

Urgences intestinales et incontinence fécale: 2 problèmes méconnus dans les MICI

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Nancy - FRANCE

Disclaimer

- This is a medical education event with the support of Janssen-Cilag NV.
- This presentation represents the opinion of the speaker and not necessarily the opinion of Janssen.
- This presentation may include discussions on off-label use of drugs.

Disclosure of conflicts of interest

Grants from AbbVie, MSD, and Takeda; reports stock options from CTMA; and reports personal fees from AbbVie, Allergan, Alma, Amgen, Applied Molecular Transport, Arena, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Celltrion, Enterome, Entera, Ferring, Fresenius, Genentech, Gilead, Hikma Pharmaceuticals, Index Pharmaceuticals, Janssen, Lilly, MSD, Mylan, Nestlé, Norgine, Oppilan Pharma, OSE Immunotherapeutics, Pfizer, Pharmacosmos, Roche, Samsung Bioepis, Sandoz, Sterna Biologicals, Sublimity Therapeutics, Takeda, Tillots, and Vifor.

IBD and health-related quality of life — Discovering the true impact ☆

The primary objective of this survey was to obtain an international perspective of the impact of IBD on patients' lives. 4670 patients completed the survey.

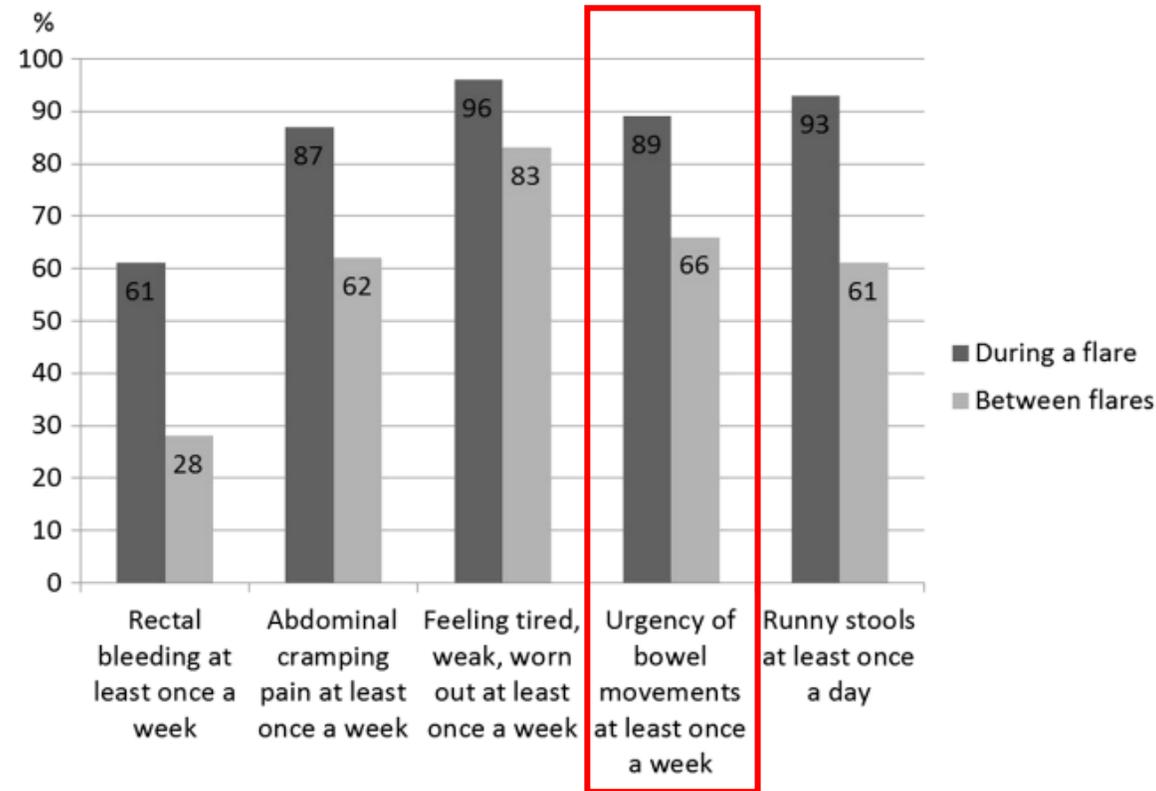


Figure 3 Symptoms during and in between flare-ups.

Critical Situations in Daily Life as Experienced by Patients With Inflammatory Bowel Disease

TABLE 2. Summary of the Subcategories, Categories, and Main Area Describing Critical Incidents in Daily Life Related to Inflammatory Bowel Disease^a

Main Area	Category	Subcategory
The bowels rule life	Losing control of the bowel	Being in a hurry and not reaching the toilet in time (39) Having to go to the toilet frequently (32) Having to sit on the toilet for a long time (8) Not having access to toilets with privacy (9)
	Having a body that smells	Smelling of feces (7) Receiving and living with a stoma (2) Leakage of stool, pus, and blood (8)
	Being unable to meet own and others' expectations	Being hospitalized (2) Making unreasonable demands and exposing one's children to risks (5) Being forced to turn down job offers (7) Unable to perform one's work (14) Being a burden to relatives/friends (11) Not being able to perform certain activities (19) Not being able to plan activities in advance and making definite plans (23)
	Not being believed or seen	Not receiving the care considered necessary (12) Being met by incomprehension on the part of authorities (11) Being denied use of a toilet (3) Not being visited when hospitalized (2)
	Experiencing frustration due to side effects and ineffective treatment	Side effects of treatment (5) Experiencing that treatment does not work (3) Need to undergo extensive examinations (2)

^aNumber of incidents in parentheses, a total of 224 critical incidents.

A Qualitative Research for Defining Meaningful Attributes for the Treatment of Inflammatory Bowel Disease from the Patient Perspective

This research employed a three-step approach:

- a literature review to identify a broad list of attributes
- a focus group meeting including patients and clinicians to assess the relevance of the attributes
- two rounds of voting to name and define each attribute

Table 2 Final list of attributes

Domain	Attribute name/descriptor
Efficacy	Abdominal pain
	Other disease-related pain (anal pain, joint pain/stiffness or eye pain, etc.)
	Bowel urgency (when you feel the need for a bowel movement, you have to rush to the toilet to avoid an accident)
	Fatigue (an overwhelming sense of continuing tiredness, lack of energy or feeling exhausted that is not relieved by rest or sleep)
Complications/risk	Risk of cancer and serious infections within the next 10 years (excluding non-melanoma skin cancer)
	Risk of mild to moderate complications (mild/moderate complications means nausea, vomiting, headache, non-serious infections, lab abnormalities, skin reactions, and infusion reactions)
	Aesthetic complications related to treatment (hair loss, unintentional weight change, facial hair, acne, puffy face)
Health-related quality of life	Emotional status
	Sexual life
	Social life and relationships (interpersonal interactions)

A simple clinical colitis activity index

Table 3 Clinical scoring system for the Simple Clinical Colitis Activity Index

Symptom	Score
Bowel frequency (day)	
1-3	0
4-6	1
7-9	2
>9	3
Bowel frequency (night)	
1-3	1
4-6	2
Urgency of defecation	
Hurry	1
Immediately	2
Incontinence	3
Blood in stool	
Trace	1
Occasionally frank	2
Usually frank	3
General well being	
Very well	0
Slightly below par	1
Poor	2
Very poor	3
Terrible	4
Extracolonic features	1 per manifestation

ACG Clinical Guideline: Ulcerative Colitis in Adults

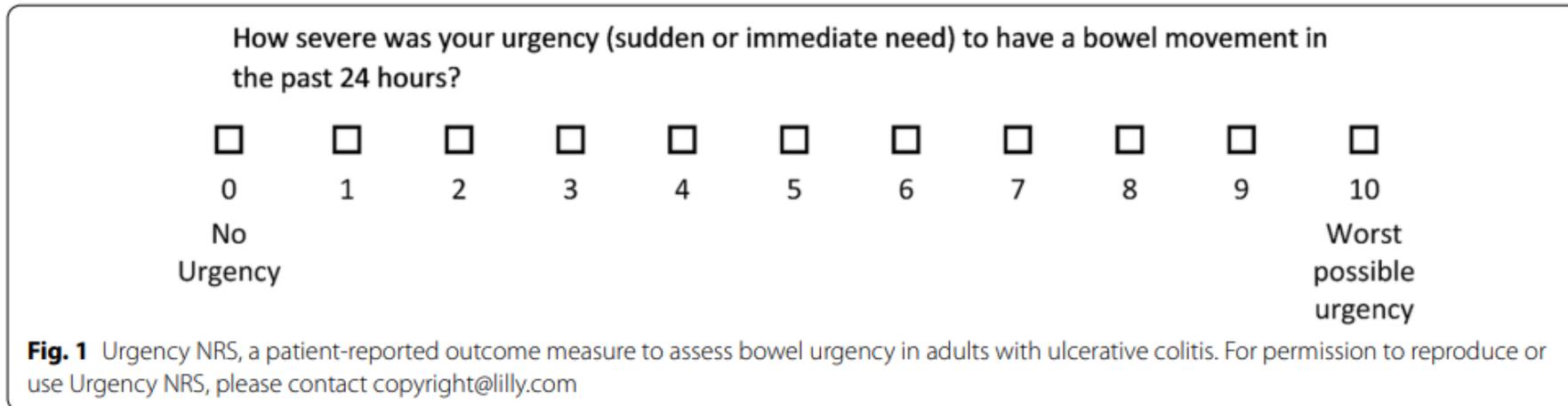
Table 4. Proposed American College of Gastroenterology Ulcerative Colitis Activity Index^a

	Remission	Mild	Moderate-severe	Fulminant
Stools (no./d)	Formed stools	<4	>6	>10
Blood in stools	None	Intermittent	Frequent	Continuous
Urgency	None	Mild, occasional	Often	Continuous
Hemoglobin	Normal	Normal	<75% of normal	Transfusion required
ESR	<30	<30	>30	>30
CRP (mg/L)	Normal	Elevated	Elevated	Elevated
FC (μg/g)	<150-200	>150-200	>150-200	>150-200
Endoscopy (Mayo subscore)	0-1	1	2-3	3
UCEIS	0-1	2-4	5-8	7-8

Incorporating patient experience into drug development for ulcerative colitis: development of the Urgency Numeric Rating Scale, a patient-reported outcome measure to assess bowel urgency in adults



The Urgency Numeric Rating Scale (NRS) is a new patient-reported measure to assess severity of bowel urgency in adults with UC.



Impacts of perianal disease and faecal incontinence on quality of life and employment in 1092 patients with inflammatory bowel disease

TABLE 3 Quality of life in patients with symptoms of faecal incontinence (\geq monthly) compared to those without

Variable	Incontinent	Continent	P-value
SF-36 (mean, IQR)			
Physical functioning	75 (65-95)	84 (75-100)	<0.0001
Limitations due to physical health	49 (0-100)	63 (25-100)	<0.0001
Limitations due to emotional problems	49 (0-100)	64 (33-100)	<0.0001
Energy/fatigue	47 (30-65)	53 (35-75)	<0.0001
Emotional well-being	71 (60-84)	74 (64-88)	0.005
Social functioning	63 (50-75)	73 (63-100)	<0.0001
Pain	66 (45-80)	75 (68-90)	<0.0001
General health	41 (25-55)	48 (30-65)	<0.0001
Number of patients \leq 65 years	483 (87%)	379 (90%)	
Job description			0.002*
No job	121 (25%)	67 (18%)	
Paid job	312 (65%)	282 (74%)	
Voluntary work	50 (10%)	30 (8%)	

Anorectal
dysfunction:
A very disabling
symptom

Chronic UC

Anorectal manometry

- 11 patients with active UC
- 7 patients with quiescent disease
- 18 healthy controls

UC, ulcerative colitis
Loening-Baucke V, et al. *Am J Gastroenterol* 1989;84:892–97

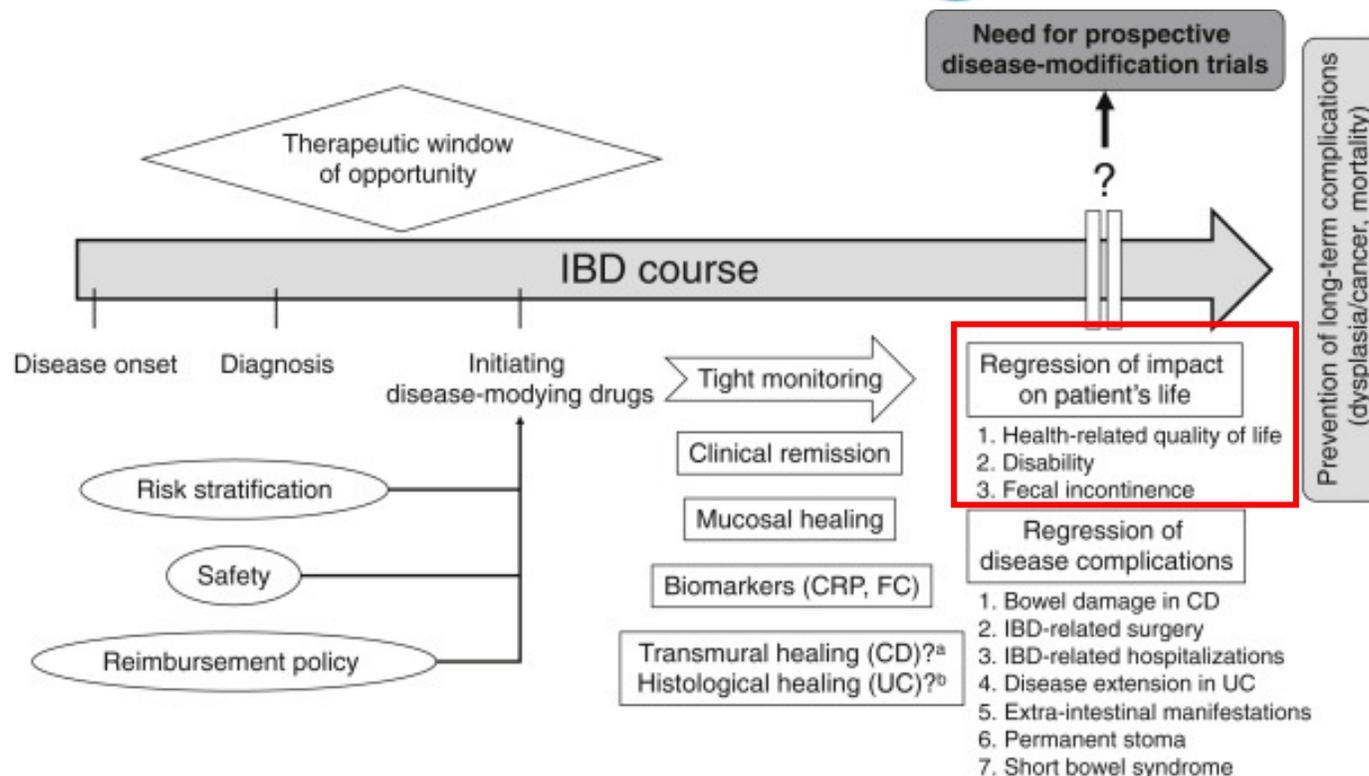
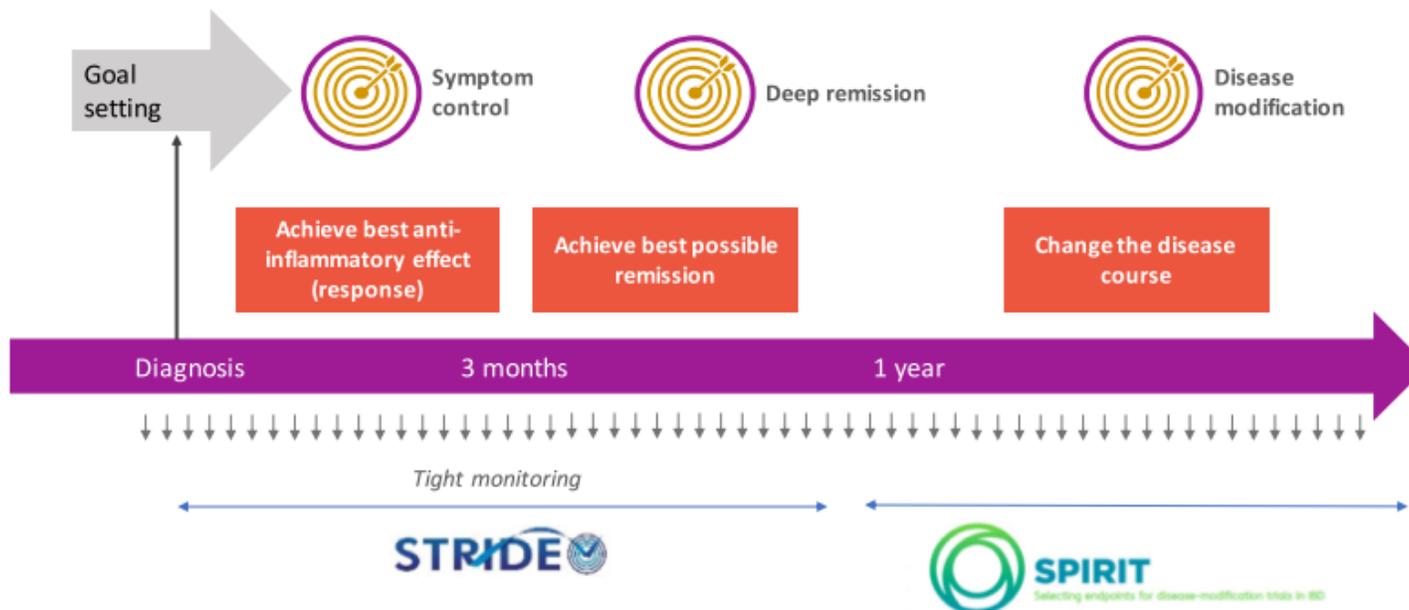
Rectal compliance was significantly reduced in patients with **active** and **quiescent** disease

Faecal continence can be permanently damaged
if persistent rectal inflammation is not timely treated

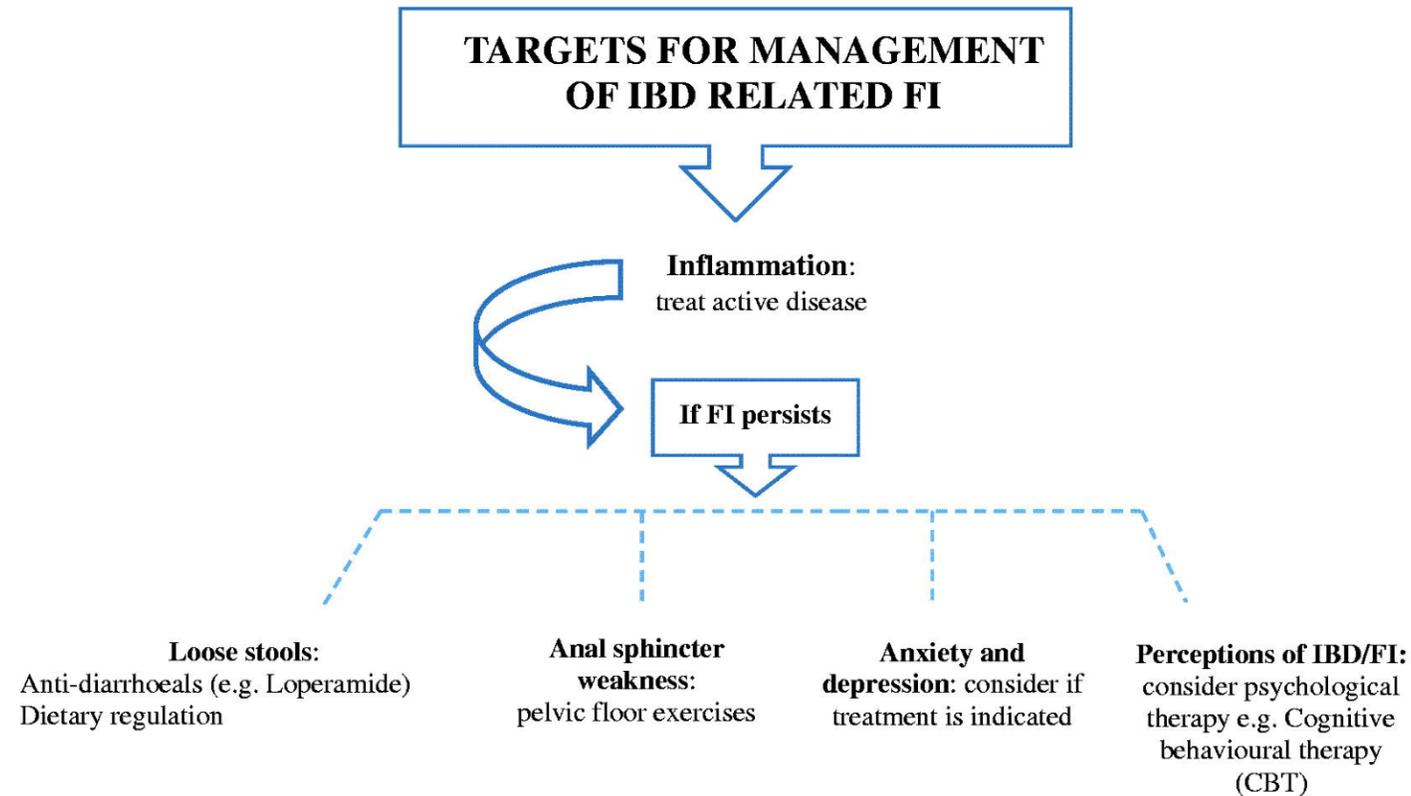
Fecal incontinence in IBD: The Nancy experience. Kurt et al. DLD 2022
“Approximately one fifth of IBD patients reported FI” in the biologics era

Selecting End Points for Disease-Modification Trials in Inflammatory Bowel Disease: the SPIRIT Consensus From the IOIBD

Proposed statement	Voting results		
	Ballots, No.	Votes at last ballot, % (n/N)	Patients' rating on a 0-10 VAS, median (IQR)
1. Health-related quality of life	1	93 (28/30)	10 (8-10) (n = 23)
Tool: Combination of IBDQ-36 + SF-36	2	85 (17/20)	
2. Disability	1	92 (23/25)	8 (5-10) (n = 23)
Tool: IBD Disability Index	1	83 (24/29)	
3. Fecal incontinence	2	85 (17/20)	8 (6-10) (n = 23)
Tool: Jorge and Wexner (Cleveland score)	1	76 (13/17)	
Time point: 6 to 12 months	1	100 (24/24)	
		50 (6 mo)/50 (12 mo)	



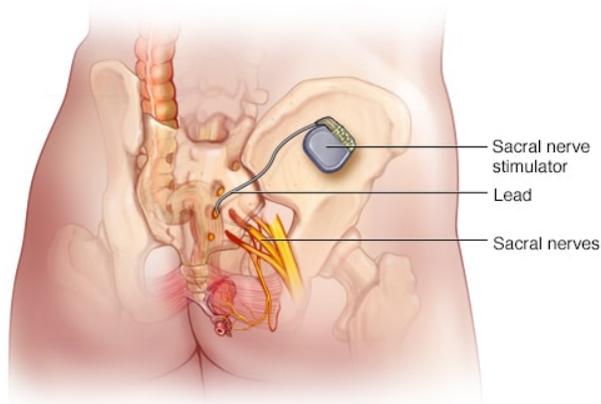
Targets for interventions for faecal incontinence in inflammatory bowel disease: a systematic review



Neuromodulation

What is sacral nerve stimulation?

An invasive method consisting in continuously stimulating the third or fourth sacral root by using a stimulation electrode implanted close to the root and a subcutaneous stimulator placed near the iliac fossa or in the lumbar region.



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Sacral Nerve Stimulation can Improve Continence in Patients with Crohn's Disease with Internal and External Anal Sphincter Disruption

Véronique Vitton, M.D.¹ • Julie Gigout, M.D.¹ • Jean-Charles Grimaud, M.D.¹ • Michel Bouvier, Ph.D.¹ • Ariadne Desjeux, M.D.¹ • Pierre Orsoni, M.D.²

Study from **2008** presenting **5 CD patients** with **anoperineal lesions** and **incontinence symptoms** for more than 1 year

Main Findings

- **Continence was improved in all treated patients.**
- **Improvement in urgency was reported by four patients.**
- At the end of the follow-up period, the median Wexner's score significantly improved from 15 to 6 and the median number of daily stools decreased from 7 to 2.
- The patients' quality of life also increased significantly.

Pelvic floor muscle training

Pelvic floor behavioral treatment for fecal incontinence and constipation in quiescent inflammatory bowel disease

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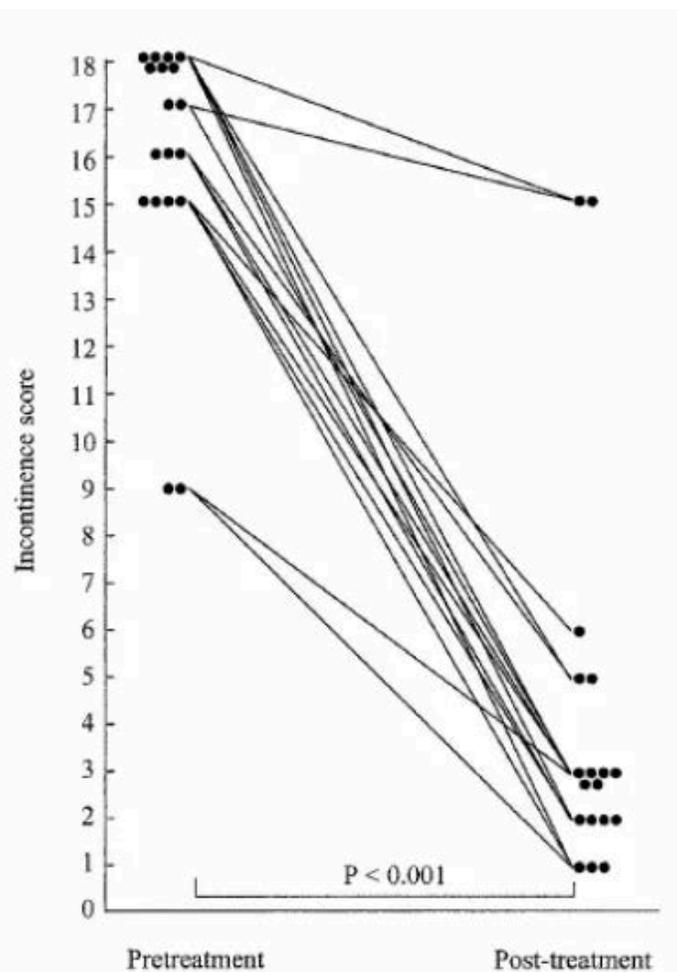
Table 2. Key symptoms targeted by treatment and response, *n* (%).

	Pre-treatment <i>n</i> = 34	Responders <i>n</i> = 21	Non-responders <i>n</i> = 8	Drop-outs <i>n</i> = 5
Urgency without incontinence	5 (15)	3/5 (60)	1	1
Urgency with fecal incontinence	12 (35)	7/12 (58)	3	2
Fecal incontinence with evacuation difficulty	11 (32)	8/11 (73)	1	2
Evacuation difficulty only	6 (18)	3/6 (50)	3	0

Main Findings

- 72% patients who completed treatment (62% of all patients) reported moderate or substantial improvement (patient rating of 6 or 7).
- **60% patients presenting urgency without incontinence reported moderate or substantial improvement.**
- Symptom scores ($p < .001$), IBD-specific quality of life ($p < .008$) and illness perception scores ($p < .003$) significantly improved.
- General quality of life, and anxiety and depression scores, did not change significantly.

Tricyclic antidepressants in urgency?



	Pretreatment	Posttreatment	P Value
Median resting anal pressure			
Daytime	64	68	NS
Nocturnal	26	16	NS
Median resting rectal pressure			
Daytime	32	32	NS
Nocturnal	12	12	NS
Median maximum anal squeeze pressure	108	123	NS
Internal sphincter relaxations			
Median no. per hour	3.1	3.3	NS
Median anal pressure	38	34	NS
Median rectal pressure	30	32	NS
Rectal motor complexes			
Median no. per hour	4.5	1.2	<0.05
Median anal pressure	49	66	<0.001
Median rectal pressure	94	58	<0.05

5-HT₃ antagonism

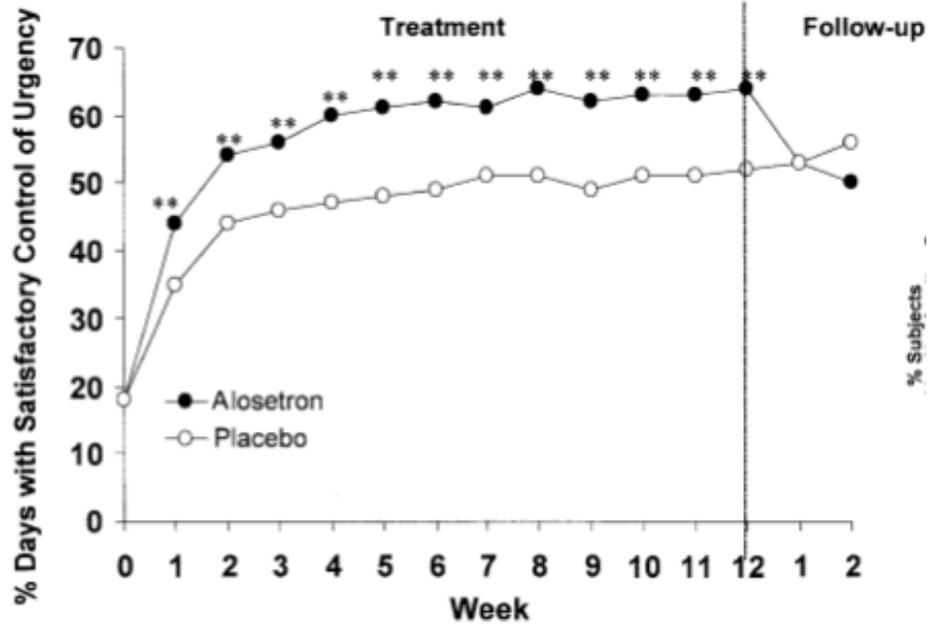


Table 2 Ondansetron effect on secondary outcomes

	ITT analysis (N=98)		PPA (N=90)	
	Treatment effect (95% CI)	p Value	Treatment effect (95% CI)	p Value
Days per week with pain	-0.3 (-0.7 to 0.1)	0.203	-0.3 (-0.7 to 0.2)	0.227
Days per week with urgency	-1.1 (-1.5 to -0.6)	<0.001	-1.1 (-1.6 to -0.7)	<0.001
Days per week with bloating	-0.7 (-1.1 to -0.3)	0.002	-0.7 (-1.1 to -0.3)	0.002
Pain score (0-3) None (0), mild (1), moderate (2) or severe (3)	-0.10 (-0.22 to 0.03)	0.119	-0.10 (-0.23 to 0.02)	0.103
Urgency score(0-3) None (0), mild (1), moderate (2) or severe (3)	-0.32 (-0.45 to -0.18)	<0.001	-0.33 (-0.47 to -0.19)	<0.001
Bloating score(0-3) None (0), mild (1), moderate (2) or severe (3)	-0.13 (-0.27 to 0.01)	0.070	-0.12 (-0.26 to 0.02)	0.103
Stool frequency reduction, %	11 (4 to 18)	0.001	11 (4 to 18)	0.002
Whole gut transit time increase*, h	10 (6 to 14)	<0.001	10 (6 to 14)	<0.001
Right colon transit time increase, h	2 (0 to 4)	0.064	2 (0 to 4)	0.082
Left colon transit time increase, h	6 (3 to 8)	<0.001	5 (3 to 8)	<0.001

Differences between ondansetron and placebo are presented.

*Numbers of patients available for analysis are 87/98 (89%) for ITT and 81/90 (90%) for PPA analysis. Lower numbers reflect patients who failed to take their markers or attend for the final X-ray.

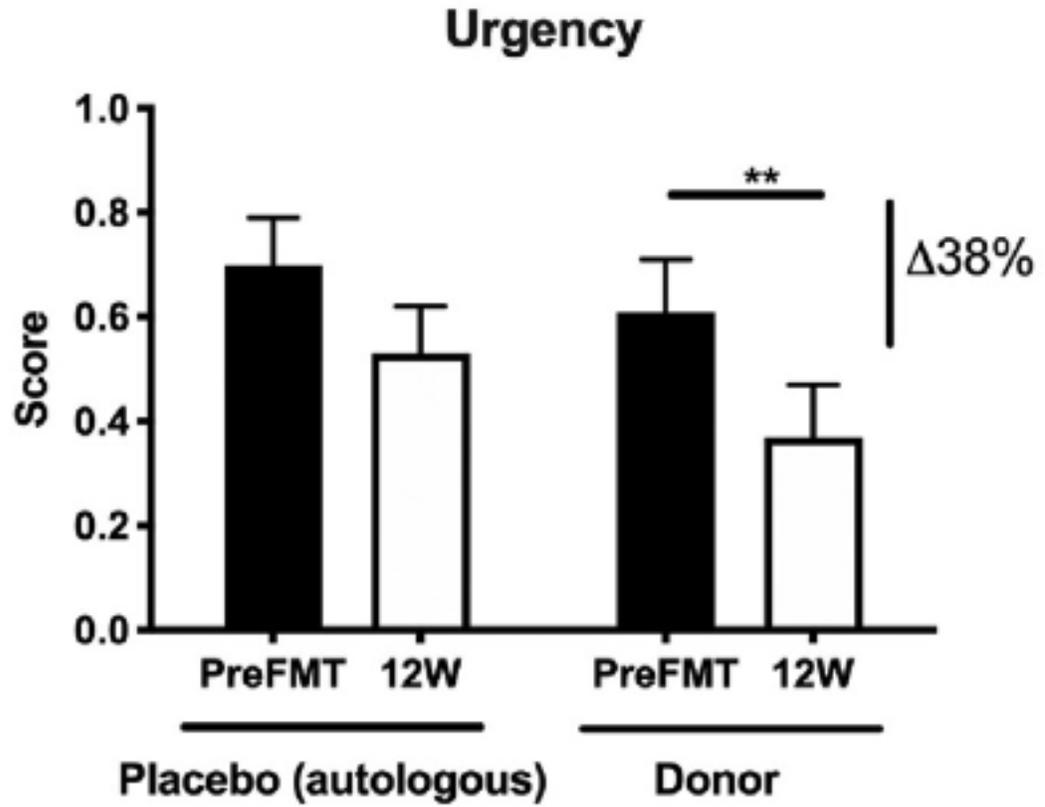
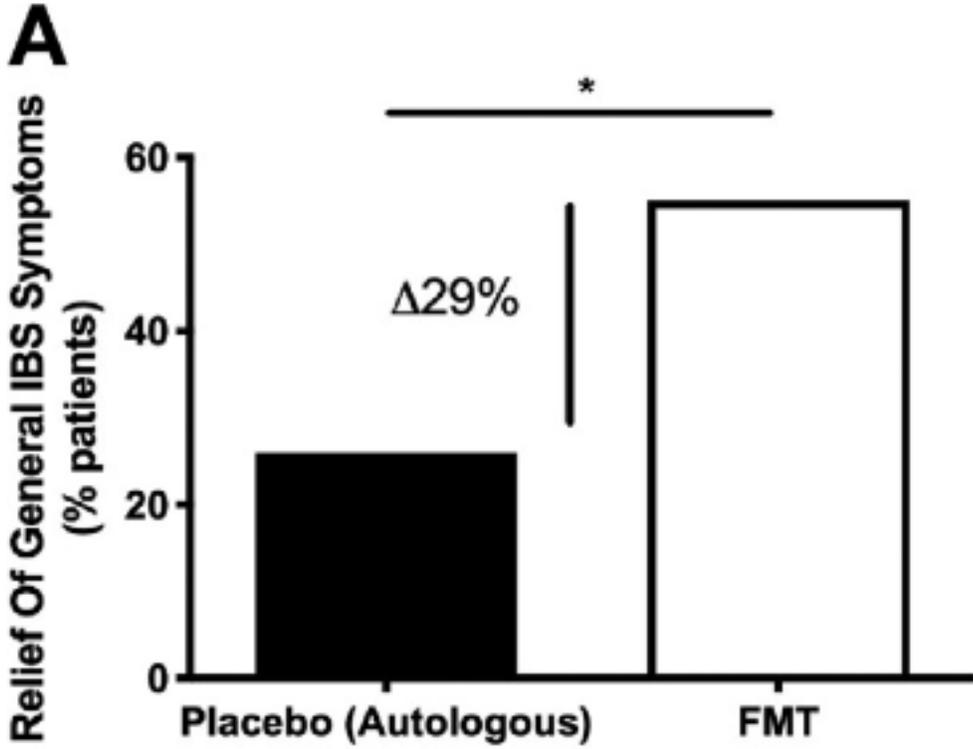
ITT, intention-to-treat; PPA, per protocol analysis.

Biofeedback?

	SC group (n = 52) ^a			BFB group (n = 40) ^a			p-Value
	Baseline	4-Month follow-up	Difference	Baseline	4-Month follow-up	Difference	
No. of daily stools	2.0 (2.0)	1.6 (0.9)	-0.4 (1.9)	2.4 (1.9)	1.7 (1.5)	-0.6 (0.8) ^{***}	0.002 ^{**}
No. of daily leaks	0.7 (1.6)	0.4 (0.5)	-0.4 (1.7) [*]	0.8 (0.7)	0.5 (0.9)	-0.3 (0.8) ^{**}	0.385
No. of daily faecal urgency	0.4 (0.3)	0.3 (0.3)	-0.1 (0.3)	0.5 (0.4)	0.3 (0.3)	-0.1(0.03) [*]	0.488
No. of daily normal stool perception	0.5 (0.3)	0.6 (0.3)	0.1 (0.3)	0.4 (0.4)	0.5 (0.4)	0.1 (0.4) [*]	0.400
No. of daily pads	0.8 (0.8)	0.6 (0.6)	-0.2(0.6) ^{**}	0.6 (0.9)	0.5 (0.6)	-0.1 (0.7)	0.694

Results expressed as the mean (standard deviation); SC, standard care; BFB: standard care + perineal retraining.

FMT in IBS



Supported online self-management versus care as usual for symptoms of fatigue, pain and urgency/incontinence in adults with inflammatory bowel disease (IBD-BOOST): study protocol for a randomised controlled trial

Table 1 The IBD-BOOST programme of studies on fatigue, pain and urgency in IBD

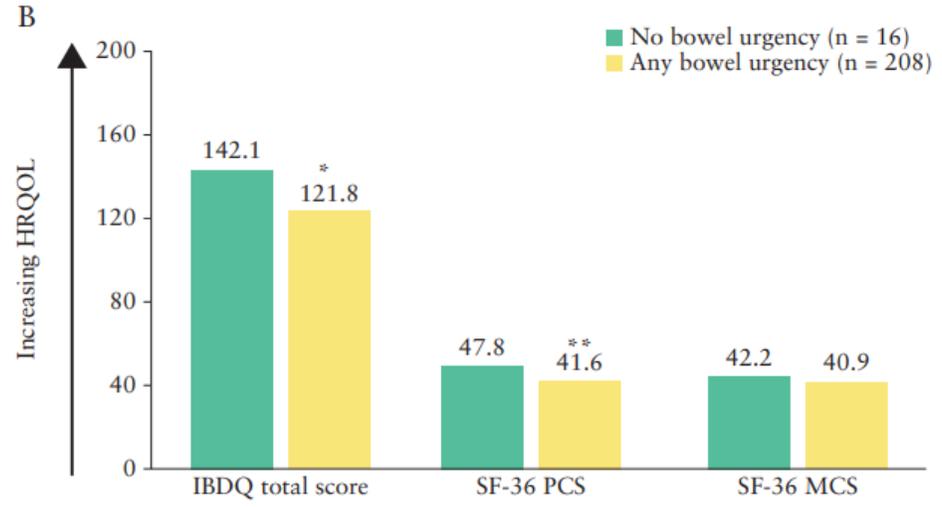
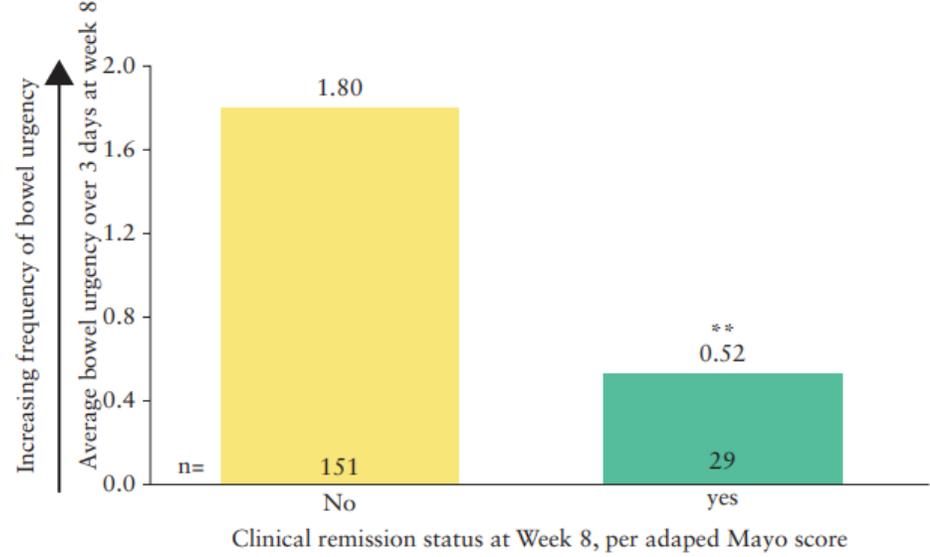
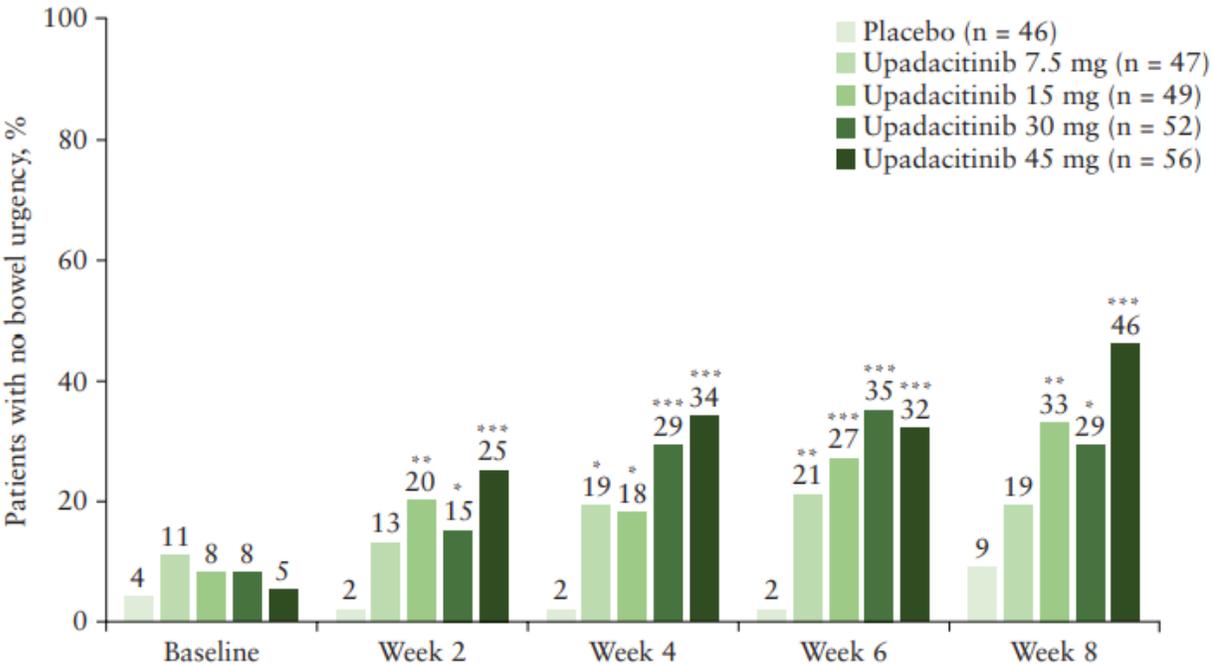
Stage 1 of the programme involved focus groups and interviews with people with IBD and IBD nurse specialists. In line with MRC guidance, these data were used alongside a theory- and person-based approach to develop a digital cognitive behavioural self-management intervention (IBD-BOOST). This stage is now completed.

Stage 2 of the programme involves a large cross-sectional survey of people with IBD to investigate the inter-relationships of IBD-related fatigue, pain and urgency/incontinence symptoms and the proportions wanting support to manage these symptoms. This stage is in progress and is not described further here.

Stage 3 of the programme is a non-randomised experimental study to test the effectiveness of a checklist and algorithm for identifying and treating medical causes of these IBD-related symptoms. The medical abnormalities detected in the study will be treated. This stage is not part of the current RCT and is not described further here.

Stage 4 (the current study) is an RCT of online self-management for symptoms of IBD fatigue, pain and urgency/incontinence (IBD-BOOST), with an embedded pilot study, health economics evaluation and process evaluation. Potential participants will already have completed the IBD survey (stage 2). Some of them will also have participated in stage 3.

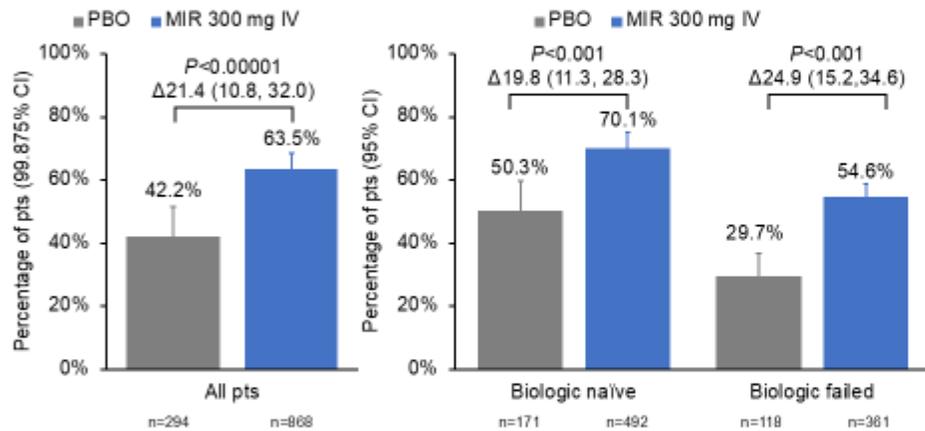
Upadacitinib Treatment Improves Symptoms of Bowel Urgency and Abdominal Pain, and Correlates With Quality of Life Improvements in Patients With Moderate to Severe Ulcerative Colitis



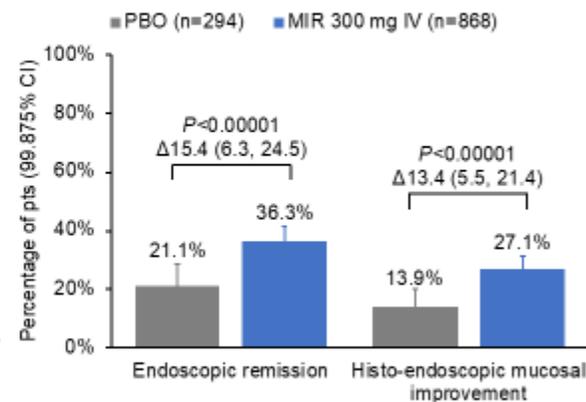
Induction treatment with upadacitinib demonstrated significant reduction in bowel urgency compared with placebo. These symptoms also correlate to clinical and HRQOL outcomes.

LUCENT 1: Efficacy and safety of mirikizumab as induction therapy in patients with moderately to severely active ulcerative colitis

Clinical response, wk 12



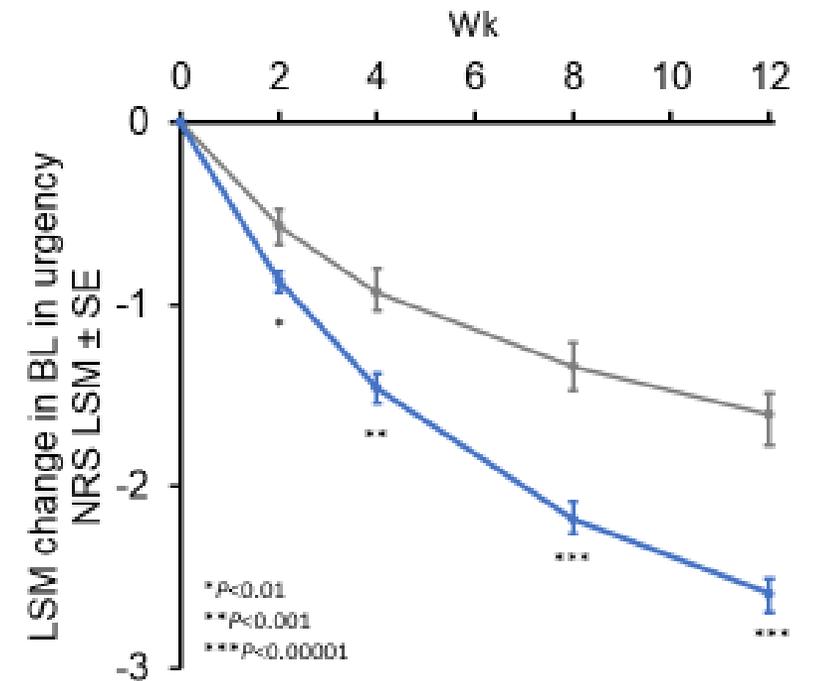
Endoscopic and histologic endpoints, wk 12



MIR 300 mg IV demonstrated efficacy in achieving key clinical and endoscopic outcomes vs PBO at wk 12 among pts with moderately to severely active UC.

NCT03518086. CI, confidence interval; IV, intravenous
D'Haens G, et al. ECCO 2022, [OP26](#)

Change from BL in bowel urgency



Conclusion

- **Fecal incontinence:** definition according to the Cleveland score
- **Bowel urgency:** sudden or immediate need to have a bowel movement
- Key symptoms for triggering clinical consideration of IBD diagnosis and defining severity of disease activity
- Negative impact on quality of life, social and emotional well-being
- Components in defining treatment goals of remission in IBD