The retrograde continence enema in children with spina bifida: not as effective as first thought

Original Article

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Abstract

Aims: To investigate the effectiveness of Peristeen retrograde continence enema (RCE) in the management of faecal incontinence in children with spina bifida.

Methods: We identified an homogenous group of spina bifida patients in whom RCE was initiated (01/2006 – 07/2013). Confidential assessments included: (1) Fecal Incontinence Quality Of Life (FIQOL), (2) St Marks Faecal Incontinence score, (3) Cleveland Clinic Constipation score, and, (4) Neurogenic Bowel Dysfunction score.

Results: 11/20 patients (mean age 14.5 ± 5.3 years) were male. 9/20 patients were still using RCE (mean follow-up 4.1 years). Three patients ceased RCE within ten days, six after 4-12 months, and two after 36-48 months. Reasons for cessation included balloon difficulties ($n = 4$), procedure deemed too difficult ($n = 4$), and pain ($n = 3$).

There were no differences between the groups in length of training time for technique, instillate fluid/volume used, and time taken to perform RCE. There were no differences between the groups for quality of life, faecal incontinence or constipation scores.

Conclusions: We demonstrated a high rate of cessation with the RCE in patients with spina bifida. This could not be explained by associated

conditions, or by enema-related parameters. One possible explanation is the lack of on-going outpatient support for the children and their families.

Keywords: spina bifida, retrograde continence enema, Peristeen, faecal incontinence

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What is already known on this topic

- (1) Children with spina bifida are commonly affected by faecal and urinary incontinence.
- (2) The management of faecal incontinence in spina bifida is complex; hence the existence of multiple non-operative and operative interventions.
- (3) Faecal incontinence may have a significant impact upon the quality of life in affected children.

What this paper adds

- (1) The retrograde continence enema may be effective in the management of faecal incontinence in a select population of children with spina bifida.
- (2) Success with the retrograde continence enema relies upon parental and patient compliance.
- (3) The current study focused upon an homogenous selection of patients, unlike the majority of similar studies published in the literature.

Introduction

Faecal incontinence affects the majority of children with spina bifida. [1] As the neurological abnormalities are life-long it is important to provide a mechanism for both the patient and their family to manage the incontinence. The psychological impact of faecal incontinence upon a child is potentially significant. [2] Consequently, the treatment regimen to manage the incontinence must be effective, but also tolerable.

Spina bifida patients may manage faecal incontinence in a number of ways. Unfortunately, the administration of oral medications often has a limited role. [3] Whilst the use of PEG3350 has increased over the last decade with greater evidence of its effectiveness in patients with idiopathic constipation, its role in the management of spina bifida patients remains unclear. [4]

The antegrade continence enema (ACE), administered via a caecostomy, was first described in 1990 by Malone *et al.* [5] The ACE has been shown to effectively treat faecal incontinence and chronic constipation in both children and adults. The most common indication for the ACE has been spina bifida. [6-9] However, as effective as this treatment regimen has proven to be, it requires an operation to form the appendicostomy or caecostomy. It is also associated with short and long term complications, including recurrent infections and possible creation of a false passage. [10]

The retrograde colonic enema (RCE) has been used effectively for many centuries. Shandling and Gilmour, at the Hospital for Sick Children Toronto, demonstrated its role in children with spina bifida over 25 years ago. [11] Since then there have been numerous modifications to improve the efficacy of this treatment modality. Whilst there is some evidence in the adult

literature of the effectiveness of RCE [12], the evidence for the paediatric population is less impressive and in more heterogenous patient populations. [3, 13-15]

We investigated the effectiveness of the Peristeen system (Coloplast, Mount Waverley, Victoria, Australia) in the management of faecal incontinence in children with spina bifida. Peristeen is an enclosed catheter system with a pre-coated catheter and a soft, inflatable balloon. The balloon catheter is placed through the anus into the rectum, and then gently inflated to create a seal. Irrigation fluid is then passed through the catheter into the rectum, with a resultant retrograde colonic washout. This aims to provide the patient with an empty distal colon and rectum until the next washout, thus reducing the risk of faecal incontinence. By focusing upon a patient group with a unifying diagnosis we wished to clearly show the outcomes for that condition alone.

Materials and Methods

All patients with spina bifida in whom Peristeen had been initiated between January 2006 and July 2013 were identified. All patients had failed more conventional forms of bowel management, including dietary modifications and oral laxative therapies and suppositories. Patients were managed at either The Royal Children's Hospital or Monash Medical Centre by the senior author (YH). An independent investigator (SKK), not involved in patient care, contacted patient families following ethical approval from both hospitals (RCH HREC 33107A, MMC HREC 14079X). Following informed consent with the parent or carer, confidential phone interviews were conducted. The data were entered into a Microsoft Excel programme (Microsoft, Seattle). All information was cross-referenced with hospital systems to ensure accuracy.

Thirty-three patients with spina bifida, in whom Peristeen was trialled, were identified. The information collected included: (1) diagnosis, (2) presence of ventriculoperitoneal shunt, (3) ventriculoperitoneal shunt revision(s), (4) associated anomalies, (5) presence of urinary incontinence, (6) management of urinary incontinence, (7) degree of mobility, (8) age at commencement of Peristeen, (9) time taken to train technique, (10) fluid used, (11) fluid volumes used, (12) duration of use, (13) complications, (14) cessation of use, and, (15) reasons for cessation.

Multiple assessments of quality of life, continence and constipation were conducted. These included: (1) Fecal Incontinence Quality Of Life (FIQOL) [16], (2) St Marks Faecal Incontinence score [17], (3) Cleveland Clinic Constipation score [18], and, (4) Neurogenic Bowel Dysfunction score.

[19] Pseudocontinence was defined as no involuntary stool loss in the preceding six months, as per Vande Velde. [13] The FIC QOL was also collected for all patients for future prospective analysis. [20]

The FIQOL scale comprises four quality of life scales, including lifestyle, coping/behaviour, depression/self-perception, and embarrassment. It has been shown to be both a reliable and valid measure in adult populations. The St Marks Incontinence score focuses upon aspects of faecal incontinence, including: (1) incontinence of solid, liquid and gas, (2) alterations in lifestyle, (3) the need for a pad, (4) the requirement for constipating medications, and, (5) an inability to defer defaecation.

The Cleveland Clinic Constipation score assesses the severity of the patient's constipation. It contains eight parameters, including frequency of bowel movements, straining, completeness of evacuation, abdominal pain, time per attempt at evacuation, type of assistance, number of unsuccessful attempts, and duration of constipation. It has been validated in adult populations. The Neurogenic Bowel Dysfunction score is a validated symptom-based score developed specifically in spinal cord injury patients with neurogenic bowel dysfunction. The score focuses upon background parameters, faecal incontinence, constipation, obstructed defaecation, and impact upon quality of life. It has been used in both paediatric and adult populations.

The mean and standard deviation (SD) are presented for symmetric data, while for skewed data the median and interquartile ranges (IQR) are shown. Differences in means between study arms were assessed using a two-sample t-test. A Mann-Whitney test was performed on skewed data.

Dichotomous outcomes were compared with the Fisher exact test. A p-value < 0.05 was considered as significant.

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Results

Interviews were conducted with 20/33 families. The remaining 13 families were either unable to be contacted, or unable to perform the questionnaire over the phone due to language difficulties. Interviews were performed with the patient's mother in 15/20, the patient's father in 5/20, and lasted 45 – 60 minutes.

Of the 20 children, 11 were male. The mean age at time of interview was 14.5 ± 5.3 years. The mean follow-up period was 4.1 years (1 – 8 years). The comparison between those patients still using Peristeen and those patients no longer using Peristeen is displayed in Table 1. The results obtained for both groups for FIQOL, St Marks Incontinence score, Cleveland Clinic Constipation score and Neurogenic Bowel score are displayed in Table 2.

There was a preponderance of males in the group in whom Peristeen was successful (7/11 [64%] versus 2/9 [22%]). The two groups were similar with regards to their ages at time of interview ($p = 0.44$) and those patients still using Peristeen commenced therapy at a younger age, though this was not statistically significant ($p = 0.23$). All patients had urinary incontinence and, in the majority, this was managed using CIC via the native urethra. There were no differences between the two groups with regards to length of time training for the technique, the instillate fluid and volume used, and the time taken to perform the regimen. There was a significant difference between the two groups in the time period for which Peristeen was employed ($p = 0.001$). Those still using Peristeen were more dependent upon others for assistance than those that ceased to use the technique (7/9 [78%] versus 4/11 [36%]).

There were no differences between the scores obtained for the two groups with regards to FIQOL, St Marks Faecal Incontinence, Cleveland Clinic Constipation and Neurogenic Bowel Dysfunction. Eight out of nine patients using Peristeen achieved pseudocontinence, while one remained incontinent. Among those patients that ceased to use Peristeen, 5/11 subsequently achieved pseudocontinence: three after migrating to ACE, two by conventional therapies (diet, suppositories). Six patients had persisting faecal incontinence. The reasons for ceasing to use Peristeen were: difficulties with the balloon (n = 4); procedure described as too difficult and invasive (n = 3) or painful (n = 3); and one patient stopped after experiencing vasovagal episodes. Three patients ceased using Peristeen within one week of commencement of the treatment.

Discussion

Colonic enemas, either retrograde or antegrade, are valuable treatment options for faecal incontinence caused by congenital malformations affecting the spinal cord or the anorectum. [13, 21] In adults with central nervous system diseases, there are no current evidence-based recommendations for faecal incontinence management. [22] Current management favours an individually-tailored, stepwise approach: typically, a form of RCE, in our study Peristeen, is part of a conservative bowel management and is trialed after failure of conventional treatment, including toileting routines and laxatives. [13, 23] Surgical procedures, including formation of appendicostomy, resection of megarectosigmoid or formation of colostomy, may be considered in patients unsuccessfully managed conservatively. [24] In patients with spina bifida and faecal incontinence, the evidence for efficacy of the RCE is based upon observational studies. [12]

In our current study of a select group of patients with spina bifida, 33 were offered Peristeen to treat faecal incontinence. Of 20 patients interviewed 11 had ceased to use Peristeen, a higher rate of failure than typically reported. In comparison, Shandling *et al.* and Vande Velde *et al.* reported respectively 4/112 and 5/116 cessations of retrograde colonic enemas in cohort studies of patients with spina bifida and faecal incontinence. [9, 13] Our results more closely resemble those of Liptak *et al.*, where 15/31 children had stopped using RCE at the end of a 30-month follow-up. [25] Interestingly, of the 15 children, six ceased in the first three weeks. In our cohort, 3/11 ceased within one week of commencing the treatment.

The distributions of neurological and neurosurgical associated anomalies, urinary incontinence, and mobility were the same in both our groups. Moreover, there were no differences in the age at commencement of Peristeen, nor the time spent training, in accordance with other studies. [13, 26] Volume of irrigation and type of instillate used, as well as time spent on irrigation, were similar between both groups, again consistent with previous studies. [27]

Harari *et al.* [28] demonstrated in a randomized controlled trial that a structured, nurse-led assessment, leading to a targeted treatment of faecal incontinence and constipation in stroke patients, improved symptoms of bowel dysfunction. Although difficult to measure or to demonstrate, regular follow-up and easy availability of professional medical or psychological support could be important components for a successful management of faecal incontinence. [13] In our cohort, there were no significant differences in the various scores used to assess bowel dysfunction between the two groups: as the severity of faecal incontinence is similar, reasons for cessation could be subjective. In our institutions, multidisciplinary teams manage children with spina bifida, including specialized stoma therapists. A difference between the needs of our cohort and the available supports for on-going therapy and troubleshooting could be an explanation for our high rate of failure. Unfortunately, the quality of the follow-up was not captured by our questionnaires.

According to a review by Vande Velde, pseudocontinence was achieved in 80% of patients using RCE. [29] Although spina bifida was the underlying condition in the majority of patients pooled, miscellaneous conditions were considered. In our study, 8/9 patients still using Peristeen

achieved pseudocontinence. This rate is compatible with the overall statement that RCE has a high efficacy in carefully selected patients. [9] Unfortunately, there are no randomized controlled studies in spina bifida patients to assess the efficacy of RCE against another form of treatment. However, the RCE was found superior to conservative bowel management in a randomized control trial in spinal cord-injured adults. [30]

A number of our patients who ceased using Peristeen were able to achieve pseudocontinence after an ACE procedure or by employing conventional therapies (diet, suppositories). Matsuno *et al.* [31] compared RCE to the ACE procedure in a retrospective study in children with spina bifida. Rates of faecal pseudocontinence were similar, 10/13 (77%) and 9/12 (75%) respectively. However, they found that procedural independence was higher in the antegrade group. In our study, patients of both groups showed a certain degree of dependence.

Limitations of our study were that it was retrospective and, as already mentioned, 13/33 were either lost to follow-up or unable to answer the questionnaires. Consequently, our cohort is small: statistical significance should be considered with caution. However, few studies report a high rate of unsuccessful management with RCE, so that this group is rarely characterized. In addition, few studies have focused on a homogenous group of spina bifida patients.

In conclusion, our study of the effectiveness of RCE in the management of faecal incontinence in children with spina bifida demonstrated a high rate of cessation. This could not be explained by associated conditions nor enema-related parameters. One possible explanation is the lack of on-

going outpatient support for the child and their family. The RCE remains an important option prior to surgery. However, long-term follow-up studies and randomized control trials comparing RCE and conventional treatments are needed to establish the true efficacy of the RCE.

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Table 1 – Characteristics of patients in whom Peristeen was still being used versus those in whom Peristeen was no longer being used

Characteristic	Still in use	No longer used
Patients	9	11
Gender		
- male	7	4
- female	2	7
Age in years (mean, (SD))	13.4 (5.8)	15.5 (5.0)
VP shunt	9	7
VP shunt revision(s)	7	6
Associated anomalies	4	2
- scoliosis	1	1
- Arnold Chiari	2	1
- epilepsy	1	0
- microcephaly	1	0
Urinary incontinence	9	11
- CIC via urethra	7	8
- CIC via Mitrofanoff	0	2
- bladder augmentation	0	1
- nil catheterisation	2	0
Mobility		
- walk independently	0	3
- with with AFO	5	2
- walk with crutches	1	1
- wheelchair	3	5
Age at commencement in years (mean, (SD))	9.4 (6.0)	12.3 (4.2)
Time for training	1 hour (1, 1h – 1d)	1 hour (1, 1h – 2d)
Instillate used		
- water	8	11
- saline	1	0

Instillate volume in millilitres (mean, (SD))	400 (180.3)	419 (140.1)
Time taken to perform in minutes (mean, (SD))	46.1 (14.7)	38.2 (17.6)
Frequency of use		
- daily	1	2
- 2 nd daily	6	4
- twice/week	2	5
Duration of use in months (median, (IQR))	48 (24 – 69)	6 (0.25 – 12) [#]
Migration to ACE	0	3
Degree of independence with RCE		
- excellent	0	2
- moderate	2	5
- dependent	7	4

[#] p = 0.001

VP – ventriculoperitoneal shunt, CIC – clean intermittent catheterisation, AFO – ankle foot orthosis, ACE – antegrade continence enema, RCE – retrograde continence enema

Table 2 – Scores of patients in whom Peristeen was still being used versus those in whom Peristeen was no longer being used

Score	Still in use	No longer used	p
FIQOL	92.9 (15.8)	85.2 (14.3)	0.28
(29 – 119, 29 = poor)			
St Marks Faecal Incontinence	14.7 (3.3)	16.7 (4.5)	0.27
(0 – 24, 24 = severe)			
Cleveland Clinic Constipation	13.1 (3.0)	10.8 (5.0)	0.24
(0 – 30, 30 = severe)			
Neurogenic Bowel Dysfunction	11.8 (5.1)	12.5 (6.8)	0.78
(0 – 47, 47 = severe)			

FIQOL = Fecal Incontinence Quality Of Life; results displayed as means (SD)

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