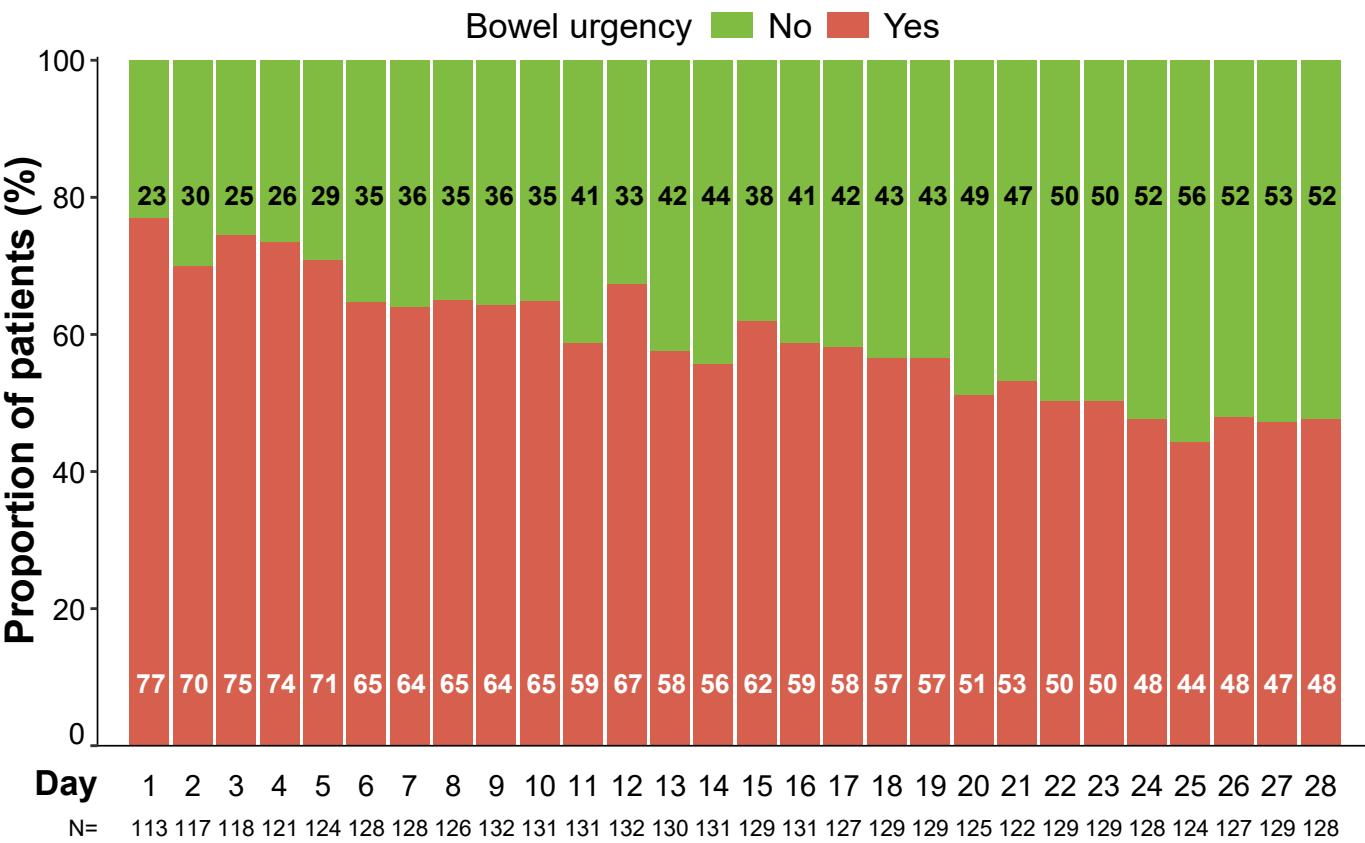


Fig. 3b. The number of patients with UC who do not experience bowel urgency more than doubled from 23.0% on d1 to 52.3% on d28.

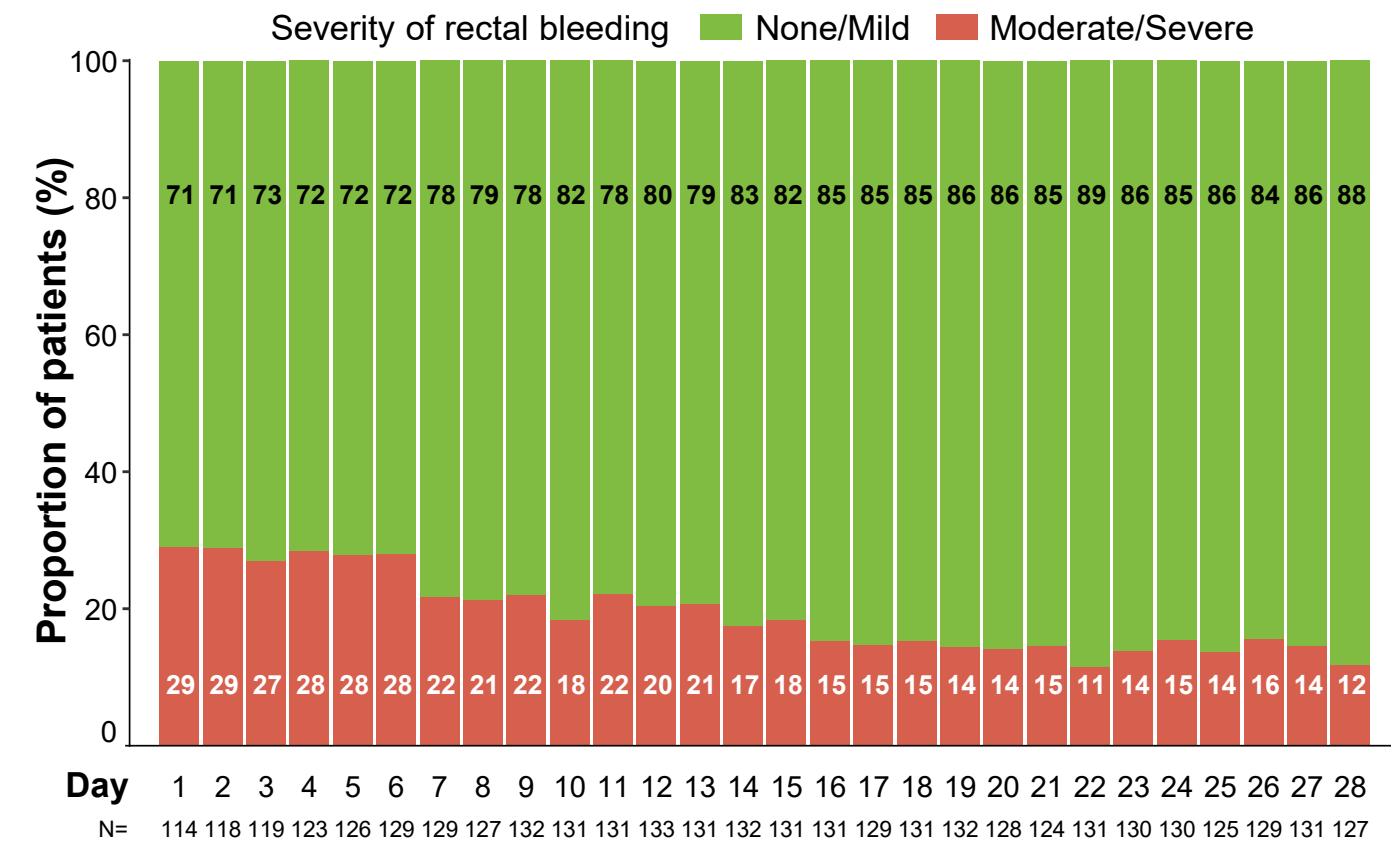


Fig. 4b. The proportion of patients with UC with moderate or severe rectal bleeding at d1 (29.0%) reduced to a proportion of 11.8% at d28.

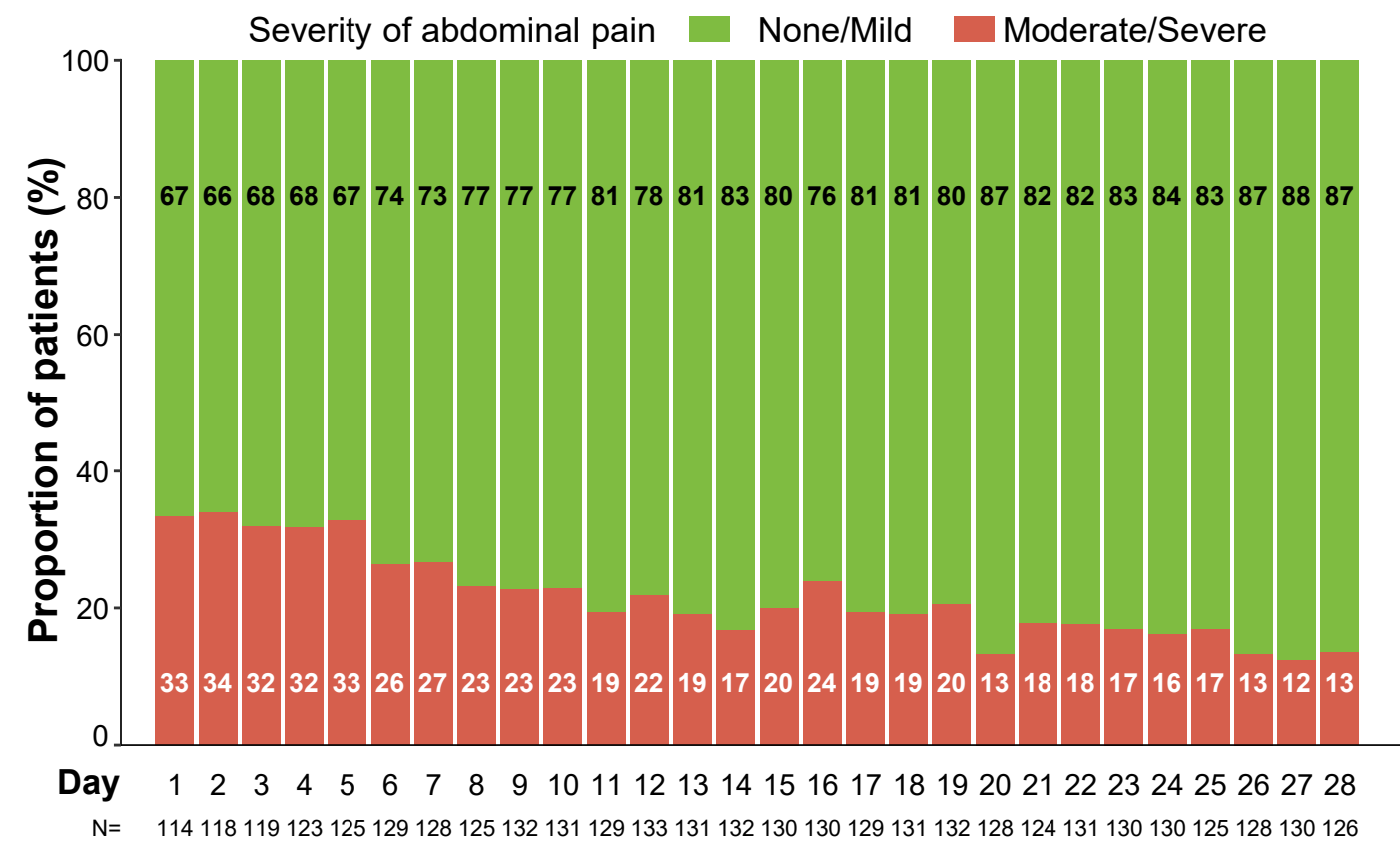


Fig. 5b. Within 28 days after the first induction dose of GUS, the proportion of patients with UC with no or mild abdominal pain increased from 66.7% to 86.5%.