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Home transcutaneous electrical stimulation to treat children with slow-transit constipation☆

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Abstract

Purpose: This study aimed to test the effectiveness of home transcutaneous electrical stimulation (TES) when patients with slow-transit constipation (STC) were trained by a naive clinician.

Methods: A surgeon was trained to teach the TES method to STC children who then self-administered at home (1 hour a day, 3-6 months) using a battery-powered interferential stimulator. Bowel diaries, PedsQL4.0 questionnaires, and radio-nuclear colonic transit studies were completed before and after treatment.

Results: Thirty-two children (16 female; mean age, 8.3 years; range, 3-17 years) self-administered 3 to 6 months of TES. Three did not return diaries. Group 1 (n = 13) started with less than 3 bowel actions per week, and group 2 (n = 16), with more than 3 bowel actions per week. Defecation frequency increased in 69% of group 1 (mean, 1.4-3.0 per week; P = .02). Soiling frequency decreased in 50% of group 2 (5.4-1.9 per week, P = .04). Of 13 patients, 7 improved with development of urge-initiated defecation. Abdominal pain decreased in 48% (1.6 episodes per week to 0.9 per week, P = .06). Stool consistency improved in 56%. There was significant improvement in child-reported and parent-reported PedsQL Scores. Colonic transit improved in 13 of 25 patients.

Conclusion: Home TES provides a new treatment for STC children, with 50% of treatment-resistant patients benefited. Success requires clinician training and close patient contact. Transcutaneous electrical stimulation increased defecation and reduced soiling.

Slow-transit constipation (STC) is a severe form of chronic constipation and may comprise up to half of the patients with chronic, treatment-resistant constipation [1]. Slow-transit constipation is characterized by slow proximal colonic transit demonstrated readily by nuclear transit scintigraphy (NTS) [2-4]. Surgery is offered as the final resort for STC children with the options including appendicostomy for antegrade continence enemas, colostomy, or colectomy [5].

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Transcutaneous electrical stimulation (TES) has been used by physiotherapists to treat painful musculoskeletal conditions and bladder incontinence for more than 20 years [6,7]. Diarrhea was reported as a side effect when treating bladder incontinence [8]. Transcutaneous electrical stimulation delivered by physiotherapists was shown to improve bowel function in STC children [9], with significantly faster colonic transit on NTS [10]. In a pilot study of STC children trained by the physiotherapist to use a battery-powered interferential machine at home, TES increased defecation frequency and reduced soiling [11]. In this study, we aimed to test the effectiveness of home TES when patients were trained by a naive clinician rather than a physiotherapist.

1. Methods

1.1. Patient group

This was a prospective study of STC children at a tertiary pediatric hospital. This study was approved by the institutional ethics committee (HREC 26173). All children had chronic constipation and soiling for a minimum of 2 years and had failed to respond to medical treatments such as dietary modifications, behavioral therapy, and oral and/or rectal laxatives and were investigated by NTS. The diagnosis of STC was made by NTS as described previously [2-4], specifically if there was more than 40% radiotracer retained in the transverse colon at 24 hours and/or more than 30 % at 48 hours or with mean geometric center of less than 2.7 and/or less than 3.7 at 24 and 48 hours, respectively. Children who fulfilled the above criteria were offered home TES. They were excluded if they had implants that may be interfered by TES, for example, children with ventriculoperitoneal shunt or cardiac pacemaker. From March 2009 to September 2010, 38 STC children (17 female; mean age, 8.9 years; range, 3-17 years) and parents were recruited, were taught to self-administer TES, and were given an interferential stimulator (see below) to take home. A surgeon (YIY) was trained by a physiotherapist on the principles and use of TES. YIY learned the problems in performing the training from the initial 6 STC patients, then he used this experience to develop the protocol for home TES and the method to collect meaningful data from patients. These were not included in the data analysis. This group highlighted the importance of establishing patient-clinician rapport to get good compliance of TES use, to gather appropriate and useful data from patients on symptoms, and to motivate patients/parents recording and returning their bowel diary. One child already had an appendicostomy for antegrade continence enemas when recruited. No children had TES before this study. At recruitment, it was explained to patients and parents that TES was an experimental and alternative treatment, and consent was obtained for their participation in the trial. It was also explained that surgery or other interventions might be considered if this treatment failed.

1.2. Stimulation regimen

Parents of the children and older children were trained to use the 9-V battery-operated, rechargeable interferential stimulator (INF 4160; Fuji Dynamics Ltd, Kowloon, Hong Kong) by YIY at a 1-hour clinic session with personal demonstration on the use of TES stimulator, proper placement of electrodes, appropriate connections of leads, and with reassurance on the safety of TES for home treatment. Stimulation was performed or monitored by the parent(s) at home (1 hour daily for 3-6 months) with frequent contacts with YIY, by telephone or e-mail, to ensure compliance of treatment and also to ensure continuous recording of bowel diary. Two self-adhesive 4-cm^2 electrodes were placed on the anterior abdominal wall at the level of the umbilicus of the child, and 2 other electrodes were placed on the back between T9 and L2 on either side (Fig. 1) [9]. The current from the electrodes was crossed diagonally from front to back. Interferential treatments delivered a 4-kHz carrier frequency, a beat frequency of 80 to 160 Hz with an intensity of less than 33 mA as previously described [9].

1.3. Outcome measures

Bowel diary and PedsQL4.0 questionnaires were administered before and during treatment. Two groups were identified by defecation frequency before treatment: group 1, less than 3 bowel actions (BAs) per week, and group 2, more than 3 BAs per week. Careful instructions were given to patients and/or parents to record the bowel diary with details on soiling, defecation frequency, stool consistency based on Bristol Stool Scale (BSS), abdominal pain, and sensation to defecate before and during treatment. Primary end points were decreased soiling, increased defecation frequency, improved stool form, and increased sensation of defecation/urge-initiated defecation. As a secondary end point, colonic transit was measured by NTS before and after TES.

The following changes were considered improvement: (1) defecation frequency of more than 3 (for those who started with <3 BAs per week), (2) an increasing proportion of stool consistency to BSS type 4, (3) reducing frequencies of soiling and abdominal pain, (4) increase of PedsQL scores, and (5) faster colonic transit. Patients who required appendicostomy formation for washout after TES were considered as failed therapy.

The effects of TES on STC symptoms were evaluated statistically by paired t test (for parametric measures) or χ^2 test (for nonparametric measures, eg, stool consistency and urge to defecate). $P < .05$ was considered significant.

2. Results

Thirty-eight STC children were enrolled. The first 6 were used for learning, and data were not analyzed. Thirty-two

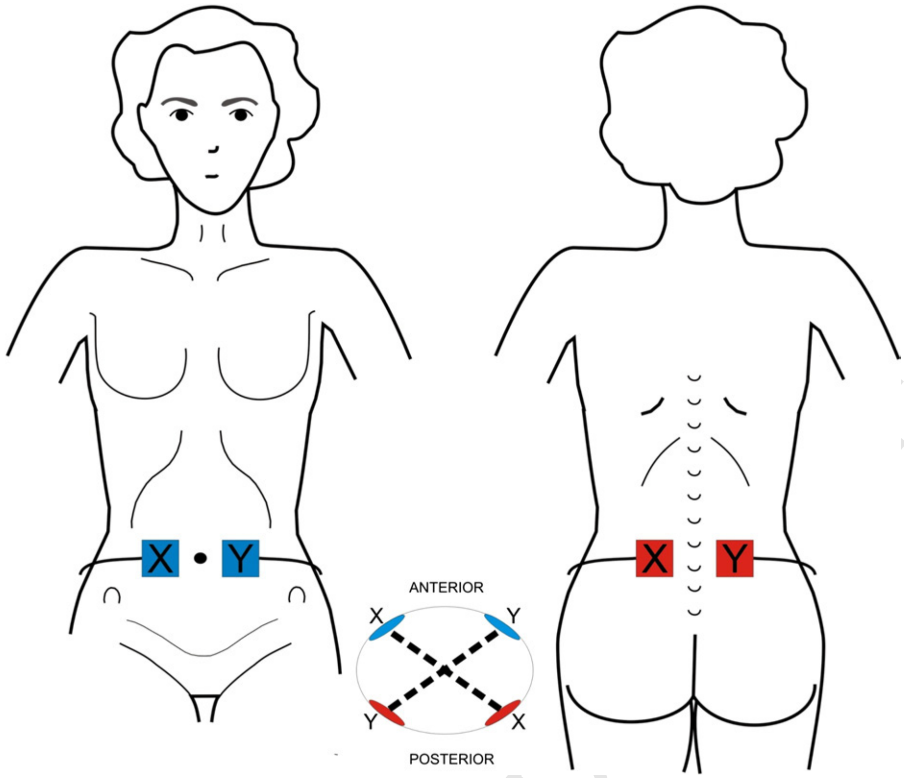

Fig. 1 Diagram of electrode placement on patient for home TES treatment. Anterior electrode placed at the level of the umbilicus and the posterior electrode placed paraspinally at T9 to L2 level. Each wire has 2 leads (XX, YY), and they are connected diagonally so that the current crossed path in the abdominal cavity.

children (16 female; mean age, 8.3 years; range, 3-17 years) underwent 3 to 6 months of TES at home with stimulation for 60 minutes a day. All completed the treatment successfully; however, 3 did not return completed bowel diaries after TES.

In 16 children who started with more than 3 BAs per week, 6 had an increase in defecation frequency, but there was no significant increase in defecation frequency in the group overall (Table 1). In the 13 children who started with less than 3 BAs per week, 9 had an increase in defecation frequency, and the overall mean defecation frequency increased significantly from 1.4 to 3.0 per week (P = .02). Soiling decreased in 45% (13/29) of patients with mean soiling frequency decreased significantly from 5.0 to 2.9 episodes per week (P < .05). Soiling decreased significantly in the group with more than 3 BAs per wk with half of this group showing a reduction in soiling. Half of the patients had reduced abdominal pain, but the overall mean reduction was not significant (P = .06). Sixteen/twenty-nine patients had stool consistency of BSS less than 4 or BSS more than 4, with 9 of 16 changed to BSS 4 (P = .05). Thirteen/twenty-nine patients had no sense of the urge to defecate. Half of these (7/13) developed urge-initiated defecation (P = .02). Of the children, 38% to 69% achieved some level of treatment success and benefited in at least 1 symptom at the end of treatment. The child with a preexisting appendicostomy improved with reduced soiling and washouts. He developed urge-initiated defecation with improved stool consistency to BSS 4.

To determine if symptom improvement produced a meaningful clinical change, we measured the quality of life before and after treatment. After TES, there was a statistically significant improvement in both child-reported and parent-reported Total, Physical and Psychosocial PedsQL Scores (Table 2).

Twenty-five children had NTS both before and after TES. Thirteen/twenty-five had faster transit with statistically significant improvement in mean colonic transit using geometric center (Fig. 2) measurements at 6 hours (mean ± SD, pre 1.2 ± 0.5 vs post 2.1 ± 0.3; P = .0004), 24 hours (mean ± SD, pre 2.7 ± 0.6 vs post 3.2 ± 0.7; P = .0007), 30 hours (mean ± SD, pre 2.9 ± 0.7 vs post 3.5 ± 0.7; P = .0076), and at 48 hours (mean ± SD, pre 3.3 ± 0.7 vs post 4.0 ± 0.7; P = .0036).

After TES, 2 children had failed and required appendicostomy formation for washout because of intractable soiling.

There was no adverse event observed or reported by STC children treated with home TES in the current trial.

3. Discussion

Transcutaneous electrical stimulation is a new treatment for children with STC. The battery-operated interferential stimulator made treatment possible at home. This treatment was well accepted by children and their parents if they were

Table 1 Outcome measures for STC children before and after TES

Outcome	Total no.	No. improved (%)	Mean ± SD		*P* (paired *t* test)
			Pre	Post	
Defecation (overall)	29	15 (52)	4.4 ± 3.9	5.3 ± 3.9	*.05*
Defecation (<3 BA/wk)	13	9 (69)	1.4 ± 1.0	3.0 ± 2.3	*.02*
Defecation (>3 BA/wk)	16	6 (38)	6.8 ± 3.6	7.5 ± 4.0	.34
Soiling (overall)	29	13 (45)	5.0 ± 6.4	2.9 ± 4.5	*.04*
Soiling (<3 BA/wk)	13	5 (38)	4.5 ± 5.6	4.0 ± 5.8	.60
Soiling (>3 BA/wk)	16	8 (50)	5.4 ± 7.1	1.9 ± 2.5	*.04*
Abdominal pain (overall)	29	14 (48)	1.6 ± 2.1	0.9 ± 1.1	.06
Abdominal pain (<3 BA/wk)	13	7 (54)	1.6 ± 2.2	0.9 ± 1.2	.26
Abdominal pain (>3 BA/wk)	16	7 (44)	1.5 ± 2.1	0.8 ± 1.0	.16
Outcome	Total	Lacking	New	% changed	*P* (χ^2)
Urge-initiated defecation (overall)	29	13	7	54	*.02*
Urge-initiated defecation (<3 BA/wk)	13	7	4	57	–
Urge-initiated defecation (>3 BA/wk)	16	6	3	50	–
BSS 4 (overall)	29	16	9	56	*.05*
BSS 4 (<3 BA/wk)	13	10	6	60	–
BSS 4 (>3 BA/wk)	16	6	3	50	–

BA/wk indicates bowel action per week.

taught and understood the safe administration of TES. Six children were needed for the clinician to learn how to teach the use and application of TES at home and to collect data. The next 32 children were able to complete the treatment successfully. Importantly, this treatment was self-administered at home rather than at a clinic with no adverse events. Of the STC children, 38% to 69% achieved some treatment success, and nearly all benefited in at least 1 symptom. Transcutaneous electrical stimulation reduced soiling and increased defecation in our previous pilot study using home TES reported by Ismail et al [11]. In that study, all 11 children treated recorded less than 3 BAs per week, and 9 of 11 children had increased defecation. Similarly, we have 9 of 13 children with less than 3 BAs per week who had increased defecation. For the group with more than 3 BAs per week, we have to look for other components of defecation such as the stool consistency, development of the urge to defecate, and soiling to assess the response to TES while defecation frequency did not change. Soiling was significantly reduced in children with more than 3 BAs per week. Improvement of stool consistency and the development of urge to defecate were equally common in both groups. These results suggest to us that defecation frequency may not be a good measure for children with more than 3 BAs per week to assess their response to treatment.

In the previous pilot study of home TES [11], the duration of treatment was 2 months for children with STC who were previously exposed to TES (given by physiotherapists for 1-2 months in the randomized, controlled trial). In the current home TES trial, the duration of treatments was slightly longer, from 3 to 6 months. The optimal duration of treatment, however, is yet to be determined.

Quality of life in STC children treated by TES improved significantly. Total PedsQL scores, the physical and the psychosocial components, were significantly improved in both the child-reported and parent-reported assessments before and

Table 2 PedsQL scores before and after TES

Age (y)	n	Scores	Reported by	Pre (mean ± SD)	Post (mean ± SD)	*P*	Healthy children (mean ± SD) [12]
≤4	7	Total	Parent	72 ± 11	85 ± 10	*<.01*	–
		Physical	Parent	87 ± 15	94 ± 12	*<.05*	–
		Psychosocial	Parent	67 ± 12	82 ± 13	*<.02*	–
5-18	25	Total	Child	64 ± 22	77 ± 19	*<.01*	86 ± 10
			Parent	61 ± 19	73 ± 18	*<.01*	84 ± 9
		Physical	Child	69 ± 22	81 ± 18	*<.01*	92 ± 8
			Parent	65 ± 18	78 ± 19	*<.01*	93 ± 9
		Psychosocial score	Child	63 ± 24	76 ± 21	*<.01*	83 ± 11
			Parent	59 ± 20	72 ± 18	*<.01*	80 ± 11

Higher score indicates better quality of life.

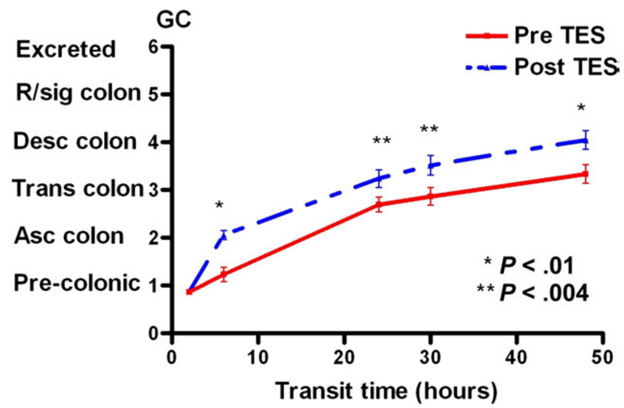

Fig. 2 Mean GC plot of NTS performed in 13 of 25 STC children before and after TES. (GC indicates geometric center; 1, precolonic; 2, ascending colon [Asc colon]; 3, transverse colon [Trans colon]; 4, descending colon [Desc colon]; 5, Rectosigmoid colon [R/sig colon]; 6, Excreted]).

after TES treatment. This suggests that the level of improvement is clinically important. These results are encouraging when we compared them with similar assessment on STC children in our previous randomized controlled trial. There was only improvement in child-reported quality of life with no significant improvement reported by parents in our previous study reported by Clarke et al [13]. This difference might be contributed by the longer duration of TES in the current group where children were given TES 1 hour daily for 3 to 6 months as compared with the previous treatment regime (20 minutes per session, 3 per week for 4-8 weeks).

As an objective assessment, NTS showed improvement of colonic transit after TES in 52% of patients. These results are consistent with our previous findings in the randomized, controlled trial with TES reported by Clarke et al [10]. In future studies, we will correlate transit study results with other outcomes and with long-term follow-up to see if the transit data predict later success. The 2 children who had appendicostomy formation had no improvement of either the symptoms or colonic transit.

Close and regular contacts by the treating clinician were important to ensure compliance of treatment and also to provide continuous support and motivation. This was also important to ensure continuous recording of bowel diaries and return of data to provide meaningful data for assessment and analysis later. However, despite this frequent contact, the placebo effect is likely to be low, as shown in our randomized trial, where there were no improvements in the placebo arm (unpublished).

Transcutaneous electrical stimulation has been used by physiotherapists for more than 20 years to treat overactive bladder, establishing its safety profile [6,7]. The trial staff were trained to use electricity safely, and patients attended a teaching session at the clinic before taking the interferential stimulator home. The learning curve with the first 6 patients (which were not reported here) is invaluable to enable the clinician to conduct the treatment with success. Problems identified on the use of the device and troubleshooting are important aspects to ensure treatment compliance at home. Continuous support and contacts were also required.

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 [14]. The stimulation parameters were similar to those used on bladder that produced diarrhea as a side effect [8]. Further studies are required to determine optimal stimulation parameters and practical features of training patients for home stimulation.

This is a single-institution study, and we hope that with future collaboration, we would be able to perform multicenter studies and also to compare the effectiveness of TES comparing with other treatments for children with chronic constipation. In addition, with more experience gained from NTS and with further severity scoring, we hope to better identify patients with severe colonic transit delay who may require longer duration of treatment. With this, we hope to improve the outcome of their intractable symptoms.

In conclusion, TES is a promising treatment for children with otherwise intractable STC. Defecation frequency increased in patients with less than 3 BAs per week, and soiling decreased in patients with more than 3 BAs per week. Successful home stimulation can be achieved by nonphysiotherapists (after training), providing that patient education and contact is maintained. Transcutaneous electrical stimulation could be tried before surgery is considered in children with chronic treatment-resistant constipation.

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Discussion

Discussant, DR JOEL SHILYANSKY (Iowa City, IA): Could you elaborate on the proposed mechanism behind this?

Response, DR YIK: We are still working on animal models and also other human studies in collaboration with the other countries to find out the exact mechanism. The proposed mechanism will be, I think, through the actually the nervous stimulation, whether it's stimulating the gut and also connecting to the brain and the brain is actually getting the gut to work harder. The other proposed mechanism is whether it's actually inhibiting the sympathetic nervous system whereby it overdrives colonic motility. And the other mechanism as you proposed by other studies actually whether you're working directly in the vasculature of the gut and also the enteric nervous system.

Discussant, DR HAYES-JORDAN (Houston, TX): Simple question, is this something that is easily adaptable to every office or medical center?

Response, DR YIK: Yes, the machine is actually pretty much available now, and in Australia it's actually approved by the FDA for use, so the cost of the machine is about 500 Australian Dollars that will be equivalent to United States dollars we well. So it's a pretty safe treatment, and you can actually deliver the package as a matter of treatment. I think it's available to children with chronic constipation, especially slow transit, as we have used it right now.

Discussant, DR RESCORLA (Indianapolis, IN): Have you had any experience with weaning children from this therapy or do you do this as a fairly chronic therapy needed for these children?

Response, MR YIK: That's a very good question. We recently conducted the long-term follow-up of children that were previously treated using this treatment. One of them actually sustained the improvement of more than three years, the other one had improvement for more than 6 months but they required a booster treatment later on.

Discussant, DR RESCORLA: During this time, did they have any medical changes as far as stool softeners and Miralax and other medicinal care?

Response, DR YIK: Yes. In order to measure the improvement I usually maintain the treatment of the patient based on the previous laxative they were on, and over time at the end of the assessment, I do also assess whether they actually have reduced the amount of laxatives. More than 50% had a reduction in the use of laxatives.

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