Evaluation of Complete Bowel Symptomatic Remission (CBSR) in Patients With Moderately to Severely Active Ulcerative Colitis

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Key Takeaways

- **The UC bowel symptom composite score is a validated assessment of bowel symptom severity in pts with UC**
- **CBSR was associated with better endoscopic outcomes and normalised HRQoL**
- **Using CBSR to assess efficacy in UC clinical trials may be a more comprehensive, stringent, and differential approach than the current convention (ie, based solely on rectal bleeding and stool frequency from Mayo score components)**

Background

Symptomatic remission in ulcerative colitis (UC) has historically been defined by 2 items on patient-reported outcomes (PROs) from Mayo Score components: stool frequency (SF) and rectal bleeding (RB)

More comprehensive symptom assessment in UC should also account for bowel urgency (BU) and abdominal pain (AP)

Objective

This analysis aimed to validate a novel PRO composite measure that includes AP, BU, RB, and SF using daily diary data from the UC Patient-Reported Outcomes Signs and Symptoms instrument (UC-PRO/SS)[1]

Methods

Population: Phase 3 ASTRO Study

- ASTRO (NCT05528510) is a phase 3, randomised, double-blind, PBO-controlled, parallel-group, multicenter trial[2]
- **Pts** (N=418):
  - Adults with moderately to severely active UC
  - History of inadequate response or intolerance to corticosteroids, immunosuppressants, biologics, Janus kinase inhibitors, and/or sphingosine 1-phosphate inhibitors (BIO/JAKi/S1Pi-IR) or were naïve to BIO/JAKi/S1Pi
- **Randomization** (1:1:1):
  - SC GUS 400 mg q4w (x3)→200 mg q4w
  - SC GUS 400 mg q4w (x3)→100 mg q8w
  - PBO
- **Pooled data** from the GUS and PBO groups collected from W0 to W12 were used to calculate and validate the UC bowel symptoms composite score

UC Bowel Symptom Measures

- Pts completed the UC-PRO/SS[1] electronic questionnaire daily for 10 consecutive days before q4w study visits from W0 through W12
- Composite bowel symptom score and remission outcomes were based on 4 items collected using the UC-PRO/SS module:
  - **AP** (pain in belly); range: 0 (no) to 4 (very severe)
  - **BU** (need a bowel movement right away); range: 0 (no) to 4 (very severe)
  - **RB** (blood in bowel movement); range: 0 (no) to 4 (always)
  - **SF** (number of bowel movements); range: 0 (0 times) to 7 (18 or more times)
- **UC bowel symptom composite:** sum of the 4 bowel item scores, ranging from 0 (no symptoms) to 19 (worst symptom severity)
- **Complete bowel symptomatic remission (CBSR):** complete resolution (score of 0) of AP, BU, and RB, with a daily SF score ≤1 (corresponding to ≤4 stools per day)

Endpoint Validation

- IBDQ and PROMIS-29 (HRQoL metrics) were used as anchors for validation analyses
- Correlations between UC bowel symptom composite scores and relevant IBDQ or PROMIS-29 components were evaluated
- Rates of W12 endoscopic endpoints are reported in subgroups with and without CBSR

*CBSR=complete bowel symptomatic remission, **GUS**=guselkumab, **HRQoL**=health-related quality of life, **IBDQ**=Inflammatory Bowel Disease Questionnaire, **PBO**=placebo, **PROMIS-29**=29-item patient-reported outcomes measurement information system, **pts**=participants, **q4w**=every 4 weeks, **q8w**=every 8 weeks, **SC**=subcutaneous, **W**=week.*

Results

All ASTRO pts had ≥1 bowel-related symptom at baseline

	Baseline (N = 393)	Week 12 (N = 387)
Pts with bowel symptoms per UC-PRO/SS, n (%)		
AP, score >0	322 (82%)	181 (47%)
BU, score >0	352 (90%)	211 (55%)
RB, score >0	382 (97%)	167 (43%)
SF, score >1	387 (98%)	259 (67%)
CBSR[a]	0	78 (20%)

	Baseline (N = 393)
UC-PRO/SS bowel symptom scores	
AP, 0 [no]–4 [very severe]	1.7 (1.1)
BU, 0 [no]–4 [very severe]	2.2 (1.1)
RB, 0 [no]–4 [always]	2.6 (0.9)
SF, 0 [0 times]–7 [18 or more times]	3.5 (1.2)
UC Bowel Symptom Composite,[b] **0–19**	10.0 (3.1)

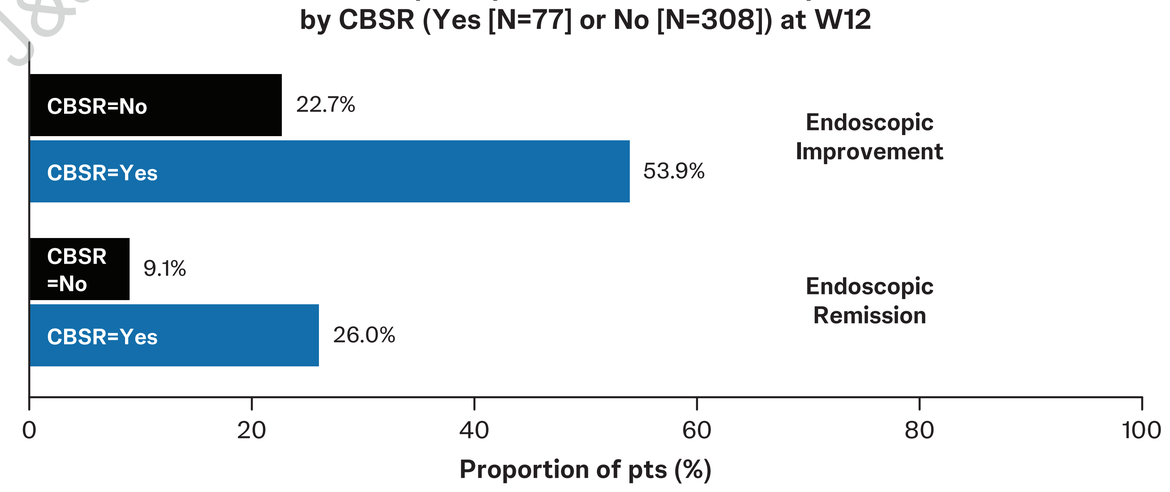
Data are reported as mean (SD) unless otherwise indicated. Data are for all ASTRO treatment groups (i.e., GUS and PBO) combined. [a]CBSR defined as AP=0, BU=0, RB=0, and SF≤1 (i.e., ≤4 times daily). [b]UC Bowel Symptom Composite defined as the sum of the AP, BU, RB, and SF scores, ranging from 0 (no symptoms) to 19 (worst symptom severity). SD=standard deviation.

Correlations between UC bowel symptom composite scores and relevant IBDQ or PROMIS-29 components were moderate to strong

	UC-PRO/SS Bowel Symptom Scores				
	AP	BU	RB	SF	Composite
IBDQ					
Total score	-0.54	-0.58	-0.52	-0.55	**-0.66**
Domain scores					
Bowel	-0.59	-0.63	-0.58	-0.58	**-0.71**
Emotional	-0.48	-0.51	-0.46	-0.47	**-0.57**
Systematic	-0.49	-0.45	-0.40	-0.45	**-0.53**
Social function	-0.43	-0.54	-0.44	-0.54	**-0.59**
PROMIS-29					
Physical health summary score	-0.44	-0.46	-0.37	-0.46	**-0.52**
Mental health summary score	-0.51	-0.46	-0.38	-0.45	**-0.53**
Item scores					
Physical function	-0.32	-0.36	-0.29	-0.35	**-0.40**
Anxiety	0.42	0.37	0.33	0.32	**0.43**
Depression	0.36	0.28	0.27	0.26	**0.33**
Fatigue	0.40	0.36	0.30	0.36	**0.42**
Sleep disturbance	0.37	0.30	0.21	0.31	**0.36**
Social participation/daily activity	-0.41	-0.48	-0.39	-0.47	**-0.52**
Pain interference	0.55	0.46	0.37	0.45	**0.53**
Pain intensity NRS	0.60	0.44	0.36	0.39	**0.52**

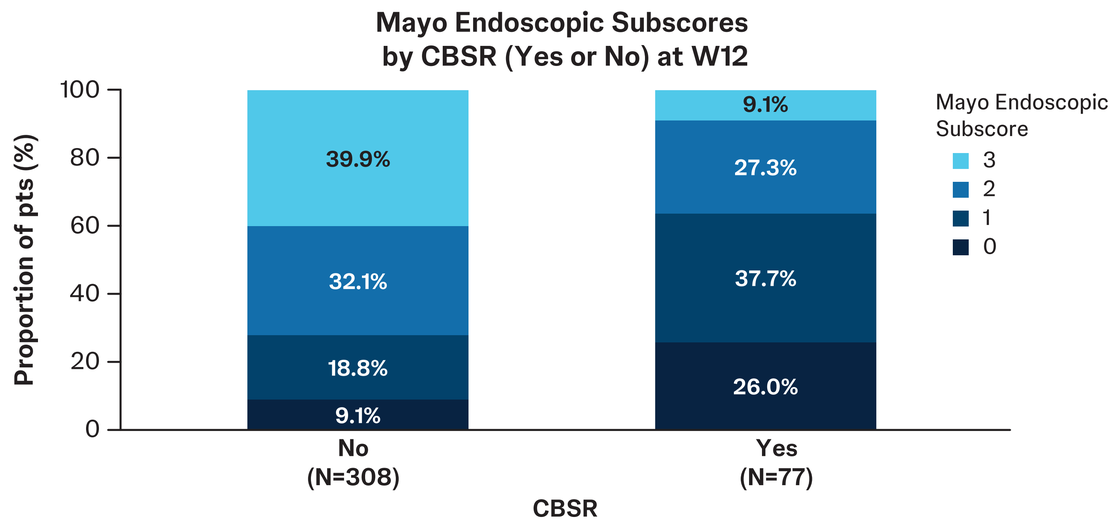
*Data presented are Spearman's correlation coefficients; all p-value <0.0001. Higher scores in IBDQ domains indicate better outcomes. Higher PROMIS-29 domain scores indicate more severe symptoms or higher functioning. Higher UC-PRO/SS symptom scores indicate more severe symptoms. **NRS**=numeric rating scale.*

More pts with CBSR achieved endoscopic improvement and endoscopic remission vs those without CBSR



CBSR: complete resolution of AB, BU, and RB (rounded weekly average score of '0') with SF score ≤1 (i.e., ≤4 times per day), based on UC-PRO/SS. Raw scores (observed) were used without adjustment. Endoscopic improvement: Mayo endoscopic subscore of 0, or 1 with no friability present on the endoscopy. Endoscopic remission: Mayo endoscopic subscore of 0. Data are for all ASTRO treatment groups (i.e., GUS and PBO) combined.

Mayo endoscopic subscores were lower (better) among pts with CBSR vs those without CBSR



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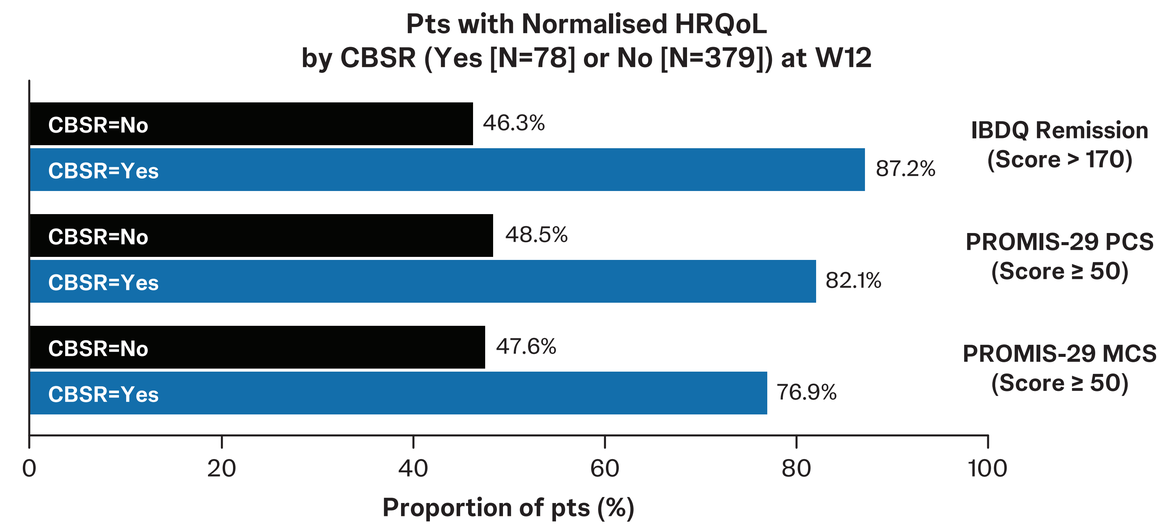
More pts with CBSR achieved HRQoL normalisation vs those without CBSR



*CBSR: complete resolution of AB, BU, and RB (rounded weekly average score of '0') with SF score ≤1 (i.e., ≤4 times per day), based on UC-PRO/SS. Normalised HRQoL: disease-specific IBDQ total score >170; generic PROMIS-29 PCS or MCS T-score ≥50. Raw scores (observed) were used without adjustment. Data are for all ASTRO treatment groups (i.e., GUS and PBO) combined. **MCS**=mental health component score; **PCS**=physical health component score.*

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