New Medicine Assessment

Transanal Irrigation/Rectal Irrigation Systems
Peristeen; Qufora; Aquaflush

Neurogenic bowel dysfunction, e.g. spinal cord injury, spina bifida, multiple sclerosis; chronic constipation including both evacuation difficulties and slow transit constipation; chronic faecal incontinence

Recommendation:

**Neurogenic Bowel Dysfunction** – (constipation, faecal incontinence and disordered defaecation) due to loss of normal sensory and/or motor control or both, as a result of central neurological disease or damage.

Peristeen (AMBER Level 0 traffic light).

Peristeen transanal irrigation system is recommended in patients who have exhausted all other conservative treatment options in the treatment of neurogenic bowel dysfunction.

Treatment should be initiated and stabilised by specialist service providers for a period of 3 months. Treatment should be considered for transfer to primary care after the initial 3 month period only where there has been a demonstrable improvement in validated measures of bowel function such as the Cleveland Clinic constipation scoring system, St Mark’s faecal incontinence score or neurogenic bowel dysfunction score.

Qufora® and Aquaflush® systems are not recommended. (GREY traffic light)

**Chronic Constipation or Chronic faecal incontinence**

Transanal Irrigation is not recommended in the treatment of patients with chronic constipation or chronic faecal incontinence. (BLACK traffic light)

Basis for Recommendation and Summary of supporting evidence:

- Transanal irrigation (TAI) (Peristeen) was compared against conservative bowel management in a 10 week randomised controlled trial (RCT) of patients with spinal cord injury and neurogenic bowel dysfunction (NBD).

- Peristeen showed statistically significant improvements in the primary endpoints of Cleveland Clinic Constipation score and St Mark’s faecal incontinence grading system when compared to conservative bowel management. Secondary quality of life endpoints also showed statistically significant improvements in TAI patients, the American Society of
Colon and Rectal Surgeons faecal incontinence subscales tended to be better in two and were statistically significantly better in two subscales in the TAI patients.

- Two prospective evaluations, of 12 and 14 months in children with spina bifida and NBD who had not responded to conservative bowel management, showed significant improvements in difficulty and / or pain during defecation, feeling of incomplete defecation, abdominal pain or discomfort before / after defecation and sweating or headache during or after defecation on TAI compared to before treatment. This was also associated with improvements in the frequency of faecal incontinence.

- Two prospective evaluations, of 3 weeks and minimum of 1 year duration in adults with NBD secondary to a range of aetiologies, showed significant improvements in patients opinion of their intestinal functionality, QoL score and degree of satisfaction on TAI compared to before treatment.

- One retrospective study of 8 weeks duration in adults with bowel dysfunction secondary to spinal cord injury demonstrated significant improvements in the NBD score after TAI compared to before therapy.

- The remaining evidence in support of TAI is limited to patient series, with the use of retrospective questionnaires and subjective beneficial effects of irrigation as criteria of success. This evidence, while indicating a treatment benefit of TAI needs to be interpreted with caution do to the lack of control groups, lack of the use of validated assessment criteria and high risk of publication bias.

- Evidence in support of the long-term use of TAI is limited to 3 retrospective studies using un-validated questionnaires. This data indicates continuation rates of 47% at 21 months, and 35% and 60% at 5-years. Factors which predict a successful outcome of TAI are yet to be established.

- Evidence in support of Qufora Mini® is limited to one 4 week retrospective audit of patients with passive faecal incontinence and / or evacuation difficulty where they had not responded to behavioural retraining and pelvic floor exercises. No evidence in support of the other 3 Qufora systems or the Aquaflush® systems was identified.

- For faecal incontinence in adults, NICE CG49 recommends rectal irrigation as one of a number of options following failure of initial management involving diet, bowel habit, toilet access, medication and coping strategies.

- NICE CG99 does not recommend transanal irrigation as an option for the management of idiopathic constipation in children, due to a lack of robust evidence for this indication.

- Current spend across Lancashire for the last three months for all three products is £68,869.33. Equivalent to £275 477.30 annually.
## Details of Review

**Name of medicine** (generic & brand name):

Transanal Irrigation Systems: Peristeen®; Qufora®; Aquaflush®

<table>
<thead>
<tr>
<th>Strength(s) and form(s):</th>
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<tbody>
<tr>
<td>The Peristeen® system consists of:</td>
</tr>
<tr>
<td>- A control unit with pump – can be used 90 times (6 month’s usage if used on alternate days)</td>
</tr>
<tr>
<td>- A water bag – can be used 15 times</td>
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<tr>
<td>- Single-use rectal catheters – available in two different sizes</td>
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<tr>
<td>- Tubing</td>
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<td>- 2 leg straps if required</td>
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There are four Qufora® systems consisting of:

- Mini System – single-use cone /pump can be used 15 times
- Bed System – single-use catheter / single-use collection bag / tube (5 uses) / water bag (5 uses)
- Balloon Catheter System – single-use rectal catheter with silicone balloon / water bag (can be used 15 times) / control unit/pump/tube (6 months with alternate day use) / Velcro straps if required
- Cone Toilet System – single-use cone / water bag (15 uses) / tube / pump

There are three Aquaflush® systems consisting of:

- Actif Irrigation Cone system – 15 single-use cones / water bag and pump (used for 15 times or one month, whichever is first), one S hook from which to hang the water bag
- Compact system – 15 single-use cones / one pump (15 uses)
- Quick system – single-use cone / water bag and pump (used for 15 times or one month, whichever is first)

**Dose and administration:**

Transanal irrigation systems empty the bowel by introducing warm water into the bowel using a rectal catheter – most often whilst sitting on the toilet. The water stimulates the bowel and flushes out the stool, leaving the lower half of the bowel empty. Initially patients irrigate daily but this can then be reduced to alternate days depending upon response. It is recommended that a regular routine is used.

**BNF therapeutic class / mode of action**

n/a
Licensed indication(s):

These products do not have a product licence/marketing authorisation. They are CE-marked medical devices.

Proposed use (if different from, or in addition to, licensed indication above):

- Neurogenic bowel dysfunction, e.g. spinal cord injury, spina bifida, multiple sclerosis;
- Chronic constipation including both evacuation difficulties and slow transit constipation;
- Chronic faecal incontinence.

Course and cost:

Annual cost assuming alternate day use (Drug Tariff February 2015)

<table>
<thead>
<tr>
<th>Product</th>
<th>Annual cost £</th>
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<tbody>
<tr>
<td>Peristeen®: 2 systems and 12 accessory units</td>
<td>£1,713.52</td>
</tr>
<tr>
<td>Qufora Mini®: 12 mini sets</td>
<td>£708.00</td>
</tr>
<tr>
<td>Qufora Cone Toilet®: 12 monthly sets</td>
<td>£1,219.92</td>
</tr>
<tr>
<td>Qufora Balloon®: 2 base sets and 12 accessory sets</td>
<td>£1,520.00</td>
</tr>
<tr>
<td>Qufora Bed®: 36 bed systems</td>
<td>£1,796.40</td>
</tr>
<tr>
<td>Aquaflush Actif Irrigation Cone®: 12 monthly sets</td>
<td>£1,212.00</td>
</tr>
<tr>
<td>Aquaflush Compact®: 12 monthly sets</td>
<td>£714.00</td>
</tr>
<tr>
<td>Aquaflush Quick®: 12 monthly sets</td>
<td>£1,222.32</td>
</tr>
</tbody>
</table>

Current standard of care/comparator therapies:

NICE CG49: the management of faecal incontinence in adults recommends the following specialist management options after initial management (which covers diet, bowel habit, toilet access, medication and coping strategies):

- pelvic floor muscle training
- bowel retraining
- specialist dietary assessment and management
- biofeedback
- electrical stimulation
- rectal irrigation.

For the management of constipation (NICE CKS):

- General lifestyle recommendations which may improve constipation include increasing dietary fibre, eating regular meals, drinking an adequate amount of fluids, and exercising. Any medication which may cause constipation should be adjusted, where possible.
- Laxatives: bulk-forming, osmotic, stimulant
- Prucalopride (for women only) or lubiprostone, in line with NICE criteria.
Peristeen®, Qufora® and Aquaflush® are different types of Transanal Irrigation Systems (TAIs) also known as rectal irrigation systems (RIs). TAI is a method used to empty the bowel of faeces (up to the splenic flexure) using warm water which is introduced with a catheter via the anus into the rectum. The water and contents of the descending colon, sigmoid colon and rectum are then evacuated. Regular and controlled evacuation in this manner aims to prevent both constipation and faecal soiling.

In 2009, St Mark’s Hospital produced guidelines for the use of rectal irrigation which were developed in conjunction with Coloplast following the introduction of the first purpose-designed, CE marked, TAI system, Peristeen®. These state the indications for the use of rectal irrigation are:

- **Chronic faecal incontinence.**
- **Chronic constipation** including both evacuation difficulties and slow transit constipation;
- **Neurogenic bowel dysfunction** (NBD) e.g. spinal cord injury, spina bifida, multiple sclerosis. ‘Neurogenic bowel’ is the term used to describe dysfunction of the colon (constipation, faecal incontinence and disordered defaecation) due to loss of normal sensory and/or motor control or both, as a result of central neurological disease or damage;

In June 2007, NICE published CG49, the management of faecal incontinence in adults. This defined faecal incontinence as the involuntary loss of solid or liquid stool and recommended rectal irrigation as one of a number of specialist management options following failure of initial management. Initial management includes an assessment of diet, bowel habit, toilet access, medication and coping strategies in addition to condition-specific interventions. Specialist management options include pelvic floor muscle training, bowel retraining, specialist dietary assessment and management, biofeedback, electrical stimulation and rectal irrigation.²

NICE Clinical Knowledge Summary (CKS) for Constipation defines constipation as defaecation that is unsatisfactory because of infrequent stools, difficult stool passage, or seemingly incomplete defaecation. Stools are often dry and hard, and may be abnormally large or abnormally small.³ Its management scenario for adults with chronic constipation is summarised here⁴:

- If faecal loading/impaction is present, it must first be relieved before commencing maintenance treatment.
- General lifestyle recommendations which may improve constipation include increasing dietary fibre, eating regular meals, drinking an adequate amount of fluids, and exercising.
- Any medication which may cause constipation should be adjusted, where possible.

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Relevant NICE guidance:

CG49 The Management of Faecal Incontinence in Adults
CG99 Constipation in children and young people: Diagnosis and management of idiopathic childhood constipation in primary and secondary care.

Background and context

Peristeen®, Qufora® and Aquaflush® are different types of Transanal Irrigation Systems (TAIs) also known as rectal irrigation systems (RIs). TAI is a method used to empty the bowel of faeces (up to the splenic flexure) using warm water which is introduced with a catheter via the anus into the rectum. The water and contents of the descending colon, sigmoid colon and rectum are then evacuated. Regular and controlled evacuation in this manner aims to prevent both constipation and faecal soiling.

In 2009, St Mark’s Hospital produced guidelines for the use of rectal irrigation which were developed in conjunction with Coloplast following the introduction of the first purpose-designed, CE marked, TAI system, Peristeen®. These state the indications for the use of rectal irrigation are:

- **Chronic faecal incontinence.**
- **Chronic constipation** including both evacuation difficulties and slow transit constipation;
- **Neurogenic bowel dysfunction** (NBD) e.g. spinal cord injury, spina bifida, multiple sclerosis. ‘Neurogenic bowel’ is the term used to describe dysfunction of the colon (constipation, faecal incontinence and disordered defaecation) due to loss of normal sensory and/or motor control or both, as a result of central neurological disease or damage;

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- If faecal loading/impaction is present, it must first be relieved before commencing maintenance treatment.
- General lifestyle recommendations which may improve constipation include increasing dietary fibre, eating regular meals, drinking an adequate amount of fluids, and exercising.
- Any medication which may cause constipation should be adjusted, where possible.
NICE CKS for Constipation recommends that laxatives are indicated in the following circumstances:

- if lifestyle measures are insufficient, or whilst waiting for them to take effect;
- for people taking a constipating drug that cannot be stopped;
- for people with other secondary causes of constipation;
- as ‘rescue’ medicines for episodes of faecal loading.

The CKS guidance recommends a stepped approach to the use of laxatives, starting with bulk-forming laxatives, adding or substituting osmotic laxatives with the addition of stimulant laxatives when clinically appropriate. If at least two laxatives (from different classes) have been tried at the highest tolerated recommended doses for at least 6 months, the use of prucalopride (in women only) or lubiprostone should be considered provided the criteria set out in the relevant NICE guidance is fulfilled. For all laxatives, trial evidence on efficacy and safety is limited. This is mainly because these agents have been in use for a long time, clinical trials were far less robust at the time they were originally licensed, and few new clinical trials have been conducted. The CKS guidance does not make any recommendation in relation to TAI in patients with constipation.

NICE CG99 from May 2010: Constipation in children and young people: Diagnosis and management of idiopathic childhood constipation in primary and secondary care includes recommendations about clinical management, diet and lifestyle, psychological interventions and the antegrade colonic enema (ACE) procedure. This guidance does not recommend the use of transanal irrigation for this cohort of patients. Of note, a decision on whether to review the guidance was taken in July 2014. Five out of six stakeholder responses received disagreed with the proposal that this guidance should not be reviewed at this time. The surveillance review states, “The stakeholders that disagreed with the decision not to update the guideline generally felt that there should be consideration of the use of rectal irrigation prior to referral for the Antegrade Colonic Enema (ACE) procedure. In particular, two studies on rectal irrigation were highlighted. One of the studies had previously been identified through the surveillance review but was excluded because the study population included children with anorectal anomaly whilst the guideline scope excluded children with constipation with a known cause. The second study was a small scale retrospective study and, from an assessment of the abstract, there was no evidence that the included population had taken an optimum amount of medicine for an appropriate time with adequate support before undertaking transanal irrigation treatment. As such, NICE concluded that it would be pertinent to await further research on the long-term benefits and harms of this management option in children with idiopathic constipation before considering for inclusion in the guideline.”

A decision was taken that the constipation in children guideline should not be updated at the time and as such, the use of TAI for idiopathic childhood constipation is currently not recommended by NICE.

**Antegrade colonic enema** – an operation which involves connecting the appendix to the abdominal wall and fashioning a valve mechanism that allows catheterization of the appendix, but avoids leakage of stool through it.
Summary of evidence

Summary of efficacy data in proposed use:

There is a limited evidence base for this procedure at present and existing protocols for TAI are based largely on expert opinion and practical experience. Published data is available for the use of TAI in the treatment of faecal incontinence and/or constipation associated with the following conditions: spinal cord injury, suprascal cauda equina, spina bifida, multiple sclerosis, faecal incontinence, idiopathic post-traumatic constipation, slow transit evacuation difficulty, low-anterior rectal resection syndrome (LARS) and ileo-anal pouch syndrome.7

One 10 week open-label, prospective, randomised controlled trial, involving five European countries, was identified.8 It compared the use of transanal irrigation (Peristeen) with conservative bowel management (defined as best supportive bowel care without irrigation – see below for details) in 87 spinal cord-injured patients with neurogenic bowel dysfunction. All patients were age 18 years or older and had at least one of the following symptoms: (1) spending a half hour or more attempting to defecate each day or every second day, (2) episodes of faecal incontinence once or more per month, (3) symptoms reflecting autonomic dysreflexia before or during defecation, and (4) abdominal discomfort before or during defecation. Patients with multiple sclerosis, cerebral palsy, cerebral apoplexy or those who had received perineal surgery were excluded.

Of the 42 patients who were randomly assigned to TAI, 2 patients were lost to follow-up prior to training, during training 3 patients discontinued due to repeated expulsion of the rectal catheters during irrigation, 5 patients discontinued treatment and a further 2 patients were lost to follow-up during the trial period. Of the 45 patients who were randomly assigned to conservative bowel management one patient was lost to follow-up and a second patient withdrew prior to training.

Two pre-specified primary endpoints were assessed; score on the Cleveland Clinic constipation scoring system and St Mark’s faecal incontinence grading system were assessed at baseline and at 10 weeks. Cleveland Clinic constipation scoring system (range, 0–30, 30 representing severe symptoms) improved from a baseline of 13.7 to 10.3 (4.4) versus change from a baseline of 12.8 to 13.2 (3.4) with conservative management (P=0.0016). St. Mark’s faecal incontinence grading system (range, 0–24, 24 representing severe symptoms) improved from a baseline of 8.8 to 5.0 (4.6) versus a change from a baseline of 8.4 to 7.3 (4.0) with conservative management (P=0.015).

The secondary quality of life endpoints (see table 1) of neurogenic bowel dysfunction score (10.4 v 13.3, p=0.048), bowel function (5.2 v 3.5, p=0.0048), general satisfaction (5.2 v 3.6, p=0.023) and improvement in quality of life (6.3 v 4.2, p=0.00009) significantly favoured transanal irrigation over conservative management. A modification of the American Society of Colon and Rectal Surgeons faecal incontinence score, showed significantly better scores for TAI in two of the four subscales and tended to be better in the other two, influence on daily activities also tended to favour TAI. The improvement in quality of life endpoints was also associated with a decrease in the time spent on bowel management daily, 47 minutes for TAI versus 74.4 minutes for conservative bowel management (p=0.04).
American Society of Colon and Rectal Surgeons faecal incontinence score - This is a symptom-related quality of life score from which four subscales can be extracted: lifestyle, coping behaviour, depression/self-perception, and embarrassment. The score was modified by replacing “symptoms of faecal incontinence” in each question with “symptoms of faecal incontinence or constipation.”

Conservative bowel management consisted of the following: bowel care was scheduled at least every 2 days, at the same time of the day and after ingestion of food and liquid to develop a habitual, predictable response and to take advantage of the gastrocolic response. Diet, fluids, and regular physical activity were used to modulate stool consistency appropriately. Use of laxatives or constipating medicine was recommended if noninterventional treatment was insufficient. Use of a large-volume phosphate enema and oral polyethylene glycol was restricted as emergency treatment for faecal impaction.

Other efficacy data:

Evidence in support of the use of TAI in children

Two prospective evaluations\(^ {10,11}\) of 14 (5-20) and 12 (4-18) months duration, reviewed the use of Peristeen in 45 and 40 children respectively. Patients had spina bifida and NBD and did not respond satisfactorily to conservative bowel management. Responses before and while using TAI demonstrated significant improvements in difficulty and / or pain during defecation (\(P<0.005\)), feeling of incomplete defecation (\(P<0.0001\)), abdominal pain or discomfort before / after defecation (\(P<0.0001\)), sweating or headache during or after defecation (\(P<0.05\)).\(^ {11}\) During TAI treatment 40/45 patients showed complete dryness stool wise with no soiling while 5 patients showed partial improvement with a varying degree of faecal soiling\(^ {10}\). Of 25 children with faecal incontinence (frequent or always) prior to TAI, 18 were pseudocontinent, two improved from frequent to occasionally and 5 from always to frequent (\(P<0.0001\)).\(^ {11}\)

The remaining evidence in support of TAI in children \(n=694\), (632 remaining patients from reference 9 and 62 Table 2) is limited to patient series with use of retrospective questionnaires with subjective beneficial effects of irrigation as criteria of success. The largest patient population studied is spina bifida (\(n=296\)), followed by mixed aetiology (\(n=226\) and Anorectal Malformations (\(n=172\)). The majority of patients were being treated with TAI to treat faecal incontinence (\(n=343\)), followed by mixed incontinence / constipation (\(n=128\)) and constipation (\(n=91\)). Treatment was classed as a success in 88% (556/632) of patients within the systematic review and 71% (44/62) of the additional studies identified (Table 2).

Evidence in support of the use or TAI in adults

Two prospective evaluations\(^ {12,13}\) of 3 weeks and minimum follow up of 1 year duration, reviewed the use of Peristeen in 36 and 80 patients respectively. Patients had NBD secondary to spinal cord injury (\(n=36\)), faecal incontinence (\(n=18\)), constipation (\(n=19\)), outlet obstruction (\(n=5\)) or combined disorders (\(n=38\)).\(^ {13}\) After 3 weeks of treatment with TAI there was a significant increase in patients opinion of their intestinal functionality (\(P=0.001\)), QoL score (\(P=0.001\)) and their degree
of satisfaction (P=0.001). After 8 weeks and 1 year, 74% and 48% of patients continued on TAI therapy respectively.

One retrospective study (available as an abstract only) of 45 patients with bowel dysfunction associated with spinal cord injury, assessed the NBD score before and after 8 weeks of TAI. At the end of the study period the NBD score (range 0-47, with 47 representing severe symptoms) decreased by 4 points (p<0.0001), with specific improvements in items related to stool frequency (p=0.036), occurrence of malaise, headache, or sweating during defecation (P: 0.043), use of drugs against constipation (P: 0.007) and frequency of faecal incontinence (P: 0.001). After 6 months, 80% of patients continued regular use of TAI.

The remaining evidence in support of TAI in adults n=1157, (1095 remaining patients from reference 9 and 62 Table 2) is limited to patient series using un-validated scoring systems. Patients had bowel dysfunction due to mixed aetiology (n=711), NBD (n=248), unknown (n=77) and following surgery (n=121). Treatment was classed as a success in 50%, 48%, 43% and 73% of patients respectively. Treatment was classed as a success in 43% of patients with constipation, 48% of patients with faecal incontinence and 54% of patients with mixed symptoms.

None of the studies of transanal irrigation using validated scoring systems and clinical measurements or prospectively collected data have addressed the long-term use of TAI. Accumulated experience from a 10-year period with 348 patients with heterogeneous background pathology found overall success in 47% of patients after a mean follow-up period of 21 months. Two studies which considered the long-term use of TAI in patients with NBD suggested continuation rates of TAI at 5-years of 35% and 60% respectively.

Though several factors have been associated with a positive outcome of TAI, no consistent and readily explainable pattern could be identified. This may be due to the multifactorial nature of the study populations described, and uncertainty in the history-taking and in the additional tests used. It is of continuous concern that use of these tests still cannot reliably indicate appropriate patient-management strategies.

Evidence in support of Qufora Mini is limited to one 4 week audit of 50 patients with passive faecal incontinence and / or evacuation difficulty where they had not responded to behavioural retraining and pelvic floor exercises. Thirty seven (74%) felt that performance of the irrigation system was good or acceptable, whereas 13 (26%) reported it to be less than acceptable to use or it did not work. When asked if they would continue using the irrigation system 18 (36%) would use it on a regular basis, 16 (32%) sometimes and 16 (32%) would not continue to use the system. No evidence in support of the other 3 Qufora systems or the Aquaflush® systems was identified.

NICE CG49 The management of faecal incontinence in adults recommends the use of TAI in the treatment of faecal incontinence as one of a number of specialist management options. The evidence in support of their recommendation relates to two trials which were included in the systematic review above. (Crawshaw 2004 and Gosselink 2005):

Crashaw et al was a retrospective evaluation of all 92 patients who had been offered rectal irrigation at Western General Hospital in Edinburgh between 1998 and 2000 at some time in their management. Rectal irrigation was initiated as a primary therapy in the absence of correctable pathology or the failure of medical and surgical treatment.
Patients were sent a postal quality of life questionnaire to assess the primary aim of the study, which was to evaluate the efficacy and acceptability of rectal irrigation in patients with disorders of faecal continence (covering faecal incontinence, idiopathic constipation and dyssynergic defaecation) that had not responded to other types of treatment.

48 (52%) of 92 completed questionnaires, 24 (50%) of the 48 patients stated their bowel control was better with the irrigation. The median bowel rating score for these 24 patients before rectal irrigation was 15 (Interquartile Range IQR 3-24). This improved to a median score of 42 (IQR 33-54) soon after irrigation and was 50 (IQR 34-65) at the time of the questionnaire. For the remaining 24 (50%) patients who did not report an improvement in bowel control using the visual analogue scale, their scores were as follows: before rectal irrigation median bowel rating score 15 (IQR 3-24), soon after irrigation 25 (IQR 12.75-46.25) and at the time of the questionnaire 19.5 (IQR 10-38).

Of the 48 patients who returned the questionnaire, 44 patients were still using rectal irrigation. Of the 4 patients who had stopped, 2 found the treatment unacceptable and 2 had a resection rectopexy with resolution of symptoms. There was no difference in the quality of life scores when the successful treatment group’s scores were compared with the QOL scores for the patients with no improvement (59.16 v 52.20; not significant).

Gosselink et al\textsuperscript{17} aimed to investigate the long-term feasibility and outcome of retrograde colonic irrigation (RCI) in patients with defaecation disturbances. This was a long-term follow-up study (median follow-up 4.7 years range 0.7-12.8 years) in a consecutive series of 267 patients with defaecation disturbances not responding to medical treatment and biofeedback therapy. This study pre-dated the advent of the first purpose-designed trans-anal irrigation system. Instead a conventional colostomy irrigation set was used which consisted of an irrigation bag, a tube and a cone-tip.

28 patients were lost to follow-up, therefore 239 patients were sent a detailed questionnaire of which 190 patients (79%) responded. Of the 190 patients, 11 (6%) did not require RCI as their symptoms resolved spontaneously and 10 (5%) patients considered RCI embarrassing and inconvenient.

The remaining group of 169 patients had the following diagnoses: 32 patients had faecal soiling, 71 patients had faecal incontinence, 37 patients suffered with obstructive defaecation and 29 had defaecation disturbances after low anterior resection or pouch surgery.

91 patients (54%) reported that RCI was effective and beneficial. Of the total group, 93 (55%) patients reported to have ceased RCI after varying amounts of time. 78 (46%) of these patients did not find RCI to be effective and in addition a further 15 (9%) patients who did report benefit of RCI also stopped treatment. Reasons given were the time-consuming aspect of RCI, irrigation-related problems and loss of irrigation-fluid throughout the day. The reported efficacy of RCI was higher among patients with obstructed defaecation (65%) and those with defaecation disturbances after lower anterior resection (79%) than in patients with soiling or faecal incontinence. The authors concluded that long-term RCI was beneficial for 45% of patients with defaecation disturbances.
Summary of safety data:

Introduction of a catheter into the rectum and administration of an enema under pressure carries the risk of potentially lethal bowel perforation. A study reviewing the long-term outcome and safety of TAI investigated the incidence of bowel perforation relating to irrigation treatment. From hospital records bowel perforation occurred in 2 of 348 patients (mean follow up 21 months). The estimated risk of enema-induced perforation was less than 1 per 50,000 irrigations (0.002%).

The RCT recorded practical problems with the use of Peristeen, and showed that difficulties with insertion of the catheter, expulsion of the catheter, leakage of irrigation fluid beside the catheter, or bursting of the rectal balloon occurred in approximately 1 in 3 patients. 3 (7.5%) patients discontinued treatment during training due to repeated expulsion of the rectal catheters during training, a further 5 (12.5%) patients discontinued treatment during the 10 week trial due to lack of compliance, dislike of treatment, balloon bursts, insufficient effect and adverse events.

Severe abdominal pain leading to hospitalization was reported for 2 (5%) patients after 3 and 9 weeks of treatment, respectively. No serious conditions were found, and symptoms improved after disimpaction of constipated stool. One of these patients decided to discontinue. Symptoms reported during or immediately after defaecation when using TAI versus conservative bowel management included abdominal cramping (15.7% of patients v 26.7% P=0.15), sweating (10.5% v 22.3% P=0.017), chills (7% v 5.8% P=0.6), pronounced general discomfort (5.9% v 20.2% P=0.062), dizziness (5.4% v 5.8% P=0.21), nausea (3% v 6.7% P=0.088), headache (3% v 6% P=0.28), facial flushing (2.7% v 8.8% P=0.16) and anorectal pain (1.4% v 9.5% P=0.41).

Strengths and limitations of the evidence:

Strengths and Limitations of the RCT:

Strengths:

- The RCT measured patient-oriented outcomes: improvement in constipation and faecal incontinence (primary endpoints) and improvement in neurogenic bowel dysfunction scores, lifestyle, coping/behaviour, depression, self-perception and embarrassment (secondary endpoints).
- The RCT included a power calculation, had a low risk of bias and measured outcomes utilising the intention to treat population

Limitations:

- The RCT only included spinal cord-injured patients with neurogenic bowel dysfunction over the age of 18 years old. Other efficacy data in support of TAI systems is limited to a small number of studies which used validated scoring systems, clinical measurements or prospectively collected data. The remainder of the evidence in support of TAI consists of patient series, with the use of retrospective questionnaires and subjective beneficial
effects of irrigation as criteria of success.

- In the RCT 30/42 patients randomised to Peristeen completed the 10 week trial – a withdrawal rate of 28.6%. Due to the nature of the intervention, the participants could not be blinded though the assessors are reported as being independent observers who had not participated in the training of the participants.
- In the RCT the following patients were excluded from the trial: previous use of transanal irrigation; evidence of bowel obstruction or inflammatory bowel disease, history of cerebral palsy or cerebral apoplexy, multiple sclerosis, diabetic polyneuropathy, previous abdominal or perineal surgery (excluding minor surgery such as appendectomy or hemorrhoidectomy), pregnancy or lactation, evidence of spinal shock, mental instability, treatment with more than 5 mg/day prednisolone, and implant for sacral nerve stimulation.
- At baseline, there was no difference between groups in the use of per-oral laxatives, rectal suppositories, or constipating medicine. At termination, these proportions were unchanged, indicating that patients using transanal irrigation still have to use adjuvant medication to support bowel function.
- Evidence in support of the Qu fora Mini system is limited to one 4 week audit in patients with passive faecal incontinence and / or evacuation difficulty, no evidence in the support of the other Qu fora devices or Aquaflush devices was identified.

Summary of evidence on cost effectiveness:

Health Technology Assessment bodies in the UK have not yet assessed the cost effectiveness of TAI devices in the treatment of Functional Bowel Disorders.

A cost effectiveness analysis of TAI versus conservative bowel management for spinal cord injury patients, based on healthcare costs in Germany, has been published. The cost effectiveness analysis is based on the efficacy data from the RCT, and was supported by the manufacturer of Peristeen.

The sensitivity analysis found that carer time could be increased up to 26% before influencing the overall result. Furthermore the price of the system for self-administered transanal irrigation could be increased up to 12% without tipping the balance. Similarly, it was possible to increase patient time spent on bowel management with transanal irrigation by up to 10% before altering the result that transanal irrigation is cheaper than conservative bowel management from a societal perspective.

It is unclear whether the assumptions made within the cost-effectiveness analysis apply within the UK NHS.
Prescribing and risk management issues:

Assessment
It is essential to carry out a full individual assessment of patient suitability prior to commencing irrigation. This will consider inclusion/exclusion criteria, assess patient motivation and acceptability of the procedure, and whether other possible alternatives have been considered or tried. This assessment should be in the format approved locally for bowel care. Digital rectal examination should be performed before the first irrigation and documented in all cases to check that there is no obstruction, that the anus is not stenosed and that there are not any painful anorectal conditions (such as anal fissure).

Informed Consent
As this is an invasive procedure informed consent from the patient must be sought prior to commencing TAI. The discussion should be documented and the patient’s consent recorded.

TAI may be used with Care and Close Monitoring in the following groups of patients according to St Marks’ Guidelines for Rectal Irrigation:

- Spinal cord injury at or above T6, monitor for autonomic dysreflexia, until it is clear that the technique is well tolerated and does not provoke autonomic dysreflexia
- Unstable metabolic conditions (frail, known renal disease or liver disease: may need to monitor electrolytes and possibly use saline rather than water for irrigation)
- Under 18 years old (consult paediatric consultant and use saline for younger children)
- Inability to perform the procedure independently or comply with the protocol in the absence of close involvement of carers (e.g. due to physical disability, cognitive impairment, major mental/emotional disorder). Experience to date with irrigation by a carer suggests that it is no more problematic than self-irrigation for physically disabled individuals
- Anorectal conditions that could cause pain or bleeding during the procedure (e.g. third degree haemorrhoids, anal fissure)

The following lists of absolute and relative contraindications are taken from a table in Emmanuel et al’s Consensus Review of best practice of transanal irrigation in adults. The authors emphasise that the lists are not exhaustive and clinicians are advised to always consider individual patient factors as well:

**Absolute Contraindications (do not use rectal irrigation):**
- Acute active inflammatory bowel disease
- Anal or rectal stenosis
- Acute diverticulitis
- Colorectal cancer
- Within three months of rectal surgery
- With four weeks after endoscopic polypectomy
- Ischaemic colitis
Relative Contraindications (use only after careful discussion with relevant medical practitioner):

- Severe diverticulosis
- Diffuse disease
- Dense sigmoid disease
- Previous diverticulitis or diverticular abscess
- Long-term steroid medication
- Radiotherapy to the pelvis
- Prior rectal surgery
- Faecal impaction
- Painful anal conditions
- Current or planned pregnancy
- Bleeding diathesis or anticoagulant therapy (not including aspirin or clopidogrel)
- Severe autonomic dysreflexia

Risks

- The risk of bowel perforation may accumulate with the number of irrigations performed. Therefore for an individual using TAI over many years, the risk may be higher than that observed in shorter-duration clinical trials.
- Prior to treatment, patients should be counselled that the procedure is invasive and has the potential to cause harm and, in rare cases, death. This should be balanced with the potential improvement in quality of life and symptoms, together with the risks associated with alternative options e.g. stoma creation.
- Patients must be educated in the management of possible bowel perforation i.e. Minor bleeding on the catheter is not a concern. More major or regular bleeding should lead to referral for flexible sigmoidoscopy. Altered (dark red) bleeding should prompt urgent referral to colorectal services. If the patient experiences a haemorrhage with or without pain, emergency care is indicated as the rectum could theoretically be perforated. This might necessitate emergency surgery and the patient should know to gain emergency medical help in this very unlikely event.¹
- Worsened faecal incontinence; minor discomfort or abdominal cramps and minor anal or rectal bleeding are other risks which should be discussed beforehand.

Training and follow-up for the patient

The following information is taken from Blackpool Teaching Hospitals’ Protocol for Rectal Irrigation and details their local procedures.²⁰

- Hourly appointments will be scheduled. Full discussion of the proposed treatment, principles of rectal irrigation and also what is expected of the patient will be determined prior to treatment. If the patient or carer is able to fully understand and carry out rectal irrigation, an appointment at home will be undertaken by the Specialist Nurse.
- The patient must give consent to this treatment being undertaken by a Specialist Nurse according to local Trust policy.
- Rectal irrigation is designed to be carried out independently in the privacy and comfort of the patient’s own home. A safe environment and easy access to toileting facilities should be in place before the procedure commences. If the patient has any problems with poor
mobility and/or dexterity then a referral onto the Occupational Therapist (OT) may be necessary. This is to assess if the patient needs to be provided with any toileting aids and/or adaptations so that the rectal irrigation system is used safely.

- Two Specialist Nurses will supervise the first use of the rectal irrigation system to help the patient, and any carer, use the system safely, optimally and with confidence. Once a patient has completed irrigation under supervision, they may try the procedure alone; however, typically more than one training session is required so each patient should be considered individually in terms of their readiness and capability to do so.
- Local Trust infection prevention procedures will be adhered to at all times.
- If irrigation is to be practised time will be taken to describe the procedure to the patient and/or carer and to answer any questions, and help manage their expectations. Explanation will also be given about an initial period of adjustment is perfectly normal and is required to establish their personalised routine. A bowel diary will be given to the patient and/or carer to record their progress during this period.
- If the patient is heavily and/or chronically constipated a digital rectal examination may be conducted. It is necessary that the rectum is clear before starting the irrigation. Therefore the GP may need to prescribe suppositories or enemas, if not contraindicated, to help clear the rectum.
- If the Coloplast Peristeen Rectal Irrigation System is being used - once the rectum is clear - the rectal catheter is primed, inserted and inflated into the lower rectum following the recommended guidelines.
- If the Manfred Sauer Quufora Rectal Irrigation System is being used – once the rectum is clear – the rectal cone is gently inserted into the lower rectum following the recommended guidelines.
- In adults approximately 200 - 500mls of warm tap water is instilled initially, over a period of 5 to 20 minutes. (In subsequent irrigations the water is then gradually increased in small increments of around 100mls until emptying is satisfactory with no leakage between irrigations. The literature, suggests that the average amount of water used is 700mls, but volumes of 250-1,000mls have also been reported).* The balloon is deflated and the water and bowel contents are evacuated.
- Any significant problems encountered during rectal irrigation or subsequently during telephone follow-up will be reported to the Consultant / GP and documented in the patient’s medical notes.
- All patients will receive the St Mark’s ‘Guidelines for the use of trans-anal irrigation.’ (Patient booklet) and telephone follow-up appointments. Contact numbers for the Specialist Nurses and the recommended Care Lines will also be given.
- All patients will, at first, be sent choice of clinic letter to confirm their appointment. Patients who are referred inappropriately, unable to comply or refuse treatment will be referred back to their Consultant/GP/Healthcare Professional to discuss alternative options.
- The outcome of rectal irrigation will be documented in the patient electronic and/or medical records and the telephone follow-up/ support program commenced. The Specialist Nurse follow up will be via telephone contact at 1 week, 1 month and 3 months. Followed by 6 monthly contacts. After 1 month a letter will be sent to the patients’ Consultant and GP with a detailed report of their progress.
Commissioning considerations:

Annual cost assuming alternate day use (Drug Tariff February 2015)

<table>
<thead>
<tr>
<th>Product</th>
<th>Annual cost £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peristeen®: 2 systems and 12 accessory units</td>
<td>£1,713.52</td>
</tr>
<tr>
<td>Qufora Mini®: 12 mini sets</td>
<td>£708.00</td>
</tr>
<tr>
<td>Qufora Cone Toilet®: 12 monthly sets</td>
<td>£1,219.92</td>
</tr>
<tr>
<td>Qufora Balloon®: 2 base sets and 12 accessory sets</td>
<td>£1,520.00</td>
</tr>
<tr>
<td>Qufora Bed®: 36 bed systems</td>
<td>£1,796.40</td>
</tr>
<tr>
<td>Aquaflush Actif Irrigation Cone®: 12 monthly sets</td>
<td>£1,212.00</td>
</tr>
<tr>
<td>Aquaflush Compact®: 12 monthly sets</td>
<td>£714.00</td>
</tr>
<tr>
<td>Aquaflush Quick®: 12 monthly sets</td>
<td>£1,222.32</td>
</tr>
</tbody>
</table>

Associated additional costs or available discounts:
No additional costs or available discounts identified.

Productivity, service delivery, implementation:

Patients from Lancashire are already being referred to specialist continence services/bowel clinics in operation throughout the region and beyond (Blackpool Teaching Hospital and University Hospital of South Manchester (Wythenshawe Hospital)). Blackpool Teaching Hospital has a protocol which explains referral pathways, training implications and on-going patient support. This may need to be compared with the other providers of rectal irrigation to ensure consistency.

Anticipated patient numbers and net budget impact:

<table>
<thead>
<tr>
<th>Prescriber Name</th>
<th>BNF Name</th>
<th>Total Items</th>
<th>Total Act Cost</th>
<th>Total Items</th>
<th>Total Act Cost</th>
<th>Items Growth</th>
<th>Cost Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCT BLACKBURN WITH DARWEN CCG</td>
<td>Peristeen</td>
<td>19</td>
<td>£2,745.15</td>
<td>19</td>
<td>£2,994.53</td>
<td>0</td>
<td>£249.38</td>
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<tr>
<td>PCT BLACKPOOL CCG</td>
<td>Peristeen</td>
<td>41</td>
<td>£4,951.30</td>
<td>37</td>
<td>£5,316.57</td>
<td>-4</td>
<td>£365.27</td>
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<tr>
<td>PCT CHORLEY AND SOUTH RIBBLE CCG</td>
<td>Peristeen</td>
<td>21</td>
<td>£4,681.36</td>
<td>48</td>
<td>£6,764.39</td>
<td>27</td>
<td>£2,083.03</td>
</tr>
<tr>
<td>PCT EAST LANCASHIRE CCG</td>
<td>Peristeen</td>
<td>73</td>
<td>£10,800.0</td>
<td>98</td>
<td>£13,507.3</td>
<td>25</td>
<td>£2,707.38</td>
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<tr>
<td>PCT FYLDE &amp; WYRE CCG</td>
<td>Peristeen</td>
<td>26</td>
<td>£3,210.50</td>
<td>41</td>
<td>£5,597.41</td>
<td>15</td>
<td>£2,386.91</td>
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<td>PCT GREATER PRESTON CCG</td>
<td>Peristeen</td>
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<td>33</td>
<td>£4,372.44</td>
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<td>-£398.28</td>
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<tr>
<td>PCT LANCASHIRE NORT CCG</td>
<td>Peristeen</td>
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<td>£3,962.31</td>
<td>20</td>
<td>£2,932.28</td>
<td>-11</td>
<td>-£1,030.03</td>
</tr>
<tr>
<td>PCT WEST LANCASHIRE CCG</td>
<td>Peristeen</td>
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<td>£7,198.81</td>
<td>54</td>
<td>£9,002.04</td>
<td>6</td>
<td>£1,803.23</td>
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</table>

298                               | 6              | 350         | 5              | 52          | £8,166.89      |
## Prescriber Name | BNF Name | Total Items | Total Act Cost | Total Items | Total Act Cost | Items Growth | Cost Growth
--- | --- | --- | --- | --- | --- | --- | ---
**PCT BLACKBURN WITH DARWEN CCG**
PCT BLACKPOOL CCG
PCT CHORLEY AND SOUTH RIBBLE CCG
PCT EAST LANCASHIRE CCG
PCT FYLDE & WYRE CCG
PCT GREATER PRESTON CCG
PCT NORTH LANCASHIRE CCG
PCT WEST LANCASHIRE CCG

**Qufora**
- **Sept - Nov 2013**
  - 5 items: £734.00
  - 19 items: £2,077.95
- **Sept - Nov 2014**
  - 14 items: £1,343.95

**Sept - Nov 2013**
- 13 items: £1,548.88
- 40 items: £3,926.51
- **Sept - Nov 2014**
  - 27 items: £2,377.63

**Qufora**
- **Sept - Nov 2013**
  - 2 items: £187.85
  - 24 items: £2,431.48
- **Sept - Nov 2014**
  - 22 items: £2,243.63

**Qufora**
- **Sept - Nov 2013**
  - 6 items: £405.63
  - 12 items: £1,156.53
- **Sept - Nov 2014**
  - 6 items: £750.90

**Qufora**
- **Sept - Nov 2013**
  - 1 item: £54.52
  - 20 items: £4,707.03
- **Sept - Nov 2014**
  - 19 items: £4,652.51

**Qufora**
- **Sept - Nov 2013**
  - 13 items: £1,548.88
  - 40 items: £3,926.51
- **Sept - Nov 2014**
  - 27 items: £2,377.63

**Qufora**
- **Sept - Nov 2013**
  - 2 items: £108.93
  - 14 items: £1,819.86
- **Sept - Nov 2014**
  - 12 items: £1,710.93

**Qufora**
- **Sept - Nov 2013**
  - 2 items: £108.93
  - 14 items: £1,819.86
- **Sept - Nov 2014**
  - 12 items: £1,710.93

<table>
<thead>
<tr>
<th>Total Items</th>
<th>Total Cost</th>
<th>Items Growth</th>
<th>Cost Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sept - Nov 2013</strong></td>
<td><strong>Sept - Nov 2014</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>39</td>
<td>£4,226.26</td>
<td>149</td>
<td>£17,569.6</td>
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<tr>
<td>6</td>
<td>£110</td>
<td>110</td>
<td>£13,343.4</td>
</tr>
</tbody>
</table>

Current spend across Lancashire for the last three months for all three products is £68,869.33. Equivalent to £275,477.30 annually.
Innovation, need, equity:

TAI as an intervention is not innovative and has been used throughout medical history to treat a range of symptoms and colonic irrigation still flourishes in alternative health.

No equity issues are anticipated

References


5. National Institute for Health and Care Excellence Diagnosis and management of idiopathic childhood constipation in primary and secondary care. Clinical Guideline 99; 2010


14. Fourtassi M, Charvier K, Hajjioui A et al. Transanal irrigations in the management of bowel dysfunction and disordered defecation after spinal cord injury. Annals of Physical and Rehabilitation Medicine 2011, 54/(e309); 1877-0657 (available as an abstract only)


Appendix 1

Coloplast has developed a symptom-based tool, the Neurogenic Bowel Dysfunction (NBD) score, to allow clinicians to assess the impact of NBD on a patient’s quality of life. The NBD score uses a validated questionnaire to help clinicians identify which patients may benefit from using transanal irrigation. The tool provides 10 questions, giving a score of between 0 and 47 – with a score of 10 or more indicating moderate to severe bowel dysfunction, which should prompt clinicians to consider the use of transanal irrigation.

The Neurogenic Bowel Dysfunction score – NBD Score

1. How often do you defaecate?
   - Daily (score 0)
   - 2-6 times per week (score 1)
   - Less than once per week (score 6)

2. How much time do you spend on each defaecation?
   - Less than 30 min. (score 0)
   - 31-60 min. (score 3)
   - More than an hour (score 7)

3. Do you experience uneasiness, sweating or headaches during or after defaecation?
   - Yes (score 2)
   - No (score 0)

4. Do you take medication (tablets) to treat constipation?
   - Yes (score 2)
   - No (score 0)

5. Do you take medication (drops or liquid) to treat constipation?
   - Yes (score 2)
   - No (score 0)

6. How often do you use digital evacuation?
   - Less than once per week (score 0)
   - Once or more per week (score 6)

7. How often do you have involuntary defaecation?
   - Daily (score 13)
   - 1-6 times a week (score 7)
   - 3-4 times a month (score 6)
   - A few times a year or less (score 0)

8. Do you take medication to treat faecal incontinence?
   - Yes (score 4)
No (score 0)
9. Do you experience uncontrollable flatus?
Yes (score 2)
No (score 0)

10. Do you have peri-anal skin problems?
Yes (score 3)
No (score 0)

Total score (between 0 and 47)
Date:

General satisfaction

Please mark the scale with a cross (x) to represent your general satisfaction with your bowel management.
(Total dissatisfaction = 0 / Perfect satisfaction = 10)
0 1 2 3 4 5 6 7 8 9 10

Severity of bowel dysfunction

Score 0-6: Very minor
Score 7-9: Minor
Score 10-13: Moderate
Score 14+: Severe
Score =

Table 1: Summary of key Transanal Irrigation RCT

<table>
<thead>
<tr>
<th>Ref</th>
<th>Trial design</th>
<th>Patients / Trial subjects</th>
<th>Trial intervention and comparison</th>
<th>Outcomes: Primary endpoint (mITT)</th>
<th>Outcomes: Key secondary / exploratory endpoints</th>
<th>Grading of evidence / risk of bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>10 week, prospective randomised controlled Trial.</td>
<td></td>
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<tr>
<td></td>
<td>Inclusion criteria:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- 18 years or older</td>
<td></td>
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<tr>
<td></td>
<td>- Spinal cord injury at any level at least 3 months after injury and at least one of the following symptoms</td>
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</tr>
<tr>
<td></td>
<td>- Spinal cord injury at any level at least 3 months after injury and at least one of the following symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Episodes of faecal incontinence once or more per month</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Symptoms reflecting autonomic dyreflexia before or during defecation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Abdominal discomfort before or during defecation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exclusion criteria:</td>
<td></td>
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<tr>
<td></td>
<td>- Coexisting major unsolved physical problems due to the injury</td>
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<tr>
<td></td>
<td>- Performance of transanal irrigation on a regular basis</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- Evidence of bowel obstruction or inflammatory bowel disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- History of cerebral palsy or cerebral apoplexy</td>
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<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mean age 49.1 years</th>
<th>28.7% female Etiology</th>
<th>64% traumatic</th>
<th>8% sequelae to operation</th>
<th>7% Tumor</th>
<th>3% slipped disc</th>
<th>2% vascular</th>
<th>2% spina bifida</th>
<th>13% other reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean duration of bowel symptoms: 57 months</td>
<td>Predominant symptom</td>
<td>Fecal incontinence 20%</td>
<td>Constipation 76%</td>
<td>Other reason 5%</td>
<td>Transanal irrigation using the Peristeen system (n=42)</td>
<td>Conservative bowel management (n=45)</td>
<td>Cleveland Clinic constipation score (range 0-30, with 30 representing severe symptoms)</td>
<td>Peristeen Baseline: 14.8</td>
</tr>
<tr>
<td>St Marks faecal incontinence grading system (range 0-24, with 24 representing severe symptoms)</td>
<td>Peristeen Baseline: 8.8</td>
<td>Termination: 5.0</td>
<td>Conservative bowel management Baseline: 8.4</td>
<td>Termination: 7.3</td>
<td>Neurogenic bowel dysfunction score (range 0-47, with 47 representing severe symptoms)</td>
<td>Peristeen Baseline: 14.8</td>
<td>Termination: 10.4</td>
<td></td>
</tr>
<tr>
<td>Modified American Society of Colorectal Surgeons FI score; Lifestyle (range 1-4, 4 represents high QoL)</td>
<td>Peristeen Baseline: 2.8</td>
<td>Termination: 3.0</td>
<td>Conservative bowel management Baseline: 2.8</td>
<td>Termination: 2.8</td>
<td>Coping/behaviour (range 1-4, 4 represents high QoL)</td>
<td>Peristeen Baseline: 2.4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Patient-oriented outcome measure? Yes
Allocation concealment? Yes
Blinded if possible? Yes Only the assessors
Intention to treat analysis? Yes
Adequate power/size? Yes
Adequate follow-up (>80%)? Yes
Level 1 evidence based on RCT with POOs and low risk of bias.
Risk of bias: Low based on allocation concealment, intention to treat analysis, adequate power and follow-up.
- Multiple sclerosis
- Diabetic polyneuropathy
- Previous abdominal or perineal surgery
- Pregnancy or lactation
- Evidence of spinal shock
- Mental instability
- Treatment with more than 5mg/day prednisolone
- Implant for sacral nerve stimulation.

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Termination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression/self-perception</td>
<td>2.4</td>
<td>2.4</td>
</tr>
<tr>
<td>Embarrassment (range 1-4, 4 represents high QoL)</td>
<td>2.7</td>
<td>3.0</td>
</tr>
<tr>
<td>Numeric box scale Bowel function; (range 0-10, 10 representing perfect function)</td>
<td>3.0</td>
<td>3.5</td>
</tr>
</tbody>
</table>

Conservative bowel management
Baseline: 2.4
Termination: 2.4

Depression/self-perception
Baseline: 2.7
Termination: 3.0

Conservative bowel management
Baseline: 2.9
Termination: 2.7

Embarrassment (range 1-4, 4 represents high QoL)
Baseline: 3.7
Termination: 3.2

Conservative bowel management
Baseline: 3.0
Termination: 2.8

Numeric box scale
Baseline: 3.0
Termination: 5.2

Conservative bowel management
Baseline: 3.2
Termination: 3.5
<table>
<thead>
<tr>
<th></th>
<th>Peristeen</th>
<th>Conservative bowel management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influence on daily activities</td>
<td>Baseline: 3.4</td>
<td>Baseline: 4.2</td>
</tr>
<tr>
<td></td>
<td>Termination: 4.5</td>
<td>Termination: 4.1</td>
</tr>
<tr>
<td>General Satisfaction</td>
<td>Baseline: 2.4</td>
<td>Baseline: 3.1</td>
</tr>
<tr>
<td></td>
<td>Termination: 5.2</td>
<td>Termination: 3.6</td>
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<tr>
<td>Improvement in Quality of Life</td>
<td>Peristeen 6.3</td>
<td>Conservative bowel management 4.2</td>
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Grading of evidence (based on SORT criteria):

<table>
<thead>
<tr>
<th>Levels</th>
<th>Criteria</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level 1</strong></td>
<td>Patient-oriented evidence from:</td>
<td>Notes: High quality individual RCT = allocation concealed, blinding if possible, intention-to-treat analysis, adequate statistical power, adequate follow-up (greater than 80%)</td>
</tr>
<tr>
<td></td>
<td>• high quality randomised controlled trials (RCTs) with low risk of bias</td>
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</tr>
<tr>
<td></td>
<td>• systematic reviews or meta-analyses of RCTs with consistent findings</td>
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<tr>
<td><strong>Level 2</strong></td>
<td>Patient-oriented evidence from:</td>
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</tr>
<tr>
<td></td>
<td>• clinical trials at moderate or high risk of bias</td>
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<td>• systematic reviews or meta-analyses of such clinical trials or with inconsistent findings</td>
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<td>• cohort studies</td>
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<td>• case-control studies</td>
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<tr>
<td><strong>Level 3</strong></td>
<td>Disease-oriented evidence, or evidence from:</td>
<td>Notes: Any trial with disease-oriented evidence is Level 3, irrespective of quality</td>
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<td></td>
<td>• consensus guidelines</td>
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<td>• expert opinion</td>
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<td>• case series</td>
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<tr>
<td>Patients</td>
<td>Study Design</td>
<td>System / Equipment</td>
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<td>----------</td>
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<tr>
<td><strong>Children</strong></td>
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| n = 24 children (median age 6 years) with faecal incontinence secondary to myelomeningocele, Hirschsprung disease, and anorectal anomalies managed with Peristeen between 2006-2011. | Retrospective case note review and assessment using a validated quality of life questionnaire (QOL) to determine pre- and post-TAIS bowel function and continence | Peristeen | • Three children did not tolerate the system  
• Median QOL scores in 20 out of 21 patients using TAIS demonstrated significant improvement in bowel management and continence  
• Nineteen of 24 patients (79%) continue to use TAIS  
• Two children discontinued use due to failure to improve continence; one underwent the Malone antegrade continence enema (MACE) procedure and one returned to oral/rectal medications | Strengths  
• Validated QOL questionnaire used  
Peristeen integrated transanal irrigation system successfully treats faecal incontinence in children. |
| n = 15 children with myelomeningocele and neurogenic bowel dysfunction | Retrospective review using a postal questionnaire | Peristeen | • 42.9 % reported an improvement in symptoms of uneasiness, headache or perspiration during or after a bowel evacuation.  
• A majority of patients reported all other symptoms as worsening.  
• 38.4 % reported an improvement in quality of life, however, 38.4 % reported no change with the remainder reporting a worsening. | Strengths  
• Structured questionnaire  
• Published even though results were mostly negative | O’Brien A, O’Mahony O, Daly E. *Irish Journal of Medical Science*, July 2014, vol./is. 183/4 SUPPL. 1(S191), 0021-1265  
Peristeen as a management for neurogenic bowel dysfunction |
- 83.3 % reported an increase or no change in time spent on bowel management.
- 61.5 % reported no change in their level of independence.
- 84.6 % experienced expulsion of the catheter and 69.2 % experienced leakage of irrigation fluid and abdominal pain during use. 69.2 % had experienced bursts of the rectal balloon at least once.

Conclusions: Peristeen did not improve symptoms of NBD, quality of life or amount of time spent on bowel management in this group of patients. Furthermore, patients encountered difficulties when using Peristeen.

**n = 23 children (median age of 7 years) with spina bifida, rectal anomalies, Hirschprung’s disease and other complex anomalies treated with Peristeen between 2007-2012.**

<table>
<thead>
<tr>
<th>Retrospective review</th>
<th>Peristeen</th>
<th>Strengths</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 23 children (median age of 7 years) with spina bifida, rectal anomalies, Hirschprung’s disease and other complex anomalies treated with Peristeen between 2007-2012.</td>
<td>Sixteen (70%) children used alternate-day irrigations, 4 (17%) daily irrigations, and 3 (13%) every third-day irrigations</td>
<td>No loss to follow-up</td>
<td>Retrospective</td>
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<td>Nine (39%) patients were taking oral laxatives</td>
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<td>Population made up of a small number of paediatric patients with very specific disorders</td>
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<td>Sixteen (70%) reported to be clean and 3 (13%) reported a significant improvement, although were having occasional soiling</td>
<td></td>
<td>Non-comparative</td>
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<td></td>
<td>Four patients (17%) did not tolerate the irrigations and underwent subsequent colostomy formation for intractable soiling</td>
<td></td>
<td>Use of Peristeen® transanal colonic irrigation for bowel management in children: a single-center experience.</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Adults</th>
<th>Retrospective review by telephone interview for patients initiated on Peristeen and continued for mean of 31 months</th>
<th>Peristeen</th>
<th>Strengths</th>
</tr>
</thead>
</table>
| n=16/20 patients with constipation +/- faecal incontinence or perineal pain and with **underlying neurologic pathology** initiated on Peristeen (4 excluded because Peristeen was not continued at the start for a variety of reasons) | 10 (62.5%) of the 16 patients were still using Peristeen after a mean of 31 months. 4 patients ceased using Peristeen at 1 month, 1 patient at 3 months and the final patient at 23 months. In 1 of these patients, a digestive complication, a sub-occlusive episode occurred requiring an emergency consultation  
Mean irrigation frequency of twice a week  
Patients required not only drugs but also additional therapeutics to bowel management: manual evacuation in 20% of cases, abdominal massages in 20% of cases too, and other type of enema in 10% of cases  
77.78% of patients experienced technical problems using Peristeen  
1 patient experienced rectorrhagia following the first irrigations  
Average consumption of laxatives reduced from 1.66 to 1.48 molecules per day but this reduction did not reach statistical significance (P=0.6783)  
Mean NBD score was 6.25/47 (6 = minor bowel dysfunction), and mean Cleveland clinic score was 0.50/20, reflecting a faecal continence practically normal. | long follow-up  
structured questionnaire |
|                 | Limitations                                                                                       |           | Retrospective  
4 patients excluded at the start  
No initial Cleveland constipation scores or NBD scores with which to compare later results  
Non-comparative  
Small number of patients |
<p>|                 | Strengths                                                                                         |           | Long-term transanal irrigation's continuation at home. Preliminary study. |</p>
<table>
<thead>
<tr>
<th>Study Design</th>
<th>Intervention</th>
<th>Findings</th>
<th>Strengths</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retrospective data review and validated patient survey system posted to patients</td>
<td>Peristeen</td>
<td>In the 10 patients still treated with Peristeen there was a mean satisfaction score with Peristeen of 9.12/10</td>
<td>Only 10 patients responded (34% response rate)</td>
<td>Very small sample size of respondents</td>
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<td>Review of symptoms and comparison of scores of faecal incontinence and quality of life before and after the treatment</td>
<td>Peristeen</td>
<td></td>
<td>90% (n = 9) thought the equipment was acceptable, 80% had issues with hygiene/embarrassment. Whilst the equipment was felt to be excellent or good in 80% of patients for ease of use, ability to clean and the time taken to use, there were significant problems encountered in terms of catheter placement (100%), balloon bursting (70%) and water leakage (70%)</td>
<td>Non-comparative</td>
</tr>
</tbody>
</table>

**Strengths**
- Structured questionnaire
- Non-comparative

**Limitations**
- Very small sample size of respondents
- Non-comparative

**References**
- Cornish J, Combellack T, Edwards K et al. *Colorectal Disease*, September 2014, vol./is. 16/(38), 1462-8910 (September 2014)
- Miller S, Artioukh D *Colorectal Disease*, September 2011, vol./is. 13/(54), 1462-8910

Rectal irrigation—who is being referred and do patients accept it?