Outcome of Transanal Irrigation for Bowel Dysfunction in Patients With Spinal Cord Injury

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Abstract

Background/Objective: To compare symptoms of neurogenic bowel dysfunction in patients with spinal cord injury (SCI) at baseline and after 10 weeks of treatment with transanal irrigation and to identify possible factors that could predict outcome of the treatment.

Methods: Sixty-two patients with SCI (45 men and 17 women; mean age, 47.5 ± 15.5 [SD] years) from 5 specialized European SCI centers were offered treatment with transanal irrigation for a 10-week period. Bowel function was assessed at baseline and at termination using the Cleveland Clinic Constipation Scoring System (CCCSS; 0–30, 30 = severe symptoms), St. Mark's Fecal Incontinence Grading System (FIGS; 0–24, 24 = severe symptoms), and the Neurogenic Bowel Dysfunction score (NBD; 0–47, 47 severe symptoms). Factors predicting improvement in bowel function scores were identified using a general linear model.

Results: Severity of symptoms at termination was significantly reduced compared with baseline values (CCCSS: -3.4 ; 95% confidence interval [CI], -4.6 to -2.2 ; FIGS: -4.1 ; 95% CI, -5.2 to -2.9 ; NBD: -4.5 ; 95% CI, -6.6 to -2.4 ; all $P < 0.0001$). Although several factors were associated with positive outcome, no consistent and readily explainable pattern could be identified. Surprisingly, hand function, level of dependency, predominant symptom, and colonic transit time were not associated with outcome.

Conclusions: Transanal irrigation in patients with SCI reduces constipation, improves anal continence, and improves symptom-related quality of life. No readily obtainable factors could predict outcome, which might be because of the relatively low number of patients. This supports the use of trial and error as a strategy in deciding on a bowel management method for neurogenic bowel dysfunction.

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Key Words: Spinal cord injuries; Constipation; Fecal incontinence; Neurogenic bowel dysfunction; Transanal irrigation; Quality of life

INTRODUCTION

During the past decade, several studies have documented the magnitude of bowel dysfunction among patients with spinal cord injury (SCI). Patients present with 1 or more of a heterogeneous cluster of symptoms including

constipation, fecal incontinence, abdominal pain, and prolonged bowel management. Severity of symptoms varies considerably among individuals (1,2).

Although these symptoms are not life threatening, they have important repercussions on emotional and social life, sometimes resulting in increased levels of anxiety and depression (2,3). In total, 39% of patients with SCI report that bowel dysfunction has some impact on their quality of life, sometimes major, and 30% regard colorectal dysfunction as worse than bladder and sexual dysfunction (1). Furthermore, symptoms are often overlooked, poorly evaluated, and insufficiently treated.

Bowel management programs have been developed empirically, with individual solutions being sought on a

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Table 1. Baseline Demographics

Age (years) [mean (range)]	47.5 (25–76)	Voluntary anal contraction	
Sex		No	54
Female	17	Yes	7
Male	45	Any anal sensation	
Etiology		No	40
Traumatic	41	Yes	22
Vascular	2	Duration of symptoms (months)	
Sequelae to operation	3	Median (range)	60 (4–776)
Tumor	5	Predominant symptom	
Spina bifida	2	Fecal incontinence	11
Slipped disk	1	Constipation	47
Other reason	7	Other	4
SCI complete/incomplete	37/25	Dependency on help to go to the lavatory	
Level of injury		Independent	31
Supraconal	61	Partly dependent	9
Conal/cauda equina (S2–S4)	1	Dependent	21
Mobility		Colonic transit time (days) [mean (SD)]	3.4 (1.5)
Walking	5	Segmental CTT (days) [mean (SD)]	
Impaired walking	9	Cecum and ascending colon	1.1 (0.8)
Using wheelchair	47	Transverse colon	0.5 (0.5)
Confined to bed	1	Descending colon	1.0 (0.8)
Hand function		Sigmoid colon and rectum	0.5 (0.5)
No restriction	44	Center	
Unilateral impaired function	2	United Kingdom	18
Bilateral impaired function	13	Sweden	7
No function	3	Denmark	9
Anal spasms		Germany	12
No	28	Italy	16
Yes	32		

trial-and-error basis (4); but evidence for the efficiency of different bowel management procedures is lacking (5).

Transanal irrigation improves bowel function in 60% to 100% of children with spina bifida, and the treatment has also been used in selected adult patients with fecal incontinence or constipation (6–14). A recent randomized controlled trial in patients with SCI with neurogenic bowel dysfunction clearly showed the benefits of transanal irrigation. Compared with best supportive bowel management without irrigation, patients with transanal irrigation had less constipation, less fecal incontinence, improved symptom-related quality of life, and reduced duration of bowel management (15). However, the effect of transanal irrigation varies among patients.

The aims of this study were to evaluate transanal irrigation for treatment of bowel dysfunction in SCI patients and to identify possible factors that could predict outcome of the treatment.

METHODS

From December 2003 through June 2005, 87 patients with SCI and neurogenic bowel dysfunction were recruited from 5 SCI centers in 5 European countries to participate in a randomized controlled trial comparing transanal irrigation with conservative bowel manage-

ment (best supportive care without irrigation) (15). Patients were randomly assigned to either transanal irrigation (42 patients) or conservative bowel management (45 patients) for a 10-week trial period. After completing the initial 10-week trial period, 20 of 45 patients in the conservative bowel management group undertook a further 10-week period on transanal irrigation. In total, 62 patients were offered treatment with transanal irrigation for a 10-week period and are the subjects of this paper.

Baseline demographic data are shown in Table 1. Patients were classified according to the International Standards for Classification of Spinal Cord Injuries (16) and divided into 2 groups: (a) supraconal SCIs (S1 or above) and (b) conal (S2–S4) or cauda equina injuries. Each group was subdivided into complete or incomplete injury groups.

Transanal Irrigation

A newly developed system for transanal irrigation, the Peristeen Anal Irrigation (Coloplast A/S, Kokkedel, Denmark) was used in this study. Using this system, irrigation can be managed without assistance from another person even by patients with poor hand function or limited mobility; however, irrigation can also be managed by a caregiver. The system consists of a coated, rectal balloon

Figure 1. Peristeen anal irrigation. (1) Coated rectal catheter with a balloon. (2) Manual pump. (3) Control unit. (4) Water bag. The catheter is inserted into the rectum and the balloon is inflated to hold the catheter in the rectum while lukewarm tap water is administered with the manual pump. Pressure generated in the bag with the manual pump drives the water into the bowel. Subsequently, the balloon is deflated, and the catheter is removed, followed by bowel emptying of the water and other bowel contents.

catheter, a control unit including a manual pump, and a water container (Figure 1). The catheter is inserted into the rectum, and the balloon is inflated to hold the catheter in the rectum while lukewarm tap water is slowly administered with the manual pump. Subsequently, the balloon is deflated, and the catheter is removed, followed by emptying of the water and other bowel contents. Volume of water used, degree of balloon inflation, and frequency of administration were determined during the first weeks of treatment. Use of oral laxatives or constipating medication was continued as required.

Specialist nurses trained the patients in transanal irrigation in the hospital or on an outpatient basis according to the local organization. Patients were encouraged to contact the specialist nurse for advice, especially in the early stages of the study.

Study Design

Bowel function was measured at baseline and at completion of the 10-week trial period. For the 20 patients who had completed a 10-week trial period on conservative bowel management before treatment with irrigation, the scores at termination from that basic study counted as baseline values for the extension study. Constipation was assessed with the Cleveland Clinic Constipation Scoring System (CCCSS) (17) (range, 0–30; 30 = severe symptoms), and fecal incontinence was

assessed with St. Marks Fecal Incontinence Grading System (FIGS) (18) (range, 0–24; 24 = severe symptoms). Furthermore, bowel dysfunction was assessed with a newly developed and validated symptom score, the Neurogenic Bowel Dysfunction (NBD) score (19), which weights each symptom of bowel dysfunction according to its impact on quality of life (range, 0–47; 47 = severe symptoms). All 3 bowel function measures were analyzed as the change in score from baseline to termination. Therefore, a negative mean score reflects an improvement in bowel function.

During the 10-week trial period, patients were contacted each week by an independent observer who had not participated in the training of the study participant. A short, structured questionnaire was completed covering symptoms during and after defecation, duration of bowel care, level of dependency, changes in additional medications known to influence bowel motility, and practical performance of the irrigation procedure.

Data were analyzed on an intention-to-treat basis. Efforts were made to ensure completion of assessments at premature withdrawal from treatment. However, a conservative strategy was used, replacing missing responses at termination with the individuals' baseline response. For missing responses in the weekly follow-up, a strategy of "last observation carried forward" was used. Baseline and follow-up values were compared using paired samples *t* tests. Significance was set at 0.05, 2-tailed. The study was powered to support the comparison of transanal irrigation with conservative bowel management (15).

To study factors predicting improvement in bowel function scores, data were analyzed using a general linear model. Baseline demographic data (Table 1) were used as explanatory variables. The variables of age, duration of bowel symptoms, and colonic transit time were treated as continuous variables, whereas all other explanatory variables were treated as categorical variables. The response variables were calculated as the difference between termination and baseline values. Variable selection was carried out with a stepwise selection algorithm. The study was conducted in accordance with the recommendations from the CONSORT statement, was registered in the publicly accessible database www.clinicaltrials.gov, and was approved by the appropriate local research ethics committees. Written consent was obtained from all patients. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

RESULTS

A total of 62 patients were offered treatment with transanal irrigation for a 10-week period. Before training was initiated, two patients withdrew. During training, 5 patients discontinued participation: 4 because of repeated expulsion of the rectal catheter during irrigation and 1

Figure 2. Trial profile.

because of leaking of water around the rectal catheter. In study weeks 1 to 10, 10 more patients withdrew: 2 because of insufficient effect, 1 because of expulsion of the rectal catheter, 1 disliked treatment, 1 because of bursts of the rectal balloon, 1 because of adverse events, and 4 lost to follow up. At discontinuation, 10 of these 15 patients completed the termination form. Therefore, assessments at termination could be determined in a maximum of 55 patients. However, missing termination responses were replaced with the individuals' baseline response to compensate for the possibility that patients who discontinue might be those with worse symptoms and poorer outcomes (Figure 2).

The changes in scores from baseline to termination are presented in Table 2. For all 3 bowel function scores, severity of symptoms at termination was significantly decreased compared with baseline values. These findings are further shown in Figure 3.

Treatment with transanal irrigation during the last 4 weeks of the trial was evaluated with regard to frequency,

volume of water used for irrigation, need for assistance, and problems related to the rectal catheter (Table 3). Space was left for comments in the questionnaire. Here, bursts of the rectal balloon during irrigation were reported by approximately 1 in 3 patients.

Multivariable analysis was applied to identify baseline variables that were significantly related to improvement in bowel function scores. The mean difference in CCCSS was -3.3 with a 95% confidence interval (CI) of -4.5 to -2.2 , reflecting an improvement in constipation-related symptoms. The difference in the constipation score depended significantly on incomplete injury and the presence of uncontrolled anal spasms and varied significantly among study centers (Table 4). The mean difference in FIGS was -4.1 with a 95% CI of -5.2 to -2.9 , reflecting an improvement in fecal incontinence-related symptoms. The difference in the fecal incontinence score depended significantly on male sex and ability to walk (Table 5). The mean difference in NBD score was -4.5 with a 95% CI of -6.6 to -2.4 , reflecting a

Table 2. Bowel Function at Baseline and at Termination

Bowel Score	Baseline	Termination	Change From Baseline to Termination	P Value
CCCSS	13.5 (12.3–14.8)	10.2 (9.0–11.3)	-3.4 (-4.6 to -2.2)	<0.0001
FIGS	8.5 (7.4–9.7)	4.5 (3.3–5.6)	-4.1 (-5.2 to -2.9)	<0.0001
NBD	15.3 (14.0–16.6)	10.8 (8.7–12.8)	-4.5 (-6.6 to -2.4)	<0.0001

CCCSS (0–30, 30 = severe symptoms), FIGS (0–24, 24 = severe symptoms), NBD score (0–47, 47 = severe symptoms). Values presented as mean (lower/upper 95% CI). Change in score is presented as the change from baseline to termination. Therefore, a negative mean reflects an improvement in the score.

Figure 3. Scatter plots of the bowel function scores. Scatter plots with baseline and termination values for all participants. Symbols above the diagonal represent improvement after treatment with transanal irrigation.

reduction in the impact of bowel dysfunction on quality of life. The improvement depended significantly on complete injury, male sex, and ability to walk, and varied significantly between study centers (Table 6).

DISCUSSION

This study confirmed the findings of previous studies that transanal irrigation improves constipation and anal continence in patients with SCI (12,14,15,20). For all outcome measures, the severity of symptoms at termination was significantly reduced compared with baseline values. The NBD score, where each symptom is weighted with respect to its impact on quality of life, was also significantly reduced indicating an improvement in quality of life. In addition to the significant differences in bowel function scores, the recent randomized study comparing transanal irrigation with best supportive bowel management without irrigation also found a significant reduction in time spent on bowel management (47 vs 74

minutes daily), significant reduction in frequency of urinary tract infections, and a strong tendency to reduce the frequent symptoms during or after defecation in favor of transanal irrigation (15). Furthermore, health economic analysis has found transanal irrigation to be cost effective from society's perspective (21).

Of 62 patients who were offered treatment with transanal irrigation, 17 patients discontinued their participation. In 7 of those 17 patients, assessment at termination was missing. These patients might have the worst symptoms and poorest outcome of treatment. For the handling of missing data values at termination, a conservative strategy was used to enable analysis of all available data. The analysis, therefore, represents a realistic estimation of the impact of transanal irrigation on bowel dysfunction in a cohort of patients with SCI.

The experience of transanal irrigation in 348 patients with heterogeneous background pathology over a 10-year period (mean follow-up: 21 months) showed

Table 3. Performance of Transanal Irrigation

	Transanal Irrigation		
	Every Day	Every Second Day	1–3 Times per Week
Frequency of irrigation*	20%	48%	30%
	None	Sometimes	Always
Difficulties with insertion of the catheter	93%	7%	0%
Expulsion of the catheter	78%	15%	7%
Leaking of irrigation fluid around the balloon	54%	30%	16%
	Yes	No	
Need for assistance to perform irrigation	40%	60%	
Volume of tap water (mL) [median (range)]	650 (0–1,500)		

Average in weeks 7–10.

*The remaining 2% covers subjects answering “none” during weeks 7–10.

Table 4. General Linear Model and the CCCSS

Parameter	Group	Estimate	95% CI
Spinal cord injury	Complete	−5.4	−7.6 to −3.2
	Incomplete	−9.1	−11.5 to −6.7
Uncontrolled anal spasms	No	2.6	0.4–4.8
	Yes	0	
Center	1	5.8	3.3–8.3
	2	4.5	1.7–7.3
	3	−2.1	−5.4–1.2
	4	0.6	−2.0–3.2
	5	0	

The mean difference in the constipation score was −3.3 with a 95% CI of −4.5 to −2.2, reflecting an improvement in constipation-related symptoms. Positive estimates reduce the difference between termination and baseline scores, whereas negative estimates increase the difference and thus the success of treatment. Predictors for positive outcome for constipation were incomplete injury and lack of uncontrolled anal spasms. Also, center was a factor.

success in 47% of patients. However, 63% of patients with neurogenic bowel dysfunction were successfully treated (22). In this short-term study, 17 of 62 patients (27%) discontinued within the first 10 weeks of treatment; of these, 11 could be regarded as failures primarily because of expulsion of the rectal catheter or leakage of irrigation fluid around the balloon. These practical problems are also found in patients with long-term use of transanal irrigation (13,14,22) and are to be expected in patients with supraconal SCI, who often have reduced rectal compliance and hyperreactivity to distension (23). This emphasizes the importance of high motivation on the part of the patients and the need for instruction, help, and support from experienced nurses with special interest in this field. It also suggests introduction of a test phase before a realistic long-term success with treatment can be expected.

The variation in the effect of transanal irrigation among patients indicates the need for knowledge to improve patient selection to the treatment. We therefore conducted a multivariate analysis in an attempt to identify single factors significantly related to successful transanal irrigation. Identifying such factors would allow prediction of those individuals most likely to benefit from treatment.

With regard to the CCCSS, patients with uncontrolled anal spasms had the greatest benefit. Such patients are likely to have rectal hyperactivity and may

therefore experience more successful evacuation after irrigation because of strong reflex rectal contractions induced by the irrigation procedure. The effect of transanal irrigation on constipation also depended significantly on incomplete injury and the study center.

With regard to FIGS, mobile patients seemed to have the greatest benefit from irrigation. In general, patients who are mobile have incomplete injuries and often experience less severe bowel dysfunction, find accessing the toilet easier, and may therefore be easier to treat. However, this finding partly contradicts results from the main study, where immobilized patients showed the greatest improvement in fecal incontinence (15). However, data from the main study were not corrected for possible confounders. Why male subjects seemed to benefit more than females remains unexplained.

Factors significantly associated with better response to irrigation with regard to the NBD score were completeness of injury, sex, mobility, and study center. The results showed that participants with complete injury and mobile participants with an incomplete injury experienced the greatest improvement in symptom-related quality of life when using transanal irrigation. Why immobile patients with an incomplete injury do worse remains unexplained. The study center attended influenced outcome. However, it is interesting that the lead center, which had the most experience in transanal irrigation, had results in the middle of the range,

Table 5. General Linear Model and FIGS

Parameter	Group	Estimate	95% CI
Sex	Male	−4.4	−5.7 to −3.1
	Female	−1.0	−3.2 to 1.2
Mobility	Walking/walking with difficulties	−3.0	−5.7 to −0.3
	Wheelchair/confined to bed	0	

The mean difference in the fecal incontinence score was −4.1 with a 95% CI of −5.2 to −2.9, reflecting an improvement in fecal incontinence. Predictors for positive outcome for fecal incontinence were male sex and ability to walk.

Table 6. General Linear Model and NBD Score

Parameter	Group	Estimate	95% CI
Spinal cord injury	Complete	−5.2	−9.6 to −0.8
	Incomplete	−0.4	−6.5 to 5.7
Sex	Male	−5.2	−8.9 to −1.5
	Female	0	
Mobility	Walking/walking with difficulties	−6.7	−11.8 to −1.6
	Wheelchair/confined to bed	0	
Center	1	9.3	5.1–13.3
	2	2.3	−3.0 to 7.6
	3	8.3	2.2–14.4
	4	0.8	−3.9 to 5.5
	5	0	

The mean difference in NBD score was −4.5 with a 95% CI of −6.6 to −2.4, reflecting an overall improvement in bowel dysfunction. Predictors for positive outcome for overall neurogenic bowel dysfunctions were complete lesions, male sex, and ability to walk. Center was also a factor.

indicating that the concept of transanal irrigation is transferable to other settings and cultures.

We would expect that poor hand function and dependency on help from others for bowel management would predict a poor outcome of transanal irrigation. To our surprise, this was not the case. This may be because of the special design of the Peristeen Anal Irrigation, which actually enables self-administered transanal irrigation for immobilized patients and for patients with poor dexterity. We would also expect that the rate of success would be lower for patients with severely prolonged colonic transit time, but it was not. Previous studies of transanal irrigation in patients with heterogeneous background pathology have otherwise shown that patients with severe constipation have lower success rates and weaker response to irrigation than patients with milder degrees of constipation (20,22). This was not the case in this study, which might indicate that the effect of the usual disordered defecation reflexes in SCI that lead to constipation is exceeded by the effect of transanal irrigation. Although several factors were associated with positive outcome, no consistent and readily explainable pattern could be identified. The reason for this could be that the study was not powered to support the multivariate analyses presented in this paper. A consequence of that is that the power of the test for significant effect of the single factors is relatively low (20–40%), with a risk of drawing falsely negative conclusions. To achieve more solid knowledge on predicting factors related to successful outcome of transanal irrigation, there is a need for a large prospective multicenter database. Until then, it is advisable to use a trial-and-error strategy for the introduction of transanal irrigation to patients with neurogenic bowel dysfunction caused by SCI.

CONCLUSION

In conclusion, transanal irrigation in patients with SCI reduces constipation, improves anal continence, and

improves symptom-related quality of life. Practical problems with the irrigation procedure are to be expected and may lead to failure of the treatment. No readily obtainable baseline characteristics could be determined to predict successful outcome of transanal irrigation.

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