Novel Treatment Options for Fecal Incontinence

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Abstract

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- acupuncture

Fecal incontinence (FI) is a devastating condition affecting a substantial portion of the population. The etiologies of FI are wide ranging, as are the treatment options. When conservative measures fail, often surgical intervention is required. As in any area where a wide range of treatment options exist, there is no one perfect solution. Fortunately, novel treatment options for FI are becoming available, namely, posterior tibial nerve stimulation, magnetic anal sphincter, stem cell transplant, pyloric transplantation, and acupuncture.

CME Objectives: The reader should be able to define and explain the utility of the less common and more novel treatment modalities for fecal incontinence, including posterior tibial nerve stimulation, the magnetic anal sphincter, stem cell transplant, and acupuncture. Comparison to more common treatments can be made. The utility of these more novel treatments can be explained, and judgment made on their potential future benefits as further research is performed.

Fecal incontinence (FI) is a distressing and all too common problem, often associated with social stigma and profound quality of life implications. It is estimated to affect 10% of adults in their lifetime.¹ FI is defined as “the involuntary loss of liquid or solid stool that is a social or hygienic problem.”² Often patients are too embarrassed to discuss the problem with health care providers, which greatly underestimates its prevalence. It is estimated that 1.4% of adults suffer from major FI at any one time, with overall published rate estimations of 0.5 to 28%.³ Estimated FI in women after vaginal delivery is thought to be 4%, with 30% of women having evidence of sphincter injury without FI.⁴ Its prevalence only increases with age, with an estimated 50% of nursing home residents suffering from the condition.⁵ The population is continuing to age, and FI will only become more prevalent, and present mounting challenges to health care providers.¹

The etiology of FI is wide ranging, and often times not attributed to a single factor. Etiologies include trauma to the anal sphincter mechanism, idiopathic degeneration of the sphincter muscle, spinal injury, pudendal neuropathy, radiation, inflammation, and many others.⁶

The management of FI is difficult, and the patient needs to be informed that treatment is of a long-term nature. Often several trials, some with limited success, are needed to be implemented before results are seen. Initial treatment is often conservative, including optimizing the patient's diet and fluid intake, and treating diarrhea if present.⁷ Subsequent management strategies often involve trials of physiotherapy/pelvic floor exercises and biofeedback. If these measures fail operative management is often required. Examples of these procedures include biologic sphincter bulking implants, sphincteroplasties, implantation of artificial sphincters or muscle transpositions, and implanted electrical stimulators.⁸ These procedures and their indications are discussed elsewhere.

As the current surgical therapies for FI are often suboptimal, much research has been invested in discovering novel surgical treatment strategies. These include magnetic anal sphincters (MASs), tibial nerve stimulation, stem cell therapy, pyloric transplant, and acupuncture.

Posterior Tibial Nerve Stimulation

Neuromodulation as a treatment for FI has its origins in the work of Melzack and Wall who first described transcutaneous electrical nerve stimulation (TENS). Described in 1965, and originally developed for analgesia purposes,⁹ this technique was later successfully used for urinary incontinence.¹⁰ TENS therapy led to the development of sacral nerve stimulation. The sacral nerve stimulator (SNS) applies a low-voltage electrical current to the sacral nerve roots. The ultimate mechanism of action is not fully understood, although it is believed it may activate latent muscle fibers of the pelvic floor muscles increasing continence by stimulation of multiple afferent sensory pathways in the spinal cord.¹¹ This treatment has successfully been applied to FI. Reports have shown an upward rate of 75% continence, with almost 100% of patients experiencing a 50% reduction in incontinent episodes.¹² Quality of life scores have also been shown to improve.

Peripheral nerve stimulation is the next iteration of sacral nerve stimulation. The rationale behind peripheral, as opposed to sacral neuromodulation, is that it is easier to access the same sacral nerves, but in a less invasive manner. The posterior tibial nerve contains sensory, motor, and autonomic fibers arising from the fourth and fifth lumbar and the first to third sacral nerve roots.¹³ Nakamura et al in 1983 first showed the efficacy of posterior tibial nerve stimulation (PTNS) in the control of urge incontinence and overactive bladder.¹⁴

Before 2003, PTNS was only trialed for urinary incontinence. Since then, several studies have been undertaken to study PTNS for the treatment of FI, and the provisional evidence is encouraging. This method is also cheaper, with a 12-week course costing \$770 to 1,800, as compared with \$8,850 to 15,000 for SNS implantation.¹⁵

The first study on the use of PTNS was published by Shafik et al in 2003. In this study, 32 patients with idiopathic FI, all whom failed conventional therapy, were studied. The Wexner scale was used to grade the FI. The patients had normal electromyography activity of the external anal sphincter, puborectalis and levator ani muscles, normal anal pressure on manometry, and normal defecography and anal ultrasound. The Stoller afferent nerve stimulator (UroSurge, Coralville, IA) was used. For 4 weeks, stimulation was done for 30 minutes every other day. The authors reported improvement in FI by 78.2%. In the patients with recurrence, retreatment achieved a success rate of 75%. Of the 32 patients treated, 27 reported a greater than 50% improvement in continence.¹⁶

The next article reporting the results of PTNS was published by Queralto et al (2006) in the *International Journal of Colorectal Disease*. Ten women with idiopathic FI were evaluated by in office examinations, endoanal ultrasonography, and anorectal manometry. All the women had intact sphincters, no anatomical rectal prolapse, and failed medical treatment. The PTNS unit used (Cefar Primo) was different to that of Shafik et al, in that stimulation was done using self-adhesive electrodes without an implantable needle electrode. The current was applied for 20 minutes daily for 4 weeks. Wexner scores improved in 8 of the 10 patients in 4 weeks. The mean improvement in scores was more than 60%.¹⁷

In 2009, two articles showing positive results with the PTNS were published. In a prospective, multicenter study by Govaert et al in *Colorectal Disease*, 22 patients were enrolled and were treated with the Urgent PC Neuromodulation System (Uroplasty Ltd, Geleen, the Netherlands). This system used a 34-gauge needle electrode. The patients were treated for 35 minutes a session, with two sessions a week for 6 weeks. After outcomes assessment, the sessions were reduced and eventually stopped. If symptoms reappeared or increased, the frequency would be increased to the last effective treatment schedule. Of the 22 patients, 18 (81.8%) had a subjective improvement, whereas 14 (63.4%) had a greater than 50% reduction in incontinence episodes at 6 weeks.¹⁸

The second article from de la Portilla et al evaluated 16 patients with severe FI. These patients were also scored using the Wexner fecal continence scale and a quality of life questionnaire. All included patients had severe FI for more than 6 months and had failed medical management. This protocol included the 34-gauge needle connected to the stimulator (Urgent PC, Uroplasty Ltd.). The patients underwent 30-minute weekly sessions for 12 weeks. If the patients had a favorable response, they were offered the second phase, consisting of biweekly session for 2 months, every 3 weeks for 2 months, and finally one session in a month. Unilateral stimulation was performed. Overall, only 44% of the patients who underwent full treatment showed improvement. The authors were unsure as to why 56% of the patients failed therapy, or if a specific group of patients is more likely to benefit. The study also looked at anorectal manometry before and after treatment, and no significant differences were seen. The long-term durability of the procedure was also brought into question in this article.¹⁹

Boyle et al (2010) published a prospective trial in the *Diseases of the Colon and Rectum* in 31 patients. All patients had urge incontinence of different etiologies, and all were work-up with a thorough history and physical, endoanal ultrasound, anal canal manometry, rectal sensation, and pudendal nerve terminal motor latencies. The percutaneous Urgent PC Neuromodulation System (Uroplasty Ltd, Manchester, UK) was used. The treatment consisted of 12 weekly 30-minute sessions, followed by two sessions 2 weeks apart, and finally one session 4 weeks later. Overall, 22 (71%) patients have a 50% reduction in incontinence episodes, and 12 (32%) patients became fully continent.²⁰

In 2012, Hotouras et al published a prospective trial with aims of distinguishing treatment effects based on the different types of FI. One hundred patients with urge, passive, and mixed FI underwent PTNS using the same stimulator and treatment protocol used by Boyle et al (2010). The treatment appeared to be beneficial to the patients with urge and mixed FI, with improvement in incontinence scores, episodes of FI, and quality of life scores. No improvement was seen in the passive incontinence group.²¹

The first randomized controlled trial using PTNS was published by Leroi et al (2012). In this study, 144 patients were randomized to an Eco Program P3 TENS (Schwa Medico, Ehringshausen, Germany) or a sham TENS unit. Two daily treatments were performed at home for three consecutive

months. Outcome measures were again measured using the Cleveland Clinic Continence Scoring System (CCS). In terms of the number of FI episodes per week, there was a statistically significant decrease from baseline in the TENS group as compared with baseline initially, but after 3 months no difference was seen. Thirty-four (47%) patients in the TENS groups had a > 30% decrease in CCS scores as compared with the 19 (27%) in the sham group, $p = 0.02$. Overall, the study did not show a benefit in terms of FI and urgency episodes as compared with placebo. But as the authors point out, the treatment is noninvasive, safe, well tolerated, and easy to perform.²²

As previously noted, multiple studies have shown benefits of percutaneous, and to a lesser extent, transcutaneous PTNS, but these were not head-to-head trials. To try and determine the difference in efficacy of percutaneous versus transcutaneous tibial nerve stimulation, George et al performed a randomized control trial published in the *British Journal of Surgery* (2013). The study randomized 30 patients, all of whom failed initial medical management, to one of three groups: percutaneous group, transcutaneous group, or sham transcutaneous group. The first two groups received twice weekly 30-minute sessions for 6 weeks. A response to treatment was defined as a 50% or greater reduction in weekly episodes of FI. Baseline data were collected and the St. Mark's continence scoring system and the Rockwood FI quality of life scoring systems were used. Nine of the 11 patients in the percutaneous groups showed a greater than 50% decrease in weekly FI episodes, whereas 5 of the 11 patients in the transcutaneous showed benefit, and only 1 of the 8 patients in the sham group demonstrated benefit at the end of the 6-week study phase ($p = 0.035$). The authors concluded that percutaneous PTNS showed a greater reduction in incontinence episodes as compared with transcutaneous stimulation. These patients were followed up over a 6-month follow-up period and the results were maintained.²³

The optimal treatment protocol for PTNS is unclear, and many regimes have been reported. Thomas et al (2013) attempted to answer this question in a randomized controlled trial comparing daily to twice weekly transcutaneous PTNS. The patients kept a continence diary and the Rockwood FI quality of life (FIQoL) and the St. Marks FI scoring systems were used. The PTNS system used was the NeuroTrac TENS (Verity Medical Ltd, Hampshire, UK). The primary outcome measured was frequency of FI episodes per week, and secondary outcomes included ability to defer defecation, frequency of defecation, and quality of life measures. Thirty patients were randomized, 15 in each group, with one patient in the daily PTNS lost to follow-up. After 6 weeks, three patients in the daily group achieved complete continence, while none in the twice weekly group did. The daily group showed a reduction in weekly FI episodes of 5 to 3.5 ($p = 0.025$), while the twice weekly groups showed a reduction that was not statistically significant. The percentage reduction in incontinence episodes is 60% in the daily group versus 50% in the twice weekly group. Two of the four quality of life measure in the Rockwood scale showed significant improvement in the daily groups, while none was significantly better in the twice weekly arm. Although this was an

underpowered study, the data suggest that daily stimulation may be more efficacious than twice weekly stimulation.²⁴

Thomas et al (2013) attempted to better define the optimal protocol by looking at bilateral transcutaneous PTNS. In this single-group pilot prospective study, 20 consecutive patients with FI who failed conservative management underwent bilateral transcutaneous PTN on a daily basis for 6 weeks. After the treatment period, 2 patients achieved complete continence, while 10 (59%) patients achieved a > 50% reduction in frequency of incontinent episodes. Incontinence episodes per week decreased from 6 to 2 ($p = 0.003$). The Rockwood FI quality of life score was also used, and a significant improvement was noted. Although there was no control group, and the sample size was small, bilateral transcutaneous PTNS did appear to be an effective treatment.²⁵

Overall, the exact role of PTNS for FI is uncertain, and the optimal protocol has yet to be determined, but the preliminary results are encouraging.

Magnetic Anal Sphincter

Another promising avenue for FI treatment is the implantation of a MAS. Sphincter augmentation was initially described and developed for the treatment of gastroesophageal reflux disease. The goal of this therapy is to augment the lower esophageal sphincter while maintaining normal gastroesophageal junction and gastric anatomy, keeping gastric contents from refluxing into the esophagus, but still have the ability to expand to allow fluid and liquid boluses to pass. Multiple reports have demonstrated its feasibility, efficacy, and safety.^{26,27}

This technology has recently been implemented in the treatment of FI. The MAS (Torax Medical, Inc, Shoreview, MN) is implanted around the external sphincter with the intent of surgically augmenting the competence of the anal sphincter. The MAS is a ring of titanium beads containing hermetically sealed magnetic cores. Titanium wires link the beads forming a flexible ring. The magnetic attraction between the beads augments the anal sphincter in its resting state. As a fecal bolus is passed through the distal rectum and voluntary Valsalva pressure is initiated, the magnetic bond is temporarily broken, allowing the voluntary passage of stool. This seal is immediately restored after.²⁸

A feasibility study was recently published by Lehur et al²⁸ in the *Diseases of the Colon and Rectum*. This was a multicenter, prospective, observational clinical feasibility study designed to evaluate device safety and efficacy. All patients had documented FI for at least 6 months. Fourteen women were implanted with the MAS device. The average follow-up was 6 months. The average number of weekly FI episodes reduced from 7.2 to 0.7 (90.9%). The average reduction in Wexner score was from 17.8 to 7.8 (54.7%). No patients in the study reported worsening of their FI scores. FIQoL was also measured. All individual scores and mean scores were improved, including lifestyle ($p = 0.008$), coping/behavior ($p = 0.008$), self-perception ($p = 0.002$), and embarrassment ($p = 0.005$). No cases of chronic obstruction were observed.²⁸

Adverse outcomes included two infections both treated with systemic antibiotics, with one requiring explant, and breakage of the devices securing suture with erosion and per anal passage. This underlies the importance of appropriate sizing. Minor adverse events, all of which resolved, included pain in two patients, rectal bleeding, and obstructed defecation for 2 days. Overall, these preliminary results demonstrate the feasibility of the new technology in treatment FI.²⁸

Two additional comparative studies were published from the same institution, using the same patient population.²⁸ The first was a nonrandomized, comparison study evaluating the MAS and the artificial bowel sphincter (ABS). The short-term results were encouraging. The operative time for the MAS was shorter (62 vs. 97.5 minutes, $p = 0.0273$), as was the length of stay (4.5 vs. 10 days, $p < 0.01$). There were no differences in early postoperative complications of MAS versus ABS (4 vs. 2, $p = 0.628$) or explantations (1 vs. 4, $p = 0.830$). In terms of FI improvements ($p < 0.002$) and quality of life ($p < 0.009$), both showed significant benefits. This study was not meant to show superiority of the MAS, but to show its efficacy.²⁹

The second study compared in a nonrandomized fashion, the MAS and the SNS. The operative times for the two implantation procedures were similar; with the notable difference being the SNS group required a second operation. The overall morbidity rates were similar, and MAS was found to be just as effective at improving continence and quality of life as the SNS.³⁰

The above studies demonstrated initial success of the MAS. In terms of its continued success in the same patient cohort, a follow-up study was published by Barussaud et al.³¹ Between 2008 and 2012, 24 women were implanted with the MAS. Of note, the original articles only reported on the implantations between 2008 and 2010. The average follow-up for the study was 17.6 (6–45) months. Two patients (8.7%) had the device removed; one spontaneously after a strong straining effort and the other in a heavy smoker was surgically explanted after developing a perirectal abscess. In terms of the number of FI episodes per 3 weeks, there was a significant improvement (32 vs. 8, $p < 0.001$). Episodes of urgency also improved (20 vs. 7, $p < 0.019$). FI quality of life score significantly improved in all dimensions and were stable over time. Sixteen (69.5%) of the patients were satisfied, meaning five showed a lack of improvement with the treatment. Overall, the authors concluded that the MAS is a safe technology and has a high chance of success, although the long-term efficacy is yet to be determined.³¹

Stem Cell Transplant

Stem cells present a tantalizing treatment option for a host of medical diagnoses. Injection of stem cells into the external anal sphincter to stimulate muscle differentiation and growth and improve sphincter function has been studied, both with and without surgical repair of the sphincter. All stem cell studies have been done in animal models, no human studies have been performed. Pathi et al showed that injection of

mesenchymal stem cells into rat sphincters increased contractile function.³² White et al injected myogenic stem cells into a transected rat sphincter and showed that when combined with sphincter repair, contractile function was increased, but not if injected without repair.³³ An Austrian study by Frudinger et al studied injection into the external sphincter of autologous myoblasts harvested from a pectoralis muscle, in women with obstetric injury. The results in 10 women were promising, showing improvement in incontinence and quality of life scores.³⁴ Stem cell therapy holds promise for the treatment of FI, but there is no direct clinical benefit at this time.

Pyloric Valve Transplant

Recreation of an autologous external sphincter for patients with a poorly functioning or surgically absent anal sphincter has been a goal for colon and rectal surgeons for many years. Pyloric valve transplant was initially studied in dogs and in cats in 1982. In 2011, Goldsmith and Chandra showed the technical feasibility of using a transposed pyloric valve mobilized to the perianal region as a replacement of an excised anal sphincter in humans.³⁵ This is a complex operation requiring removal of the pylorus, reconstruction of continuity via a gastroduodenostomy or gastrojejunostomy, and mobilization of the pylorus on an omental pedicle, and suturing of the pylorus to the descending colon and anal canal. A short-term follow-up study of 17 patients showed improved anal manometric resting and squeeze pressures. The patients who had sphincter augmentation had better scores than those whose sphincter was surgically absent. There were no quality of life scores.³⁶ This technique has been criticized for possible long-term complications including constipation and potential dumping symptoms, as well as being an unnecessarily complex procedure simply to avoid a colostomy bag.³⁷

Acupuncture

Finally, acupuncture has been shown to improve bladder dysfunction in some patients. An Italian study using traditional Chinese acupuncture technique showed an improvement in sustained anal squeeze by anal manometry. In addition, patient with irregular or loose stools reported improvement in continence. Acupuncture is thought to work by “neuromodulation,” similar to effects achieved by sacral nerve stimulation.³⁸

Conclusion

FI treatment can be difficult and time consuming, for both patients and providers, often times requiring multiple failed treatment attempts before even a modest improvement is seen. As there is no standard treatment modality, and no one best option, newer alternatives are in development and are rapidly becoming available. Studies are needed to confirm their efficacy, but there is optimism that a better solution will soon become available.

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