



Rectal Irrigation (RI) in the Treatment of Defecation Disorders – A Retrospective Evaluation of a Prospective Database

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Abstract

Background: Rectal Irrigation (RI) has been used in defecation disorders to relieve symptoms and improve quality of life (QOL). We aimed to evaluate the efficacy and acceptability of RI using health outcome measures.

Methods: The study was a retrospective review of a prospective database of patients who had rectal irrigation between 2002 and 2005. The efficacy of rectal irrigation was determined by quantification of symptoms using general standardized questionnaires (GSQ). The acceptability of rectal irrigation was determined using the general health outcome measure SF-36 and the Fecal Incontinence Quality of Life (FIQL) questionnaire.

Results: A total of 175 patients underwent rectal irrigation. There were 111 successful cases and 64 failures. Analysis was done only for the successful ones. Before rectal irrigation, the number of patients who completed GSQ, SF-36 and FIQL were 72, 71 and 32 respectively. Of these only 43, 43 and 22 completed the GSQ, SF-36 and FIQL respectively after rectal irrigation. GSQ analysis showed significant improvement in symptoms of straining, incomplete emptying, wind leakage and urinary leak before and after RI. SF-36 demonstrated significant difference in physical functioning (Z score -2.34; p< 0.05), social functioning (Z score -2.17; p< 0.05) and general health (Z score -1.97; p< 0.05), before and after RI (95%CI). FIQL analysis showed no statistically significant difference in the QOL after RI.

Conclusion: In patients with defecation disorders, RI can offer symptomatic improvement. Most patients find the treatment acceptable.

Keywords: Incontinence; scoring systems; Outcomes; Constipation; Rectal irrigation

Introduction

Defecation disorders present with a wide spectrum of symptoms and etiologies [1]. A recent review [2] highlighted psycho-social distress along with impaired quality of life (QOL). The problem persists widely in the community and patients represent a diverse group. A systematic review reported a prevalence of 0.4-18% for fecal incontinence [3]. Among the institutionalized, prevalence is approximately 50%, with an annual incidence of 20% developing incontinence [4]. Most patients are managed by conservative and pharmacological methods. There exists an unfortunate group of patients who do not respond to either. An important measure of the severity of Defecation disorders is their effect on QOL. More than 50% of patients with major fecal incontinence report a significant negative impact on QOL [5]. Various therapies have been proposed to relieve the patients of their symptoms and improve their QOL. Rectal irrigation (RI) is one such therapeutic method [6]. The colorectal unit in Hull has been offering RI since 2002. The present study evaluates the efficacy and acceptability of RI in the treatment of Defecation disorders.

Materials and Methods

Between 2002 and 2005 patients initially deemed suitable were referred to the RI clinic. A preliminary senior consultation was followed by a detailed history, examination and investigations

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to assess each patient's suitability for RI. The majority of the patients had experienced either no improvement or minimal improvement with pharmacological agents and conservative measures prior to surgical intervention.

A colorectal nurse practitioner offered a detailed explanation of the procedure and informed written consent was obtained. Patients were given patient dairies and questionnaires to fill in at home. RI was commenced three weeks later, with the return of pre-irrigation questionnaires. Either a gravity-assisted or pump-assisted method was offered. A further set of questionnaires were filled in six weeks after RI. Patients quantified their symptoms (before and after RI) to determine the efficacy of RI. The questionnaires used were the general health outcome measure SF-36, the Fecal Incontinence Quality of Life (FIQL) questionnaire and a general standardized questionnaire (GSQ) exploring the symptomatology of Defecation disorders. The efficacy of RI was evaluated by examining self-reported improvement of symptoms in response to RI in terms of the GSQ and the visual analogue scale (VAS). The general and specific health outcome measures, namely SF-36 and FIQL, evaluated acceptability. For the purposes of this study success was defined as improvement in the symptomatology and continuation of RI. Failure was defined as lack of benefit from RI. The questionnaires used are briefly described below.

Short form 36

This is a general health outcome measure consisting of physical and mental component scores. The eight health concepts captured by the questionnaire are physical functioning (PF), physical health (PH), emotional problems (EP), and energy fatigue (EF), emotional well T being/mental health (EW), social functioning (SF), pain (P) and general health (GH).

FIQL questionnaire

This is a validated QOL questionnaire specifically designed for patients with fecal incontinence [7]. The four health concepts assessed by the questionnaire are lifestyle, coping behavior, depression/self-perception and embarrassment.

GSH questionnaire

The GSH questionnaire was developed in the academic surgical unit in Hull and was internally validated. It assesses the common symptoms associated with Defecation disorders. This tool was used to compare the symptoms before and after RI. The symptoms considered were frequency of bowel movement, consistency of stools, mucous leakage, liquid leakage, solid leakage, wearing pad for bladder symptoms, wearing pad for bowel symptoms, swollen area between anus and vagina, feeling of bowel pushing forwards into vagina, need to self-help to empty bowel, micturition urgency, frequency of straining at stool, feeling of incomplete emptying, wind leakage, pressure application on the area between the anus and vagina, leakage of urine on coughing or sneezing, urgency to empty bowel and bowel problems affecting life.

Data was gathered for presenting symptoms, previous therapies and surgeries. Reminders were sent to non-responders. A review was undertaken using the prospectively maintained database and case notes.

The broad overlap in symptoms and aetiologies made analysis particularly challenging. For the purposes of this article the definitions for continence disorders have been deliberately kept broad. Patients were divided into two categories depending on their

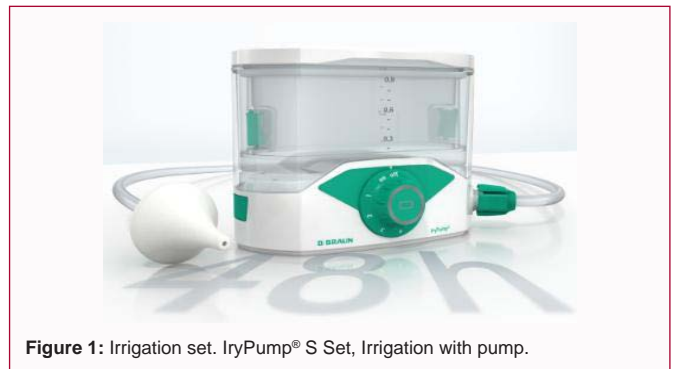


Figure 1: Irrigation set. IryPump® S Set, Irrigation with pump.



Figure 2: The Peristeen (Coloplast A/S Humlebaek Denmark) transanal irrigation system.

primary symptom of either incontinence or constipation. The term incontinence was used to describe the involuntary escape of faeces and includes those patients with primary sphincter problems, patients with rectal compliance problems leading to urge incontinence and patients who describe fecal soiling [8]. Constipation was defined as the inability to evacuate the rectum when desired and included normal transit constipation, slow transit constipation, obstructed defecation and dyssynergic defecation [9].

The techniques and apparatus of irrigation have undergone changes with time. Dansac's stomal irrigation set was used in the early phase of the study for RI. This was later followed by the Coloplast stoma irrigation set for gravity assisted RI and later the Qufora irrigation system. A pump assisted irrigation set was also used, the Irrimatic pump (B Braun, Sheffield, UK) (Figure 1). However, subsequently, the Peristeen Anal Irrigation System (Coloplast Limited, Peterborough) has been licensed for use and prescription in the UK for trans-anal irrigation [10] and has now replaced the majority of other irrigation systems (Figure 2).

Our early patients used the stomal irrigation sets for RI. Initially patients undertook irrigation on a daily basis using 1.5 L of tap water at body temperature. Irrigation was commenced sitting on the toilet with the water bag hanging on a hook with the bottom of the water bag just above head height. The cone was lubricated and inserted into the anus holding it firmly, in order to give a good seal.

Between 300 and 500 mLs of water was instilled under gravity in a gravity assisted method or the same amount using a pump. Patients were informed that the irrigation process should be gentle and not uncomfortable in any way. Once the water flow had stopped patients waited for 1–2 minutes before removing the cone, resulting in an immediate evacuation of water and stool. This irrigation process was undertaken three times. Normally the first irrigation is followed by a hard pellet-like/semisolid cleanse, the second is a brown fluid and third one is near normal clear water.

Patients were told they should expect an urge to defecate for 10–

Table 1: SF-36 before and after RI demonstrating improvement in QOL.

SF-36 sub-scale	Pre-RI [Median, (IQR)]	Post-RI [Median, (IQR)]
Physical functioning	66.6 (32.5-88.1)	75 (40-100)
Physical health	12.5 (0-100)	50 (0-100)
Role: physical, emotional problems	33.3 (0-100)	66.6 (0-100)
Role: emotional, energy fatigue	37.5 (15-50)	40 (25-50)
Emotional wellbeing	55 (40-60)	60 (50-75)
Social functioning	50 (25-75)	62.5 (50-87.5)
Pain	40 (22.5-67.5)	55 (32.5-90)
General health	45 (20-65)	50 (33.3-75)

RI= Rectal Irrigation; IQR= Interquartile Range; QOL=Quality of Life

Table 2: SF-36 components before and after RI using non parametric tests.

SF-36 sub-scale	Negative ranks	Positive ranks	Tied ranks	Z value	p values
Physical functioning	8	20	14	-2.34	0.020**
Physical health	8	12	20	-1.68	0.093*
Role: physical, emotional problems	9	7	25	-0.08	0.937
Role: emotional, energy fatigue	18	15	8	-0.40	0.693
Emotional wellbeing	14	23	4	-1.84	0.066*
Social functioning	10	25	7	-2.17	0.030**
Pain	13	19	10	-1.87	0.061*
General health	14	25	3	-1.97	0.049**

RI= Rectal Irrigation** 95%CI, *90%CI

Table 3: FIQL components before and after RI.

FIQL sub-scale	Pre-RI [Median, (IQR)]	Post-RI [Median, (IQR)]
Lifestyle	2.9 (2.0-3.8)	3.1 (2.4-3.5)
Coping	2.3 (1.5-3.7)	2.9 (1.7-3.1)
Depression	3 (2.3-4.0)	3.1 (2.3-4.1)
Embarrassment	2.7 (1.3-3.8)	2.7 (1.7-3.7)

FIQL= Fecal Incontinence Quality of Life; RI= Rectal Irrigation; IQR=Interquartile Range

Table 4: FIQL components before and after RI using non parametric tests.

FIQL sub-scale	Negative ranks	Positive ranks	Tied ranks	Z value	p values
Lifestyle	5	5	0	0.000	1.000
Coping	5	5	1	-0.15	0.878
Depression	7	7	0	-1.16	0.245
Embarrassment	4	3	3	-0.17	0.863

FIQL= Fecal Incontinence Quality of Life; RI= Rectal Irrigation

15 minutes after the third irrigation but should not experience the urge to defecate again for 12–24 hours. Once proficient, patients were encouraged to adopt the volume of water and frequency of irrigation to suit their own needs.

Data collection was done methodically. Patients were given diaries and questionnaires to fill in. The diaries consisted of incontinence and bowel movement details. The questionnaires consisted of the GSQ, the SF-36 and the FIQL. In addition, a linear scale was used to quantify any reduction in the severity of the symptoms after RI to produce a VAS. Lastly measures of satisfaction of medical care and self-efficacy were also filled in. The SPSS and SF-36 analysis packages were used for analysis.

Results

A total of 175 patients underwent RI. There were 111 successful cases and 64 failures. Analysis was done only for the successful ones.

The failed cases consisted of people who did not attend, people whose symptoms were resolved by medication and cases where RI was not effective. The patient groups were predominantly female (n=154, 88%) with similar proportions of female patients in both the successful cases (n=97, 87.4%) and failed cases (n=57, 89.1%). The mean age of our patient group was 52.6 years (± 15.08 SD). The median follow up was 20 months (IQR=10-30). The SF-36, FIQL and general standardized questionnaires were analyzed before and after RI.

SF-36

Seventy-one of the 111 patients completed the SF-36 questionnaire before treatment, and 43 of these patients also completed the questionnaire after treatment. Subscales were calculated on a score of 0 to 100, with 0 being the 'worst' score and 100 being the 'best'. The higher scores meant a better quality of life. Table 1 shows the median (pre-RI) and median (post-RI) scores for each of the subscales of SF-

Table 5: GSQ analysis pre and post RI.

Analysis of GSQ	Pre	Post	Wilcoxon signed rank test
Straining - Always	52.2% (n=36)	14.0% (n=6)	Z=3.2, p<0.001
Incomplete Emptying - Always	69.0% (n=49)	23.8% (n=10)	Z =3.3, p<0.001
Wind Leak – 2+ times per day	59.7% (n=37)	39.5% (n=15)	Z =2.2, p<0.05
Urinary Leak - Always	25.1% (n=14)	14.6% (n=6)	Z =2.1, p<0.05
Apply pressure – All or some of the time	48.5% (n=33)	36.8% (n=14)	Z =2.0, p<0.05
Urinary Leak on coughing/sneezing - Always	25.1% (n=14)	14.6% (n=6)	Z =2.0, p<0.05
Urgency to empty – Always/daily	34.3% (n=24)	14.6% (n=6)	Z =1.7, p=0.08

Table 6: Wilcoxon signed rank test shows improved bowel and bladder function after RI on the VAS.

VAS	Negative ranks	Positive ranks	Tied ranks	Z value	p values
Bowel function	28	5	6	-3.579	<0.001
Urinary function	19	7	14	-2.329	0.020

RI = Rectal irrigation

VAS = Visual analogue scale

Table 7: Comparison of success and failures in patients undergoing RI for Defecation disorders.

	Successful cases		Failed cases		Total	
	Count	%	Count	%	Count	%
Constipation	83	61%	52	39%	135	80%
Incontinence	16	64%	9	36%	25	15%
Miscellaneous	5	63%	3	37%	8	5%

36. There was an improvement in QOL after RI.

Comparison of various components of SF-36 before and after RI using non-parametric tests showed a significant difference in PF, SF and GH as shown in Table 2.

The Wilcoxon signed rank test demonstrated a significant difference in PF, SF and GH between the pre- and post-treatment status. Table 2 also shows that there were positive shifts in sub-scales PH, EW and P. These differences were significant at the 90% CI but not at the 95%CI.

FIQL questionnaire

Thirty-two of the 111 patients completed the FIQL questionnaire before RI and 22 of these patients after RI. Table 3 shows the median value (pre-RI) and median value (post-RI) for each of the subscales. The post-RI median value is equal or higher than the pre-RI measure. This suggests that there was a slight improvement in QOL measured by the FIQL questionnaire post- RI. Non parametric tests are shown in Table 4.

The Wilcoxon signed rank test did not demonstrate any significant difference in any of the subscales of FIQL. This may be due to the large amount of missing data and 'not applicable' answers to the individual items on the questionnaire.

GSQ

Seventy-two of the 111 patients completed the GSQ questionnaire before RI, and 43 completed it after RI. GSQ analysis (Table 5) showed significant improvement (95%CI) in symptoms of straining, incomplete emptying, wind leakage, perineal pressure and urinary leakage before and after RI. At 90%CI there was improvement in urgency and bowel problems affecting QOL.

There was no significant difference between pre- and post-RI in frequency of bowel movements, consistency of stools, mucous

leakage, liquid leakage, solid leakage, wearing pad for bladder symptoms, wearing pad for bowel symptoms, swollen area between anus and vagina, feeling of bowel pushing forwards into vagina, micturition urgency, need to self-help to empty the bowel or difficulty reaching the nearest toilet on time to pass urine.

Visual analogue scale

Sixty-eight of the 111 patients completed the VAS questions before RI and 42 after RI. Evaluation of the two visual analogue scores, for bowel (Figure 3) and urinary function (Figure 4, Table 6) suggests reduction in the severity of the problems affecting QOL. The median values for severity of bowel function affecting QOL before and after RI were 90 (IQR=80-100) and 65 (IQR=15-90) respectively. The median values for urinary function before and after treatment were 12.5 (IQR=0-50) and 10 (IQR=0-28.75) respectively. These results suggest improvement in symptom severity and in turn improved QOL. The Wilcoxon signed rank test (Table 6) demonstrated a difference in pre- and post-RI problem severity on the VAS, indicating that a greater proportion of patients recorded an improvement following RI. The various pathologies for which RI was undertaken were categorized broadly into constipation, incontinence and miscellaneous. Treatment success and failure are shown in Table 7.

Discussion

The prevalence surveys suggest fecal incontinence affects more than 1% of the population with 0.7% having symptoms which impact on QOL [11] and 2.6% suffering from some form of anal incontinence. Among those who reported some fecal incontinence, 10% experienced the problem at least weekly, yet only 36% had consulted their general practitioner [12]. Self-reported data on constipation in an English population suggests that 10% of women and 2% of men experience constipation, and 52% of women and 39% of men reported regular straining to stool [13]. There do not appear to be any reliable figures available to give an indication of the numbers of individuals affected by incomplete evacuation. Such data are obtained from those who have consulted a member of the health care team or who have been approached and will admit to this problem. There may be many more too embarrassed to report these symptoms [14].

Disorders of Defecation cover a spectrum of conditions including fecal incontinence, idiopathic constipation, and dyssynergic Defecation [8,9]. Patients can experience symptoms varying from urgency of Defecation and incontinence, to difficulty initiating

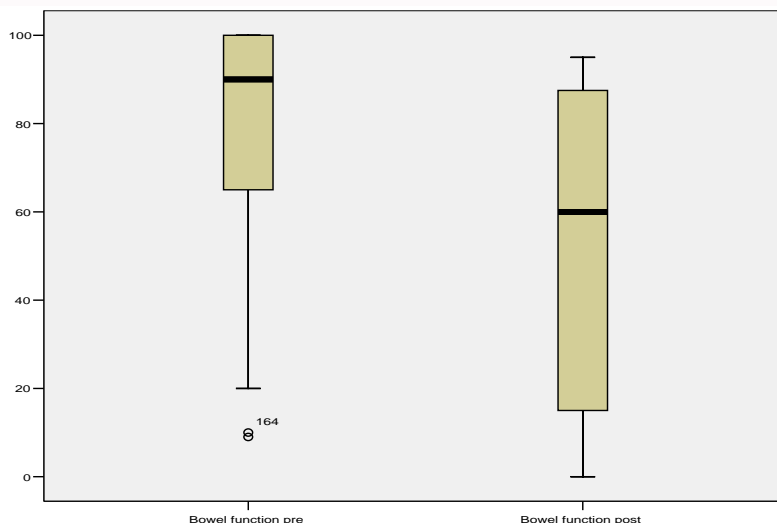


Figure 3: Visual analogue scale showing reduction in the severity of the bowel problems affecting quality of life.

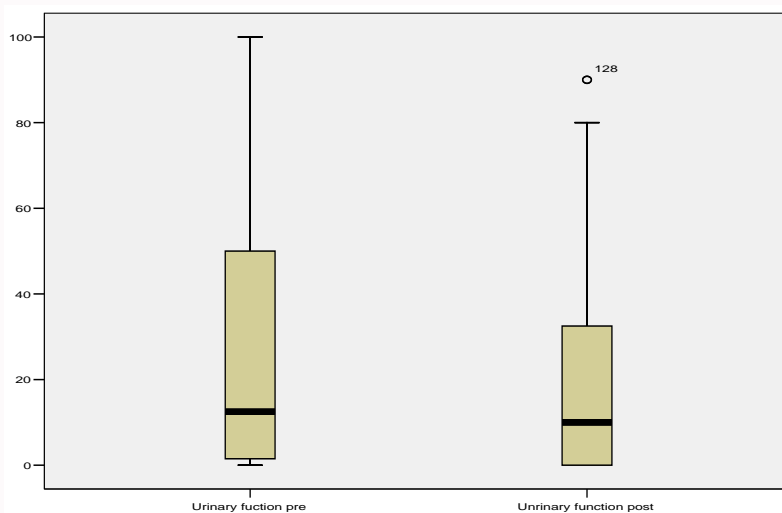


Figure 4: Visual analogue scale showing reduction in the severity of the bladder problems affecting quality of life.

Defecation and constipation. Sometimes the symptomatology can be overlapping, and around 30% of patients presenting with fecal incontinence also complain of difficulty evacuating their bowel [1,15].

RI has also been shown to be of benefit to patients with a whole spectrum of pathologies from organic to functional by improving symptoms and QOL [6]. A review by Tod and colleagues, evaluating RI for functional bowel disorders, suggested this as a successful treatment option for some people [16]. Moreover, other authors confirmed that RI is a valuable tool for treating patients with functional bowel disorders [17]. It has been shown to improve symptoms of constipation, fecal incontinence, and the quality of life in patients with spinal cord injuries [18]. Studies have also evaluated long-term results of trans-anal irrigation for Defecation disturbances and have concluded that trans-anal irrigation is simple and safe for long-term treatment and is of most benefit to patients with neurogenic bowel dysfunction [19]. RI now forms a part of the conservative treatment algorithm in the Netherlands for management of fecal soiling with normal ano-rectal function [20]. A prospective study of colonic irrigation for the treatment of Defecation disorders, by a group in Maastricht concluded that retrograde colonic irrigation

is an undervalued but effective alternative treatment for intractable Defecation disorders [21].

The current study is a retrospective review of a prospective database of patients who underwent RI for various evacuatory disorders from 2002 to 2005. An attempt has been made to measure both the generic as well as specific QOL using SF-36 and FIQL. Studies examining the effect of biofeedback on fecal incontinence compared to simple sphincter exercises alone suggest that biofeedback produces better results but whether this is due to a placebo interaction with the therapist rather than the treatment itself is debatable [15]. Initial results suggest intensive nursing input plays an important role in the treatment of these patients. However, the sustained improvement in bowel control noted in our patients responding to RI suggests the beneficial effect is more than just a placebo effect. If it were a simple placebo effect one would expect to see the improvement in symptomatology diminish over time as the input from the specialist nurse decreased.

RI is a method of management that is time-consuming and therefore requires commitment from the participants. It has no

apparent side-effects and can be discontinued or recommenced at any time. The kits are economical and RI is easily supervised by nursing staff, thus freeing precious time at otherwise busy colorectal clinics. The Peristeen Anal Irrigation System (Coloplast Limited, Peterborough) (Figure 2) is licensed for use and prescription in the UK for trans-anal irrigation [10] and has replaced the majority of other older irrigation systems. The approximate initial cost of the irrigation system is around 100 GBP [22].

In summary, this study demonstrated significant QOL improvement in the subscales of PF, SF and GH at the 95% CI and in PH, EW and P at the 90%CI using the generic QOL measure. FIQL revealed only a modest improvement in QOL which was not statistically significant. Our GSQ demonstrated a significant difference before and after RI in the following symptoms at the 95%CI: frequency of straining at stools, feeling of incomplete emptying, wind leakage, pressure application on the area between the anus and vagina, leakage of urine on coughing, sneezing. At 90%CI there was reduction in urgency and bowel problems affecting QOL. There was no significant difference in pre and post-RI for frequency of bowel movement, consistency of stools, mucous leakage, liquid leakage, solid leakage, wearing pad for bladder symptoms, wearing pad for bowel symptoms, swollen area between anus and vagina, feeling of bowel pushing forwards into vagina, micturition urgency, need to help yourself empty the bowel on reaching the nearest toilet on time to pass urine. The VAS not only demonstrated a clear benefit in terms of reduction of the severity of the symptoms in bowel function but to a limited extent in bladder function also where there was an associated bladder dysfunction.

In this study RI seemed to help both constipation and fecal incontinence. In patients with incontinence it helped by washing out the rectum and by giving them a window of respite for their activities, thereby improving QOL. The varied pathologies for which RI was undertaken and analysis of success and failures are represented in this study. There are a few limitations to this study, which need to be highlighted. The analysis was carried out only on successful cases, meaning there is no information regarding the cases that failed and the reasons for failure. The poor return of completed questionnaires may reflect patient embarrassment due to the nature of the problem. Though there was noticeable improvement in the QOL according to the SF-36, the difference for the FIQL failed to reach statistical significance, possibly due to small numbers and too many 'not applicable' responses. There could be a bias in the results to a more favorable outcome as patients who have had an unfavorable experience or outcome from RI may be less likely to respond to the questionnaire. Alternatively, those patients who are still using the technique and anticipate a need for further input from the Coloproctology clinic might be more motivated to respond. The questionnaire was a 'snap shot' documenting the patient condition at a single time point and asked them to recall their previous symptoms, which in turn could bias these results. The median follow up was 20 months; there currently is no further long-term outcome data. The complex symptomatology of this heterogeneous group evaluated with the GSQ makes quantitative assessment difficult hence the VAS being added to rate the reduction in the severity of the symptoms after RI. Overall, RI produced an improvement in self-reported bowel function in this non-selected group with multiple patho-physiologies.

Conclusion

RI can offer symptomatic improvement to patients with Defecation

disorders where other conservative and pharmacotherapies have failed. Most patients find the treatment efficacious and acceptable. It should be considered an important tool in the armamentarium for the management of Defecation disorders.

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