Home Transcutaneous Electrical Stimulation Therapy to Treat Children With Anorectal Retention: A Pilot Study

Yee Ian Yik, MRCS, Ed, MS, PhD, MBBS*†‡; Lefteris Statopoulos, MD*§; John M. Hutson, MD, UMelb, MD, Monash, DSc, UMelb*†¶; Bridget R. Southwell, BSc Hons, MSc, PhD*†

Aim: As transcutaneous electrical stimulation (TES) increased defecation in children and adults with Slow-Transit Constipation (STC), we performed a pilot study to test if TES can improve symptoms (defecation and soiling) in children with chronic constipation without STC and transit delay in the anorectum.

Methods: Children with treatment-resistant constipation presenting to a tertiary hospital had gastrointestinal nuclear transit study (NTS) showing normal proximal colonic transit and anorectal holdup of tracer. TES was administered at home (1 hour/day for 3 months) using a battery-powered interferential stimulator, with four adhesive electrodes (4 × 4 cm) connected so currents cross within the lower abdomen at the level of S2–S4. Stimulation was added to existing laxatives. Daily continence diary, and quality-of-life questionnaires (PedsQL4.0) were compared before and after TES.

Results: Ten children (4 females: 5–10 years, mean 8 years) had holdup in the anorectum by NTS. Nine had <3 bowel motions (BM)/week. After three months TES, defecation frequency increased in 9/10 (mean 0.9–4.1 BM/week, \( p = 0.004 \)), with 6/9 improved to \( \geq 3 \) BM/week. Soiling reduced in 9/10 from 5.9 to 1.9 days/week with soiling, \( p = 0.004 \). Ten were on laxatives, and nine reduced/stopped laxative use. Quality-of-life improved to within the normal range.

Conclusion: TES improved symptoms of constipation in >50% of children with treatment-resistant constipation with isolated holdup in the anorectum. Further studies (RCTs) are warranted in these children.

Keywords: chronic constipation, interferential current, neuromodulation, paediatric

Conflict of Interest: John Hutson and Bridget Southwell are members of an Advisory Committee for GI Therapies. Yee Ian Yik and Lefteris Statopoulos have no competing financial or other interests. Bridget Southwell and John Hutson have developed a new device to treat constipation and have received government and investment funding to develop the device. The device was not yet a prototype and was not used in this study. Bridget Southwell has received consultant fees from the startup company—GI Therapies. Knowledge from this study was used in the design of the new device. Bridget Southwell and John Hutson have a patent for treatment of chronic constipation using transcutaneous electrical stimulation. Bridget Southwell has a design patent for a new device to treat constipation.

INTRODUCTION

Constipation in children is common and symptoms vary from mild and short-lived to severe and chronic. Symptoms such as fecal incontinence, fecal impaction and abdominal pain can persist despite treatment. Current treatments of adults and children with chronic constipation include dietary modifications, laxatives, and behavioral training (1,2), but chronic constipation can persist...
into adulthood in one third of children, despite medical treatment (3).

Colon transit is used to categorize constipated patients into three groups with normal transit, slow transit (generalised slow movement through the colon), and accumulation of markers in the anorectum (4–6). Slow transit constipation (STC) is characterised by ineffective colonic propulsion. Anorectal accumulation of tracer may be due to pelvic floor dysfunction, poor relaxation of the pelvic floor muscles, inadequate propulsive forces during defecation, anismus, or withholding behaviour and is termed outlet obstruction (4) or defecatory disorder (DD). Accumulation in the anorectum is the commonest transit pattern in patients with chronic constipation (4).

Some patients with outlet obstruction respond poorly to conservative treatment (7), which includes adequate intake of fluids, dietary fibre supplementation, and laxatives followed by biofeedback training (5,7,8). Surgical management is only rarely offered to patients with disabling symptoms. Caecal or appendix stoma with antegrade enemas have been successful in some children with DD (9,10). In adults, DD are primarily treated with pelvic floor retraining using biofeedback (5,8), but this may be less effective in children (8).

Defecation requires co-ordinated sensorimotor functioning of the anus and rectum (11). Rectal hyposensitivity may occur due to defects in rectal sensory nerves or to brain processing (12). The sacral nerves contain both sensory and motor nerve fibres as well as sympathetic and parasympathetic nerve fibres (13). Balloon distension in the anorectum produces an anal contractile response recognized as the urge-to-defecate (14). Many children with constipation report no urge-to-defecate (15). While rectal manometry provides the best measure of sensory perception, urge-to-defecate provides a simple indicator of sensory perception.

Neuromodulation is a promising treatment for selected patients with chronic constipation (16). We have previously shown that transcutaneous electrical stimulation (TES) with interfamilial current across the abdomen using adherent skin electrodes can improve bowel function in children with STC (17–20). Other groups have shown improvement in children with spina bifida, and with voiding dysfunction with constipation (21,22) and in adults with STC, functional dyspepsia, and irritable bowel syndrome with constipation (IBS-C) (23,24) using TES. Chang et al. 2003 (25) showed that intranal electrical stimulation was also effective in adult constipated patients (mixed AR, STC, and normal transit constipation, NTC) (25). In this pilot study, we aimed to determine whether daily treatment at home using TES over the lower abdomen and sacral nerves could affect defecation, soiling, transit site or quality of life in ten children with holdup in the anorectum. When combined with images taken at 0–2 hours after ingestion of radioactive tracer, scintigraphy can identify patients with delayed gastric emptying in combination with constipation (26). Delayed gastric emptying can occur secondary to rectal distension (27), so we measured gastric emptying as well as transit through the small and large intestine. As an increase in urge to defecate could indicate modulation of afferent signalling (25), we measured changes in this sensation.

**METHODS**

**Patient Group**

This was a pilot study of children with chronic constipation carried out in a tertiary pediatric centre after institutional Ethics Committee approval (HREC 30029A). For inclusion children had chronic constipation for more than six months (Table 1) and had been referred to surgeons after failure of multiple medical treatments by paediatricians or gastroenterologists. Initial assessment ruled out organic causes of constipation. All were on 1–4 classes of laxatives (Table 1) on presentation.

From March 2009 to December 2011, ten children diagnosed with anorectal retention by NTS (NTS) were recruited. The standard test for the site of hold-up in chronic constipation is sitz markers and x-rays (6), but NTS is available at some centres and provides more information. Our paediatric radiologists have extensive experience (28) with NTS. Patients drank dairy or soy milk containing Gallium-67 citrate (0.16–0.33 MBq/kg) and gamma camera images were taken at 0, 30, 60, and 120 mins, then 6, 24, 30, and 48 hours. The bowel was divided into six Regions-of-Interest (ROI, 1 pre-colonic, 2 = caecum/ascending colon, 3 = transverse colon, 4 = descending colon, 5 = recto-sigmoid colon, and 6 = excreted). The radioactive counts in each region were counted and corrected for decay. The geometric centre (GC) of radioactivity is a standard measure for nuclear medicine and is calculated at each time point from the corrected activity in each region as a fraction of the total activity multiplied by the region number (28,29): GC = [%ROI1 + %ROI2 + %ROI3 + %ROI4 + %ROI5 + %ROI6] / 100, where % is the % of radioactivity in the region at that time.

The gastrointestinal transit (GIT) index is the sum of the GC at 6, 24, 30, and 48 hours. The smaller the GIT, the slower the transit. Normal transit has a GIT index of ≥ 12.5 (6,28,29). Another measure of transit is % of radioisotope retained in the recto-sigmoid colon at 48 hours. Retention of <40% is defined as normal transit in children (28). Gastric emptying was measured as gastric emptying half-time.

### Table 1. Characteristics of Patients Before Study.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td></td>
</tr>
<tr>
<td>Total number of patients</td>
<td>10</td>
</tr>
<tr>
<td>Age (years)</td>
<td>7.8 ± 1.8</td>
</tr>
<tr>
<td>Female</td>
<td>4</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>17.0 ± 4.3</td>
</tr>
<tr>
<td>Other medical conditions</td>
<td>7</td>
</tr>
<tr>
<td>Duration of constipation</td>
<td>3</td>
</tr>
<tr>
<td>Since birth (delayed meconium passage)</td>
<td></td>
</tr>
<tr>
<td>Family history of constipation</td>
<td>2</td>
</tr>
<tr>
<td>Duration of constipation (years)</td>
<td>4.6 ± 1.0</td>
</tr>
<tr>
<td>Age at AR diagnosis (years)</td>
<td>7.6 ± 1.9</td>
</tr>
<tr>
<td>Duration of constipation before AR diagnosis (years)</td>
<td>3.0 ± 2.2</td>
</tr>
<tr>
<td>Number of doctors consulted before AR diagnosis</td>
<td>4.5 ± 1.0</td>
</tr>
<tr>
<td>Symptoms</td>
<td></td>
</tr>
<tr>
<td>Defecation frequency</td>
<td>0.9 ± 0.8</td>
</tr>
<tr>
<td>(bowel motions/week)</td>
<td></td>
</tr>
<tr>
<td>Soiling frequency (days/week)</td>
<td>5.9 ± 1.9</td>
</tr>
<tr>
<td>Abdominal pain (days/week)</td>
<td>1.3 ± 1.3</td>
</tr>
<tr>
<td>Stool consistency (hard)</td>
<td>5</td>
</tr>
<tr>
<td>Stool size (large)</td>
<td>2</td>
</tr>
<tr>
<td>Have bloating</td>
<td>4</td>
</tr>
<tr>
<td>No urge to defecate</td>
<td>2</td>
</tr>
<tr>
<td>Weak urge to defecate</td>
<td>8</td>
</tr>
<tr>
<td>Retention in anorectum in NTS</td>
<td>10</td>
</tr>
<tr>
<td>Laxative use</td>
<td></td>
</tr>
<tr>
<td>Laxative use before TES (yes)</td>
<td>10</td>
</tr>
<tr>
<td>Used &gt; 2 subclasses*</td>
<td>3</td>
</tr>
<tr>
<td>Also use enemas</td>
<td>3</td>
</tr>
</tbody>
</table>

Data shown as mean ± SD or actual number.

*Four subclasses of laxatives were identified: bulk, softener, stimulant, and osmotic.
(t1/2) and % tracer retained in the stomach at 2 hours. Normal gastric emptying is defined as t1/2 ≤ 50 min and stomach retention at 2 hour ≤15% (26).

Children included in this study had AR, defined as >60% of the radiotracer retained in the recto-sigmoid colon at 48 hours and the GIT index ≥12.5 (28). Exclusion criteria included ventriculoperitoneal shunt or cardiac pacemaker, STC on NTS transit study or previous TES.

TES was proposed as an experimental and alternative treatment at the time of recruitment, and written informed consent was obtained. From March 2009 to December 2011, ten children were recruited (separate from our previously published data) (18,19,26,30,31).

Stimulation Regimen

Parents and children were trained at a one-hour session to use the 9-V battery-operated, rechargeable interferential stimulator (INF 4160, model FD-09, Fuji Dynamics Ltd., Hong Kong), proper placement of electrodes, connection of leads and wires, and reassurance on the safety of TES for home treatment. A photo of the electrode positions was taken home by the patient/parent with written instructions. Patients were contacted by phone to check settings and use and sent a photo of electrode position after 1 week to ensure correct placement. TES was performed at home, one hour daily for three months. Two anterior self-adhesive 4 × 4 cm² electrodes were placed on the abdominal wall just above the pubic symphysis and two posterior electrodes were placed on the sacral dimples on either side (S2–4) (Fig. 1). The electrodes were connected diagonally. Interferential current used a constant current with one channel at 4000 Hz and the second sweeping 4080–4160 Hz with an adjustable intensity less than 33 mA. The current was increased until the child reported sensory awareness but without visible muscle contractions (17,19).

Outcome Measures

A diary (on defecation frequency, fecal incontinence, abdominal pain, urge-to-defecate, and laxative use) was recorded daily before and during treatment and PedSQL4.0 questionnaires (according to age groups) were administered before and after three months’ TES treatment. Instructions were given on how to record the diary. Baseline data were recorded for one month before TES. Defecation frequency was recorded as bowel motions/day (BM/day). Fecal incontinence and abdominal pain were measured as days/week with symptom occurrence. Stool consistency was measured using the Bristol Stool Scale (BSS) (32). Urge-to-defecate was measured using a visual analogue scale (0 = no urge, 1–3 = weak, 4–7 = moderate, 8–10 = strong urge). Patients were asked if they felt any sensation of the need to defecate before they did a bowel motion and if so how strong was the sensation.

The primary outcome measure was defecation frequency. Fecal incontinence episodes/week, laxative use, episodes of abdominal pain/week, urge-to-defecate, and quality of life (PedSQL, parent and child-reported) and GIT measured by NTS before and after TES outcomes were secondary.

The following changes were considered improvement:

1. defecation frequency of ≥3 BM/week;
2. reduced days of soiling and abdominal pain (measured as days/week with symptoms);
3. reduced use or discontinued use of laxative;
4. increased PedSQL scores; and
5. faster colonic transit (with a higher GIT indicating faster transit) or increased excretion at 48 hours.

Symptoms of constipation were evaluated statistically by paired t-test (for parametric measures) or Wilcoxon Paired test (for nonparametric measures). Data were analyzed in STATA 12 and then graphical presentation was performed using Prism 6. Data are expressed as mean ± SD. p < 0.05 was considered significant.

Compliance

For the first week, patients were telephoned each 2–3 days for support, answer questions and ensure they were performing the stimulation each day and filling in diaries. Patients were reviewed in person by YYY every 2–3 weeks to supply additional electrode pads.
ensure proper technique, and collect bowel diaries. Regular emails and phone contacts were maintained throughout. The patients recorded how long they performed the stimulation each day and the intensity of current applied. Diaries were checked to see if they were performing the stimulation for an hour each day.

RESULTS

Demographics of each patient and the group is shown in Table 1. Mean (SD) age at diagnosis of AR was 7.8 ± 1.8 years. Mean (SD) symptom duration was 4.6 ± 1.0 years. Three children had delayed passage of meconium at birth. All ten children used laxatives before the study. Two used 1 subclass, six used 2–3 subclasses, and two used 4 subclasses without success in overcoming their constipation. All had straining to defecate. Before stimulation, nine patients had <3 BM/week (0.9 ± 0.8/week). Five had hard stool consistency (Type 2–3 BSS). All had fecal incontinence (soiling) with mean days of fecal incontinence/week 5.9 ± 1.9 and mean days of abdominal pain/week 1.2 ± 1.1. Nine children fulfilled the Rome II criteria for functional constipation and PACCT criteria for chronic constipation (<3 BM/week, soiling >1/week, straining to defecate). One child had 3 BM/week but was included as he had daily soiling and hard stool and anorectal retention on NTS, which was seen in all ten patients, with normal transit in the proximal colon. Four patients had slower proximal colonic transit but did not reach the criterion for STC (GIT index < 12.5). Four had bloating (Table 1), two had no urge-to-defecate, and eight had a weak urge-to-defecate (Fig. 3d).

All ten children completed three months of TES. Compliance was measured from the daily diaries. Seven patients were compliant throughout, and missed 1–2 days only. Three patients missed 3–5 weekends. There were no adverse events.

After three months of electrical stimulation, defecation frequency (mean, SD) increased in 9/10 children (0.9 ± 0.8 to...
3.2 ± 2.3  p = 0.004; Fig. 2). Six had increased defecation frequency from <3 bowel motions (BM)/week into the normal range of >3 BM/week (Fig. 3a). In the other four children, three had increased defecation frequency, but still <3 BM/week, and one child had no change in defecation frequency. The child with 3 BM/week at baseline increased to 7 BM/week.

Fecal incontinence (soiling) reduced significantly in nine children from (5.9 ± 1.9 days/week before stimulation to 1.9 ± 2.0 days/week (p = 0.004; Fig. 3b). One child continued to have persistent fecal incontinence and no change in BM frequency.

Only 6/10 children had abdominal pain (1.20 ± 1.1 days/week). After TES, they reported a decreased occurrence of these episodes to 0.2 ± 0.4 day/week (p = 0.03; Fig. 3c).

Urge-to-defectate was initially absent in two and weak in eight. The mean (±SD) VAS score (0 = no urge, 10 = strong urge) increased significantly from 1.5 ± 1.2 to 4.4 ± 2.6, (p = 0.004) reflecting improved urge to defecate after TES. After TES, four children had weak sensation of urge (VAS 1–3), four developed moderate sensation (VAS 4–7), and two developed strong sensation of urge (VAS 8–10; Fig. 3d). One child felt no change in urge-to-defecate.

Before the study all children were using laxatives. Three stopped laxatives at the start of TES and seven started stimulation using laxatives daily. After three months of TES, two more children had stopped laxatives, and four had reduced their use of laxative use. Only one child remained on the same amount of laxatives throughout (Fig. 3e). The child with 3 BM/week at the start, had increased to 7 BM/week and ceased laxatives.

Using the PedsQL, the child and parent-reported scores for physical, psychosocial, and total domains were below the normal range before TES. PedsQL scores reported by both parents and children significantly improved into the normal range after TES (Fig. 4).

All ten children had NTS before and after TES. However, for one patient, the pretreatment study was performed elsewhere and numerical data on isotope location were not available, so this patient was not included in NTS analysis. Five children had faster transit after stimulation, but there was no significant improvement in the median GIT index (Fig. 5a). There was a trend toward a greater excretion of radioisotope at 48 hours after TES (p = 0.09; Fig. 5b). Two children had delayed gastric emptying, similar to what we found previously in STC [19], and both had improved gastric emptying after TES.

**DISCUSSION**

This pilot study suggests that TES could improve bowel function in children with AR. After three months of TES for 1 hour/day, 9/10 children had an increased defecation frequency (6 to ≥3 BM/wk), decreased fecal incontinence and increased quality of life. Nine children were able to reduce or stop their laxative medication and there was improvement in their quality-of-life into normal range. We thus observed a significant clinical improvement in bowel function. There was a trend to increased excretion at 48 hour on NTS but no significant change in transit rate in this small group of patients.

Our previous studies using TES were on children with STC. Using the same electrical frequency and treatment duration as in this study, there was increased defecation frequency, decreased fecal incontinence, and abdominal pain in 50% of children with STC (19,20). In a randomized control trial, TES improved the quality of life in STC children when compared with sham stimulation (33) and colonic transit time was accelerated. This pilot study used the same treatment method and electrical parameters but with a lower position of the electrodes, to target treatment to the anorectum rather than the transverse colon. The number of patients was too small to observe a significant change in transit rate but after TES there was a trend to more excretion of radiotracer at 48 hours.

In addition to STC, interferential current has been used to improve continence in children with myelomeningocele (21). Under TES applied x3/week for 20 min, 8/15 children reported increased defecation frequency after six months. Anorectal manometry showed a decreased recto-rectal inhibitory reflex and decreased sphincter pressure in these children.
Disordered defecation is often the sum of several disturbances to anorectal and colonic physiology (11). Spontaneous defecation requires co-ordinated anorectal sensorimotor functioning (11) and rectal perception is important in normal defecation (14,34,35). In some adult patients, rectal hyposensitivity may be due to a primary defect in sensory neuronal functioning, and normal cerebral processing (12). The sacral nerves contain both afferent (sensory) and efferent (motor) fibre nerve fibres from different levels of the sympathetic and parasympathetic nerve fibres (13). Experience with sacral nerve stimulation suggests that normalisation of rectal hyposensitivity is associated with symptom improvement (11).

Many children with constipation report that they have no urge-to-defecate (15). In patients with rectal hyposensitivity on balloon distension, impaired perception of rectal distension may be due to abnormal rectal compliance (abnormal rectal wall properties), or impairment of the afferent sensory nerve pathway (36). While rectal manometry is the best measure of sensory perception, urge-to-defecate provides a simple indicator, and improved sensation of this urge could indicate modulation of afferent signallng (25). In the current study, TES increased the urge-to-defecate in most of the children, suggesting there was modulation of afferent signaling, directly or indirectly.

TES to treat bowel dysmotilities began in the mid 2000s, with studies showing positive results in a range of paediatric conditions including STC (17,18,20,31,33,37,38), spina bifida (21), voiding dysfunction with constipation (22) and in adults with STC (39), functional dysphagia (23), and IBS-C (24) using TES with electrodes over the abdomen. There have also been positive results using stimulation with an anal electrode in adults with AR (25). Stimulation of the pudendal nerve using acupuncture and electrical acupuncture also helps to decrease urgency frequency (40), severe constipation (41,42), diarrhoea (43), fecal incontinence (44–46), and IBS (47).

One third of patients with chronic constipation also have delayed gastric emptying (26,48). This could be secondary to rectal or colonic distension (27,49). In this study, the two children with delayed gastric emptying improved with TES. This could be due to modifying the inhibitory reflex in the rectum or ileum (52). The effect of TES may also be direct on the stomach or nerves controlling the stomach, as Koklu et al. (23) showed that TES across the back improved symptoms (epigastric discomfort, pyrosis, bloating, early satiation, and postprandial fullness) in adults with functional dyspepsia.

**LIMITATIONS**

This pilot study has several limitations and hence cannot answer several issues about the efficacy of TES. The patient group is small and the duration of follow-up is short. Efficacy of TES needs to be assessed over a longer time frame and in larger randomized control trials. The mechanisms of action of interventional currents are still unclear. Electrical stimulation could modulate the activity of sensory and motor spinal nerves, sympathetic and parasympathetic nerves, and nerves of the enteric nervous system or smooth muscle cells. Studies using sacral nerve stimulation, suggest that sensory or afferent nerves are affected (13,50). In this study, the children developed awareness of the urge-to-defecate. Thus, TES may also work via modulating sensory nerves. Kajbafzadeh et al. hypothesized that TES influenced sacral reflexes since they observed significantly improved sphincter pressure and recto-anal inhibitory reflex (21). In children with STC, TES increased propagating pressure waves on colonic manometry (33). In this pilot study, electrodes were over the suprapubic and sacral regions to target the pelvic organs while, in children with STC, electrodes were placed between T9 and L2 (17,20,30). Further studies are required to determine the optimal parameters of stimulation and the position of electrode placement. The colonic transit on NTS was normal as far as the recto-sigmoid in these children. After electrical stimulation therapy, we observed a trend toward a greater excretion of the radiotracer at 48 hours. In future studies, scintigraphic evaluation could be extended to 72 or 96 hours to assess the severity of retention and to measure the excretion rate.

In conclusion, TES produced a global clinical improvement of bowel function in a group of chronic constipated children with anorectal retention: defecation frequency increased to a normal range in 50% of children, fecal incontinence episodes reduced and quality-of-life improved in 90% of them. As the study was not placebo-controlled and no objective measures were performed, a placebo effect cannot be ruled out. More studies are warranted to determine if, TES could be an additional treatment in children with anorectal retention that has not responded to other treatments.

**Acknowledgements**

We would like to thank Duncan Veysey for performing the transit studies and Prof David Cook for diagnosis. Thank you to Yee Ling Yik for drawing Fig. 1. A PhD Scholarship from the Malaysian Government supported Yee Ian Yik. This work was presented as an abstract and poster presentation at American Gastroenterology Association, DDW 2013.

**Authorship Statements**

This work was performed by Yee Ian Yik as part of his PhD study. Bridget Southwell and John Hutson supervised Yee Ian Yik. The Medical Imaging Department at The Royal Children’s Hospital, Melbourne performed nuclear transit studies. Yee Ian Yik, Bridget Southwell, and John Hutson designed the research study. Yee Ian Yik performed the research. Yee Ian Yik and Bridget Southwell analyzed the data. Bridget Southwell and John Hutson edited the manuscript. Lefteris Stathopoulos assisted with drafting the paper from Yee Ian Yik’s PhD thesis. All authors approved the final version of the manuscript.

**How to Cite this Article:**


**REFERENCES**


