

# Comparison of Symptoms, Healthcare Utilization, and Treatment in Diagnosed and Undiagnosed Patients With IBS-D

Lin Chang, MD<sup>1</sup>; Kavita Aggarwal, PharmD<sup>2</sup>

<sup>1</sup>David Geffen School of Medicine, University of California, Los Angeles, CA, USA; <sup>2</sup>Salix Pharmaceuticals, Ltd., Raleigh, NC, USA

## INTRODUCTION

- Irritable bowel syndrome (IBS) is a heterogeneous functional bowel disorder in which patients experience multiple symptoms, such as abdominal pain, altered bowel function, and bloating<sup>1,2</sup>
- Up to 45 million North Americans suffer from symptoms of IBS,<sup>2</sup> yet ~75% remain undiagnosed with the condition

## OBJECTIVE

- To compare symptom characteristics, physician visits, and treatments administered for symptom management in individuals medically diagnosed with diarrhea-predominant IBS (IBS-D) versus those undiagnosed despite having sought medical attention for IBS-related symptoms

## METHODS

- Inclusion criteria: Individuals ≥18 years from a general US population sample who had previously responded to an invitation to be participants in various surveys and who indicated in a profile questionnaire that they have experienced gastrointestinal (GI) issues
  - An invitation to complete an online survey was sent via e-mail to all individuals in the database, with 2 to 3 additional e-mail reminders sent to nonresponders
  - Patients were incentivized to participate via a point system redeemable for various rewards (eg, gift cards)
- This survey was conducted from September 1 to September 15, 2014, and assessed the frequency and severity of GI symptoms, number and type of healthcare visits, general well-being, management of symptoms, and treatment satisfaction
- Individuals classified as "diagnosed IBS-D" self-reported that a healthcare provider had diagnosed them with IBS
- Individuals classified as "undiagnosed IBS-D":
  - Although not formally diagnosed with IBS by a healthcare provider, individuals were determined to have IBS symptoms according to Rome III criteria<sup>3</sup> based on their survey responses: abdominal pain and discomfort at least 2 to 3 times per month for at least the previous 3 months
    - Accompanied by more frequent bowel movements and looser formed stools; improvement in pain or discomfort with a bowel movement
  - Patients could not have noted constipation as "always" occurring, nor associated stomach issues predominantly accompanied by constipation
  - Patients also could not have reported bloody stools >5 times in the previous month or have had previous GI or abdominal surgery
- Symptom severity scored on 7-point scale (1 = very mild; 7 = very severe); disruptiveness scored on 7-point scale (1 = not at all disruptive; 7 = extremely disruptive); satisfaction with current treatments ranked on 7-point scale (1 = extremely unsatisfied; 7 = extremely satisfied)
- Adjustments to daily living were determined based on 11 predefined responses or a choice of "other" or "none of the above" to the question: "Which, if any, of the following things do you do in your day-to-day life in order to manage your [IBS/stomach problems]?"
- Statistically significant differences between diagnosed and undiagnosed populations were calculated using a z-test for proportions

## RESULTS

- 126,057 invitations were sent out via e-mail, 23,707 (18.9%) clicked on the link to take the survey, and 1924 (1.5%) met eligibility criteria and completed the survey
- Of the 1924 individuals who completed the survey, 1094 (56.9%) had been diagnosed with IBS and 830 (43.1%) were not medically diagnosed despite meeting Rome III criteria for IBS-D
- Diagnosed group was significantly more likely than the undiagnosed group to be white, female, and ≥60 years of age (Table 1)
- Compared with undiagnosed individuals, those diagnosed with IBS-D were significantly more likely to have had a longer duration of symptoms (≥10 years), consulted ≥3 physicians, and had previous GI or abdominal surgery (Table 2)

## RESULTS

- The majority (>80%) of both diagnosed and undiagnosed patients considered their symptoms to be moderate in intensity (Table 2)

Table 1. Population Demographics

Characteristic	Individuals, %	
	Diagnosed With IBS (n = 1094)	Undiagnosed (n = 830)
Male:Female	22:78 <sup>a</sup>	36:64
Age range, y		
18-39	38	40
40-59	40	48
≥60	22 <sup>a</sup>	12
Race/Ethnicity		
White	93 <sup>a</sup>	86
Black	3	6
Hispanic/Latino	3	5
Asian-American/Asian	2	4
Other ethnicity	1	3

<sup>a</sup>P < 0.05 vs undiagnosed.

Table 2. Symptom History

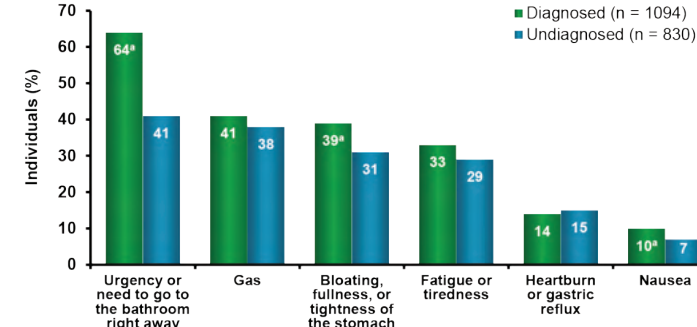
Parameters	Individuals, %	
	Diagnosed With IBS (n = 1094)	Undiagnosed (n = 830)
Symptom duration, y		
<5	25	66
5-10	20 <sup>a</sup>	16
≥10	55 <sup>a</sup>	18
History of GI/abdominal surgery	52 <sup>a</sup>	37
Consulted ≥3 physicians		
Symptoms <5 years	22 <sup>a</sup>	6
Symptoms 5-10 years	38 <sup>a</sup>	17
Symptoms ≥10 years	50 <sup>a</sup>	29
Consultation with gastroenterologist		
Symptoms <5 years	51 <sup>a</sup>	25
Symptoms 5-10 years	56 <sup>a</sup>	30
Symptoms ≥10 years	67 <sup>a</sup>	45
Symptom intensity		
Mild (score 1-2)	3	6
Moderate (score 3-5)	81	86
Severe (score 6-7)	16 <sup>a</sup>	8

<sup>a</sup>P < 0.05 vs undiagnosed.

- When experiencing abdominal pain and discomfort associated with loose stools or diarrhea, several additional symptoms were experienced "always or most of the time" (Figure 1)
- A significantly larger percentage of diagnosed patients reported that bowel movement urgency and diarrhea were severe and disruptive (Figure 2)
- To manage symptoms, diagnosed patients made more adjustments to daily activities than did undiagnosed patients (mean [out of 11 predefined choices], 3.7 vs 2.9, respectively; P < 0.001), had tried more IBS treatments (mean, 4.9 vs 3.4; P < 0.05), and were currently using more IBS treatments (mean, 2.6 vs 2.1; P < 0.05)
- Furthermore, <30% of diagnosed and <20% of undiagnosed patients had tried therapies with established efficacy in IBS-D (Figure 3)
- Only 15% and 9% of diagnosed and undiagnosed patients, respectively, expressed satisfaction (score, 6-7) with current treatments
- Multiple explanations for symptoms were provided to patients by healthcare providers; a larger number of undiagnosed versus diagnosed patients were given no explanation for their symptoms (32% vs 10%; P < 0.05; Table 3)

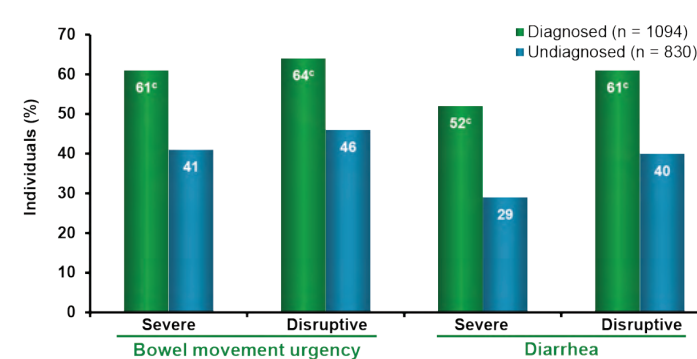
## RESULTS

Figure 1. Additional Symptoms Experienced "Always or Most of the Time"



<sup>a</sup>P < 0.05 vs undiagnosed.

Figure 2. Severity<sup>a</sup> and Disruptiveness<sup>b</sup> of Bowel Movement Characteristics



<sup>a</sup>Score of 6 or 7 on a 7-point scale (1 = very mild; 7 = very severe).

<sup>b</sup>Score of 6 or 7 on a 7-point scale (1 = not at all disruptive; 7 = extremely disruptive).

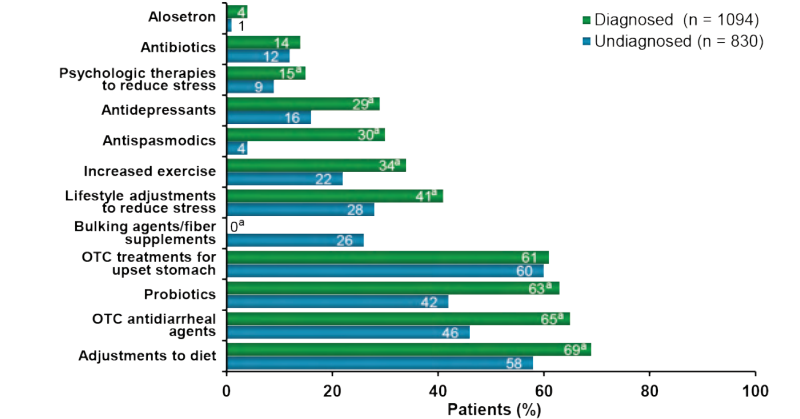
<sup>c</sup>P < 0.05 vs undiagnosed.

## CONCLUSIONS

- >40% of surveyed individuals with IBS symptoms had not been medically diagnosed with IBS
- Patients with an established diagnosis of IBS were more likely to experience bowel movement urgency and diarrhea that was severe and disruptive; however, most were not being treated with IBS therapies with proven efficacy
- Multiple potential explanations for GI symptoms are communicated to individuals by physicians
- More effective education about diagnosing IBS and appropriate treatment options is warranted for healthcare providers and patients

## RESULTS

Figure 3. Treatment Options Administered to Help Manage Symptoms of IBS



<sup>a</sup>P < 0.05 vs undiagnosed.

OTC = over the counter.

Table 3. Healthcare Provider Explanations for IBS/GI Symptoms

Factor indicated by physician as contributing to symptoms	Individuals, %	
	Diagnosed With IBS (n = 1094)	Undiagnosed (n = 830)
Stress or anxiety	67 <sup>a</sup>	37
Particular foods my body is sensitive to	58 <sup>a</sup>	32
An imbalance of bacteria within my stomach or gut	34 <sup>a</sup>	16
Family genetics	32 <sup>a</sup>	14
Poor diet	31	27
This is just the way my body works	21 <sup>a</sup>	7
Not getting enough exercise or being out of shape	19	19
Hormonal changes	12	12
Eating at certain times of the day	12	12
Aging	9	11
Effect of something in my environment I'm being exposed to	6	5
Other	4	4
None	10 <sup>a</sup>	32
Mean no. of explanations physicians provided to patients	3.1	2.3

<sup>a</sup>P < 0.05 vs undiagnosed.