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ORIGINAL ARTICLE

Management of Patients with Ulcerative Proctitis: A Global Survey

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Abstract

Background and Aim Ulcerative proctitis affects approximately 30% of patients with ulcerative colitis. Disease control is essential to maintain quality of life and to prevent disability and disease progression. The aim of this study was to investigate current practice on isolated proctitis management across the globe.

Methods Physicians with experience in treating inflammatory bowel diseases (IBD) were invited to participate in an anonymous, multiple-choice survey between January and February 2025.

Results The survey included 460 physicians from 66 countries. Most participants (87.9%) assessed clinical activity of isolated proctitis within 3 months of treatment initiation, 75.9% used fecal calprotectin, and 67.1% used C-reactive protein to measure disease activity. Endoscopic assessment was performed 3 to 6 months (34.2%) or 6 to 12 months (48.4%) after treatment induction. In this survey, 49% of participants were more reluctant to begin an advanced therapy in patients with isolated proctitis compared to pancolitis or left-sided colitis. About two-thirds of participants were less likely to use biologics in combination with immunosuppressants in isolated proctitis compared to left-sided or pancolitis. Anti-TNF (tumor necrosis factor) was the preferred choice in first-line advanced therapy after failing conventional treatment (48.4%).

Conclusion This study highlighted differences in management of isolated proctitis compared to left-sided colitis or pancolitis. This is likely explained by the fact that isolated proctitis patients were historically excluded from clinical trials; therefore, management relied on extrapolation of data from studies on more extensive disease.

Keywords Proctitis · Ulcerative colitis · Survey · Practice

Abbreviations

5-ASA	5-Aminosalicylate
CRP	C-reactive protein
IBD	Inflammatory bowel disease
IL	Interleukin
IQR	Interquartile range
JAK	Janus kinase
PRO	Patient-reported outcomes
S1P	Sphingosine-1-phosphate
TNF	Tumor necrosis factor

Introduction

Ulcerative proctitis, also called isolated proctitis, is a common and often highly symptomatic form of inflammatory bowel disease (IBD). At diagnosis of ulcerative colitis (UC), around 30% of patients have inflammation limited to the rectum [1]. Despite the disease being limited to the rectum, ulcerative proctitis is often responsible for distressing symptoms resulting in a significant reduction in quality of life.

Controlling the disease in isolated proctitis is recommended to preventing disease extension [2]. Conventional treatment begins with first-line topical rectal 5-aminosalicylic acid (5-ASA) and steroids, followed by oral 5-ASA as second-line treatment [3]. Systemic steroids are often required if symptoms cannot be controlled with topically acting medications.

One-third of patients with ulcerative proctitis are refractory to the above conventional therapy with 5-ASA and steroid [4]. Evidence regarding the efficacy of treatment with immunomodulators, biologics or small molecules in proctitis is limited [5–8]. Etrasimod, a small-molecule selective sphingosine-1-phosphate (S1P) receptor modulator, is approved for moderate-to-severe UC and is the first randomized controlled clinical program to include a cohort

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of patients with isolated proctitis. In this clinical program, etrasimod demonstrated similar efficacy in patients with isolated proctitis and the overall population, supporting the use of advanced therapy in refractory isolated proctitis [9, 10]. Recently, a phase 2 study evaluating tamuzimod in induction treatment for UC, a S1P receptor modulator, included patients with isolated proctitis [11]. Future trials are needed to investigate the efficacy of future drug classes in patients with ulcerative proctitis [12].

We aimed to investigate current practice on management of isolated proctitis. We conducted a global survey to investigate the management and treatment of patients with ulcerative proctitis.

Methods

A survey was designed to gather information from clinicians worldwide who are involved in IBD care. The physicians were recruited through newsletter/direct emails. The survey was conducted from January to February 2025 using an online platform. The survey including included screening questions at the beginning to ensure that respondents were part of the target population. Email registration was used to prevent duplicate responses. Responses were collected anonymously. Permission for data collection was obtained from participants at the start of the survey. Both the survey and the invitation emails were in English. All questions in the survey were in multiple-choice format.

The questionnaire consisted of 52 questions grouped into 4 sections (Supplementary Fig. 1). The first section focused on demographics, specialty, and level of experience. The other sections covered various aspects of ulcerative proctitis care, including clinical practice and attitudes toward isolated proctitis identification/symptoms, disease activity measurement attitudes, and current practice on isolated proctitis treatment including the use of advanced therapies.

This study was conducted in accordance with the principles of the Declaration of Helsinki. The survey was non-interventional and was not intended to provide clinical data for treatment decisions. Ethics approval was therefore not required. Informed consent was also not necessary as all data were completely anonymized.

Results

Demographics

In total, 460 physicians from 66 countries worldwide participated in the survey (Table 1 and Supplementary Table 1). Approximately 7000 physicians were contacted, and 550 responded, resulting in a response rate of 7.9%.

Table 1 Demographics of survey respondents

Number of respondents	460
Age of respondents, *n* (%)	
18 to 24 years old	1 (0.2)
25 to 34 years old	43 (9.4)
35 to 44 years old	104 (22.6)
45 to 54 years old	167 (36.3)
55 to 64 years old	102 (22.2)
65 to 74 years old	32 (6.7)
75 or older	11 (2.4)
Country of respondents, *n* (%)	
Europe	286 (62.2)
South America	79 (17.2)
Asia	30 (6.5)
Middle-East	33 (7.2)
Africa	19 (4.1)
North America	7 (1.5)
Oceania	6 (1.3)
Speciality of respondents, *n* (%)	
Gastroenterology	411 (89)
Surgery	29 (6.3)
Internal Medicine	16 (3.5)
Nurse	4 (0.9)
Years of experience in the IBD field, *n* (%)	
0 – 10 years	117 (25.4)
10 – 20 years	158 (34.4)
> 20 years	185 (40.2)
Number of IBD patients per year, *n* (%)	
< 100 patients	97 (21.1)
100 – 500 patients	189 (41.1)
500 – 1000 patients	111 (24.1)
> 1000 patients	63 (13.7)
Sector of activity, *n* (%)	
Private	120 (26.1)
Public	340 (73.9)

IBD Inflammatory Bowel Disease

The most representative countries were Spain (20.7%), Italy (19%), and Brazil (10.4%). Gastroenterologists were the most represented specialists (89%), followed by surgeons (6.3%), internal medicine doctors (3.5%), and other health care professionals (0.9%). Health care professionals who responded to the survey had ability to making treatment decisions and prescribe therapy. Most respondents had more than 10 years (34.4%) or 20 years (40.2%) of experience in the field of IBD. The number of patients with IBD seen per year ranged from < 100 (21.1%), to < 500 (41.1%), and to < 1000 (24.1%). Only a small percentage of physicians visited > 1000 patients per year (13.7%). Most participants worked in a public hospital (73.9%).

Symptom Perception in Isolated Proctitis

In this survey of IBD treating physicians, bowel urgency, impact on social life, psychological disorders, and fecal incontinence were the most common symptoms reported in patients with isolated proctitis (Fig. 1).

Disease Activity Measurement Attitudes

Participants agreed that the association of diarrhea and rectal bleeding (PRO-2) is a good representation of clinical disease activity in patients with isolated proctitis (mean: 6.96/10). The majority assessed the patient's clinical activity within 3 months of beginning treatment (0–1 month: 24.8%, 1–2 months: 37.0%, 2–3 months: 26.1%) (Fig. 2).

In this study, 75.9% of participants reported they often use fecal calprotectin to measure disease activity. In many cases, they assess fecal calprotectin level less than 6 months after beginning treatment (1–2 months: 23.0%, 2–3 months: 44.0%, 3–6 months: 25.1%). 60% of participants who do not currently have access to routine fecal calprotectin reported that the reimbursement of fecal calprotectin would increase their willingness to use it.

Most participants (67.1%) reported they often use C-reactive protein (CRP) to measure disease activity, typically within the first 3 months of treatment (1–2 months: 29.3%, 2–3 months: 35.8%).

Many participants also report assessment of endoscopic disease activity between 6 and 12 months (48.4%) after treatment induction. However, 84.1% adapt the time required for achieving endoscopic improvement after starting treatment according to the type of treatment (Fig. 2). With topical or oral 5-ASA, azathioprine, anti-tumor necrosis factor (TNF), vedolizumab, ustekinumab, interleukin (IL) 23 inhibitors, and S1P receptor modulators, they mainly perform endoscopy assessment 6 to 12 months after treatment initiation. For treatment with oral or topical steroids, and Janus kinase (JAK) inhibitors, they assess endoscopic treatment response sooner at 3 to 6 months after treatment induction.

For patients in clinical remission, monitoring of symptoms and biomarkers is typically performed every 6 months (54.0% and 59.0%, respectively) (Fig. 3). For endoscopic monitoring, colonoscopy and flexible sigmoidoscopy are usually performed every 5 years (29.0% and 22.0%, respectively), and > 5 years (31.0% and 27.0%, respectively).

Current practice on isolated proctitis treatment including the use of advanced therapies.

When compared to ulcerative colitis (pancolitis or left-sided colitis), the participants of this survey are more reluctant to begin an advanced therapy in patients with isolated proctitis (49.0%). In their practice, they often use infliximab (mean: 6.5/10), vedolizumab (5.6/10), upadacitinib (4.9/10), ustekinumab (4.8/10), and tofacitinib (4.5/10) for the treatment of refractory proctitis (Fig. 4).

Participants are less likely to use biologics in combination with immunosuppressants to treat refractory isolated proctitis, compared to pancolitis or left-sided colitis (61.0%).

Regardless of reimbursement and price issues, anti-TNF (43.4%) are the preferred first-line therapy in patients with ulcerative proctitis failing conventional treatment. Other treatments used in first line are vedolizumab (25.7%), S1P receptor modulators (13.3%), JAK inhibitors (13.1%), IL23 inhibitors (9.1%), and ustekinumab (6.1%) (Fig. 5).

Discussion

To the best of our knowledge, this is the first survey specifically designed to investigate the current management of patients with isolated proctitis. The survey addressed various aspects of patient care including clinical practice and attitudes toward isolated proctitis identification, disease activity measurement attitudes, and current treatment of isolated proctitis, including the use of advanced therapies.

It has been well established that bowel urgency and fecal incontinence are highly correlated with a compromised quality of life and yet remain challenging to treat [13, 14]. On a scale of 0 (lowest agreement value) to 10 (highest agreement

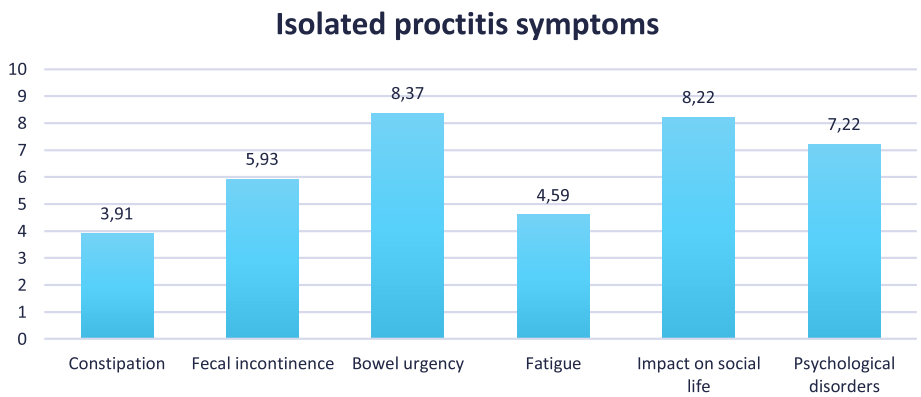

Fig. 1 Isolated proctitis symptoms

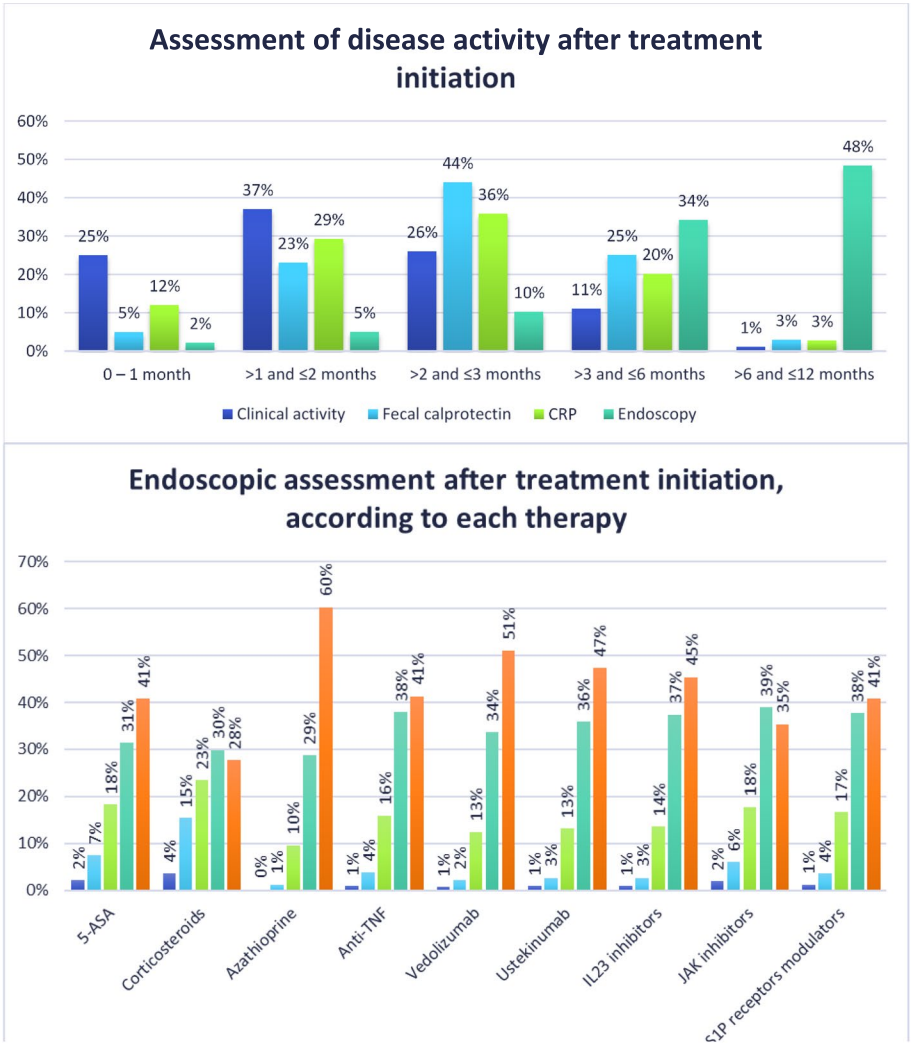

Fig. 2 Assessment of disease activity after treatment initiation

value), the majority of physicians reported that bowel urgency was a commonly reported symptom in patients with isolated proctitis, with over 77% valuing bowel urgency at least 8/10. Many physicians also agreed that fecal incontinence remains a common challenge in this population, with over 30% valuing fecal incontinence at least 8/10.

Three quarters of participants of our survey often use fecal calprotectin to measure disease activity. A recent study showed a significant association with disease extent and fecal calprotectin in UC [15]. In endoscopically active UC, fecal calprotectin levels were significantly lower in proctitis (440 [IQR 175–1350] mg/kg) as compared to left-sided colitis (840 [IQR 298–2011] mg/kg, $p = 0.048$) or pancolitis (1690 [IQR 723–2582] mg/kg, $p = 0.00005$) [15]. In this study, fecal calprotectin was found to be a reliable marker of mucosal healing across all disease extents [15].

In our survey, the majority of participants assess endoscopic disease activity between 6 and 12 months after treatment induction, and adapt the time required for achieving the goal after starting treatment according to the type of treatment. Liu et al. assessed the importance of the key treat to target end-point endoscopic healing on ulcerative proctitis outcomes [16]. In this study, endoscopic healing was associated with lower IBD-related healthcare utilization and IBD-related complications, suggesting this target applies to ulcerative proctitis in addition to more extensive UC [16].

Approximately, half of the participants in this survey were more reluctant to begin an advanced therapy in patients with isolated proctitis compared to left-sided colitis or pancolitis. The aim of treating ulcerative proctitis is to induce and maintain clinical remission, and prevent disease progression [17, 18]. Patients with ulcerative proctitis are thought to have a lower risk of severe aggravations, as well as a lower need for systemic steroids, immunosuppressive drugs, colectomy and hospitalization than those with the left-sided form of UC and pancolitis, which are also associated with higher rates of local and systemic complications and a need for intensified treatment [19]. In a multicenter pediatric cohort of patients with refractory ulcerative proctitis, biologics or other immunosuppressive treatments were needed in 37%

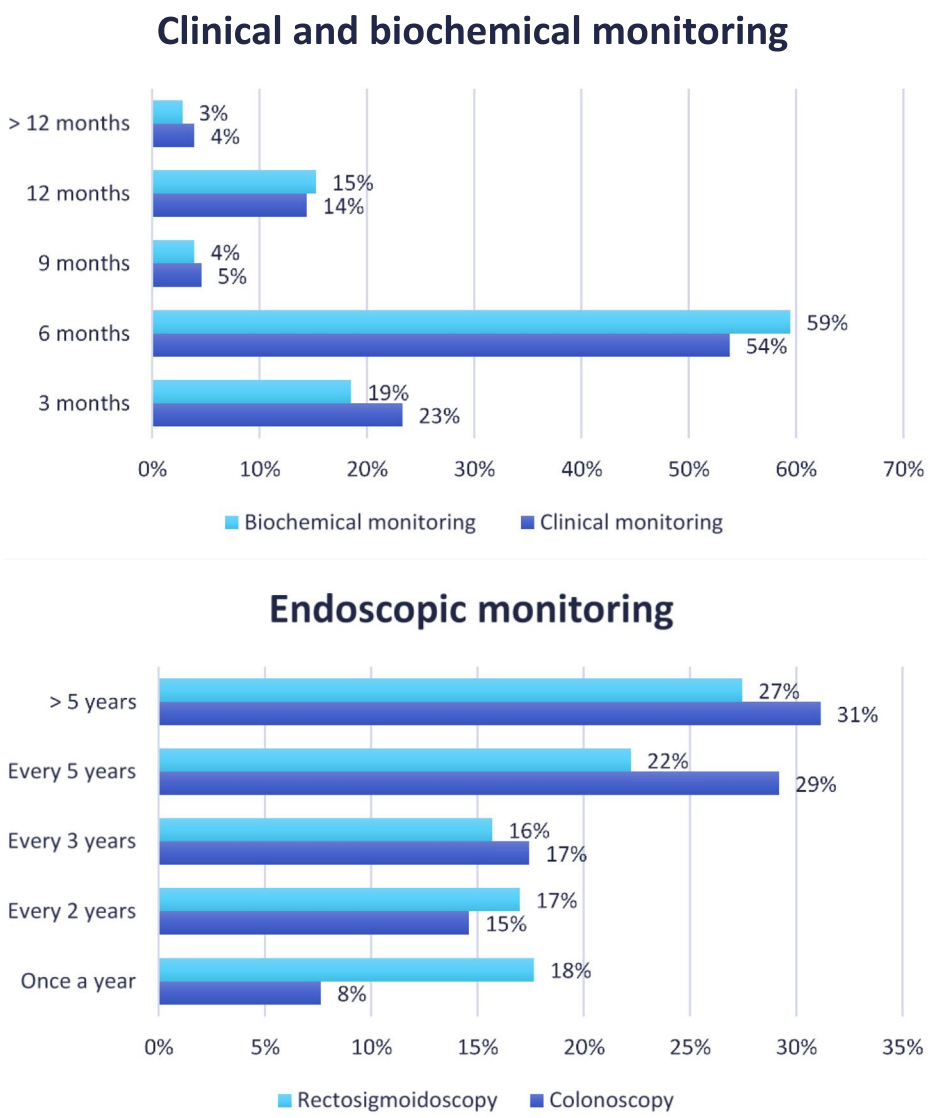

Fig. 3 Monitoring of patients in clinical remission

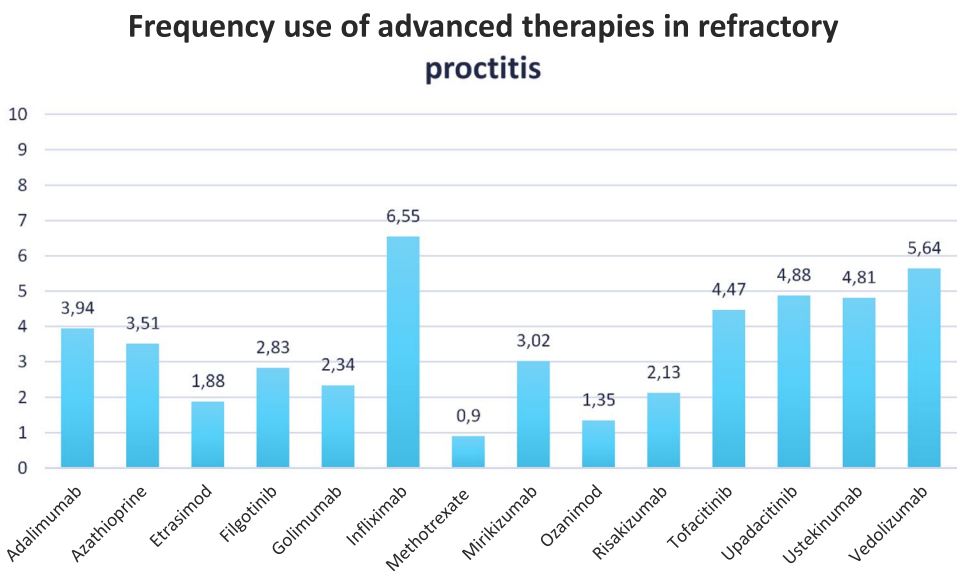

Fig. 4 Frequency use of advanced therapies in refractory proctitis

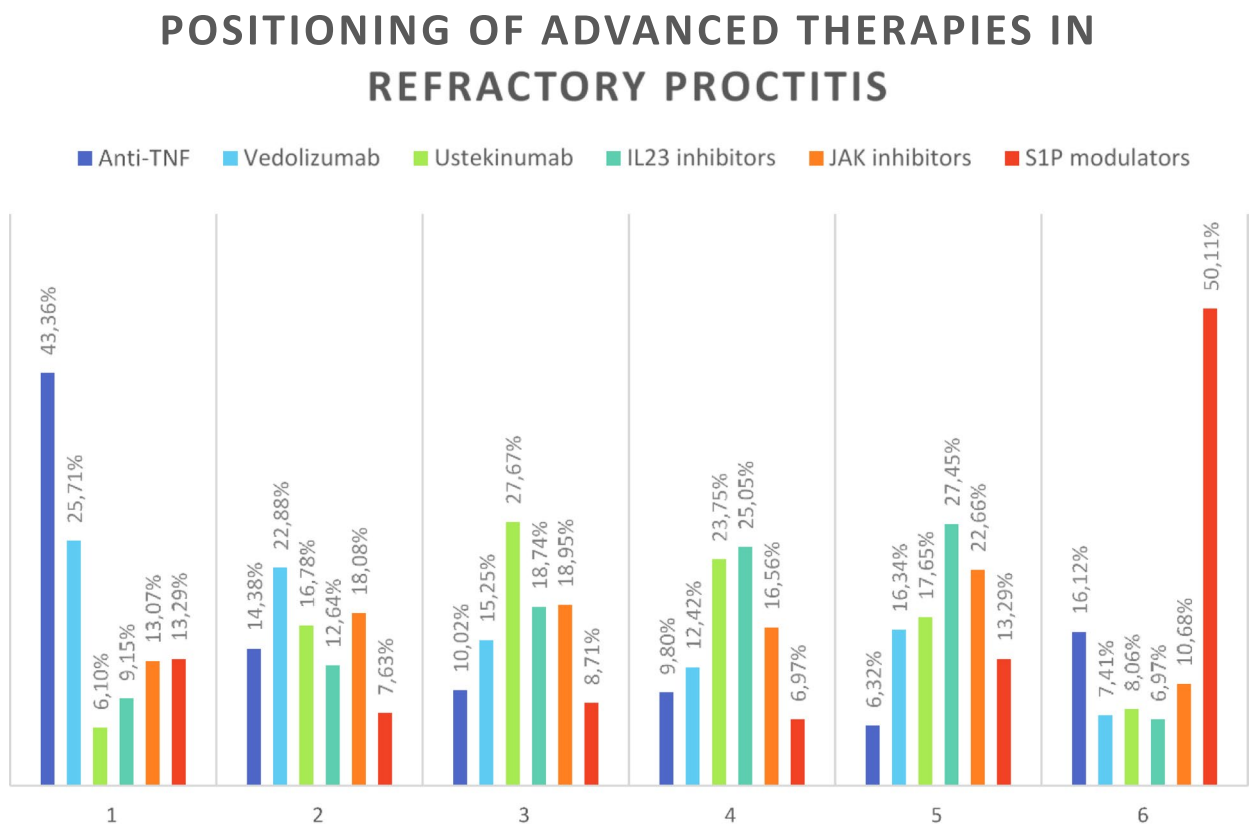

Fig. 5 Positioning of advanced therapies in refractory proctitis

of patients [20]. Among patients with refractory ulcerative proctitis in the prospective ENEIDA registry, 11% required immunosuppressant therapy, and 4.2% required at least one biologic agent [21]. For refractory proctitis, defined as when conventional therapies fail to improve symptoms, anti-TNF with or without thiopurines in combination, as well as small molecules and other biologics should be considered [22]. Recently, a multicenter retrospective cohort showed that the efficacy and safety profile of advanced therapies in patients with ulcerative proctitis was similar to that in patients with more extensive UC [23]. In a retrospective cohort study by Dalal et al. vedolizumab was associated with higher odds of steroid-free clinical remission at one year compared to anti-TNF agents for biologic naïve patients with ulcerative proctitis [24]. Inclusion in clinical trials would provide more robust data on the efficacy of advanced therapies in isolated proctitis, which would allow clinician to have a greater understanding of the expected efficacy of treatments for this entity [25].

To date, etrasimod is the only advanced therapy approved for treatment of active UC that included patients with isolated proctitis in the pivotal, phase 3, randomized clinical trials. Post-hoc analyses of this population demonstrated that etrasimod was efficacious and well tolerated in patients with isolated proctitis, and that etrasimod-treated patients achieved significantly higher rates of clinical remission at week 12 and week 52, compared to placebo. Patients with isolated proctitis receiving etrasimod also demonstrated significantly greater rates of improvement in rectal bleeding (by week 2), symptomatic remission (by week 4), and bowel urgency (by week 12 (earliest time point evaluated)) [10].

This study is the first global survey focused specifically on ulcerative proctitis, with large sample size and responses from 66 countries. The majority of respondents had more than 10 years of IBD experience. The survey covered key clinical domains as symptoms, monitoring, and treatment. There are some limitations as the use of convenience sampling, a lack of data validation (self-reported), and an English-only format for the survey. Availability of medication varies among countries and also in public/private practices. This may also affect how providers make decisions about therapy.

In future, additional studies focused on the management of ulcerative proctitis are needed in order to advance our understanding of the disease and improve patient care. Inclusion of patients with isolated proctitis in clinical trials can help to establish efficacy in this population and to standardize treatment protocols. These changes will be beneficial for all patients with isolated proctitis to receive evidence-based care and lead to more consistent and effective management.

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Author Contributions LPB conceived the study. BC and LS wrote the article and created figures and tables. All the authors critically reviewed the manuscript's content and supervised the project. The manuscript was approved by all the authors.

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Data Availability The data underlying this article are available in the article and the supplementary material.

Declarations

Conflict of interest BC has received lecture and/or consulting fees from AbbVie, Amgen, Celltrion, Ferring, Galapagos, Janssen, Lilly, Nordic Pharma, Pfizer, and Takeda. LS reports no conflict of interest. AD reports fees for participation in clinical trials, review activities such as data monitoring boards, statistical analysis, and end-point committees from Abivax, AbbVie, Bristol Myers Squibb, Dr Falk Foundation, Galapagos, Gilead, Janssen, and Pfizer; consultancy fees from AbbVie, Alfasigma, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Dr Falk Foundation, Ferring Pharmaceuticals, Fresenius Kabi, Galapagos, Janssen, Lilly, MSD, Pfizer, Pharmacosmos, Sandoz, Stada, Takeda, Tillotts, and Vifor Pharma; payment from lectures including service on speakers bureaus from AbbVie, Alfasigma, Biogen, CED Service GmbH, Celltrion, Falk Foundation, Ferring, Galapagos, Gilead, High5MD, Janssen, Materia Prima, MedToday, MSD, Pfizer, Streamed-Up, Takeda, Tillotts, and Vifor Pharma; and payment for manuscript preparation from Abbvie, Falk Foundation, J&J, Takeda, Thieme, and UniMed Verlag. SG has received lectures and advisory committes for Janssen, AbbVie, and Takeda. AH served as consultant, advisory board member or speaker for AbbVie, Abivax, Arena, Atlantic, AstraZeneca, Bristol Myers Squibb, Celgene, Celltrion, Falk, Galapagos, GSK, Eli Lilly, Janssen, Johnson & Johnson, MSD, Napp Pharmaceuticals, Pfizer, Pharmacosmos, Roche, Shire, and Takeda. VJ has received has received consulting/advisory board fees from AbbVie, Alimentiv Inc. Arena pharmaceuticals, Asahi Kasei Pharma, Asieris, AstraZeneca, Bristol Myers Squibb, Celltrion, Eli Lilly, Ferring, Flagship Pioneering, Fresenius Kabi, Galapagos, GlaxoSmithKline, Genentech, Gilead, Janssen, Merck, Mylan, Pandion, Pendopharm, Pfizer, Protagonist, Reistone Biopharma, Roche, Sandoz, Second Genome, Takeda, Teva, Topivert, Ventyx, and Vividion; and speaker's fees from, AbbVie, Ferring, Galapagos, Janssen Pfizer Shire, Takeda, and Fresenius Kabi. TK served as an advisory board member, consultant, or speaker for AbbVie, Alfresa Pharma, Alimentiv, Bristol Myers Squibb, Celltrion, Covidien, EA Pharma, Eli Lilly, Ferring Pharmaceuticals, Galapagos, Gilead Sciences, Janssen Pharmaceuticals, JIMRO, Kissei Pharmaceutical, Kyorin Pharmaceutical, Mitsubishi Tanabe Pharma, Mochida Pharmaceutical, MSD, Nippon Kayaku, Pfizer, Sanofi, Sekisui, Takeda, and Zeria Pharmaceutical and has received research funding from AbbVie, Alfresa Pharma, Bristol Myers Squibb, EA Pharma, Gilead Sciences, Helmsley Charitable Trust, Kyorin Pharmaceutical, Miyarisan, Mochida Pharmaceutical, Nippon Kayaku, Otsuka Holdings, Pfizer, Sekisui Medical, Samsung, Takeda, and Zeria Pharmaceutical. PGK received speaking and consultancy honorarium from Abbvie, Johnson and Johnson, Pfizer, Takeda, Celltrion and Sanofi. He also received scientific grants from Takeda and Pfizer and did clinical research for Lilly, Ventyx, Roche and Takeda. 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