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Consensus Review of Best Practice of Transanal Irrigation in Children

*Giovanni Mosiello, †David Marshall, ‡Udo Rolle, §Célia Crétolle, ||Bruno G. Santacruz, ¶Jason Frischer, and #Marc A. Benninga

See ''Transanal Irrigations: A Few Considerations'' by Ambartsumyan on page 341.

ABSTRACT

Pediatric patients with either functional or organic bowel dysfunction may suffer from constipation and fecal incontinence and represent a complex group in whom management is often difficult. Many noninvasive and invasive treatments have been proposed, with variable efficacy and adverse effects. Transanal irrigation (TAI) is now an accepted alternative, in both children and adults, for bowel dysfunction that has not responded to conservative and medical therapies. There is, however, still some uncertainty about the use of TAI in pediatric populations. Hence, a group of specialists from different nations and pediatric disciplines, all with long-standing experience of bowel management in children, performed a literature search and had round table discussions to determine the best-practice use of TAI in the pediatric patient population. Based on these findings, this article provides best-practice recommendations on indications, patient selection, important considerations before treatment, patient and family training, treatment regimens, troubleshooting, and practical aspects of TAI. We conclude that careful patient selection, a tailored approach, directly supervised training, and sustained follow-up are key to optimize outcomes with TAI in children with functional or organic bowel dysfunction.

Key Words: anorectal malformation, best practice, bowel dysfunction, children, neurogenic bowel, transanal irrigation

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What Is Known

- Transanal irrigation is an increasingly accepted treatment in children with bowel dysfunction who do not respond to conservative treatments.
- In recent years, data have been published on the efficacy of transanal irrigation in pediatric patient populations such as anorectal malformations and functional constipation.
- Although the use of transanal irrigation in adults has been standardized, the practice in children still remains largely empirical.

What Is New

- The first best-practice article based on published evidence and professional experience, aimed at healthcare professionals who manage pediatric bowel dysfunction and who currently use transanal irrigation or would like to initiate in its use.

In children, constipation and fecal incontinence (FI) may be the result of either organic or functional disorders (1–7). Organic causes are rare and typically congenital, and predominately have a neurological or anatomical origin. This is the case in patients with neurogenic bowel dysfunction (NBD), which in children is mainly related to open or closed spina bifida, and in patients with anorectal malformations or Hirschsprung disease.

In >95% of the children, after appropriate medical evaluation, the symptoms cannot be attributed to another medical condition and are therefore called functional (1,2). Indeed, functional constipation (FC), complicated by FI, affects up to 29.6% of children and can negatively impact their quality of life (QoL) (3,4). In >90% of affected patients, FI is a result of fecal retention, whereas the remaining cases fulfill the Rome IV criteria for functional nonretentive fecal incontinence (FNRFI) (1).

Today, transanal irrigation (TAI) is an accepted treatment in children and adults with bowel dysfunction (BD) who do not respond to conservative and medical treatments. TAI use in adults is well-defined (8) in a stepwise pyramid of care, that can be applied

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From the *Neuro-Urology Unit, Department of Surgery, Bambino Gesù Pediatric Hospital, Rome, Italy, the †Department of Pediatric Surgery/Urology, Royal Belfast Hospital for Sick Children, Belfast, United Kingdom, the ‡Department of Pediatric Surgery and Pediatric Urology, Frankfurt University Hospital, Frankfurt, Germany, the §Department of Visceral Pediatric Surgery, Necker-Enfants Malades Hospital, Paris Descartes University, Paris, France, the ||Coloplast A/S, Humlebaek, Denmark, the ¶Cincinnati Children's Hospital, Cincinnati, OH, and the #Department of Pediatric Gastroenterology, Emma Children's Hospital/Academic Medical Center, Amsterdam, The Netherlands.

Address correspondence and reprint requests to Dr Giovanni Mosiello, Pediatric Urologist and Pediatric Surgeon, Department of Surgery, Bambino Gesù Pediatric Hospital, Piazza S.Onofrio, 4, 00165 Rome, Italy (e-mail: giovanni.mosiello@opbg.net).

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when conservative and medical treatment of BD (such as dietary and lifestyle advice, regular use of laxatives, suppositories, enemas, or manual evacuation) have failed.

TAI involves a large-volume water irrigation of the rectum and colon performed by introducing a catheter (often with a balloon) or a cone through the anus. TAI was introduced into current clinical practice by Shandling and Gilmour (9) in 1987 to treat constipation and improve fecal continence in children with NBD. On the basis of high success rates, reaching 100% in some studies, TAI was further applied to adults and children in whom other medical treatments had failed (10–13). Other empirical treatments and procedures have been proposed to treat nonresponsive BD including biofeedback and neuromodulation with inconsistent results in children (14–16). Therefore more invasive surgical interventions are sometimes offered, for example, the malone antegrade colonic enema (MACE) (17). Importantly, recent studies using TAI in children have reported high rates of success, both in clinical bowel outcomes and in improvement of QoL (13,18–21). Therefore, some authors recommend that TAI should be considered before any surgical treatment in children with BD (20,21).

Because there is still some uncertainty about the correct use of TAI in pediatric populations, the aim of this work is to provide a best-practice consensus review based on experience and a literature review to facilitate its use in clinical practice.

MATERIALS AND METHODS

A consensus group of specialists from France, Germany, Italy, the Netherlands, United Kingdom, and USA, and from various pediatric disciplines including gastroenterology, colorectal surgery, pediatric surgery, and neurourology, all with a long-term experience of NBD and TAI, produced this consensus review on the basis of existing published literature and their own clinical experience.

For the literature review, PubMed, CINAHL, and The Cochrane Library were searched from inception to June 2016. The inclusion criteria were articles published in the English language from January 1, 1980 to July 1, 2016 resulting from using the following search terms: (''transanal irrigation,'' OR ''anal irrigation,'' OR ''colonic irrigation,'' OR ''bowel enema'') AND (''neurogenic bowel,'' OR ''constipation,'' OR ''fecal incontinence,'' OR ''faecal incontinence'') AND (''children,'' OR ''pediatric,'' OR ''paediatric,'' OR ''pediatr*,'' OR ''child*''). The results of the search were then reviewed by at least 2 of the authors, as a minimum to title and abstract level (when available). Articles were rejected on the initial screen if they failed to meet our inclusion/exclusion criteria, whereas potentially relevant studies, and studies in which the title and abstract provided insufficient information were retrieved as full-text articles. Exclusion criteria were acute use of TAI (eg, for disimpaction or diagnostic use), studies in which adult patients (>18 years of age) were included and in which results from children were not reported separately, children receiving enemas (understood as instillation per rectum of a low-volume medicated substance), children with an antegrade continence enema (ACE/MACE) only or not reported separately, and educational materials and opinion papers. To support, complement, or contrast the results of the literature search, the authors made use of their clinical and practical expertise, experience, and opinions. Individual group members prepared a write-up each on a single section, and consensus was reached by several round-table discussions and common writing and review of the overall article.

RESULTS

Literature Review

A total of 404 potentially relevant articles and abstracts were identified; 369 through the search in PubMed and The Cochrane Library and 35 articles in CINAHL (all of which were previously identified in the search in PubMed or deemed not relevant). After applying the exclusion criteria to the results, 27 articles were included and 377 articles were excluded (15 of the latter were excluded only after being reviewed as full-text papers) (Fig. 1). Reasons for exclusion were ''abstract not available'' (n = 1), ''editorial comment'' (n = 1), ''duplicates'' (n = 39), ''acute use only, disimpaction or preparation for colonoscopy'' (n = 6), ''educational and/or review papers'' (n = 21), ''out of scope MACE/ACE'' (n = 120), ''out of scope other reason'' (n = 185), and ''other including animal studies'' (n = 4).

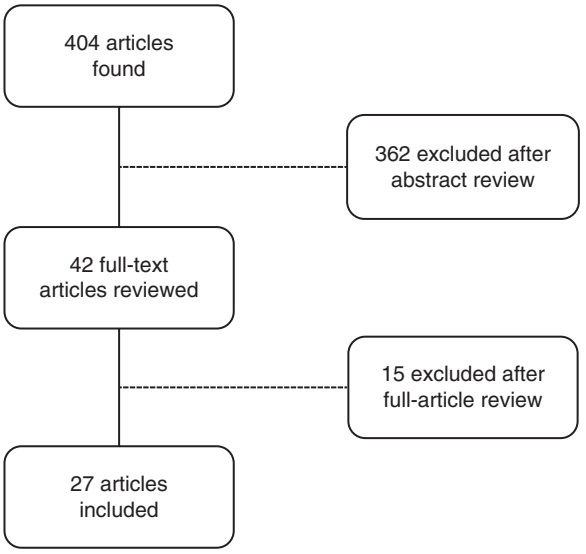

FIGURE 1. Literature review inclusion/exclusion process.

Four of the 27 included studies were cohort studies (1 prospective and 3 retrospective) and had an Oxford Centre for Evidence-Based Medicine rating of 3. The remaining 23 studies were case series (14 prospective and 9 retrospective) and had an Oxford Centre for Evidence-Based Medicine rating of 4. Data from the 27 included studies regarding underlying condition of the patient population are depicted in Table 1.

Patient Characteristics

In total, 1040 patients were included in the 27 studies. Most patients (686/1040) had NBD as underlying condition, mainly spina bifida. Three hundred seventy-two were boys and 388 were girls, although some studies did not report sex, leaving 280 patients (27%) as undefined. The average age of the patients was 8.5 years (range 1–25 years).

Main Findings

Based on the literature review, the average success rates of TAI in children are estimated to be 78% (77.7%, range 53%–97%) for FI, 78% (range 53%–97%) for constipation, and 84% (range 60%–100%) when reported as overall improvement of symptoms (Supplemental Digital Content, Table, *http://links.lww.com/MPG/A862*). Success rates in terms of satisfaction with TAI and QoL were scarce in the selected articles, but Cazemier et al 2007 (23) reported satisfaction rates of approximately 90%, Corbett et al, 2014 (20) reported QoL improvement in 95% of children, and Koppen et al 2016 (13), reported a parent satisfaction of 86%. Discontinuation or failure of treatment with TAI ranged from 5% to 36%. Not all

TABLE 1. Number of patients in the included 27 studies, per underlying condition

References	Number of children per condition				
	Neurogenic bowel dysfunction*	Hirschsprung disease	Anorectal malformations	Functional constipation/ fecal incontinence	Others
Alenezi et al (21)	18				
Ausili et al (12)	60				
Blair et al (22)	21	3	7		
Cazemier et al (23)	29	4	7	5	3
Choi et al (24)	44				
Choi et al (25)	53				
Chrzan et al (26)				50	
Corbett et al (20)	15	4	5		
Fernandez Eire et al (27)	33				
Kelly et al (28)	24				
Koppen et al (13)				67	
Liptak et al (29)	31				
Lopez Pereira et al (11)	28				7
Marte et al (30)	16				
Märzheuser (31)			30		
Märzheuser et al (32)			58		
Matsuno et al (33)	13				
Mattsson and Gladh (34)	40				
Midrio et al (18)	37		41		
Nasher et al (35)		2	1	7	
Neel (36)	13				
Ng et al (37)	2	2	11	26	1
Pacilli et al (38)	11	1	6		5
Shandling and Gilmour (9)	112				
Vande Velde et al (39)	25				
Walker and Webster (40)	11		1		
Wide et al (41)	50				
Total	686	16	167	155	16

*Includes spina bifida, spinal cord injury, and other neuropathy.

studies reported the reason for failure or discontinuation of the treatment and in some cases there may be more than 1 reason. In the studies that reported such reasons, the most common were lack of efficacy (responsible for approximately 36% of discontinuations), dislike or embarrassment of treatment (approximately 17%), and later remission of symptoms (responsible for approximately 15% of discontinuations). Other less frequent reasons reported for failure or discontinuation included noncompliance, pain on insertion, and catheter expulsion.

The median follow-up time was 23 (range 1–144) months of treatment. Most selected articles concerned patients with spina bifida, and it was therefore not possible to infer associations between TAI performance and etiology. The literature did not allow comparison of results according to which TAI device was used.

Consensus Recommendations

Indications for Transanal Irrigation and Management of Neurogenic and Functional Bowel Dysfunction

Management of neurogenic/anatomical and functional BD consists of nonpharmacological and pharmacological treatment modalities. As described in both the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN)/North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) and NICE guidelines (42) education and demystification are the first steps before starting the treatment of children with functional BD. It is important to provide information on prevalence, symptoms, treatment options, and prognosis. A nonaccusatory approach is of major importance, because these entities may be accompanied by feelings of guilt, shame, and anger in both children and their parents (42). The most important step in the nonpharmacological management is instituting a toilet program. Although inadequate fiber intake is associated with FC, there is insufficient evidence to support the use of supplementary fiber in addition to the daily recommended intake in children with FC. The ESPGHAN/NASPGHAN guidelines recommend a normal fiber and fluid intake and normal physical activity in children with constipation. The ESPGHAN/NASPGHAN guidelines recommend a normal fiber and fluid intake and normal physical activity in children with constipation.

Pharmacological treatment of constipation-associated FI consists of disimpaction by either oral or rectal route followed by maintenance treatment and follow-up (42). For the minority of patients with FNRFI, constipating agents rather than laxatives may be more appropriate (43). It is well known that retrograde enemas are therapeutically effective in treating constipation in children with a neurological disorder, including spina bifida, but little knowledge exists about the role of retrograde enemas in the maintenance treatment of children with FC (44). A randomized clinical trial showed that application of enemas on a regular basis is well-tolerated in children with chronic constipation, but also that they

had no additional benefit over conventional treatment with oral laxatives in the maintenance phase of treatment (45). Other conservative methods include biofeedback (14) and noninvasive forms of nerve stimulation (46). In patients for whom conservative and medical methods for managing either organic or FC and/or FI are not successful, or where there is a different patient preference, TAI is proposed (13,18). If TAI is ineffective, the next step to consider would be more invasive therapies such as sacral nerve modulation (16) or MACE (17). Furthermore, new oral drugs such as lubiprostone and linaclotide have been shown effective in adult patients (47,48). Few data are, however, currently available in the pediatric literature to suggest the best next step if TAI fails. In patients not responding to any of the previous treatments, or again when patient preference dictates, the last step in the proposed pyramid would be surgical procedures including bowel resection and/or stoma formation (17). A bowel management pyramid for children (Fig. 2) is proposed based on an adaptation of the one suggested for the adult population by Emmanuel et al, 2013 (8). Briefly, the pyramid is divided into 4 levels based on the invasive nature of the method. Conservative management and TAI constitute non- or minimally invasive methods, whereas MACE, sacral neuromodulation, bowel resection, and stoma formation are more invasive.

Even though it may be less invasive than the MACE procedure, sacral nerve modulation (SNM) lacks the amount of evidence and its conclusiveness that several years of positive experience with MACE has. Furthermore, SNM is not licensed in some regions for use in children.

Patient Selection for Transanal Irrigation

Progress and eventual outcome of TAI are highly dependent on an individual child and family, and their interaction together. A full assessment in advance is often needed of the child's and family's motivation and cognitive ability. Moreover, physical factors such as anorectal anatomy, paraplegia, obesity, manual dexterity (especially in those with spinal conditions, or with upper-limb abnormalities), and balance may dictate the child's capacity, amongst other things, to sit on the toilet and successfully perform TAI.

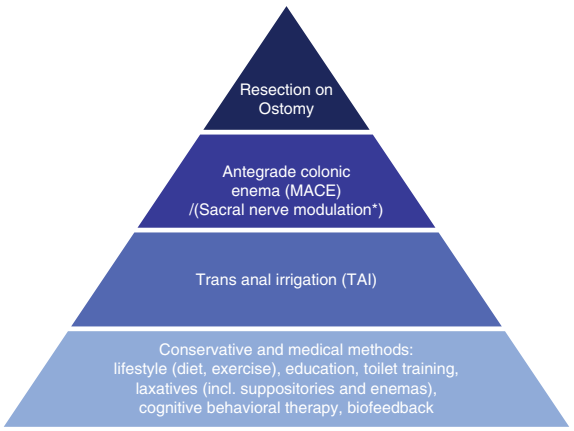

FIGURE 2. Proposed bowel management pyramid for children with bowel dysfunction. A proposed stepped approach to the treatment of bowel dysfunction, based on the invasiveness of the different approaches. The base layer represents ''conservative methods'' and medical approaches. TAI is proposed as an additional conservative treatment. The next step consists of the MACE procedure or nerve stimulation techniques (*where available and approved for use in children). It is important to note that sacral nerve modulation lacks the amount of evidence and its conclusiveness that several years of positive experience with MACE has. The last step in the pyramid, when previous therapies have been tried or deemed inappropriate involves more radical surgical approaches such as resection or ostomy. MACE = malone antegrade colonic enema.

It is important to differentiate between a functional and organic defecation disorder, and more specifically differentiate between FC and FNRFI. A normal colonic transit time, using radio-opaque markers, in combination with the absence of either abdominal or rectal fecal impaction confirms the diagnosis FNRFI. In a minority of cases magnetic resonance imaging of the spine and anorectal manometry are helpful to find organic causes for defecation problems (5,42).

A list of possible indications for TAI in children is provided in Table 2. Although rare congenital anorectal conditions such as Hirschsprung disease and anal stenosis typically present at the neonatal age, occasionally milder forms may persist unrecognized in older children with constipation and/or FI. Therefore, a proper history should be taken in any child under consideration for TAI, to exclude a delay in the first passage of meconium and to ensure that the caliber of solid stool is normal. The anus should, at the very least, be externally inspected to ensure normal anatomy and physiology. Children who have previously been operated on for any congenital anorectal condition may have constipation and/or FI because of a secondary postoperative stricture or anal stenosis. This possibility mandates assessment by a specialist pediatric surgeon, ideally the original operator, so that TAI is not administered inappropriately to a child who instead needs revisionary or alternative surgery.

Constipation and/or FI in children can be a presenting feature of nonaccidental injury, whether psychological or physical, including sexual abuse. Therefore, it is mandatory to consider this possibility as an underlying cause before pursuing any treatment. If there are any suspicions, referral is necessary to an expert in child protection for further evaluation. Furthermore, nonaccidental injury should be reconsidered if any child is unduly upset by passage of the rectal catheter/cone. Similarly, fabricated illness may manifest with symptoms of BD, necessitating the involvement of an appropriate pediatric specialist and/or pediatric psychiatrist, which may obviate the need for intrusive physical treatments such as TAI.

Probably the most important prerequisite for pediatric TAI to be effective in the early stages is to ensure that the patient is not affected before instituting TAI. Instead, starting with a relatively empty colon will allow TAI to begin with low volumes and minimal use of stimulant laxatives, thereby reducing the risk of off-putting cramps. Fecal impaction may sometimes be verified by simple abdominal examination alone. If necessary, rectal fecal impaction can be confirmed by rectal examination (which is appropriate if the child has absent anorectal sensation), abdominopelvic ultrasound, or abdominal x-ray. The cumulative radiation burden, however, makes x-ray inadvisable for repeated assessments (49). Fecal impaction before starting TAI can be treated with high-dose oral laxatives, enemas, or, as a last resort, manual disimpaction under general anesthesia (50).

The contraindications for the use of TAI in children are similar to those established for the adult patient population (8), except for the minimum age of the patient, which is dictated by the regulatory approvals in each region. As a guide, this is usually 3 years of age in Europe and 2 years of age in the USA. Some contraindications that are especially relevant in the pediatric patient population are listed in Table 2. Healthcare professionals should always study in detail the latest approved and valid Instructions for Use of the device(s) available in their territory, and be aware of both the absolute and relative contraindications that may be listed there.

TABLE 2. Pediatric indications and contraindications for transanal irrigation

Indications
Neurogenic bowel dysfunction due to spinal abnormalities, spinal cord injury, or cerebral palsy
Patients with sequelae of anorectal malformations or Hirschsprung disease
Fecal incontinence due to iatrogenic injury (including tumor surgery sequelae)
Medical therapy–resistant functional constipation
Medical therapy–resistant functional fecal incontinence, either retentive or nonretentive (FNRFI)
Contraindications
Known anal or colorectal stenosis
Active inflammatory bowel disease
Within 3 months of anal or colorectal surgery
Ischemic colitis

The list of contraindications is not extensive and may be device-specific or differ according to regulatory approvals in different parts of the world. Healthcare professionals should always study in detail the latest approved and valid instructions for use (IFU) of the device(s) available in their territory, and be aware of both the absolute and relative contraindications that may be listed there. FNRFI = functional nonretentive fecal incontinence.

Special Pediatric Considerations Before Starting Transanal Irrigation

There are many parallels to the approach in adults advocated by Emmanuel et al (8). There are, however, several distinct differences, which must be fully understood before embarking on treatment of children, particularly if the healthcare professional involved is more experienced with an adult patient population. Essential preparation requires an appropriately experienced healthcare professional to provide the child and parents with detailed explanations and discussions, which may take several meetings. Regarding the assessor/trainer, their competencies are more important that their actual title (eg, nurse, urotherapist, continence advisor, stoma nurse or therapist, doctor, etc). They have to be properly trained and experienced not only in TAI, but also in the management of constipation/FI, recognizing the need for safeguarding vulnerable children and families. A supervising pediatric clinician is recommended for the benefit of both the child/family and the other professionals involved. Long-term success also mandates the availability of regular and on-going support from these same healthcare professionals, to encourage patience and perseverance in the early stages, because it may take several weeks and sometimes longer to achieve reliable success. When age, mental and emotional maturity, and physical condition allow it, we encourage the patient's self-management of the TAI procedure. Rates of independent use in children vary in the literature, but seem to relate to the underlying pathology and to age alone. In one study, 79% of children with anorectal malformations ages 4 to 18 (mean 11) years were performing TAI themselves, including one 7-year-old (32), compared with only 16% of younger children in another study with mostly neurogenic conditions (20). Advice can also later be offered on how to adapt the acquired routines to permit and encourage social events, family holidays, residential trips, sleepovers, and other normal childhood activities. Children may not fully understand the rationale for their treatment, particularly if they are especially young or have associated learning difficulties. Therefore, the approach needs to be tailored toward the cognitive, educational, and psychological status, maturity, and motivation of the individual child and family, on whom the ultimate success of TAI is so dependent. Explanation of the technique is required in a positive child-friendly way, for example, with picture books, films, Web sites, or toy models. Children are often understandably embarrassed by, or wary of, the rectal approach, and are particularly likely to be put off if they experience pain, a burst balloon, or premature expulsion of the catheter in the early stages of starting TAI (37). In certain cases, the input of a clinical psychologist familiar with the pediatric population may prove helpful in unraveling the basis of any fears that a child may have, and may optimize adherence with the proposed treatment. When the child is still too anxious, it may be best to deliver training in small steps or consider reintroduction of TAI at a later stage as the child matures.

Training Before Starting Transanal Irrigation

Because TAI carries a small risk of serious complications (see section ''Complications of Transanal Irrigation'' and Table 3), it is absolutely essential that patients, families, or caregivers are properly trained before starting treatment. This also implies a need for formalized training of those healthcare professionals who are guiding the families in the use of TAI. In addition to familiarization with the equipment, and how to perform the technique safely, training must include explaining to the caregivers the symptoms of colonic perforation, and how to proceed in these emergency circumstances (52). The first session of TAI must be performed under the supervision of an experienced healthcare professional and preferably in a medical facility (52). Because TAI will generally be performed in the child's home, there is an obvious benefit to a third party such as a nurse specialist supervising TAI there during follow-up.

Proposed Treatment Regimen in Transanal Irrigation

Tonicity of Irrigant

Most clinicians in Europe and North America recommend simple tap water as the irrigant.

Any condition that features severe colonic dilatation or dysmotility may, however, theoretically predispose to prolonged retention of the irrigant, which, if hypotonic, could in theory be absorbed and cause iatrogenic hyponatremia. Some authors recommend ''periodic evaluations'' of serum electrolytes (53). To avoid this theoretical risk altogether, some units instead use normal (0.9%) saline as the irrigant. On the contrary, there are now enough published reports of successful and safe colonic irrigation including TAI with tap water to suggest that these concerns are unlikely (11,12,32,35). Therefore, the authors of this consensus paper do not routinely measure electro-

TABLE 3. Complications that may occur due to transanal irrigation

	%	n	Ref
Pain on insertion	24	42	(37)
Emotional distress	24	42	(37)
Catheter expulsions	17	35	(11)
	10–20	78	(18)
	<33.3	32	(10)
Burst of balloon	5–14.6	78	(18)
Leakage (occasionally)	<26	35	(11)
	>50	32	(10)
Abdominal pain	3.3	60	(12)
Bowel perforation	0.0002		(51)

lytes, but if symptoms or signs of electrolyte imbalance present themselves, laboratory tests should be performed.

Sterility of Irrigant

Any source of drinkable water should suffice. Where the cleanliness of the tap water is doubtful, either cooled boiled or bottled water is recommended to avoid transmission of organisms such as amoeba or cryptosporidium.

Temperature of Irrigant

It is recommended that the irrigating solution should be close to body temperature (36°C–38°C), to reduce discomfort and nausea/vomiting from reflex bowel spasm, which can also lead to premature expulsion of the solution before it has had a chance to act on the stool.

Volume of Irrigant

The lowest volume of irrigant should be used that achieves the desired effect. Most specialist groups known to the authors use a volume of irrigant of 10 to 20 mL/kg (13,18,38), with a maximum total volume of 1 L (8). This calculation should be based on *ideal* body weight for height rather than the actual weight of an obese child. In selected or nonresponding patients, a more individualized approach can be considered, which may include information from imaging studies (6,31).

Use of Laxatives

Although some patients may be able to discontinue the use of laxatives after initiating TAI, others will require continued use, either at the same or reduced doses. This should be assessed individually in each patient. For a patient who has been requiring oral laxatives for a long time, there may be some merit in continuing these until he/she has become successfully established on TAI, and then gradually weaning off the laxatives as tolerated. Other clinicians add a stimulant or lubricant (such as bisacodyl, glycerin, polyethylene glycol, or Castile soap) to the colonic irrigation fluid (13). By achieving a more thorough colonic evacuation (54), this may permit a longer interval between TAI sessions, which may be an important option for those with busy social lives. Very little evidence or experience, however, exists regarding the addition of substances to the irrigation water, and to the knowledge of this authors this constitutes and off-label use. Finally, hyperphosphatemia, hypocalcemia, and hypokalemia have been associated with the use of phosphate enemas (55) and chemical colitis with use of castile or glycerin soap (56).

Frequency of Transanal Irrigation

Ideally TAI should be carried out at roughly the same time of the day, to recruit the beneficial effect of the ''body clock'' on gastrointestinal motility. Most units begin TAI on a daily basis until a successful routine is established. After that, some reduce 1 day of TAI per week every few weeks, progressing to 6 days per week, then to 5 days per week, and so on. Others reduce more rapidly by simply moving straight to TAI on alternate days. The emphasis should be on reducing the total time the child spends in the bathroom each week, as this has been shown to be a major benefit of TAI (11,20,32). Clearly, if the original constipation/incontinence relapses after reducing the frequency of TAI, the patient should return to the previously successful frequency.

Troubleshooting

It is almost inevitable that some difficulties will arise during the initiation of TAI. Therefore, it is recommended that the trainer and/or the clinician arrange a review visit after several weeks, and again several months later, to fine-tune the technique as needed. Even long after a successful schedule has been established, the long-term need for the readily available support (ideally via initial telephone or email contact) of a healthcare professional who is familiar with the child and family, and trained and experienced in the use of TAI, cannot be overemphasized. Some manufacturers of TAI devices offer a follow-up and support program to TAI users, which can be a helpful complement. Some suggestions for the more common problems that may occur, adapted from the adult patient population (8) are provided in Table 4.

TABLE 4. Troubleshooting in pediatric transanal irrigation

Fear or frustration regarding equipment or procedure
- Allow child to handle equipment and be involved in choosing type of irrigation
- Ensure comfortable toilet posture (with a footstool if feet do not touch the ground) to promote pelvic floor relaxation
- If appropriate, encourage child to perform irrigation themselves, with assistance/supervision, because this helps with compliance, engagement, and independence (the latter is good for privacy and dignity, but also for later residential trips, etc)
- Use distraction techniques (eg, homework/books/toys/gadget/music/TV on a desk in front of the toilet)
- Star charts and appropriate rewards to encourage cooperation and motivation
- Reduce volume of irrigant, and avoid laxative in irrigant initially, until child accepts washout procedure
- Adjust volume of irrigant and laxatives to achieve either shorter sessions or less frequent sessions, according to the preference of the child and the family's schedule
- Try an alternative device (eg, switch from catheter to a cone, or from pump to gravity-feed, or vice versa)
- Clinical psychological input if fear persists
- Consider possibility of nonaccidental injury

Difficulty inserting catheter/cone or instilling irrigant
- Likely due to rectal impaction. If this is the case, proceed to disimpaction before resuming TAI
- Re-evaluate the child/caregiver's technique
- Adjust volume of irrigant and check the speed of instillation
- If these difficulties are recurrent, increase volume and/or frequency of TAI to ensure evacuation is adequate

Expulsion of the catheter, where used
- Check for and treat rectal impaction (see above Difficulty inserting catheter/cone or instilling irrigant)

Inflate balloon more slowly, and minimize balloon inflation
- Conversely, ensure balloon adequately inflated (test the balloon outside patient), but no more than 2 complete pumps in children
- Check correct water temperature (at body temperature, approximately 36°C–38°C)
- Instill water more slowly, or split the irrigation into two consecutive episodes, 10–15 min apart, using half the irrigant volume each time
- If persistent, change from catheter to cone device

Leakage of irrigant around the catheter/cone
- Ensure catheter/cone is properly located
- Check for and treat of fecal impaction (see above difficulty inserting catheter/cone or instilling irrigant)
- Check correct water temperature (at body temperature, approximately 36°C–38°C)
- Where used, increase balloon inflation up to maximum of 2 complete pumps (first test balloon outside patient)
- Instill water more slowly

Pain (rectal and/or abdominal)
- A medical practitioner shall confirm the absence of anal lesions

- Ensure the right catheter or cone size is used (where pediatric sizes are available)
- If the irrigation is performed on the toilet, ensure the child is seated comfortably and relaxed (a footstool can help)
- If cramps, discomfort, or pain occur while instilling the irrigation, pause instillation for a few moments. Once discomfort has subsided, continue instilling more slowly (may take up to 10 min in total). It may also be useful to allow the bowel to empty first, before restarting again to instill the rest of the water. The pain should subside after a few days of use with this protocol
- Ensure that irrigant is warm enough (at body temperature, approximately 36°C–38°C)
- Ensure that bladder is empty
- Abdominal massage can help spasmodic pain
- Delay timing of session so as not to perform on a full stomach (especially if also nausea/vomiting)
- Reduce or stop use of laxative (whether oral or in irrigant)
- Start with smaller volume of irrigant (eg, 5–10 mL/kg) and gradually increase toward 20 mL/kg, as tolerated
- Consider poor compliance with TAI, leading to painful fecal impaction
- If pain is severe/persistent, stop irrigating and consider possible bowel perforation; a medical emergency

Bleeding

- A small amount of bleeding is to be expected occasionally
- More copious, or regular, bleeding requires further investigation (including hematological)
- Significant hemorrhage suggests possible rectal perforation, even if no obvious pain: this is a medical emergency
- Consider possibility of non-accidental or fabricated injury

Risk of autonomic dysreflexia, and/or TAI-induced autonomic symptoms (eg, facial flushing, sweating, palpitations, dizziness)

- If at risk of autonomic dysreflexia (typically spinal lesion above T6), medication should be immediately available in the room
- Ensure the bladder is empty
- Instill the irrigant slowly
- Limit time on toilet up to that safely tolerated
- Check for and treat fecal impaction (see difficulty inserting catheter/cone or instilling irrigant)
- If symptoms are significant, ensure child is not alone at any time during irrigation session
- If autonomic dysreflexia occurs, stop irrigation immediately, and treat as an emergency as advised by child's spinal specialist
- Further assessment and possibly other interventions are then required before continuing with TAI

Irrigant is not expelled after TAI

- Replace the catheter to exclude retained fluid within the rectum
- Check for and treat fecal impaction (see above difficulty inserting catheter/cone or instilling irrigant)
- Repeat irrigation (only once more in any one day, without any additives to the irrigation water and considering isotonic saline if normal tap water was used in the first irrigation)
- Use adjunctive measures such as abdominal massages (in the direction of the colon from caecum to rectum), raising intra-abdominal pressure (through leaning back/forward/sideways, bracing of abdominal muscles, blowing bubbles, coughing or pushing up with hands on toilet seat), gently tapping the sacrum, digital rectal stimulation (only if insensate), or digital evacuation of solid stool from rectum (only if insensate)
- Ensure patient is adequately hydrated
- Consider use of laxatives (either oral or in irrigant)
- If these difficulties are recurrent, consider instilling the irrigant faster and/or perhaps switching from tap water to isotonic saline
- Ensure there are no signs of colonic perforation

No stool is evacuated after TAI

- See above irrigant is not expelled after TAI
- Split the irrigation into 2 consecutive episodes, 10–15 min apart, using half the irrigant volume each time
- Increase volume of irrigant (some children may have chronic megarectum/megacolon)
- If recurrent, consider use of laxatives (either oral or in irrigant)
- No stool may be present if a good result was obtained at last irrigation: if this happens regularly, reduce frequency or volume of irrigation
- If no stool for several days, suspect fecal impaction; assess and treat accordingly
- Consider extreme withholding behavior
- Check family compliance and accuracy of parental reporting: if in any doubt, a short period of more closely supervised sessions may help

Fecal incontinence between sessions of TAI

- If acute, consider gastroenteritis or intercurrent illness (eg, urinary tract infection in a neuropathic patient)
- Otherwise, generally suggests incomplete emptying: if soon after TAI, sit on toilet for longer
- Increase volume of water by small increments (eg, 2 mL/kg) every few sessions, until satisfactory evacuation achieved with no fecal incontinence
- If persistent, consider ultrasound/contrast study during TAI to confirm irrigant reaches caecum
- Keep catheter/cone in rectum for several minutes after instillation completed (especially if laxative in irrigant), to increase exposure of stool and colon to irrigant
- Encourage use of adjunctive measures during TAI (see above Irrigant is not expelled after TAI)
- Split the irrigation into 2 consecutive episodes, 10–15 min apart, using half the irrigant volume each time
- Increase frequency of TAI
- Consider use of laxatives (either oral or in irrigant)
- Conversely, consider reducing or discontinuing laxative (either oral or in irrigant) if stool is always soft, with no evidence of fecal impaction, in case of overstimulation (unusual)
- If problem persists, a pediatric Anal Plug may help

Leakage of water between sessions of TAI

- Reduce volume of irrigant instilled
- Reduce or discontinue laxative (either oral or in irrigant)
- Split the irrigation into 2 consecutive episodes, 10–15 min apart, using half the irrigant volume each time
- If problem persists, a pediatric anal plug may help

TAI = transanal irrigation.

Success Rates of Transanal Irrigation

Success rates of TAI obviously vary between the different underlying conditions of the patients, indications, and circumstances of use. Also, definitions of success differed among studies and among patient populations. The use of TAI in children with spina bifida and neurogenic BD resulted in significant improvement of FI in one of the studies, as 72% of 35 patients gained continence with the treatment modality suggested (11). Notably, the rate of patients with partial to total independence in toileting increased from 28% to 48% in the same study. A questionnaire study (41) compared 2 different methods of bowel management (TAI vs MACE) in pediatric patients with NBD due to myelomeningocele. The authors found no difference between the groups in the rates of fecal leakage or children's satisfaction, but a significantly higher satisfaction in parents of patients using MACE. In a review article of pediatric TAI (19), children ages 3 to 16 years with spina bifida, anorectal malformation, and sacral agenesis were studied. Most parents reported an improvement of the child's FI and a positive effect on children and family life was noted. A database study (37) reported on a heterogeneous group of pediatric patients using TAI in

which most patients (62%) experienced idiopathic constipation; one quarter of the patients were classified as ''nonadopters,'' meaning that they discontinued the use of TAI within 1 month. Among the so-called ''adopters,'' a successful outcome was seen in 84%. Younger age was predictive for nonadopters.

An Italian multicenter study was conducted in children with anorectal malformation and spinal cord lesions with previous unsatisfactory bowel management. Patients were initiated on TAI (18) and evaluated at baseline and after 3 months of using TAI by completing a questionnaire on bowel function and QoL, and the Bristol Stool Chart. The authors concluded that all patients had improvement in these scores. Furthermore, all patients initiated on TAI continued its use at 3 months' follow-up. Some studies on children with myelomeningocele (12,30) have also reported a significant reduction in urinary tract infections after starting TAI.

Complications of Transanal Irrigation

The most severe complication of TAI is bowel perforation (Table 3). A recent review article by Christensen et al (51), estimated the overall risk of perforation in the most recent years available to be in the order of 2 per 1 million procedures (all patient groups and ages). The same article provided extensive data on bowel perforation in 49 cases during 2005 to 2013, which pointed to increased risk during initiation of treatment and after pelvic surgery. Bowel perforation appears to be rare in children, with only 1 of those 49 cases being a child, corresponding to a rate in the order of 1 in 1 million procedures. Historically, perforations were not rare in diagnostic procedures such as contrast enema. By comparison, perforation risk during other procedures may be as high as 1 in 1000 during colonoscopy (57), or 1 in 40,000 during flexible sigmoidoscopy (58). In addition to perforations, some minor complications and complaints have been recorded. Some of these are frequent, and they represent a concern as they can lead to noncompliance and discontinuation of the TAI procedure.

DISCUSSION

This article reports data from the review of the existing literature and our personal shared experiences, with the intention to define indications and provide practical advice on using TAI. Different surgical therapeutic approaches have been used in children with BD over time including colostomy and MACE (17). Over the last 10 years, some centers, however, report having largely replaced surgical procedures for bowel continence in children with the introduction of TAI (21,28).

Based on the literature and our personal experience, TAI represents an effective and safe therapeutic approach for treating BD in children. Although TAI practice has been standardized in adults (8), its introduction in children has so far been without a standardized approach; hence, this consensus report on best practice.

Different commercial devices have been designed to facilitate the TAI practice and are available using a balloon catheter or cone tip, with water instillation regulated either by gravity or by manual or electronic pumps (Peristeen Coloplast, t, Qufora MBH, Irypump BBraun, Navina Wellspect). It shall be noted that at the time of writing this article, some of these devices had not been tested and/or approved for use in pediatric patients. Most of the reported experiences and recent published evidence are related to 1 device (Peristeen), but the possible advantages or disadvantages of the different devices remain unclear and are beyond the scope of this article. Just as for the choice of catheter for clean intermittent urethral catheterization, the specific patient's needs should guide the product choice, which may also be influenced by availability, reimbursement, and clinical support in different global settings. Whatever device is to be used to perform TAI, it is important that it will be available to the family as soon as training has been completed. Conversely, the device should only be used by the patient once the training has been completed. Parameters must be individualized and attention must be paid to adherence and follow-up. In some of the published studies with adult patients, a large number of patients discontinued TAI (59), and critical points determining compliance included education, training, and ongoing support over time (eg, home visit, phone call, outpatient clinic evaluation, patient support programs). Adherence to treatment seems to be higher in the studies with a pediatric population, but many of those are for the moment based on short- or mid-term, with only a few studies reporting data beyond 3 years of use (21,23,39). It still remains to be confirmed if this higher adherence remains in longer-term follow-up and for all indications.

Because one of the major concerns remains the limited evidence base, future research should include randomized controlled clinical trials around the world in patients with different pathologies, comparing safety, efficacy, and defining outcome measures including patient and parental satisfaction. Moreover, industry should be encouraged to produce specific devices for the pediatric age group that are different from adapted devices designed for adults. Finally, the putative benefits and disadvantages of different irrigation fluids (saline, added laxatives) and concomitant use of probiotics and prebiotics should be examined.

CONCLUSIONS

Pediatric patients with either functional or organic BD represent a complex group in whom management is often difficult. Many patients undergo multiple noninvasive and invasive treatments without benefit. Because of the frequent failure of these standard treatments, TAI has become a valuable therapeutic alternative that may prevent surgical intervention. Patient selection, dedicated healthcare professionals, thorough training, and careful follow-up are the key to TAI success. Healthcare professionals should always use a tailored approach to the individual patient considering the different underlying bowel pathologies, presenting symptoms, and personal and family dynamics, to increase efficacy and adherence.

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