

Presenting the Latest Data and Initiating Conversations in Crohn's Disease Management

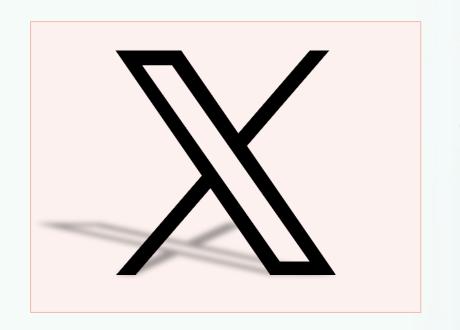


This activity is supported by an educational grant from Lilly.



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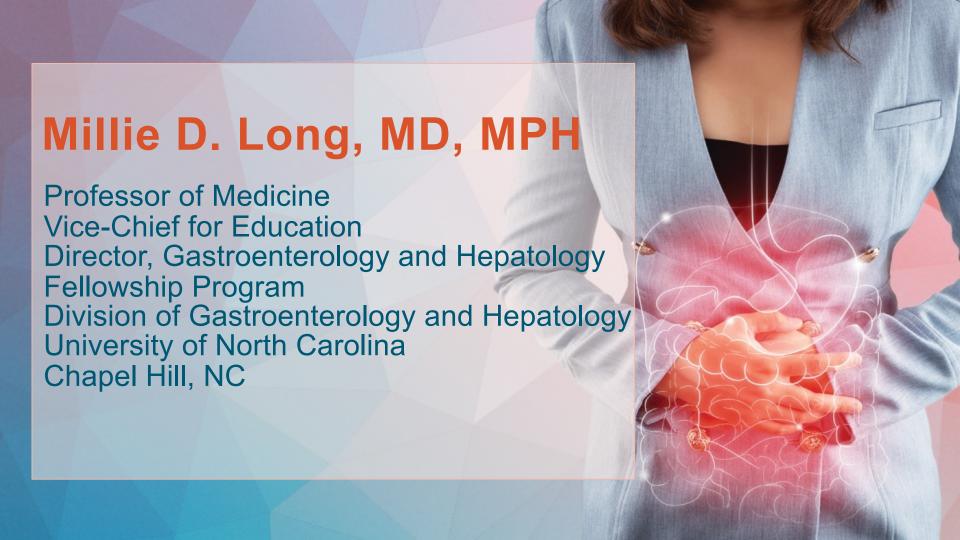


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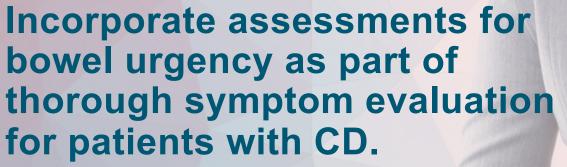
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Recognize the frequency of bowel urgency in patients with Crohn's disease (CD) and the impact on patient quality of life (QoL).

LEARNING OBJECTIVE





LEARNING OBJECTIVE



Engage patients in open communication about their bowel urgency as part of shared decision-making in order to improve clinical outcomes.

LEARNING OBJECTIVE



Audience Response



How often do you incorporate bowel urgency assessments into your evaluation of patients with Crohn's Disease (CD)?

- A. Always
- B. Usually
- C. Seldom
- D. Never



Symptom Impact in CD

Millie D. Long, MD, MPH

The Impact of Bowel Urgency: The Patient Perspective Cristina C.

Unmet Needs in Crohn's Disease





Risk stratification



Individualized therapy



Therapeutic ceiling and sequencing



Treatment for special populations



Improved monitoring strategies



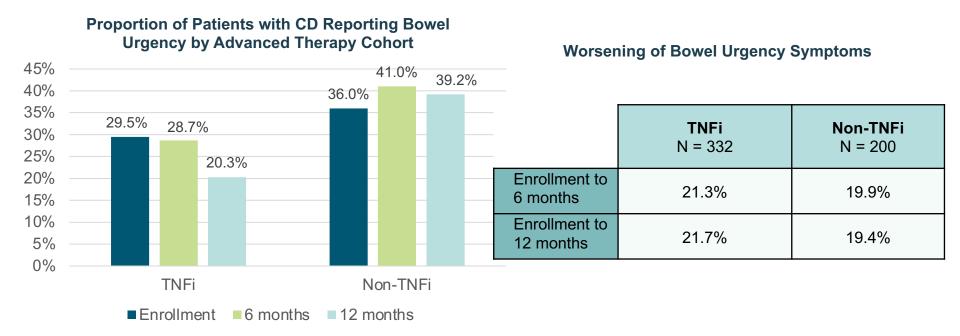
Therapeutic de-escalation strategies



Restoring quality of life



Patients with CD Experience Persistent Bowel Urgency Despite Use of Advanced Therapies





Symptoms Most Impacting QoL in CD





Symptoms Most Impacting QoL in CD



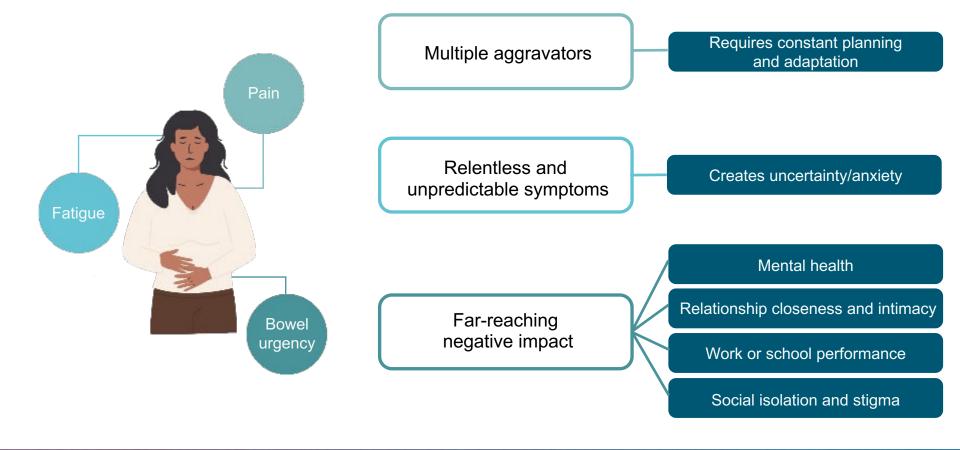
Multiple aggravators

Relentless and unpredictable symptoms

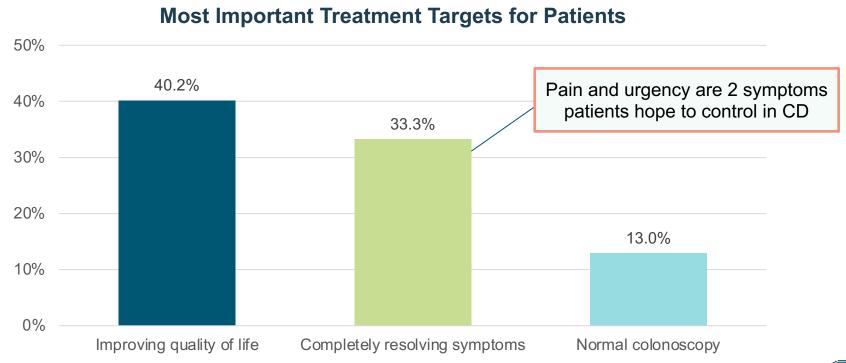
Far-reaching negative impact



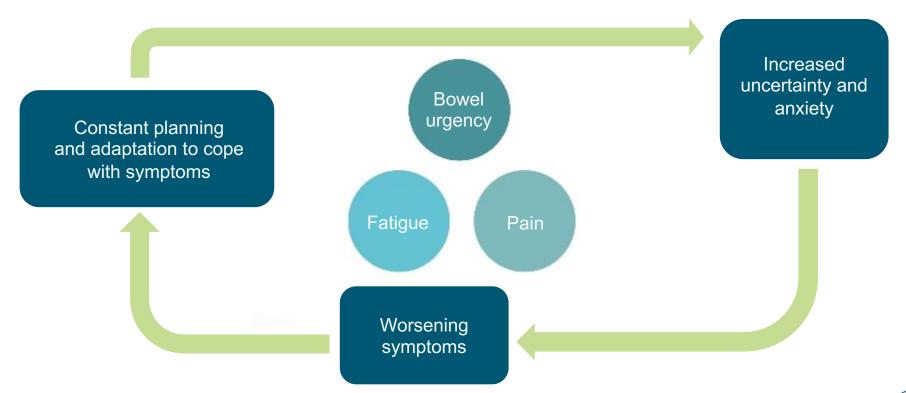
Symptoms Most Impacting QoL in CD



Patient Perspective: Top Symptoms They Want Resolved are Pain and Urgency



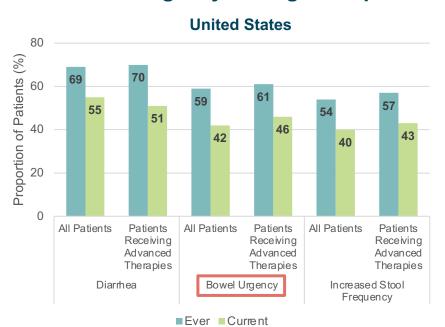
The Cycle of Adaptation to a "New Normal"

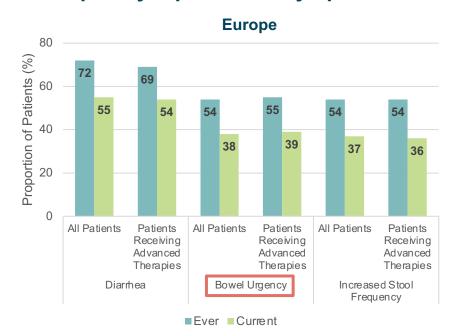




CONFIDE Survey Results

Bowel urgency among the top three most frequently reported CD symptoms

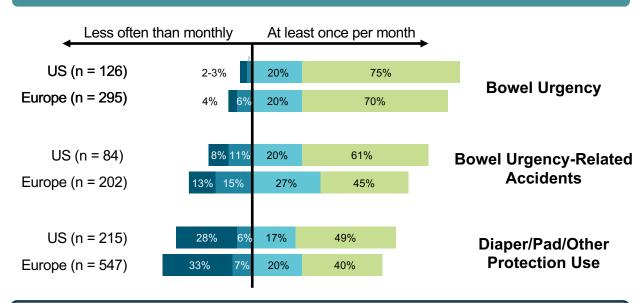






CONFIDE Survey Results





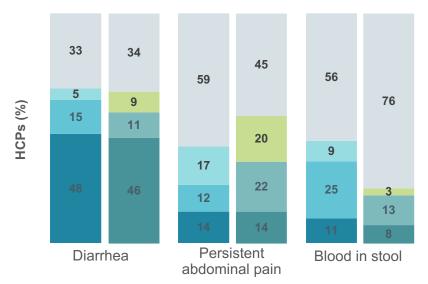
Bowel urgency is just as much of an issue in CD as it is in UC



CONFIDE Survey Results: HCP-Reported

81% of US and 85% of European HCPs did not rank bowel urgency among the symptoms most reported by patients

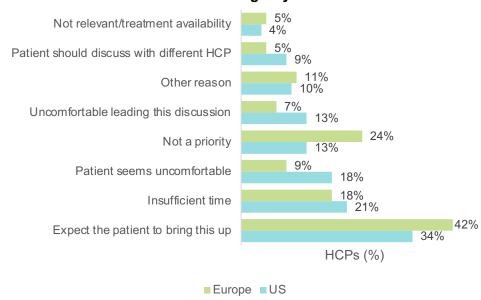
Ranking of *HCP-perceived* top three CD symptoms reported by patients



US: ■1 ■2 ■3 ■ Not Ranked Europe: ■1 ■2 ■3 ■ Not Ranked

HCPs do not proactively discuss bowel urgency and bowel urgency-related accidents with patients

HCP-reported reasons for not proactively discussing bowel urgency



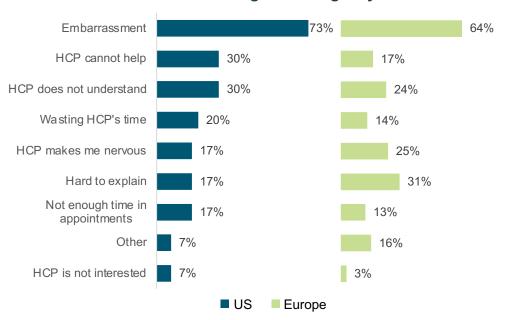


HCPs = health care professionals.

CONFIDE Survey Results: Patient Reported

- Embarrassment was the most common reason for patient discomfort in discussing bowel urgency and bowel urgency-related accidents with HCPs
- Only 40% of US and 27% of European patients were completely comfortable discussing bowel urgency with their HCPs

Patient-reported reasons for not feeling comfortable discussing bowel urgency



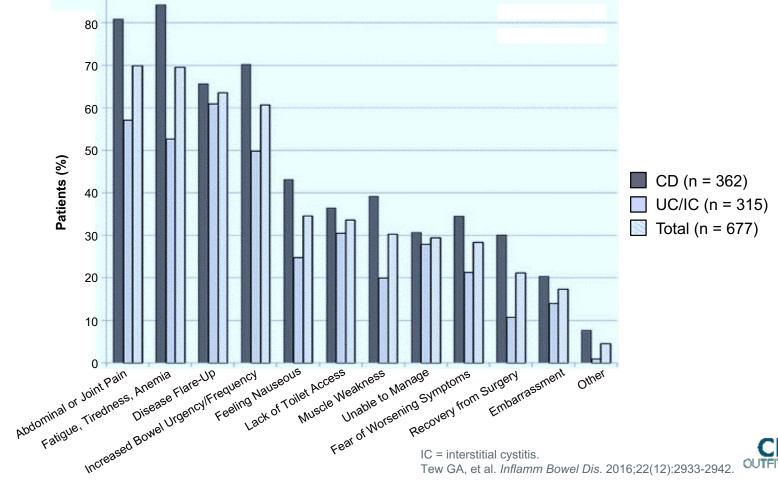


Impact of IBD on Daily Activity

- ▶ 79% of patients limited physical activity
- 34% of patients reported avoiding running or jogging
- Reasons for limited activity
 - ► 70% fatigue/tiredness
 - ► 69% disease flare-ups
 - ▶ 61% increased toilet urgency

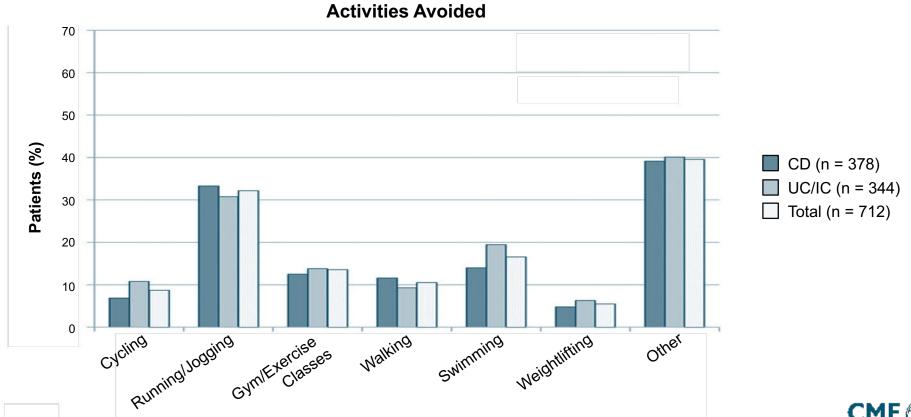


Reasons for Avoiding Activity in IBD



Tew GA, et al. Inflamm Bowel Dis. 2016;22(12):2933-2942.

Activity Adaptation in Patients with IBD



IBD and **Sexual Health**

 Sexual functioning, satisfaction, and drive can be negatively impacted by IBD and can impact QoL



70% never or rarely ask patients about sexual dysfunction

75% did not change treatment if a patient reported sexual dysfunction

Gastroenterology survey reported barriers to addressing sexual dysfunction during appointments

Lack of knowledge (80%)

Lack of experience (58%)

Lack of time (44%)

Embarrassment (30%)

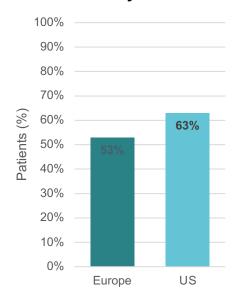


Impact of Bowel Urgency on Sexual Activity

Patient-provided reasons for avoiding or decreasing sexual activity



% of patients who avoided or decreased sexual activity in the last 3 months





MUSIC Study: Significant Proportion of Patients with CD Reported Bowel Urgency

Characteristic	Bowel Urgency (UNRS 2–10)* n = 883	No or Minimal Bowel Urgency (UNRS 0-1)* n = 650	P Value**
Age (years), mean (SD)	54.1 (15.5)	53.4 (16.1)	.320
Female gender, n (%)	632 (73)	452 (70)	.290
Education (> high school), n (%)	789 (89)	601 (92)	.039
Caucasian (White), n (%)	789 (89)	592 (91)	-
Current smoking (yes), n (%)	29 (3)	11 (2)	.053
Body mass index, mean (SD)	26.8 (6.3)	25.3 (4.9)	< .001
Disease duration (years), mean (SD)	25.7 (14.1)	23.7 (13.7)	.003
Ever GI surgery (yes), n (%)	540 (61)	311 (48)	< .001
Ever GI hospitalization (yes), n (%)	649 (73)	417 (64)	< .001
Number hospitalizations, mean (SD)	3.9 (2.6)	3.1 (2.3)	< .001
Remission (yes), n (%)	544 (62)	599 (92)	< .001

58% of patients reported bowel urgency

Bowel urgency was higher among patients with active disease vs. those in remission (87% vs 48%, p < .001)

^{**}Chi-square test was used to compare no or minimal bowel urgency vs bowel urgency for each of the categorical variables and t-test was used for continuous variables.

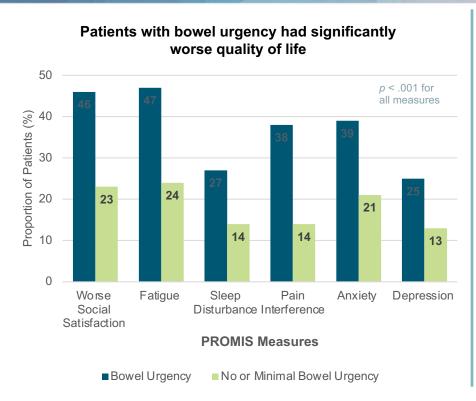
GI = gastrointestinal: SD = standard deviation.



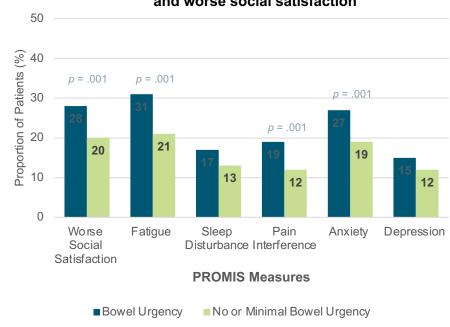


^{*}Urgency was measured using 11-point UNRS: 0-1 = no minimal bowel urgency, 2-10 = bowel urgency.

MUSIC Study: Bowel Urgency Negatively Impacted Quality of Life in CD









Summary: Impact of Bowel Urgency

- Urgency is prevalent in Crohn's disease
- Embarrassment is a common reason patients avoid bringing it up
- Almost half of patients report using pads, liners, or diapers at least once a week due to bowel urgency
- Patients frequently avoid physical and social activities due to bowel urgency
- Urgency is the most commonly reported reason for decreasing sexual activity



Assessments for Bowel Urgency

Marla Dubinsky, MD

Audience Response



Which of the following assessments captures bowel urgency impact in patients with CD?

- A. CDAI
- B. HBI
- C. UNRS
- D. IBDQ
- E. I don't know



Defining Bowel Urgency



Definition Use in Study	
Inability to defer defecation for more than 15 minutes	
No definition	20
Not making it to the toilet in time	1
Immediate need to defecate	1
Hurry to/immediately go to the bathroom/unable to make it in time	1
Simple Clinical Colitis Activity Index (SCCAI) definition	
Having to rush to the toilet to avoid an accident	1
Sudden and severe urge to defecate	
Inability to defer defecation for more than 5 minutes after the first call to stool	
Having to urgently visit the toilet to pass stool	
Urgency to go to the bathroom	
An irresistible and urgent desire to defecate	



Barriers to Identifying Bowel Urgency in Patients with CD

Does normal stool frequency mean no bowel urgency?



55% of patients report urgency symptoms with no change in stool frequency





Commonly Used CD Disease Activity Indices

- ► Clinical Disease Activity Index (CDAI)
- ► Harvey-Bradshaw Index (HBI)
- ► Inflammatory Bowel Disease Questionnaire (IBDQ)
- ► Patient reported outcome-2 (PRO-2)



Commonly Used CD Disease Activity Indices

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- Patient reported outcome-2 (PRO-2)

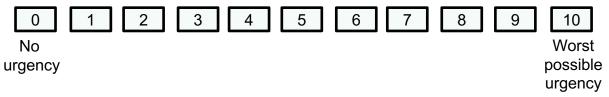
None of the commonly used scales capture bowel urgency severity



Urgency Numeric Rating Scale (UNRS)

Patients with CD have indicated that it is important to have a bowel urgency scale that distinguishes between different levels of severity instead of just a yes or no

How severe was your urgency (sudden or immediate need) to have a bowel movement in the past 24 hours?



- ▶ Patients report the severity of their bowel urgency symptoms over the past 24 hours
 - Weekly average scores are calculated as mean score over a 7-day period
 - Higher scores indicate worse urgency severity (e.g., immediacy of need to have a bowel movement)

The UNRS was used in the mirikizumab phase III studies to assess bowel urgency whereas the upadacitinib phase III studies used a yes/no binary scale



Second N-ECCO Consensus Statements in Caring for Patients With IBD

"A major life impact is the **need to be near a toilet**. **Urgency** can be severe, with some patients reporting less than 30 seconds between calls to stool and actual defecations. Fear of losing bowel control is so great that some patients always worry about where the nearest toilet is."

"Recent evidence suggests that, at some point of the disease course, between 31% and 74% of people with IBD experience fecal incontinence, not necessarily related to disease activity."

"Despite it being a major concern, incontinence is rarely reported to or addressed by clinicians."



FDA Guidance for Developing New Drugs in CD

"We encourage sponsors to explore the effect of an investigational drug on additional symptoms of CD identified by subjects as important but that are not captured within the CDAI (e.g., urgency) using fit-for-purpose patient-reported outcome (PRO) instruments."



Assessment of Bowel Urgency: Patient-Reported Outcomes



FDA and EMA have recommended that clinical parameters, endoscopic findings, and patient-reported symptoms be separately quantified and reported in IBD trials



PRO tools developed per FDA guidance that include measures of urgency:

- Symptoms and ImpactsQuestionnaire for CD (SIQ-CD)
- Crohn's Disease Patient-Reported Outcomes Signs and Symptoms (CD-PRO/SS) Diary
- UNRS

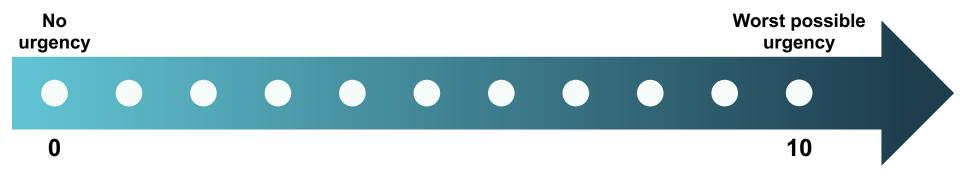
Note: Apart from the UNRS, the other PROs listed include multiple items and measure symptoms assessed by traditionally used scales (e.g., SES-CD, CDEIS) and therefore may be duplicative



Recent Innovations: Urgency Score for Adults with CD



How severe was your urgency (sudden or immediate need) to have a bowel movement in the past 24 hours?



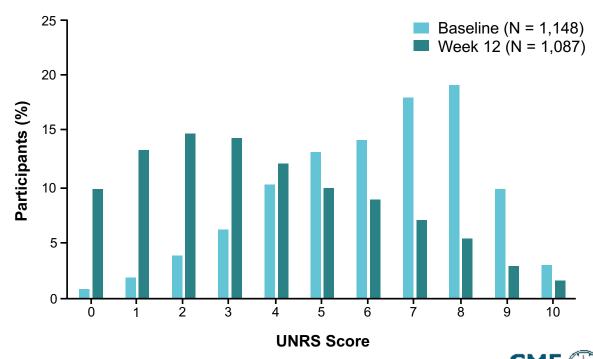
Urgency Score

- Bowel urgency is a distinct symptom of CD
- Urgency score is correlated highly with patient global rating of severity scores



Psychometric Evaluation of UNRS: UNRS Score Distributions

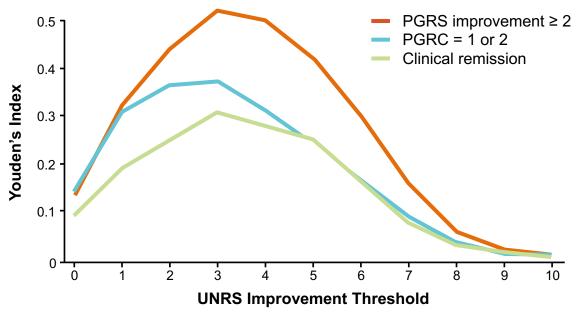
- Participants registered full range of weekly average UNRS scores (0 to 10) at baseline and at Week 12
- Mean UNRS score was higher (worse) at baseline than at Week 12 (6.2 vs 3.7)
- Weekly averages were appropriate to summarize daily UNRS scores





Psychometric Evaluation of UNRS: Patient Improvement from Baseline





≥ 3-point improvement on UNRS yields best balance between sensitivity and specificity of any UNRS threshold at identifying large improvement in overall symptom severity

Youden's Index from an anchor-based analysis of improvement in UNRS from baseline to week 12 Clinical remission was defined as Mayo stool frequency subscore of 0, or 1 with $a \ge 1$ -point decrease from baseline; a Mayo rectal bleeding subscore of 0; and a Mayo endoscopic subscore of 0 or 1 (excluding friability)



Why Bowel Urgency Matters: Summary









Bowel urgency is one of the most important symptoms for patients and has a significant impact on patient quality of life and psychosocial function.

HCPs are not always routinely assessing bowel urgency in clinical practice, and there is a communication gap between HCPs and their patients.

Bowel urgency is being increasingly recognized in guideline recommendations and consensus statements as a key component of CD. The UNRS moves beyond yes/no data and assesses severity over time; it has utility in both clinical trials and clinical practice.

Dubinsky MC, et al. *Qual Life Res.* 2023;32(12):3403-3415. Petryszyn PW, Paradowski L. *Adv Clin Exp Med.* 2018;27:813-818. Rubin DT, et al. *Inflamm Bowel Dis.* 2021;27:1942-1953. Ueno F, et al. *J Gastroenterol.* 2017;52:555-567. Ananthakrishnan AN, et al. *Gastroenterology.* 2021;160:445-451. Bernstein CN, et al. *J Clin Gastroenterol.* 2016;50:803-818. Kemp K, et al. *J Crohns Colitis.* 2018;12:760-776. Lamb CA, et al. *Gut.* 2019;68(Suppl 3): s1-s106. Surti B, et al. *Dig Dis Sci.* 2013;58:1313-1321.



Treatment Planning

Angelina E. Collins, MSN, ANP-BC

The Impact of Bowel Urgency: The Patient Perspective Cristina C.

Patient Case: Victoria M., 29 y/o woman

- ► HPI: 29-year-old woman diagnosed with colonic Crohn's disease with perianal phenotype CD 3 years ago
- ► Current treatment: Infliximab 5 mg/kg every 8 weeks



Patient Statements

"I worry about having access to a bathroom at work and have cut back my hours."

"I have stopped going out with friends and family if I am unsure of the bathroom situation." "I haven't been able to make it to the bathroom in time twice this month and have started carrying extra clothes."



Patient Case: Vittoria M. (continued)



Urgency-Related Symptoms

"I worry about having access to a bathroom at work and have cut back my hours."

"I have stopped going out with friends and family if I am unsure of the bathroom situation." "I haven't been able to make it to the bathroom in time twice this month and have started carrying extra clothes."

Patient Treatment Goals

Identify the ideal number of hours/shift length and develop a work bathroom plan.

Identify "rescue interventions" to support social and family activities.

Identify potential bowel urgency triggers.
Trial interventions to improve overall bowel control.



Discussion: What Would You Do Next for Victoria?

Faculty Discussion



Next Steps: Victoria M.



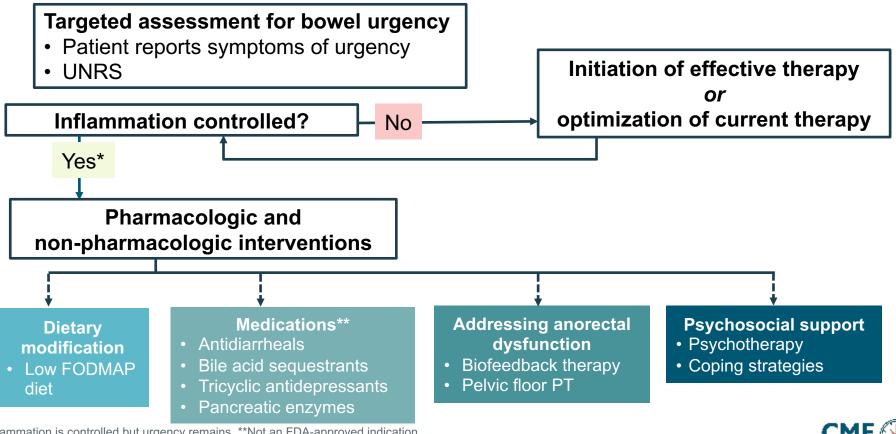
Lab (normal range)	Patient Values
Infliximab trough (goal ≥ 5 µg/mL)	6 μg/mL
CRP (< 5 mg/L)	12 mg/L
Fecal calprotectin (50-200 µg/mg)	310 µg/g
Stool culture, enteric pathogens	Negative
Clostridioides difficile	Negative
Ova and parasite negative	None seen

Colonoscopy: Mild Crohn's disease

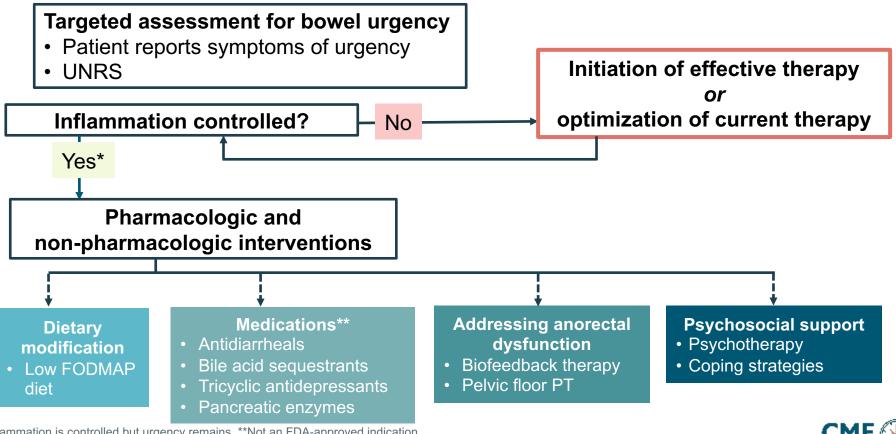




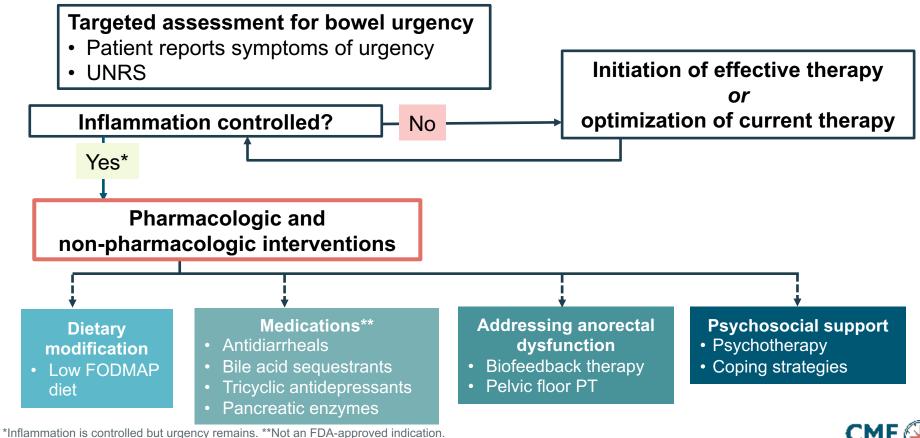














When Inflammation Is Under Control Pharmacotherapy



Antidiarrheals*

- Antidiarrheal agents (e.g., loperamide) can improve bowel urgency caused by both inflammatory and non-inflammatory mechanisms
- Normalizes colon transit time and is thought to increase internal anal sphincter (IAS) tone
- ► These agents are not FDA approved to treat bowel urgency



When Inflammation Is Under Control **Pharmacotherapy**

Antidiarrheals**

Studies have indicated that loperamide decreases several functional gastrointestinal symptoms, such as fecal urgency and stool frequency, and can improve stool consistency and resting anal sphincter function in individuals with diarrheapredominant IBS and inactive IBD.

Patients with CD

Loperamide vs placebo over 1 week (van Outryve and Toussaint)

After first week (1 mg after each unformed stool):

- Both investigator's and patients' evaluations of global efficacy* were significantly in favor of loperamide (p = .025 and p = .020)
- Patient-reported severity of diarrhea was improved with loperamide compared to placebo (p = .046)
- Change in abdominal pain was significant for loperamide oxide (p = .020) but not for placebo

After second week (responders to first week continued to 1 mg twice daily)

Both the investigator's and the patients' assessments of global efficacy and symptom improvement continued to favor loperamide (difference was not significant)



^{*}Improved stool consistency, decreased fecal urgency and stool frequency. **Not an FDA-approved indication.

Pharmacotherapy

Tricyclic Antidepressants*



Idiopathic fecal incontinence (IFI)

n = 18 with IFI

▶ 8 (44%) complained of urgency of defecation

n = 24 controls



Amitriptyline 20 mg daily x 4 weeks



Evaluated before and after 4 weeks of therapy:

- ▶ Idiopathic fecal incontinence scores
- Number of bowel movements
- ► Computerized ambulatory anorectal pressures
- ▶ Pudendal nerve terminal motor latencies



After 4 weeks, 13 (72%) of patients with IFI experienced a "satisfactory result" (no soiling episodes or **urgency of defecation** at all and full continence to fluid and solid stool)

Incontinence			
Median pretreatment score	16	p < .001	
Median posttreatment score	3		

Bowel Frequency (BM/day)			
Median pretreatment	3	n < 001	
Median posttreatment	1	p < .001	





When Inflammation Is Under Control Pharmacotherapy Tricyclic Antidepressants*

Results of Pretreatment and Posttreatment Anorectal Physiology Measurements in Patients with Idiopathic Fecal Incontinence

	Pretreatment	Posttreatment	<i>P</i> Value
Median resting and pressure			
Daytime	64	68	NS
Nocturnal	26	16	NS
Median resting rectal pressure			
Daytime	32	32	NS
Nocturnal	12	12	NS
Median maximum and 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	< .05
Median anal pressure	49	66	< .001
Median rectal pressure	94	58	< .05

^{*}Tricyclic antidepressants are not FDA approved for treatment of bowel urgency. NS = not significant; pressures are in centimeters of water. Santoro GA, et al. *Dis Colon Rectum*, 2000;43(12):1676-1681.



Patient Case: Henry T., 55 y/o man

- ► HPI: diagnosed with CD 3 years ago
 - No previous surgeries for Crohn's disease, prior cholecystectomy
- Current treatment: Ustekinumab 90 mg every 8 weeks (previously on infliximab)
- ► Current symptoms: reports fatigue, making it difficult to concentrate at work, and bowel urgency, making it difficult to leave the house or be away from a restroom after eating any food
- Previous interventions for urgency:
 - Previously tried prn loperamide 2 mg after meals, then 4 mg after meals with limited relief to urgency
 - Amitriptyline 10 mg at bedtime x 3 month trialed, limited improvement to urgency
 - Difficulty following a low-FODMAP diet and gave up after 2 weeks



Next Steps: Henry T.

- Laboratory and stool studies
 - ► FCP, CRP
 - Consider infectious workup
 - enteric pathogens, Clostridioides difficile, ova/parasite testing
- Plan for colonoscopy
- Review for changes in home, work, and social life
 - Identify potential stress or anxiety triggers for bowel urgency



Patient Case: Henry T. (continued)

Lab (normal range)	Patient Values
CRP (< 5 mg/L)	4 mg/L
Fecal calprotectin (50-200 µg/mg)	45 μg/g
Stool culture, enteric pathogens	Negative
Clostridioides difficile	Negative
Ova and parasite negative	None seen

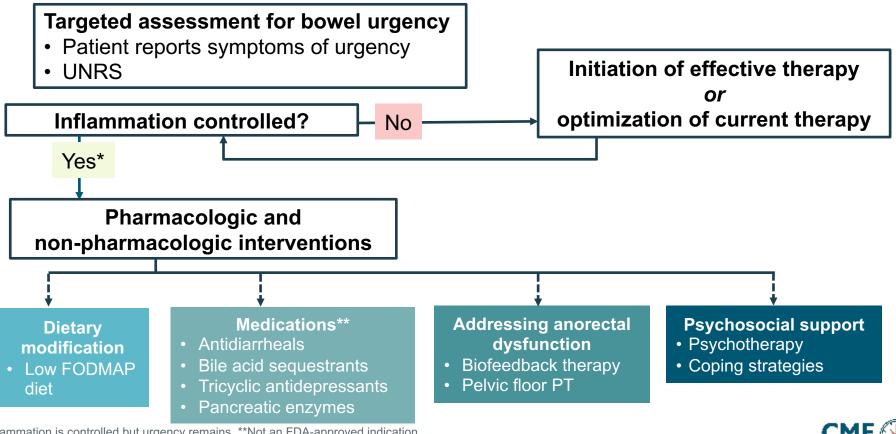


Colonoscopy report: normal vascular pattern visible throughout (possible tertiary arborization), no spontaneous bleeding or bleeding to light touch

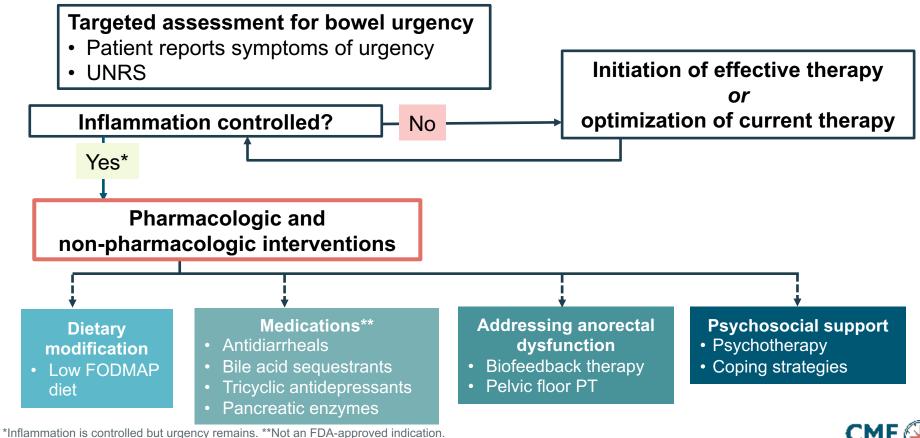
Discussion: How Would You Have Conversations About Treatment Options with Henry?



Faculty Discussion



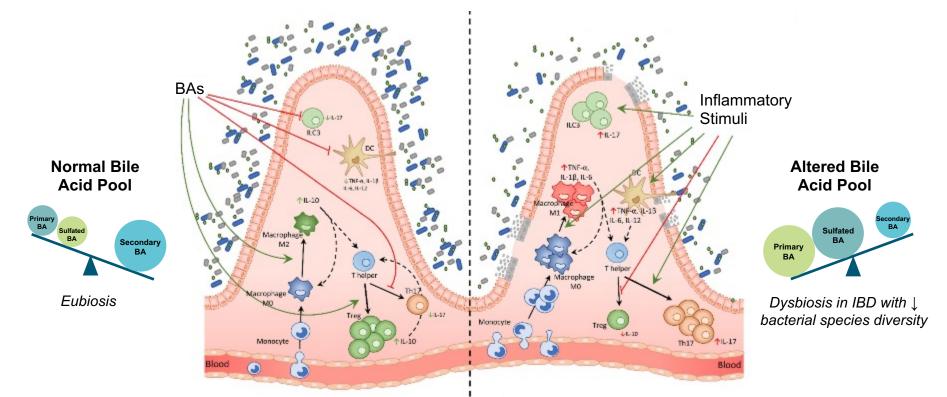






Bile Acid Malabsorption (BAM) in IBD

Tolerogenic Immune Response



Pro-Inflammatory Immune Response



Bile Acid Malabsorption (BAM) in IBD

Abnormal SeHCAT retention seen in:

90% of patients *with* bowel resections

28% of patients who had not undergone resection



Addressing Anorectal Dysfunction

Rectal inflammation is the main cause of bowel urgency in IBD

Other potential causes:

IBS

Bile acid malabsorption

Small intestinal bacterial overgrowth

Poor rectal compliance

Neurologic

Anal sphincter dysfunction



Biofeedback Therapy

Components of Biofeedback Therapy for Fecal Incontinence and Bowel Urgency

Phase 1: Assessment and Education

 Evaluation of defecation behavior with manometry or electromyography (EMG) probe

Phase 2: Active Exercise and Training

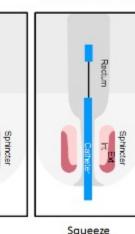
- Strength training—improve speed, duration, and timing of voluntary contractions of the external anal sphincter
- Rectal sensory training—tolerate larger volumes until a normal level of urge sensation is achieved
- Coordination training—increase voluntary anal contraction in response to rectal filling to increase threshold for urgency

Phase 3: Weaning and Reinforcement

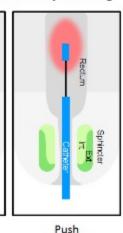
- As patient gains confidence in muscle control, the frequency of therapy is reduced
- Number, frequency, intensity, and duration of sessions highly individualized for each patient

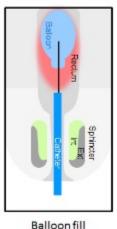
Biofeedback is a self-regulation technique that attempts to teach patients with defecatory defects to strengthen pelvic floor muscles, retain rectal sensation, and coordinate pelvic floor muscles during evacuation

Anorectal manometry testing



Resting





Contraction

■ Relexation

Lee HJ, et al. *J Neurogastroenterol Motil.* 2013;19(4):532-537. Western Sydney University: GI Motility Disorders Unit. 2018.



Biofeedback Therapy

Frequency of dyssynergic defecation in IBD

45-97% patients w/out IPAA

25-75% of patients with IPAA

Pooled response rate to biofeedback therapy

70% (95% CI 55%-84%) w/out IPAA

86% (95% CI 67%-98%) with IPAA



Pelvic Floor Training

- ▶ Pelvic floor muscle training, with or without biofeedback therapy, improved fecal incontinence in 20/25 (80%) of patients with guiescent IBD
- Patients with IBD completing treatment (n = 29) demonstrated improved symptom scores (p < .001), IBD-specific QoL (p = .008) and illness perception scores (p = .0030)
- ► Those who are most likely to benefit are individuals experiencing fecal incontinence or impaired evacuation and exhibit dysfunction in pelvic floor or anal sphincter muscles
 - Pelvic floor dysfunction diagnosis: anal manometry, balloon expulsion testing, EMG, defecography, or ultrasound

Pelvic muscle contraction strength can be diminished in shortened, tight, or tense muscles





Pelvic Floor Training

- Pelvic floor muscle training does not solely include strength training.
- Incorporates exercises to:
 - Improve the awareness of muscle contraction and relaxation
 - Coordinate with abdominal and diaphragm muscles for the normal functions of continence and effective defecation

Behavioral Treatments Tailored to Individual Patient Symptoms

- Pelvic floor muscle training, with or without biofeedback
- Toileting behavior modifications
- Urge resistance or deferral techniques
- Lifestyle changes
- Emotional support



Patient Case: Victoria M. (continued)



Urgency-Related Symptoms

"I worry about having access to a bathroom at work and have cut back my hours."

"I have stopped going out with friends and family if I am unsure of the bathroom situation." "I haven't been able to make it to the bathroom in time twice this month and have started carrying extra clothes."

Patient Treatment Goals

Identify the ideal number of hours/shift length and develop a work bathroom plan.

Identify "rescue interventions" to support social and family activities.

Identify potential bowel urgency triggers.

Trial interventions to improve overall bowel control.



Patient Case: Shared Decision-Making

Assess

Patient's beliefs, behavior, knowledge

Advise

Provide specific information about health risks and benefits of change

Agree

Collaboratively set goals based on patient's interest and confidence in ability to change behavior

Assist

Identify personal barriers, strategies, problemsolving techniques, and social support

Arrange

Specify a plan for follow-up

Shared Decision-Making Considerations

- How do we approach conversation with our patient who is accepting their "new normal"?
- ► How do we discuss the connection between urgency and fatigue with our patient?
- How do we present the concepts of mind/body, brain/gut dysregulation to our patient?
- ► How do we approach the conversation of home environment and lifestyle/life events going on in the patient's life?



Audience Response

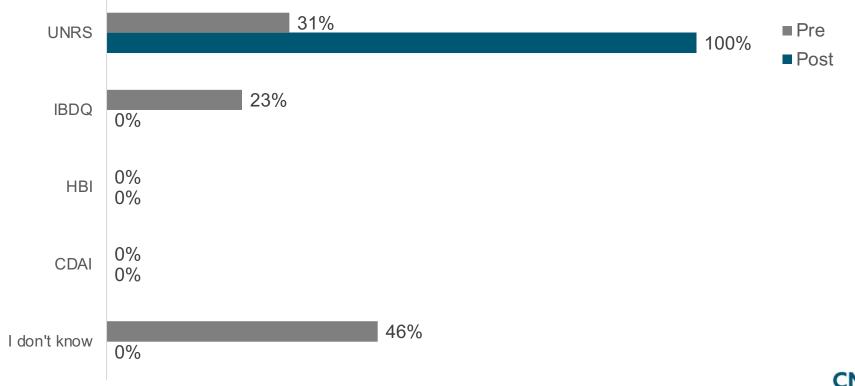


Which of the following assessments captures bowel urgency impact in patients with CD?

- A. CDAI
- B. HBI
- C. UNRS
- D. IBDQ



Which of the following assessments captures bowel urgency impact in patients with CD?





Audience Response



Now, how often will you incorporate bowel urgency assessments into your evaluation of patients with Crohn's disease (CD)?

- A. Always
- B. Usually
- C. Seldom
- D. Never



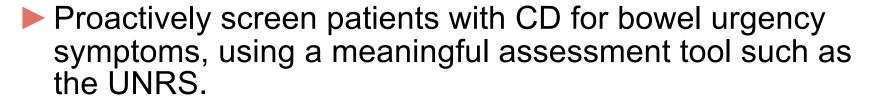
Now, how often will you incorporate bowel urgency assessments into your evaluation of patients with Crohn's disease (CD)?





SMART Goals

Specific, Measurable, Attainable, Relevant, Timely



- Increase the percentage of patients with CD who have an individualized treatment plan to address bowel urgency during periods when inflammation is controlled.
- ► Improve the proportion of patients with CD who identify personalized treatment goals for addressing the impact of bowel urgency and other CD symptoms on daily life.





Additional Resources

To learn more, scan the QR code to access additional educational resources.





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