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

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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, randomized, 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) or were naïve to BIO/JAKi/S1Pi
- **Randomization** (1:1:1):
  - SC GUS 400 mg q4w (×3)→200 mg q4w
  - SC GUS 400 mg q4w (×3)→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)
- **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

AP=abdominal pain, BIO/JAKi/S1Pi-IR=biologics, Janus kinase inhibitors, and/or sphingosine 1-phosphate inhibitors, BU=bowel urgency, CBSR=complete bowel symptom remission, GUS=ipsekumab, HRQoL=health-related quality of life, IBDQ=Inflammatory Bowel Disease Questionnaire, PBO=placebo, PROMIS-29=Patient-Reported Outcomes Measurement Information System 29-item profile, pts=patients, q4w=every 4 weeks, q8w=every 8 weeks, RB=rectal bleeding, SC=subcutaneous, SF=stool frequency, UC=ulcerative colitis, UC-PRO/SS=Ulcerative Colitis Patient-Reported Outcomes Signs and Symptoms, W=Week.

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)**

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)

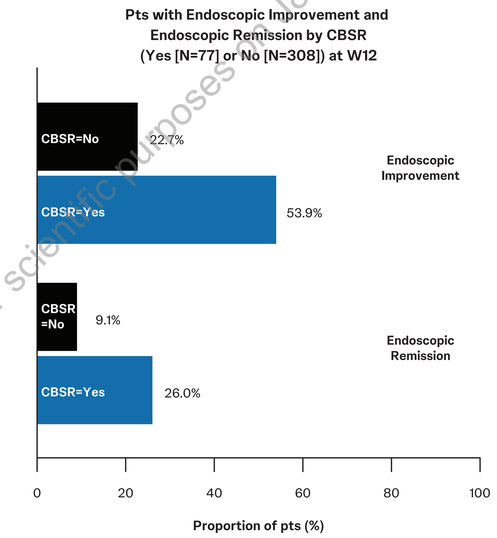
Data are reported as mean (SD) unless otherwise indicated. Data are for all ASTRO treatment groups (i.e., GUS and PBO) combined. [a]CBSR defined as AP=0, BU=0, RB=0, and SF≤1 (i.e., ≤4 times daily). [b]UC Bowel Symptom Composite defined as the sum of the AP, BU, RB, and SF scores, ranging from 0 (no symptoms) to 19 (worst symptom severity). AP=abdominal pain, BU=bowel urgency, CBSR=complete bowel symptom remission, N=total number of patients, n=number of patients in subgroup, RB=rectal bleeding, SD=standard deviation, SF=stool frequency, UC-PRO/SS=Ulcerative Colitis Patient-Reported Outcomes Signs and Symptoms.

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**

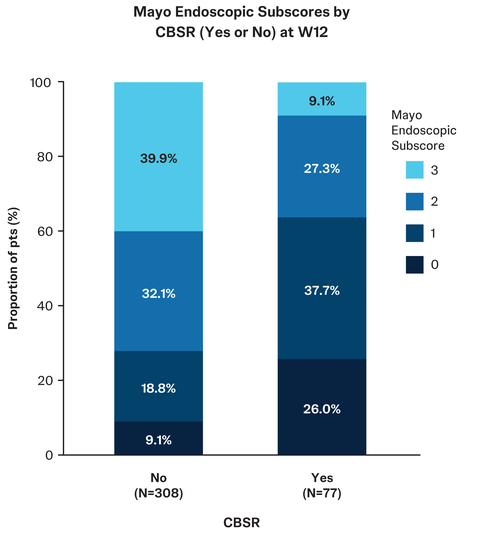
Data presented are Spearman's correlation coefficients; all p-value <0.0001. Higher scores in IBDQ domains indicate better outcomes. Higher PROMIS-29 domain scores indicate more severe symptoms or higher functioning. Higher UC-PRO/SS symptom scores indicate more severe symptoms. AP=abdominal pain, BU=bowel urgency, IBDQ=Inflammatory Bowel Disease Questionnaire, NRS=numeric rating scale, PROMIS-29=Patient-Reported Outcomes Measurement Information System 29-item profile, RB=rectal bleeding, SF=stool frequency, UC-PRO/SS=Ulcerative Colitis Patient-Reported Outcomes Signs and Symptoms.

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



CBSR: complete resolution of AP, 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. AP=abdominal pain, BU=bowel urgency, CBSR=complete bowel symptom remission, GUS=ipsekumab, N=total number of patients, PBO=placebo, pts=patients, RB=rectal bleeding, SF=stool frequency, UC-PRO/SS=Ulcerative Colitis Patient-Reported Outcomes Signs and Symptoms, W=Week.

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



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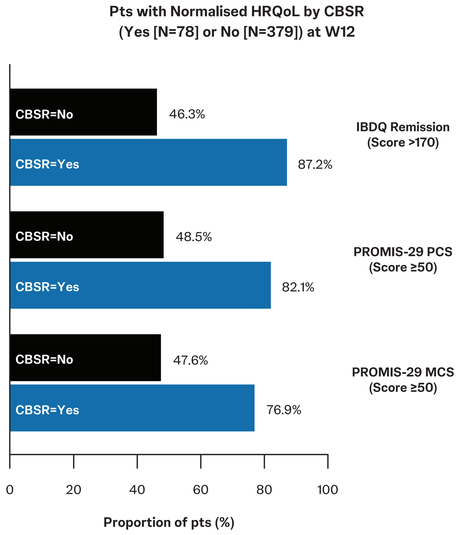
More pts with CBSR achieved HRQoL normalisation vs those without CBSR



CBSR: complete resolution of AP, 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. AP=abdominal pain, BU=bowel urgency, CBSR=complete bowel symptom remission, GUS=ipsekumab, HRQoL=health-related quality of life, IBDQ=Inflammatory Bowel Disease Questionnaire, MCS=mental component score, N=total number of patients, PBO=placebo, PCS=physical component score, PROMIS-29=Patient-Reported Outcomes Measurement Information System 29-item profile, pts=patients, RB=rectal bleeding, SF=stool frequency, UC-PRO/SS=Ulcerative Colitis Patient-Reported Outcomes Signs and Symptoms, W=Week.

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