

A RANDOMISED CONTROLLED TRIAL OF A PROGRESSIVE PROTOCOL FOR NEUROGENIC BOWEL MANAGEMENT

Hypothesis / aims of study

The impact of spinal cord injury (SCI) on bowel function and control is profound and has major implications for quality of life following injury. Bowel management programmes are based on regular routine, dietary manipulation, laxatives, rectal stimulation and manual evacuation of stool. Abdominal massage may be used, and anecdotally skin touch stimulation may also be employed. Some bowel management interventions are often regarded as 'invasive' (manual evacuation of stool, anorectal digitation) and are unpopular with patients and healthcare professionals. Despite the importance of this area of care to these patients there is very little evidence to support nursing practice. Hence, the development of bowel management programmes relies upon the experience of the healthcare professional and trial and error. The aim of this study was to evaluate the effectiveness of physical assistive techniques for bowel management when combined in a bowel management programme. A step-wise protocol was developed which would allow both the impact of each intervention and the effects of the combined interventions to be assessed. A randomised controlled trial was conducted to address the following research questions:

- Can the use of a stepwise progressive protocol improve bowel care in chronic SCI individuals by reducing the level of intervention required for management as ordered on the stepwise protocol, or by reducing the duration of each management episode?
- Is the use of a stepwise progressive protocol for bowel management acceptable to SCI individuals?
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Study design, materials and methods

A stepwise protocol was developed in which interventions were ordered from the least invasive to the most invasive (see Figure 1), based on previously published work (1).

Step 0	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7
Gastrocolic reflex	Abdominal massage	Peri-anal digitation	Ano-rectal digitation	Glycerin suppositories	Rectal laxative	Manual evacuation	Oral laxative

The findings of a previous similar study undertaken with newly injured individuals (2) were used to assist in the calculation of the sample size. While the aim of this study was not the same as the first, no other information was available on which to base a power calculation. To achieve an 80% power to detect a 40% decrease in patients needing laxatives, (significance level of 5% (two tailed)) and using McNemar's test for paired measurements a sample size of 175 individuals was required. The number would also provide over 90% power to detect a decrease of 60% in patients requiring manual evacuation, starting from the pilot study baseline level of 88%. Again, this is based on McNemar's test, with two-sided significance level of 5%. Individuals SCI for more than 1 year post discharge with any level and density of injury were eligible. All participants maintained a two week bowel diary prior to random allocation to intervention (progressive protocol) or control (usual bowel care) groups. Those allocated to the intervention were given verbal and printed information about how to follow the protocol. At each episode of bowel care, the protocol was followed until evacuation was achieved. The main outcome measure was a bowel diary (including dietary/fluid intake once a week) in which participants recorded duration of each episode, interventions used, and results. Participants could remain in the study for up to 6 weeks.

Results

Sixty eight individuals were recruited to the study: 33 to the control group, 35 to the intervention group. Their demographic and injury details are presented and compared in Table 1. Baseline bowel diaries demonstrated that while all individuals used a narrow range of options to manage their bowel, the way in which they combined and ordered the interventions varied from individual to individual. Recruitment to the study was challenging and the drop out rate from the study was significantly higher in the intervention group than the control group ($p=.02$).

		Control	Intervention	Test Statistic	Sig.
				Mann-Whitney U	
Age at study	Median years	47	49.50	553.50	0.76
Duration of injury	Median years	11	17	455.00	0.18
				Chi Square	
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		

'Intention to treat' analysis was undertaken. There was no difference in dietary or fluid intake between the groups. Time to stool and total bowel care took longer in the intervention group though this did not reach significance, except in weeks 3 and 6 respectively. Compliance with the protocol was incomplete but the intervention group used steps 0 – 4 significantly more often than the control group ($p=.01-.001$), but use of steps 5 – 7 were not different. Median level at which stool passage commenced was significantly lower in the intervention group ($p=.01-.05$). The use of a progressive protocol reduced neither the duration of bowel care nor the level of intervention required for effective bowel care. However, the small sample size means there was a risk of a type 1 error.

Interpretation of results

The systematic use of less invasive interventions in a stepwise protocol did not reduce the need for more invasive techniques such as manual evacuation and oral laxatives for bowel care, nor was the protocol able to deliver the reduction in duration of care that was the stated objective of more than 20% of study participants. However, the reduced level of intervention resulting in stool passage in the intervention group suggested that less invasive interventions can make a contribution to bowel management. The higher drop out rate from the intervention group underlines the individual nature of bowel care in chronic SCI; a rigid protocol reduces the ability of individuals to adjust and adapt their programme to meet their own perceived needs and is unacceptable to many.

Concluding message

The study was limited by a small sample size, and by the self administration of the intervention and reporting of the results. However, the results of this study clearly point to the need for manual evacuation in conservative bowel management and suggest that inflexible protocols which do not allow for individual variation in response to bowel management interventions are not appropriate in addressing the needs of chronic SCI individuals. The findings lend support to the use of less invasive interventions in a more flexible way; working with individuals in guided experimentation to identify those interventions which best suit them is a more appropriate way of developing effective bowel management in this population.

References

Spinal Cord (1997), **35** 2, 116-120.
British Journal of Nursing (2006), **15** 20, 1108-1113.

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HUMAN SUBJECTS: This study was approved by the Vale of Aylesbury Local Research Ethics Committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.