

# *Evidence summary*

*Transanal irrigation for the  
management of bowel  
dysfunction in adults*

2018

# Transanal irrigation for the management of bowel dysfunction in adult patients

## Introduction

This booklet summarises some of the key data on the use of transanal irrigation (TAI) and Peristeen® in adult patients, primarily those with neurogenic bowel dysfunction (NBD), in terms of efficacy, safety, well-being, quality of life, and overall cost to society.

## Defaecation disturbances affect many individuals

Bowel dysfunction is a term that englobes a range of defaecation disturbances, mainly constipation and faecal incontinence. Constipation of any cause is a hugely prevalent problem. Data from the UK estimate that, at any one time, up to 1 in 7 adults are affected by it.<sup>1</sup>

Some groups of patients are particularly prone to develop bowel dysfunction; spinal cord-injured patients (SCI), patients with spina bifida, multiple sclerosis and other neurologic conditions conform a group called neurogenic bowel dysfunction (NBD). The neurologic damage or malfunction present in these conditions causes deficient or absent sensitivity, motility and neurologic control over the large bowel and sphincters.

There are many other causes of bowel dysfunction; in some patients it will be caused by pelvic muscle dysfunction or prolapse, in others it can be due to obstructed defecation (for example in cases of rectocele), whereas in other patients it may be due to iatrogenic post-surgical sequelae, or in women with obstetric sphincter injury after vaginal delivery.

Finally there will be a large group of patients where no anatomic, neurologic or iatrogenic cause can be found; these will be often referred to as functional or idiopathic bowel dysfunction patients.

- Moderate-to-severe NBD symptoms affect approximately half of all patients with SCI<sup>2</sup>
- Approximately 70% of patients with multiple sclerosis develop bowel symptoms<sup>3</sup>

## The importance of an effective bowel care routine

The symptoms of bowel dysfunction can cause significant physical and emotional distress, affecting self-esteem,<sup>4</sup> personal relationships,<sup>4</sup> and social life.<sup>5</sup> Quality of life has been observed to decrease as the severity of NBD increases<sup>2</sup> and patients with SCI report that bowel dysfunction impacts more on life than any other SCI-related impairment.<sup>6</sup> As well as being socially disabling, NBD may cause patients to experience pain, bloating and discomfort on a regular basis. Many patients with NBD spend a significant part of their day on bowel management: 14% to 63% spend more than 1 hour on each episode.<sup>7</sup>

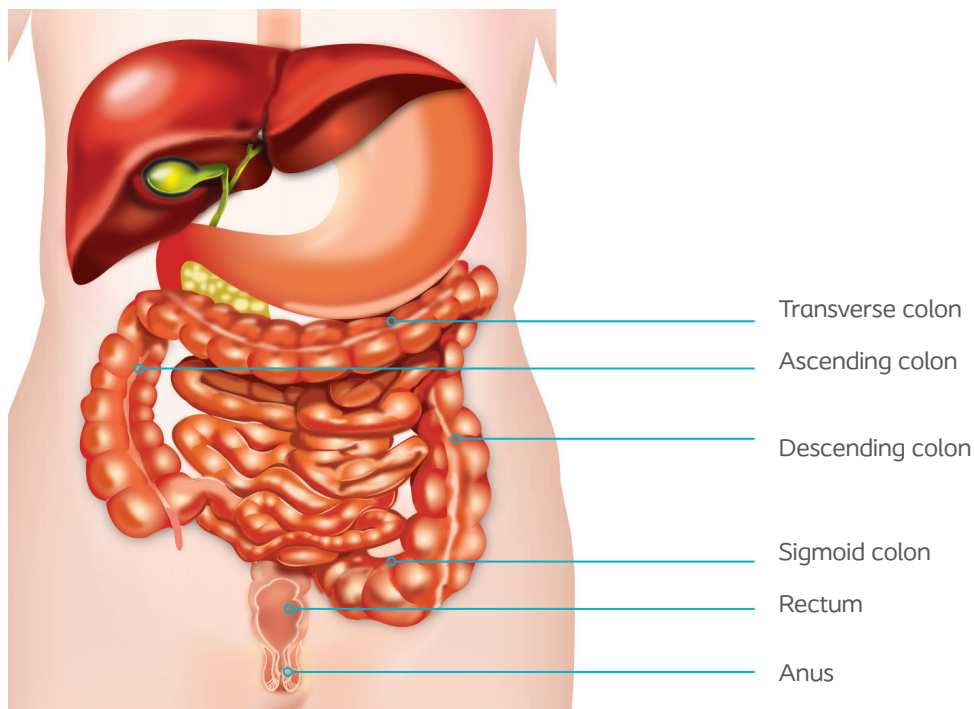
# Transanal irrigation

## – putting patients in control

In addition to providing relief from the symptoms of bowel dysfunction, the ideal bowel management routine should support the patient's dignity and independence to help promote their self-esteem and minimise the cost of assistance from healthcare professionals and carers.

TAI is a technique used to empty faeces from the bowel in a controlled manner and is an alternative to conventional bowel management strategies. Water is introduced into the rectum and colon via the anus, and subsequently evacuated into a toilet together with the content of the descending colon, sigmoid and rectum.

Figure: The bowel

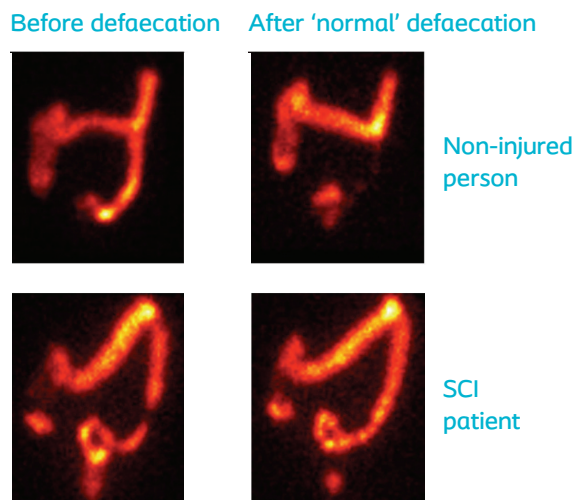


Conducting TAI on a regular basis can be used to help prevent accidents in patients with faecal incontinence; clinical studies observe fewer urinary tract infections (UTIs) than conservative bowel management strategies.<sup>7,8</sup> In addition, regular evacuation of the recto-sigmoid area promotes transport through the entire colon, therefore helping to prevent blockages in patients with constipation. TAI should always be started under a healthcare professional supervision. However, after an initial period of training, many individuals can successfully take control of their own bowel management by conducting TAI, without the help of a carer.

# How transanal irrigation works to normalise bowel function

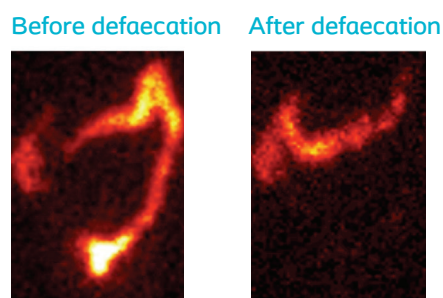
Radiographic markers and contrasts can be used to visualise the contents of the bowel (the scintigraphy method). Using this technique, the images below show how SCI can affect emptying of the bowel.<sup>9</sup> In a non-injured person, the rectum and most of the descending colon are empty after defaecation. In contrast, in a patient with SCI, a lot of faeces remain in the bowel after defaecation, putting the person at risk of a faecal incontinence episode.

Figure: Scintigraphic images of the bowel without using TAI



The following two images show the bowel contents of an SCI patient – this time before and after defaecation using TAI. After TAI, the contents of the rectum, sigmoid and most of the descending colon have been efficiently emptied; the image resembles what would be seen after defaecation in a non-injured person. After TAI, new faeces take an average of two days to reach the rectum,<sup>9</sup> helping users of TAI to remain continent between regular irrigations.

Figure: Scintigraphic images of the bowel in an SCI patient using TAI



# Index of studies

A randomized, controlled trial of transanal irrigation versus conservative bowel management in spinal cord-injured patients Christensen P, et al. <i>Gastroenterology</i> 2006;131:738–747	6
Treatment of neurogenic bowel dysfunction using transanal irrigation: a multicenter Italian study Del Popolo G, et al. <i>Spinal Cord</i> 2008;46:517–522	10
Cost-effectiveness of transanal irrigation versus conservative bowel management for spinal cord injury patients Christensen P, et al. <i>Spinal Cord</i> 2009;47:138–143	12
Long-term outcome and safety of transanal colonic irrigation for neurogenic bowel dysfunction Faaborg PM, et al. <i>Spinal Cord</i> 2009;47:545–549	14
Long-term efficacy and safety of transanal irrigation in multiple sclerosis Passananti V et al. <i>Neurogastroenterol Motil.</i> 2016 Sep;28(9):1349-55	16
Long-term follow-up of retrograde colonic irrigation for defaecation disturbances Gosselink MP, et al. <i>Colorectal Dis</i> 2005;7:65–69	18
Neurogenic bowel dysfunction score Krogh K, et al. <i>Spinal Cord</i> 2006;44:625–631	20
Review of the efficacy and safety of transanal irrigation for neurogenic bowel dysfunction Emmanuel A. <i>Spinal Cord</i> 2010;48:664–673	23
Neurogenic bowel management after spinal cord injury: a systematic review of the evidence Krassioukov A, et al. <i>Spinal Cord</i> 2010;48:718–733	24
Transanal irrigation therapy to treat adult chronic functional constipation; systematic review and meta-analysis Emmett et al. <i>BMC Gastroenterology</i> (2015) 15:139	26
Transanal irrigation for disordered defecation: a systematic review Christensen P, Krogh K. <i>Scand J Gastroenterol</i> 2010;45:517–527	28
Transanal irrigation for the management of neurogenic bowel dysfunction: summary of benefits	30

# A randomized, controlled trial of transanal irrigation versus conservative bowel management in spinal cord-injured patients<sup>7</sup>

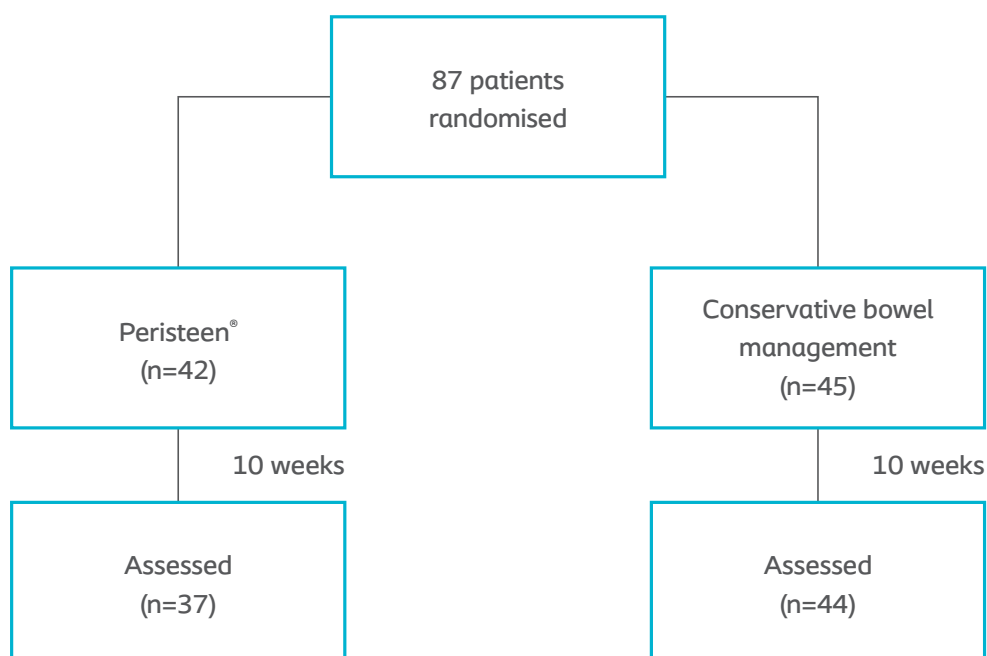
Christensen P, et al. *Gastroenterology* 2006;131:738–747

## Intervention:

Transanal irrigation (TAI) with Peristeen® vs conservative bowel management (best supportive care without irrigation).

## Study design:

Large, prospective, multicentre, randomised controlled trial (10 weeks).

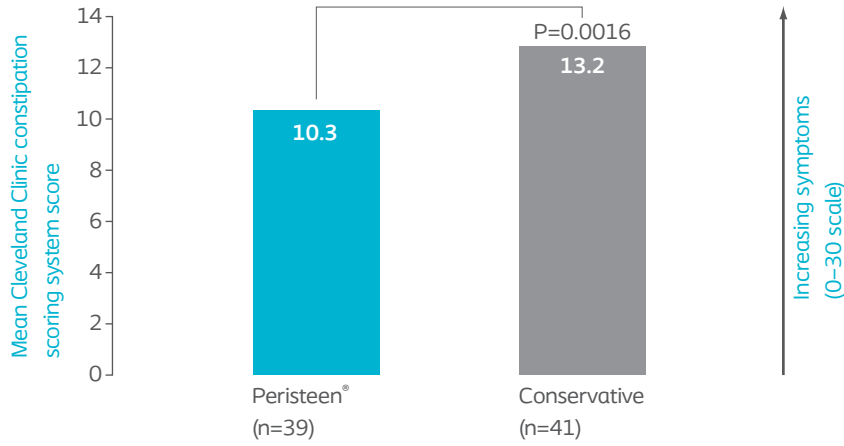


## Patients:

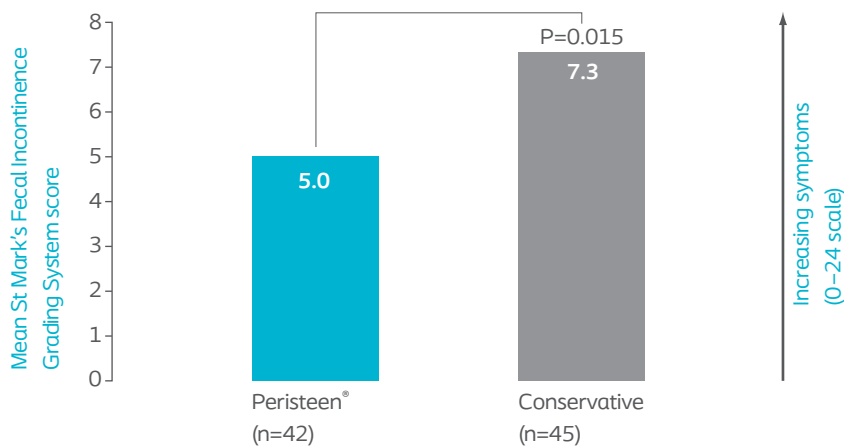
- 87 spinal cord injured adults (including spina bifida, n=2)
- Lesion complete (n=48) or incomplete (n=39)
- 74% T9 or above injury
- Predominant symptom constipation (n=66), faecal incontinence (n=17), or other (n=4)

**Key efficacy data:**

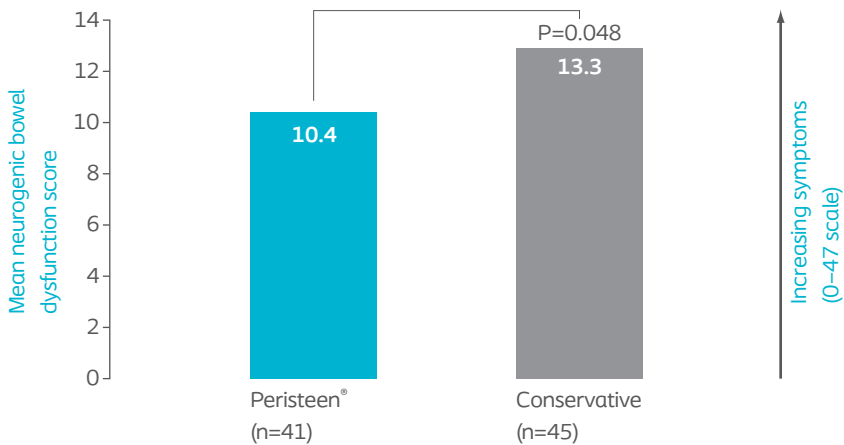
- Significantly reduced symptoms of constipation with Peristeen® vs conservative bowel management



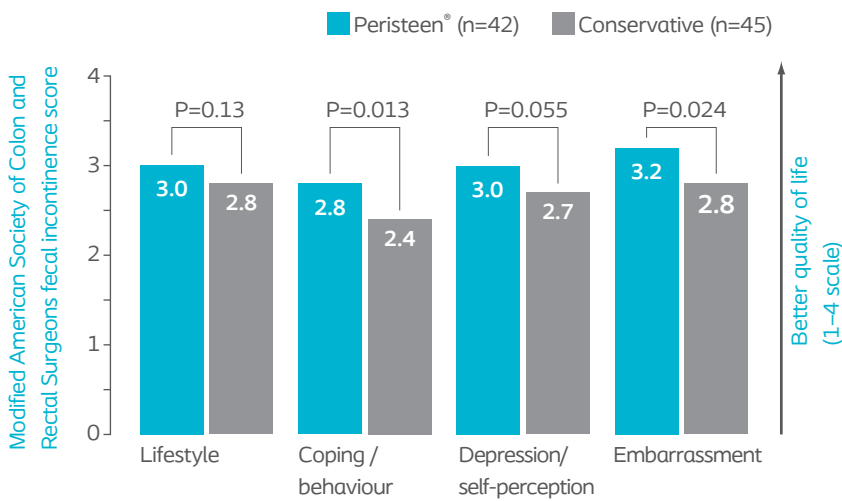
- Significantly reduced symptoms of faecal incontinence with Peristeen vs conservative bowel management



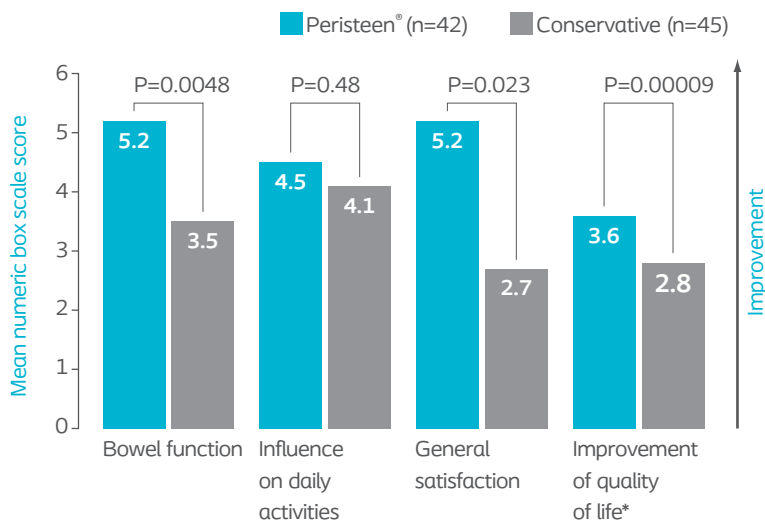
- Significantly reduced symptoms of neurogenic bowel dysfunction with Peristeen vs conservative bowel management



- Improved symptom-related quality of life with Peristeen® vs conservative bowel management

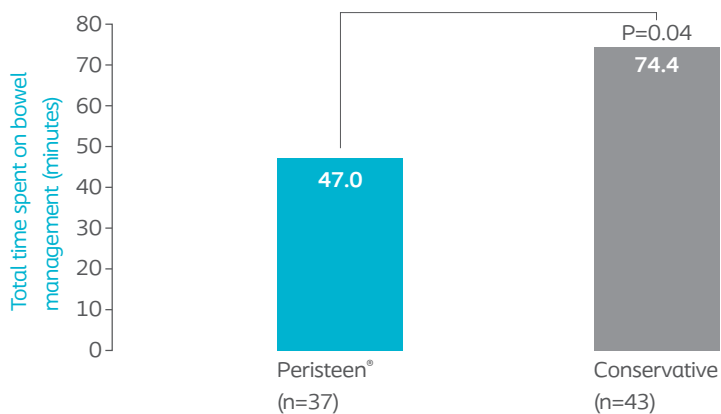


- Improved bowel function, general satisfaction and quality of life with Peristeen vs conservative bowel management



\* n=35 Peristeen; n=44 conservative

- Reduced daily time spent on bowel management with Peristeen vs conservative bowel management





#### Key safety data:

- During the trial, fewer urinary tract infections (UTIs) with prescribed antibiotics were reported in the Peristeen® group (5.9%) than in the conservative bowel management group (15.5%;  $P=0.0052$ )
- Few and only mild side effects were reported. Four patients reported adverse effects while using Peristeen; none were considered serious or related to irrigation
- No serious episodes of autonomic dysreflexia were reported; symptoms indicating autonomic dysreflexia (sweating, headache, flushing, or pronounced general discomfort) tended to be less frequent in the Peristeen group than in the conservative bowel management group (17.3% vs 30.0%, respectively;  $P=0.099$ )

#### Conclusions:

- Peristeen reduced symptoms of constipation and faecal incontinence compared with conservative bowel management in a large ( $n=87$ ), randomised controlled multicentre trial of bowel management strategies in patients with spinal cord injury (SCI)
- Peristeen was safe, with only mild and transient side effects
- Peristeen was associated with significantly fewer UTIs than conservative bowel management
- Peristeen significantly improved symptom-related quality of life compared with conservative bowel management
- Peristeen significantly reduced time spent on bowel management compared with conservative bowel management, freeing-up nearly 30 minutes a day for other activities

# Treatment of neurogenic bowel dysfunction using transanal irrigation: a multicenter Italian study<sup>10</sup>

Del Popolo G, et al. *Spinal Cord* 2008;46:517–522

## Intervention:

Transanal irrigation (TAI) with Peristeen®.

## Study design:

Prospective, before–after study (3-week).

## Patients:

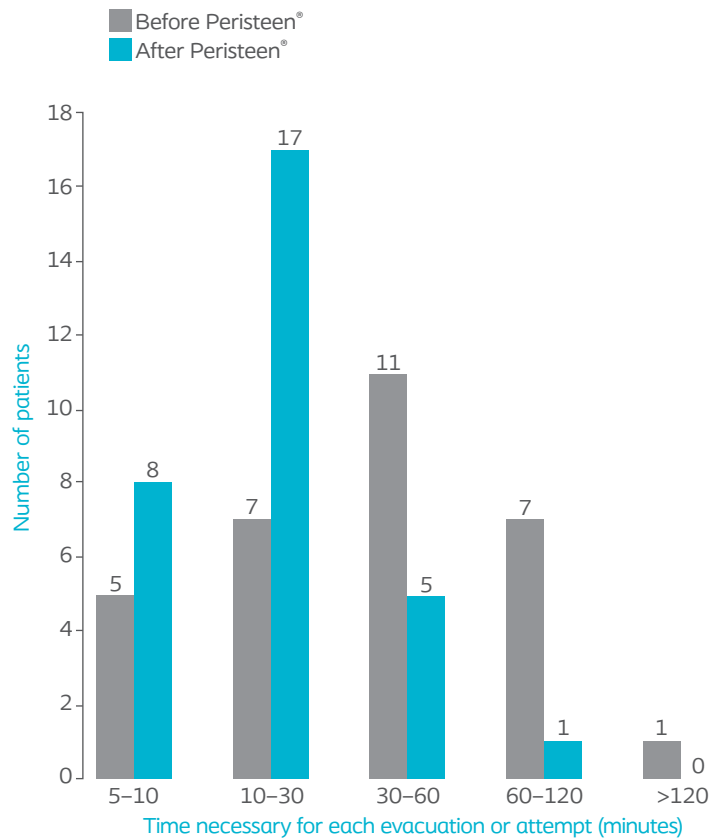
- 33 spinal cord injured adults (spina bifida, n=12; multiple sclerosis, n=2; trauma, n=14; other, n=5); 32 completed the study
- Lesion complete (n=13), incomplete (n=14), or not specified (n=6)
- Predominant symptom constipation (n=27), faecal incontinence (n=4), or not specified (n=2)

## Key efficacy data:

- Compared with baseline, significant ( $P=0.001$ ) improvement in patients' opinion of:
  - Intestinal function
  - Quality of life
  - Degree of satisfaction
- A successful outcome was reported for 68% of patients with faecal incontinence and 63% with constipation
- Before starting Peristeen, eight patients (24%) reported spending >1 hour on each evacuation or attempt at evacuation; after starting Peristeen, this was reduced to just one patient (3%)
- Reductions were reported in pharmaceutical use and dependence on caregivers
- 90% of patients did not report any urinary tract infections (UTIs) during the study, while 39% reported having more than two UTIs a year on entrance into the study

## Key safety data:

- No adverse events were reported



**Conclusions:**

- Peristeen significantly improved patients' opinion of intestinal functionality after 3 weeks compared with baseline
- Patients reported significantly improved quality of life and degree of satisfaction after 3 weeks of treatment with Peristeen compared with baseline
- Peristeen was equally successful in spinal cord injury patients with faecal incontinence and constipation
- After 3 weeks of treatment, Peristeen was associated with reduced pharmaceutical use, low incidence of UTIs, reduced time spent on evacuation, and reduced dependence on caregivers
- Peristeen had a good safety profile

# Cost-effectiveness of transanal irrigation versus conservative bowel management for spinal cord injury patients<sup>11</sup>

Christensen P, et al. *Spinal Cord* 2009;47:138–143

## Intervention:

Transanal irrigation (TAI) with Peristeen® vs conservative bowel management (best supportive care without irrigation).

## Study design:

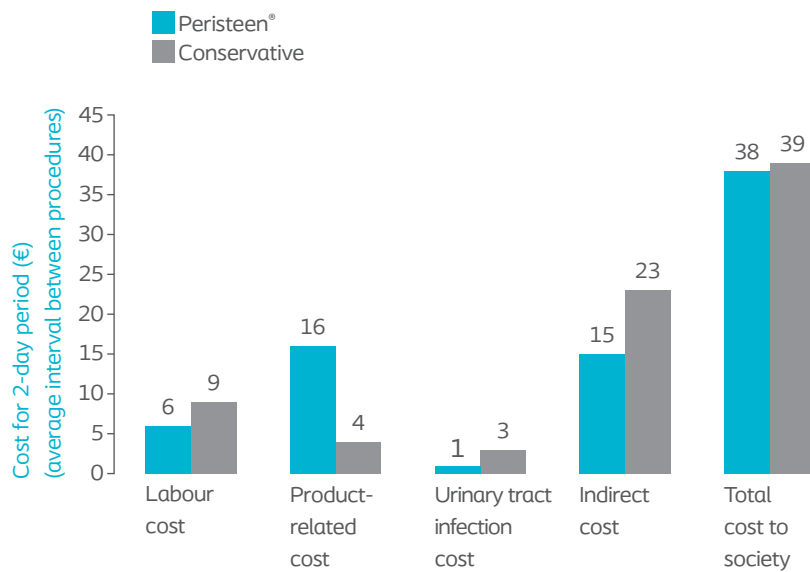
Health economic analysis of data from the randomised controlled trial (see pages 6–9; Christensen P, et al. *Gastroenterology* 2006;131:738–747).

## Patients:

- 87 spinal cord injured adults (including spina bifida, n=2)
- Lesion complete (n=48) or incomplete (n=39)
- 74% T9 or above injury
- Predominant symptom constipation (n=66), faecal incontinence (n=17), or other (n=4)

## Key efficacy data:

- Peristeen was associated with lower total cost to society than conservative management, when considering:
  - Urinary tract infection (UTI) cost (cost for general practitioner visit, urine test, antibiotics)
  - Labour cost (cost of carer helping with bowel management and changes/baths because of soiling)
  - Total product-related costs (cost of products used for changes/baths because of soiling, products for TAI, and constipation medicine)
  - Indirect cost (patient productivity increases when less time is spent on bowel management)
- The cost for a 2-day period was less with Peristeen than conservative management when non-product related costs were factored in
- TAI with Peristeen significantly improved all outcome measures of bowel function, including symptoms of constipation, faecal incontinence and neurogenic bowel dysfunction score (see pages 7–8)



### Conclusions:

- Peristeen significantly reduced symptoms of neurogenic bowel dysfunction compared with conservative management
- In patients with spinal cord injury, self-administered TAI with Peristeen was associated with lower total cost to society than conservative bowel management
- Product-related costs were offset by:
  - Lower costs for a carer to help with bowel management and changes/washing due to leakage
  - Lower costs associated with UTIs
  - Lower indirect costs as a result of increased productivity by patients due to spending less time on bowel management

# Long-term outcome and safety of transanal colonic irrigation for neurogenic bowel dysfunction<sup>12</sup>

Faaborg PM, et al. *Spinal Cord* 2009;47:545–549

## Intervention:

Transanal irrigation (TAI) with rectal balloon catheter (48%), cone-shaped colostomy tip (32%), other system (20%).

## Study design:

Long-term follow-up study (mean, 1.6 years; range, 0.1–9.5 years).

## Patients:

211 patients, predominantly spinal cord injured (n=173; including spina bifida, n=32) or with multiple sclerosis (n=25) or other central nervous system aetiology (n=13) using TAI after failure of conservative bowel management.

## Key efficacy data:

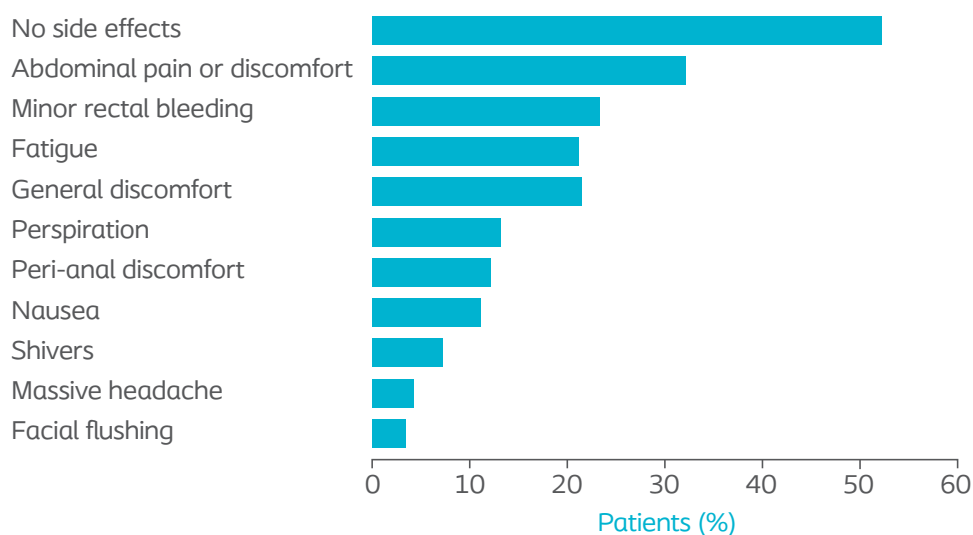
- Treatment success was recorded at long-term follow-up (defined as patient still using TAI at follow-up or had continued using it until they died or symptoms resolved)
- Treatment discontinuations were most frequent during the first few months of treatment; however, at 3 years the success rate stabilised at 35% for the entire group

Neurogenic bowel dysfunction aetiology	Patients with treatment success, %*
<b>Total spinal cord injury (n=173)</b>	<b>49</b>
Traumatic spinal cord injury (n=74)	53
Spina bifida (n=32)	50
Prolapsed intervertebral disc (n=29)	45
Spinal stenosis (n=17)	50
Intraspinal haemorrhagia (n=4)	50
Intraspinal tumour (n=10)	50
Intraspinal infection (n=7)	43
<b>Multiple sclerosis (n=25)</b>	<b>40</b>
<b>Other central nervous system aetiology (n=13)</b>	<b>31</b>
Stroke or cerebral palsy (n=10)	30
Parkinson's disease (n=3)	33
<b>TOTAL (n=211)</b>	<b>46</b>

\* At mean follow-up of 1.6 years

**Key safety data:**

- Minor side effects were reported in 48% of patients
- One non-lethal bowel perforation occurred in  $\approx$  50,000 irrigations



**Conclusions:**

- Overall, treatment success was achieved in 46% of long-term users of TAI, in whom conservative bowel management had failed
- Among the subgroup of patients with spinal cord injury (SCI) using TAI long term, treatment success was achieved in 49%
- One in five treatment discontinuations occurred during the first few months of treatment, after which the rate of discontinuations slowed
- TAI had a good safety profile when used long term
- The risk of bowel perforation with TAI was low (estimated risk 0.002% per irrigation)

# Long-term efficacy and safety of transanal irrigation in multiple sclerosis<sup>8</sup>

Passananti V, Wilton A, Preziosi G, Storrie J.B and Emmanuel A. *Neurogastroenterol Motil.* 2016 Sep;28(9):1349-55

## Intervention:

Transanal irrigation with Peristeen<sup>®</sup> on 49 patients from 2 centers in the UK. All patients had a confirmed diagnosis of multiple sclerosis (MS) and neurogenic bowel dysfunction (NBD) of at least 6 months, with bowel symptoms that had not responded adequately to lifestyle or optimal laxative therapy.

## Study design:

A prospective data collection that started in 2008 and continued throughout the study period until 2014. Data on bowel function (NBD score) and quality of life (EQ5D) was collected prospectively prior and after initiation of treatment with Peristeen. Resource utilization data (UTIs, hospital admissions and length of stay, GP, dietician and specialist visits) was collected throughout the study period based on patient recall and subsequently validated by comparing the responses with data in the patients' electronic records. Carer dependency (by a professional or a family member) was also assessed.

There was at least 1 year of follow-up data on all patients at the end of the study period (July 2014).

## Patients:

- Patients were recruited from two specialized units in London (UK)
- All patients had a confirmed diagnosis of multiple sclerosis (MS) and neurogenic bowel dysfunction (NBD) of at least 6 months, with bowel symptoms that had not responded adequately to lifestyle or optimal laxative therapy
- 76% were women, and the mean age was 51 years (range 26-80)
- Mean period between diagnosis and beginning with Peristeen was 12 years (range 2-31)
- Prior to starting TAI with Peristeen, the majority of patients had moderate or severe bowel dysfunction (29% and 47% respectively), as measured by the NBD score



#### Key efficacy data:

- Mean follow-up upon end of study period was 40 months
- Overall, 55% of patients were successfully using the product at the end of the study period
- Those who discontinued did it mostly due to dislike of the treatment (55% of those who stopped)
- Type and severity of symptoms at baseline did not correlate with interruption of therapy
- The only predictive factor of treatment success in this analysis was impaired anal electrosensitivity
- All patients who continued to irrigate improved their NBD score versus baseline
- Among patients with faecal incontinence (FI), the mean weekly frequency of FI episodes fell significantly from 4.8 at baseline to 0.9 ( $p < 0.005$ )
- HRQoL was assessed by means of EQ-5D. Mean EQ-5D utilities declined over time, irrespective of whether patients were still using TAI. The VAS instrument in the EQ-5D questionnaire improved by 42% for those continuing treatment, while it decreased by 6% for those who discontinued. However, the change in utility by means of EQ-5D was not statistically significant. The results suggest that the generic EQ-5D tool is insensitive to the effects of TAI in this population
- Resource utilization: Compared to the year prior to starting TAI, the annual number of treated UTIs was reduced by 54% and the annual number of hospitalizations was reduced by 41%, in the patients using TAI. Visits to the GP, specialist and dietician were reduced by 27%, 19% and 55% respectively
- The level of carer dependency was also reduced, as 44% of patients experienced a decline in the need for assistance

#### Key safety data:

- Safety was not specifically assessed. The authors report that 2 patients developed adverse events (one fresh anal bleeding and one abdominal cramps)

#### Conclusions:

- This study comprises the largest series to date of MS patients with NBD that use TAI
- At a mean follow-up of 40 months, the authors report a 55% rate of successful continuation of therapy
- The long term data on NBDscore and FI episodes confirm that TAI is an effective treatment option for MS patients with NBD who have not responded to first line therapy
- The authors found that TAI with Peristeen reduced the use of other healthcare services, especially the amount of hospitalizations and the number of treated UTIs

# Long-term follow-up of retrograde colonic irrigation for defaecation disturbances<sup>13</sup>

Gosselink MP, et al. *Colorectal Dis* 2005;7:65–69

## Intervention:

Transanal irrigation (TAI) using conventional colostomy irrigation set comprising an irrigation bag, tube and cone-tip (Biotrol Iryflex, B. Braun Medical B.V., Oss, Netherlands).

## Study design:

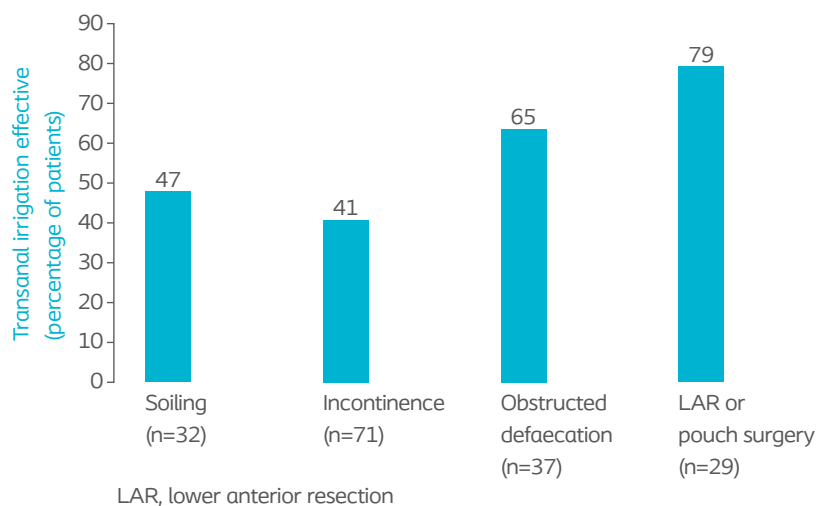
Long-term, follow-up study (median follow-up, 4.7 years; range, 0.7–12.8 years) in a consecutive series of 267 patients who were offered retrograde colonic irrigation.

## Patients:

169 patients with disturbed continence or obstructed defaecation (not responding to medical treatment or biofeedback) who both started irrigation and returned a questionnaire.

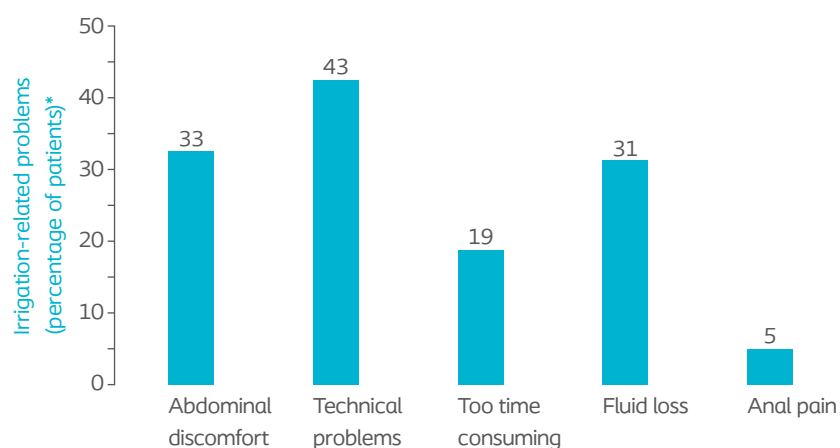
## Key efficacy data:

- Overall, TAI was reported to be effective in 54% of patients
- TAI was particularly effective in patients with defaecation disturbances due to obstruction or after low anterior resection or pouch surgery
- TAI was stopped by 78 patients in whom it was not effective and by 15 patients who encountered a benefit, giving an overall long-term success rate of 45%



### Key safety data:

- Of the patients who regularly performed TAI at the time of follow-up (n=76), 74% reported irrigation-related problems – most commonly technical problems



\*Approximate numbers

### Conclusions:

- TAI can be used successfully in the long term to manage symptoms of defaecation disturbances
- TAI is an effective therapeutic approach for a variety of defaecation disturbances including soiling, faecal incontinence, obstructed defaecation, and after low anterior resection or pouch surgery
- After a median follow-up of 4.7 years, more than half (54%) of patients with defaecation disturbances of mixed aetiology considered TAI to be effective
- The most commonly reported therapy-related problems among long-term users of TAI were technical in nature

# Neurogenic bowel dysfunction score<sup>14</sup>

Krogh K, et al. *Spinal Cord* 2006;44:625–631

## Aim:

To develop and validate a symptom-based score for neurogenic bowel dysfunction (NBD).

## Scope:

Cross-sectional analysis of a questionnaire sent to 589 Danish individuals with spinal cord injury (SCI); questions included: background parameters (n=8), faecal incontinence (n=10), constipation (n=10), obstructed defaecation (n=8) and impact on quality of life (n=3); the reproducibility and validity of each item within the questionnaire were also tested.

## Key findings:

- A total of 424 individuals with SCI (72%) responded to the questionnaire
- Reproducibility and validity were 'good' or 'very good' for most questions describing severity of symptoms and bowel-emptying procedure:
  - Only 'fair' for average time required for each defaecation and frequency of digital stimulation/evacuation, probably caused by a larger number of possible answers
- Reproducibility and validity were 'fair', 'good' or 'very good' for questions relating to quality of life
- Telephone interviews determined that some questions were not well defined:
  - Few individuals knew how to define constipation
  - Respondents did not know whether the severity of their symptoms had changed or they had learnt to live with the symptoms
- Median NBD score was 10 (range 0–31):
  - 90% of respondents had scores between 0 and 18
- Mean score differed significantly ( $P < 0.001$ ) between patients reporting different levels of impact on quality of life:
  - 15.2 for those reporting 'major impact'
  - 11.4 for those reporting 'some impact'
  - 8.1 for those reporting 'minor impact'
  - 4.8 for those reporting 'no impact'

### NBD score versus *impact* on QoL caused by bowel dysfunction

	Very minor dysfunction (NBD 0–6)	Minor dysfunction (NBD 7–9)	Moderate dysfunction (NBD 10–13)	Severe dysfunction (NBD ≥14)	Total
Major impact on quality of life	0% (n=0)	13% (n=7)	10% (n=10)	38% (n=40)	57
Some impact on quality of life	8% (n=8)	13% (n=7)	30% (n=30)	27% (n=28)	73
Little impact on quality of life	34% (n=34)	46% (n=24)	36% (n=36)	29% (n=30)	124
No impact on quality of life	58% (n=58)	27% (n=14)	23% (n=23)	6% (n=6)	101
<b>TOTAL</b>	<b>100 (28%)</b>	<b>52 (15%)</b>	<b>99 (28%)</b>	<b>104 (29%)</b>	<b>355</b>

#### Conclusions:

- 10 of the 28 items investigated were found to have acceptable validity and reproducibility
- Associations between the 10 items included in the NBD score and self-reported impact on quality of life were very strong and most were highly significant
- The questions were designed for use in adults; only 4 respondents were aged less than 15 years and so any potential bias caused by instruction from parents is likely to be insignificant
- Individuals with severe symptoms should be referred to centres with special interest in the evaluation and treatment of bowel symptoms in individuals with SCI
- This NBD score is valid for SCI patients

*“It is our hope that the score can be used to make future studies of bowel symptoms in SCI patients comparable and to assess changes in bowel function when treatment modalities are evaluated”*

# *Literature Reviews and Meta-analysis*

# Review of the efficacy and safety of transanal irrigation for neurogenic bowel dysfunction<sup>15</sup>

Emmanuel A. Spinal Cord 2010;48:664–673

## Aim:

To summarise current evidence for the efficacy and safety of transanal irrigation (TAI) in patients with neurogenic bowel dysfunction (NBD).

## Scope:

Online literature search via PubMed for articles describing the use of TAI in NBD.

## Key findings:

- 23 relevant articles were identified
  - 1 large randomised controlled trial in adults with spinal cord injury (SCI)<sup>7</sup>
  - 22 mostly retrospective or observational studies
- TAI was more effective than conservative bowel management in individuals with SCI with respect to long-term improvements in symptoms and quality of life
- In children and youths with NBD associated with spina bifida, symptoms of constipation and faecal incontinence can be reduced with TAI
- TAI can also be an effective therapy for bowel dysfunction caused by a range of other neurological disorders, including multiple sclerosis (MS), Parkinson's disease, stroke, cerebral palsy or cerebral thrombosis

## Conclusions:

- TAI is superior to conservative management for treating individuals with NBD
- There is a need for larger and longer-term trials of TAI in specific NBD populations, especially adults with spina bifida or MS

*“Taken together, these data show that for patients with SCI, TAI is more effective than conservative bowel management, resulting in an improvement in symptoms and quality of life, and that success is maintained in the long term”*

# Neurogenic bowel management after spinal cord injury: a systematic review of the evidence<sup>16</sup>

Krassioukov A, et al. *Spinal Cord* 2010;48:718–733

## Aim:

To summarise the evidence for the management of neurogenic bowel dysfunction (NBD) in individuals with spinal cord injury (SCI).

## Scope:

Online database search followed by manual search of retrieved articles published from 1950 to July 2009.

## Key findings:

- 57 relevant articles were identified
- The level of evidence offered by each study was rated on a scale from 1 to 5:
  - 25 describe non-pharmacological conservative management strategies
  - 10 describe pharmacological treatment strategies
  - 22 describe surgical interventions
- 4 studies describe the use of transanal irrigation (TAI) to improve bowel management in SCI patients

## Conclusions:

- More than one treatment strategy is often necessary to develop an effective bowel routine
- Multi-faceted bowel management strategies are usually the first approach and are supported by lower-level evidence
- Some pharmacological interventions are supported by strong evidence, although some require further investigation into their safety
- Surgical interventions are not routinely used and are supported by lower-level evidence
- The use of TAI in individuals with SCI is supported by Level 5 (one observational study), Level 4 (two pre–post studies) and Level 1 (one large, good-quality, multicentre, randomised controlled trial) evidence
- The use of common, validated scoring systems such as the NBD score and the International Bowel Function Data Sets should be implemented to allow comparisons of results and meta-analyses



## Key publications on TAI in adult populations with NBD

Publication; country; score; research design; total sample size	Methods	Outcome
Christensen et al 2006, <sup>7</sup> Denmark; PEDro score = 7; randomised controlled trial; N=87	<b>Population:</b> TAI group: mean age: 47.5 years; level of injury: T10–S1, 23 complete and 12 incomplete <b>Conservative management group:</b> mean age: 50.6 years; T10–S1, 23 complete and 23 incomplete <b>Treatment:</b> TAI (Peristeen) or conservative management (PVA clinical guidelines) for 10 weeks <b>OM:</b> CCCSS, FIGS, a faecal incontinence score	<ol style="list-style-type: none"> <li>1. TAI group scored better on symptom-related QoL, CCCSS, FIGS, and NBD</li> <li>2. Improvement found in the TAI group was not confined to the more physically able patients</li> <li>3. The frequency of urinary tract infection was lower in the TAI group</li> </ol>
Christensen et al 2008, <sup>17</sup> USA; Downs and Black score = 20; pre–post; N=55	<b>Population:</b> mean age 47.5 ± 15.5 years; level of injury: 61 supraconal, 37 complete, 25 incomplete <b>Treatment:</b> TAI (Peristeen) for 10 weeks <b>OM:</b> CCCSS, FIGS, and NBD	<ol style="list-style-type: none"> <li>1. CCCSS, FIGS, and NBD scores improved</li> <li>2. TAI significantly reduced constipation, improved anal continence, and improved symptom-related QoL</li> </ol>
Christensen et al 2000, <sup>18</sup> Denmark; Downs and Black score = 17; retrospective interviews and case series; N=29; 19 SCI patients	<b>Population:</b> ECC group: mean age: 39.9 years, range: 7–72 years; level of injury: T2–T11, conal or cauda equina injuries (n=15). MACE group: mean age: 32.8 years, range:15–66 years; level of injury: C5–T2 (n=4) <b>Treatment:</b> ECC versus MACE <b>OM:</b> colorectal function, practical procedure, impact on daily living and QoL, general satisfaction	<ol style="list-style-type: none"> <li>1. The ECC was successful in 53% of participants (8 subjects)</li> <li>2. The MACE procedure was successful in 75% of participants (3 subjects)</li> <li>3. Successful treatment with the ECC or the MACE led to significant improvements in QoL</li> </ol>
Del Popolo et al 2008, <sup>10</sup> Italy; Downs and Black score = 14; pre–post; N=32	<b>Population:</b> median age: 31.6 years, 13 complete, 14 incomplete <b>Treatment:</b> TAI (Peristeen®) for 3 weeks <b>OM:</b> QoL; use of pharmaceutical, incidence of incontinence and constipation, abdominal pain or discomfort	<ol style="list-style-type: none"> <li>1. Significant increase in QoL scores and improvements of constipation</li> <li>2. Significant decrease in abdominal pain and incidence of incontinence</li> <li>3. Nine patients reduced or eliminated pharmaceutical use</li> </ol>
Faaborg et al 2009, <sup>12</sup> Denmark; Downs and Black score = 13; observational; N=211	<b>Population:</b> median age 49 years, range: 7–81 years; aetiology: 74 traumatic, 32 spinal bifida, 29 prolapsed intervertebral disk, 38 other, 38 non-SCI <b>Treatment:</b> TAI <b>OM:</b> rate of success (treatment was successful if (1) currently using TAI, (2) the patient used TAI until death, or (3) symptoms resolved while using TAI)	<ol style="list-style-type: none"> <li>1. 42 patients stopped TAI in the first 3 months</li> <li>2. Success in 98 patients after 19 months; and 73 patients after 3 years of follow-up</li> <li>3. Abdominal pain, minor rectal bleeding, and general discomfort were observed in 101 patients</li> </ol>
Puet et al 1997, <sup>19</sup> USA; Downs and Black score = 12; case series; N=31	<b>Population:</b> age: NA; level of injury: 8 tetraplegic, 4 complete; 23 paraplegic, 9 complete <b>Treatment:</b> pulsed irrigation <b>OM:</b> efficacy of technique, outpatient use	<ol style="list-style-type: none"> <li>1. Success in removing stool in all but 3 patients</li> <li>2. 11 patients had multiple procedures</li> </ol>

Abbreviations: CCCSS, Cleveland Clinic Constipation Scoring System; ECC, enema continence catheter; FIGS, St Mark's Fecal Incontinence Grading System; MACE, Malone antegrade continence enema; NBD, neurogenic bowel dysfunction; OM, outcome measures; PEDro, Physiotherapy Evidence Database; PVA, Paralyzed Veterans of America; QoL, Quality of life; TAI, transanal irrigation.

*“Transanal irrigation is a promising technique to reduce constipation and faecal incontinence”*

# Transanal irrigation therapy to treat adult chronic functional constipation: systematic review and meta-analysis<sup>20</sup>

CD Emmett, HJ Close, Y Yiannakou and JM Mason. *BMC Gastroenterology* (2015) 15:139

## Intervention:

None. Systematic review and meta-analysis.

## Study design:

The paper attempts at answering the following research question: What is the strength of the evidence for transanal irrigation (TA) therapy for chronic functional constipation, with reference to effectiveness, safety and methodological quality of studies?

The authors perform a fixed- and random-effect meta-analysis of 7 eligible studies of TAI (with different devices) for the management of chronic functional constipation, available at the time of the search (until April 2015).

For the purposes of this review, 'chronic functional constipation' refers to any condition fitting broadly within this definition, with no clear underlying cause. This includes obstructed defecation syndrome (ODS), functional defecation disorder (FDD), chronic idiopathic constipation (CIC), and constipation-predominant irritable bowel syndrome (IBS-C). This excludes patients with constipation secondary to any other medical condition, such as neurogenic bowel dysfunction.

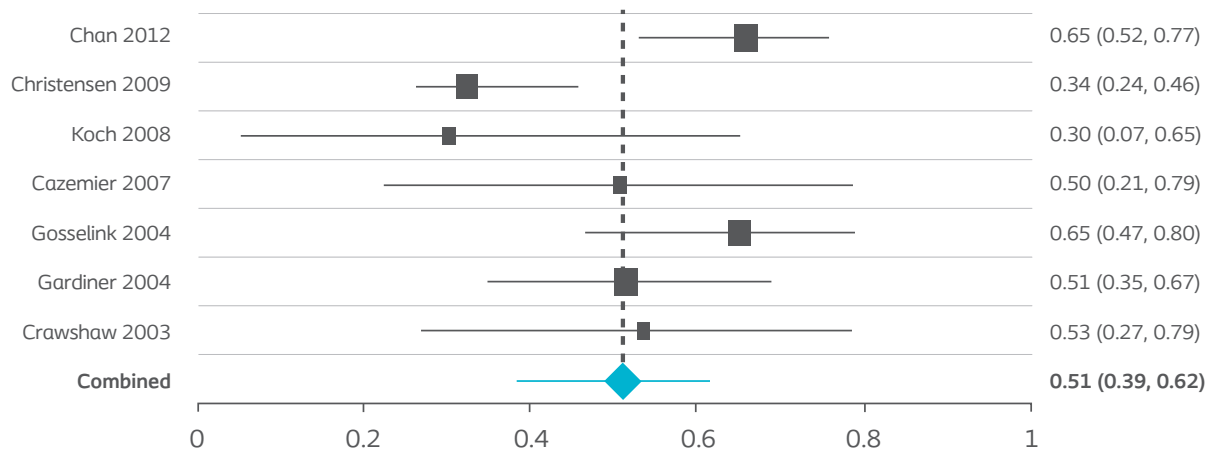
The primary outcome was the proportion of patients with investigator-reported positive outcome to TAI. The secondary outcome included response by constipation type, duration of treatment use and safety of treatment.

## Patients:

A total of 254 patients participated in the 7 studies that were included in the review. Average number of patients per study was 36 (range 10-79).

## Key efficacy data:

- The proportion of patients who had a positive outcome to therapy varied from 30 % to 65 %. Overall, 128 of 254 patients had a positive response to TAI. A fixed effect analysis of proportions gave a pooled response rate of 50.4 % (95 % CI: 44.3–56.5 %)
- 4 of the studies reported results by different sub-types of functional constipation. There was no consistent pattern of differences between them. However, small sample sizes, outcome measure and methodological weaknesses limited a meaningful comparison



#### Key safety data:

- One study (Christensen et al. 2009)<sup>21</sup> reported bowel perforation in 2 patients, estimating less than 0.002% risk per irrigation. No studies reported mortality
- One or more side effects were experienced by a large proportion of patients. The most commonly reported were abdominal cramps/discomfort (33-40%) , anorectal pain (5-25%) and leakage of irrigation fluid (30-75%)

#### Conclusions:

- The studies retrieved were small and not of robust methodological quality. Evidence for the use of TAI in chronic functional constipation was low at the time this study was performed
- The aggregate success rate based on the 7 studies was around 50%
- The majority of patients experienced some form of adverse event, although these were mostly minor, reversible and self-limiting. Irrigation can be considered a safe therapy, when used with proper training

# Transanal irrigation for disordered defecation: a systematic review<sup>22</sup>

Christensen P, Krogh K. *Scand J Gastroenterol* 2010;45:517–527

## Aim:

To summarise the accumulated evidence and experience of transanal irrigation (TAI) in the treatment of disordered defaecation.

## Scope:

Online database search for TAI articles published up to and including September 2009; reference lists of relevant articles were also searched.

## Key findings:

- 27 relevant articles were identified, describing treatment in 1,901 individuals aged between 7 months and 90 years
- One study was conducted as a multicentre, randomised controlled trial of TAI versus conservative bowel management in individuals with spinal cord injury
- Indications covered the full spectrum of conditions resulting in disordered defaecation
- TAI was used in a variety of strategies: from front-line treatment to salvage therapy
- 12 studies evaluated treatment in a total of 672 children:
  - Successful in 81% of constipation cases
  - Successful in 90% of faecal incontinence cases
  - Successful in 66% of mixed symptom cases
- 17 studies evaluated treatment in a total of 1,229 adults:
  - Successful in 45% of constipation cases
  - Successful in 47% of faecal incontinence cases
  - Successful in 59% of mixed symptom cases
- Inconsistent measurement of quality of life improvement confounds comparison and assessment; overall, the trend is stable and predictable: a treatment-associated reduction in symptoms raises quality of life scores

## Conclusions:

- Very few controlled trials have been performed; current practice is based mainly on clinical experience or short-term follow-up in a small group of individuals
- Given the especially encouraging results in children with spina bifida or severe constipation, TAI should be considered for bowel dysfunction in these patient groups
- TAI represents a simple, reversible treatment option if conservative bowel management is unsuccessful, and should be considered before irreversible surgical procedures are considered
- The authors propose a scheme by which a series of flexible interventions could be considered sequentially in order to optimise TAI for each individual and increase the likelihood of treatment success



# Transanal irrigation for the management of bowel dysfunction in adults: summary of benefits

Benefit	Reference
<b>Neurogenic Bowel Dysfunction</b>	
✓ Reduces symptoms of constipation compared with conservative bowel management	7, 8
✓ Reduces symptoms of faecal incontinence compared with conservative bowel management	7, 8
✓ Reduces incidence of urinary tract infections	7, 8
✓ Improves patients' opinion of intestinal functionality compared with baseline	10
✓ Improves symptom-related quality of life compared with conservative bowel management	7
✓ Reduces carer dependency	8
✓ Reduces time spent on bowel management compared with conservative bowel management	7, 10, 11
✓ Is well tolerated and has a good safety profile in the short and long term	7, 12, 21
✓ Is associated with lower total cost to society than conservative bowel management	11
<b>Functional Constipation</b>	
✓ Shows promise as an effective and well-tolerated therapeutic approach for a variety of defaecation disturbances due to chronic functional constipation	13, 20, 22

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