

The BURDEN IBS-C Study (Better Understanding and Recognition of the Disconnects, Experiences, and Needs of Patients With Irritable Bowel Syndrome With Constipation)

Eamonn M.M. Quigley, MD¹; John Horn, PharmD²; Michele Kissous-Hunt, PA-C, DFAAPA³; Lucinda A. Harris, MD⁴

¹Houston Methodist Hospital, Houston, TX, USA; ²University of Washington Medicine Pharmacy Services, Seattle, WA, USA; ³Mount Sinai GI, New York, NY, USA; ⁴Mayo Clinic Scottsdale, Scottsdale, AZ, USA

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Introduction

- Irritable bowel syndrome with constipation (IBS-C) is a chronic gastrointestinal disorder affecting approximately 5% of the United States population (~16 million people),¹ though prevalence may be underestimated as many people exhibit IBS-C symptoms without a formal diagnosis.^{1,2}
- IBS-C is characterized by recurrent abdominal pain related to defecation and/or associated with reduced stool frequency and lumpy/hard stools.²
- Limited literature exists evaluating the disease pathway of IBS-C sufferers in the United States, especially comparing patient experiences to the perceptions of healthcare providers (HCPs) who regularly treat patients with IBS-C.
- The current study, BURDEN IBS-C, is the companion study of BURDEN-CIC, an identically designed survey targeted to individuals with chronic idiopathic constipation (CIC) and whose results have been reported.³

Objective

- The BURDEN IBS-C Study was designed to assess the impact of IBS-C on quality of life (QOL), productivity, personal activities, and level of treatment satisfaction in a representative sample of the US population to better understand and recognize the treatment needs of individuals with IBS-C and the HCPs who treat IBS-C patients.

Methods

- The BURDEN IBS-C Study utilized 2 author-developed online surveys: one for adults with IBS-C (IRB-approved) and another for HCPs who treat IBS-C patients.
- Patient Questionnaire**
 - BURDEN IBS-C recruited adults suffering with IBS-C; patients eligible to participate either had been formally diagnosed with IBS-C by an HCP (diagnosed group) or fulfilled Rome IV criteria for IBS-C, as determined in the Screening Section of the questionnaire (undiagnosed group).
 - Enrolled panelists completed an online, self-administered questionnaire, with answer types including dichotomous, multiple-choice, and open-ended formats, as well as Likert rating scales (1–5 or 1–7).
 - Respondents were not eligible to participate in BURDEN IBS-C if they had CIC, irritable bowel syndrome with diarrhea, inflammatory bowel disease, diverticulitis, diverticulosis, spastic colon, celiac disease, cancer of the gastrointestinal tract, or if they had regularly taken an opioid (narcotic) within the past 3 months.
 - The Patient Questionnaire sample was normalized (weighted) to correct for any biases in sampling or non-response using demographic and geographic distributions from the Current Population Survey as benchmarks.⁴
- HCP Questionnaire**
 - The survey was targeted to gastroenterologists, primary care physicians, nurse practitioners, and physician assistants who actively treat patients with IBS-C.
 - HCPs were recruited independently of participants in the Patient Questionnaire.

Results

Table 1. IBS-C Respondent Demographics

	Total Respondents N=1311
Female	72%
Age, yrs, mean (SD)	46.0 (15.6)
Age at Symptom Onset, yrs, mean (SD)	43.8 (16.0)
Race / Ethnicity	
White / non-Hispanic	65%
Black / non-Hispanic	10%
Mixed / non-Hispanic	5%
Other / non-Hispanic	4%
Hispanic	17%
Highest Education Level	
High school – no graduation	5%
High school – diploma / GED	31%
College – no graduation	23%
College – graduation	30%
College – post-graduate	12%

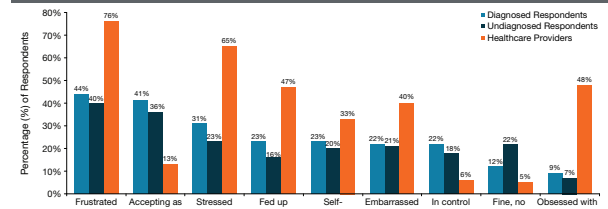
- A total of 1,311 respondents with IBS-C completed the survey (Table 1), of which 29% were not formally diagnosed but rather fit the Rome IV criteria for IBS-C (undiagnosed respondents).

Table 2. Healthcare Provider Demographics

	Gastroenterologist N=155	Primary Care Physician N=76	Nurse Practitioner N=50	Physician Assistant N=50
Males	84%	75%	8%	34%
Age, years, mean (SD)	48.8 (8.2)	50.7 (5.9)	48.6 (7.6)	44.3 (9.0)
Years in Clinical Practice, years, mean (SD)	17.3 (7.4)	20.2 (6.1)	15.0 (5.5)	16.2 (7.2)
Time Spent in Direct Patient Care, mean (SD)	96.5% (5.1%)	97.6% (4.2%)	97.0% (5.6%)	96.4% (5.6%)
Practice Setting				
Community practice	62%	57%	34%	40%
Solo practice	21%	32%	32%	48%
Hospital-based practice	9%	8%	18%	10%
Academic practice	8%	3%	8%	–
Medical Specialty				
Primary care / general practice	–	100%	38%	34%
Gastroenterology	100%	–	38%	53%
Internal medicine	–	–	18%	12%

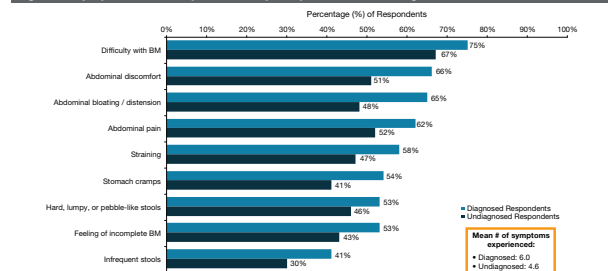
- A total of 331 HCPs completed the survey (Table 2). On average, HCP respondents were in clinical practice for 17.5 years and spent 96.6% of their time in direct patient care.

Figure 1. Patient Assessment of Their IBS-C Feelings and HCP Perspective on Patient Assessments



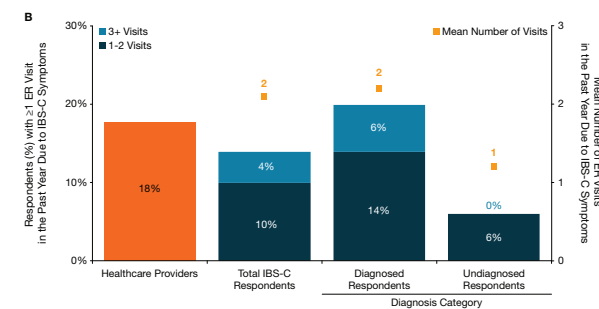
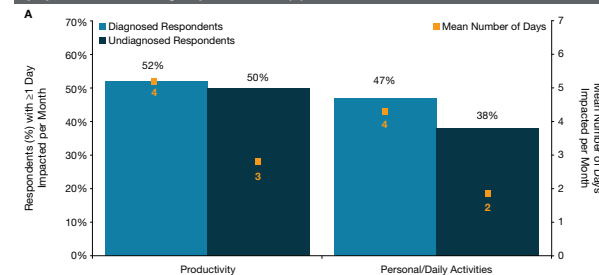
- IBS-C respondents most commonly reported feeling *frustrated* and *stressed* regarding their IBS-C (Figure 1), with 59% describing symptoms as *somewhat* to *extremely bothersome*. Yet, nearly 40% of respondents were *accepting* of IBS-C as part of their daily life.
 - The trend of feelings was similar between the diagnosed and undiagnosed groups, except for the inverse relationship of feeling *fine, no big deal*, a difference in attitude that may partly explain why the undiagnosed respondents remain undiagnosed.
- HCPs agreed that patients were *frustrated* and *stressed*; however, HCPs were less likely to recognize patients are *accepting* of IBS-C and were more likely to believe patients are *obsessed with symptoms*.
- While one-fifth (~20%) of the IBS-C respondents thought they were *in control* of their IBS-C, only 6% of HCPs thought their typical IBS-C patient was *in control* of their symptoms.

Figure 2. Symptoms First Experienced by Respondents Suffering From IBS-C



- Respondents reported experiencing multiple stool and abdominal symptoms at the onset of their IBS-C, with diagnosed patients reporting a larger number of initial symptoms than undiagnosed respondents (Figure 2).

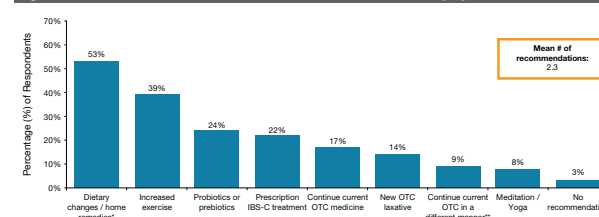
Figure 3. IBS-C is Associated with Impacted Productivity and Personal Activities (A) and Symptom-Related Emergency Room Visits (B)



Mean number of days impacted (A) or emergency room (ER) visits (B) includes respondents whose estimate was 0. HCPs were asked: "What percent of your IBS-C patients have been to Emergency Room/ UrgiCare Centers because of their symptoms?"

- A large percentage of respondents had productivity (work/school) and/or personal activity (social events/hobbies) impacted by IBS-C symptoms ≥ 1 day in a typical month, with HCPs estimating averages of 9 days/month and 4 days/month, respectively (Figure 3A).
- HCPs were aligned with patients in recognizing the rate of emergency room visits due to IBS-C symptoms, with similar rates across HCP type (range, 16% to 21%) (Figure 3B).

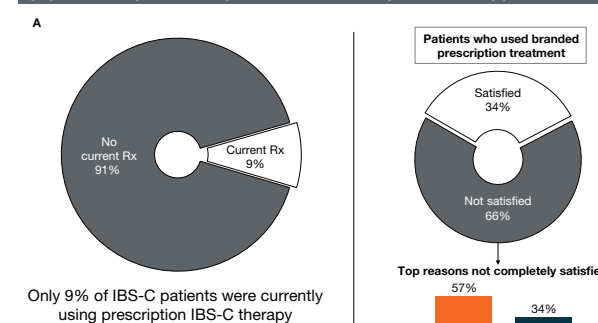
Figure 4. Initial HCP Recommendations for the Treatment of IBS-C Symptoms



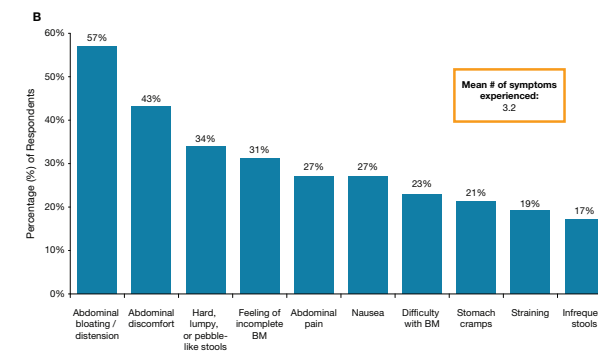
Of diagnosed patients. *Examples: caffeine, prunes, milk of magnesia, laxative teas, and mineral oil, etc.; includes gluten-free or FODMAP diets. **Different manner refers to a change in frequency or dose size. OTC=over-the-counter.

- Patient respondents reported that their HCP initially recommended general dietary changes / home remedies and increased exercise (Figure 4), which are recommended by ACG guidelines and which may have been tried by patients prior to consulting an HCP.

Figure 5. Patient Satisfaction with Prescription Therapies for the Treatment of IBS-C (A) and Symptoms Still Experienced Despite Current IBS-C Prescription Treatment (B)



Only 9% of IBS-C patients were currently using prescription IBS-C therapy



(A) Left: Of respondents who had ever used any treatment. Right: Of patients who were past and/or current users of branded prescription medication (Rx). (B) Of patients currently taking a prescription treatment for IBS-C. BM=bowel movement.

- Only 9% of respondents were currently taking a prescription treatment for their IBS-C symptoms (Figure 5A); although in Figure 4 it was reported that 22% were recommended prescription treatment initially.
- Of IBS-C patients currently using a prescription IBS-C treatment, 66% were not completely satisfied, primarily due to lack of efficacy, with 20% reporting dissatisfaction due to diarrhea as a medication side effect. Similarly, 59% of IBS-C sufferers reported that their OTC laxative caused diarrhea at least some of the time.
- Only 21% of HCPs were *satisfied* or *completely satisfied* with current prescription IBS-C treatments, citing *inadequate efficacy* (55%) and *diarrhea* (41%) as challenges most frequently experienced in treating IBS-C.
- Despite taking a prescription IBS-C treatment, patients still experienced several IBS-C symptoms (Figure 5B), suggesting that these treatments are not adequate in fully addressing IBS-C.
 - Notably, abdominal bloating/distention was the most frequent residual symptom, followed by abdominal discomfort. This suggests that current prescription treatment may be effective at reducing abdominal pain, but not necessarily secondary abdominal symptoms, which can be just as bothersome.^{5,6}

Discussion

- The BURDEN IBS-C Study confirmed the physical, psychosocial, and clinical impact of IBS-C, emphasizing the substantial burden on QOL associated with IBS-C.
- Attitudinal disconnects were uncovered regarding the impact and experience of IBS-C, with HCPs mostly believing that patients were *obsessed with IBS-C symptoms* and patients indicating that they were *accepting* of their IBS-C.
- Despite using a variety of treatments, only 20% of respondents felt they were *in control* of their IBS-C symptoms and even fewer HCPs (6%) felt their patients were *in control*, which was reflected by the number of days with QOL negatively impacted.
- Fewer than half of the patients initially recommended a prescription therapy by their HCP were currently taking a prescription treatment, suggesting that patients either did not want to take or decided to discontinue the prescription treatment.
- Compared to the results of the BURDEN-CIC Study,³ both IBS-C and CIC sufferers reported similar feelings toward their condition, negative impact on productivity and personal activities, and dissatisfaction with available treatments.
 - IBS-C respondents tended to report more abdominal symptoms when describing the onset of disease, while CIC respondents more frequently reported stool symptoms, supporting the concept that these disorders exist on a continuum,² primarily delineated by stool frequency and abdominal pain.
 - HCPs were less likely to initially recommend their IBS-C patients continue OTC treatments than their CIC patients and were more likely to recommend probiotics/prebiotics; however, rates of all other initial recommendations were similar.
 - A lower percentage of IBS-C patients were currently using prescription therapy than CIC patients (9% vs 16%), and a higher percentage of IBS-C patients reported dissatisfaction with their branded prescription (66% vs 59%), which may partly be due to the higher frequency of residual symptoms that IBS-C patients experienced despite prescription therapy.
- Perhaps because IBS-C is a heterogeneous disorder, patients commonly expressed general dissatisfaction with currently available treatments, and most HCPs also felt that more effective and tolerable medications are needed for IBS-C treatment.

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