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ORIGINAL RESEARCH

Broad Impact of Bowel Urgency in Ulcerative Colitis and Crohn's Disease: US, European, and Japanese Patient and Healthcare Professional Perspectives from the Communicating Needs and Features of IBD Experiences (CONFIDE) Survey

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ABSTRACT

Introduction: Bowel urgency affects the quality of life of patients with Crohn's disease (CD) and ulcerative colitis (UC). This study used data from the Communicating Needs and Features of IBD Experiences (CONFIDE) survey to explore patient and healthcare professional (HCP) perceptions on the broad impacts of bowel urgency on patients' emotions and daily lives.
Methods: Online, quantitative, cross-sectional surveys were conducted among patients with moderate-to-severe UC or CD (defined based on previous treatment, steroid use, and/or hospitalization) and HCPs specialized in gastroenterology in Europe (France, Germany, Italy, Spain, UK), United States (US), and Japan. Data were summarized using descriptive statistics.
Results: The analysis included 200 US, 556 European, and 124 Japanese patients with UC and 215 US, 547 European, and 99 Japanese patients with CD; and 200 US, 503 European, and 100 Japanese HCPs. Patients experiencing bowel urgency in the past month and HCPs reported high emotional (up to: 97% patients, 97% HCPs) and daily life (up to: 85% patients, 97% HCPs) impacts due to bowel urgency in the US, Europe, and Japan. In all geographies, these impacts were similar among patients with UC and CD. Although patients and HCPs reported a

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broad impact of bowel urgency, HCPs perceived a higher impact than patients, but it was not among the top three most impactful symptoms on HCPs' treatment decisions.

Conclusions: Bowel urgency affects the emotions and daily life of patients with UC or CD in the US, Europe, and Japan. A multidisciplinary approach is required to enhance care and develop suitable treatment strategies.

Keywords: Bowel urgency; Crohn's disease; Ulcerative colitis

Key Summary Points

Why carry out this study?

Bowel urgency is a common and debilitating symptom of ulcerative colitis and Crohn's disease that impairs patients' quality of life.

Patients' and healthcare professionals' perspectives on the multidimensional impacts of bowel urgency are not well studied in ulcerative colitis and Crohn's disease.

What was learned from this study?

Patients and gastroenterology healthcare professionals in the US, Europe, and Japan reported a high emotional and daily life impact of bowel urgency in moderate-to-severe ulcerative colitis and Crohn's disease.

Despite the broad impact, bowel urgency was not among the top three most impactful symptoms on gastroenterology healthcare professionals' treatment decisions.

It is important to evaluate the multifaceted impacts of bowel urgency to identify gaps in patient care and effectively address this issue across geographies.

INTRODUCTION

Ulcerative colitis (UC) and Crohn's disease (CD) are chronic inflammatory conditions often accompanied by gastrointestinal and systemic symptoms [1, 2]. One of the most common and disruptive manifestations of UC and CD is bowel urgency, defined as a sudden and immediate need for a bowel movement [3–5]. Although > 70% of patients with UC or CD experience bowel urgency [6–8], it remains to be a relatively overlooked symptom that is often conflated with other symptoms of abnormal anorectal function, such as stool frequency, fecal incontinence (passive incontinence or fecal leakage), or diarrhea [5, 6, 9–11].

The unpredictable nature and severity of bowel urgency causes considerable anxiety and embarrassment, making it one of the leading concerns among patients with UC or CD [4, 9, 12]. It often disrupts their daily lives, impacting work/education, social interactions, and participation in physical activities [12–14]. Patients frequently experience anxiety and fear of potential bowel urgency-related accidents and limited toilet accessibility, which may lead to an avoidance of public places [4, 6, 8, 15]. Additionally, many patients feel embarrassed to discuss bowel urgency with healthcare professionals (HCPs), who may in turn not prioritize addressing this important symptom [3]. Previous studies have also shown bowel urgency to be associated with morbidity, higher disease activity, and reduced quality of life (QoL), affecting patients' emotional and psychological functioning [9, 13, 16]. Recognizing the high burden for patients who suffer from it and its association with prolonged corticosteroid use, hospitalization, and colectomy, bowel urgency has been included as an endpoint in recent clinical trials for UC and CD [17–20].

Despite growing real-world evidence on the importance of bowel urgency in UC and CD, research examining its impact on patients' daily activities and mental well-being is limited. While few qualitative or survey-based studies have shed light on patients' experiences with bowel urgency, they have largely been focused on patient populations in individual countries [9, 12, 15, 21]. Furthermore, there is a lack of studies that capture the nuanced narratives of both patients and HCPs across diverse geographies.

The Communicating Needs and Features of IBD Experiences (CONFIDE) study aimed to understand the experience and impact of UC and CD symptoms on patients' lives and identify the communication gaps between HCPs and patients in the United States (US), Europe [France, Germany, Italy, Spain, and the United Kingdom (UK)], and Japan. Previously reported CONFIDE data highlighted bowel urgency as a common and impactful symptom among patients in the US and Europe [22–24]. The current analyses aimed to further explore patient and HCP perspectives on the broad impact of bowel urgency on patients' emotions and daily lives from a global perspective, including data from the US, European, and Japanese populations.

MATERIALS AND METHODS

The CONFIDE Surveys

The CONFIDE study was a point-in-time observational study comprising two online, quantitative, cross-sectional surveys: one for patients with UC or CD, and another for prescribing HCPs managing UC and/or CD. Here, we present the survey results from patients and HCPs in the US, Europe (France, Germany, Italy, Spain, and the UK), and Japan. The CONFIDE surveys were developed using inputs from patients with UC and CD, as well as from prescribing gastroenterologists. The surveys were also translated into the local language of each participating country and culturally adapted to reflect regional nuances in question phrasing and interpretation. Appendix A details all patient and HCP survey questions included in this study. Additional details regarding survey design and data collection have been described in earlier publications [22, 23].

Study Population

Patients and HCPs were recruited via online panels. Respondents were required to provide informed consent and were screened online to ensure that only eligible patients and HCPs completed the surveys.

Patients aged ≥ 18 years with a self-reported HCP diagnosis of moderate-to-severe UC or CD were included in this survey. Moderate-to-severe disease was defined as (1) having received anti-tumor necrosis factor, anti-integrin, Janus kinase inhibitor, anti-interleukin-12/23, or immunomodulator treatment in the past year, and/or (2) having received steroid treatment for at least 1 month in the past year, and/or (3) having been hospitalized for at least 4 consecutive weeks during the past 5 years. Patients with a history of colectomy were excluded. The proportion of patients with self-reported concomitant irritable bowel syndrome in each country was capped at 20% of the total sample size.

Eligible HCPs were gastroenterologists, inflammatory bowel disease (IBD) nurse specialists (UK only), internal medicine with gastroenterology (GI) focus, nurse practitioners (US only), or physician assistants (US only). HCPs included were responsible for making prescribing decisions for ≥ 10 patients with UC or CD (of which ≥ 5 patients in a month had moderate-to-severe disease) and spent ≥ 50% of working time actively seeing patients.

Survey Content

The surveys were conducted to explore the patient and HCP perceptions on experience, burden, and impact of UC or CD-related symptoms on patients' overall QoL.

To assess symptom experience, patients were presented with a list of 30 symptoms and asked to indicate: (1) symptoms they had experienced in the past month (i.e., currently experiencing), and (2) symptoms they had ever experienced. In order to assess the patients' severity of UC- or CD-related bowel urgency, those who reported currently experiencing bowel urgency were asked to rate their urgency severity over the previous three days using the Urgency Numeric Rating Scale (NRS), on a scale of 0 (no urgency) to 10 (worst possible urgency) [25]. These patients were also asked to indicate the extent to which bowel urgency interfered with 12 different aspects of their daily lives, on a scale of

1 (not at all) to 7 (a great deal), with the option to select "not applicable" as a response. HCPs were asked to rate the extent to which bowel urgency affects various aspects of patients' daily lives, on a scale 1 (no impact at all) to 7 (impacts a great deal), with 0 indicating "no opinion". Patients who reported currently experiencing bowel urgency and HCPs were asked to rate the emotional impact of bowel urgency based on a range of mental health-related issues. Patients rated the impacts on a scale 1 (does not make me feel like this at all) to 7 (makes me feel like this a great deal). HCPs rated the impacts on a scale of 1 (patients do not experience at all) to 7 (patients experience a great deal), with 0 indicating "no opinion". Mean ratings of 1–3 were defined as "low impact", while ratings of 4–7 were considered as "high impact" for both patients and HCPs. HCPs were also asked to rate the top three symptoms that had the greatest impact on their treatment decisions.

Statistical Analysis

Data were summarized using descriptive statistics. Categorical and ordinal variables were presented as frequencies (HCPs or patients) and percentages. Continuous variables (e.g., age, time since diagnosis) were presented as number of observations (HCPs or patients), means, and standard deviations. Direct comparisons between data from patients with UC and CD and between geographies were not performed.

Compliance with Ethics Guidelines

All participants provided informed consent to participate in the study via an IRB-approved informed consent form. The protocol and supporting data collection materials were approved by the Western Institutional Review Board (study number: 1307697). The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and was consistent with Good Pharmacoepidemiology Practices and applicable laws and regulations of the countries where the study was conducted. Patients and HCPs were paid a nominal honorarium for completing the surveys.

RESULTS

Demographics and Clinical Characteristics

Patients with moderate-to-severe UC or CD were contacted between 1 July and 9 September 2021. Of the 18,002 patients with UC who were contacted, 200 US, 556 European, and 124 Japanese patients completed the survey. Of the 2706 patients with CD who were contacted, 215 US, 547 European, and 99 Japanese patients completed the survey. Mean ages in the populations with UC and CD were 40.4 and 40.9 years for US patients, 38.9 and 38.0 years for European patients, and 48.8 and 43.0 years for Japanese patients, respectively. The majority of the patient population across geographies were male (54.9–70.2%). Among patients with UC, mean (SD) time since diagnosis was 7.9 (8.6), 7.9 (7.5), and 12.5 (7.5) years for US, Europe, and Japan, respectively, and 8.7 (8.6), 9.2 (8.5), and 15.7 (10.2) years among those with CD. A total of 76.5% US, 54.1% European, and 41.9% Japanese patients with UC were receiving advanced therapies (biologic therapy, biosimilars, or Janus kinase inhibitors) at the time of survey completion. Among patients with CD, 58.1% US, 63.4% European, and 86.9% Japanese patients were receiving advanced therapies. Key patient demographics are reported in Table 1.

Between 28 May and 2 October 2021, 840 HCPs were contacted, and 200 US, 503 European, and 100 Japanese HCPs completed the surveys. Table 1 displays key HCP demographics. Overall, most HCPs were male (US: 78.0%; Europe: 70.8%; Japan: 92.0%) and gastroenterologists (US: 88.0%; Europe: 93.2%; Japan: 100.0%).

Patient-Reported Experience and Burden of Bowel Urgency

A greater proportion of Japanese patients with UC than US and European patients reported ever experiencing bowel urgency (US: 61.5%; Europe: 45.0%; Japan: 79.0%). For patients with CD, more than half of the patient population across all three geographies reported

Table 1 Demographics and characteristics of patients and HCPs

Patients with UC	**US (*N* = 200)**	**Europe (*N* = 556)**	**Japan (*N* = 124)**
Mean age, years (SD)	40.4 (10.8)	38.9 (8.8)	48.8 (10.5)
Sex, *n* (%)			
Male	123 (61.5)	319 (57.4)	87 (70.2)
Female	77 (38.5)	236 (42.4)	37 (29.8)
Prefer not to say	–	1 (0.2)	–
Ethnicity, *n* (%)			
White	155 (77.5)	518 (93.2)	–
Hispanic/Latino	23 (11.5)	3 (0.5)	–
African American	18 (9.0)	–	–
Japanese	–	21 (3.8)	124 (100.0)
Other[a]	4 (2.0)	14 (2.5)	-
Time since diagnosis of UC (mean years [SD)]	7.9 (8.6)	7.9 (7.5)	12.5 (7.5)
Current treatments, *n* (%)			
5-ASA	27 (13.5)	283 (50.9)	92 (74.2)
Corticosteroids	81 (40.5)	347 (62.4)	33 (26.6)
Immunomodulators	49 (24.5)	214 (38.5)	37 (29.8)
Anti-TNF biologic therapy	93 (46.5)	300 (54.0)	37 (29.8)
JAK inhibitor	37 (18.5)	58 (10.4)	6 (4.8)
Anti-IL-12/23 p40 biologic therapy	19 (9.5)	60 (10.8)	5 (4.0)
Anti-integrin biologic therapy	61 (30.5)	118 (21.2)	6 (4.8)
Patients receiving advanced therapies[b], *n* (%)	153 (76.5)	301 (54.1)	52 (41.9)
Patients with CD	**US (*N* = 215)**	**Europe (*N* = 547)**	**Japan (*N* = 99)**
Mean age, years (SD)	40.9 (11.4)	38.0 (9.7)	43.0 (10.8)
Sex, *n* (%)			
Male	118 (54.9)	303 (55.4)	67 (67.7)
Female	97 (45.1)	244 (44.6)	31 (31.3)
Prefer not to say	–	–	1 (1.0)
Ethnicity, *n* (%)			
White	175 (81.4)	515 (94.1)	–
Hispanic/Latino	21 (9.8)	1 (0.2)	–
African American	12 (5.6)	–	–
Japanese	2 (0.9)	19 (3.5)	99 (100.0)

Table 1 continued

Patients with CD	**US (*N* = 215)**	**Europe (*N* = 547)**	**Japan (*N* = 99)**
Other[c]	5 (2.3)	12 (2.2)	–
Time since diagnosis of CD [mean years (SD)]	8.7 (8.6)	9.2 (8.5)	15.7 (10.2)
Current treatments, *n* (%)			
5-ASA	51 (23.7)	169 (30.9)	32 (32.3)
Corticosteroids	126 (58.6)	271 (49.5)	18 (18.2)
Immunomodulator	84 (39.1)	255 (46.6)	15 (15.2)
Anti-TNF biologic therapy	93 (43.3)	289 (52.8)	79 (79.8)
JAK inhibitor	18 (8.4)	47 (8.6)	1 (1.0)
Anti-IL-12/23 p40 biologic therapy	18 (8.4)	69 (12.6)	11 (11.1)
Anti-integrin biologic therapy	43 (20.0)	154 (28.2)	6 (6.1)
Patients receiving advanced therapies[b], *n* (%)	125 (58.1)	347 (63.4)	86 (86.9)
HCPs	**US (*N* = 200)**	**Europe (*N* = 503)**	**Japan (*N* = 100)**
Sex, *n* (%)			
Male	156 (78.0)	356 (70.8)	92 (92.0)
Female	40 (20.0)	139 (27.6)	8 (8.0)
Prefer not to say	4 (2.0)	8 (1.6)	–
Primary specialty[d], *n* (%)			
Gastroenterologist	176 (88.0)	469 (93.2)	100 (100.0)
Internal medicine with GI focus/specialization	2 (1.0)	3 (0.6)	–
IBD nurse specialist	–	31 (6.2)	–
Nurse practitioner	11 (5.5)	–	–
Physician assistant	11 (5.5)	–	–
Year of qualification, *n* (%)			
Before 1985	22 (11.0)	57 (11.3)	6 (6.0)
1985–2018	173 (86.5)	434 (86.3)	88 (88.0)
After 2018	5 (2.5)	12 (2.4)	6 (6.0)

Values are mean (SD) or *n* (%), unless otherwise indicated

5-ASA 5-aminosalicylic acid, *CD* Crohn's disease, *GI* gastroenterology, *HCP* health care professional, *IBD* inflammatory bowel disease, *IL* interleukin, *JAK* Janus kinase, *N* number of patients, *n* number of patients in the subgroup, *SD* standard deviation, *TNF* tumor necrosis factor, *UC* ulcerative colitis, *UK* United Kingdom, *US* United States

[a] Other races included Asian-Indian subcontinent, Asian-other, Korean, Middle Eastern, Afro-Caribbean, and other

[b] Adalimumab (including biosimilars), infliximab (including biosimilars), golimumab, certolizumab pegol, vedolizumab, natalizumab, ustekinumab, and tofacitinib

[a] Other races included Asian-other, Chinese, Korean, Afro-Caribbean, Native American, Mixed race, South-East Asian, and other

[d] US HCPs included nurse practitioners and physician assistants; UK HCPs included IBD nurse specialists

ever experiencing bowel urgency (US: 58.6%; Europe: 53.9%; Japan: 56.6%). In the UC population, a greater proportion of US patients reported currently experiencing bowel urgency (in the past month) than European and Japanese patients (US: 47.0%; Europe: 29.7%; Japan: 25.0%). Among patients with CD, proportions were consistent across geographies (US: 42.3%; Europe: 38.0%; Japan: 32.3%; Fig. 1a). Similar results were observed among patients receiving advanced therapies (Fig. 1b).

Most patients who were experiencing bowel urgency in the past month rated its severity between 6 and 8 using the 11-point Urgency NRS scale (UC, US: 64.9%; Europe: 66.1%; Japan: 64.5%; CD, US: 65.9%; Europe: 62.5%; Japan: 43.8%; Fig. 2). Mean urgency NRS scores were similar among US and European patients (UC: 6.9 and 6.8; CD: 7.0 and 6.7, respectively) but moderately lower for the Japanese population (UC: 6.1; CD: 5.6). Additionally, 3.2% of the UC Japanese population reported no urgency (score 0/10 on the NRS scale), while no patients from the US or European populations reported scores = 0.

Patient and HCP Perceptions of the Impact of Bowel Urgency on Daily Life

Patients with UC or CD experiencing bowel urgency in the past month reported a substantial impact of this symptom on various aspects of their daily lives. On a scale of 1–7, mean ratings of daily life impact ranged from 2.6 to 5.2 for patients with UC and from 2.8 to 5.3 for patients with CD (Fig. 3). Patients with UC reported the highest impact of bowel urgency on their food/drink choices and intake; mean ratings were 5.2 each in the US, 5.0 each in Europe, and 4.2 each in Japan, respectively. Patients with CD reported the highest impact of bowel urgency on their ability to participate in spontaneous/unplanned activities and on their food/drink choices; mean

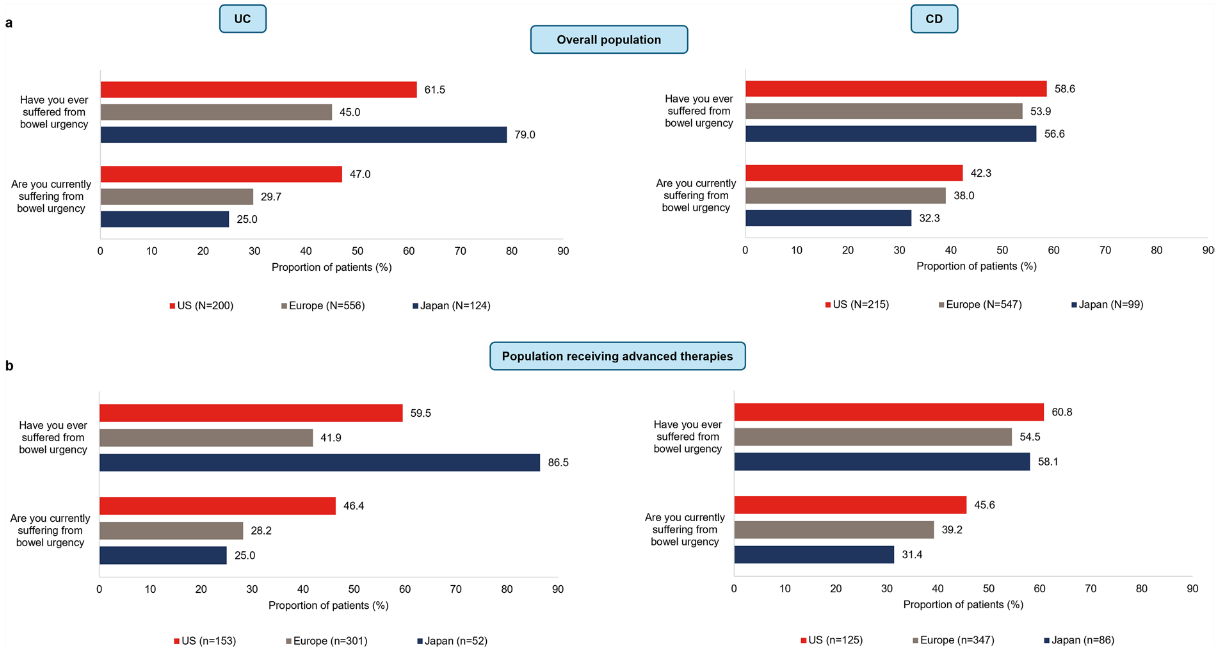

Fig. 1 Patient experiences of bowel urgency in UC and CD. **a** Proportion of patients who reported ever and currently suffering from bowel urgency. Patients were asked which symptoms they have ever suffered from and currently suffer from (i.e., in the past month), and symptoms were selected from a list of 30 options. **b** Proportion of patients who reported ever and currently suffering from bowel urgency in the subset of patients receiving advanced therapies. *CD* Crohn's disease, *N* number of patients, *n* number of patients in the sub-population, *UC* ulcerative colitis, *US* United States

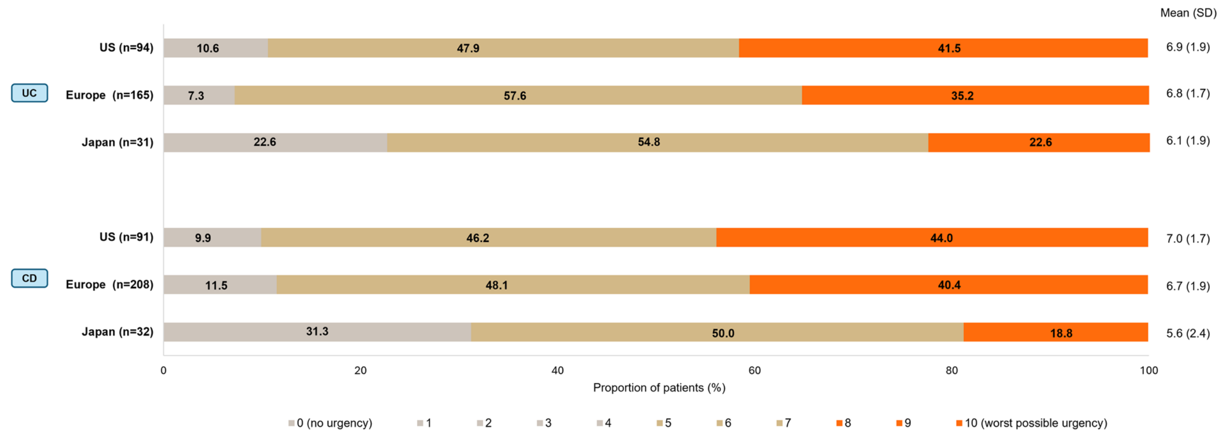

Fig. 2 Urgency numeric rating scale scores. Patients experiencing bowel urgency in the past month rated their urgency (sudden or immediate need) to have a bowel movement in the past 3 days [from 0 (no urgency) to 10 (worst possible urgency)]. *CD* Crohn's disease, *n* number of patients experiencing bowel urgency in the past month, *SD* standard deviation, *UC* ulcerative colitis, *US* United States

ratings were, 5.1 and 5.3 in the US, 5.2 and 5.1 in Europe, and 4.7 and 4.8 in Japan, respectively. While findings were similar across US and European populations, a smaller proportion of Japanese patients reported a high impact (scores ranging from 4 to 7) of bowel urgency on their daily lives. In particular, patients in the US and Europe were more likely to report that bowel urgency significantly influenced their clothing choices compared to Japanese patients. Specifically, over 59% of US and European patients with UC or CD reported a high impact, while less than 38% of Japanese patients with the same diagnoses felt the same way.

HCPs perceived a high impact of bowel urgency on the daily lives of patients with UC or CD across all geographies, with mean ratings ranging between 4.6 and 5.8 for all 12 surveyed parameters (Fig. 4). HCPs also perceived the impact of bowel urgency on patients with UC or CD to be similar. Additionally, mean ratings reported by HCPs were numerically higher than those reported by patients for all parameters (Figs. 3, 4). For both patients with UC and CD, HCPs perceived the greatest impact of bowel urgency on patients' ability to travel and participate in spontaneous/unplanned activities. The mean ratings for UC were 5.7 each in the US, 5.8 and 5.7 in Europe, and 5.7 and 5.4 in Japan, respectively. For CD, the mean ratings were 5.7 each in the US and Europe, and 5.7 and 5.4 in Japan, respectively. Patient and HCP-reported impact of bowel urgency on the daily lives of patients with UC or CD in each European country are presented in Supplementary material S1 and S2, respectively.

Patient and HCP Perceptions of the Emotional Impact of Bowel Urgency

Among patients experiencing bowel urgency in the past month, most patients with UC or CD reported a high emotional impact, with mean ratings ranging between 3.5 and 5.8 (on a scale of 1–7), for all nine surveyed parameters (Fig. 5). Patients with UC reported a high impact of bowel urgency on anxiety/nervousness (mean ratings, US: 4.8; Europe: 4.9; Japan: 5.8). For most parameters, patient perspectives were consistent across all three geographies. However, a greater proportion of the Japanese population with UC reported a high impact of bowel urgency on anxiety/nervousness, depression, and feelings of humiliation on having bowel urgency-related accidents in public, than the US and European populations. Among patients with CD, feeling humiliated when bowel urgency-related accidents occurred in public, and anxiety/nervousness were reported

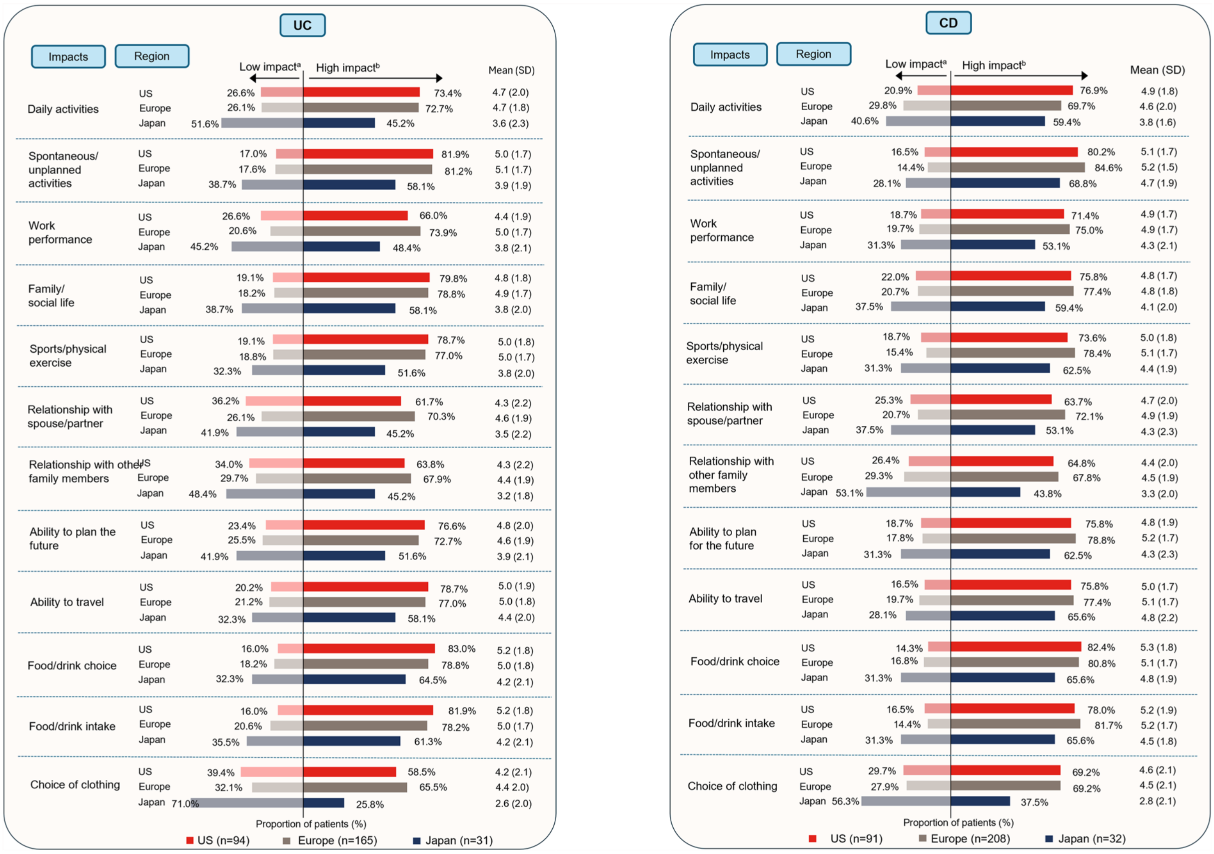

Fig. 3 Impact of bowel urgency on daily lives of patients with UC or CD. Patients who reported experiencing bowel urgency in the past month were asked to rate the extent to which bowel urgency interferes with various aspects of daily life on a scale of 1–7, where 1 = does not interfere at all and 7 = interferes a great deal. The percentages may not add up to 100% because they have been rounded-off to the nearest decimal point, while some patients reported "not applicable" as a response to the survey question (data not shown). [a]Patients who rated low impact of bowel urgency (rating from 1 to 3). [b]Patients who rated high impact of bowel urgency (rating from 4 to 7). *CD* Crohn's disease, *n* number of patients experiencing bowel urgency in the past month, *SD* standard deviation, *UC* ulcerative colitis, *US* United States

by patients as the highest emotional impacts of bowel urgency. Mean ratings were, 4.9 and 5.0 in the US, 5.3 and 5.1 in Europe, and 5.7 and 5.5 in Japan, respectively. In general, patient perspectives were consistent across the US and European CD population. When compared to US and European patients with CD, a similar proportion of Japanese patients reported a high emotional impact of bowel urgency on anxiety/nervousness, depression, and feelings of humiliation on having bowel urgency-related accidents in public, whereas other parameters were reported as having a low emotional impact by Japanese patients (Fig. 5).

HCPs perceived their patients with UC and CD to experience a high impact of mental health-related issues due to bowel urgency (Fig. 6). The most commonly experienced HCP-reported mental health-related issues among patients with UC and CD included feeling anxious/nervous, frustration at not being able to participate in spontaneous/unplanned activities, humiliation from bowel urgency-related accidents in public, and panic and embarrassment when having to run to the bathroom. On a scale of 1–7, mean HCP ratings were > 5 for all surveyed parameters across geographies. Additionally, mean ratings reported by HCPs were

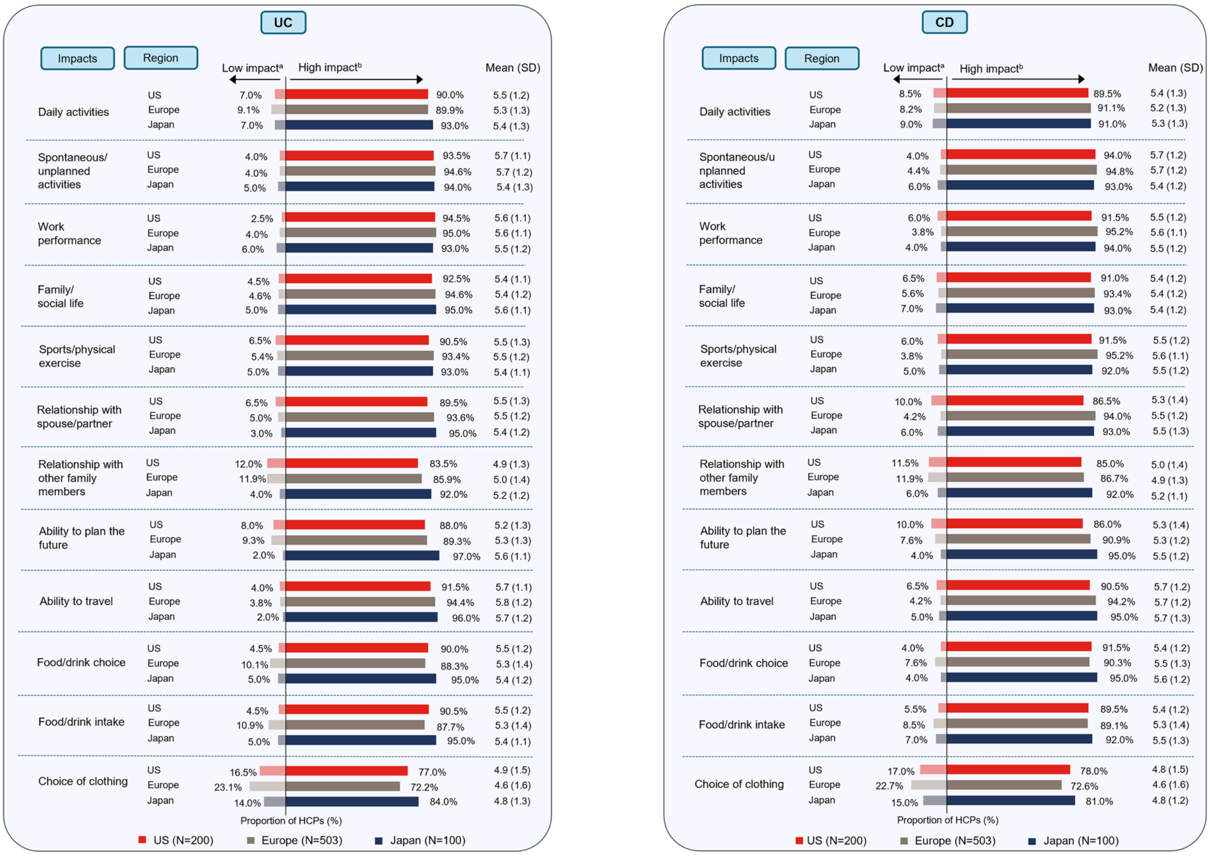

Fig. 4 HCP-perceived impact of bowel urgency on daily lives of patients with UC or CD. HCPs were asked to rate the extent to which bowel urgency impacts different aspects of daily life of patients on a scale of 1–7, where 1 = no impact at all and 7 = impacts a great deal (and 0 = no opinion). The percentages may not add up to 100% because they have been rounded-off to the nearest decimal point, while some HCPs reported "no opinion" as a response to the survey question (data not shown). [a]HCPs who rated low impact of bowel urgency (rating from 1 to 3). [b]HCPs who rated high impact of bowel urgency (rating from 4 to 7). *CD* Crohn's disease, *N* number of HCPs, *HCP* health care professional, *SD* standard deviation, *UC* ulcerative colitis, *US* United States

generally higher than those reported by patients for all emotional parameters (Figs. 5 and 6). Patient and HCP-reported emotional impact of bowel urgency on patients with UC and CD in each European country are presented in Supplementary material S3 and S4, respectively.

HCP Perceptions of the Impact of Bowel Urgency on Treatment Decisions

HCPs were asked to rank the top three UC- or CD-related symptoms that had the greatest impact on their treatment decisions (Fig. 7). US, European, and Japanese HCPs ranked blood in stool, diarrhea, and increased stool frequency as the most impactful symptoms for patients with UC. For patients with CD, the top three HCP-perceived most impactful symptoms were diarrhea, blood in stool, and persistent abdominal pain. A minority of HCPs identified bowel urgency as one of the top three symptoms affecting treatment decisions for UC and CD (US: 21.5% and 12.0%, Europe: 22.3% and 10.9%, Japan: 13.0% and 6.0%, respectively).

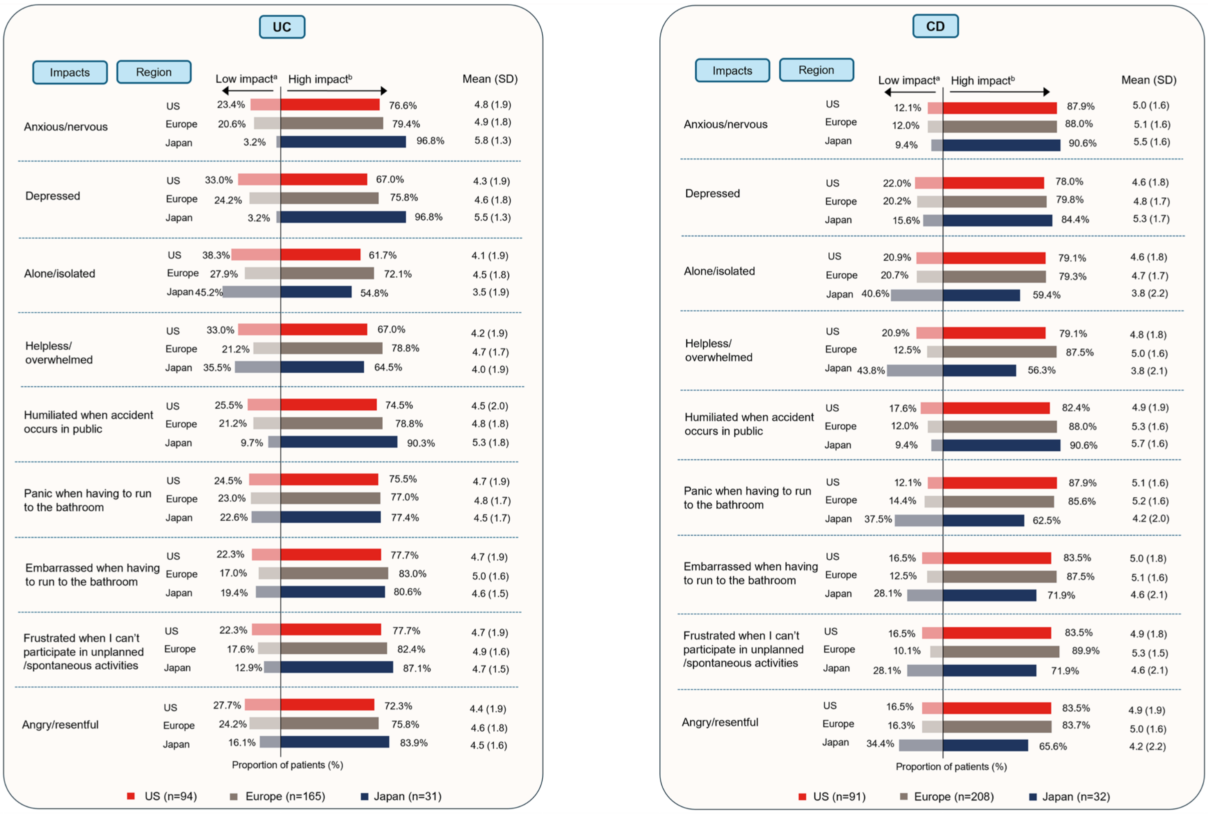

Fig. 5 Emotional impact of bowel urgency on patients with UC or CD. Patients who reported experiencing bowel urgency in the past month were asked to rate the emotional impact of bowel urgency based on a range of mental well-being issues on a scale of 1–7, where 1 = does not make me feel like this at all and 7 = makes me feel like this a great deal. [a]Patients who rated low impact of bowel urgency (rating from 1 to 3). [b]Patients who rated high impact of bowel urgency (rating from 4 to 7). *CD* Crohn's disease, *n* number of patients experiencing bowel urgency in the past month, *SD* standard deviation, *UC* ulcerative colitis, *US* United States

DISCUSSION

Bowel urgency is a common symptom in both UC and CD, and it ranks as one of the top concerns for which patients seek relief [10]. Previous studies from the CONFIDE survey have reported bowel urgency as a burdensome and impactful symptom of UC and CD in the US, Europe, and Japan. These reports highlighted that bowel urgency and fear of bowel urgency-related accidents were among the top reasons why patients declined participating in work/school, social events, and sports/physical exercise, and avoided sexual activities [22, 23, 26, 27]. This analysis from the CONFIDE survey presents the views of patients with UC or CD and HCPs on how bowel urgency affects various aspects of patients' emotions and daily life in the US, European, and Japanese populations. The distinctive aspect of this analysis was that the survey incorporated comprehensive feedback from both HCPs and patient advisors during development, ensuring the findings reflected both HCPs' opinions and patient priorities. Further, collecting responses to mirrored survey questions from patients and HCPs enabled a parallel exploration of their perspectives.

Our findings emphasize that bowel urgency is one of the most disruptive and distressing symptoms of IBD [15]. Notably, this disruption is not only limited to physical symptoms but extends to the fear and anticipation of bowel urgency, which can affect patients both emotionally and

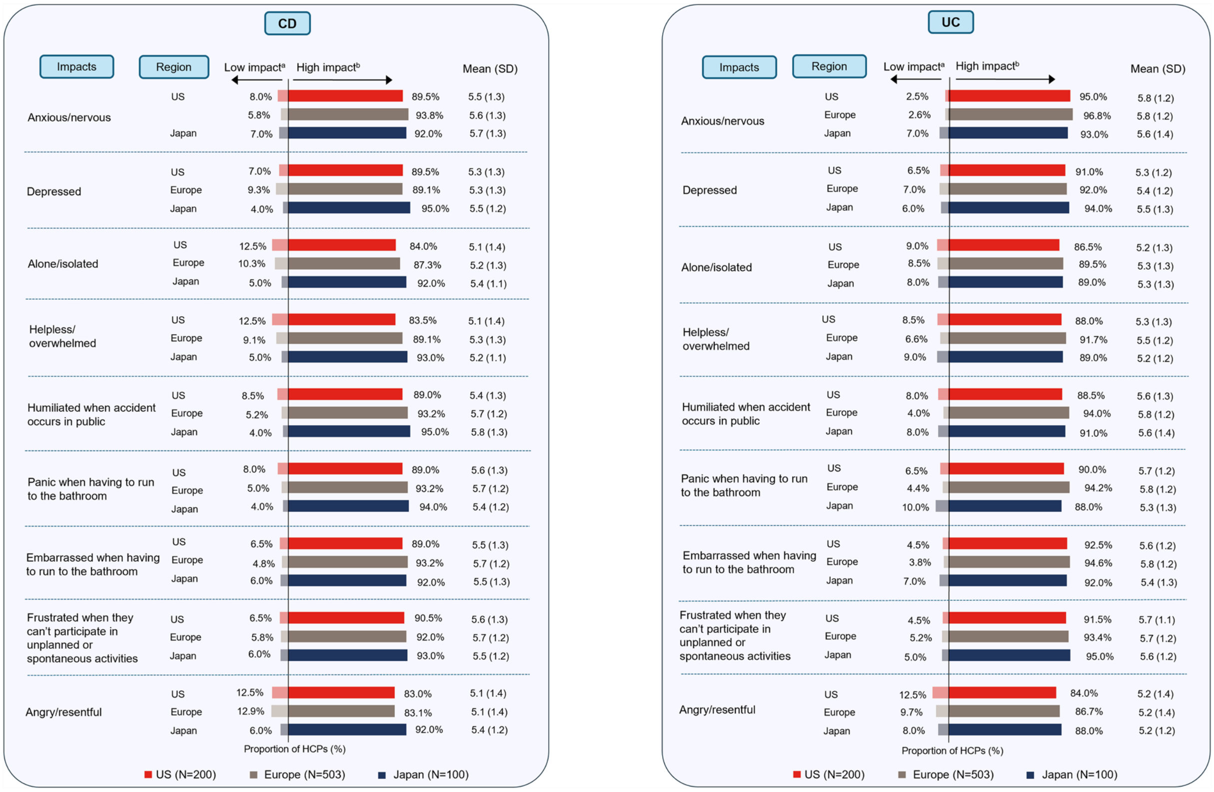

Fig. 6 HCP-perceived emotional impact of bowel urgency on patients with UC or CD. HCPs were asked to rate the emotional impact of bowel urgency on a scale of 1–7, where 1 = patients do not experience at all and 7 = patients experience a great deal (and where 0 = no opinion). The percentages may not add up to 100% because they have been rounded-off to the nearest decimal point, while some HCPs reported "no opinion" as a response to the survey question (data not shown). [a]HCPs who rated low impact of bowel urgency (Rating from 1 to 3). [b]HCPs who rated high impact of bowel urgency (Rating from 4 to 7). *CD* Crohn's disease, *N* number of HCPs, *HCP* health care professional, *SD* standard deviation, *UC* ulcerative colitis, *US* United States

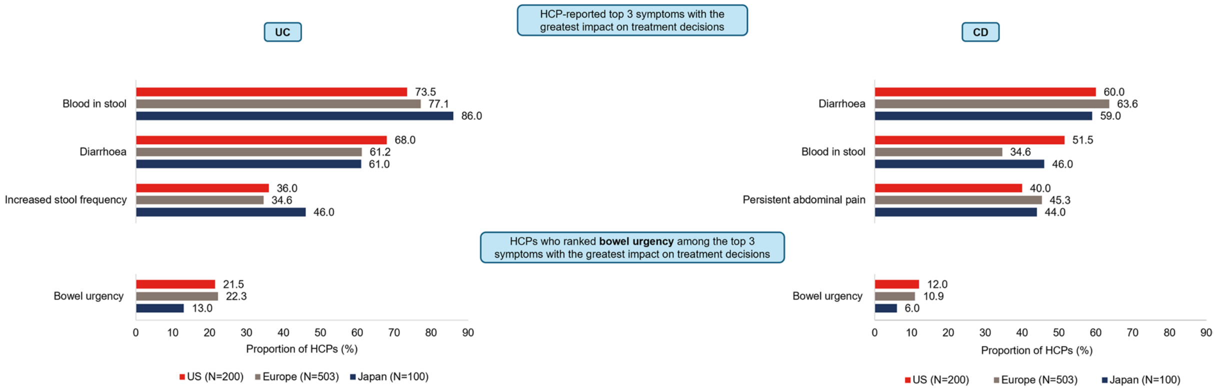

Fig. 7 HCP-perceived most impactful symptoms on treatment decisions. HCPs were asked to choose (from a list of possible symptoms) the top three most impactful symptoms on treatment decisions. *CD* Crohn's disease, *HCP* health care professional, *N* number of HCPs, *UC* ulcerative colitis, *US* United States

socially [4, 28]. Similar to previous studies [3, 4, 29], a high impact of bowel urgency on patients' emotions and day-to-day activities was reported by HCPs and patients across the US, Europe, and Japan in both UC and CD. Despite the clinical differences between the diseases, experience and impacts of bowel urgency were similar among patients with UC and CD. This highlights the need to further explore the mechanisms underlying this important symptom.

UC and CD peak incidence is between 15 and 40 years of age, often coinciding with critical life milestones such as career growth, developing personal relationships, and family planning [30, 31]. During this time, bowel urgency symptoms can significantly impact emotional well-being, which in turn may affect work productivity and social activities. Conversely, the emotional and daily life effects of bowel urgency can exacerbate UC and CD symptoms, creating a vicious cycle of worsening symptoms and QoL. Previous studies have reported a high emotional burden of bowel urgency, which considerably impacts patients' overall QoL [15, 28]. In concordance with these reports, HCPs, as well as patients with UC or CD in the US, Europe, and Japan, reported a high emotional impact of bowel urgency across a range of emotional aspects, including depression, anxiety, panic, embarrassment, anger, frustration, and loneliness/isolation. The results also showed that patients and HCPs reported a high impact of bowel urgency on patients' social lives and relationships with spouse/family members, which are crucial aspects of overall QoL. Bowel urgency also limited the patients' ability to travel, plan for spontaneous activities, clothing and food choices, physical activities, and future planning.

Notably, HCPs reported a higher emotional and daily life impact of bowel urgency compared to that reported by patients for both UC and CD in all geographies studied, which could be due to patients underestimating the impacts. Despite the HCPs' perspectives, bowel urgency was not among the top three HCP-reported symptoms impacting their treatment decisions for patients. Only a small proportion of HCPs (< 23% for UC and < 12% for CD) considered bowel urgency among the top three most impactful symptoms influencing treatment decisions. Although HCPs are aware of the debilitating effects of bowel urgency, it was not among their top treatment priorities. This highlights a misalignment between patient and HCP perspectives. Patients with UC or CD have previously reported that a reduction in frequency and severity of bowel urgency is crucial for improving their QoL [6, 15]. Furthermore, bowel urgency is believed to be driven primarily by active inflammation, underscoring the need to assess and address bowel urgency in addition to other key UC and CD symptoms [3, 6]. A multidisciplinary approach where treatment strategies involve referral for mental health counseling and support in addition to treatment of UC or CD may be helpful. Also, there is a need for increased awareness to reduce the stigma associated with bowel urgency and urge incontinence and provision of community facilities such as access to support networks and hospital-based continence services [4, 32].

As noted in previous results from the CONFIDE study, current findings emphasize the similarities in the burden and impact of bowel urgency in UC and CD [22]. The emotional and daily life impact of bowel urgency, as reported by patients and HCPs, was similar among patients with UC or CD in the US, Europe, and Japan.

Patient and HCP-reported impacts of bowel urgency on patients' daily life and emotions were similar among US and European populations. Some differences in the patient experiences of bowel urgency were noted between Japanese and US/European patients. A greater proportion of Japanese patients with UC reported ever experiencing bowel urgency compared to US and European patients. However, bowel urgency was among the top three most common symptoms experienced in the past month by patients with UC or CD among US and European populations but not among Japanese patients [22–24]. Further, Japanese patients reported less severe bowel urgency (as measured using the Urgency NRS). Although HCPs' perception of the broad impacts of bowel urgency on the daily lives of patients was similar across geographies, Japanese patients reported a lower impact on their daily lives than US/European patients for both UC and CD. A similar trend was observed for all the emotional impacts of bowel urgency, except anxiousness/nervousness, depression, and humiliation when an accident occurs in public, which were similar in patients with UC, regardless of geography. In patients with CD, Japanese patients reported a lower impact of feeling alone/isolated and helpless/overwhelmed compared to US and European patients. This could be due to differences in the baseline characteristics between Japanese and US/European patients, such as higher age, lower disease severity in the Japanese population enrolled in the CONFIDE survey, and longer disease duration among Japanese patients [24]. Further, social and cultural differences between Japanese and Western populations might play a role in shaping patient attitudes and medical care.

Even though both patients and HCPs recognize the significant burden of bowel urgency, this symptom is often not adequately addressed in clinical practice. To tackle sensitive topics such as bowel urgency, which is often associated with embarrassment and stigma for both patients and HCPs, cultural attitudes and social expectations play a crucial role. Thus, it is essential to raise awareness among patients and HCPs globally to explicitly evaluate and manage this significant symptom and align on treatment priorities. Moreover, incorporating bowel urgency-related endpoints in clinical trials will help tailor treatments to better address this cumbersome symptom in CD and UC.

Limitations

Limitations of this study included: (1) direct comparisons between data from US, Europe, and Japan could not be conducted; (2) this study was limited to patients with “moderate-to-severe” CD in the US, Europe, and Japan; therefore, the results may not represent the full CD population worldwide; and (3) due to the self-report design of the survey, disease type/location (e.g., Montreal classification) could not be assessed. Other limitations pertaining to the CONFIDE survey have been previously reported (22, 23).

CONCLUSIONS

Bowel urgency broadly affects the emotional well-being and daily life of patients with UC or CD in the US, Europe, and Japan. Bowel urgency was not among the top three most impactful symptoms on HCPs’ treatment decisions despite the impact reported by both HCPs and patients, with HCPs perceiving a numerically higher impact than patients. There is a need to assess the multifaceted impacts of bowel urgency on patients’ overall QoL to identify the gaps in patient care, enabling further efforts to address and treat this important issue.

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Declarations

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