ORIGINAL ARTICLE

The need for manual evacuation and oral laxatives in the management of neurogenic bowel dysfunction after spinal cord injury: a randomized controlled trial of a stepwise protocol

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Study design: Randomised controlled trial.

Objectives: High-quality evidence for interventions in bowel management (BM) after spinal cord injury (SCI) is lacking and BM programs are developed empirically. This randomized, controlled trial compared usual care with a stepwise protocol based on earlier published work to examine whether systematic use of less invasive interventions could reduce the need for oral laxatives and invasive interventions such as manual evacuation, and improve BM outcomes in individuals with chronic SCI.

Setting: United Kingdom.

Methods: In all, 68 individuals were recruited (35 in intervention group), median age 47 years (range 24–73 years), median duration of injury 16 years (range 1–47 years). Bowel diaries were maintained for a maximum of 6 weeks while the intervention group followed a stepwise protocol designed to test interventions singly and in combination. Measures of quality of life and preferences for different bowel care interventions were recorded.

Results: The stepwise protocol did not improve BM outcomes; fecal incontinence was more frequent ($P=0.04$); the need for oral laxatives and invasive interventions was not reduced ($P=0.4$). Bowel care took consistently longer in the intervention group.

Conclusions: The study findings support the need for manual evacuation in BM and provide evidence of acceptability of the technique to SCI individuals. For some individuals oral laxatives are an essential part of management. The results are in contrast with previous studies in younger samples with shorter duration of injury.

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Keywords: spinal cord injury; neurogenic bowel dysfunction; bowel management; manual evacuation; oral laxatives; randomized controlled trial

Introduction

Loss of voluntary control over bowel function is often the most distressing aspect of spinal cord injury (SCI).^{1,2} A bowel management (BM) program that is effective, timely and sustainable is essential but may require considerable time, self-discipline and possibly a carer. When BM is ineffective, bowel dysfunction may dominate day-to-day life, severely curtailing community reintegration and reducing quality of life.^{3–5} Neurogenic bowel dysfunction can result in considerable morbidity, such as autonomic dysreflexia, impaction, hemorrhoids, abdominal pain, rectal bleeding, rectal prolapse, anal fissure, bloating, nausea, constipation and prolonged evacuation.^{1,3,4,6,7}

Bowel management programs are based on regular routine, dietary manipulation, laxatives, digital and pharmacological rectal stimulation, manual evacuation of stool and assistive interventions such as abdominal massage. There is little evidence to support these interventions individually or in combination. Development of an individual program depends on the experience of the health-care practitioner and trial and error. Use of manual evacuation of stool is reported in 8–68%^{1–3,8,9} but there is little evidence of the need for and acceptability of the procedure.¹⁰ Anecdotally it is regarded as invasive and may be unacceptable to patients, carers and staff. Oral laxative use is reported in 39–60% of SCI individuals.^{1,3,9,8,11} Studies examining dosage and side effects in the neurogenic population are lacking and anecdotally there is much anxiety regarding long-term use of stimulant laxatives.

This study aimed to evaluate the need for oral laxation and manual evacuation and the effectiveness of assistive

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techniques for neurogenic BM when combined in a program.

Materials and methods

Participants

A postal survey of BM was sent to the entire population of a single SCI center.³ Of 1334 respondents, 164 individuals also participated in a study of BM interventions using anorectal manometry. A subset of this sample undertook this study. Informed consent was obtained. Approval was given by the local research ethics committee. Inclusion criteria were aged ≥ 18 years, traumatic or non-traumatic SCI, ASIA impairment scale grade A to D, discharged from initial rehabilitation ≥ 1 year before the study. Exclusion criteria were pregnancy, current or past bowel disease or major surgery and presence of a stoma.

A 2-week bowel diary was maintained before attending for clinical assessment, anorectal manometry and completion of baseline outcome measures.

Intervention group

A stepwise protocol (Table 1), based on earlier published work,^{12,13} was developed. Interventions were ordered from the least to most invasive to allow assessment of both effect of each intervention and effects of combined interventions, while ensuring effective BM. Participants worked through the stepwise protocol until bowel evacuation was achieved. To allow time to establish the new routine, participation was planned for 6 weeks.

Participants received verbal and written preparation and a 6-week bowel diary to record all interventions and resulting evacuations, duration of BM, frequency of FI (defined as any passage of stool outside a planned BM episode), stool consistency using the Bristol Stool Form Scale¹⁴ and other relevant information, for example, bleeding or pain. Frequency of BM episodes during the study was the same as the participants' usual routine. A single day food and fluid diary was included for each week of the bowel diary. Weekly support phone calls were made to all participants.

Control group

The control group undertook their usual type, number and order of interventions to achieve evacuation, maintaining the same diaries as the intervention group.

Objectives

The following hypotheses were addressed:

- (1) The use of a progressive protocol will improve bowel evacuation by reducing the level of intervention, according to stepwise protocol, required to evacuate the bowel compared with a control group.
- (2) The use of a progressive protocol will improve BM by reducing duration of bowel care compared with a control group.

Outcome measures

Dual primary outcome measures were duration of BM and level of intervention required to complete evacuation.

Table 1 The stepwise protocol and rationale for order

Step	Intervention	Purpose	Rationale for order
0	Stimulation of gastro-colic reflex 20 min before starting bowel care	Promote 'mass movement' of stool through the bowel by stimulating colonic peristalsis.	Non-intimate, non-invasive stimulation of a natural physiological reflex.
1	Abdominal massage	Stimulate movement of stool through the colon.	Involves touching of the body, but not in an intimate or invasive way. No known side effects.
2	Perianal digitation	Stimulate reflex relaxation of anus/contraction of rectum.	Intimate but not invasive.
3	Anorectal digitation	Stimulate reflex relaxation of anal canal/contraction of rectum.	Moderately invasive but brief, limited opportunity for anorectal damage if properly conducted. Can produce a response more rapidly than suppositories.
4	Glycerin suppositories	Stimulate reflex relaxation of anal canal/reflex contraction of rectum, lubricates stool.	Moderately invasive, involves use of irritant substance, can result in soiling because of retention of melted suppositories, irritation of rectal mucosa.
5	Rectal stimulants: bisacodyl suppositories or micro-enema	Deliver stimulant/osmotic laxative to rectal mucosa.	Moderately invasive, use of rectal stimulant/osmotic laxative, can result in prolonged reflex rectal activity leading to incontinence, abdominal cramping, irritation of rectal mucosa, can result in soiling because of retention of melted suppositories.
6	Manual evacuation	Mechanical removal of stool from the bowel using a digit.	Very intimate and invasive, may be prolonged, low acceptability to patients and carers, risk of damage to anorectal mucosa if poorly conducted.
7	Stimulant oral laxative	Produce increased colorectal contractions.	Not intimate or invasive but has a systemic effect, which may result in abdominal cramps, pain, bloating and incontinence and may impair bowel function in the longer term.

Secondary outcomes were time to stool, level of intervention at which evacuation began and frequency of FI.

There is no literature regarding preferences of SCI individuals concerning BM intervention. All study participants were also asked to rank the BM interventions according to what they would prefer to use.

Sample size

To achieve an 80% power to detect a 40% decrease in patients needing laxatives, assuming a significance level of 5% (two sided) and using McNemar's test for paired measurements, a sample size of 175 individuals was required.

The same sample size would provide 90% power to detect a decrease of 60% in patients requiring manual evacuation, starting from a baseline level of 88% from a previous study.¹³

Randomization

Participants were randomized using computer-generated block randomization, four subjects to each block.

An individual not involved in the study placed each allocation in a sealed, opaque, consecutively numbered envelope. Allocation was unknown until consent was obtained.

Statistical methods

All data were entered onto a statistical software package (SPSS version 13 for Windows). Continuous data were analyzed using parametric tests if normally distributed (Student's *t*-test for independent variable, paired Student's *t*-test for two related variables); otherwise non-parametric tests were used (Mann-Whitney *U*-test for comparing independent variables, Wilcoxon signed-ranks test for related variables and the Kruskal-Wallis test for more than two variables). Categorical data were examined with the Pearson's chi-square test and correlations were conducted using Spearman's rho.

Analysis was conducted on an intention-to-treat basis, with the number of participants available for each test indicated. Data were analyzed in weeks, to allow change during the study to be detected. Frequency of BM varied between participants, so frequency data for interventions are presented as the percentage of BM episodes in which an intervention was used.

The sample

Figure 1 summarizes the flow of participants through the study.

In all, 68 individuals were recruited, 33 to the control group, 35 to the intervention group; no significant difference was found between the groups' demographic and injury details (Table 2). Baseline BM variables are presented in Table 3. There were no significant differences between the groups regarding duration of bowel care or level of intervention required to complete evacuation at baseline.

Results

Duration of participation in the study and data collected are summarized in Table 4. Reasons for withdrawing from

Figure 1 Flow of participants through the study.

the trial before 6 weeks are shown in Table 5. Intervention group members were significantly more likely than control group members to leave the study early ($P=0.02$).

Duration of bowel care was consistently longer in the intervention group (weekly means 48–67 min) than the control group (weekly means 32–37 min), significant only in week 6 ($P=0.05$). The hypothesis that use of a progressive protocol would improve bowel evacuation by reducing duration of BM episodes was not upheld.

Table 6 shows frequency of use of interventions as a percentage of all BM episodes, except manual evacuation, which is shown as a percentage of successful BM episodes. (Manual evacuation can only be used when stool is present in the rectum and can therefore only be recorded in episodes where stool was passed). The range was 0–100% in all cases except where shown.

Interventions 0–4 were used significantly more often by the intervention group ($P=0.01$), but there was no significant difference in frequency of more invasive interventions (5–7). There was no difference between the groups in the level of intervention at which bowel evacuation was completed ($P=0.4$ –0.1). Systematic use of less invasive interventions did not reduce the need for more invasive interventions. The hypothesis that use of a progressive protocol would reduce level of intervention required to complete evacuation was not upheld.

Compliance with the protocol was incomplete. To reach step 7 all previous steps should have been used; interventions 0–6 should have been used at least as often as step 7. Steps 5 and 6 were used less often than step 7.

Other outcome measures

Time to first stool was consistently longer in the intervention group (weekly mean 15–28 min) than the control group (weekly mean 10–14 min) ($P=0.2$ –0.5).

Table 2 Demographic and injury data for the sample

	Control (range)	Intervention (range)	Test statistic Mann–Whitney U-test	P-value
Age at study (median years)	47 (27–62)	49.50 (24–73)	553.50	0.76
Age at injury (median years)	31.74 (7–52)	24.57 (15–66)	499.00	0.33
Duration of injury (median years)	11 (1–42)	17 (2–47)	455.00	0.18
			Chi-Square	
Gender				
Female	12	11	0.18	0.79
Male	21	24		
Traumatic or non-traumatic				
Traumatic	29	34	2.14	0.14
Level of injury				
Cervical	9	16	0.20	0.20
Thoracic	21	18		
Lumbar	3	1		
Asia grade				
A	19	17	0.74	0.74
B	3	5		
C	2	4		
D	9	9		
Bowel function				
Reflex	28	31	0.20	0.65
Flaccid	5	4		

Table 3 Variables relevant to bowel function at baseline

	Control		Intervention		Test statistic Mann–Whitney U-test	P-value
	n	Median (range)	n	Median (range)		
Duration of bowel management (minutes)	26	35 (5–310)	30	45 (1–265)	335.50	0.37
Time to stool (minutes)	24	9	29	19	257.00	0.10
Level of intervention to open bowels	20	6 (3–8)	21	6 (0–8)	205.00	0.11
Level at which BM completed	24	7 (1–8)	25	6.5 (0–7)	305.50	0.38
% of BM episodes successful	27	100 (50–100)	29	100 (50–100)	317.50	0.12
Number of medications daily	33	2 (0–7)	35	2 (0–9)	–0.273	0.97
Portions of fruit/vegetables daily	32	2.5 (0–6)	33	3 (0–5)	0.506	0.92
Portions of whole grain foods daily	32	0.75 (0–3)	35	1.75 (0–5)	0.699	0.57
Fluid intake—ml per 24 h	32	1400 (600–3590)	35	1525 (800–3900)	0.526	0.15

Abbreviation: BM, bowel management.

Time in minutes has been rounded to the nearest whole number.

Table 4 Participation in study

	Control group Total recorded	Per control participant (n = 33) Median (range)	Intervention group Total recorded	Per intervention group participant (n = 35) Median (range)	Mann– Whitney U-test	P-value
BMEs recorded	1003	22 (0–211)	511	18 (0–69)	406.00	0.03
Days in trial	1194	42 (0–42)	882	42 (0–42)	415.50	0.01
Weeks in trial	170	6 (0–6)	125	6 (0–6)	412.50	0.01

Abbreviation: BME, bowel management episode.

Modal level at which stool evacuation began was significantly lower in the intervention group (weekly mode level 4) compared with the control group (weekly mode 6) ($P=0.05$ – 0.01) in weeks 1–4. All interventions except

perianal skin stimulation initiated an evacuation at least once.

Frequency of FI was significantly higher in the intervention group (weekly median 0–10 episodes) than the

Table 5 Reasons for withdrawal from the trial before 6 weeks

	Control intervention	
Felt protocol ineffective		3
Bladder infection (taking antibiotics—diarrhea)		1
Community nurse unwilling to participate		1
Health reasons unrelated to trial		1
Other (holiday, effective advice at first interview)		4
Attended second interview but never returned diary	2	
Unknown	5	6
Total	7	17

Table 6 Bowel management interventions used in the trial

Step	Control group		Intervention group		P-value
	Number of times used	Used in % of BM episodes	Number of times used	Used in % of BM episodes	
0	153	15.25	368	72.01	<0.001
1	137	13.65	340	66.53	<0.001
2	0		232	45.40	<0.001
3	284	28.31	325	63.60	<0.001
4	386	38.48	302	59.09	0.01
5	107	10.66	86	16.82	NS
6	376	42.29 ^a	239	56.5 ^a	NS
7	361	35.99	229	44.81	NS

Abbreviation: BM, bowel management; NS, not significant.

^aPercentage of successful bowel management episodes.

Figure 2 First three preferences for interventions.

control group (weekly median 0–5 episodes) for 4 out of 6 weeks of the trial ($P=0.02$ – 0.05). There was no difference between the groups in the percentage of BM episodes where stool was passed, stool consistency or diet and fluid intake.

The first three preferences among interventions indicated by participants are shown in Figure 2. Abdominal massage, oral laxatives and glycerin suppositories accounted for more than 65% of the first choices indicated. Manual evacuation was the first choice of 12% of participants, medicated suppositories of 5% and digital stimulation of 4.5%.

Discussion

Use of assistive, less invasive, techniques in a stepwise protocol for BM did not reduce duration of bowel care or the need for manual evacuation of stool and oral laxatives in individuals with chronic SCI. Indeed, it prolonged time taken for BM.

These findings contrast with previous published findings in which overall level of intervention and duration were reduced in both new and chronic SCI individuals after a similar protocol.^{12,13} However, the samples in these previous studies were younger and injured for a shorter time. Increasing age and duration of injury are associated with increased use of medicated rectal stimulants, manual evacuation and oral laxatives;³ response to less invasive BM techniques may be reduced as time since injury increases. The earlier studies were conducted with inpatients; BM was delivered or overseen by nurses. In this study, BM was conducted by individuals in the community. However, a lower level of intervention initiated evacuation in the intervention group suggesting that less invasive techniques such as stimulating the gastrocolic reflex and abdominal massage may have a role in the bowel evacuation process.

Laxative use is associated with FI and difficulty with evacuation, and regular use may lead to an increased need for laxatives over time,^{2,7} hence long-term use is often discouraged. However, no studies have elucidated a causal relationship and the direction of the association is open to debate, that is, are laxatives used more by individuals with these problems or do they cause them? Increased FI in the intervention group (with unchanged laxative use) suggests that laxatives alone do not explain increased FI. Age and duration of injury may be associated with reduced responsiveness to laxatives; megacolon and megarectum are common in chronic SCI of more than 10 years duration¹⁵ and contribute to reduced responsiveness to both laxative therapy and physical interventions.

Participants indicated a preference for less physically invasive interventions. Although manual evacuation was infrequently a first choice in a hypothetical situation, for many manual evacuation of stool is an essential part of effective BM. Systematic use of other interventions did not avoid its use. It is a controversial intervention, with many nurses/carers uncertain regarding their role.¹⁶ Limited understanding of the need for this intervention has resulted in difficulties for SCI individuals when nursed in general hospitals,¹⁷ and the community. However, manual evacuation is associated with shorter duration of bowel care^{3,8} and it is the most common intervention among UK community-based SCI individuals.³ It is acceptable to SCI individuals because it is an effective intervention.

Digital anorectal stimulation was infrequently used by this sample. It has been reported that just 38–42% of those whom it may benefit use the technique and it is associated with longer duration of care.³ Using the stepwise protocol, anorectal stimulation initiated stool passage less frequently than gastrocolic reflex, glycerin suppositories or manual evacuation. This apparent lack of effectiveness may be

related to age and duration of injury, and development of megacolon, and may explain, along with its very personal, physical nature, why it is not a preferred option.

Medicated rectal stimulants were the first choice of only 5% of participants, and they were sometimes omitted as a step in the protocol. The reason for this is not clear. Anecdotally, medicated rectal stimulants are thought to increase episodes of FI but there is little evidence for this.

The use of a stepwise protocol for bowel care restricted the ability of participants to adjust their BM program to meet their own needs. Baseline assessments indicated that although all individuals used a narrow range of interventions, the combinations, timing and ordering was individual. BM routines commenced in a specialist unit before discharge will develop after discharge.^{18,19} The bowel program developed by SCI individuals reflects not only their residual bowel function, mobility, manual dexterity and the availability of assistance but is also shaped by lifestyle demands and personal preferences. The need to meet commitments within and outside the home restricts the time individuals choose to spend on BM; being independent will likely influence the choice of intervention. The degree of individuality developed after discharge in BM indicates that rigid protocols are inappropriate.³

Recruitment issues

Recruitment to this study was challenging. The study was underpowered. However, there was no indication of a trend to uphold the hypotheses—rather the reverse. The majority of interventional bowel-related studies in this population report very small samples and this may reflect generally low recruitment rates.²⁰

Among those that attended for the previous anorectal physiology study but who declined inclusion in this trial, a number of issues regarding BM research were identified. Many felt that they lacked time because of work, educational, family or carer commitments, BM had to fit into an often tight schedule. This may have led to a selection bias toward more available older or less independent participants. Those receiving assistance with BM were often unwilling to approach their carer to participate. Those receiving care from a working partner often already experienced some anxiety regarding the effect of their bowel care needs; any change to their routine that might affect their 'balancing act' was unwelcome.

Although dissatisfaction with BM may increase motivation to participate in research, many individuals, even those frankly dissatisfied, were unwilling to examine alternatives, which might increase risk of FI or greater duration of BM. There was an acceptance of the *status quo*; they had learned how to cope with their altered bowel function and BM as they now conducted it, possibly using reappraisal strategies.²⁰ Individuals indicated that allowing the research to impinge on their everyday life was unacceptable. These views underline how integral BM is to everyday life and illustrate why recruitment is so problematic.

Conclusions

Systematic use of assistive interventions does not reduce the need for manual evacuation and oral laxation in chronic SCI. Manual evacuation of stool is accepted as essential if unwelcome by many. Inflexible protocols are inappropriate in addressing the needs of these individuals. Working with SCI individuals in guided experimentation to identify interventions, which best suit them, is a more appropriate way of developing effective BM than advocating rigid protocols. Recruitment into interventional BM trials is challenging, and samples may not be representative of the general SCI population.

Conflict of interest

The authors declare no conflict of interest.

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