Decision Guide for Bowel Management incorporating Transanal Irrigation

Introduction

Constipation and faecal incontinence are symptoms associated with major impairment of quality of life. Such bowel dysfunction can arise from a variety of causes. Neurological diseases are commonly associated with bowel dysfunction and this may be termed neurogenic bowel dysfunction (NBD). Of those with spinal cord injury up to 95% report constipation and 75% have experienced episodes of faecal incontinence. Two-thirds of individuals with MS experience constipation and/or faecal incontinence and in spina bifida patients, only 32% report normal bowel function. Constipation affects between 25-63% of those with Parkinson's Disease (depending on definition used). Stroke may also result in (NBD), with chronic faecal incontinence occurring in 15% of patients. Constipation complicates opioid use in up to 60% of cases, and with the increased prescribing of these agents, opioid induced constipation is an increasingly prevalent problem. Nevertheless, an idiopathic aetiology remains the commonest cause of presentation with constipation and faecal incontinence. Increased age is correlated with idiopathic causes and with an aging population, the prevalence of such symptoms is ever increasing.

Effective treatment options for these conditions are therefore essential. Recent years have seen the advent of novel pharmacological agents to treat constipation, for example prucalopride for constipation, linaclotide for constipation predominant IBS and naloxegol to treat opioid induced constipation. Despite this, there remain many patients with refractory symptoms.

Transanal irrigation (TAI) has emerged as an acceptable solution for many of these patients. The patient, under specialist supervision, is taught how to insert either a catheter or cone into the anus. Warm water is then introduced into the bowel until the urge to defaecate is felt. Upon removal of the cone or catheter water is expelled along with the contents of the proximal colon and rectum. The

exact mechanism of action is unclear. There is likely to be a degree of 'flushing' and also stimulation of peristaltic contractions which aids expulsion of faeces out of the anus. By regularly emptying the bowel in this manner, TAI is intended to help re-establish control of bowel function and enable the user to choose the time and place of evacuation thus re-instating more predictable evacuation. In patients with faecal incontinence, efficient emptying of the colon and rectum means that new faeces does not reach the rectum for about two days, thereby preventing leakage between irrigations In patients with constipation, regular evacuation of the rectosigmoid region can promote transport through the entire colon and therefore prevent blockages and faecal loading.

TAI was initially studied in a randomised controlled trial and there are now over 100 reports of using this technique in the literature. Studies into the long-term results of TAI found that approximately 60% continue with treatment at long-term follow-up, and resulted in lower rates of stoma surgery, UTIs, episodes of faecal incontinence with improved quality of life compared to conservative bowel care. This was associated with a lifetime cost saving of £21,768 per patient compared to continuation of standard bowel care.

One modality of trans anal irrigation has recently been appraised by the National Institute for Clinical Excellence (NICE) and deemed to be an appropriate and cost-effective therapy for patients with both neurogenic and idiopathic bowel dysfunction. The NICE recommendation was that patients needed access to a comprehensive range of TAI options to tailor treatment to individual needs.

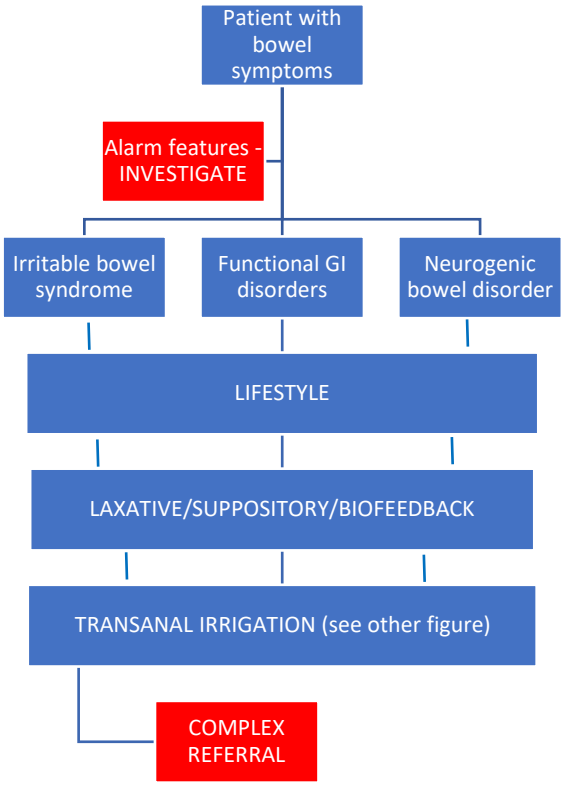
In recent years, a range of TAI systems has emerged, intended to make this therapy available to a wider range of patients as well as optimising long-term adherence. Whilst there exists a best practice review of how to initiate therapy, this was written prior to the advent of the newer systems. In addition, publication of the NICE guidance increases awareness of TAI and may lead to an increase in its use by healthcare professionals. This expert consensus report has therefore been written to

help clinicians determine the optimal equipment to use for each individual patient when initiating TAI. The rapid evolution of this therapy means that there is little Grade A evidence available to develop formal guidance.A consensus review of best practice was thought to represent the most appropriate means of arriving at clinically meaningful advice.

The review covers practice in adults only, and a similar exercise in paediatric practice is recommended. It encompasses all the systems of TAI available at the time of writing. The consensus group had a detailed and structured round-table discussion during which this pathway of care was developed, and this manuscript arose from that process. The meeting of the group was facilitated by an unrestricted grant from MacGregor Healthcare Ltd. The company had no input into the discussion or role in the development of the pathway and manuscript.

This review is presented in a deliberately pictorial way in order to make it as user-friendly as possible. Information is presented in boxes and tables in order to allow novice and experienced clinicians to have access to a handy summary guide to assist consultations and practical discussions. The intention is to have an evidence-based(where available) and expert consensus guide to optimise safe practice of transanal irrigation in a climate that sees both increasing availability of the systems and an expanding potential patient population.

Pathway


Patient with bowel symptoms
Alarm features - INVESTIGATE
Irritable bowel syndrome
Functional GI disorders
Neurogenic bowel disorder
LIFESTYLE
LAXATIVE/SUPPOSITORY/BIOFEEDBACK
TRANSANAL IRRIGATION (see other figure)
COMPLEX REFERRAL

Service aspects

A critical first step in establishing a service is to set up a pathway of care according to local practice and service availability. This in turn requires setting up or working with a local multi-disciplinary group of healthcare professionals. This should include a practitioner with a knowledge of bowel dysfunction a service manager and relevant clinicians with an interest in the disease area). It may be helpful to develop a pro forma to ensure that appropriate patients are referred to the service, and to facilitate triage. Having a local multidisciplinary team will facilitate maintenance of necessary training and competencies, which is important in what is an evolving field. Teams may choose to have face-to-face or virtual meetings according to preference, but such meetings are encouraged to ensure clinical governance as well as permitting audit of local performance.

Clinicians should have appropriate TAI and refresher training with e.g. at least twice a year on the use of products. This is especially important given the rapid evolution of systems and studies investigating the use of TAI in different patient groups. Box 3 summarises the aspects that need to be considered as part of maintaining competency.

- In-person initial training
- On-line modules to maintain skills (every 24 months)
- Training modules to include:
    - Anatomy and physiology
    - Equipment-specific updates
    - Digital rectal examination
    - Patient selection and contra-indications
    - Demonstrate practical ability to train patient
    - Help develop paperwork What does this mean?
    - Test clinical scenarios

Box 3: Recommended training requirements for healthcare professionals in the TAI team

An additional important step is defining the patient populations who will be offered transanal irrigation. The largest body of evidence exists for neurogenic bowel dysfunction (both upper motor neurone type injury as well as cauda equina type lesions), and NICE guidance accepts the place of TAI

in managing functional bowel disorders. There is data for efficacy in faecal incontinence as well as constipation, whether related to slow transit or rectal evacuation difficulty.

Since transanal irrigation is not the first-line option, it is important that the local pathway also defines what conservative bowel management comprises. Equally important is having a monitoring tool to recognise when there has been adequate response to care and when care needs to be escalated. These aspects are beyond the scope of this review, but have been addressed recently.

Patient assessment

A careful assessment of the patient is needed before undertaking TAI in order to confirm the reason for initiation; Box 1 depicts the conditions in which the therapy has been successfully used. Beyond these conditions, it is important to document the patient's primary reason for needing escalation of therapy (failure of conservative therapy, complications of that therapy, for example, unpredictability of bowel function, dependence on carer). Additionally, a focussed history will identify any criteria that would contraindicate the therapy, as documented in Box 2. Specifically, with regard to pregnancy it is the recommendation that patients are allowed to continue therapy if they are already using TAI, but a clear discussion of the risk: benefit ratio should be undertaken and documented. Starting during pregnancy is not advocated.

Complementing the history, it is recommended to use validated symptom severity scores to both monitor response and support the health economic case of the service. Such scores exist for neurogenic bowel dysfunction as well as functional bowel disorders. In the emerging therapeutic area of low anterior resection syndrome following colonic resection for cancer, there are also scoring systems available. Comprehensive assessment allows the best choice of TAI system to be made available to the patient, depending on their health and social circumstances, as outlined below.

Patient selection factors

Beyond identifying symptoms, the assessment process is critical to helping identify the optimal irrigation system for a patient to use. The corollary of this is that it will identify the systems that do not suit a patient.An outline of the key parameters to consider is shown in Table 1. Assessment of suitability for TAI should include a digital rectal examination, , preferably within 48 hours of the first actual irrigation in order to ensure that there is no faecal impaction, and hence that the procedure can be safely performed.

Home environment	
Access to toilet / commode chair	Influences choice of reservoir
Toilet room and wall surface	Wall mounted water bag
Noise issues in the toilet	Dignity and privacy factors
Nearest tap available	To allow filling of reservoir
Carer dependence	Relevant for toilet access and transfers
Toilet position	
Ability to be instructed re toileting technique	Teach toilet position (brace, sit forward, knees raised)
Stability on toilet	
Stability if seated upright	Relates to safety of catheter use
Stability if leaning	Relates to safety if holding cone in place
Manual function	
Dexterity	Safe insertion of catheter/cone, able to connect parts
Strength	Ability to use balloon pump
Wrist flexibility	Ability to hold cone in place and use the pump
Body habitus	
Buttock contour	Possibility of holding on to cone without hands
Buttock size	Can the patient reach to insert/hold catheter/cone
Skin Integrity	
Psychological function	
Cognitive/language/visual impairment	Ability to understand and see instructions patient / carer
Obsessionality	Need to avoid excessive irrigation - safety checklist
History of abuse	May need additional counselling re safe use
Examination features	
Perianal sensation	Optimises safe catheter insertion
Digital rectal examination	Anal tone – catheter may be preferred if poor tone
	Stool – to exclude faecal impaction

Equipment choices

Considering the factors in table 1 will optimise the choices offered to the patient. Table 2 gives an outline of considerations in terms of equipment choice. It is recommended that clinicians using TAI as a therapy have access to a range of systems – both catheter and cone systems, low and high volume systems, manual and electronic pump systems. The key is to have a discussion between instructor and patient about types of equipment, and to make a best fit choice. Having trained the patient and/or carer on how to safely use the equipment they should be reassured that it can take up to 8 weeks to establish a good routine with irrigation. If results are poor after this time it may be pertinent to reconsider the options and select an alternative system. or example when a patient has used low volume and requires a higher volume system. Table 2 outlines the different systems available, classified according to the pump system used. Text in black depicts the indications that may support use of certain systems based on the assessment above. Text in red shows the systems whose use may would not be possible if the condition mentioned is present.

	Low volume with hand pump	High volume pump without gravity	High volume with gravity	Electronic pump
General			If there is poor wall access, bathroom items or stand accessories can be provided	Cone if there is cognitive dysfunction Electronic pump may be unsuitable if there is cognitive dysfunction Noise issues
Cone	Cognitive dysfunction Obsessionality / anxiety Abuse history Poor upright stability Poor hand strength/dexterity	Obsessionality / anxiety Abuse history Cognitive dysfunction Poor upright stability Poor hand strength/dexterity	Cognitive dysfx Obsessional / anxiety Abuse history Poor hand strength/dexterity	Cone if cognitive dysfunction Obsessional / anxiety Abuse history Poor hand strength/dexterity
Catheter	Poor stability Poor hand function	Poor stability Poor hand function	Poor stability Poor hand function	Poor stability Poor hand function

not if obsessionality	Poor dexterity	Poor dexterity Noise	Poor hand strength Poor dexterity	Poor hand strength Poor dexterity
Bed system	Poor stability Bed bound	Poor stability Bed bound	Poor stability Bed bound	Poor stability Bed bound

Black = factors that may indicate potential advantage of a system; Red = factors that may preclude use of a system

Equipment choice by symptoms

, it is important to also recognise that the mechanism of action of the low and high volume systems (triggering local washout or greater peristalsis, respectively) means that certain types of TAI are better suited to use for particular symptoms or aetiologies of bowel dysfunction. Since large volume irrigation instils water more proximally in the colon, it appears to trigger peristalsis in the descending and sigmoid colon. As such it may be better suited to treat patients with slow transit and those neurogenic patients with supraconal spinal cord or cortical (e.g. Parkinson's disease, multiple sclerosis) disease. The corollary is that small volume and cone irrigation are easier to administer, with low volume better suited to treating patients with passive faecal incontinence and lower motor neurone spinal cord injuries. Equally, cone systems are safer, and have never been reported as causing intestinal perforation, and as such are especially recommended in patients with low anterior resection syndrome (LARS) when the colonic anastomosis should not be excessively challenged. Colonic perforation is a very rare complication of transanal irrigation, and does not appear to be cumulative, in other words the risk does not increase with time, but rather reflects an absolute risk. This risk is most often related to sub-optimal instruction of the patient or inappropriate patient selection.

Box 4 gives a summary of recommendations about systems to consider in different clinical scenarios.

- Urge faecal incontinence
  - Cone or catheter
  - Larger volumes often needed to achieve sufficient voiding, so bulb is not first choice
- Passive faecal incontinence and post-defaecatory soiling
  - Cone first choice (then catheter)
  - Bulb is first choice ahead of catheter
- Slow transit constipation
  - Cone or catheter
  - Larger volumes are needed to achieve sufficient voiding in this whole gut slow transit condition, so bulb is not first choice
- Rectal evacuation difficulty
  - Any system, according to patient choice and suitability
- Low anterior resection syndrome (LARS)
  - Cone first choice (preferably avoid catheter)
  - Bulb or pump (max 400ml)
- Upper motor neurone lesion
  - Catheter system preferred
- Lower motor neurone lesion
  - Cone system may be preferred

Box 4: Choice of TAI system according to symptoms and indications

Patient resources

Patient information and training is critical to successful initiation and adherence with TAI. As such, the authors have developed a range of accessories to help explain TAI to new patients, as well as to be used as part of training.

Aids to teaching TAI can include diagrams and equipment literature alongside plastic rectums that can be used to demonstrate the filling up and emptying effect……. Providing athorough explanation is critical to long-term adherence with therapies and the illustration of degree of colonic emptying obtained with TAI may be used as a helpful image to explain the mechanism and efficacy of TAI. Most TAI manufacturers have helpful illustrative pictures, video material and step-by-step guidance to

explain the practical aspects of the technique: it is important to reiterate that these materials are intended to complement, and not replace, formal one-to-one training. In addition, demonstration equipment with a “plastic rectum” is highly valued by many healthcare professionals, especially if the first irrigation is to be done by the patient on their own.

It is regarded as mandatory to ensure that patients are fully instructed about the potential risks of TAI. Themost serious complication is the risk of perforation, estimated at 2 per million **(need ref).** Minor and transient side effects include….Patients should be counselled about the symptoms to look out for. Formal signing of consent is not mandated but may be undertaken by some healthcare professionals. but considered best practice (as agreed by Northern Irrigation Professional Group)

Initialising treatment

Initial training of the patient / carer may occur in either the home or clinical setting, according to circumstance. Accordingly, it may be that irrigation is not actually performed with the clinician present. The authors concluded that irrigation in the clinical setting is not always possible for various reasons including lack of suitable facilities in the clinic, time constraints and also unknown effects of first irrigation incontinence or discomfort as the patient returns home. However, if being trained in the home setting, supervised irrigation is reasonable. Sufficient time should be allocated to both assess the patient, decide on the appropriate kit and then initiate training: this may take up to 60 minutes

By the end of the training session (which may sometimes run in to a second appointment) the patient needs to be supervised as being able to assemble the kit. A digital rectal examination is preferable prior to using TAI and is typical in spinal cord injured patients. Some practitioners encourage the

patient to use a glycerine suppository before irrigation to clear any hard stool that may be present in the distal rectum. To get the patient acclimatised to the treatment, low volumes should generally be used. The authors recommend a starting volume of up to 500mls depending on the patients response.. Over subsequent days, the volumes should increase up to an amount which gives the urge to defaecate and adequate evacuation, but should generally be less than 800ml. If a catheter system is being used, the balloon should be inflated according to manufacturers instructions ensuring sits securely in the in the distal rectum. Warm tap water is used, some systems have a temperature gauge which is helpful but typically the temperature of water to wash one's face is recommended.

Daily use of irrigation is recommended in the first 2-3 months in order to get the patient quickly used to the procedure and to allow them to make fine tuning adjustments to their routine in a responsive way. Once settled in to a routine an alternate day approach may be possible since there may be large volumes cleared, and hence less need to irrigate often. Patient preference, and to a lesser extent, local practices should be deciding factors in this decision. Patients would leave the training with a contact number or email in order to feedback and ask questions that may arise. A clear follow up plan can be mutually decided, although it is recommended that the first month is where most support for the patient is required and therefore follow up may be more intense. Suggestions are displayed from group consensus. The clinician should have standard protocols in place to liaise with the GP and supplies distributor at the end of the training, so that the patient can seamlessly commence self-treatment. When the patient is taking laxatives, the authors generally recommend continuing such treatment at the start of TAI treatment, and where possible weaning the medication according to response to the new treatment.

Follow-up

Early liaison between patient and irrigation specialist is essential to trouble shoot problems that may develop, as well as promote adherence with therapy. Any appropriate adjustment to lifestyle, laxatives or other medications can be discussed at that point. In some cases, the irrigation system being used may need altering if practical usage difficulties emerge. Typically, this initial contact is by phone but is recommended to be one to two weeks after starting treatment. There are a number of factors that may be tailored to optimise the efficacy of the treatment, as outlined in Figure 2.

Subsequent follow up of any adjustments made should be at two to four-week intervals until a stable regime has been arrived at. Once things are stable, the patient may be discharged to the GP's care if that is the local pathway – alternatively some specialist centres prefer to keep the patient under occasional review. This follow-up is especially valuable in the neurogenic bowel dysfunction group, since disease progression may result in deteriorating symptoms despite previously stable therapy response.

Given the chronic nature of the conditions for which irrigation is used, self -management is key. Patient empowerment through giving information from healthcare professionals can be enhanced by establishing patient groups in a local area.

Paperwork

Sample paperwork is attached to support healthcare professionals providing a TAI service. The intention is to ensure appropriate patient selection, use of the optimal equipment, effective training on safe and effective use and hence to optimise long-term adherence.

- Care pathway
- MDT referral tool

- Patient selection tool
- Patient assessment pro forma
- Assessment visit checklist
- Trouble-shooting flow charts

Summary

Transanal irrigation is now an established therapy to manage bowel dysfunction both in neurogenic and functional bowel disorders. As the technique becomes more widespread, and with a greater range of products available, it becomes ever more essential for the clinician to have up to date information on treatments available. This review has outlined the factors that are key to patient assessment, selection of the most appropriate equipment and how this can help optimise patient outcomes.