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Patient-Reported Disease Activity in a Large Sample of Ulcerative Colitis (UC) Patients Using Social Media-Delivered Questionnaires

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INTRODUCTION

- One percent of the U.S. population (~3 million people) live with inflammatory bowel disease (IBD), consisting of Crohn's disease (CD) and ulcerative colitis (UC). There are approximately 1 million UC patients in the U.S.[1,2]
- UC is a lifelong, chronic condition with no cure. UC patients must manage the unpredictable nature of the condition (i.e., symptoms, intermittent flares, and periods of remission that all vary in length, frequency, and severity).
- Patient-reported outcomes (PROs) used for approval of UC treatments include number of bowel movements and bloody stools.[3] These outcomes do not comprehensively represent the real world experience of UC patients.

OBJECTIVES

- To understand patient perspectives on UC, including disease activity and disease burden.
- We hypothesized that UC patients experience disease activity despite being on treatment, and that current PROs used for approval of UC treatments do not comprehensively capture the full impact of disease activity on patients' lives.

METHODS

- The IBD In America survey recruited patients via InflammatoryBowelDisease.net and associated social platforms, from February 12, 2019 to June 20, 2019.
- Inclusion criteria
  - 18+ years of age
  - living in the U.S.
  - diagnosed with IBD (e.g., Crohn's Disease, Crohn's Colitis, UC, and indeterminate colitis)
- Patients' demographics, treatment experience, perceptions of disease activity and burden (including perception of flares/remissions, IBD symptoms, and QoL) were collected.
- Patients were categorized into disease activity groups based on their self-reported number of flares, defined as "*a temporary intensification of symptoms*" experienced in the past year:
  - Response categories were: 0, 1, 2-4, 5-7 and 8 or more flares in the past year.
  - The 2-4 and 5-7 categories were collapsed due to the low number of patients in the 5-7 category and to simplify reporting.
- Four mutually exclusive groups were created and collectively, they are referred to as the "consistent" group. (**Table 1**)
- Two "inconsistent" groups were identified:
  - Patients who reported no flares in the past year, but also reported not being in remission. Remission defined as "*a significant reduction of your symptoms without an actual cure.*"
  - Patients who had one or more flares in the past year, but who reported being in remission for 1 year or more.
- The data were analyzed descriptively. Continuous variables are reported in means and standard deviation. Categorical variables are reported as N (%).

RESULTS

DEMOGRAPHICS

- A total of 1,705 respondents completed the survey; of these respondents, 487 were patients with UC.
- The population represented all geographic regions of the U.S.; 89% reported their UC was moderate to severe; and 51% were currently taking 5ASAs, 23% immunomodulators, and 37% biologics/Janus Activating Kinase (JAK) inhibitors. (Data not shown)
- Overall, mean (SD) age of the population is 45±16 years old, 418 (86%) female, and 443 (91%) White/Caucasian. Sixty percent (n = 297) of the population reported currently consuming alcohol, and 12% (n = 61) considered themselves a current smoker or tobacco chewer. A total of 395 (80%) reported that they have been diagnosed with UC for ≤6 years. The most common reported comorbidities are anxiety/panic disorders (38%) and mood disorders (29%). Interestingly, in addition to being diagnosed with UC, 133 (27%) reported they also have comorbid IBS diagnosis. (**Table 1**)

Table 1. Demographics and Respondent Characteristics

		Consistent Groups				Inconsistent Groups	
	Total N = 487	In remission + no flares in last year n = 86	1 flare in last year n = 77	2 to 7 flares in last year n = 176	8 or more flares in last year n = 111	In remission for 1 year or more + flare(s) in last year n = 23	Not in remission + no flares in past year + symptoms in past month n = 14
Female[a], n (%)	**418 (86)**	73 (85)	69 (90)	154 (88)	93 (84)	21 (91)	8 (57)
Age (years), mean (SD)	**45.6 (16.0)**	45.5 (14.8)	42.2 (17.0)	44.9 (16.0)	47.9 (16.6)	46.9 (14.0)	52.6 (15.0)
White/Caucasian, n (%)	**443 (91)**	80 (93)	73 (95)	153 (87)	104 (94)	21 (91)	12 (86)
4-year college & advanced degree(s), n (%)	**234 (48)**	56 (65)	44 (57)	81 (47)	41 (38)	7 (30)	5 (35)
Time Since Diagnosis, n (%)							
<1 year	**221 (45)**	44 (51)	36 (47)	78 (44)	46 (41)	12 (52)	5 (36)
1 up to 6 years	**174 (36)**	31 (36)	33 (43)	59 (34)	43 (39)	6 (26)	2 (14)
6 up to 10 years	**32 (7)**	5 (6)	2 (3)	13 (7)	5 (5)	4 (17)	3 (21)
10+ years	**60 (12**	6 (7)	6 (8)	26 (15)	17 (15)	1 (4)	4 (29)
Current Alcohol User[b], n (%)	**297 (60)**	64 (75)	48 (63)	103 (58)	62 (57)	15 (65)	5 (35)
Current Smoker/Tobacco User[c], n (%)	**61 (12)**	3 (3)	13 (16)	23 (13)	17 (15)	2 (8)	3 (21)
Top 5 Comorbidities[d], n (%)							
Anxiety/Panic disorders	**183 (38)**	27 (31)	26 (34)	62 (35)	56 (50)	9 (39)	3 (21)
Mood disorders	**142 (29)**	22 (26)	16 (21)	51 (29)	43 (39)	8 (35)	2 (14)
GERD	**137 (28)**	22 (26)	22 (29)	52 (30)	31 (28)	5 (22)	5 (36)
Obesity	**136 (28)**	23 (27)	21 (27)	52 (30)	32 (29)	5 (22)	3 (21)
IBS	**133 (27)**	15 (17)	17 (22)	54 (31)	37 (33)	4 (17)	6 (43)

Abbreviations: GERD, gastroesophageal reflux disease; IBS, irritable bowel syndrome
Due to rounding to the nearest full number, totals for percentages may not always add up to 100%.
[a]1 respondent identified as "Other." [b]Collapsed the following response categories "Once a month," "2-4 times a month," "2-4 times a week," and "4+ times a week." Not including patients who chose "Prefer not to answer" (n = 6). [c]Collapsed the following response categories: "Smoke cigarettes or other tobacco products," "Chew tobacco," and "Use e-cigarettes/vape." This question is a "Select all that apply." Not including patients who chose "Prefer not to answer" (n = 11)." [d]Column totals will be larger than base and percentages will be larger than 100% as the question is "Select all that apply."

DISEASE ACTIVITY GROUPS

Overall, 60% do not classify themselves as being in remission and 79% experienced flares in the past year. (**Table 2**)

- In the consistent groups, as the number of flares increase from 1 flare to 8 or more flares in the last year, the percent of patients who reported that they are not currently in remission increases (61% to 91%).
- Only 86 patients (18%) report both being in remission and having no flares within the last year.

Table 2. Patient-Reported Disease Activity Categories[abcd]

		Consistent Groups				Inconsistent Groups	
	Total N = 487	In remission + no flares in last year n = 86	1 flare in last year n = 77	2 to 7 flares in last year n = 176	8 or more flares in last year n = 111	In remission for 1 year or more + flare(s) in last year n = 23	Not in remission + no flares in past year + symptoms in past month n = 14
Patient reported remission							
Currently in remission	**194 (40)**	86 (100)	30 (39)	45 (26)	10 (9)	23 (100)	–
Not currently in remission	**293 (60)**	–	47 (61)	131 (74)	101 (91)	–	14 (100)
Patient reported flares							
No flare(s) in past year	**100 (21)**	86 (100)	–	–	–	–	14 (100)
Flare(s) in past year	**387 (79)**	–	77 (100)	176 (100)	111 (100)	23 (100)	–

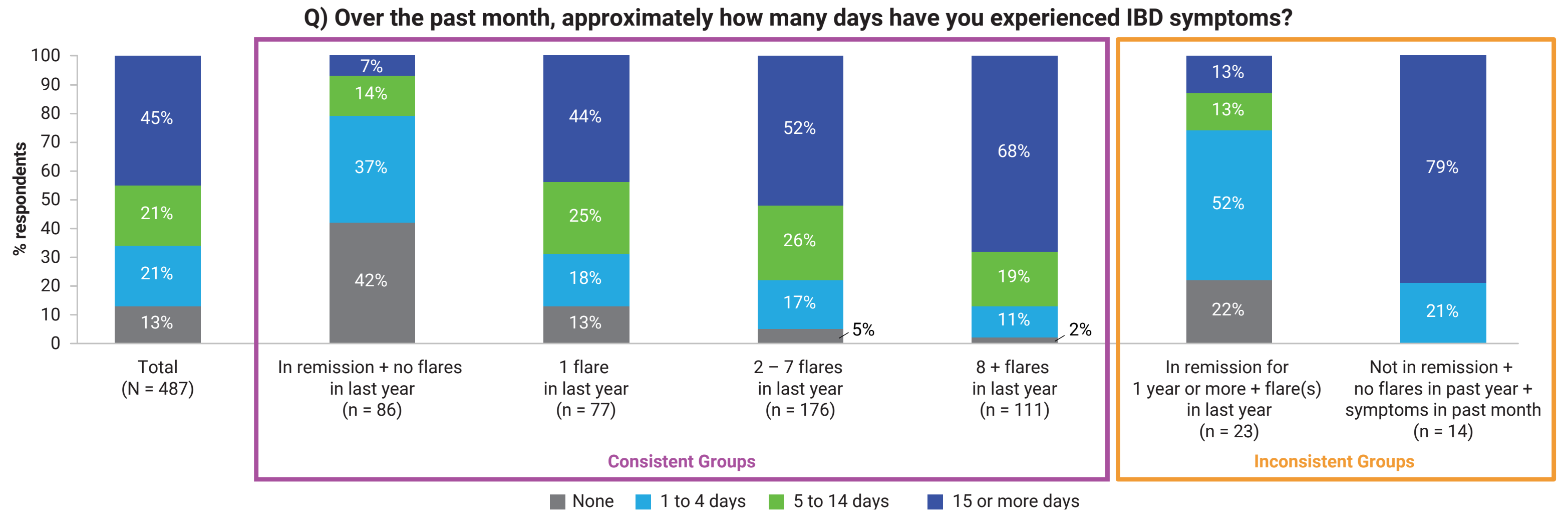
[a]Which statement best applies to you and your IBD journey? (1) I am currently in remission, (2) My IBD had gone into remission, but is once again active, (3) I have never gone into remission. [b]How long have you been in remission? [c]Over the past year, approximately how many IBD flares have you experienced? [d]Over the past month, approximately how many days have you experienced IBD symptoms?

NUMBER OF DAYS WITH UC SYMPTOMS

Despite treatment, 45% of patients experienced 15+ symptom days in the past month. (**Figure 1**)

- In the "consistent" groups: Patient reports of symptom-free days trended with disease activity from 42% (no flares) to 2% (8+ flares); a reverse trend from 7% to 68% was observed for the percent of patients with 15+ symptom days.
- In the "inconsistent" groups:
  - For patients who reported being in remission for more than one year, but who also reported flare(s), 74% reported less than 5 or no symptoms days in the past month.
  - For patients who had no flares, but did not report remission, 79% experienced 15 or more symptom days in the past month.

Figure 1. Number of Days With UC Symptoms in the Past Month by Disease Activity



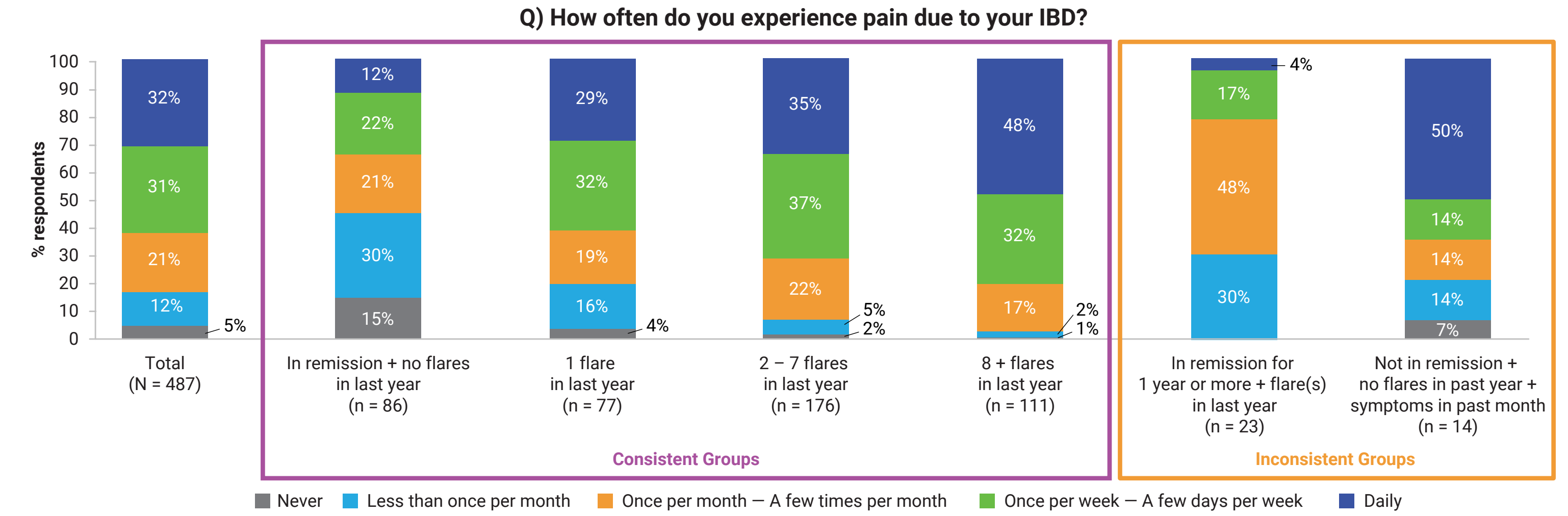
Response categories have been collapsed as follows: "1 to 4 days" [Combination of 1 to 2 days and 3 to 4 days], "5 to 14 days" [Combination of 5 to 9 days and 10 to 14 days], 15 or more days [Combination of 15 to 19 days and 20 or more days].

FREQUENCY OF UC PAIN

Overall, daily pain was experienced by 32% of the total population. (**Figure 2**)

- For "consistent" groups: Patient reports of pain-free days trended with disease activity from 15% (in remission, no flares) to 1% (8+ flares); a reverse trend from 12% to 48% observed for the percent of patients with daily pain.
- For "inconsistent" groups:
  - For patients who are in remission but did experience flare(s) in the past year, 21% reported pain as frequently as once per week or more.
  - For patients who had no flares in the past year but did not report remission, 50% experience UC pain daily.
- Interestingly, only 12 out of a total of 487 patients (2.5%) report being pain-free, symptom-free in the past month, flare-free in the last year, and perceived themselves to be in remission (data not shown).

Figure 2. Frequency of UC Pain by Disease Activity



Response categories have been collapsed as follows: "Once per month - A few times per month" [Combination of once per month and A few times per month], "Once per week - A few days per week" [Combination of once per week and A few days per week].
Due to rounding to the nearest full number, totals for percentages may not always add up to 100%.

MOST FREQUENTLY MENTIONED UC SYMPTOMS

In the overall sample, fatigue/low energy is the most frequently reported (86%) UC symptom experienced within the past month. (**Table 3**)

- After fatigue/low energy, urgency to move bowels (80%), abdominal pain/cramps (76%), joint pain/inflammation (67%), and bloating (66%) are the most frequently reported symptoms.
- For most symptoms, there was an increasing reporting trend with increasing disease activity in the consistent groups.

Table 3. UC Symptoms Mentioned by Disease Activity[a]

		Consistent Groups				Inconsistent Groups	
	Total N = 425[b]	In remission + no flares in last year n = 50	1 flare in last year n = 67	2 to 7 flares in last year n = 167	8 or more flares in last year n = 109	In remission for 1 year or more + flare(s) in last year n = 18	Not in remission + symptoms in past month + no flares in past year n = 14
Fatigue/low energy	**364 (86)**	36 (72)	56 (84)	146 (87)	99 (91)	14 (78)	13 (93)
Urgent need to move bowels	**338 (80)**	34 (68)	56 (84)	131 (78)	95 (87)	11 (61)	11 (79)
Abdominal cramps and/or pain	**322 (76)**	26 (52)	50 (75)	133 (80)	93 (85)	15 (83)	5 (36)
Joint pain and/or inflammation	**286 (67)**	28 (56)	43 (64)	111 (67)	81 (74)	14 (78)	9 (64)
Bloating	**260 (66)**	28 (56)	45 (67)	110 (66)	82 (75)	6 (33)	9 (64)
Fullness in abdomen	**247 (58)**	19 (38)	39 (58)	104 (62)	73 (67)	7 (39)	5 (36)
Chronic/persistent diarrhea	**234 (55)**	9 (18)	35 (52)	95 (57)	80 (73)	7 (39)	8 (57)
Nausea	**232 (55)**	15 (30)	37 (55)	91 (55)	74 (68)	7 (39)	8 (57)
Rectal bleeding	**202 (48)**	2 (4)	29 (43)	95 (57)	65 (60)	4 (22)	7 (50)
Loss of appetite	**191 (45)**	8 (16)	36 (54)	84 (50)	55 (50)	3 (17)	5 (36)

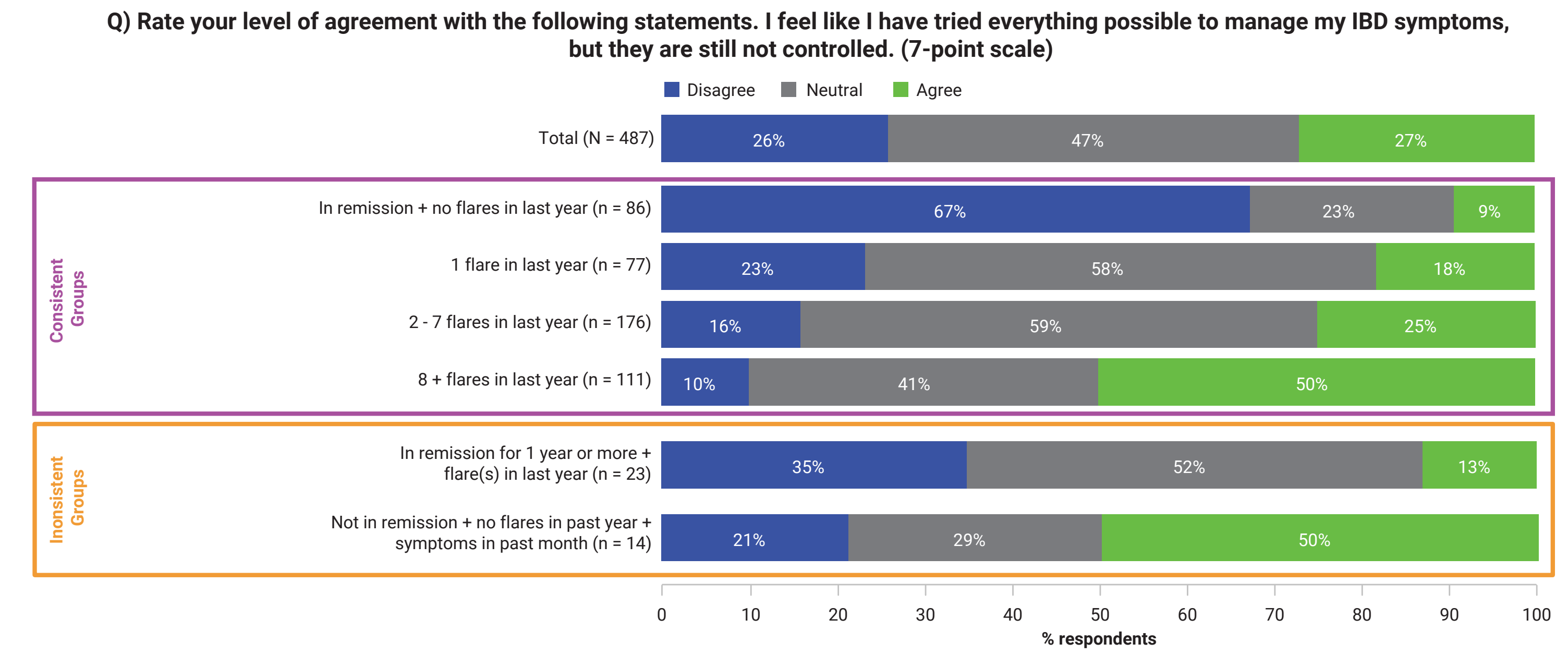
[a]Column totals will be larger than base and percentages will be larger than 100% as the question is "Select all that apply." [b]N size is less than overall sample (n=487) as only patients who experienced symptoms in the prior month were asked this question.

CONDITION LACK OF CONTROL

Overall, 27% of patients agreed that their UC is still not controlled after trying everything possible to manage their symptoms. (**Figure 3**)

- In "consistent" groups: Patient agreement of whether they feel their UC symptoms are not controlled after trying everything possible to manage their symptoms trended with disease activity from 9% (in remission, no flares) to 50% (8+ flares).
- In "inconsistent" groups:
  - In the group who reported remission but with flare(s) in the past year 13% agree that after trying everything possible, their UC is still not controlled.
  - In contrast, 50% of patients who had no flares in the past year but did not report remission agreed that their UC condition is not controlled after trying everything possible to manage their UC condition.

Figure 3. Condition Lack of Control by Disease Activity



Response categories have been collapsed as follows: "Agree" [Combination of top two box responses on a 7-point scale 6= Agree and 7= Strongly Agree], "Neutral" [Combination of 3 and 4], "Disagree" [Combination of bottom two box responses on a 7-point scale 1= Strongly Disagree and 2= Disagree].
Due to rounding to the nearest full number, totals for percentages may not always add up 100%.

LIMITATIONS

- Patient-reported number of flares in the past year consistently trended in the same direction with other disease indicators (e.g., remission status, frequency of symptoms, frequency of UC pain, and ability to control one's symptoms). It suggests that these patient-relevant outcomes, in addition to clinical measures (e.g., frequency of bowel movements and number of bloody stools), may provide a more comprehensive view of patient experience and disease activity.
- Based on outcomes that are relevant and meaningful to them, only a small proportion (< 5%) of UC patients in this study perceived their disease to be fully controlled and optimally managed.
- This is a convenience sample where systematic sampling method was not implemented. Results may be subject to volunteer bias and recall bias, and thus not as generalizable. In qualitatively comparing the population characteristics of this survey and the general UC population in the U.S., they are comparable in age of diagnosis,[4] but overrepresented on female and White/Caucasian.
- Validated scales/measures were not used throughout the survey. It is difficult to draw convergence of these outcomes with other commonly accepted validated scales.

CONCLUSIONS

This study demonstrates the need to determine key relationship between clinical measures and a broader array of relevant and meaningful real-world outcomes highlighted by UC patients that are not measured in traditional clinical trial settings. Improved understanding of this relationship can provide a more holistic view to improve management of UC patients.

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