Patient characteristics (irritable bowel syndrome with constipation [IBS-C]): baseline results from LOGIC (Longitudinal Outcomes study of GI symptoms in Canada)

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ABSTRACT

Background: Abdominal pain/discomfort, bloating and constipation are gastrointestinal (GI) dysmotility and sensory symptoms related to irritable bowel syndrome (IBS): Dysmotility symptoms are associated with impaired quality of life (QoL) and increased health care utilization. LOGIC is an ongoing, prospective, observational study designed to evaluate the treatment patterns and health outcomes of patients with IBS symptoms in Canada

Methods: 1,553 patients with IBS-type symptoms were enrolled from 147 community and specialist physician sites across Canada. Clinical data and patient-reported outcomes (PROs) were collected at baseline; PROs are completed at Months 1, 3, 6, 9 and 12. QoL and patient's health state were assessed using IBS-QOL and EQ-5D questionnaires, and work productivity by using the WPAI:IBS. Resource utilization included number and type of physician visits, procedures and treatments

Results: Baseline data were obtained from 1,553 patients, of whom 1,321 (85%) were women. Patients had a mean age of 46 years and mean disorder duration of 11 years (1 month–69 years). Self-reported bowel patterns were predominantly constipation (39%) and alternating (37%). The mean overall IBS-QOL (mean score on 0–100 scale) was 66; food avoidance (52) and health worry (59) were the most serious concerns, followed by body image (61), dysphoria (67) and interference with activity (67). The WPAI:IBS indicated a 6% loss of work time, with approximately 34% impairment in overall work productivity and 37% impairment in daily activities. In the preceding month, patients had on average 0.76 consultations with a family doctor and 0.07 specialist visits. More than two-thirds reported a history of undergoing a medical procedure, the most common being abdominal ultrasound (51%), barium X-ray (45%), and colonoscopy (35%). The most common prescription (Rx) medications reported at baseline included tegaserod (26%) and pinaverium bromide (9%). Within the previous 4 weeks, fiber (30%), laxatives (28%) and analgesics (39%) were the most commonly reported non-Rx medications

Conclusions: These baseline data are consistent with previous findings showing significant use of medications and healthcare resources with concomitant low QoL in patients with GI dysmotility symptoms. This study will follow patients for 1 year, providing insights into the assessment, treatment and outcomes of IBS symptoms in Canada

BACKGROUND

- Irritable bowel syndrome (IBS) is a chronic, episodic gastrointestinal (GI) motility and sensory disorder that is characterized by abdominal pain/discomfort, bloating and an altered bowel habit, i.e. constipation (IBS-C), diarrhea (IBS-D), or alternating constipation/diarrhea (IBS-A)[1]
- IBS adversely impacts on patient quality of life (QoL)[2–4]

BACKGROUND (cont'd)

- The multiple symptoms of IBS negatively affect many aspects of patients' lives, such as sleep, travel, diet, intimacy and leisure activities[2,5–8]
- The QoL of IBS patients is substantially diminished compared with the general population and also patients who have other episodic, chronic disorders such as gastroesophageal reflux disease, migraine or asthma[9,10]
- IBS is associated with considerable direct costs (use of healthcare resources) and indirect costs (work productivity).[2] In the US, the annual direct cost of IBS is estimated to be $10.5 billion (1999 $), excluding the cost of prescription (Rx) and over-the-counter (OTC) drugs[4]
- The indirect costs associated with presenteeism (impairment while at work) and absenteeism (missed days of work) attributable to IBS are estimated to be as high as $20 billion (2000 $)[2]
- The burden of illness associated with IBS is high. In Canada, wages lost because of IBS amount to $1 billion per year, and both direct and indirect costs amount to approximately $1.37 billion per year[11]
- No observational studies have been conducted to follow IBS patients over the course of 1 year with the aim of collecting prospective information on health outcomes

OBJECTIVE

- LOGIC (**L**ongitudinal **O**utcomes study of **G**I symptoms in **C**anada) is an ongoing, prospective, observational study designed to evaluate the treatment patterns and health outcomes of patients with IBS symptoms in Canada
- This analysis assessed the baseline characteristics of IBS patients included in the above study

METHODS

- Overall, 1,553 patients with IBS-type symptoms were enrolled from 147 community and specialist physician sites in Canada
- Clinical data and Patient-Reported Outcomes (PROs) were collected at baseline. PROs were also completed at Months 1, 3, 6, 9 and 12 of the study (Figure 1)
- Baseline information relating to the frequency, intensity and distress/bothersomeness (scored on a 0 to 5-point scale), associated with five IBS symptoms (abdominal pain/discomfort, bloating, constipation, diarrhea and gas) were collected using the IBS Subject Symptoms Questionnaire
- QoL and utility were assessed using IBS-QOL[12] and EQ-5D questionnaires, and work productivity by using the WPAI:IBS[13]
- Data collected on healthcare resource utilization included the number and type of physician visits, procedures and treatments
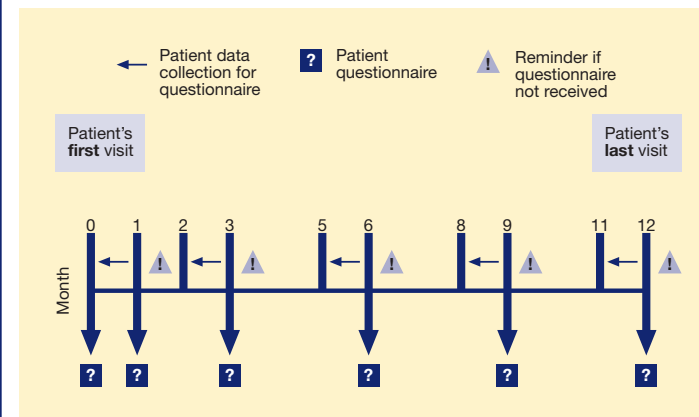
METHODS (cont'd)

Figure 1. Data collection timescale.

RESULTS

- Baseline data were obtained from 1,553 patients (Table 1)

Table 1. Patient demographics at baseline (n=1,553).

Patient characteristics	
Gender: women, n (%)	1,321 (85)
Mean age (years)	46
Race: Caucasian, %	87
Employed, n (%)	921 (59)
Married, %	53
Mean duration of IBS in years (range)	11 (1 month–69 years)
Predominant bowel habit, %*	
Constipation	39
Diarrhea	6
Alternating	37
Met Rome II criteria, %	75

*18% of subjects either provided no response/left question blank or chose 'normal' as a response

- The most common Rx medications reported at baseline were tegaserod (26%) and pinaverium bromide (9%)
- In the 4 weeks preceding the study, analgesics (38.8%), fiber (30.1%) and laxatives (27.6%) were the most commonly reported non-Rx medications used by patients (Table 2)
- Figure 2 shows the overall frequency, intensity, and distress/bothersomeness associated with the five IBS symptoms listed in the IBS Subject Symptoms Questionnaire, as reported by patients at baseline
- In the 4 weeks prior to study entry, patients had on average, 0.76 consultations with a family doctor and 0.07 specialist visits

RESULTS (cont'd)

Table 2. Commonly used IBS treatments reported at baseline.

Treatment	Overall use (n=1,483) n (%)
Analgesics	575 (38.8)
Fiber	446 (30.1)
Laxatives	409 (27.6)
Acid reducers	389 (26.2)
Gas relief	282 (19.0)
Antidiarrheal products	232 (15.6)
Stool softeners	221 (14.9)
Other	212 (14.3)
Homeopathic medications	103 (6.9)

*Includes patients who reported a frequency of 'Most' or 'All' of the time, a 'Severe' or 'Extreme' intensity, and 'Quite a bit' or 'Extreme' distress/bothersomeness
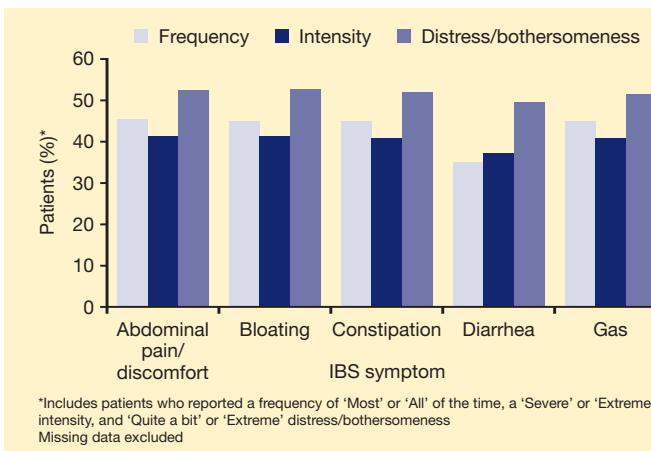Missing data excluded

Figure 2. IBS patients' symptoms at baseline.

- Overall, 73% of patients had undergone a medical procedure to investigate their GI symptoms, the most common being abdominal ultrasound (51%), barium X-ray (45%), colonoscopy (35%) and abdominal X-ray (29%)
- The mean overall IBS-QOL score (0–100 scale) was 66.0. Food avoidance (51.6) and health worry (58.8) were the most serious concerns, followed by body image (60.6), dysphoria (66.5), and interference with activity (66.5) (Figure 3)
- Baseline data from the EQ-5D questionnaire reported a mean utility index value of 0.64 (where 0 = death and 1 = perfect health). Data from pain/discomfort and anxiety/depression questions were the primary contributors to this overall value
- Of the patients enrolled, 921 (59%) were employed at the time of the study. Data from the WPAI:IBS reported a 6% absenteeism rate (loss of work time), 31% presenteeism (impairment while at work), with 34% impairment in overall work productivity and 37% impairment in daily activities

RESULTS (cont'd)
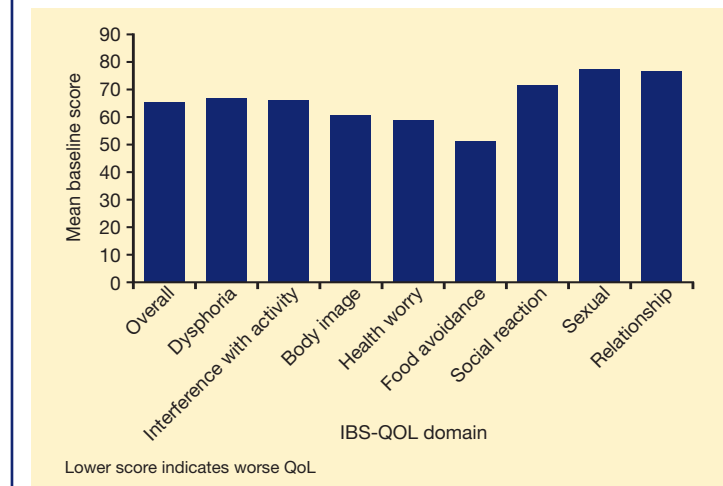

Lower score indicates worse QoL

Figure 3. Mean baseline IBS-QOL scores.

CONCLUSIONS

- IBS has a substantial impact on patients' QoL and is associated with considerable use of Rx and non-Rx medications, which are likely to contribute to the socioeconomic impact of IBS
- This is the first longitudinal, community-based study to follow patients with IBS for 1 year. An initial evaluation of the baseline data indicates that significant use of medications and healthcare resources was directly associated with low QoL in patients with IBS
- Baseline data from the LOGIC study confirm that IBS restricts both social interactions/relationships and work productivity, with patients reporting high absenteeism through illness due to IBS-type symptoms, and reduced productivity and performance at work

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