# Results From the BURDEN-CIC Study (Better Understanding and Recognition of the Disconnects, Experiences, and Needs of Patients With Chronic Idiopathic Constipation)

### Background

- Chronic idiopathic constipation (CIC) is a common functional gastrointestinal (GI) disorder with a prevalence ranging from 2% to 27% in adults, averaging ~14%, and a prevalence that generally increases with age.<sup>1,2</sup>
- While literature exists on the direct cost of managing patients with CIC and the reduced health-related quality of life (HRQOL) of these patients, data regarding patients' experiences throughout the course of CIC and treatment are limited, which underscores the need to explore these issues in greater detail.
- The BURDEN–CIC Study was designed to better understand the experiences, attitudes, and unmet needs of patients with CIC and to assess where there is alignment vs disconnection with the understanding of the HCPs who treat these patients.

## Objective

To assess the impact of CIC on HRQOL, productivity, personal activities, and level of treatment satisfaction in a representative sample of the US population to further define the treatment needs of patients and their HCPs.

## Methods

• The BURDEN–CIC Study utilized 2 author-developed online surveys: one for adult patients with CIC (IRBapproved) and another for HCPs who treat CIC patients.

### **Patient Questionnaire**

- BURDEN–CIC recruited adult patients suffering with CIC; patients eligible to participate either had been formally diagnosed with CIC by an HCP (diagnosed group) or fulfilled Rome IV criteria for CIC, 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 questions, as well as Likert rating scales (1–5 or 1–7).
- Patients were not eligible to participate in BURDEN–CIC if they had irritable bowel syndrome with constipation (IBS-C), inflammatory bowel disease, diverticulitis, diverticulosis, spastic colon, celiac disease, or cancer of the GI tract, or if they had regularly taken an opioid (narcotic) within the past 3 months.

### **HCP Questionnair**

• The survey was targeted to gastroenterologists, primary care physicians, nurse practitioners, and physician assistants who actively treat patients with CIC and who were recruited independently of participants in the Patient Questionnaire.

### **Statistical Analysis**

• The patient sample was normalized (weighted) to correct for any biases in sampling or non-response and to reflect current US Census demographic benchmarks.

### More Severe CIC Patients

• A subanalysis of patients with "more severe" CIC was conducted in respondents who had: (1) productivity impacted by CIC symptoms ( $\geq 1$  day in the past month), OR (2) personal activity impacted by CIC symptoms  $(\geq 1 \text{ day in the past month})$ , OR (3) an emergency room visit for CIC-related symptoms ( $\geq 1$  visit in the past year), OR (4) a current prescription treatment for CIC.

## Results

- A total of 1,223 patients with CIC completed the survey.
- The majority of patients had been diagnosed with CIC; however, some respondents were not formally diagnosed but rather fit the Rome IV criteria for CIC and were termed the "undiagnosed" population (15%).

### Table 1a. CIC Patient Demographics

	Diagnosed Patients N=1035	Undiagnosed Patients N=188	Total Patients N=1223
Female, n (%)	69%	71%	69%
Age, yrs, mean (SD)	48.2 (18.0)	52.7 (18.0)	49.1 (18.0)
Age at Symptom Onset, yrs, mean (SD)	44.2 (17.5)	52.0 (18.5)	44.9 (17.7)
Race / Ethnicity (n, %)			
White / non-Hispanic	62%	80%	65%
Black / non-Hispanic	14%	8%	13%
Mixed / non-Hispanic	3%	3%	3%
Other / non-Hispanic	4%	1%	3%
Hispanic	17%	9%	16%
Highest Education Level (n, %)			
High school – no graduation	7%	8%	7%
High school – diploma / GED	28%	25%	27%
College – no graduation	26%	26%	26%
College – graduation	28%	27%	28%
College – post-graduate	11%	15%	12%

 A total of 331 HCPs completed the online survey. These HCPs were in clinical practice for >17 years (mean, 17.5) years) and spent >95% of their time in direct patient care (mean, 96.8%).

	Primary Care					
	Gastroenterologist N=155	Physician N=76	Nurse Practitioner N=50	Physician Assistant N=50		
Male, n (%)	84%	75%	8%	34%		
Age, yrs, mean (SD)	48.8 (8.2)	50.7 (5.9)	48.6 (7.6)	44.3 (9.0)		
Years in Clinical Practice, yrs, 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, n (%)						
Community practice	62%	57%	34%	40%		
Solo practice	21%	32%	30%	48%		
Hospital-based practice	9%	8%	18%	10%		
Academic practice	8%	3%	8%	-		
Medical Specialty (n, %)						
Primary care / general practice	_	100%	38%	34%		
Gastroenterology	100%	_	38%	53%		
Internal medicine	_	_	18%	12%		





Respondents could choose more than one option.



- with personal activities.
- at work or in school. are weekends.

Percentages may not total 100% due to rounding.

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Figure 1. Patient Assessment of their CIC Feelings and HCP Perspective on Patient Assessments

□ All CIC Patients ■ More Severe CIC Patients ■ Healthcare Professionals



 Patients used many terms to describe how they felt about their CIC, with most indicating negative emotions. • While more than 40% of patients reported being frustrated with CIC, over a third reported that they are "accepting" of their condition, which may indicate that they are settling when it comes to their condition and treatment. The report of "acceptance" was not noted frequently by the HCPs.

• Many HCPs aligned with patients, believing that patients were "frustrated," "stressed," and "fed up"; however, many HCPs also thought that their patients were "obsessed with symptoms" and "lacking answers," and only 10% of HCPs thought their patients were "in control" of their CIC.



• A large percentage of CIC patients, including more severe CIC patients, indicated that CIC symptoms interfered

- 62% of all CIC patients were affected 4 out of 30 days per month. • Patients indicated that their CIC symptoms impacted their productivity by missing a considerable number of days

- 37% reported 72 days/year are affected, which is even more significant because 104 days of the calendar year



Respondents could choose more than one option. BM=bowel movement

- (eg, abdominal pain, cramps, nausea) than were the total CIC population.

Figure 4. Initial HCP Recommendations for the Treatment of CIC Symptoms



Does not include gluten-free and FODMAP diets; does include home remedies (eg, caffeine, prunes, milk of magnesia, laxative teas, mineral oil). \*\*Meaning a change in frequency or dosage DTC=over-the-counter.

- Most CIC patients reported experiencing constipation-related symptoms for a median of 15 months before seeking HCP care; however, 30% experienced CIC symptoms for >4 years before seeking care.
- CIC patients reported their HCP initially recommended general dietary changes, increasing daily activity/exercise continuing on their current over-the-counter (OTC) medication, or starting a prescription CIC treatment.

Rx=prescription.

- In a single answer question, 59% of patients reported being not satisfied or not completely satisfied with current chronic prescription treatments
- The top reasons were efficacy (55%) and side effects (35%).
- Diarrhea was the most common side effect, noted by 54% of CIC patients who discontinued their prescription treatment.





Respondents could choose more than one option. BM=bowel movement.

Despite using a prescription treatment, 84% reported a wide variety of residual CIC symptoms, indicating that additional treatment options could be of benefit to many of these CIC patients.



### Figure 7. Greatest Perceived Challenges by Healthcare Professionals in the Management of Patients With CIC

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Respondents could choose more than one option

- Despite various OTC and prescription therapies, HCPs indicated that CIC remains a challenging disorder to manage.
- The top treatment challenges were inadequate response (55%), compliance (55%), treatment-related diarrhea (34%), lack of treatment options (34%), and treatment-related side effects other than diarrhea (25%).
- HCPs specifically indicated that managing treatment-related diarrhea was challenging, believing that it "prevents patients from enjoying daily activities" (42%), causes patients to "travel less" (40%), and results in "embarrassment due to having to use the bathroom frequently" (37%).
- In a separate question on satisfaction, 78% HCPs reported being not satisfied or not completely satisfied with current prescription treatments.
- Finally, 82% of HCPs and 70% of patients did not agree that "diarrhea is an acceptable outcome of taking my medication.

## Summary

- The BURDEN–CIC Study confirmed the significant physical, psychosocial, and medical toll of CIC symptomatology, including stress and frustration associated with CIC.
- Patients with CIC have a reduced overall QOL, with significant impairments in productivity and participation in personal activities.
- Many CIC patients indicated feeling "frustrated" with their CIC but nonetheless were "accepting" of the disorder, suggesting that they felt there was little else that could be done.
- CIC patients and HCPs were not fully satisfied with the treatment options (both OTC and prescription) for CIC available at the time of the survey, primarily because of side effects and lack of efficacy. Notably, only 16% of the CIC patients in this study reported taking a current prescription for CIC, despite the fact that prescription CIC medications have been available for over a decade.

### Conclusion

- The observation that many patients are accepting of their CIC suggests that this may represent a subtle yet important attitudinal disconnect between patients and their healthcare providers.
- There still remains an unmet need for treatments that are effective and well tolerated to alleviate and manage CIC symptoms.

## References

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