

Long-Term Outcome and Safety of Transanal Irrigation for Constipation and Fecal Incontinence

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PURPOSE: This study evaluated long-term results of transanal irrigation for defecation disturbances.

METHODS: Three hundred and forty-eight patients [248 women and 100 men; median age 52 years (range, 5–85)] suffering from constipation and fecal incontinence were introduced to transanal irrigation. Patients using transanal irrigation at follow-up received a mailed questionnaire describing bowel function and practical procedures. Results from patients not responding and patients no longer using transanal irrigation were drawn from hospital records and telephone interviews. Background variables were analysed using multivariate logistic regression.

RESULTS: After a mean follow-up of 21 months (range, 1–116) 163 of 348 patients (47 percent) had a successful outcome from treatment with transanal irrigation. Success rates varied between patients with different underlying pathology: neurogenic bowel dysfunction, 67 of 107 (63 percent); anal insufficiency, 36 of 70 (51 percent); sequela to anorectal surgery, 14 of 48 (29 percent); idiopathic constipation, 27 of 79 (34 percent); and miscellaneous, 19 of 44 (43 percent). Factors correlating with positive outcome were neurogenic bowel dysfunction and anal insufficiency as underlying pathology, low rectal volume at urge to defecate, low maximal rectal capacity, and low anal squeeze pressure increment. Two nonfatal bowel perforations were found in approximately 110,000 irrigation procedures.

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CONCLUSIONS: Transanal irrigation is simple and safe for long-term treatment for defecation disturbances with greatest benefit in patients with neurogenic bowel dysfunction.

KEY WORDS: Constipation; Fecal incontinence; Neurogenic bowel dysfunction; Transanal irrigation; Enema.

Transanal colonic irrigation has recently become an established treatment for chronic constipation and fecal incontinence in selected patients.^{1–4} In patients with functional bowel symptoms of heterogeneous origin, 41 to 75 percent of patients with fecal incontinence and 40 to 65 percent of patients with constipation benefit from the treatment. A recent randomized, controlled trial demonstrated the benefit of transanal irrigation in patients with spinal cord injuries and with neurogenic bowel dysfunction.⁵ Compared to best supportive bowel care without irrigation, patients treated with transanal irrigation had fewer complaints of constipation, less fecal incontinence, improved symptom-related quality of life, and reduced time consumed on bowel management procedures.

However, the effect of transanal irrigation varies among patient groups and long-term data are lacking. Accordingly, the aims of this study were to present our long-term experiences with transanal irrigation and to identify factors that could predict the outcome of transanal irrigation thereby improving future patient selection.

MATERIALS AND METHODS

At Aarhus University Hospital, Denmark, selected patients with fecal incontinence and constipation resistant to first line treatment with behavioral and dietary modification, biofeedback, oral laxatives, anal suppositories, mini enema, or constipating medicine were introduced to transanal irrigation.

Transanal irrigation was carried out using either a rectal balloon catheter (Fig. 1; Peristeen® anal irrigation system, Coloplast A/S, Kokkedal, Denmark or Mallinckrodt, St. Louis, MO) or a cone shaped colostomy tip (Alterna®, Coloplast A/S, Humlebaek, Denmark). The catheter was inserted into the anal canal. If the rectal balloon catheter was used, the balloon was inflated to keep the catheter in the rectum while a tap water enema was administered. If a cone shaped colostomy tip was used, it had to be supported manually. When the enema was installed and the catheter removed, the bowel emptied the enema and other bowel contents. A specialist nurse carried out training on an outpatient basis. Patients were encouraged to keep frequent telephone contact when the procedure was initiated. The frequency of enema administration and volume of water used as maintenance therapy were determined by trial and error during the first few months. In patients with fecal incontinence, the enema induced evacuation of the left colon and rectum,⁴ preventing fecal leakage between washouts and reestablishing control over time and place

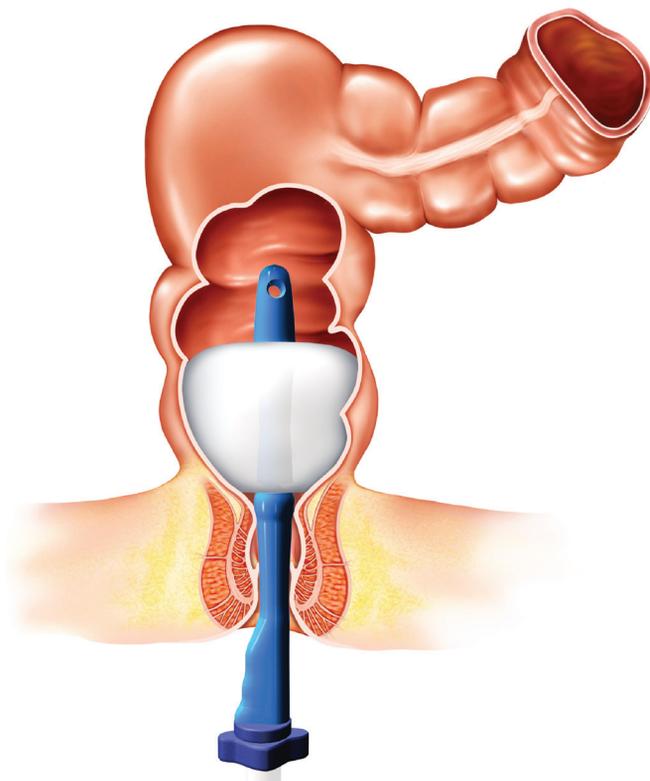


FIGURE 1. Methods of transanal irrigation. Transanal irrigation is carried out using either a rectal balloon catheter or a cone shaped colostomy tip. If the rectal balloon catheter is used the catheter is inserted in the rectum and the balloon is inflated to keep the catheter in the rectum while a tap water enema is administered. When the enema has been installed and the catheter has been removed, the bowel will empty the enema and other bowel contents. Figure used with permission from Coloplast A/S, Kokkedal, Denmark.

TABLE 1. Overall outcomes of transanal irrigation

Background pathology	n	Success	Failure	Success (%)
Spinal cord injury	68	42	26	62
Spina bifida	18	12	6	67
Multiple sclerosis	10	5	5	50
Cerebral thrombosis	10	7	3	70
Parkinson's disease	1	1	0	100
Idiopathic fecal incontinence	49	25	24	51
Obstetric sphincter injury	21	11	10	52
Sequelae from rectal surgery	15	6	9	40
Sequelae from rectal prolapse	21	5	16	24
Sequelae from anal surgery	12	3	9	25
Idiopathic constipation	79	27	52	34
Slow transit constipation	43	14	29	
Obstructed defecation	30	13	27	
Undetermined	6	0	6	
Miscellaneous	44	19	25	43
Total	348	163	185	47

for defecation. In constipated patients, the regular evacuation of the rectosigmoid prevented constipation.

From January 1994 to January 2004, 348 patients with defecation disturbances [248 women and 100 men; median age 52 years (range, 5–85)] were introduced to transanal irrigation. Information about background pathology, predominant symptom, and anorectal physiology tests were collected from hospital records. In 172 patients, transanal irrigation was performed to relieve fecal incontinence, and in another 172 patients, to treat constipation, and in 4 patients, the indication for treatment could not be determined from the hospital records. Evaluation of patients prior to treatment was conducted in accordance with the heterogeneous background pathology. In most patients, the evaluation included anorectal physiology tests, *e.g.*, determination of anal resting and squeeze pressures, rectal capacity, anorectal sensibility tests, rectal balloon expulsion test, and anal sphincter electromyography, endoanal ultrasonography, defecography and radiologically-determined colorectal transit time.

The heterogeneous composition of patient background pathology is shown in Table 1. The patients with idiopathic constipation according to the Rome criteria ($n = 79$),⁶ were subdivided into a) slow transit constipation, *i.e.*, prolonged colonic transit time ($n = 43$), b) obstructed defecation, *i.e.*, normal colonic transit time ($n = 30$), and c) undetermined ($n = 6$). The patients with miscellaneous course ($n = 44$) were mainly: encopresis ($n = 7$), anal atresia ($n = 3$), sequelae from hysterectomy ($n = 4$), radiotherapy to cervical cancer ($n = 4$), and scleroderma ($n = 3$).

In April 2004, 134 of 348 patients were registered as no longer using transanal irrigation. Their hospital records were used to determine the reason for discontinuing treatment and to determine the length of time before discontinuing. The remaining 214 patients, who were

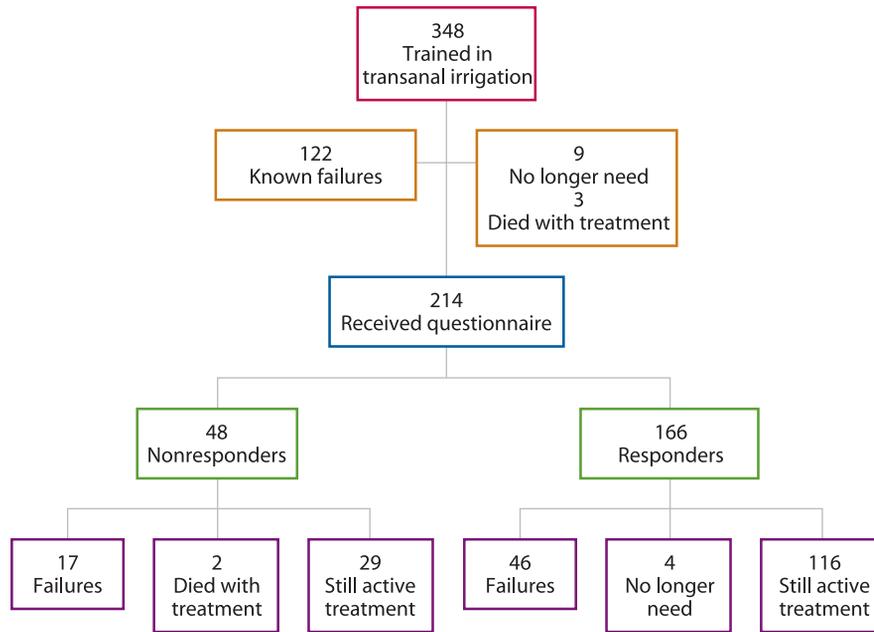


FIGURE 2. Profile of the entire cohort treated with transanal irrigation.

registered as possible users of transanal irrigation, received a mailed questionnaire describing treatment status, bowel function and practical procedures. Of those, 166 (78 percent) returned the questionnaire. From this survey, everyday performance and data regarding possible side effects were drawn. Data for the 48 patients not responding were drawn from their hospital records. If there was any doubt about treatment status at follow-up, patients were contacted by telephone (Fig. 2).

Patients still using transanal irrigation at follow-up, patients in which symptoms had resolved during treatment and therefore no longer needed the treatment, and patients with successful treatment of their bowel symptoms but who had died for reasons not related to treatment were regarded as having a successful outcome of transanal irrigation.

In order to estimate the five-year course with transanal irrigation, a Kaplan-Meier plot was used with the variable background pathology divided into five groups: a) neurogenic bowel dysfunction (spinal cord injury, spina bifida, multiple sclerosis, cerebral thrombosis, and Parkinson’s disease), b) anal insufficiency (idiopathic fecal incontinence, and obstetric sphincter injury), c) sequela to anorectal surgery (sequela to surgery for rectal prolapse, sequela to rectal surgery, and sequela to anal surgery), d) idiopathic constipation, and e) miscellaneous. Log-rank test was used; the level of significance was 5 percent.

In order to investigate potential background factors predicting the outcome of transanal irrigation, data were analyzed using multivariate logistic regression analysis assuming a multiplicative model. In the basic model, the

independent variables were age, gender, predominant symptom, and background pathology. The variable background pathology was divided into main patient groups as outlined above, however the very heterogenous subgroup, miscellaneous, was excluded from this analyses. The dependent variable was successful treatment with transanal irrigation. The level of significance was 5 percent. Subsequently, the anorectal physiology parameters were analyzed separately in a new multivariate logistic

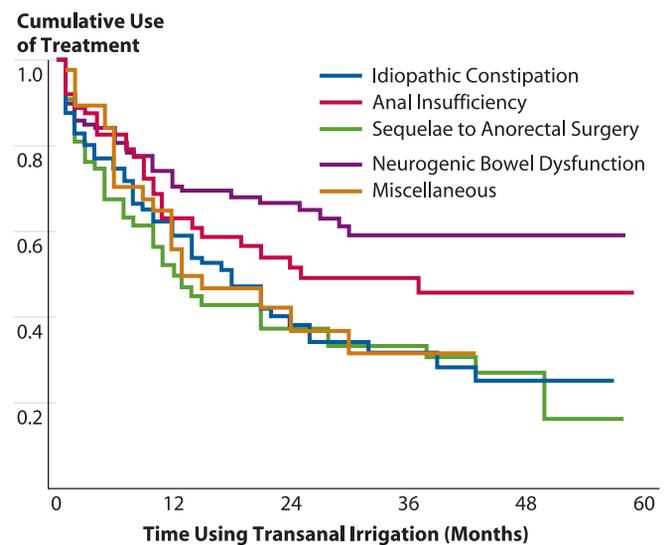


FIGURE 3. Time course for outcomes for transanal irrigation treatment. The estimated five-year course with transanal irrigation is sorted by main patient groups (n = 324, in 24 patients follow-up time missing). Significant difference was found between groups (log-rank test, $P < 0.003$).

TABLE 2. Reasons for failure of transanal irrigation treatment^a

Reason	n = 185, n, %
Unsatisfactory effect	76 (41)
Fecal incontinence	30 (16)
Time consumption	23 (12)
Dislike treatment	22 (12)
Side effects	27 (15)
Leakage of irrigation fluid	16 (9)
Expulsion of the rectal catheter	8 (4)
Other	10 (5)

^aData from the entire cohort, collected from hospital records and questionnaire. Multiple reasons possible.

regressions model making correction for those background variables significantly associated with effect of transanal irrigation.

RESULTS

After a mean follow-up of 21 months (range, 1–116), data from the entire cohort showed that 145 of 348 patients were still using transanal irrigation, 13 patients had stopped because symptoms had resolved during treatment, and 5 patients had died for reasons not related to treatment but after successful treatment of their bowel symptoms. Accordingly, 163 patients (47 percent) had a successful outcome of treatment with transanal irrigation. Outcome data sorted by background pathology is presented in Table 1.

Significant differences were found in the five-year course between patient groups (log-rank test, $P < 0.003$, Fig. 3). In 185 patients (53 percent) the treatment had failed. The median time using irrigation before discontinuing was

8 months (range, 1–85). Reasons for discontinuing treatment and time before discontinuing are listed in Table 2.

Data regarding every day performance of transanal irrigation was obtained from patients still using transanal irrigation on a regular basis and who had answered the questionnaire (n = 116). The frequency of irrigation was: each day, 36 percent; every second day, 35 percent; 2 to 3 times per week, 25 percent; and once per week or less, 14 percent. Mean total time spent at the lavatory with irrigation was 34 minutes (range, 7–120). A rectal balloon catheter was used in 69 percent, a colostomy irrigation tip was used in 25 percent, and other types of catheters were used in 7 percent. The mean volume of tap water was 961 mL (range, 10–2000); sodium phosphate or table salt was added to the irrigation fluid in 8 percent of patients. Additional oral constipating agents were used in 15 percent and oral laxatives in 60 percent of patients. Practical problems with the irrigation procedure were: pain with insertion of the catheter, 25 percent; expulsion of the catheter, 39 percent; leakage of irrigation fluid besides the catheter, 75 percent; and dependent on caretaker help to perform irrigation, 15 percent. Side effects are displayed in Fig. 4.

From hospital records bowel perforation related to irrigation treatment occurred in 2 of 348 patients treated with transanal irrigation. For the entire cohort, mean follow-up was 21 months and the median frequency of irrigation was every second day. Therefore, approximately 110,000 irrigations had been performed at the time of follow-up. Thus, the estimated risk of enema-induced perforation was less than 0.002 percent. One patient had an intra-abdominal perforation on the antimesenteric side of the sigmoid colon with fecal peritonitis requiring acute surgery with creation of a sigmoid colostomy. One

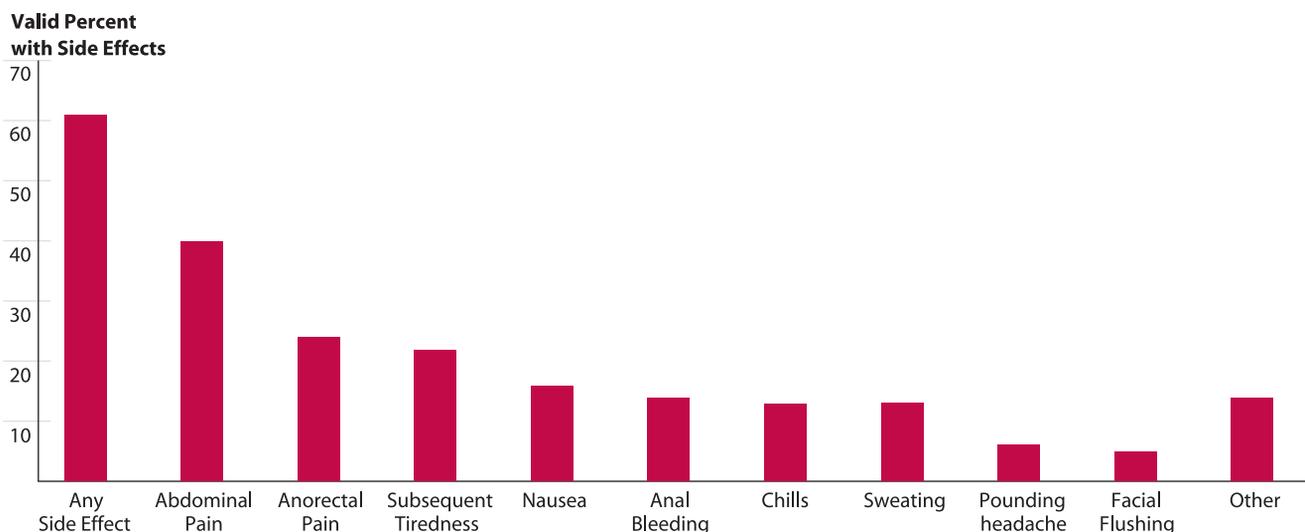


FIGURE 4. Side effects with transanal irrigation defined as “considerable inconvenience” during or after irrigation in at least one out of four irrigation procedures. Data was obtained from patients still using transanal irrigation on a regular basis and who had answered specifically in the questionnaire (n = 112). Data reported in percent. Multiple answers were allowed.

TABLE 3. Predictors of successful outcomes with transanal irrigation^a

Background variables:	n = 300, n	Odds ratio	95% Confidence intervals	P value
Background pathology				
Neurogenic bowel dysfunction	106	2.61	1.27–5.36	0.009
Anal insufficiency	70	3.18	1.41–7.18	0.005
Sequelae to anorectal surgery	45	1.16	0.50–2.72	0.72
Chronic constipation	79	1.00		
Gender				
Female	221	1.75	0.95–2.72	0.075
Male	79	1.00		
Age (years)				
0–17	10	0.88	0.21–3.74	0.86
18–40	70	0.61	0.31–1.24	0.17
41–60	122	0.68	0.38–1.21	0.19
61+	98	1.00		
Predominant symptom				
Constipation	153	1.18	0.58–2.4	0.65
Fecal incontinence	147	1.00		

^aBasic multivariate logistic regression model (n = 300). Forty-four patients with miscellaneous background pathology and the four patients with missing predominant symptom were excluded from the analyses. Odds ratio and level of significance is compared to the group with an odds ratio of 1.

patient had a perforation of the posterior rectum below the peritoneal reflection initially treated with broad spectrum intravenous antibiotics. Subsequently, a sigmoid colostomy was constructed to resolve the initial problems of major fecal incontinence and constipation and to defunction the perforated rectum.

At follow-up, failure of treatment had led to invasive surgical procedures in 81 patients: sacral nerve stimulation, n = 18; Malone Antegrade Continence enema, n = 20; sigmoid colostomy, n = 24; Malone Antegrade Continence enema combined with a sigmoid colostomy, n = 13; and ileostomy, n = 6. The rate of invasive surgical procedures corresponded to 44 percent of patients experiencing treatment failure with transanal irrigation or treatment failure in 23 percent of the total number of patients offered transanal irrigation.

Our data showed that the underlying pathology was significantly related to the outcome of transanal irrigation (Table 3). Furthermore, low rectal volume at urge to defecate, low maximal rectal capacity, and a low increment in anal squeeze pressure were associated with successful outcomes (Table 4).

DISCUSSION

Functional bowel symptoms including constipation and fecal incontinence are common and they often affect patients’ work life, social activities, and quality of life. However, treatment of functional bowel symptoms is

often based on a few patient series with short follow-up periods and only few small, controlled trials have been performed.⁷ The variety of treatment options reflects the heterogeneous background pathology and the literature does not support any treatment in favor of another.⁸ Thus, the therapists are left in treatment anarchy based on local preferences and trial and error solutions.

Transanal irrigation is an established treatment modality for constipation and fecal incontinence in children with spina bifida.^{1,9} In adult patients with spinal

TABLE 4. Anorectal physiology predictors of successful outcomes with transanal irrigation^a

Anorectal physiology variables:	n	Odds ratio	Confidence intervals	P value
Anal resting pressure, cm H ₂ O				
0–25	39	1.59	0.73–3.47	0.24
26–50	74	1.81	0.98–3.39	0.06
50+	161	1.00		
Anal squeeze pressure, cm H ₂ O				
0–25	13	1.44	0.44–4.72	0.54
26–50	44	1.26	0.62–2.58	0.52
50+	196	1.00		
Anal squeeze pressure increment, cm H ₂ O				
0–15	83	2.11	1.06–4.21	0.033
16–30	61	0.73	0.36–1.46	0.38
31+	121	1.00		
Anal sensory level, mA				
0–5	103	0.80	0.29–2.17	0.66
5.1–10	77	0.67	0.25–1.80	0.42
10.1+	23	1.00		
First sensation, mL				
0–50	73	1.11	0.51–2.42	0.81
51–150	130	1.21	0.60–2.44	0.60
151+	49	1.00		
Urge to defecate, mL				
0–50	30	3.12	1.20–8.13	0.02
51–150	121	1.09	0.61–1.94	0.77
151+	92	1.00		
Maximum tolerable rectal volume, mL				
0–100	33	2.51	1.04–6.00	0.039
101–200	111	1.24	0.71–2.16	0.44
201 +	119	1.00		
Balloon expulsion				
Able	71	0.55	0.22–1.38	0.20
Unable	37	1.00		
Sphincter electromyography at defecation				
Raised	38	1.86	0.77–4.50	0.17
Normal	68	1.00		
Colonic transit time				
Prolonged	119	1.15	0.63–2.06	0.65
Normal	121	1.00		

^aExtended multivariate logistic regression model. Forty-four patients with miscellaneous background pathology were excluded from the analyses. Anorectal physiology tests were conducted prior to treatment in accordance with the heterogeneous background pathology resulting in different numbers for each anorectal physiology variable. Continuous variables were turned into appropriate factor variables. Each variable was analyzed separately, corrected for the background variables statistically significantly associated with successful treatment with transanal irrigation (“background pathology”). Odds ratio and level of significance is compared to the group with an odds ratio of 1.

cord injuries, transanal irrigation is superior to best supportive bowel care without irrigation and significantly improved quality of life.⁵ Transanal irrigation is also recommended in other selected adult patients with functional bowel symptoms.^{3-5,10,11}

The present study presents the cumulated experiences from a 10-year period with 348 patients with heterogeneous background pathology. First line treatment with conservative bowel management such as laxatives, suppositories, mini enemas, constipating agents, or biofeedback had been ineffective for all patients. Overall success was found in 47 percent of patients with the best results found among patients with neurogenic bowel dysfunction where transanal irrigation was successful in approximately two out of three patients. In patients with idiopathic fecal incontinence or fecal incontinence secondary to obstetric anal sphincter lesions, transanal irrigation was successful in half. However, only one in three patients with chronic idiopathic constipation or symptoms secondary to anorectal surgery continued transanal irrigation. This message was confirmed in the multivariate logistic regression model making corrections for age, gender, and predominant symptom.

Treatment was introduced in this cohort on liberal indication and often with a high risk of failure as a rescue treatment in patients awaiting invasive surgery. Therefore the present results are not comparable with results from other treatment modalities for defecation disturbances, as for example sacral nerve stimulation where patients have been selected through a test phase. If a test phase of three months is incorporated in the present data, the overall success rate increases from 47 to 56 percent (Fig. 3). The main dropout occurs in the beginning of the treatment. Furthermore, the steep curve course in idiopathic constipation compared to the more plateau-like curve course in the other patient groups also indicate development of tolerance to the treatment in this particular group. This finding is in accordance with a previous scintigraphic study showing that colorectal emptying during transanal irrigation is significantly greater in patients with spinal cord injury or idiopathic fecal incontinence than in those with chronic idiopathic constipation.⁴

In recent long-term studies, transanal irrigation was effective in 57 to 65 percent of patients with obstructed defecation.^{10,11} In the present study, only 43 percent of patients with obstructed defecation had a successful outcome. The rate of successful outcomes was only slightly better than in patients with slow transit constipation. This inconsistency calls for randomized, controlled trials with uniform classification of constipation and well defined end points. Accordingly, colonic transit time could not predict the outcome of transanal irrigation in the total group of patients.

A previous study found transanal irrigation effective in 79 percent of patients with defecation disturbances after

surgery for rectal cancer or pouch surgery,¹¹ but the present study only found 40 percent of these patients to have successful outcomes. These patients are often difficult to manage and a permanent stoma seems the only option if transanal irrigation fails, but further studies are needed to look into treatment alternatives as sacral nerve stimulation to enable patient selection for optimal treatment.

If initial treatment with transanal irrigation fails, it can be combined with oral laxatives or constipating medicine. Furthermore, addition of stimulating agents to the irrigation fluid is also a possibility, though the use is based on limited scientific evidence,^{1,12-14} and warrants further study of different irrigation fluids in transanal irrigation.

In accordance with previous studies, we found that many patients frequently experienced episodes of leakage of the irrigation fluid and expulsion of the catheter.^{3,11} Our general approach to these practical problems is to adjust the volume used for irrigation and air in the rectal balloon or change type of catheter. Clarification is needed as to in which patients a rectal balloon catheter should be used and in which a cone shape colostomy tip would be better.

Mild and transient symptoms during or after irrigation are to be expected as reported in the present study. However, a recent randomized, controlled trial comparing transanal irrigation with best supportive bowel care without irrigation in spinal cord injury patients found that symptoms during or after defecation tended to be less frequent in the transanal irrigation group, and also found urinary tract infections significantly less frequent in the transanal irrigation group.⁵

In the ten-year period of the present study, two patients had a bowel perforation related to transanal irrigation with an estimated risk of enema-induced perforation at 0.002 percent. Although this risk is low, introduction of a catheter into the rectum and administration of an enema under pressure always carries the risk of a potentially lethal bowel perforation.¹⁵ Therefore, medical personnel dealing with transanal irrigation should know about the signs and treatment of colonic perforation, and should inform patients before treatment initiation.¹⁶

Multivariate regression analysis was used to identify single factors significantly related to successful outcome among the battery of anal physiology parameters. Low rectal volume at urge to defecate and low maximal rectal capacity were significantly associated with successful outcome. It is unclear whether the result of a washout is achieved by a simple mechanical washout or by colonic mass movements induced by the enema. However, studies have shown that colonic mass movements can be induced by enemas.¹⁷ The parasympathetic innervation of both the rectum and the left colon is from the sacral spinal cord. Accordingly, a low rectal capacity may also reflect a low capacity of the left colon and thereby the left colon is more likely to react with contractions after distension by the irrigation fluid. The success of low increment in anal squeeze pressure remains to be explained.

The lack of further significant prognostic variables among the anorectal physiology tests either reflects a type 2 error with too small of a sample size or indicates that anorectal physiology testing and colonic transit time do not contribute to patient selection to transanal irrigation.

The present study offers some information about patient selection to transanal irrigation, but randomized trials are needed to position transanal irrigation within a treatment algorithm for functional bowel dysfunction. However, on the basis of the present study, a new randomized, controlled trial, and the lack of treatment alternatives we recommend transanal irrigation as the first line treatment to patients with neurogenic bowel dysfunction.

In patients with anal insufficiency, a sphincter defect should be surgically corrected. In patients with intact sphincters, our current strategy is to offer sacral nerve stimulation. This treatment has excellent results and patients have a permanent solution without the daily trouble with the irrigation procedures. However, if treatment fails, transanal irrigation can be performed with success in more than half of the patients.

CONCLUSIONS

Transanal irrigation is simple and safe for long-term treatment for defecation disturbances with greatest benefit in patients with neurogenic bowel dysfunction. In patients with chronic idiopathic constipation, defecation disturbances after anorectal surgery or miscellaneous functional bowel problems, transanal irrigation can be tried as a simple and reversible treatment but whether it is superior to other nonsurgical procedures remains to be studied. However, it is our current strategy to offer transanal irrigation before surgical procedures such as sacral nerve stimulation, Malone Antegrade Continence enema, colectomy with ileorectal anastomosis, STARR procedure, or a sigmoid colostomy is considered, and in many patients surgery can actually be avoided.

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