

## Rectal irrigation (DROP-List)

This is one of a number of bulletins providing further information on medicines and medical devices contained in the PrescQIPP DROP-List Devices (Drugs or Devices to Review for Optimised Prescribing).<sup>1</sup> The DROP-List incorporates drugs prescribed across the NHS that are considered low priority and poor value for money. Some of the NICE 'Do Not Do' items are included, as are drugs that could potentially be provided as self care, with advice and support from community pharmacists. A number of medical devices are now also included; where appropriate, the need for local pathways and waste minimisation strategies is considered for these products. This bulletin focuses on rectal irrigation and provides the rationale for ensuring it is only used as part of an appropriate patient care pathway that incorporates a robust patient selection process. Further bulletins, including the medical devices DROP-List,<sup>2</sup> are available on the PrescQIPP website, [www.prescqipp.info](http://www.prescqipp.info)

### Recommendations

- Rectal irrigation is a highly specialist management option and should only be considered as part of an appropriate locally commissioned bowel care pathway. It is not recommended for initiation by GPs in primary care, without specialist management.
- Rectal irrigation has been used in the management of chronic constipation and/or chronic faecal incontinence due to neurogenic bowel dysfunction and functional bowel disorders.
- Clinical evidence supporting the use of this intervention is very limited:
  - » The only indication for which there is randomised controlled trial evidence (from one study) supporting rectal irrigation is spinal cord injury with neurogenic bowel dysfunction in adults.
  - » For other indications, data are largely derived from uncontrolled case series.
- Rectal irrigation should therefore only be considered where initial treatment with other less invasive options has proved unsuccessful. Initial management may include diet, bowel habit, toilet access, medication, and coping strategies. This is in line with NICE guidance on managing faecal incontinence in adults (CG49).
- NICE guidance on the diagnosis and management of idiopathic constipation in children and young people (CG99) does not include rectal irrigation as a treatment option prior to surgical intervention.
- A medical evaluation by an appropriate specialist is necessary before starting rectal irrigation. In some people endoscopic investigation is needed before rectal irrigation can be commenced.
- Consider using an appropriate, validated scoring system at baseline and at reviews to help identify those benefitting from treatment.
- Mild and transient symptoms, such as abdominal pain, chills, nausea and minor rectal bleeding, are seen frequently during or after rectal irrigation. There is also potential for autonomic dysreflexia, which is of particular concern in those with spinal cord injury with lesions located at or above T6.
- Although extremely rare, rectal irrigation carries a risk of bowel perforation, which can be fatal. Patients should be taught to recognise the symptoms of colonic perforation and what actions to take.
- Comprehensive training for the individual, plus on-going support are essential for safe and efficient long term use of rectal irrigation.

- Minimise waste by ensuring the correct type and quantity of consumables are ordered. This should take into account the frequency of irrigation and the number of uses appropriate for the product.
- Products should not be added to GPs repeat prescribing systems at initiation. Once a consistent routine of irrigation has been established (often on alternate days) it may be appropriate to add only items that need to be ordered on a monthly basis to the repeat prescribing system. Treatment should be reviewed regularly.
- For those taking laxatives before starting irrigation, it is prudent to continue these in the usual dose until irrigation is established. They may subsequently be able to gradually stop taking laxatives, but many continue to need them.

## Background

### Rectal irrigation systems

Rectal irrigation therapy, also referred to as anal irrigation or trans-anal irrigation, is used as a treatment for bowel dysfunction. Body temperature tap water is instilled into the rectum via the anus, using either a balloon catheter or cone shaped delivery system. The catheter or cone is usually attached via a plastic tube to an irrigation bag holding up to two litres of water. Low volume systems without an irrigation bag are also available.<sup>3</sup> Most systems include a hand-held manual pump, with the exception of one with an electronic pump.<sup>4-7</sup> The frequency and volume of irrigation depends on the individual's response to treatment.<sup>3</sup> Irrigation should be performed daily initially, and then reduced to alternate days where possible;<sup>8</sup> for most people irrigation on alternate days (or less frequently) is suitable.<sup>9,10</sup> On removal of the catheter or cone the water is evacuated into the toilet (or collection bag for one system), along with the contents of the sigmoid and possibly the descending colon.<sup>11</sup>

For a summary of the different rectal irrigation systems available including details of their components and the number of times they can be used, see attachment 1. Some of the systems included can also be used for colostomy irrigation, but this technique is beyond the scope of this bulletin.

### Potential indications

Rectal irrigation is intended to help re-establish controlled bowel function and enable the user to choose the time and place of evacuation.<sup>11</sup> It has been used in managing:

- Neurogenic bowel dysfunction, e.g. due to spinal cord injury, spina bifida, multiple sclerosis.
- Chronic constipation, including both evacuation difficulties and slow transit constipation.
- Chronic faecal incontinence.<sup>10</sup>

In those with faecal incontinence, emptying of the colon and rectum means that new faeces do not reach the rectum for an average of two days, thereby preventing leakage between irrigations.<sup>11</sup> In those with constipation, proposed mechanisms of action include simple mechanical washout, colonic movement stimulated by the washout, or a combination of these.<sup>3</sup>

## National guidance

The National Institute of Health and Care Excellence (NICE) have not produced a technology appraisal for rectal irrigation therapy.

### Faecal incontinence

NICE guidance on the management of faecal incontinence in adults (CG49) includes rectal irrigation as a possible specialist management option after initial management (which covers diet, bowel habit, toilet access, medication and coping strategies). Other specialist management options include:<sup>12</sup>

- Pelvic floor muscle training
- Bowel retraining

- Specialist dietary assessment and management
- Biofeedback
- Electrical stimulation.

NICE recognise that there is only limited evidence that these interventions have clinical benefits over and above those of initial management. Therefore they are only recommended for consideration in those who are not responding adequately to initial management.<sup>12</sup>

The Royal College of Surgeons and the Association of Coloproctology of Great Britain and Ireland have produced a commissioning guide for faecal incontinence. It suggest rectal irrigation should be accessible as part of a bowel care pathway for faecal incontinence. The commissioning guide includes pathways for faecal incontinence and rectal irrigation, which could be adapted for local use ([www.rcseng.ac.uk/library-and-publications/college-publications/docs/faecal-incontinence-guide/](http://www.rcseng.ac.uk/library-and-publications/college-publications/docs/faecal-incontinence-guide/)).

It states that specialist management should be considered for those with:

- Refractory symptoms after initial management (including dietary modification, medication and advice on use of continence products)
- Gross sphincter pathology (congenital malformation)
- Relevant co-morbidity (neurological disease)

For the majority, a nurse or therapist led specialised bowel management clinic should be appropriate. Rectal irrigation may be one of several treatment options available in this setting.<sup>13</sup>

## Constipation

The NICE Clinical Knowledge Summary on managing constipation in adults recommends the following for chronic constipation:<sup>14</sup>

- Lifestyle advice – regarding diet, fluid intake, exercise and toileting routines
- Avoiding medications that can constipate, where possible
- Laxatives
- Prucalopride or lubiprostone, in accordance with their licensed indications and NICE criteria for use.

Indications for referral include suspicion of cancer or other underlying cause, where treatment has been unsuccessful and where faecal incontinence is present.<sup>14</sup>

Rectal irrigation is not discussed, and NICE have not produced a clinical guideline for the management of constipation in adults.

In 2010 NICE published a guideline on the diagnosis and management of constipation in children and young people.<sup>15</sup> The guideline does not recommend or discuss the use of rectal irrigation. For idiopathic constipation, after treatment for faecal impaction (where present), maintenance treatment should include laxatives. It should also incorporate a combination of negotiated and non-punitive behavioural interventions and dietary modifications to ensure a balanced diet and sufficient fluids are consumed.

Those who still have unresolved symptoms on optimum management should be referred to a paediatric surgical centre to assess their suitability for an antegrade colonic enema (ACE) procedure.<sup>15</sup>

In 2014, stakeholder feedback was assessed during surveillance of this guideline. It suggested that rectal irrigation should be considered prior to referral for surgical intervention with the ACE procedure. Four members of the guideline development group were consulted; their feedback was mixed but they generally indicated that the research evidence in this area is not robust. They felt it would be premature to consider rectal irrigation for inclusion in the guideline at this time, and the guideline was not updated.<sup>16</sup>

## Other recommendations

The International Children's Continence Society recommends rectal irrigation as a treatment option for children with neurogenic bowel dysfunction.<sup>17</sup>

A consensus expert review on best practice in rectal irrigation was published in 2013. It emphasises the importance of consultation with a specialist health care professional before instigating the irrigation procedure. Careful patient selection, directly supervised training with expert operators and sustained follow-up are needed to optimise outcomes with the technique.<sup>8</sup>

## Clinical effectiveness

### Neurogenic bowel dysfunction

One prospective, multi-centre, randomised controlled trial (RCT) by Christensen et al 2006 has compared rectal irrigation with conservative bowel management (best supportive bowel care without irrigation).<sup>18</sup> Eighty-seven adults with spinal cord injury with neurogenic bowel dysfunction were enrolled for the ten week trial period, using the Peristeen® rectal irrigation system. Exclusion criteria included history of cerebral palsy or cerebral apoplexy, multiple sclerosis and diabetic polyneuropathy. For both of the primary endpoints below, a statistically significant difference in mean score (standard deviation) favouring rectal irrigation compared with conservative management was demonstrated:

- Cleveland Clinic constipation scoring system (range, 0–30, 30=severe symptoms) – mean score 10.3 (4.4) for rectal irrigation versus 13.2 (3.4) (P=0.0016) for conservative management.
- St Mark's faecal incontinence grading system (range, 0 –24, 24=severe symptoms) – mean score 5.0 (4.6) for rectal irrigation versus 7.3 (4.0) (P=0.015) for conservative management.

Statistically significant differences in favour of rectal irrigation were also observed for some secondary outcomes including neurogenic bowel function score, some aspects of a symptom-related quality of life score and total time for bowel care. Those in the rectal irrigation group were generally more satisfied with their treatment than those receiving conservative management. The authors also noted a statistically significant reduction in the number of urinary tract infections in the rectal irrigation group.<sup>18</sup>

Several other studies investigating rectal irrigation in neurogenic bowel dysfunction have been published, but no further RCTs were identified. The other studies are generally non-comparative and the majority included small numbers of patients.<sup>11</sup>

A systematic review of the use rectal irrigation in children and young people with neurogenic bowel was published in 2013. The populations studied included those with spinal cord injury and spina bifida. Sixteen studies were included (eight of which used saline rather than water for irrigation). No RCTs were identified; studies were case series with no control or matched groups and as such are more susceptible to bias. The authors concluded that although rectal irrigation could be an effective treatment, more rigorous research is needed to determine its efficacy, acceptability and effect on quality of life.<sup>19</sup>

### Functional bowel disorders

A 2015 systematic review with meta-analysis evaluated the evidence for rectal irrigation therapy in adults with chronic functional constipation. Seven eligible uncontrolled studies (n=254 patients) of retrospective or prospective design were identified. Study methodology was generally considered to be weak and most were at serious risk of bias. All studies used high-volume irrigation. The proportion of patients with a positive outcome based on investigator-reported response for each study was 50.4% (95% CI: 44.3–56.5%). The authors note that by comparison, response rates for drug treatments in this group of patients has been reported as 20-40%, although these data are from prospective RCTs reporting symptom based primary end-points. Whilst the findings of this meta-analysis are encouraging, it demonstrates that the evidence base for rectal irrigation in functional constipation is currently weak; well-designed prospective trials are required.<sup>3</sup>

## Mixed populations

A 2010 systematic review considered a broader view of the evidence base for the use of rectal irrigation for disordered defecation, without limiting the scope to specific groups of patients.<sup>20</sup> Twenty seven studies were identified, only one of which (by Christensen et al 2006, described above) was an RCT. None of the remaining studies used a control group. Most used retrospective questionnaires and subjective beneficial effects of irrigation as criteria of success. A small risk of overlapping cases between studies was noted. Twelve studies (n=672) described the use of rectal irrigation in children; 88% of patient cases were regarded as treatment successes. Seventeen studies (n=1229) evaluated the intervention in adults, with 53% of patient cases regarded as treatment successes.

The data provided only limited support for long term use of rectal irrigation. One of the studies described the accumulated experience from a ten year period with 348 patients with heterogenic background pathology. It found overall success in 47% of patients after a mean follow-up period of 21 months. The same study also found the best results to be among patients with neurogenic bowel dysfunction.<sup>20</sup>

The findings of this systematic review are again limited by the quality of the available evidence. Furthermore, the approach of considering data for rectal irrigation as a therapy for several conditions together has been questioned. Scintigraphic studies have suggested that those with slow colonic transit and functional constipation may have a different response to irrigation, with reduced colonic clearance compared with spinal cord injured patients.<sup>3</sup>

## Safety

Mild and transient symptoms, such as abdominal pain, chills, nausea and minor rectal bleeding, may occur during or after irrigation. It has been estimated from six predominantly small uncontrolled studies (smallest n=39, largest n=348, 1 RCT) that such effects are to be expected in 38%–74% of patients.<sup>20</sup> Technical problems with the irrigation can also be experienced; for example in one study burst of the rectal balloons were reported in approximately one in three patients.<sup>18</sup>

The potential for autonomic dysreflexia is of particular concern in those with spinal cord injury with lesions located at or above T6. Common symptoms are pounding headache, facial flushing, sweating, bradycardia and piloerection. Symptoms usually resolve when the initial stimulus is removed, but they can progress to severe complications.<sup>20</sup>

Introduction of a catheter into the rectum and administration of water under pressure carries the risk of potentially fatal bowel perforation. Based on the reporting of perforations compared with catheters dispensed, the estimated risk of irrigation-induced perforation has been calculated as one per 50,000 irrigations (0.0002%). However, this is only an estimate as the true incidence of perforation in this community-provided treatment is not accurately quantifiable.<sup>8</sup> In 2011, the Medicines and Healthcare Products Regulatory Agency (MHRA) issued a Medical Device Alert to warn of the risk of bowel perforation (in relation to the Peristeen® system). They highlight the need for comprehensive training and awareness of risk in those using the system. A medical evaluation by a doctor with appropriate expertise is also necessary before using the system.<sup>21</sup> Patients should be taught to recognise the symptoms of colonic perforation and what actions to take.<sup>8</sup>

The MHRA and the manufacturer of Peristeen® issued further alerts in 2014 to draw attention to changes to the indications, contraindications, precautions and warning sections of the product information. More detailed instructions for patient examination before starting rectal irrigation was also added. This included the need for digital rectal examination and, in some cases, endoscopic investigation before rectal irrigation is commenced.<sup>22,23</sup> The updates were prompted by the publication of a consensus review of best practice of rectal irrigation in adults. Table 1 outlines the absolute and relative contraindications for rectal irrigation, in accordance with the consensus review.<sup>8</sup>

**Table 1. Absolute and relative contraindications for rectal irrigation<sup>8</sup>**

Absolute contraindication	Relative contraindication
Anal or rectal stenosis	Severe diverticulosis: <ul style="list-style-type: none"> <li>• Diffuse disease</li> <li>• Dense sigmoid disease</li> <li>• Previous diverticulitis or diverticular abscess</li> </ul>
Active inflammatory bowel disease	Long term steroid medication
Acute diverticulitis	Radiotherapy to the pelvis
Colorectal cancer	Prior rectal surgery
Within three months of rectal surgery	Faecal impaction
Within four weeks after endoscopic polypectomy	Painful anal conditions
Ischaemic colitis	Current or planned pregnancy
	Bleeding diathesis or anticoagulant therapy (not including aspirin or clopidogrel)
	Severe autonomic dysreflexia
As the list may not be exhaustive, the clinician is recommended to always consider individual patient factors as well.	

## Considerations

- Comprehensive training for the individual, plus on-going support are essential to safe and efficient long term use of rectal irrigation. The hands-on training process should be supported by locally produced written information in an accessible form, and may be supplemented by commercial information.<sup>8</sup>
- Although several factors have been associated with a positive outcome, no consistent and readily explainable predictors of outcome have yet been identified. Nonetheless, those with neurogenic bowel dysfunction seem to do better than those with functional disorders. The consensus of a group of specialists with experience in prescribing and monitoring patients using rectal irrigation is as follows:
  - » A trial-and-error strategy for the introduction of rectal irrigation should be applied, individualised to each patient.
  - » For patients with idiopathic constipation and faecal incontinence, rectal irrigation should only be considered after appropriate conservative therapies, including biofeedback (where available) have been tried without success.
  - » Response to treatment may also depend on the individual's psyche and motivation. For example, demonstrated adherence with regard to other hospital follow-up is likely to influence their safe and long-term use of rectal irrigation. These factors should be considered as part of the baseline assessment.
  - » The individual's degree of manual dexterity should also be taken into account.<sup>8</sup>
- It is important to set realistic expectations for those starting rectal irrigation to reduce the risk of frustration and early discontinuation. It may take 4-12 weeks of trial-and-error to establish a reliable and effective routine.<sup>8</sup>

If success has not been achieved by 8-12 weeks, a re-evaluation needs to be undertaken. This should incorporate the views of the user (and carer if appropriate) to identify problems and practical issues. Some may be able to safely and effectively continue with rectal irrigation, but for others alternative treatments will be needed.<sup>8</sup>

Greater support is needed whilst treatment is initiated and an individual routine is established. Subsequent follow-ups may become less intensive over time, but should happen at least annually.<sup>8</sup>

Using an appropriate, validated scoring system at baseline and at reviews could help to identify those benefitting from treatment. Validated scoring systems include the Cleveland Clinic constipation scoring system, the St Mark's faecal incontinence grading system and the neurogenic bowel function score.<sup>18</sup>

Of the rectal irrigation systems available, much of the published evidence (including the one available RCT) relates to the Peristeen® system.<sup>18</sup> It remains to be ascertained whether one system outperforms the other.<sup>8</sup>

Alongside the evidence, the individual's needs must be considered when choosing an appropriate irrigation system.<sup>8</sup>

For those taking laxatives before starting irrigation, it is prudent to continue these in the usual dose until irrigation is established. They may subsequently be able to gradually stop taking laxatives.<sup>10</sup> However, one study found that after a mean follow up of 21 months 60% of those using rectal irrigation also took laxatives.<sup>9</sup>

### Costs

For the estimated monthly costs of the different available systems, see attachment 1. For some systems the average monthly cost quoted is based on the system being used for a specific time period (from six months to three years for some systems). It should be noted that rectal irrigation can have a high drop-out rate. For example, among 211 patients with neurogenic bowel dysfunction treated with rectal irrigation, 46% and 35% were successfully treated after a mean follow-up of 19 months and three years, respectively.<sup>8</sup>

### Savings

In England and Wales, over £14.8 million is spent on rectal irrigation systems over the course of a year (ePACT June to August 2016).

Savings may be achieved by:

- Having clear patient care pathways that incorporate a robust patient selection process. Pathways should facilitate access to treatment where it is appropriate and prevent improper use.
- Minimising waste by ensuring the correct type and quantity of consumables are ordered. This should take into account the frequency of irrigation and the number of uses appropriate for the product.
- Monitoring prescribing data to identify inappropriate items or quantities.

**A 20% reduction in prescribing (by reducing wastage and any inappropriate prescribing) would produce savings in the order of over £2.9 million annually (ePACT June to August 2016). This equates to £4,879 per 100,000 patients.**

### Summary

- Rectal irrigation is a highly specialist treatment that should only be considered as part of an appropriate locally commissioned bowel care pathway. The clinical evidence supporting its use is very limited, particularly outside the indication of spinal cord injury with neurogenic bowel dysfunction. As such, its use should only be considered in those whose bowel dysfunction has not responded to initial treatment, where it may offer a less invasive option than surgery. Careful patient selection, training and follow-up are essential.

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## Additional PrescQIPP resources



Briefing



Data pack



Summary of systems

Available here: <https://www.prescqipp.info/resources/category/348-rectal-irrigation-drop-list>

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