Long-term effects of transabdominal electrical stimulation in treating children with slow-transit constipation

Leanne C.Y. Leonga, b, Yee Ian Yika, c, g, Anthony G. Catto-Smith c, d, Val J. Robertsonf, John M. Hutsona, c, e, Bridget R. Southwella, c, d,⁎

aSurgical Research Group, Murdoch Children's Research Institute, Melbourne, VIC 3052, Australia
bDepartment of Medicine, University of Melbourne, Melbourne, VIC 3010, Australia
cDepartment of Paediatrics, University of Melbourne, Melbourne, VIC 3010, Australia
dDepartment of Gastroenterology and Nutrition, Royal Children's Hospital, Melbourne, VIC 3052, Australia
eDepartment of Urology, Royal Children's Hospital, Melbourne, VIC 3052, Australia
fUniversity of Newcastle, Newcastle, NSW 2300, Australia
gDepartment of General Surgery, Faculty of Medicine, University of Malaya, 50603 Kuala Lumpur, Malaysia

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Abstract
Aims: Transcutaneous electrical stimulation (TES) was used to treat children with slow-transit constipation (STC) for 1 to 2 months in a randomized controlled trial during 2006 to 2008. We aimed to determine long-term outcomes, hypothesizing that TES produced sustained improvement.

Methods: Physiotherapists administered 1 to 2 months of TES to 39 children (20 minutes, 3 times a week). Fifteen continued to self-administer TES (30 minutes daily for more than 2 months). Mean long-term follow-up of 30 of 39 patients was conducted using questionnaire review 3.5 years (range 1.9-4.7 years) later. Outcomes were evaluated by confidence intervals or paired t test.

Results: Seventy-three percent of patients perceived improvement, lasting more than 2 years in 33% and less than 6 months in 25% to 33%. Defecation frequency improved in 30%. Stools got wetter in 62% after stimulation and then drier again. Soiling improved in 75% and abdominal pain in 59%. Laxative use stopped in 52%, and 43% with appendicostomies stopped washouts. Soiling/Holschneider continence score improved in 81% (P = .0002). Timed sits switched to urge-initiated defecations in 80% patients. Eighty percent of relapsed patients elected to have home stimulation.

Conclusion: TES holds promise for STC children. Improvement occurred in two thirds of children, lasting more than 2 years in one third, whereas symptoms recurred after 6 months in one third of children.

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Constipation affects 3% of children, with a third of these developing chronic constipation [1-3]. Chronic constipation can be categorized into separate groups including those with normal proximal transit but hold-up at the anorectum (anorectal retention/functional fecal retention) and those with delayed colonic transit (slow-transit constipation, STC).
The latter may comprise up to a half of the patients with chronic treatment-resistant constipation [4].

Studies suggest that transcutaneous electrical stimulation (TES) improves bowel function in children with STC [5-8]. There were significant improvements in clinical symptoms (more regular defecation, reduction in soiling and abdominal pain) and colonic transit on nuclear transit scintigraphy within 2 months of stimulation [5-7]. However, the long-term results of TES are unknown. In this study, we aimed to review long-term outcomes of children after randomized controlled trial (RCT) to find out how long the effects of TES last.

1. Methods

From April 2006 to October 2008, 39 STC children completed an RCT using TES [6-8] (ethics 23040, 26174A, 30116A). All children were diagnosed with STC using nuclear transit scintigraphy, as described previously [9]. Initially, 46 children were randomized into 2 groups (Fig. 1A), with stimulation administered by physiotherapists (20-minute sessions, 3 times per week for 4 weeks) followed by an 8-week rest and a second month of stimulation: group I received 1 month sham and 1 month active stimulation and...
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2. Results

Of 39 patients (22 boys and 17 girls; mean age 11.6 years at start of trial) who completed the trial between 2006 and 2008, 15 were randomized for 1-month stimulation (group I), 19 for 2-month stimulation (group II), and 5 who had appendicostomies were given manometry as well (group III). In 2010, 26 of 34 of subjects in the RCT trial and 4 of 5 from group III agreed to participate in a long-term review. In these 30 patients, home stimulation after the trial was performed by 7 of 15 patients in group I, 6 of 11 in group II, and 2 of 4 in group III. Reasons for nonparticipation in follow-up were changed address/contact number, lack of time, inconvenience, or personal issues. Mean time interval after RCT completion was 3.5 years (range, 1.9 to 4.7 years; median, 3.8 years) and sex ratio of participants was 16 boys to 14 girls.

Many (62%-77%) patients perceived that at least 1 symptom (defecation, soiling, abdominal pain) had improved after the RCT. Improvement lasted a long time (≥2 years) in 27% to 37%. One third of these had home stimulation after relapse. Improvement was sustained for less than 6 months in 16% to 33%. Most (80%) of these children had home stimulation after relapse.

For defecation, the main change was in stool consistency and development of sensory perception rather than in defeation frequency. Most patients had defeation frequency in the normal range (≥3 and ≤14 per week) both before stimulation (23/30, 77%; 95% CI, 58%-90%) and at long-term follow-up (19/30, 63%; 95% CI, 44%-80%). Compared with prestimulation levels, mean defeation per week decreased (P = .04; Fig. 1B), but frequency increased in 9 (30%) of 30 patients (95% CI, 15%-49%) patients. Stool consistency became wetter immediately after stimulation (increased to BSS 6-7, P < .0001) and returned to prestimulation levels at long-term follow-up (Fig. 1C).

The Holschneider continence questionnaire measures incontinence (ie, soiling), and this score (0-12, poor = 0) was improved 1.0 to 4.6 years posttrial in 17 of 21 children (P = .0002; Fig. 1E). By-pass soiling is a major problem for children with chronic constipation, and only 6 patients had no soiling. At long-term follow-up, soiling was improved in 18 (75%) of 24 (95% CI, 53%-90%), with no change in 6 of 24 (Fig. 1F). Only half (9/18) of the patients with improvement had home stimulation. Abdominal pain occurred in 22 patients and improved in 13 (59%) of 22 (95% CI, 36%-79%) during stimulation but showed only a slight reduction in mean levels in long-term follow-up (Fig. 1F).

These patients were diagnosed with intractable constipation after not responding to medical treatment >2 years. At the start of the trial, 23 were on laxatives and 7 were on washouts. At long-term follow-up, 12 (52%) of 23 (95% CI, 31%-73%) stopped using laxatives, 4 (17%) of 23 (95% CI, 5%-39%) reduced the use of laxatives, and 3 (43%) of 7 (95% CI, 10%-82%) children with an appendix stoma for antegrade enemas ceased washouts (Fig. 1G). Effects were delayed but developed with time after stimulation. At long-term follow-up, of 19 patients with normal stool frequency, 11 (58%; 95% CI, 34%-80%) were not using laxatives or washouts anymore. Laxative use/washouts worsened in 4 (13%) of 30 (95% CI, 4%-31%).

3. Discussion

Many (>62%) patients (from all groups) perceived that TES had improved some symptoms of their constipation.
TES improved rectal sensory perception and soiling/incontinence but not defecation frequency or abdominal pain. Despite having chronic constipation, many of these children defecate more than 3 times per week at baseline. Although there was a decrease in mean defecation frequency, one third of patients perceived improvement in defecation. Apart from defecation frequency, the volume and consistency of stools can change. For most patients, stool consistency became wetter after the trial and then returned to midrange at long-term follow-up. The volume of stools was not measured. Importantly, there was a change from sitting on the toilet at predetermined times to children feeling the urge to defecate and going to the toilet in response to urge, indicating improved rectal sensory input. In addition, laxative use decreased for 17 patients with 12 using no laxatives after 1.9 to 4.7 years. Soiling decreased with an improvement in incontinence (Holschneider score).

We cannot exclude the possibility of a placebo effect. Results after 1 month of stimulation have been reported previously [6,7]. Patients in group I (sham) did not have a change in colonic transit rate [7], whereas there were small changes in group II (active). Because the ethics committee and trial staff felt it was not ethical to deny these patients active treatment, they were then given 1 month of active stimulation. After the RCT, all patients were offered home stimulation, and about half chose to have it. This study addresses the number of patients showing long-term improvement. Because all patients have received active stimulation treatment, we could not compare “sham” and “active” treatment at long-term follow-up. It will be difficult to determine this unless a group of 40 to 50 children are left with only diet and laxative treatment for 4 years at the same time as TES patients.

Sacral nerve stimulation (SNS) increases defecation and colonic motility for adults with STC [12]. This method is successful but involves surgically implanting electrodes onto the spinal nerves and a stimulator under the skin on the buttocks. It has been shown to work for children [13]. TES is noninvasive and far cheaper than SNS and is effective in two thirds of patients. It may be that many children will respond to TES, and those who do not could be treated with SNS. We are currently testing TES on children with anorectal retention.

TES has been used by physiotherapists for more than 20 years to treat overactive bladder, establishing its safety [14,15]. Battery-operated machines make daily home treatment possible. Physiotherapists are trained to use electricity safely, and patients should visit a physiotherapy clinic before taking home battery-operated machines. We know from other studies in our group that patients require extensive training and education in the use of the machine. The mechanism of TES action is not clear. In principle, electrical stimulation could activate sensory nerve fibers in the skin, sensory and motor nerves in the spinal nerves, sympathetic and parasympathetic nerves, enteric nerves in the bowel wall or pacemaker cells in the intestine (interstitial cells of Cajal), and intestinal muscle cells [1]. The stimulation parameters were copied from those used on the bladder that produced diarrhea as a side effect [16]. Further studies are required to determine optimal stimulation parameters and practical features of training patients for home stimulation.

TES is a promising treatment for children with STC. In this series, clinical improvement occurred in two thirds (67%) of the children, lasting more than 2 years in about half of them, whereas symptoms recurred after 6 months in the remaining patients.

References