Impact of Abdominal **Symptoms in Patients With Chronic Idiopathic Constipation** (CIC) in the United States

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OBJECTIVE

Our study examined the impact of abdominal symptoms on those with CIC by looking at their disease burden, care-seeking behavior, treatment, and satisfaction with control of symptoms, care and treatment

CONCLUSIONS

CIC patients commonly suffer with abdominal symptoms typically associated with IBS-C patients highlighting the overlap of these two common disorders of gut-brain interaction



Respondents currently taking a prescription medication (with/without an over-the-counter medication) for their symptoms reported being more satisfied than dissatisfied with the control of their CIC, while those currently taking only an over-the-counter medication reported being more dissatisfied than satisfied with the control of their CIC



Abdominal symptom impact in CIC patients is high. One-third sought care due to abdominal symptoms, and abdominal symptoms were the most-reported reasons for ER visits or hospitalizations

Disclosures

References

- 2. Lacy BE et al. Aliment Pharmacol Ther. 2007:25:599-608.

- 5. Heidelbaugh JJ et al. Am J Gastroenterol. 2015:110:580-5

INTRODUCTION

Background

- · Chronic idiopathic constipation (CIC) is estimated to impact up to 14% of the general population1,2
- CIC can negatively impact quality of life: self-confidence, relationships, and interfere with school, work, and family activities1,3,4
- Patients with CIC report a variety of abdominal symptoms beyond reduced stool frequency or straining¹; one study found 66% of those with CIC experience
- abdominal symptoms once or more per week5
- However, our understanding of these additional symptoms is limited

METHODS

A. Data Collection

RESULTS

Characteristics

Female

- · An observational, cross-sectional study design used data collected through an online survey of United States (U.S.) adults aged ≥18 years
- Data was collected for approximately 1 week each month from August 2020 through December 2021
- Survey participants were recruited from a research panel that used digital finderprinting and multiple quality control measures to ensure each participant was unique and valid, and to identify fraudulent responses
- · All data were self-reported

Survey and Rome IV CIC Cohort Populations

ns participants did not meet Rome IV criteria for CIC (n=9.204)

10.2% (n=941) not experiencing symptoms for >6 months (2nd Rome IV criteria)

22.0% (n=2.026) reported loose stools without laxatives (3rd Rome IV criteria)

and had a mean age of 45.1 (SD 16.8) years (Table 1)

54.3% (1.111) of CIC patients were employed (Table 1)

7.1% (n=649) met Rome IV criteria for IBS-C (4th Rome IV criteria)

60.7% (n=5.588), not experiencing ≥2 symptoms in the past 3 months (1st Rome IV criteria

CIC patients were primarily female (68.4%, n=1,843), White (80.9%, n=2,180),

• 75.5% (n=2,036) of CIC patients were educated more than high school (Table 1)

Table 1, Rome IV CIC Cohort Characteristics

• Of 29,359 total participants, 9.2% (n=2,696) met criteria for CIC (Figure 1)

Figure 1. Rome IV CIC Cohort Population

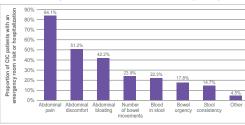
B. Survey Design

- · An IBS/CIC module was developed by AbbVie, Ironwood and experts in IBS/ CIC and was included in a larger national health research survey
- Survey participants selecting "IBS" "constipation (chronic, or more than occasional)" (constipation) or "diarrhea (chronic, or more than occasional)" (diarrhea) in the comorbid conditions section of the survey were routed to the module. Participants who did not select these conditions continued with the survey questions asked of all participants
- The initial questions of the module screened for CIC using Rome IV criteria. Module questions assessed the following endpoints: abdominal symptoms, medication use, healthcare visits or emergency department visits or hospital admissions due to symptoms, and satisfaction with symptom control using prescription (Rx) vs. over-the-counter (OTC) medications
- Survey questions asked of all participants included demographic. socioeconomic, and comorbid conditions questions
- The module and survey were reviewed by an Institutional Review Board before fielding began in August 2020
- · A pilot of the module confirmed the questions and response options were easily understood and the module length was appropriate

C. CIC Cohort Criteria

- To participate in the survey, participants were required to be aged ≥18 years and to reside in the U.S.
- Emergency Room (ER) Visits or Hospitalizations Due to Symptoms Of CIC patients, 32.0% (n=862) had been to an ER or were hospitalized for symptoms, and 15.7% (n=422) had been to an ER or were hospitalized in the
- 12 months was 2.9 (SD 2.2) (n=421)
- in the past 12 months (84,1%) (n=355) (Figure 2)

or Hospitalization in the Past 12 Months (n=422)



CIC, chronic idiopathic constipation

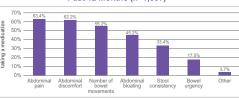
Treatment for Symptoms in the Past 12 Months

- 91.1% (n=2,456) of patients took a medication in the past 12 months to manage symptoms (medications: prescription, over-the-counter, complementary therapies or alternative medications (CAM) or did not remember the treatment type) (Table 2)
- The most common symptom that led to taking medication was abdomina pain (63.4%) (n=1,557) closely followed by abdominal discomfort 62.2% (n=1,527) (Figure 3)

Table 2. Treatment for Symptoms in the Deet 42 Month

Table 2. Treatment for Symptoms in the Past 12 Months				
	Rome IV CIC Cohort (N=2,696)			
	%	N		
Have you taken any medication to manage your bowel movement related symptoms and/or abdominal symptoms in the past 12 months? (n=2,696)				
Rx	38.5%	1,038		
OTC	74.4%	2,006		
CAM	15.1%	406		
Do not remember	1.3%	36		
None, never taken any medication	8.9%	240		
Proportion taking an Rx, OTC, CAM or did not remember treatment type in the past 12 months	91.1%	2,456		

Past 12 Months (n=1,557)



Severity was self-reported on a scale from 0 (not at all severe) to 10 (extremely severe) "Frequency rating: "All of the time," "Most of the time," "Sometimes," "Rarely," and "Neverif don't experience this" NA, not applicable: SD, standard deviation

% N 68.4% 1,843

Rome IV CIC Cohort

(N=2.696)

Age, mean (SD)	45.1	(16.8)
Black or African American	10.6%	286
White	80.9%	2,180
Other	8.5%	230
Hispanic, Latino or Spanish origin	10.0%	269
Northeast	18.7%	504
Midwest	22.5%	607
South	38.2%	1,031
West	20.5%	554
Charlson Comorbidity Index (CCI) score, mean	(SD) 0.8	(1.6)
Body Mass Index (BMI) (Ibs/in2), mean (SD)	27.8	(7.3)
Median household income (Census derived from code), mean (SD)	m zip 64,556	(26,352)
Proportion educated more than high school	75.5%	2,036
Proportion employed (1)	54.3%	1,111

(1) WPAI fielded Dec 2020-Dec 2021 CIC chronic idiopathic constination: SD standard deviation

Care Due to Bowel Movement Related Symptoms and/or Abdominal Symptoms (Symptoms)

Visits With a Healthcare Provider Due to Symptoms

- Of CIC patients, 90.8% (n=2,449) sought medical care for symptoms, and 58.9% (n=1,589) sought care in the past 12 months
- Of those with a visit for symptoms in the past 12 months, 34.3% (n=841) reported cancelling a healthcare visit due to COVID-19
- Mean number of visits for symptoms in the past 12 months was 3.3 (SD 2.8) (n=1.567)
- Of CIC patients who sought care in the past 12 months, 33 1% (n=526) sought care due to not getting adequate relief of and/or worsening abdominal symptoms

- past 12 months Mean number of ER visits or hospitalizations for symptoms in the past
- Abdominal pain was the most common reason for an ER visit or hospitalization

Figure 2. Symptoms Leading to an Emergency Room Visit





Change in number movements Visual expansion abdominal area Stool consistend Bowel urgency Staining Other**

None of these

- To qualify as a CIC patient and be included in the CIC cohort, participants had to meet the following inclusion/exclusion criteria: - Inclusion criteria
 - Self-reported IBS, constipation, or diarrhea as a
 - comorbid condition
 - Meet Rome IV criteria for CIC⁴
- Exclusion criteria:

past 3 months:

Self-reported IBS, constipation, or diarrhea as a comorbid condition but did not meet Rome IV criteria for CIC · Meet Rome IV criteria for IBS-C

D. Rome IV Criteria for CIC⁴

· Experienced at least two of the following symptoms in the

- Fewer than 3 bowel movements per week
- Straining during at least 25% of bowel movements
- Sensation of incomplete emptying after bowel movements at least 25% of the time
- Sensation that stool could not be passed when having a
- bowel movement for at least 25% of bowel movements
- Needing assistance with at least 25% of bowel movements
- Lumpy or hard stools with more than 25% of bowel movements
- Experienced at least two of the symptoms for >6 months

- Indicated loose stools were rarely present without the use of laxatives
- Did not qualify for IBS-C under Rome IV criteria: 1) experienced recurrent abdominal pain on average at least 1 day per week in the past 3 months: had two or more of the following associated with abdominal pain: bowel movement, change in the number of bowel movements, or change in the form of bowel movements: 3) experienced at least two associations for >6 months; and 4) only Bristol Stool Form Scale (BSFS) stools 1 and/or 2 ≥25% of the time and BSFS stools 6 and/or 7 ≤25% of the time

Analyses

- · Outcomes were analyzed descriptively: categorical data were described by percentage, and continuous data were described by mean and standard deviation
- All analyses were carried out with unweighted data

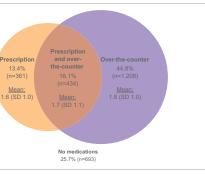
Limitations

- Data were self-reported and participants were limited to those with computer access
- · Bowel and/or abdominal symptoms could have been attributed to more than iust CIC
- · The study was undertaken during the COVID-19 pandemic, which may have impacted outcomes
- Some outcomes had a small sample size and must be interpreted with caution

Current Treatment for Symptoms

- 74.3% (n=2,003) of CIC patients currently take a prescription and/or an over-the-counter medication to manage symptoms (Figure 4)
- 29.5% (n=795) currently take a prescription medication with or without an over-the-counter medication for symptoms
- 44.8% (n=1,208) currently take an over-the-counter medication without taking a prescription medication for symptoms
- Mean number of medications currently taken for symptoms was 2.2 (SD 1.5) (n=2.003)

Figure 4. Treatments Currently Taken for Symptoms



Symptom Experience

95.3% (n=2,569) of CIC patients experienced ≥1 symptoms in the past 7 days Abdominal discomfort was the symptom most experienced in the past 7 days (58.4%) (n=1,574) (Table 3)

Painful bowel movements received the highest severity rating (6.0 [SD 2.2]) (n=889) (Table 3)

- Of symptoms experienced in the past 7 days, straining was experienced with the greatest frequency (59.9%) (n=921) (other response options: sometimes, rarely, and never) (Table 3)

 Abdominal pain was ranked the most bothersome symptom (26.5%) (n=681) (Figure 5)

Table 3. Symptoms Experienced in the Past 7 Days

	Symptom experience, severity and frequency			
	Experienced N = 2,696 % (N)	Severity* Mean (SD) (N)	Frequency "all" or "most of the time"** % (N)	
mfort	58.4% (1,574)	5.1 (2.1) (1,574)	41.3% (650)	
	57.0% (1,538)	5.8 (2.2) (1,538)	59.9% (921)	
	49.8% (1,343)	5.6 (2.1) (1,343)	47.1% (633)	
ng	49.1% (1,323)	5.4 (2.3) (1,323)	50.1% (663)	
ete emptying	37.2% (1,004)	5.8 (2.3) (1,004)	56.7% (569)	
vements	33.0% (889)	6.0 (2.2) (889)	46.0% (409)	
er of bowel	27.3% (735)	5.2 (2.4) (735)	42.0% (309)	
of belly or distension)	23.5% (634)	5.5 (2.4) (634)	49.1% (311)	
y	22.8% (614)	5.7 (2.2) (614)	51.6% (317)	
	14.9% (401)	5.7 (2.3) (401)	34.4% (138)	
	10.8% (292)	5.3 (2.6) (292)	34.6% (101)	
	1.4% (38)	6.0 (2.9) (38)	71.1% (27)	
	4.7% (127)	NA	NA	

Figure 5. Ranking of the Most Bothersome Symptom (n=2,569)



CIC, chronic idionathic constination

Symptom Burden

When asked which symptom predominantly limits the ability to work or conduct household chores, abdominal pain was the most reported response (33.6%) (n=906) (Table 4)

Table 4. One Predominantly Limiting Symptom

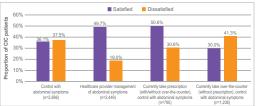
	Rome IV CIC Cohort (N=2,696)				
	%	N			
In your opinion, which symptom predominantly limits your ability to work or conduct household chores? Select only one response. (n=2,696)					
Abdominal pain	33.6%	906			
Abdominal discomfort	16.4%	441			
Straining	8.3%	225			
Abdominal bloating	7.5%	201			
Painful bowel movements	7.0%	190			
Feeling of incomplete emptying	5.4%	146			
Bowel urgency	5.0%	135			
Change in the number of bowel movements	4.8%	130			
Visual expansion of belly or abdominal area (distension)	3.9%	104			
Stool consistency	1.7%	45			
Staining	1.3%	35			
Other	1.3%	36			
None of these; Nothing limits my ability	3.8%	102			

CIC, chronic idiopathic constipation

Satisfaction

- · CIC patients were slightly more dissatisfied than satisfied with overall control of their abdominal symptoms (37.5% vs 36.1%) (Figure 6)
- · CIC patients were more satisfied than dissatisfied with healthcare provider management of their abdominal symptoms (49.7% vs 19.0%) (Figure 6)
- · Those currently taking a prescription medication with or without an over-the-counter medication were more satisfied with the overall control of their abdominal symptoms than those currently taking an over-the-counter medication only (50.6% vs 30.0%) (Figure 6)

Figure 6. Satisfaction With Healthcare Provider's Management of Abdominal Symptoms and Treatment to Manage Abdominal Symptoms



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