RESEARCH

How are we managing fistulating perianal Crohn's disease? Results of a national survey of consultant gastroenterologists

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ABSTRACT

Objective Fistulating perianal Crohn's disease represents a significant challenge to both clinicians and patients. This survey set out to describe current practice and variation in the medical management of this condition.

Design A survey was designed by an expert group of gastroenterologists and surgeons with an inflammatory bowel disease (IBD) interest. The questionnaire aimed to capture opinions from consultant gastroenterologists with a UK practice on the management of acutely symptomatic fistula, assessment of a new fistula presentation, medical management strategies and surgical intervention. The survey was piloted at the British Society of Gastroenterology Clinical Research Group meeting, and distributed at UK gastroenterology meetings.

Results There were 111 completed responses (response rate 55%). Following clearance of sepsis, 22.1% of respondents would wait 6 weeks or more before commencing medical therapy. Antibiotics were used by 89.2%, with a variable duration. First-line medical therapy was thiopurine for 48% and antitumour necrosis factor (TNF) for 50% of respondents. These were used in combination by 44.4%. Interval to escalation of therapy (if required) varied from 1 month to a year. Anti-TNF therapies were favoured in deteriorating patients. An IBD multidisciplinary team was accessible to 98%, although only 23.6% routinely discussed these patients. Optimisation strategies for anti-TNF and thiopurines were used by 70% of respondents. Recurrent sepsis, refractory disease and patient choice are indications for surgical referral.

Conclusion These results illustrate the huge variation in practice and lack of consensus among physicians for the optimal medical management of perianal Crohn's disease. There are gaps in knowledge that require targeted research.

INTRODUCTION

A perianal fistula complicates Crohn's disease in around 30% of patients.¹ This is associated with significant disability from long-term discharge, pain and incontinence, as well as recurrent perianal sepsis and repeated surgical interventions. As few as one-third of patients will achieve long-term closure of their fistula.² Management of Crohn's anal fistula has been identified as a research priority by the James Lind Alliance and the Association of Coloproctology of Great Britain and Ireland.^{3,4}

Despite the impact of this condition, there are few large clinical trials in well-described patient cohorts. Crohn's anal fistula was included as subgroup analyses in early trials of antitumour necrosis factor- α (anti-TNF- α) medications.^{5,6} Although the pivotal ACCENT-II trial assessed anti-TNF- α in fistulating Crohn's disease, this was in a mixed cohort of enterocutaneous and perianal fistulae.⁵ As a result, clinical guidelines are based on a limited evidence base.

There are a number of guidelines for this condition from UK and international bodies.⁷⁻⁹ In broad terms, they advocate treatment of sepsis by a colorectal surgeon with or without an MRI scan to determine anatomy. This should be followed by medical therapy with biological agents, with or without antibiotics or immunosuppression such as thiopurines. These guidelines lack explicit detail on the indications for duration of, and timing between, interventions. There is also little information on the management of refractory fistulae. Before developing clinical pathways and tools to improve the care of these patients,

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it is important to define variation in practice and areas of uncertainty.

Aim

The aim of this study was to explore variations in clinical practice of UK consultant gastroenterologists in the management of Crohn's anal fistula.

METHODS

A questionnaire was designed by an expert group of gastroenterologists and surgeons with an inflammatory bowel disease (IBD) interest. It aimed to capture practice in the management of acutely symptomatic fistula, assessment of new fistula presentation, medical management strategies and when surgical opinions were sought on stoma or proctectomy (see online supplementary appendix A). The survey intended to capture personal practice, so it did not reference specific guidelines. It was designed to be completed by consultant gastroenterologists only. Replies were anonymous.

Responses were designed to be binary (yes/no), describe frequency using a 4-point scale (always, sometimes, occasionally, never) or selection of options from a menu. Where options (eg, choice of drugs) were provided, instructions of 'select one' or 'select as many as apply' were clearly written, with an 'other' option provided. Where specific time scales were required, these options were provided (eg, 2 weeks, 4 weeks). Free text boxes were provided to describe indications for surgical referral.

The questionnaire underwent a pilot at the British Society of Gastroenterology (BSG) Inflammatory Bowel Disease Clinical Research Group meeting in November 2015. Feedback from respondents was solicited, and minimal amendments were required. The survey was opened to recruitment at specialist postgraduate gastroenterology meetings (BSG annual conference and Sheffield Gastroenterology Symposium).

Numerical data from the questionnaire were collated and presented in a descriptive manner only. Free text data on indications for stoma and proctectomy were collated and representative statements reported.

RESULTS

Responses from the pilot confirmed appropriateness of question wording, but free text comments advised reordering drug options in treatment questions. A total of 111 responses were obtained through the various conferences. The overall response rate was 55%. Response rates to questionnaire items ranged from 79.2% to 100.0%.

Initial management and assessment

At initial presentation of a symptomatic fistula, 91 of 111 (81.9%) respondents would undertake imaging as their first action. If imaging was required, 108 of 111 (97.2%) respondents would obtain MRI pelvis and 1/111 (0.9%) endoanal ultrasound. Eighteen of 111 (16.5%) would refer directly to a surgeon. If referral

Figure 1 Minimum tests required for assessment of patient with Crohn's anal fistula.

for urgent sepsis management was required, 102 of 111 (93.5%) respondents would refer to a named surgeon, with the remaining 7 (6.5%) referring patients to the emergency surgery team.

Respondents indicated that they would 'Always' (60/107 (56.0%)) or 'Frequently' (45/107 (42.0%)) use antibiotics in the acutely symptomatic fistula. Only 2/107 (1.8%) indicated they would never use antibiotics in this setting. The antibiotic of choice was metronidazole for 91/107 respondents (85.0%), ciprofloxacin for 67 (62.6%) and co-amoxiclav for 27 (24.2%).

Respondents were asked to indicate the minimum set of investigations for a patient with an existing diagnosis of Crohn's disease who presents with a new perianal fistula. MRI pelvis would be required by 92/111 (82.9%) respondents, flexible sigmoidoscopy by 48 (43.2%), faecal calprotectin by 35 (31.5%) and colonoscopy by 33 (29.7%). Rigid sigmoidoscopy would be requested by one (0.9%), barium enema by one (0.9%) and examination under anaesthetic by nine (8.1%) (figure 1).

A further scenario was described of a patient with a perianal fistula and clinical suspicion of underlying Crohn's disease. Colonoscopy was the preferred investigation in this setting, with 88/107 respondents indicating they would always request this.

Management following clearance of sepsis

Respondents were asked to describe the interval they would normally leave between the clearance of perianal sepsis and the commencement of medical therapy (excluding antibiotics). This interval was 2 weeks for 41/103 respondents (39.8%), 4 weeks for 39 (37.8%)

respondents, 6 weeks for 18 (17.4%) respondents and 8 weeks for 4 (3.8%) respondents. One response (0.9%) indicated an interval of more than 9 weeks before commencing medical therapy.

When asked if respondents required evidence of sepsis clearance prior to medical therapy, 25/106 (23.6%) indicated they always required evidence, 54 (51%) frequently asked for evidence and 27 (25.4%) occasionally asked for evidence. The evidence taken into account was surgeons' report from examination under anaesthetic (EUA) by 80/106 (75.5%), patient symptoms by 74 (69.8%), repeat imaging by 76 (71.7%) and overall disease activity by 44 (41.5%).

An IBD multidisciplinary team (MDT) was accessible to 106/108 respondents (98.1%). Of these, 25 (23.6%) of respondents indicated they always discuss patients with fistulating perianal Crohn's disease (FPCD) in this setting. This was done 'frequently' by 54 (51.0%) of respondents and 'occasionally' by 27 (25.4%). No respondents with access to an MDT reported a practice of not discussing these patients in the MDT.

First-line medical therapy

Initial medical therapy was reported by 93 respondents. Of these, 54 (48.6%) respondents would use thiopurines as first-line agent and 56 (50.4%) anti-TNF- α agents. Twenty-seven (29.0%) and 16 (17.2%) would add antibiotics to thiopurine and anti-TNF therapy, respectively. Thirty-one (33.3%) would combine antibiotics, thiopurines and anti-TNF- α therapy, and nine (9.7%) would use thiopurines and anti-TNF- α therapy alone (figure 2).

Figure 2 Initial medical therapy. TNF, tumour necrosis factor.

Respondents were asked to define their first-line anti-TNF- α agent, if appropriate. Of 85 responses, 74 (87.1%) use infliximab as their first choice agent, with 11 (12.9%) using adalimumab. Free text comments indicated that this reflected clinician preference, but that patient choice was often important to this decision.

Where antibiotic therapy was considered, 89 respondents offered a preference. Of these, 49 (55.0%) would use ciprofloxacin and 39 (43.8%) would use metronidazole. Co-amoxiclav was the preferred agent of one respondent. The typical period of antibiotic therapy was described as 1 week by 2/89 respondents (2.2%), 2 weeks by 37 (41.5%), 1 month by 35 (39.3%), 2 months by 10 (11.2%) and more than 2 months by 5 (5.6%).

When asked if the presence of proctitis altered therapeutic strategy, 70 (68%) indicated that it did alter management and 33 (32%) indicated that it did not. Of the 70 where proctitis altered management, 21 (30%) said it altered surveillance strategies, 21 (30%) said it altered duration of therapy, 56 (80%) would use per rectum (PR) medications and 26 (37%) said it would change the choice of medical agent.

Monitoring and escalation

Following initiation of therapy, 26/87 (29.9%) respondents would assess response to therapy at 1 month, 52 (59.8%) would assess at 3 months, 6 (6.9%) at 6 months and 3 (3.4%) indicated variation in follow-up based upon severity of disease. Respondents were then asked to define the interval between commencing a drug and escalating therapy. Of the 108 respondents, one (0.9%) would escalate after 1 month of therapy,

26 (42.6%) would escalate after 3 months of therapy, 40 (37.0%) would escalate after 6 months of therapy and one each (0.9%) after 12 and 24 months (figure 3). This decision was based on clinical symptoms (rather than time bound) by 19 respondents (17.6%).

To monitor response to treatment after commencement of medical therapy, 66/111 (59.4%) respondents would do so on a clinical basis, and 53 (47.7%) indicated they would usually ask for repeat imaging.

In a patient who was stable or improving on first-line therapy, 2/107 (1.9%) would stop medical therapy, 14 (13.1%) would step down medical therapy and 91 (85.0%) would continue current therapy. Thirty respondents offered a choice of step-down medical agent: 1 (3.3%) to aminosaliculates (from azathioprine), 16 (53.3%) to thiopurine agents (from dual therapy with anti-TNF agents), two (6.6%) to methotrexate (from anti-TNF agents), 4 (13.3%) to infliximab (from dual therapy with azathioprine or reduction of dose in two cases), and 7 (23.3%) to adalimumab (monotherapy from dual therapy with azathioprine). In free text comments on second-line and third-line escalation therapies, adalimumab was well represented. Vedolizumab was reported as a second-line or third-line option by five respondents. A small number of respondents included surgical therapy as a second-line or third-line intervention in a deteriorating patient.

In the context of a patient with deteriorating fistulating disease, 32/111 respondents (28.8%) would change medical therapy, 56 (50.5%) would undertake further pelvic imaging and 23 (20.7%) would refer to a

Figure 3 Intervals between commencement of therapy, reassessment and escalation.

surgeon for further assessment. These categories were mutually exclusive.

Of the 77 respondents who offered a choice of escalation medical therapy, 2 (2.6%) would convert to azathioprine (from aminosalicylates or steroids), 41 (53.2%) to infliximab (from thiopurines) and 25 (32.5%) to adalimumab (from thiopurines or infliximab). Alternate strategies were proposed by nine (11.7%) of respondents and were typically escalating doses of anti-TNF- α therapy.

When asked about strategies to optimise drug dosages, 78/111 (70.2%) indicated that they checked thiopurine blood levels, 78 (70.2%) checked blood anti-TNF- α drug levels and 61 (54.9%) screened for anti-TNF antibodies.

Involvement of surgeons

Respondents were asked to indicate reasons for surgical referral. Long duration on immunosuppressant agents was the indication for 17/111 (15.3%), loss of response to drugs in 82/111 (73.9%) and impact of fistula on quality of life in 59/111 (53.2%).

Free text responses were sought on reasons for consideration of stoma. These were typically intractable sepsis, fistula refractory to medical therapy, negative impact of disease on quality of life and patient choice. One respondent indicated they would refer only if advised by the MDT. A second question asked about reasons for referral for proctectomy. The answers to this question were virtually identical to consideration of stoma, except for the addition of proctitis as an indication.

DISCUSSION

This exploratory survey of UK consultant gastroenterologists suggests considerable variation in management strategies for fistulating perianal Crohn's disease. There is notable variation in the choice of first-line medical therapies and reassessment strategies. Perhaps reassuringly, there was wide access to an IBD MDT, and consensus on indications for surgical intervention.

Current guidance from the European Crohn's and Colitis Organisation advocates early sepsis control and assessment of anatomy, treatment with metronidazole, and anti-TNF with or without thiopurine, with clinical assessment at least every 3 months. Reassessment of fistula and consideration of stoma are advised in persistent symptomatic disease.⁷ The BSG guidelines advocate antibiotics and thiopurine agents as early therapy, with anti-TNF agents used in severe fistulating disease.⁹ Results from our survey do not show strict adherence to either one of these approaches, with a clear split between thiopurine first and anti-TNF first. Our survey indirectly suggests that the more complex or difficult to manage the fistulating disease is, the less certainty there is on subsequent management steps. This is shown by the divergent opinion in escalation and reassessment strategies.

The variation identified may reflect a number of issues: limited evidence base upon which to formulate guidance or limited awareness of guidelines. For example, the use of aminosalicylates and corticosteroids reported here is not supported by current evidence.^{10 11} This variation might also be attributed to clinician factors, such as disagreement with the guidelines, systemic factors or consideration of guidelines as a suggestion rather than requiring strict adherence.^{12 13} It is also important not to underestimate the clinician's experience of the local population and their preferences. Patients may disagree with treatment strategies in other settings and omit drugs to avoid side effects.¹⁴

The survey also highlights variation around the timings in the management pathway, including intervals between commencing therapy, reassessment and escalation. There was disparity in the suggested interval from drainage of sepsis to commencement of medical therapy, with many clinicians expecting an interval of a month or more. It is not entirely clear whether this reflects clinician preference or factors related to healthcare system pressures. In addition, responses did not reflect a need for a more aggressive medical approach in those with proctitis,¹⁰ with about a third of respondents indicating that it did not alter their management. The described indications for stoma and proctectomy agree with published consensus.¹⁰

We have not been able to identify corresponding work from other countries. A recent cohort demonstrated that 60% of patients with perianal fistula were treated using anti-TNF- α therapy. The same study noted wide variation in the use of antibiotics.¹⁵ A retrospective cohort also found variation in the use of medical therapies aside from biologics.¹⁶ Notably, both of these studies were performed in centres with a developed IBD service.

There are limitations to survey-based research, specifically responder bias and questionnaire utility. The response rate of 55% compares favourably with other surveys of gastroenterologists.¹⁷⁻¹⁹ Despite this, the results provide a reflection of variation in UK medical management of this condition. Free text responses confirmed that respondents were not only IBD subspecialists, with a number of respondents indicating that they did not regard themselves as IBD experts and would seek advice at second-line or third-line therapy (or earlier). The spread of recruitment across national meetings limits responders to those engaging with professional development or research activities, but avoids issues of geographical clustering.

The decision to include clinicians with specialist and non-specialist practice was an active one—we aimed to record a reflection of 'real world' clinical practice. We recognise that the development of subspecialisation will vary across differing units, but the description of variation in practice and uncertainty will help identify potential improvements that are widely applicable. While our response rate was 55%, this is favourable

Table 1 Domains and elements of variation in practice, and potential research questions

Domain	Variation	Relevant research questions
Initial management and assessment	Use of endoscopic examination Impact of proctitis on medical management Use of pelvic imaging	What clinicopathological features affect initial management of Crohn's anal fistula?
First-line medical therapy	Biological first versus thiopurine first therapy Use of antibiotics	Does combination of antitumour necrosis factor, thiopurine and antibiotic offer treatment benefit versus other drug combinations?
Monitoring and escalation	Time to commencement of immunosuppression Time to assessment of clinical response	Can immunosuppression be started safely immediately following drainage of sepsis? What is the appropriate time to wait for assessment of clinical response/escalation of therapy?
Involvement of surgeons	Indications for referral for surgical input	When does surgical treatment offer benefit to patients, including improvement in symptoms or quality of life?

compared with other recent clinician surveys; others have found response rates of up to 30% for physicians in general,^{20 21} or 20% for gastroenterologists.²² Our corresponding surgical survey achieved a response rate in excess of 70%, although this is unusual and probably related to trainee-driven recruitment at centre level.²² Reasons for non-completion might be related to unfamiliarity with the condition or perceived length of the questionnaire. Surgeons were not included in this survey as we have previously undertaken a similar assessment of their practice.²³ In that study, 64% of surgeons would ask for anti-TNF therapy as first-line treatment, and that indicated that proctitis had an impact on their treatment strategies.

Medical therapy is just one component of a complex stepwise treatment pathway for patients with Crohn's disease and perianal fistulae, and physicians work together with surgeons, radiologists and specialist nurses to deliver this. Existing studies suggest benefit of this model.^{24 25} It is therefore important that the therapeutic strategy and goal are shared by physician, surgeon and patient to help reconcile complex medical and surgical pathways, which helps ensure

timely investigation and intervention. MDT meetings are clearly central to this, but other steps to facilitate patient flow between medical and surgical services are needed—for example, protocols to allow direct referral from IBD specialist nurses to specialist surgical teams. Joint medical and surgical IBD clinics may help in the initial assessment and also after an emergency admission and examination under anaesthetic to agree and plan anti-TNF therapy.

This survey was intended to provide insight into clinician-level management of patients with Crohn's anal fistula as a starting point for work to standardise care. Areas of practice with significant variation are presented in [table 1](#). Areas for further assessment include timing of assessment following initiation of medical therapy and subsequent escalation of medical therapy. With the need for strong antibiotic stewardship, the type and duration of antibiotic treatment also need clarifying. It would also be prudent to explore patient experience around the treatment of perianal Crohn's fistula. In the meantime, it is important that UK specialty associations recognise and address variation in management through further research, educational outreach, audit and guidelines.

Significant of this study

What is already known on this topic

- ▶ Crohn's anal fistula is a challenging condition to manage, and medical gastroenterologists are typically the lead clinicians for these patients.

What this study adds

- ▶ This study has demonstrated variation in the management of Crohn's anal fistula, particularly related to timing of interventions and reassessment.

How might it impact on clinical practice in the foreseeable future

- ▶ Work is required to harmonise practices across the UK and ensure best outcomes for patients. Specific research is required to address areas lacking evidence, including the impact of timing of interventions on outcomes.

CONCLUSION

There is variation in the choice and timing of medical therapies for perianal Crohn's fistula. This may reflect a limited and uncertain evidence base, rejection of guidelines by clinicians or an absence of national guidelines. Management delays resulting from this variation are likely to contribute to the significant debility experienced by patients with this condition.

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Contributors All named authors (MJL, AH, NSF, SRB, AJL) were involved in design of the study, collection and analysis of data, and manuscript preparation. The listed collaborators provided feedback on the design of the survey and undertook data collection. All have reviewed the final manuscript.

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Competing interests AH has contributed to advisory boards or lectured for AbbVie, MSD, Hospira and Napp Pharmaceuticals. AJL is an advisory board member or received lecture fees from Takeda Pharma, AbbVie, Vifor Pharma, Dr Falk and Shield Therapeutics. The other authors have no conflicts of interest to declare.

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