

BURDEN OF DISEASE AMONG ULCERATIVE COLITIS PATIENTS WITH ISOLATED PROCTITIS IN THE UNITED STATES AND EUROPE

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Introduction

- Approximately 30% of ulcerative colitis (UC) patients present with isolated proctitis (IP), or ulcerative proctitis at diagnosis^{1,2}, which is associated with distressing symptoms such as abdominal pain and bowel urgency.
- According to ECCO consensus guidelines, IP patients not responding to conventional treatment are considered refractory if they have failed oral steroids combined with oral and rectal 5-ASA therapy³.
- There is a little real-world evidence regarding the use of advanced therapy (AT; specifically, infliximab, adalimumab and golimumab) in treatment of refractory IP^{4,5}.
- In addition, patients with IP not responding to conventional treatment are understudied and underrepresented in phase 3 clinical trials for AT.

Objective

- We aimed to understand disease burden among IP patients by describing clinical characteristics according to disease extension and treatment experience.

Methods

- Data were drawn from the Adelphi UC Disease Specific Programme (DSP™), a real-world, cross-sectional survey of gastroenterologists (GIs) and their consulting patients in France, Germany, Italy, Spain, the United Kingdom (UK) and the United States (US) from October 2020 – March 2021⁶⁻⁸.
- GIs reported patient demographics, disease extension, symptoms, components of the full Mayo score (allowing total scores to be calculated for patients), and treatment profile at time of consultation. Treatment history and disease extent at diagnosis were captured retrospectively through patient medical records.
- Patients with a history of physician-assessed moderate-severe UC were included; those with different disease extension at diagnosis and consultation were not included.

- Patients were categorised by disease extent as IP (IP at diagnosis and consultation) or as more extensive UC (MEUC; where disease extended beyond IP at both diagnosis and consultation).
- IP patients were further categorised as refractory and non-refractory based on treatment experience since diagnosis:
 - Refractory IP patients had received an immunomodulator (IM) and/or AT. Receipt of IM/AT was considered a proxy for failing oral steroids combined with oral and rectal 5-ASA therapy.
 - Non-refractory IP patients had only received 5-ASAs and/or steroids.
- All analyses were descriptive.

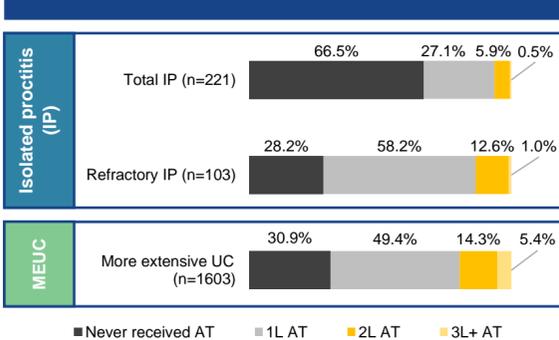
Results

- A total of 273 physicians reported on 1,828 patients from the US (n=376), France (n=284), Germany (n=339), Italy (n=304), Spain (n=355) and the UK (n=170).
- Since diagnosis, 33.5% of total IP, 71.8% of refractory IP, and 69.1% of MEUC cohorts had received AT (Fig. 1).
- At time of consultation, 32.6% of total IP, 69.9% of refractory IP and 66.2% of MEUC cohorts were receiving AT (Fig. 2).

	Isolated proctitis (IP)			MEUC
	Total IP (n=221)	Non-refractory IP (n=118)	Refractory IP (n=103)	
Age, mean (SD)	39.3 (13.7)	39.5 (14.3)	39.0 (13.1)	40.2 (14.5)
Sex, male, n (%)	109 (49.3)	65 (55.1)	44 (42.7)	891 (55.4)
Region				
US, n (%)	45 (20.4)	24 (20.3)	21 (20.4)	331 (20.6)
Europe ¹ , n (%)	176 (79.6)	94 (79.7)	82 (79.6)	1276 (79.4)
Time since diagnosis	n=197	n=106	n=91	n=1477
Years, median (IQR)	2.0 (0.9, 3.7)	1.7 (0.6, 3.3)	2.6 (0.9, 3.9)	2.8 (1.1, 6.3)

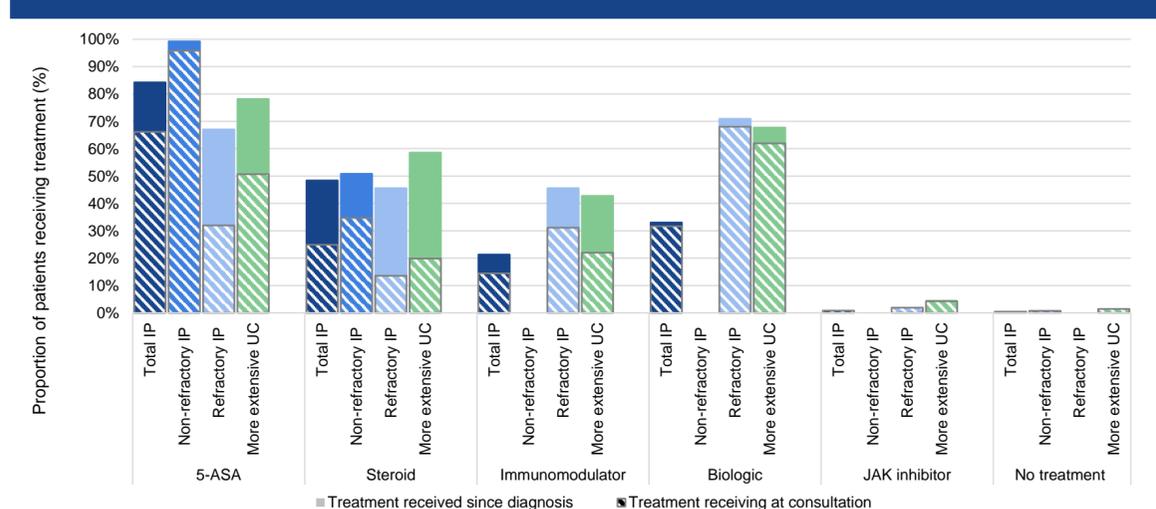
IP, Isolated proctitis; IQR, Interquartile range; SD, Standard deviation; UC, Ulcerative colitis; US, United States. ¹Includes France, Germany, Italy, Spain, the United Kingdom

Figure 1. AT experience since diagnosis



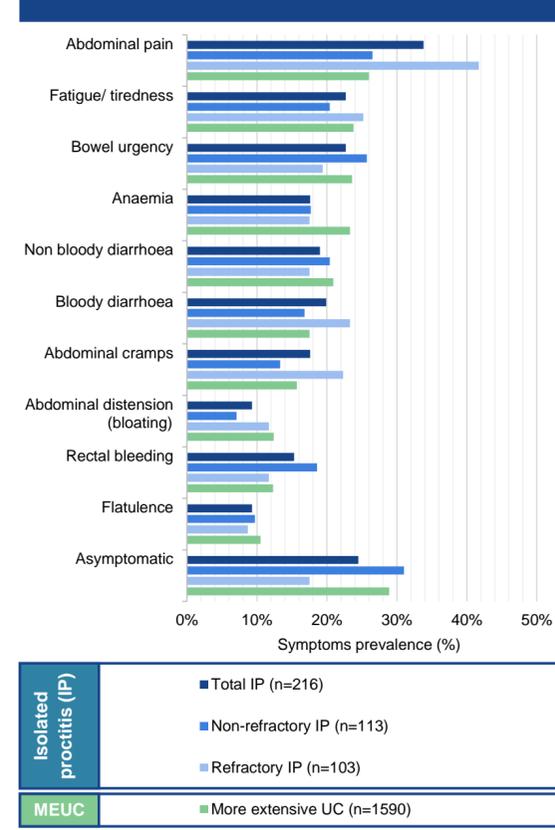
IP, Isolated proctitis; MEUC, More extensive ulcerative colitis; UC, Ulcerative colitis. Advanced therapy: Biologic (anti-TNF, anti-integrin, anti-IL 12/23) and Janus kinase inhibitor. Missing data not imputed. By definition, all non-refractory IP patients had not received an advanced therapy.

Figure 2. Treatment(s) received since diagnosis and at consultation



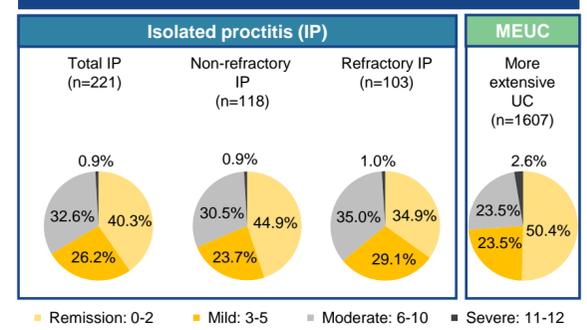
Isolated proctitis (IP): n=221, Non-refractory IP: n=118, Refractory IP: n=103, More extensive UC: n=1603; 5-ASA, 5-Aminosalicylic acid; JAK, Janus kinase; Steroid treatment includes all routes of administration; Non-refractory IP cohort defined as never having received immunomodulator, biologic or JAK inhibitor. Not receiving treatment only reported for treatment receiving at consultation.

Figure 3. Top ten most reported symptoms



IP, Isolated proctitis; MEUC, More extensive ulcerative colitis; UC, Ulcerative colitis. ¹Top ten symptoms based on more extensive ulcerative colitis population; Missing data not imputed; n numbers given where sample size varies.

Figure 4. Disease activity at consultation (defined by Mayo score¹)



¹Based on derived Mayo scores
IP, Isolated proctitis; MEUC, More extensive UC; UC, Ulcerative colitis

Limitations

- Participating patients may not reflect the general UC population as the DSP only included patients with a consultation in the study time frame. Patients who consulted more frequently have a higher likelihood of being included.
- Due to the cross-sectional nature of the study, patients within the sample are at different stages of their disease journey. Of the patient groups analysed, MEUC patients had the longest disease duration, which allowed for extended time for observation of treatment experience for these patients relative to other cohorts.

Conclusions

- Patients with IP experience a similar symptom burden to the MEUC population, despite currently available treatments for UC.
- While typically only conventional treatments are recommended for IP patients, approximately one third of patients with IP have received AT since diagnosis.
- The high AT use and low rate of remission indicates undertreatment of IP patients and a need for therapies with proven efficacy in this population, particularly after conventional therapy use.
- Additional analyses are needed for UC patients who experience a decrease or increase in the disease extent involved.

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Abbreviations

AT, advanced therapy; DSP, Disease Specific Programme; GIs, gastroenterologists; IM, Immunomodulator; IP, Isolated proctitis; IQR, interquartile range; JAK, Janus kinase; MEUC, More extensive ulcerative colitis; UC, Ulcerative colitis; UK, United Kingdom; US, United States; 5-ASA, 5-Aminosalicylic acid

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Disclosure of interests

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