Transanal irrigation for the management of neurogenic bowel dysfunction: evidence summary

A randomized, controlled trial of transanal irrigation versus conservative bowel management in spinal cord-injured patients

Treatment of neurogenic bowel dysfunction using transanal irrigation: a multicenter Italian study

Cost-effectiveness of transanal irrigation versus conservative bowel management for spinal cord injury patients

Long-term outcome and safety of transanal colonic irrigation for neurogenic bowel dysfunction

Long-term outcome and safety of transanal irrigation for constipation and fecal incontinence

Transanal irrigation for the treatment of neuropathic bowel dysfunction

Long-term follow-up of retrograde colonic irrigation for defaecation disturbances

Neurogenic bowel dysfunction score

Review of the efficacy and safety of transanal irrigation for neurogenic bowel dysfunction
Emmanuel A. Spinal Cord 2010;48:664–673

Neurogenic bowel management after spinal cord injury: a systematic review of the evidence

Transanal irrigation for disordered defecation: a systematic review

Transanal irrigation for the management of neurogenic bowel dysfunction: summary of benefits
Transanal irrigation for the management of neurogenic bowel dysfunction

Introduction
This booklet summarises key data on the use of transanal irrigation (TAI) for the management of neurogenic bowel dysfunction (NBD), primarily in patients with spinal cord injury (SCI) and spina bifida, in terms of efficacy, safety, well-being, quality of life, and overall cost to society.

Defaecation disturbances affect many individuals with neurological damage or disease
The term NBD describes a range of defaecation disturbances, including constipation and faecal incontinence, caused by neurological damage or disease. NBD is common following SCI, and in patients with spina bifida, multiple sclerosis, and other neurological diseases.

- Moderate-to-severe NBD symptoms affect approximately half of all patients with SCI
- Constipation is very common among children and young adults with spina bifida and approximately one third are faecally incontinent
- Approximately 68% of patients with multiple sclerosis develop bowel symptoms

The importance of an effective bowel care routine
The symptoms of NBD can cause significant physical and emotional distress, affecting self-esteem, personal relationships, and social life. Quality of life has been observed to decrease as the severity of NBD increases and patients with SCI report that bowel dysfunction impacts more on life than any other SCI-related impairment. 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. Furthermore, complete assistance from a care giver is required by 23% and some help is required by 12%.
Transanal irrigation – putting patients in control

In addition to providing relief from the symptoms of NBD, 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. 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 medical 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 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. 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

<table>
<thead>
<tr>
<th>Before defaecation</th>
<th>After ‘normal’ defaecation</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
</tr>
</tbody>
</table>

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, helping users of TAI to remain continent between regular irrigations.

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

<table>
<thead>
<tr>
<th>Before defaecation</th>
<th>After defaecation</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image3.png" alt="Image" /></td>
<td><img src="image4.png" alt="Image" /></td>
</tr>
</tbody>
</table>
A randomized, controlled trial of transanal irrigation versus conservative bowel management in spinal cord-injured patients


**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)

87 patients randomised

- Peristeen (n=42)
- Conservative bowel management (n=45)

Assessed (n=37) 10 weeks

Assessed (n=44) 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

• 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\(^\text{12}\)


**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


**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


**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

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

aAt 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 ~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 outcome and safety of transanal irrigation for constipation and fecal incontinence


**Intervention:**
Transanal irrigation (TAI) with a rectal balloon catheter (Peristeen or Mallinckrodt; 69%), Alterna cone-shaped colostomy tip (25%), other catheter (7%)

**Study design:**
Long-term follow-up study (mean, 1.8 years; range, 0.1–9.7 years)

**Patients:**
348 patients with various defaecation disturbances and using TAI after first-line treatments had failed

**Key efficacy data:**
- Treatment success (defined as patient still using TAI, or had continued using it until they died or symptoms resolved) was recorded at the long-term follow-up

<table>
<thead>
<tr>
<th>Defaecation disturbance aetiology</th>
<th>Patients with treatment success, %a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurogenic bowel dysfunction (n=107)</td>
<td>63</td>
</tr>
<tr>
<td>Spinal cord injury (n=68)</td>
<td>62</td>
</tr>
<tr>
<td>Spina bifida (n=18)</td>
<td>67</td>
</tr>
<tr>
<td>Multiple sclerosis (n=10)</td>
<td>50</td>
</tr>
<tr>
<td>Parkinson’s disease (n=1)</td>
<td>100</td>
</tr>
<tr>
<td>Cerebral thrombosis (n=10)</td>
<td>70</td>
</tr>
<tr>
<td>Anal insufficiency (n=241)</td>
<td>40</td>
</tr>
<tr>
<td>Idiopathic faecal incontinence (n=49)</td>
<td>51</td>
</tr>
<tr>
<td>Obstetric sphincter injury (n=21)</td>
<td>52</td>
</tr>
<tr>
<td>Sequelae from rectal surgery (n=15)</td>
<td>40</td>
</tr>
<tr>
<td>Sequelae from rectal prolapse (n=21)</td>
<td>24</td>
</tr>
<tr>
<td>Sequelae from anal surgery (n=12)</td>
<td>25</td>
</tr>
<tr>
<td>Idiopathic constipation (n=79)</td>
<td>34</td>
</tr>
<tr>
<td>Miscellaneous (n=44)</td>
<td>43</td>
</tr>
<tr>
<td><strong>TOTAL (n=348)</strong></td>
<td>47</td>
</tr>
</tbody>
</table>

*aAt mean follow-up of 1.8 years*
• The majority of treatment discontinuations occurred during the start of treatment; if the first 3 months of treatment was considered a ‘test phase’, the overall success rate for patients continuing treatment increased from 47% to 56%

**Key safety data:**

• Mild and transient symptoms were reported by about 60% of active users of irrigation
• Non-lethal bowel perforation occurred in two patients in ~110,000 irrigations

**Conclusions:**

• Treatment success was achieved in 47% of the cohort of long-term users of TAI, in whom first-line treatment had failed; TAI was often given to patients awaiting invasive surgery and therefore at high risk of treatment failure
• TAI was particularly effective in patients with neurogenic bowel dysfunction, with a success rate of 63%
• The majority of treatment discontinuations occurred during the start of treatment; the overall success rate was 56% among patients who continued to use TAI after a 3-month ‘test phase’
• 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)
**Intervention:**
Transanal irrigation (TAI) with Peristeen

**Study design:**
Prospective study (mean follow-up, 12 months; range, 4–18 months)

**Patients:**
40 children and youths (mean age, 12.5 years; range, 6–25 years) with spina bifida and neurogenic bowel dysfunction (NBD) that did not respond satisfactorily to conventional bowel management

**Key efficacy data:**
- In the 35 patients who completed the study, there was a significant improvement in symptoms of bowel dysfunction while using Peristeen
- Peristeen significantly reduced:
  - Difficulty and/or pain during defaecation (P<0.005)
  - Feeling of incomplete evacuation (P<0.0001)
  - Leakage of faeces (P<0.0001)
  - Abdominal pain or discomfort before or after defaecation (P<0.0001)
  - Sweating or headache during or after defaecation (P<0.05)
- Peristeen significantly improved patients’ opinion of intestinal functionality (P<0.0001)
- Peristeen reduced the total time spent on bowel management; before Peristeen, 63% of children spent >1 hour; with Peristeen, this was reduced to 3%
- Independence was improved with Peristeen; before Peristeen, 28% of patients were partially or totally independent in terms of bowel evacuation; with Peristeen, 46% were partially or totally independent

**Key safety data:**
- No adverse events were reported
Conclusions:
- Peristeen is an effective therapeutic approach in children and youths with spina bifida and NBD
- After changing from conservative bowel management to Peristeen, patients experienced significantly reduced symptoms of bowel dysfunction, including faecal incontinence
- Using Peristeen led to greater partial or total independence, reducing the need for assistance with bowel evacuation in children and youths with spina bifida
- Peristeen significantly reduced the total time spent on bowel management, decreasing the proportion of children spending more than an hour on bowel management from 63% to 3%
- Peristeen had a good safety profile in children and youths with spina bifida and NBD
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

Long-term follow-up of retrograde colonic irrigation for defaecation disturbances

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.

**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


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

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

**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"
Review of the efficacy and safety of transanal irrigation for neurogenic bowel dysfunction

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)
  • 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”
### Key publications on TAI in paediatric populations with NBD

<table>
<thead>
<tr>
<th>TAI intervention</th>
<th>Study design</th>
<th>Patients</th>
<th>Key efficacy and safety results</th>
<th>Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enema catheter (saline enema)</td>
<td>Prospective, before–after study (follow-up at 18 and 30 months)</td>
<td>• 31 children and youths with spinal cord disease (spina bifida, n=30) or injury (n=1) • Mean age 9 years (range, 3–19 years)</td>
<td>• Significantly increased proportion of continent stools, from 28% to 94% (P&lt;0.01) • Significantly decreased proportion of constipated stools, from 55% to 15% (P&lt;0.01) • Increased satisfaction with bowel programme • No adverse events reported</td>
<td>Liptak, Revell 1992&lt;sup&gt;23&lt;/sup&gt;</td>
</tr>
<tr>
<td>Enema catheter (saline enema)</td>
<td>Descriptive study (follow-up duration not reported)</td>
<td>• 112 children and youths with spina bifida and faecal incontinence • Age range 4–20 years</td>
<td>• Continence achieved in 100% of patients • Allergic phenomena reported in 3 patients (possibly due to manufacturing inconsistency in catheter components)</td>
<td>Shandling, Gilmour 1987&lt;sup&gt;21&lt;/sup&gt;</td>
</tr>
<tr>
<td>Enema catheter (saline enema)</td>
<td>Descriptive study (up to 30 months’ follow-up)</td>
<td>• 33 children and youths with spina bifida and neurogenic faecal incontinence • Mean age 12 years (range, 5–22 years)</td>
<td>• Continence achieved in 32 of 33 patients</td>
<td>Eire et al 1998&lt;sup&gt;21&lt;/sup&gt;</td>
</tr>
<tr>
<td>Irrigation cone</td>
<td>Retrospective, descriptive study</td>
<td>• 24 children with spina bifida who had failed manual evacuation or who had a non-functioning sphincter</td>
<td>• Continence achieved in 21 of 24 patients</td>
<td>Vande Velde et al 2007&lt;sup&gt;22&lt;/sup&gt;</td>
</tr>
<tr>
<td>Cone-tipped catheter (hand-warm tap water)</td>
<td>Questionnaire follow-up and chart review (mean follow-up, 33 months; range, 6–55 months)</td>
<td>• 41 children and youths with spina bifida and bowel dysfunction • Constipation and faecal incontinence in 27% of patients each • Mean age 8 years (range, 7 months to 22 years)</td>
<td>• Complete faecal continence achieved in 66% of patients • Constipation remained in 39% of patients; no cases of faecal retention or impaction • All patients reported either high (63%) or good (37%) levels of satisfaction with therapy</td>
<td>Schöller-Gyüre et al 1996&lt;sup&gt;23&lt;/sup&gt;</td>
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<tr>
<td>Stoma Cone Irrigation Set or Coleotip (luke-warm tap water)</td>
<td>Questionnaire follow-up study (median follow-up, 1.5 years; range, 4 months to 8 years)</td>
<td>• 40 children with spina bifida and neurogenic bladder and bowel • Median age 2 years 8 months (range, 10 months to 11 years)</td>
<td>• 85% of patients/parents were satisfied with the procedure • All 40 patients were constipation-free • 35 of 40 patients were faecally continent • 35 of 40 patients remained on TAI at follow-up</td>
<td>Mattsson et al 2006&lt;sup&gt;24&lt;/sup&gt;</td>
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<td>Peristeen</td>
<td>Prospective study (mean follow-up, 12 months; range, 4–18 months)</td>
<td>• 40 children and youths with spina bifida and neurogenic bowel dysfunction that did not respond to conventional bowel management</td>
<td>• Significant reduction in symptoms of bowel dysfunction • Reduced proportion of patients spending &gt;1 hour on bowel management from 63% to 3% • Increased proportion of patients partially or totally independent in terms of bowel management from 28% to 46%</td>
<td>López Pereira et al 2009&lt;sup&gt;27&lt;/sup&gt;</td>
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<tr>
<td>Peristeen</td>
<td>Prospective before–after study (follow-up at 3 months)</td>
<td>• 60 young patients with myelomeningocele and chronic constipation or unsatisfactory bowel management • Mean age 12.5 years (range, 8–17 years)</td>
<td>• Relief from constipation in 60% and from faecal incontinence in 75% of patients • Improved quality of life, including degree of general satisfaction (P&lt;0.001) • Fewer urinary tract infections (14 before vs 6 after; P&lt;0.01)</td>
<td>Ausili et al 2010&lt;sup&gt;25&lt;/sup&gt;</td>
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Neurogenic bowel management after spinal cord injury: a systematic review of the evidence


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

<table>
<thead>
<tr>
<th>Publication; country; score; research design; total sample size</th>
<th>Methods</th>
<th>Outcome</th>
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</table>
| Christensen et al 2006;<sup>6</sup> Denmark; Downs and Black, PEDro score = 7; randomised controlled trial; N=87 | **Population:** TAI group: mean age: 47.5 years; level of injury: T10–S1, 23 complete and 12 incomplete  
**Conservative management group:** mean age: 50.6 years; T10–S1, 23 complete and 23 incomplete  
**Treatment:** TAI (Peristeen) or conservative management (PVA clinical guidelines) for 10 weeks | 1. TAI group scored better on symptom-related QoL, CCCSS, FIGS, and NBD  
2. Improvement found in the TAI group was not confined to the more physically able patients  
3. The frequency of urinary tract infection was lower in the TAI group |
| Christensen et al 2008;<sup>26</sup> USA: Downs and Black, score = 20; pre–post; N=55 | **Population:** mean age 47.5 ± 15.5 years; level of injury: 61 supracaortal, 37 complete, 25 incomplete  
**Treatment:** TAI (Peristeen) for 10 weeks | 1. CCCSS, FIGS, and NBD scores improved  
2. TAI significantly reduced constipation, improved anal continence, and improved symptom-related QoL |
| Christensen et al 2000;<sup>27</sup> Denmark; Downs and Black, score = 17; retrospective interviews and case series; N=29; 19 SCI patients | **Population:** 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)  
**Treatment:** ECC versus MACE  
**OM:** colorectal function, practical procedure, impact on daily living and QoL, general satisfaction | 1. The ECC was successful in 53% of participants (8 subjects)  
2. The MACE procedure was successful in 75% of participants (3 subjects)  
3. Successful treatment with the ECC or the MACE led to significant improvements in QoL |
| Del Popolo et al 2008;<sup>28</sup> Italy; Downs and Black, score = 14; pre–post; N=32 | **Population:** median age: 31.6 years, 13 complete, 14 incomplete  
**Treatment:** TAI (Peristeen) for 3 weeks  
**OM:** QoL; use of pharmaceutical, incidence of incontinence and constipation, abdominal pain or discomfort | 1. Significant increase in QoL scores and improvements of constipation  
2. Significant decrease in abdominal pain and incidence of incontinence  
3. Nine patients reduced or eliminated pharmaceutical use |
| Faaborg et al 2009;<sup>29</sup> Denmark; Downs and Black, score = 13; observational; N=211 | **Population:** median age 49 years, range: 7–81 years; aetiology: 74 traumatic, 32 spinal biffda, 29 prolapsed intervertebral disk, 38 other, 38 non-SCI  
**Treatment:** TAI  
**OM:** 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) | 1. 42 patients stopped TAI in the first 3 months  
2. Success in 98 patients after 19 months; and 73 patients after 3 years of follow-up  
3. Abdominal pain, minor rectal bleeding, and general discomfort were observed in 101 patients |
| Puet et al 1997;<sup>30</sup> USA; Downs and Black, score = 12; case series; N=31 | **Population:** age: NA; level of injury: 8 tetraplegic, 4 complete; 23 paraplegic, 9 complete  
**Treatment:** pulsed irrigation  
**OM:** efficacy of technique, outpatient use | 1. Success in removing stool in all but three patients  
2. 11 patients had multiple procedures |

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 for disordered defecation: a systematic review


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
“Moreover, transanal irrigation outperformed conservative bowel management, and transanal irrigation is thus both cheaper and more effective than conservative bowel management”
### Transanal irrigation for the management of neurogenic bowel dysfunction: summary of benefits

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Reference</th>
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<tbody>
<tr>
<td>SCI</td>
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<tr>
<td>✓ Reduces symptoms of constipation compared with conservative bowel management</td>
<td>9, 13</td>
</tr>
<tr>
<td>✓ Reduces symptoms of faecal incontinence compared with conservative bowel management</td>
<td>9, 13</td>
</tr>
<tr>
<td>✓ Reduces incidence of urinary tract infections</td>
<td>9</td>
</tr>
<tr>
<td>✓ Improves patients’ opinion of intestinal functionality compared with baseline</td>
<td>12</td>
</tr>
<tr>
<td>✓ Improves symptom-related quality of life compared with conservative bowel management</td>
<td>9</td>
</tr>
<tr>
<td>✓ Improves quality of life compared with baseline</td>
<td>12</td>
</tr>
<tr>
<td>✓ Reduces time spent on bowel management compared with conservative bowel management</td>
<td>9, 12, 13</td>
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<tr>
<td>✓ Is well tolerated and has a good safety profile in the short and long term</td>
<td>9, 14, 15</td>
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<tr>
<td>✓ Is associated with lower total cost to society than conservative bowel management</td>
<td>13</td>
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<tr>
<td>Spina bifida</td>
<td></td>
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<tr>
<td>✓ Shows promise as an effective and well-tolerated therapeutic approach in children and youths with spina bifida and neurogenic bowel dysfunction</td>
<td>8, 10, 14, 15, 19–24</td>
</tr>
<tr>
<td>✓ Reduces symptoms of constipation and faecal incontinence in children and youths with spina bifida and neurogenic bowel dysfunction*</td>
<td>8, 10, 14, 15, 19–24</td>
</tr>
<tr>
<td>✓ Reduces incidence of urinary tract infections</td>
<td>10</td>
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<tr>
<td>Other</td>
<td></td>
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<tr>
<td>✓ Shows promise as an effective and well-tolerated therapeutic approach for a variety of defaecation disturbances due to neurogenic bowel dysfunction and other causes</td>
<td>14–16</td>
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</tbody>
</table>

*References must be used together to support the statement


Coloplast develops products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use our products, we create solutions that are sensitive to their special needs. We call this intimate healthcare.

Our business includes ostomy care, urology and continence care and wound and skin care. We operate globally and employ more than 7,000 people.