



Perspective Article

Transanal Irrigation for the Management of Functional Bowel Disorders: An Observational Study

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Citation: Henderson M, Chow J, Ling J, Ng CE, Embleton R, et al. (2022) Transanal Irrigation for the Management of Functional Bowel Disorders: An Observational Study. Int J Nurs Health Care Res 5: 1360. DOI: 10.29011/2688-9501.101360

Received Date: 01 November, 2022; **Accepted Date:** 11 November, 2022; **Published Date:** 16 November, 2022

Abstract

Aim: The aim of the PERSPECTIVE* study was to examine the burden of a wide range of functional bowel disorders (FBDs) on quality of life, work productivity and healthcare utilisation and to explore patients' perceptions of using transanal irrigation (TAI) to manage these conditions. This paper reports the findings related to TAI. **Method:** This large observational study utilised two existing cohorts of people - the ContactME-IBS database and an in-service transanal irrigation database. 4794 people were invited to participate in a single online questionnaire. **Results:** 183 (20%) respondents reported experience of TAI. 110 (60%) of these continue to irrigate. Many patients were still irrigating after 5 years, with variable frequency, suggesting they choose a regime to suit their illness and lifestyle. Effectiveness of TAI at 3 months was shown to correlate positively with effectiveness at 6 months, with a trend for this effectiveness to continue up to 12 months and beyond, supporting the notion that it remains effective in the longer term. Three quarters of patients treated with TAI for diarrhoea were still irrigating. **Conclusion:** PERSPECTIVE has demonstrated a treatment success rate of 60% with benefits continuing long term. TAI was shown to benefit patients with diarrhoea and mixed or alternating bowel symptoms. To date, there has been little assessment of the use of TAI for these symptoms which may merit future research.

Keywords: Constipation; Diarrhoea; Effectiveness; Functional bowel; Irritable bowel syndrome; Transanal / rectal irrigation

***PERSPECTIVE:** Patient pERSpective of functional bowel disorders: Effects on lifestyle, experienCe of Transanal Irrigation and effects of the COVID-19 pandEmic.

What does this paper add to the literature?

This paper has shown that transanal irrigation may be an effective treatment for all types of functional bowel disorders, including diarrhoea and mixed or alternating symptoms, with benefits continuing long term. Effectiveness of TAI at 3 months is a reasonable indicator of effectiveness at 12 months and beyond.

Introduction

Functional Bowel Disorders (FBDs) are gastrointestinal conditions which include Irritable Bowel Syndrome (IBS), functional constipation and functional diarrhoea. In all these conditions, patients experience a change in their bowel frequency and form, with IBS diagnosed if these symptoms are accompanied by abdominal pain (and often bloating), IBS can be either constipation (IBS-C) or diarrhoea (IBS-D) predominant or may alternate between the two (mixed IBS). Evacuatory dysfunction includes symptoms of excessive straining and a sensation of incomplete emptying. Faecal incontinence is the accidental passage of stool from the rectum. Drossman et al. [1] describe the classification of FBDs using ROME IV criteria. Symptoms may overlap and not sit neatly under one condition.

More than 1 in 4 adults in the UK, Canada and the US experience a FBD that affects quality of life and increases use of gastrointestinal healthcare [2]. IBS alone affects between 1 in 11 and 1 in 26 people globally [3].

In clinical practice, patients describe FBDs as a taboo subject [4], affecting quality of life [5] and healthcare utilization [6].

Transanal Irrigation (TAI) is a specialist treatment for symptoms of bowel dysfunction. It enables the user to choose the time and place of evacuation, potentially re-establishing bowel control and improving quality of life [7]. The effectiveness of TAI has been demonstrated in some FBDs. For example, a systematic review by Emmett et al. [8] concluded an aggregate success rate of 50% for functional constipation, similar to that for neurogenic conditions. TAI can improve various bowel related symptoms such as general well-being, rectal clearance, bloating, abdominal pain, and bowel frequency [9].

Thus far, research into the impact of FBDs and the effectiveness of TAI, has focused on specific conditions. Therefore, the aim of the PERSPECTIVE* study was to examine the burden of a wide range of FBDs on lifestyle including quality of life, work productivity and healthcare utilization and to explore patients' perceptions of using TAI to manage these different conditions. In this paper we report the findings on using TAI.

Materials and Method

Study population and design

A single, online questionnaire and convenience sampling of two existing cohorts of people were used:

1. ContactMe-IBS (established in 2017) -a dedicated registry of people with IBS who have given consent to be contacted to participate in research. They may be in primary or secondary care. The registry has national coverage. ContactMe is owned by the NHS (County Durham and Darlington NHS Trust). Registrants are mainly in the Northeast (as promoted within DBDS) and Southwest where GPs are particularly research active with ContactME-IBS.
2. Transanal irrigation (TAI) database (established in 2019) - a database of patients who have commenced transanal irrigation under the care of Durham Bowel Dysfunction Service, in secondary care.

Through registration on either (or both) of these databases, interested people give their permission to be contacted about research opportunities without obligation to participate. Neither database specifies the type of functional bowel disorder.

For inclusion in the study, participants had to be aged 18 years or older and have symptoms of bowel dysfunction. They had to be registered on one of the two databases and be able to understand written and spoken English (for questionnaire completion). People who did not respond to the invitation or reminder email were excluded.

Materials

The questionnaire consisted of eight sections (including personal information) with a completion time of approximately 25 minutes. The first section was designed to characterize symptoms. ROME IV criteria were used to identify primary diagnostic groups: Irritable Bowel Syndrome (constipation (IBS-C) or diarrhoea (IBS-D) predominant or mixed (IBS-M)), Functional Constipation (FC), Faecal Incontinence (FI), or Functional Diarrhoea (FD). There are no ROME IV criteria for Evacuatory Dysfunction (ED), so questions were developed.

As an observational study without a control sample, consensus was that at least 300 respondents would give credible results. Data were captured digitally via RED Cap. This is a secure, web-based application designed exclusively to support data capture for research studies.

All people registered on the Contact Me -IBS registry (4480) and on the TAI database (259) were invited to participate in the study by email. Fifty-five people requested and were sent paper versions of the questionnaire. Participation in the study involved reading the participant information sheet and then completing the single questionnaire online (Table 1).

Section	Validated Tool Used
Personal information: date of birth, gender, ethnicity	N/A
A: Characterization of symptoms (IBS-C, IBS-D, IBS-M, functional constipation, functional diarrhoea, faecal incontinence, evacuatory dysfunction)	ROME IV criteria for all symptoms except evacuatory dysfunction (study questions developed)
B: Transanal Irrigation as a Treatment for Bowel Symptoms	Study questions developed about use and effectiveness of TAI
C: Patient Assessment of Bowel Symptoms on Quality of Life	Modified PAC-QOL
D: General Health	EQ5D-5L
E: Healthcare Utilization	Study questions developed
F: Work Productivity and Activity Impairment	Work Productivity and Activity Impairment (WPAI) Questionnaire: Bowel Symptoms
G: Effects of COVID-19 Pandemic	Study questions developed

Table 1: The Perspective Questionnaire.

Data Analysis

As this was a hypothesis generating study the analysis was mainly descriptive. Correlational factors between subtype and gender and effectiveness of TAI over time were explored.

Results

Data were collected over a 4-week period, October - November 2021. There were 1176 responses overall (25% response rate) with complete data sets for 933 (79%) of these. Here, we report the data on ‘Transanal Irrigation as a Treatment for Bowel Symptoms’.

One hundred and eighty-three (20%) of all respondents have experience of using TAI. Of these, 110 (12%) currently use irrigation and 73 (8%) reported having been taught to use it but

stopped. The average age of respondents with irrigation experience was 54 years (range 17 - 89 years). 166 (91%) are female, only 16 (9%) are male, 1 preferred to self-describe gender. 178 (97%) of respondents are of white ethnicity.

Results suggest diagnosis of functional bowel disorders is complex. PERSPECTIVE identified 20 subtypes or subtype combinations, where mixed symptoms were present. However, respondents were classified by predominant symptoms using ROME IV criteria (which do not account for mixed symptoms), and study specific questions developed for evacuatory dysfunction. Thus, TAI users were classified into 10 diagnostic groups, 10 respondents were unclassified. Functional constipation and IBS-M were the biggest reasons for using irrigation - 24% and 21% respectively (Figure 1).

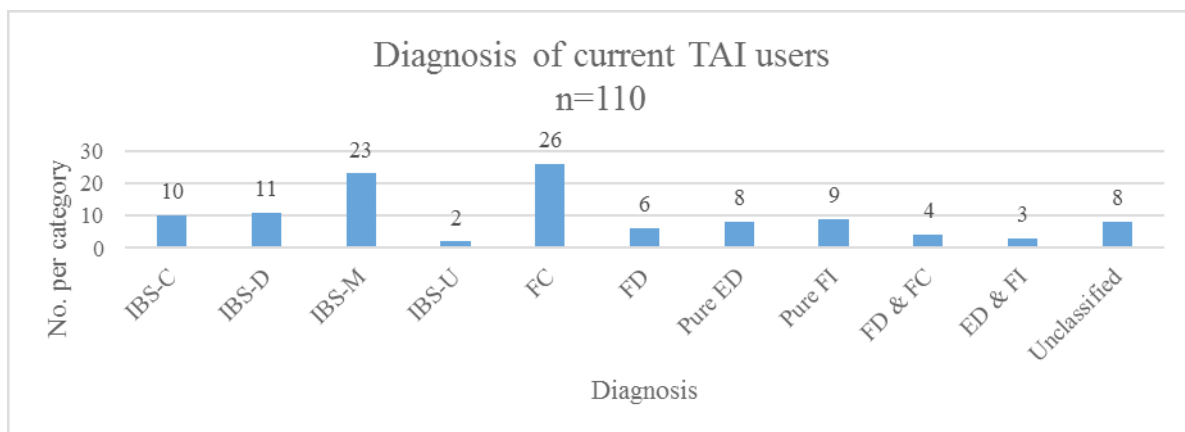


Figure 1: Diagnosis of current TAI users.

Note: IBS-C: Irritable Bowel Syndrome (constipation predominant), IBS-D: Irritable Bowel Syndrome (diarrhoea predominant), IBS-M: Irritable Bowel Syndrome (mixed symptoms), IBS-U: Irritable Bowel Syndrome (unclassified symptoms), FC: Functional Constipation, FD: Functional Diarrhoea, Pure ED: Pure Evacuatory Dysfunction, Pure FI: Pure Faecal Incontinence.

For simplicity, respondents were classified according to predominant bowel symptoms: constipation, diarrhoea or mixed. The highest proportion of females were irrigating for constipation type symptoms (43, 44%). The number of male irrigators is small overall (16) with TAI being used predominantly for diarrhoea-type symptoms (5, 46%) (Figure 2).

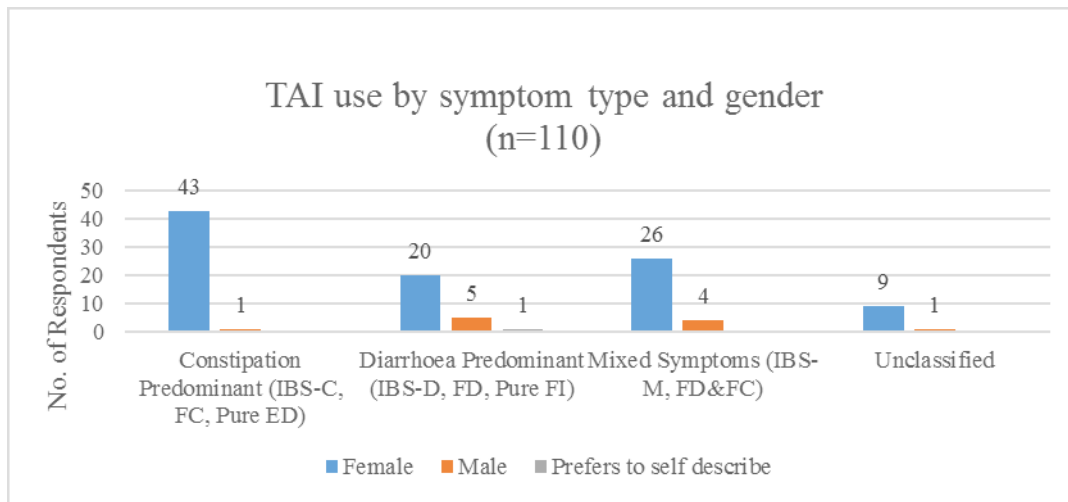


Figure 2: TAI use by symptom type and gender.

Respondents waited a long time to get started on TAI. The highest proportion (48, 44%) had symptoms for 10 or more years (Figure 3). Results showed a trend for those with mixed or constipation symptoms to start irrigation at about the same time, and sooner than those with diarrhoea (8.1 versus 8.06 versus 6.5 years respectively).

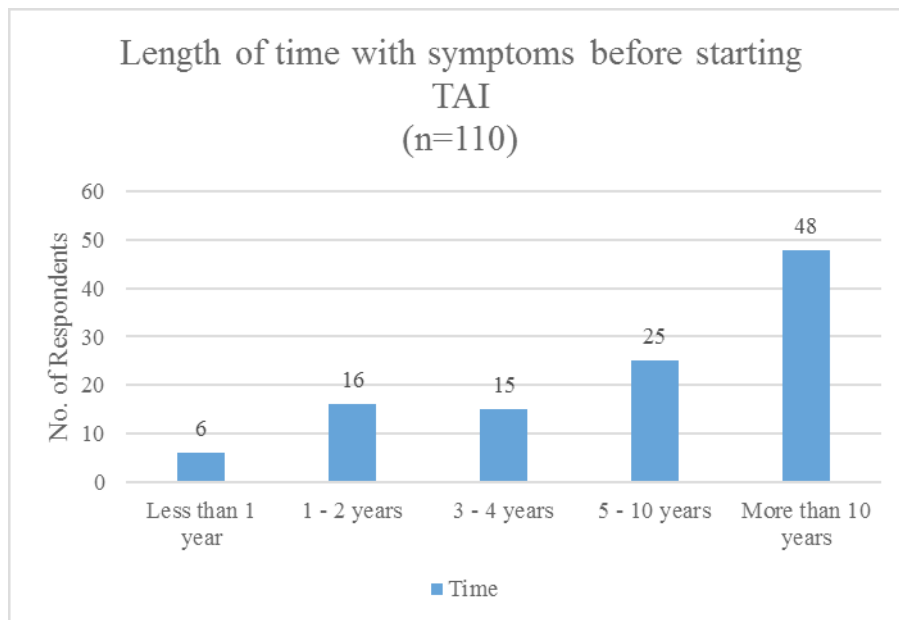


Figure 3: Getting started on TAI.

The frequency of TAI is variable. Most respondents irrigated regularly (from daily up to 4 times per week. Although, over a third (38, 35%) irrigate sporadically, from once per week to less than once per month (Figure 4).

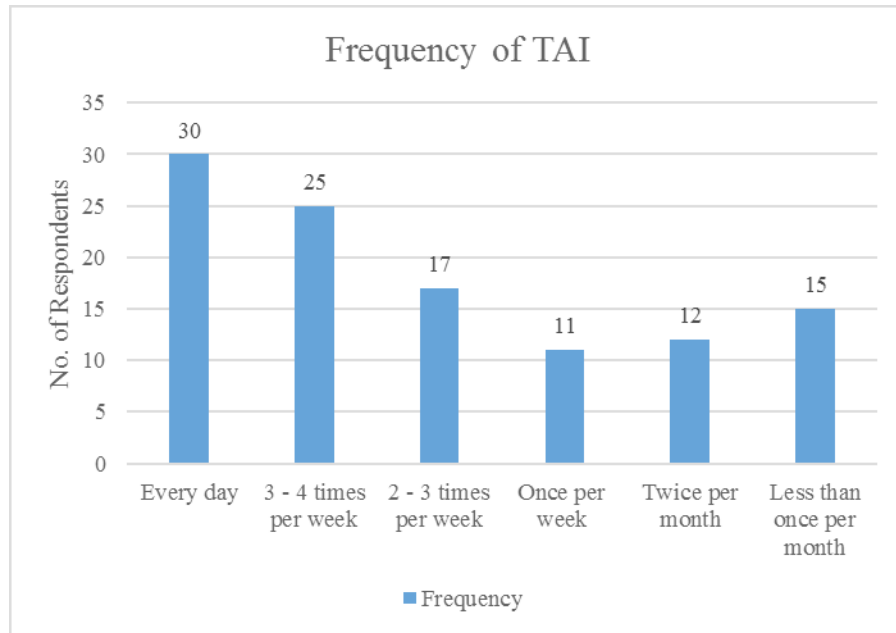


Figure 4: Frequency of TAI.

Respondents were asked to score how effective they thought TAI was at 3, 6 and 12 months, using a scale of 0 -10 where 0 = no benefit and 10 = excellent.

Effectiveness of TAI at 3 months correlates positively with effectiveness at 6 months, that is, if TAI is effective at 3 months it is likely to still be effective at 6 months ($R=0.77$, $R>0.7$ indicates strong positive correlation, figure 5). Figure 6 shows the trend for that effectiveness to continue up to 12 months. These results suggest that when TAI is effective at 3 months, it is a reasonable indicator that it will be effective at 12 months.

Regarding the effectiveness scores, lower scores at 3 months ($<6/10$), tended to increase at 6 months, and conversely, higher scores at 3 months ($>6/10$) were decreased at 6 months ($R^2=0.39$, $R=0.63$, a moderate positive correlation as $0.5<R<0.7$). Perhaps this regression towards the mean is to be expected; initial effectiveness may be more obvious to the patient who has been experiencing symptoms for some time compared to effectiveness that has gone on for up to 12 months.

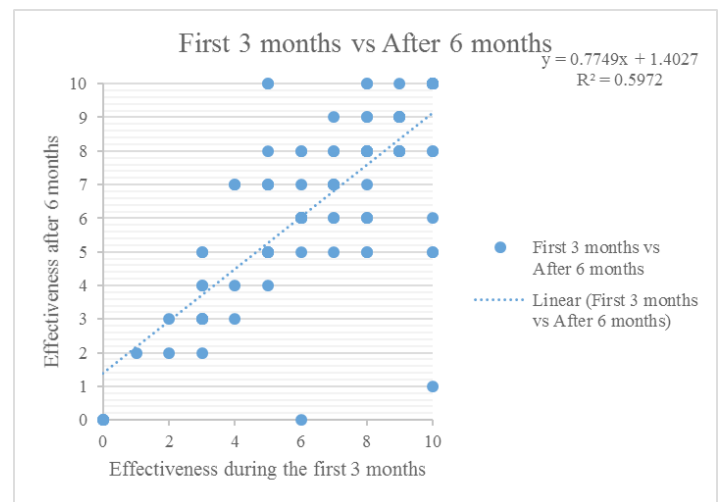


Figure 5: Effectiveness of TAI between 3 and 6 months.

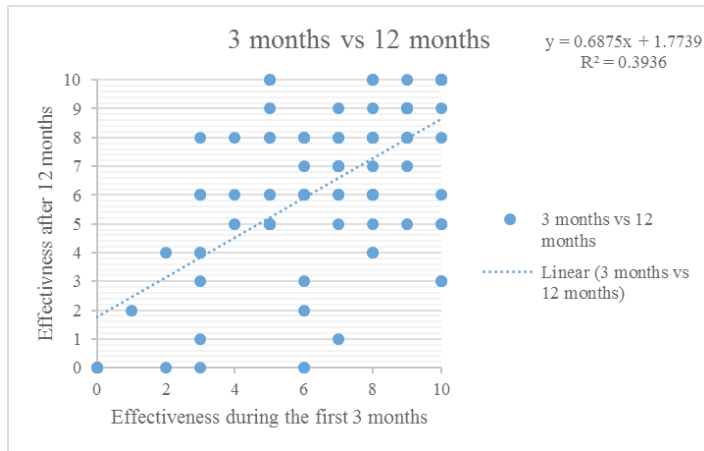


Figure 6: Effectiveness of TAI between 3 and 12 months.

There was a trend (not statistically different) for TAI to be more effective in females. Using the T test - female (n=98) mean 6.69 (variance 7.78), male (n=11) mean 5.54 (variance 6.27) p > 0.1).

At 3 months, the trend (not statistically different) was to be more effective in IBSC than IBSM or IBSD. Using ANOVA test - IBSC mean 7.1 (variance 7.87) > IBSM mean 6.09 (variance 8.89) > IBSD mean 6.30 (variance 8.89), p = 0.67. The largest proportion of respondents have been irrigating for 5-12+ years. Overall, 58 (53%) have been irrigating for 3 or more years, supporting the notion that TAI remains effective in the longer term (Figure 7).

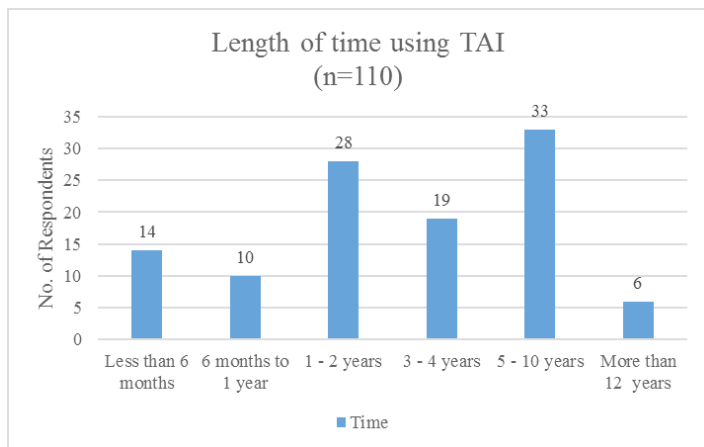


Figure 7: Length of time using TAI.

Of those with TAI experience, 110 (60%) continue irrigating. There is variation between symptom types, those with diarrhoea are the highest proportion that continue irrigating (26,74%). Of those that stopped irrigating (73, 40%), the highest proportion had mixed symptoms (26, 87%) (Figure 8). These differences are not statistically significant.

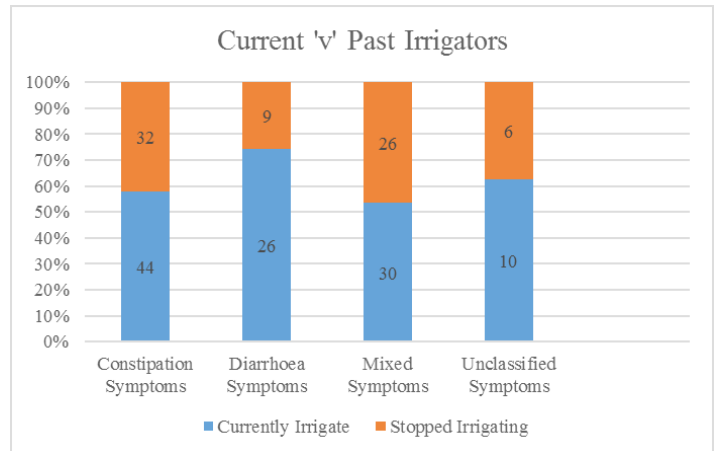


Figure 8: Symptom type: current and past irrigators.

The most common reason for stopping irrigation was that it did not improve symptoms. Of all the ‘other’ reasons cited for stopping irrigation – cost was mentioned by 6 (25%) of respondents. This may have been a reference to prescription costs, also ‘private or beauty clinics’ and ‘colonic irrigation’ were mentioned by some respondents. Three of the four who went on to have bowel surgery had stoma formation (Table 2).

Reasons for Stopping TAI	Number of Responses	
	Past Irrigators	Current Irrigators
Irrigation didn't improve symptoms	25	8
Irrigation increased abdominal pain	11	2
Equipment difficult to use	7	2
Bowel symptoms improved; irrigation not needed	6	4
Too time consuming	4	1
Rectal bleeding	2	3
Didn't like the feeling of irrigation	2	1
Didn't like the idea of irrigation	1	1
Lack of support with irrigation	1	1
Other reason	14	10
Total: 106	73	33

Table 2: Reasons for stopping TAI.

Throughout this study, the treatment has been referred to as transanal irrigation. Anecdotally, there is much debate amongst Health Care Professionals (HCPs) about what it should be termed. When asked, 173 people responded to this question. When names were suggested (rectal, anal or transanal irrigation), rectal irrigation was most favoured (34, 20%). However, most respondents 118 (68%) did not mind what we call it.

Discussion

The aim of this paper was to report on people's experiences of using TAI as a treatment for a broad range of FBDs. People were recruited from two existing databases, offering a snapshot of national usage for a mixed population of people. Most respondents were from secondary care (TAI database), some were in primary care. 60% of patients who started TAI are still on it. Continuing irrigation can be argued as a surrogate for efficacy because irrigation is time-consuming and requires motivation, it is reasonable to expect that people will only irrigate if it is helping them. This 60% efficacy rate is consistent with other studies that have examined the effectiveness of TAI [8,9]. One key finding of this study is that TAI can benefit patients with diarrhoea and mixed or alternating bowel habits. This has not been previously established and merits further research.

Irrigation guidelines recommend the frequency of irrigation can be reduced from daily to alternate days, once a good routine is established [7]. Our results suggest that people use irrigation in a way that suits their illness and lifestyle from daily to intermittent irrigation frequency. A high proportion of respondents (39, 35%) are long-term irrigators (over 5 years) suggesting infrequent irrigation remains sufficiently effective for the long-term management of symptoms.

Almost half (44%) of current irrigators had bowel symptoms for a very long time (10 or more years) before starting irrigation. The likeliest reason for this is the delay in patients getting to specialist services which is typically 10-15 years after onset of symptoms. Reasons for this may be varied including patients not presenting to healthcare early on, having convoluted journeys to get to specialist services or TAI being seen as a treatment of last resort. Our data has shown TAI to be an effective treatment for a range of FBDs, and it may be valuable where other measures have failed. Raising awareness amongst HCPs of these benefits might enable patients to get started sooner.

This study has shown that if irrigation is effective at 3 months, it tends to be effective at 12 months. With strong patient-practitioner relationships, there might be an initial placebo effect of positive results with TAI, however, placebo responses typically last up to 12 weeks [10]. Therefore, reported effectiveness at 12 months is unlikely to be the result of a placebo effect. These results might be reassuring for patients undertaking TAI. Emmanuel et

al (2019) [7] suggest onward referral after 3 months if TAI is not working and these results support this recommendation. This may help HCPs identify those patients that need further discussion at MDT or onward referral sooner.

Clinical caseloads and both databases are strongly female dominant. Perhaps this reflects real life experience where a higher proportion of women than men experience bowel dysfunction, especially constipation. Many factors influence this including childbirth, as well as length of colon and colonic transit time, both of which are longer in women [11]. So, it is unsurprising that, in this study, 91% of those with irrigation experience are female and the main reason for irrigation was found to be constipation-type symptoms. In contrast, males reported predominantly diarrhoea-type symptoms. We did not ask whether diarrhoea resulted from laxative use (for constipation). It was not possible to assess statistical differences in effectiveness of irrigation between types of symptoms and gender due to the small number of males.

Our results show that respondents with diarrhoea symptoms were the largest cohort to continue irrigating. 20 (77%) of those with diarrhoea also had faecal incontinence. Bildstein et al (2017) [12] reported similar results, that patients with faecal incontinence were more likely to continue with irrigation than patients with slow transit constipation or obstructed defaecation (54.5% and 33% respectively). Future research could try to establish whether the high burden of faecal incontinence makes irrigation more worthwhile.

Of those who start irrigation, a drop-out rate of 34 -57% after the first year has been recognised [12,13]. Our results reflect a similar rate of 40%. In this study, the most common reason for stopping was that it failed to improve bowel symptoms. Other reasons for stopping, such as pain, bleeding, and equipment difficulties, were in keeping with Bildstein et al (2017) [12] who found that 59% of their patients stopped for reasons unrelated to efficacy. Successful irrigation requires structured training and support to help mitigate some of these issues. Knowing what to expect and having a supportive patient-HCP relationship may help some patients to overcome these issues and continue irrigating.

Thirty three percent (33) of our respondents had stopped and then re-started irrigation, perhaps due to a lack of alternative treatments. Our findings suggest that patients stop irrigating for a myriad of reasons, perhaps the option to try again in the future could remain available.

Functional bowel disorders are complex with multifactorial causes. They can be difficult to treat but TAI compares favourably. For example, Prucalopride, for chronic constipation and usually prescribed in secondary care, had a response rate of 28% [14]. Even with the best education and support TAI will not work for all patients [15]. However, PERSPECTIVE has demonstrated a very

acceptable treatment success rate of 60%.

Limitations of this Study

This study did not set out to test a hypothesis. PERSPECTIVE was an observational study without a control sample. As data were collected retrospectively, people may have misremembered or forgotten details of their treatment and/or symptoms. There may be recall bias in remembering how effective irrigation was during the first 12 months.

There is potential bias within the results as patients undergoing TAI are usually under the care of specialist teams which are generally highly motivated and experienced. These patients may be more likely to have better perceived outcomes with irrigation. Conclusions are not definitive, but the findings reveal a snapshot of irrigation usage and perceived effectiveness for people with different functional bowel disorders, within primary and secondary care.

Conclusions

This study has shown that where TAI is effective at 3 months, there is a good likelihood of this effectiveness being maintained longer term, with little drop-off at 12 months and with many patients still irrigating after 5 years. While TAI is relatively well studied in constipation, there has been little assessment of its use in diarrhoea, mixed IBS or faecal incontinence. Our data suggests that it is important to consider these conditions in future research. Further work is also needed to show why there is a difference between males and females in the use and efficacy of TAI. HCPs should have a greater awareness of the possible benefits of TAI in FBDs and consider approaches to maximize effectiveness of this therapy in conditions where effective treatments are limited.

Ethical Approval

The Health Research Authority approved this study prior to commencement. Research Ethics Committee reference 21/SW/0086 (IRAS ID 296856).

Funding

PERSPECTIVE was sponsored by County Durham & Darlington NHS Trust (CDDFT). Funding was from MacGregor Healthcare Limited.

Declaration of Interest

At the time of the study Michelle Henderson (Principal Investigator) was employed as Academic Clinical Nurse Specialist at CDDFT. She is now Clinical Education Manager at MacGregor Healthcare.

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