

Using patients' experiences with enema design to improve quality of life in patients with IBD

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Purpose: To gain insight from people in The Netherlands with inflammatory bowel disease (IBD) on their experiences with enema use, and their views on the use of enemas and mode of enema delivery.

Methods: A total of 112 patients from The Netherlands with physician-diagnosed Crohn's disease, ulcerative colitis, or other intestinal problems completed an online questionnaire of 24 questions. These included: sociodemographic and clinical characteristics, enema use, adherence, perceived advantages/disadvantages of enema use, ideal enema design, and patient views on medication, and on drugs and medical care in general. All respondents had personal experience with enema use and were members of the Patient Intelligence Panel. The Medication Adherence Report Scale and Beliefs about Medicines Questionnaire were also used to assess patient responses.

Results: Respondents reported overall satisfaction with their last enema use (4.3 on a scale of one to seven), with the main reasons for dissatisfaction being difficulty of administration and pain. Perception of enema convenience was rated 3.3 on average; one-fifth of respondents gave the lowest rating of "very problematic." Three distinct improvements for enema design were suggested. Respondents were generally neutral or positive in their beliefs on enema medication, but were more neutral to negative in their views of drugs and prescribing in general.

Conclusion: Real-life data on the views of patients with inflammatory bowel disease towards enema use are limited. Patients in this study were aware of the importance of adherence with their enema, but mainly did not regard it as convenient or easy to administer, and reported discomfort with enema use. Enema design was deemed by respondents as worth improving, and suggested improvements aimed to improve comfort with enema delivery. Adherence scales may be a valuable means of assessing views on medication in patients with inflammatory bowel disease.

Keywords: inflammatory bowel disease, enema, adherence, quality of life, beliefs about medicines questionnaire

Introduction

Both Crohn's disease (CD) and ulcerative colitis (UC) are chronic inflammatory bowel diseases (IBD) with intermittent, episodic progression. CD is an inflammatory disease of the gastrointestinal mucosa,¹ which is classified and defined by the gastrointestinal region involved and may be localized or extensive.^{2,3} UC is characterized by periods of active disease and remission that result in inflammation of the colonic mucosa. It is normally confined to the colon, with occasional ileal involvement, and it always involves the rectum. It may be classified as ulcerative proctitis (inflammation of the anus and rectum), left colitis (inflammation of the sigmoid and descending colon), or extensive colitis (from the rectum to the transverse colon and beyond) (Figure 1).^{4,5} It is a severe disease that can be potentially life-threatening.⁶

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IBD symptoms contribute to poorer quality of life (QoL) during active disease episodes,⁴ and severe attacks are also characterized by malaise, fever, and anorexia.⁵ Initial symptoms and signs of CD can be more subtle than those of UC, but most commonly include chronic diarrhea, abdominal pain, and weight loss. Blood and/or mucus may be seen in the stool, but bloody diarrhea is less common in patients with CD than in those with UC, and patients with CD are more likely to have abdominal pain or nonspecific abdominal symptoms.^{1,3}

The etiology of both CD and UC is unknown, although both diseases are thought to be caused by a combination of genetic and environmental factors.^{5,7} Although IBD onset can occur at any age, the peak age of onset is approximately 15–30 years in both CD and UC.^{4,8} Incidence and prevalence of IBD have increased in the past 50 years, and appear to be higher in developed countries – particularly in Europe and the US. In Europe, an estimated 1 million patients have CD, and 1.4 million have UC.⁷ Reported CD and UC incidence and prevalence vary considerably, particularly among different populations.^{7,9,10} Increasing trends in both UC and CD incidence have been reported almost globally,^{11,12} and particularly high rates of IBD have been reported in certain regions, one of which is The Netherlands.¹³ IBD incidence rates for The Netherlands of 6.9 per 100,000 for CD and 10 per 100,000 for UC have been reported.¹³

Treatment

The main goal of treatment for both UC and CD is to rapidly induce and maintain disease remission; as the precise disease etiology is unknown, therapy cannot be directly targeted to the cause of the disease. Symptoms are managed with medication, lifestyle, and dietary change, and treatment can be either maintenance for remission or acute to treat inflammation and any associated infection.^{3,5}

Disease site is important in IBD therapy; some drugs with local activity (such as mesalazine aminosalicylate preparations and budesonide) may be more effective when delivered topically.² Both aminosalicylate and corticosteroid therapy can be administered orally, intravenously, or rectally. Enema administration involves the delivery of fluid via the anus into the rectum and lower intestine using a flexible tube with a hole in the tip, which can be attached to a delivery container or solution bag (Figure 2). There are two main enema types: (1) evacuation enemas, which facilitate the passage of feces, and (2) retention enemas, which are designed to be retained in the rectum for a longer period of time and are used for drug delivery.^{14,15}

Aminosalicylate enemas are effective in improving symptoms and inducing and maintaining remission in patients with

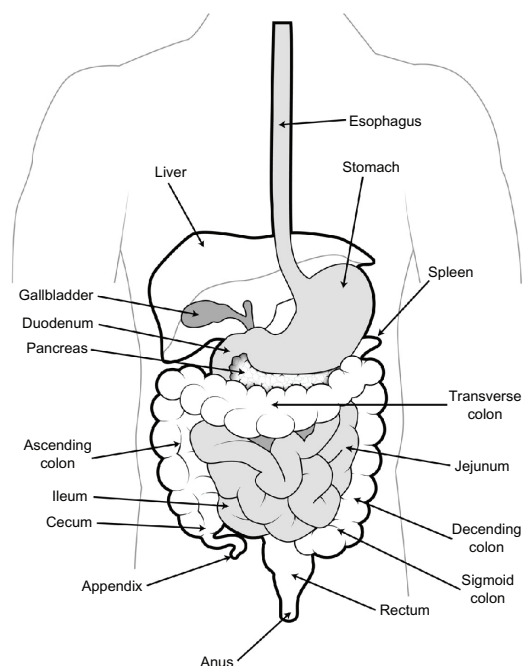


Figure 1 Anatomy of the colon.

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IBD.^{2,16} Rectal formulations can optimize drug delivery to the affected region, while minimizing systemic absorption of the drug and reducing associated side effects,^{4,17} but require drug retention, which can be difficult for patients.^{4,18} Rectally administered treatments can be more effective than orally delivered treatments,^{19,20} and have shown efficacy in patients unresponsive to oral therapy.^{18,21}

Combination oral and rectal therapy is also effective in inducing and maintaining remission in patients with UC,

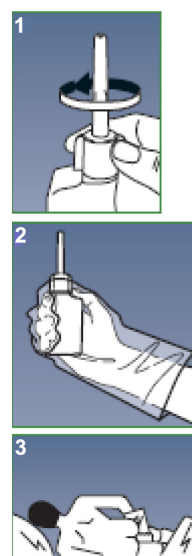


Figure 2 How to administer an enema.

and can be more effective than oral therapy alone.^{20,22} The European Crohn's and Colitis Organization consensus guidelines on treatment of CD recommend that therapy for active, mild-to-medium severity left-sided UC should begin with combination therapy of aminosalicylate enema plus oral mesalazine;^{2,16} this is also supported by the British Society of Gastroenterology⁶ and American practice guidelines.^{20,21} It is also important to tailor therapy to the individual patient, and to involve the patient in all therapeutic decisions.^{2,16}

Therapy adherence and QoL in patients with IBD

Most patients with IBD will need lifelong therapy, and adherence is a key factor in treatment success. Improving patient adherence is an important means of improving QoL and long-term health outcomes in patients with UC.⁴ Methods of encouraging self-management, such as a prototype Internet diary for patients with CD, provide opportunities for improved QoL.²³

QoL is very important in patients with IBD,²⁴ as many patients live with a considerable symptom burden, despite medical treatment,^{3,5} and QoL is frequently impaired.^{25,26} Although disease activity has a major effect on QoL,²⁷ fatigue, sleep disturbance, and general impact on normal life are also important consequences of IBD.²⁴ Quality of care (particularly in relation to provision of information), cost, and courtesy have also been shown to affect QoL in patients with IBD.²⁸

Enema adherence

Adherence with topical therapies can be poor,²² and they are more likely to be associated with nonadherence than oral therapy.^{29,30} Enemas can be uncomfortable for the patient; administration can stimulate the urge to defecate, and this, combined with the need for enema retention, can cause patient embarrassment and discomfort. Complications may include leakage, bloating, irritation, bleeding, swelling, or prolapse of the rectal tissue.^{15,18} As lower adherence may be related to lower remission rates in patients with IBD,³¹ it is important to maximize patient comfort and tolerance with enema delivery.

There is little discussion in the literature of patient views on enema use and satisfaction. Many studies of enema tolerability focus on comparisons between enema types, rather than patient views and feedback on the enema itself.^{17,32} Further, many studies consider therapy for either CD or UC, without combining considerations from patients with

IBD in general. Patient feedback on enema use is extremely valuable. It is important to have a greater understanding of factors inhibiting adherence with topical treatment, and how this can be used to improve patient comfort.

Use of enemas is not always popular with patients,^{33,34} however, and adherence can be poor.^{29–31} Current literature has little information regarding patient views on enema use, and the relationships between this and treatment adherence. The objective of this study was to gain insight from people with CD or UC in The Netherlands (an area with high incidence of IBD) on their experiences with enema use, and their feelings and viewpoints on enema use. The research question was: what views do patients with IBD have on enema use and delivery system/mode?

Methods

Data collection

An online questionnaire-based study of adult patients with CD, UC, or other (unspecified) intestinal problems, who had personal experience with enema use and were willing to discuss their experiences and views, was performed. The questionnaire was developed by Patient Intelligence Panel (PIP Health, London, UK; a patient research company) in collaboration with the authors, and sent by email to members of PIP Health's online Patient Intelligence Panel (www.piphealth.nl) during the period December 1–10, 2012. All participants were aged 18 years or over, had been physician diagnosed with either CD, UC, or other intestinal problems, and had previously indicated a willingness to participate in surveys on their IBD. The 254 Dutch panel members were sent an email containing a link to an online survey. In total, 112 panel members completed the survey – a response rate of 44%. Data analysis took place in December 2012. The questionnaire consisted of 24 questions focusing on: respondents' sociodemographic and clinical characteristics, use of enema (drug type and mode of administration), patient adherence, perceived advantages/disadvantages of enema use and patient views on ideal enema design, and patient perceptions about their medication for IBD and views on drugs and medical care in general. Patient responses to these last two questions were assessed using the validated Beliefs about Medicine Questionnaire (BMQ).³⁵ Patient adherence to medication was measured through the Medication Adherence Report Scale (MARS) scale using a ranking scale of one to five.^{36,37} The questionnaire was also designed to obtain respondent opinions and feedback on enema use and ideal design, assessed with open questions.

Particular focus was given to the analysis of respondent answers to the following questions and scales to determine patient views and satisfaction with their treatment:

- Satisfaction with enema use (on a ranking scale of one to seven), and reasons for dissatisfaction (if any).
- Adherence to medication administered by enema using the MARS-5 scale (on a ranking scale of one to five).
- Personal feelings on enema medication using the BMQ (on a ranking scale of one to five).
- Views on suggested improvements in enema design (open, tick-box, and ranking).

Patients' responses to the question: "Are you satisfied with the last enema you used" were rated on a scale of one (very dissatisfied) to seven (very satisfied).

Patients were asked "Do you think you are adherent with your enema medication?," and given a choice of four answers (yes, totally agree; yes, agree; no, disagree; no, completely disagree). The responses to "totally agree" and "agree" were combined to give an overall self-reported adherence rating.

Patient's views on suggested improvements in enema design consisted of three sections. The first was an open question on suggested improvements by respondents when given a picture of a standard enema applicator; respondents were then asked to describe exactly what they liked/disliked about enema design, and to provide suggestions for improvements. These were then analyzed to identify particular issues/components/aspects in design suggestion. The second section incorporated a series of four structured questions on enema design, to which respondents could agree/disagree on a ranking scale of one to five using tick-boxes; an average ranking score was taken for each question, and the percentage of respondents agreeing with each question was calculated. The third section included a list of eleven potential improvements to enema design, from which respondents were asked to select the three which they felt would be the most important; the percentage of responses to each question was calculated, and selections were ranked in order of popularity.

Respondent feelings on enema medication and on drugs in general were taken using the BMQ. Patient responses to the various questions were combined, and the average scores (by ranking scale) determined to gain an indication of overall trends in patient views.

Results

All 112 respondents lived in The Netherlands and had been diagnosed with UC, CD, or other intestinal problems. All were aged 18 years or over; 29% (n = 32) were male and 71% (n = 80) were female. The largest proportion of patients was aged 36–45 years.

Of the study respondents, 38.5% had a diagnosis of CD (n = 43), 59% were diagnosed with UC (n = 66), and 2.5% reported other intestinal problems (n = 3). One may, therefore, expect patients with UC to have more experience with enema use. Of those respondents with CD, 35% were male (n = 15) and 65% were female (n = 28); of those with UC, 21% were male (n = 14) and 79% were female (n = 52); all three respondents with other intestinal problems were male. Respondents reported use of the following enema medications: mesalazine (Salofalk®, Pentasa®, Asacol®), corticosteroid (beclomethasone, prednisone, budesonide), and combination (mesalazine/corticosteroid).

Enema use

All respondents who participated in this study had experience with the use of enemas to administer medication as this was a screening question in the survey. A total of 22% (n = 25) of respondents reported that they currently used an enema; the remaining 78% (n = 87) had experience with enema use. Enema medication types used are detailed in Table 1 (if respondents had experience with multiple types of enema medication, the type that they last used was included). The most commonly used enema was Salofalk (35%) and the next most commonly used was Pentasa (15%). Only mesalazine and beclomethasone enemas were included in the study analysis as these are recommended as first-line therapy by European (European Crohn's and Colitis Organization) and

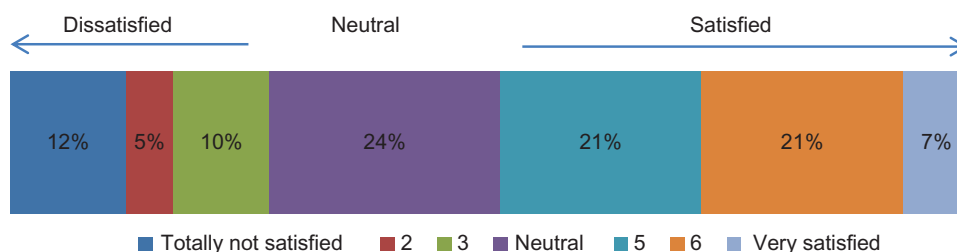


Figure 3 Distribution of patient satisfaction with last enema use.

Table 1 Enema types and demographics

Enema type	Total		Disease type				Sex of patient			
	n	%	Ulcerative colitis		Crohn's disease		Male		Female	
			n	%	n	%	n	%	n	%
Mesalazine enemas										
Salofalk®	39	35%	24	36%	15	35%	10	31%	29	36%
Pentasa®	17	15%	8	12%	9	21%	9	28%	8	10%
Salofalk foam	11	10%	8	12%	3	7%	3	9%	8	10%
Mesalazine (Asacol®)	6	5%	1	2%	3	7%	4	13%	2	3%
Corticosteroid enemas										
Beclomethasone	10	9%	8	12%	2	5%	2	6%	8	10%
Combination enemas										
Beclomethasone/mesalazine	12	10%	8	12%	3	7%	2	6%	9	11%
Other*	17	16%	9	14%	8	19%	2	6%	16	20%
Total	112	100%	66	100%	43	100%	32	100%	80	100%

Notes: *Not included in the study (see Table 2); three respondents indicated that they were diagnosed with "intestine problems" and not Crohn's disease or ulcerative colitis.

Dutch treatment guidelines (Dutch Institute for Healthcare Improvement; CBO) for IBD; other medications used by respondents are detailed in Table 2.

Satisfaction with last enema use

Respondents were asked "Are you satisfied with the last enema you used?," and responses were rated on a scale of one (very dissatisfied) to seven (very satisfied). Scores below four can be interpreted as dissatisfied, and scores above four as satisfied.

As can be seen in Figure 3, the largest proportion of patients rated themselves as neither greatly satisfied, nor dissatisfied with enema use. At either end of the scale, 12% were totally not satisfied and 7% very satisfied; the average respondent score was 4.3.

Respondents who were not satisfied with their last used enemas were asked to indicate their reasons for dissatisfaction from a selection of answers (Figure 4), or to give their own reasons (Table 3).

As seen in Table 3, the main two reasons for dissatisfaction were difficulty and awkwardness of administration in both men and women, followed by painful administration due to abdominal cramps and finding it difficult to empty the enema by squeezing (both higher in women). A much greater proportion of men also reported painful administration due to enema circumference (29%) than did women (10%),

while a much greater proportion of women reported dissatisfaction due to embarrassment (35%) than did men (12%). This information is only from respondents who expressed dissatisfaction with their enema use ($n = 57$; 17 males and 40 females).

Inconvenience of enema use

Patient perception of enema use in terms of convenience/difficulty was rated on a scale of one to seven; where one was "very annoying" and seven was "not at all annoying/difficult" (Figure 5). In general, scores below four can be interpreted as very inconvenient, and scores above four can be seen as satisfactory. Respondents gave an average rating of 3.3. A total score of less than four can be interpreted as a high level of patient annoyance/perception of difficulty with enema use. A total of 21% of respondents rated enema use as "very problematic" (the lowest rating) and only 5% rated enema use as not difficult.

Patient adherence to enema use

When asked "Do you think you are adherent to your enema medication?," 81% of respondents considered themselves adherent (33% responded "absolutely agree" and 54% responded "agree"). The question that followed asked respondents to rate to what extent they considered themselves to be adherent to their enema medication on a scale of one to seven, where one was fully nonadherent and seven was fully adherent; average respondent score was 5.6 – indicating moderate to good compliance. The main reason why respondents demonstrated low scores for adherence (three or less "or" less than four) was that they felt that they do not always need to use the medication. Respondents scoring themselves as low for adherence were further asked why they saw themselves as nonadherent.

Table 2 Other enema treatment types not included in the study

Other, namely corticosteroid enemas	n
Prednisone	4
Entocort® (budesonide)	3
Budenofalk® (budesonide)	2
Cannot remember	8

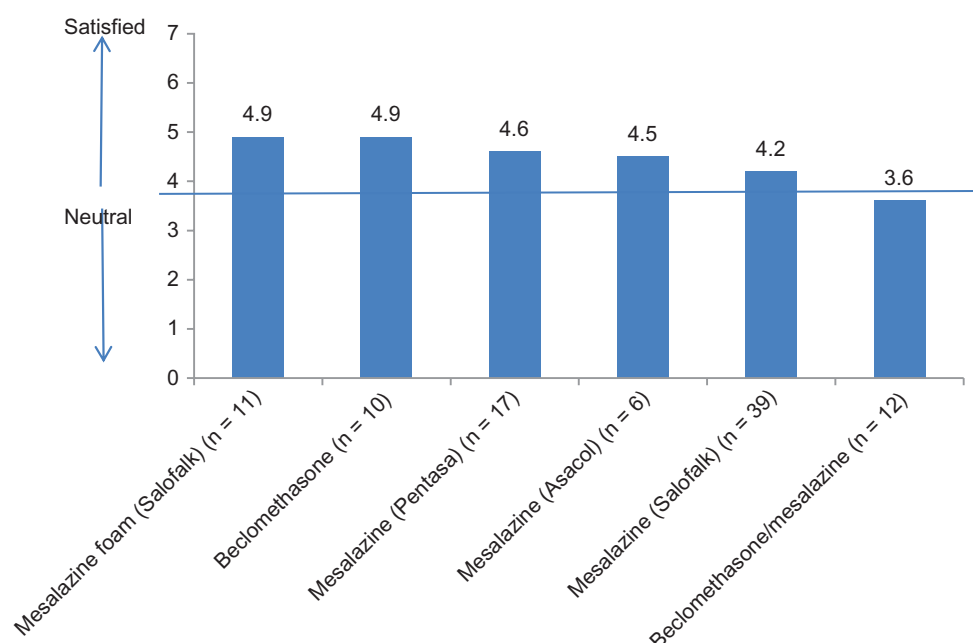


Figure 4 Patient satisfaction score with last used enema.

Some felt that the enema was not effective, and therefore they did not think that it was worth using anymore. A small group of others indicated that they did not know exactly why they were nonadherent because they no longer use an enema. All open answers to this question can be found in Table S1.

Respondents were also requested to report their adherence to enema medication by completing the MARS (Table 4),

in which a score of one indicated “always” and a score of five, “never.” Overall, those respondents who used an enema scored highly on the MARS scale, indicating good adherence – particularly with regards to enema dosage and frequency of administration. Slightly lower adherence was seen in regular administration (Table 4).

Table 3 Reasons for dissatisfaction with last used enema

	Total		Patient gender			
	n	%	Male		Female	
			n	%	n	%
Administration is awkward/tricky/difficult	26	46%	6	35%	20	50%
Administration is painful (abdominal cramps)	20	35%	4	24%	16	40%
The enema is difficult to empty	20	35%	5	29%	15	38%
Embarrassment	16	28%	2	12%	14	35%
Administration is painful (hard tip)	14	25%	3	18%	11	28%
Other*	10	18%	2	12%	8	20%
Administration is painful (circumference of end of enema, pain in anus)	9	16%	5	29%	4	10%
Irritation of the anus	9	16%	3	18%	6	15%
Total	57	100%	17	100%	40	100%

Notes: *Other reasons given for dissatisfaction with last used enema in the open-ended field were: causes smelly stools or flatulence; no effect/does not work – complaint continued; difficulty in retaining medication (leakage); insertion of too much air with medication; irritation of the intestinal wall; and disease activity subsided. Some respondents expressed more than one reason for dissatisfaction.

Switching enema brand

Respondents were asked “Have you ever asked your physician for a different type of enema and changed your enema brand?” Of the 112 respondents, 68% (n = 76) reported never having switched their brand of enema; respondents with CD switched less frequently (74%) than respondents with UC (65%). The 32% of respondents (n = 36) who reported having switched brand were asked “Why did you change to another brand of enema?” and given a choice of responses (Table 5). The most commonly given reason for switching was that the enema was not effective enough (64%), followed by inconvenience of enema use due to pain associated with enema administration (25%).

Enema design and functionality

A picture of an enema applicator (Figure 6) was included in the questionnaire. Respondents were asked to describe exactly what they did and did not like about an enema, and what points could be improved. Of the 112 responses, 13 people responded that they did not know, and 28 had no suggestions for improvement (it is unclear whether they had

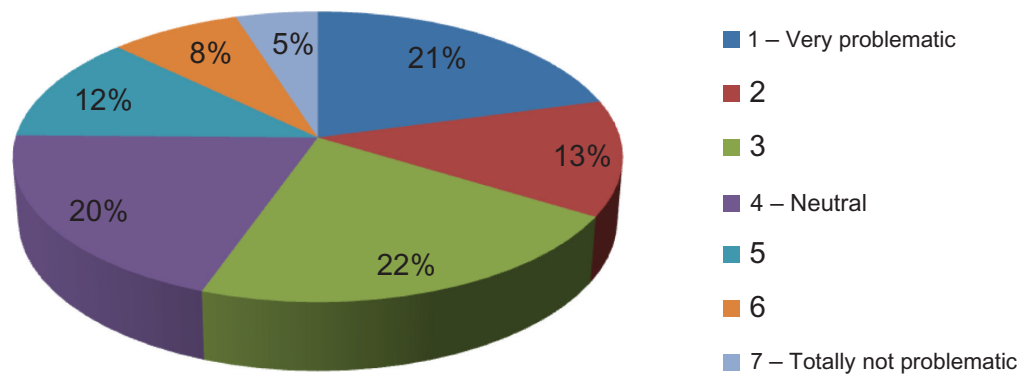


Figure 5 Distribution of patient perception of enema use.

no opinion or just found no issues with the enema design and functionality).

The remaining 71 respondents gave a variety of suggestions for improvements (Table S2). Overall, two major points were made. Firstly, that the bottle is often clumsy to handle and hard to empty completely by squeezing. Secondly, that the tip of the enema was hard and could be painful to insert; the tip could be softened to make it less painful during insertion. The point was also made that introducing a curved or angled delivery tube may improve retention of medication, and may also reduce introduction of air with the enema, which can lead to trapped wind. The answers of all 112 respondents to this open question are available online at www.piphealth.nl.

Closed questions/statements drafted by the project coordinator at PIP Health were then asked, with the respondents encouraged to agree or disagree on a scale of one to five – with one being “strongly agree” and five being “totally disagree.” All scores below three may therefore be interpreted as a positive opinion regarding the statement. Questions and patient responses are given in Table 6. The highest score was given to the statement:

Table 4 Medication Adherence Report Scale scores for respondent adherence to enema medication: questions and average responses

Question asked	Average MARS response
I forget that my enema should be administered	4.2
I change the dosage of my enema	4.4
I stop administering my enema for a while	3.9
I decide to skip a dose	3.9
I administer far less from my enema than what the doctor prescribed	4.2

Notes: One = always; two = common; three = uncommon; four = almost never; five = never.

Abbreviation: MARS, Medication Adherence Report Scale.

“It would be an advantage if the enema is easier to squeeze empty,” followed by “It would be an advantage if the enema would have a softer point/tip” with a score of 2.2 – this supports the patient suggestions for improvement given above.

Respondents were then asked to select three elements from a list that they felt would improve an enema the most, with the following being the most popular: (1) softness of tip (68%); (2) thickness of applicator – thinner circumference (46%); and (3) curved applicator (angle in the tube) (38%).

Patient beliefs in enema medication

Respondents were also requested to report their views on the medication and enemas they use, and how they feel about drugs and medical intervention in general, using a series of questions scored according to the BMQ on a scale of one to five, where a score of one indicated “always” and a score of five, “never.” They were asked firstly: “How do you feel about the drug and the enema you are using?” and then asked to give a rating of one to five to the various responses, where one was “strongly disagree” and five was “strongly agree.” Average responses are given in Table 7.

Table 5 Reasons for changing enema brand

Response selected (n = 36)	Total	
	n	%
The previous enema was not effective enough	23	64%
The previous enema was not easy to use due to pain	9	25%
The previous enema was difficult to empty	6	17%
With the previous enema I could not contain the medications inside of me	7	19%
The previous enema was not easy to use due to difficulties inserting the enema	6	17%
Other reason given	5	14%



Figure 6 Image of a standard transparent enema applicator (standard-size applicator is approximately 17 cm long in total, with a tube length of approximately 6 cm and a reservoir of approximately 8.5 × 4.5 × 3.5 cm).

Overall, the responses indicate that respondents are aware of their need to take medication – agreeing with the statements that refer to their health without medicine being worse. The response to fears of dependency on medication are overall more neutral, as is the response to the statement “My medicines disrupt my life” and “I am not sufficiently aware of what my meds do.”

Respondents were then asked “How do you feel about drugs in general?” and were asked to give a rating of one to five to the various responses, where one was “strongly disagree” and five was “strongly agree.” Average responses are given in Table 8.

Overall, the patient responses tend to be more neutral, although they are slightly higher in response to the statements “Doctors rely too much on drugs” and “If doctors had

Table 6 Closed questions on improvements to enema design (one = totally agree, seven = totally disagree)

Statement provided	Average score	Percentage of respondents in agreement (N = 112)
It would be an advantage if the enema is easier to squeeze empty	1.6	89%
It would be an advantage if the enema would have a softer point/tip	2.2	87%
It would be an advantage if the end of enema (applicator) would be curved (at an angle in order to facilitate insertion)	2.6	76%
It would be an advantage if the enema tip was thinner	2.4	63%

Table 7 How do you feel about the drug and the enema you are using?

Statement	Average response (N = 112)
At the moment my health depends on the use of my medication	3.45
I worry about the fact that I have to take medication	2.98
My life would be very difficult without medication	3.76
Sometimes I worry about the effects of taking my medication in the long term	3.65
Without my medication I would be very sick	3.71
I am not sufficiently aware of what my medications do	2.54
My future health depends on my medicines	3.62
My medicines disrupt my life	2.54
Sometimes I'm afraid that I will become dependent on my medication	2.91
My medications keep the state of my health from getting worse	3.70
These drugs have unpleasant side effects	3.04

Notes: One = strongly disagree; two = disagree; three = no clear opinion; four = agree; five = strongly agree.

more time for their patients, they would prescribe fewer medicines.”

Discussion

Major results

This study found that respondents were satisfied overall with their enema use, although the largest proportion of respondents rated themselves as neutral (an average score of 4.3 on a ranking scale of one [very dissatisfied] to seven [very satisfied]), with 12% very dissatisfied and 7% very satisfied. The main reason for dissatisfaction was difficulty/awkwardness of administration (both men and women), but pain was also given. When asked to rate their perception of enema convenience, however, respondents were less satisfied

Table 8 How do you feel about drugs in general?

Statement	Average response (N = 112)
Doctors prescribe too many drugs	2.68
People that are using medicine should stop their treatment every now and then	2.63
Most medicines are addictive	2.56
Using natural remedies is safer than using drugs	2.73
Medicines do more harm than good	2.37
All drugs are poisons	2.63
Doctors rely too much on drugs	2.82
If doctors had more time for their patients, they would prescribe fewer medicines	2.82

Notes: One = strongly disagree; two = disagree; three = no clear opinion; four = agree; five = strongly agree.

and a high level of annoyance/perception of difficulty was seen with enema use.

Self-reported adherence to enema medication was overall good, with an average score of 5.6 on a scale of one to seven (moderate to good compliance), which was also reflected in good scores for adherence on the MARS. Two-thirds of respondents reported never switching enema brand, with respondents with CD switching even less frequently than those with UC. Lack of efficacy was given as the main reason for switching, followed by inconvenience due to pain.

Research comparison

Several recent studies have reviewed self-reported treatment adherence in patients with IBD, using the BMQ-Specific scale, Satisfaction with Information about Medicines Scale, or the Morisky Medication Adherence Scale.^{38–40} Two of these found self-reported adherence by patients with IBD to be overstated, compared with more objective methods,^{38,39} although the third reported that the Morisky Medication Adherence Scale was a successful means of identifying adherence.³⁹ The current study provides yet another comparison point for physicians, patients, governmental bodies, and pharmaceutical companies to become more “patient intelligent” by using the MARS in patients with IBD, along with the BMQ and an original questionnaire designed by the authors. Patient intelligence can be a valuable source of information, helping health care providers to better understand and apply the patient viewpoint to both treatment and health economic models.^{41,42}

A gold standard for assessment of adherence in IBD has not yet been developed, and nonadherence can be difficult to identify.^{38–40} Screening tools such as the Morisky Medication Adherence Scale and MARS may be an effective way of monitoring adherence; a recent study reported overestimation of adherence by physicians in 67% of patients studied.^{40,43} In the current study, respondent answers to the questions on their beliefs in enema medication (the BMQ questions) may indicate a potential discordance in doctor–patient communication. As the therapeutic relationship and patient confidence in treatment is thought to be a factor in adherence,^{36,44} and higher patient–physician discordance on wellbeing has been associated with treatment nonadherence,⁴⁴ this is an important consideration. Further, a greater focus on patient reported outcomes is needed. It is important that patients feel involved in the decision-making process for their treatment, as this can promote treatment acceptance, which may also improve adherence.⁴⁵

Study limitations and future research needs

Potential study limitations include the relatively small size of the sample, and the limited number of treatments represented in this research group. The only types of medication included were mesalazine (Salofalk, Pentasa, and Asacol) and beclomethasone; as this is not a full representation of the treatment types available by enema, further research could include a greater range.

Another potential limitation is that all respondents signed up for involvement via a patient panel (PIP Health), and have all indicated their willingness to discuss their disease. As patient engagement with treatment may relate to adherence, these patients may be more likely to be adherent to treatment than those in the general population. As the adherence data is self-reported, it may also not be fully representative of actual patient adherence.

Real-life data on the views of patients with IBD towards enema use is limited. This study provides a good foundation into patient viewpoints on their IBD, its management, and in particular the use of enemas. Future research could include the wider patient population with IBD, both in The Netherlands, and in other areas of high IBD incidence.

Research and clinical implications

The therapeutic relationship and patient confidence in their treatment and physician are major factors in patient adherence to medication.^{36,44,46} Adherence scales may be a valuable tool for assessing patient perception of their disease and treatment adherence, and further testing and validation could be supported by more objective methods, such as urine testing.³⁹ In this study, the patient responses to the questions on their beliefs in enema medication (the BMQ questions) suggests that both patient education and the doctor–patient relationship could be improved in patients with IBD. More patient intelligence on the views of patients with IBD on enema use could potentially improve disease management and QoL.

Enema design is also very important – both in improving patient QoL and in effective drug administration.^{30,47} Given the views that respondents gave on design, it seems that improvements are called for. Firstly, a softer, more flexible bottle to make handling easier and facilitate emptying; secondly, a softer tip which would be less painful to insert; and thirdly, a curved or angled delivery tube which may improve medication delivery.

Conclusion

Disease site is important when considering therapy for IBD, and topically administered treatment can be very effective.

Enema use is therefore an important part of therapy, but can be associated with inconvenience and discomfort, and compliance can be poor. This study has provided novel and important insights into patient perception of their enema use, and into factors which may make enema use more comfortable and acceptable. Further work in this area would be valuable to assess insights into enema use and perceptions on drugs and IBD management in a larger population, as would further use and validation of adherence scales in patients with IBD, and redesign of enemas.

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Supplementary data

Table S1 Open respondent answers to Question 12 regarding nonadherence to enema medication

If you consider it as therapy, can you tell me why you ever miss an enema administration?

Open answers:

I do not use it anymore

I think it's average

Too much pain

I wanted to go on an errand or visiting somewhere and if I had used the enema then could not

Sometimes I think it would not help

I do not use it

I have often forgotten and if that does not cause significant discomfort, then it is attractive to skip it sometimes. Until it goes wrong of course, but I'll take that risk then

Little to no complaints

I think the enemas are too expensive so I stopped earlier to see if that causes discomfort. If it does, then I [will use the] enema

Too tired, painful, suffer from wrist problem so insertion is harder than normal though, any excuse is [a good] one

Because it is too painful to insert

[It's] okay

Forget

Do not

Because I do not need it

Not always necessary

Do not know

[It's] okay

I do not use them

If I'm really tired at the end of a long day, I only want my bed

You can always try, not so?

Not really

Because it really does not help

Annoying

Note: These answers have been translated from Dutch and are as close as possible to the original patient responses.

Table S2 Respondent suggestions for enema improvement

- If the point is a more curved shape the bottle will not be so difficult to hold. And there will probably be less air [inserted at the same time]
- [Change the] top
- That the insertion point is softer. It is mainly what is painful [to insert]
- The bottle is often too clumsy to empty by squeezing. And I do not [like to] ask for help
- The bottle is too hard (plastic) and difficult to empty by squeezing
- The bottles for the Entocort® enema were difficult to squeeze empty. You can never do it yourself
- A really terrible odor develops just after administration. Later, it's fine
- The sheath [should be] smaller
- The enema should be easier to squeeze so you can almost certainly administer the entire contents
- The enemas that I use are made by the pharmacy and fine with me
- If the length of the enema was longer [there would be a] benefit from higher rising administration
- The plastic tube could be made of a softer rubber or silicone-like material. This would be less hard and make application easier
- The point is pretty hard. You must administer the whole thing while it [the rectum] is inflamed, that deserves [to be] a little softer
- The point is too hard and the bottle can't be completely emptied by squeezing. A softer, easier to squeeze bottle and a less hard point!
- The point is rather large. Bag must be emptied by squeezing
- The tip of the enema is often too hard
- The point would have to be made softer
- The rounding
- The shape of the reservoir
- This is Pentasa®, too much content, difficult to empty by squeezing, and sharp edges when inserting
- Thickness is very thick
- It seems clumsy to administer. I find myself the foam canister is the best way
- Transparency of the bag is fine, you can see exactly what still remains after administration
- Thinner cannula and something so that when you prepare the enema it is immediately warm
- A convenient bottle that is easy to squeeze empty!
- Fine, the one in this picture is less fine as no harmonica on it that makes it easier to squeeze
- Empty bottle is hard to squeeze nozzle is very hard
- Good: long and thin snout and handy; bad: the harmonica form of Salofalk® enemas (from bottom to top at the muzzle) are much easier to use when inserting
- Hard long and cannot be emptied [by squeezing]
- The thick end
- It is inconvenient to administer. Especially if you are by yourself, and you do not want someone to help you
- The squeezing of the casing
- It should be easier [to administer]
- The administration of the enema is not a problem
- The end is rather "hard." It would be nice if the end would be more flexible, softer
- Here you can see exactly everything that you've used so [it's] positive for me
- Does not seem to be transparent
- Quantity of view [of solution] in the bag
- I use other enemas. It seems to me [they are] difficult to squeeze empty
- I use foam enemas for better insertion. This enema has no aluminum tube, which works fine. The enema above is a straight line, there is no angle for ease of use
- I had a different kind of enema
- I had just round bottles, but 10 years ago
- I have no trouble with those things if necessary it must [be used]
- I have used them a few years ago that I found annoying was the air that sometimes comes along [is administered alongside the enema]
- I like the harmonica bottle's better
- I think it's good, it looks just as scary as [medicine]
- I do not know, my enema looks different. Just shake and it's ready, it gives a foam dosage which is very pleasant
- I use enemas of 60 cL, hence it [this feedback is] for 60 mL bottle, my experience has been from 13 with Crohn's, as the 60 cL is bigger you only have to penetrate it once
- You never get the bottle completely empty
- You have [to get] the air out properly otherwise you do not get [it] in and I think that should be improved
- Sometimes you have to put [the enema in with] quite some force to prevent the enemas from leaking when you are administering
- Color
- A curved bottle is good for someone with muscle disease

(Continued)

Table S2 (Continued)

- Empty by squeezing
- Seems difficult to squeeze empty
- Must be easily rolled and pipe is long enough and the fluid should not be reduced
- Clumsy
- Clumsy and [have to] hold before you insert, yet [fluid can] spurt out because the “bottle” is so soft
- Clumsy to empty itself by squeezing the grip, and shape and hardness of the squeeze portion
- [Make the] point less hard
- [Make the bottle] round not square
- Some enemas need to be refrigerated. Very annoying. It will always remain embarrassing!
- Some enemas are hard to squeeze empty. No further improvement points, an enema is never any fun
- Sometimes too thick to insert and empty, and sometimes difficult to squeeze
- Insertion point is too cold
- Found it difficult to empty by squeezing
- Well, you see how much is gone [with a clear bottle]. Disadvantage, very difficult to finish [empty]
- Softer material especially where it goes into your anus
- Looks good. But if the package you need to press to empty is of plastic it is difficult to completely empty
- Do not (answer × 13)
- No suggestions (answer × 28)

Note: These answers have been translated from Dutch and are as close as possible to the original patient responses.

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