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Malone Antegrade Continence Enemas vs. Cecostomy vs. Transanal Irrigation—What Is New and How Do We Counsel Our Patients?

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Abstract

Purpose of Review No gold standard exists for managing neurogenic bowel dysfunction, specifically in individuals with spina bifida. Since the International Children's Continence Society published its consensus document on neurogenic bowel treatment in 2012, an increased focus on why we must manage bowels and how to improve our management has occurred. This review provides updated information for clinicians.

Recent Findings A surge in research, mostly retrospective, has been conducted on the success and satisfaction of three types of management for neurogenic bowel. All three management techniques have relatively high success rates for fecal continence and satisfaction rates. Selection of which treatment to carry out still is debated among clinicians.

Summary Transanal irrigation is a safe and effective management option for neurogenic bowel that does not require surgery. Antegrade enemas can be carried out via cecostomy tube or Malone antegrade continence enema with similar fecal continence outcomes.

Keywords Neurogenic bowel · Spina bifida · Fecal incontinence · Antegrade continence enemas · Cecostomy · Transanal irrigation

Introduction

As the care of individuals with spina bifida has improved, so too have the lifespans of those affected. The healthcare and quality of life needs of these individuals have necessitated changes to our clinical practice. Many clinicians in the urology field, who care for individuals with neurogenic bowel secondary to spina bifida, are tasked with helping individuals achieve their goals for management of their neurogenic bowel dysfunction (NBD). NBD is characterized by chronic constipation and/or fecal incontinence. NBD is associated with decreased health-related quality of life, decreased school attendance, increased discrimination, and increased depression [1, 2•]. Fecal incontinence secondary to NBD is associated with lower educational attainment and lower employment rates in adults with myelomeningocele, the most severe form of spina bifida [3•]. NBD can also contribute to urinary incontinence, urinary tract infections, ventriculoperitoneal shunt malfunction, skin breakdown, hemorrhoids, and anal fissures, which may lead to increased hospital and emergency department use [4–10].

Each individual with NBD is affected differently and has unique goals which define bowel care success. Some of these goals involve predictability in the timing of passing their bowels, reducing constipation, having independence with a bowel regimen, or reducing fecal incontinent episodes. A survey of Spina Bifida Association clinics demonstrated that urology clinicians most commonly manage NBD in multidisciplinary clinics, followed by rehabilitation medicine and developmental pediatricians. Physicians, advanced practice providers (nurse practitioners and physician assistants), and nurses are often all involved in NBD management.

The importance of fecal continence has been highlighted in recent years with the help of the National Spina Bifida Patient Registry (NSBPR). The NSBPR was established by the Centers for Disease Control and Prevention to support efforts directed toward improving the consistency and quality of care for spina bifida patients, and to provide an infrastructure to

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support spina bifida clinical research. In 2009, the NSBPR began accruing participants at ten clinics and expanded in 2011 to 21 other spina bifida centers. Sawin and colleagues analyzed the fecal continence rates among the first ten NSBPR clinics and found that only 30% of spina bifida patients reported themselves as having fecal continence [11]. As the NSBPR expanded, these rates were reexamined in 3252 individuals and only 43% reported having fecal continence [12]. The continence rates differed by type of spina bifida; those with myelomeningocele had the lowest rates of both urinary and fecal continence compared with other forms of spina bifida [12]. These fecal continence rates are lower than most clinicians, families, and patients find acceptable. There are likely modifiable factors that can improve these continence rates, and understanding the latest literature related to NBD treatment options is a critical step in improving this care.

The International Children's Continence Society (ICCS) provided a consensus document on therapeutic interventions for NBD in 2012. The ICCS remarked that transanal irrigation (TAI) is an important treatment for NBD as it allows for regular bowel irrigation and reduces the risk of fecal incontinence [13]. They note the difficulties in TAI in younger children due to the cooperation often needed from the child. Malone antegrade continence enemas (MACE) were also recommended as being highly effective and safe for children with NBD. ICCS noted that in 2012, there was still a true lack of research into the efficacy of different managements and that most clinicians relied on their clinical experience rather than on formal research. This report will present to the reader a high-level overview of the research that has been completed since 2012 to add to the evidence that clinicians use when conservative measures are not enough to reach an individual's goals for their NBD.

Transanal Irrigation

TAI is the instillation of large volumes of fluid (normally water) into the rectum and colon by a catheter (often with a balloon) or a cone through the anus. This was first introduced in 1987 by Shandling and Gilmour [9]. TAI was first approved in the USA in June 2012 as a commercially available product (Peristeen® Coloplast A/S) but other products exist and are in various stages of approval in the USA while already being used globally (Navina® Wellspect; IryPump® Braun). Most TAI products recommend using 10–20 ml/kg of fluid during each use (max 1 L). These are usually prescribed to be used daily to every other day. Due to the increase in available commercial products globally, a new focus on these products has emerged over the past 8 years.

TAI has been integrated into NBD care in many practices as a treatment prior to surgical intervention or as an alternative to surgical intervention (MACE or cecostomy mainly). Although literature seems to demonstrate that this is a safe and effective treatment for some with NBD, it is not covered by all insurances in the USA, limiting large-scale acceptance of this treatment option. TAI is often touted as an option for independence, but studies are showing that independence may not be as common with TAI as we had originally hoped. In children, this expectation should be given with caution as some studies identify that up to 76% of children with spina bifida using TAI still required a caregiver to perform their irrigation. This may increase with age and in adulthood but more studies are needed to determine this [14, 15].

The National Institute of Health and Care Excellence (NICE) has provided a positive recommendation for TAI for those requiring additional treatment strategies beyond conservative measures to manage NBD [14].

Successes

TAI has been well defined for use in adults with NBD as part of a stepwise pyramid of care (Fig. 1). It was also recently recommend to be used as part of a stepwise approach to NBD care in recent consensus documents [16••]. A recent literature review found average success rates of TAI in children to be 77.7% (range 53–97%) for achieving fecal continence, 78% (range 53–97%) for improving constipation, and 84% (range 60–100%) for overall improvement in symptoms [15••]. Literature on quality of life improvements after TAI are sparse, but do show improvement [17–19].

Several retrospective reviews have been completed at single centers globally to assess success of TAI [20–22]. Twenty-two children with spina bifida who underwent a week long inpatient bowel management program with TAI using balloon catheters attached to a gravity feed bag found that 77% were continent of stool by the end of the program [21]. Nine of the 22 patients required adjustments to their TAI program and five opted to stop TAI and proceed with a MACE.

TAI does not require any surgical intervention which is why it is often adopted as a step after failed conservative therapy and before surgical intervention. It can be used to see how well an individual and/or caregivers adhere to a strict bowel program before surgery, or to achieve improvement in NBD while deciding if bladder reconstruction is needed (often these surgeries would be completed concurrently), or to eliminate the need for surgical intervention entirely if it works well for the individual.

Cautions and Considerations

Cone enemas are often utilized before more formal devices and are often carried out with the individual lying on the floor while the cone is placed and the fluid is administered. This can often be carried out in younger children easily and caregivers can then assist in transferring a child to a commode to empty

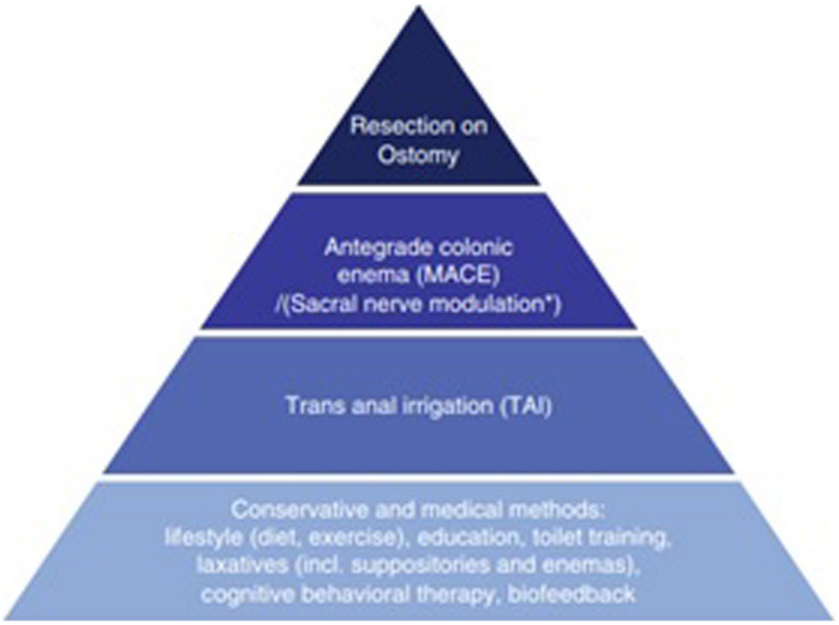

Fig. 1 Proposed bowel management pyramid for NBD. Used with permission from Mosiello et al. [15••]

the bowels. Some individuals can perform a cone irrigation themselves and will not move onto other TAI devices. Before trying TAI, the dexterity and core stability of an individual must be considered. Individuals should be able to transfer and sit on a commode or toilet to perform TAI. In order to increase the odds of independence, individuals will need the dexterity to insert something into their anus while sitting. Clinicians should also examine the anus externally at minimum to ensure normal anatomy and physiology [15••]. Contraindications for TAI include known anal or colorectal stenosis, active irritable bowel disease, being within 3 months of anal or colorectal surgery, and ischemic colitis.

A commonly reported problem is leakage of irrigation fluid during TAI administration. This can often be fixed by changing the volume in the balloon that is in the rectum. Some with hypotonia may require larger volumes in the balloon to completely fill and occlude the rectum to allow irrigation fluid to flow above the catheter and not leak around it. In others, decreasing the volume in the balloon has been helpful to reduce spontaneous expulsion of the balloon from the body during TAI. Troubleshooting of TAI often requires regular follow-up with a skilled clinician with experience in TAI. This follow-up can occur in person or remotely, but having regular access to a supportive and knowledgeable clinician who can provide modifications to TAI routines will likely improve overall success, adherence, and satisfaction of TAI. This is especially important in the early stages of TAI as it may take several weeks or longer to achieve reliable success, and small alterations to a TAI program may be needed.

Another common challenge is leakage of fluid and/or stool within 1–2 h after the TAI is completed. This may be evidence of incomplete evacuation of the bowel and might be improved with increased frequency of irrigation, or increased volume of irrigation fluid.

Reported rates of discontinuation or failure of TAI range from 5 to 36% in the literature, with the most common reason for discontinuation being a lack of effect at achieving continence [15••]. A separate study of 20 children with spina bifida who were trained on TAI and then contacted 4 years after initiation found that only nine were still using TAI [23]. Most of these individuals stopped TAI within the first year due to it being either "too difficult," painful, or having issues with the balloon. Perhaps, some of these concerns could have been ameliorated with closer follow-up after initiation.

Safety

The most severe potential complication of TAI is bowel perforation, a recent audit of these found 2 perforations per 1 million procedures (all patient groups and ages) [24]. Globally, from 2005 to 2013, there were 49 reported cases, which identified an increased risk of bowel perforation at the initiation of treatment and after pelvic surgery. In children, bowel perforation appears to be exceedingly rare, with only 1 of the 49 cases occurring in a child (rate of 1 in 1 million procedures) [24].

Cecostomy

Cecostomy tubes are placed percutaneously to allow antegrade enemas to be utilized. The tube is placed into the cecum and needs to be exchanged periodically; many centers use their interventional radiologists to manage these

exchanges. There are several tubes that can be used, such as a Chait Trapdoor™ (Cook Medical) or MIC-KEY™ (Avanos Medical, Inc.) button or a newer balloon catheter that has FDA approval for antegrade enemas use (AMT MiniACE™ Applied Medical Technologies, Inc.). MACE/cecostomy tubes have been carried out in 17.3% of NSBPR individuals (2009–2014 data) [25••].

Successes

A recent literature review looking at cecostomy tubes and MACE for evidence of continence rates and complications identified 166 children from only three retrospective studies [26–29]. The literature in this field is lacking. Literature review found no differences in the number of patients who achieved continence with MACE versus cecostomy tube (80% versus 70%, $p = 0.76$), but those with cecostomy tubes required fewer additional surgeries in follow-up [26].

An evaluation of 86 individuals cared for by either Nationwide Hospital or the University of Iowa sought to evaluate the effectiveness of cecostomy tubes in achieving fecal continence. The researchers compared those with cecostomy tube with those without a cecostomy tube. Forty-eight percent of those with cecostomy tubes had near or complete fecal continence, 40% had partial continence, and 12% were still incontinent [30•], Overall, 88% of those with a cecostomy were satisfied and 92% stated that they would do a cecostomy again [30•].

Cautions and Considerations

Cecostomy tubes do require regular replacement and should not be used in patients who may not have continued access to healthcare or who are at high risk of being lost to follow-up. Often, the replacement requires sedation. Cecostomy tubes require the use of an indwelling device which some individuals may be adverse to and therefore it is less inconspicuous than a MACE often is. Patients prone to skin breakdown and infection should be cautioned due to the contact of a cecostomy tube to the external abdominal skin for prolonged periods of time; a wound or ostomy specialist can be utilized to assist in properly caring for cecostomy tubes and to preserve skin integrity.

Fecal leakage around the insertion site of a cecostomy tube can occur and the reported rates of this show high heterogeneity. Excessive granulation tissue is also common in those with a cecostomy tube [26].

Safety

Safety rates for NBD management in the spina bifida population are not readily available. Complications can arise and should be discussed with caregivers and individuals considering cecostomy tube placement. Such complications include difficulty flushing the tube which can lead to fecal impaction, tube obstruction, tube fracture, tube dislodgement, and pericecal abscess.

Malone Antegrade Continence Enemas

The antegrade continence enema operation was first described by Malone et al. in 1990. The procedure generally entails taking a small segment of the intestine, typically the appendix, and bringing it up to the skin level in a non-refluxing manner to create a stoma where a catheter can be temporarily placed to instill fluids to provide evacuation of stool [31, 32].

MACEs have commonly been used to help achieve fecal continence in patients with NBD and are often carried out when other bladder reconstruction surgeries are completed. This coupling of surgeries reduces the need for additional anesthetics for individuals who often undergo many surgeries in their lifetime. An analysis of the 5209 individuals with spina bifida from the NSBPR from 2009 to 2015 found that MACEs were used by 17.7% of adults and 27.2% of adolescents [3].

Successes

MACE success rates for fecal continence from many studies since 1990 tend to be relatively high, with many studies reporting success rates ranging from 59 to 97% [26, 33–39]. These high success rates are encouraging, but as many have pointed out should be assessed in the setting that variation regarding selection of those who undergo a MACE may predispose them to have higher rates of continence once the procedure is completed [25••].

Variances by clinic regarding which individuals receive surgical intervention have been reported [25••]. Procedures were more likely in patients who were older, white, non-ambulatory, with higher level lesion, with myelomeningocele lesion, and with private health insurance (all $p < 0.001$, and female ($p = 0.006$)) in the NSBPR. Interestingly, the clinic itself was associated with the odds of surgery. This association suggests the presence of significant variation in the use of NBD procedures among NSBPR clinics. Overall intervention rate was 19%, with ranges among clinics from 3 to 38%; this was significant even after correction for clinical and non-clinical factors [25••].

Cautions and Considerations

Two schools of thought are often used for irrigation solutions for MACEs. Some centers opt for high-volume tap water enemas while others opt for lower volume solutions that combine water with an irritant, such as soap suds or glycerin. Two retrospective single-intuition reviews examined the use of irritants and found that adding an irritant to tap water or normal

saline increased the success of achieving fecal continence with a MACE [35, 40]. Glycerin acts as an osmotic laxative that promotes water absorption in the colon, thereby stimulating peristalsis [35, 41]. Studies have found that it demonstrated less irritation to the rectal mucosa in rats than phosphate enemas, which are also commonly utilized [42]. Some clinics prefer normal saline over tap water due to concerns of electrolyte imbalances [43]. One study identified that two-thirds of their patients failed irrigation with normal saline alone and had additives added to their irrigation which increased their success rates of achieving fecal continence [40]. These considerations should also be considered for those with a cecostomy tube. Often, the diameter of the cecostomy tube is too narrow for some thick solutions to easily be instilled but less viscous solutions may improve fecal continence rates.

A single institution retrospectively reviewed their patients who underwent MACE over a 3-year period ($n = 6$) and found that the mean operative time was 168 min (range 122–228) and the mean length of hospital stay was 2 days (range 1–4 days) [33]. This review was compiled from a very small sample size, but does bring up the consideration of length of hospital stay that is often required for those who receive a MACE versus non-surgical options. Robotic laparoscopic MACE surgeries may be an option that is safe and minimally invasive for those requiring MACE without bladder reconstruction concurrently; success rates and complication rates of this approach have not been thoroughly investigated and is an area in need of further research [44].

Decisional regret analysis for MACE and cecostomy tube procedures was completed by one clinic where they identified that 53% of the group (81 parents and children with spina bifida) had some form of regret. Most of this regret was identified as mild with only 5 individuals having moderate to severe regret. On regression analysis, persisting fecal incontinence was strongly associated with decisional regret as would be expected (OR 4.4, 95% CI 1.1–18.1, $p < 0.001$). Regret also increased as the age at which surgery was completed, particularly in children operated on at ages 13–15 years [45].

MACEs require intermittent catheterization use to perform irrigation. This can be a good option for those who are prone to skin irritation from an indwelling device that rests on the skin, like a cecostomy tube. For those individuals who perform bladder catheterization, utilizing a MACE can often feel like a familiar process and compliance may be improved.

Safety

Concerns for redo surgeries related to complications, such as stomal stenosis, must be discussed with patients. Prior studies have identified similar success rates of achieving fecal continence in spina bifida individuals between retrograde enemas and a MACE (80% vs 81%) but have noted that 23% needed redo surgery on their MACE during 5 years of follow-up [34]. The most common cause of redo surgery is stomal stenosis with several studies demonstrating similar rates of stenosis [40, 46]. One group found that their stomal stenosis rates were significantly higher in those who were obese preoperatively, and this should be considered in subject selection [46].

Conclusions

What Should the Clinician Do?

The need still exists for prospective trials looking at NBD management options. No prospective randomized trials exist comparing these treatment options. This type of study would likely be difficult to conduct. Individuals with NBD have varying goals and anatomical changes that will dictate the best option for management.

Also to be considered with any bowel program is the timing for introduction. Frequent conversations around fecal incontinence, constipation, and goals/expectations of the caregiver and individual with NBD are important starting in infancy. Many caregivers come to clinic with questions regarding constipation and fecal continence when a child is still in pre-school in hopes of working toward fecal continence before a child enters school. From clinical experience getting caregivers and individuals involved in NBD care while they are young, with hopes of working towards finding an acceptable management technique by school age is important. Studies have found that early placement of cecostomy tubes or MACE may contribute to improved quality of life in children [47]. I would argue that early adoption of TAI would likely carry similar levels of improvement in quality of life. TAI may be a good non-surgical option for families not wishing to have surgery completed or who may need bladder surgery in the future and would like to have the option of combined surgery at an older age for bladder and bowel concerns. Many individuals with NBD find that they can achieve fecal continence without surgical intervention (60% of those in the NSBPR) and rushing to a surgical intervention is not recommended, but may be needed to achieve NBD treatment goals.

Utilization of a step-wise approach, as suggested by Mosiello et al., should be considered by centers caring for individuals with NBD [15••]. If individuals reach the level of antegrade continence enemas, the cautions and considerations should be thoroughly discussed between cecostomy tubes and MACE. Individuals should be closely followed by a clinician dedicated to achieving their NBD goals and who has the capacity to have frequent contact with the individual and caregiver during the first several months of starting a new therapy. Individuals can be moved through a stepwise program until they find a treatment regimen that they are satisfied with. A wonderful website has been put together by Colleen Payne, a mother of a child with spina bifida, that introduces

families to NBD and treatments; it is not moderated by any medical or clinician group, but can be a resource for families who seek to talk to their peers regarding NBD (https://spinabifidabowelmanagement.com).

Compliance with Ethical Standards

Conflict of Interest Maryellen S. Kelly is on the advisory board for Coloplast A/C.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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