ORIGINAL CONTRIBUTION

Preliminary Results of Sacral Transcutaneous Electrical Nerve Stimulation for Fecal Incontinence

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BACKGROUND: Fecal incontinence is a common debilitating condition.

OBJECTIVE: The aim of this study is to investigate the feasibility of sacral transcutaneous electrical nerve stimulation as an alternative treatment modality for fecal incontinence.

DESIGN: All consecutive patients who presented with fecal incontinence to the senior author's clinic were prospectively recruited between June 2009 and September 2010. The severity of their fecal incontinence was assessed by the Wexner and Vaizey scores and anal physiology.

MAIN OUTCOME MEASURES: Any improvement following a period of sacral transcutaneous electrical nerve stimulation treatment was determined by repeating the scores. In addition, patient satisfaction with the procedure was assessed by using a patient impression score.

RESULTS: Twenty female patients with a median age of 57.5 years (range, 30–86) were evaluated. The median follow-up was 10 months (range, 5–12 months). Two patients did not record a change in their Vaizey score. The overall mean Wexner score was 7.9 ± 4.2 before in comparison with 4.0 ± 3.1 after sacral transcutaneous electrical nerve stimulation treatment ($p < 0.0001$, CI = 2.2–5.7, SE = 0.832). The overall mean Vaizey score was 12.7 ± 5.7 before in comparison with 5.8 ± 5.6 after sacral transcutaneous electrical nerve stimulation treatment ($p < 0.0001$, CI = 4.5–9.4, SE = 1.162). The pretreatment patient impression score was set at a mean of 1 ± 0 in comparison with 2.8 ± 1.1 after sacral transcutaneous electrical nerve stimulation treatment ($p < 0.0001$, CI = 1.2–2.3, SE = 0.25).

CONCLUSION: The preliminary results suggest sacral transcutaneous electrical nerve stimulation is a promising noninvasive alternative to existing modalities in the treatment of idiopathic fecal incontinence.

KEY WORDS: Fecal incontinence; Transcutaneous electrical nerve stimulation; Wexner score.

Fecal incontinence is a prevalent condition accounting for 8.3% of the US adult population.[1] The higher rates are associated with advancing age, parity, anorectal surgery, and chronic medical conditions. It has a disabling impact on the quality of life.[2] Medical management consists of dietary improvement, bulking agents, antidiarrheal drugs, which may be effective in mild fecal incontinence. Novel medical approaches including estrogen replacement therapy and oral amitriptyline have variable outcome. Biofeedback therapy is noninvasive and cost-effective, and it has no complications. However, patients must be compliant and cooperative for its success. Furthermore, it can be incorporated with electromyography or balloon-pressured rectal sensory feedback.[3] Sphincter repair is reserved for those with an anatomical defect refractory to medical management.

In 1995, Matzel et al[4] introduced the use of sacral nerve stimulation to treat idiopathic fecal incontinence. Such neuromodulation has been shown to have a success rate up to 100%,[5] especially in combination with medical management. Recently, transcutaneous electrical nerve stimulation (TENS) of the posterior tibial nerve (PTN-TENS) has been successfully used to control idiopathic fecal incontinence.[6] Transcutaneous electrical nerve stimulation is simple to perform, noninvasive, and very cheap. Our study aims to demonstrate prospectively the feasibility and effectiveness of sacral TENS (S-TENS) in the treatment of fecal incontinence, primarily assessing patient continence scores.

Financial Disclosure: None reported.

Podium presentation at the meeting of the American Society of Colon and Rectal Surgeons, San Antonio, Texas, June 2 to 6, 2012.

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Dis Colon Rectum 2013; 56: 348–353
DOI: 10.1097/DCR.0b013e31827aed41

TABLE 1. Vaizey score

	Never	*Rarely*	*Sometimes*	*Weekly*	*Daily*
Solid stool	0	1	2	3	4
Liquid stool	0	1	2	3	4
Gas	0	1	2	3	4
Change in lifestyle	0	1	2	3	4
				No	Yes
Wear a pad/plug				0	2
Taking constipating agents				0	2
Inability to defer defecation for 15 min				0	4

METHODS

All consecutive patients who presented with fecal incontinence to the senior author's clinic were prospectively recruited between June 2009 and September 2010. These patients were all assessed with a detailed obstetric history and a flexible sigmoidoscopy. For those patients, who were suspected clinically to have sphincter injuries, underwent endoanal ultrasound and anal-rectal physiology.

The severity of their fecal incontinence was estimated by using the Wexner and Vaizey scores (Table 1).[7] The Vaizey score is the Wexner score with additional parameters such as the use of constipating agents and the inability to defer defecation for 15 minutes. Any improvement in the patients' symptoms was assessed by the Wexner and Vaizey score at follow-up. In addition, a patient impression score (4 = cured/discharged from follow-up; 3 = much improved; 2 = slightly improved; 1= no change; 0 = worse) was also used to determine whether patients felt that S-TENS made a difference in their quality of life. The study was approved by the institution's research and development department and written consent was obtained.

Inclusion Criteria

Patients were included if they were adult and had had symptoms of fecal incontinence for more than 6 months refractory to medical management, not limited to certain level of severity of incontinence.

Exclusion Criteria

Patients were excluded if they refused consent to the study, were pregnant, and had a cardiac implant, full-thickness rectal prolapse, and anorectal pathology such as IBD.

S-TENS Protocol

Patients were encouraged to continue their medical therapy such as dietary optimization, bulking or antidiarrheal agents, and pelvic floor exercise. Loaned to our patients were digital TENS (Neurotrac, Hampshire, UK) machines (Fig. 1) that were preprogrammed by our physiotherapist, who undertook S-TENS training with the patients and supervised their treatment. Patients gradually increased duration of S-TENS therapy for the first 5 days of use from 2 to 8 hours per day to avoid skin irritation.

Day 1 and 2: 2 hours in the morning and 2 hours in late afternoon

Day 3 and 4: 3 hours in the morning and 3 hours in late afternoon

Day 5 onward: 8 hours

Patients were warned to switch off TENS while driving or operating potentially dangerous machinery. However, patients were advised to continue their daily activities to demonstrate the true benefits of S-TENS therapy.

Two self-adhesive surface electrodes were placed over sacral foramen on each side of the natal cleft, 3 to 4cm apart (Fig. 2). The area covered by the pads would include the S3 distribution, and, in general, any localization technique is not required. The stimulation was set at a frequency of 10 Hz, pulse width of 250 ms, and conventional continuous TENS mode. Patients were educated to adjust the current amplitude at a level sufficient to produce a background of mild tingling sensation, between 10 and 30 mA, to confirm active stimulation. Written protocol was also provided to patients with regard to how electrodes should be managed and how pads should be placed and removed.

The patients would then be reviewed after 1 month by the physiotherapist, largely for compliance; and reviewed every 3 to 6 months by the senior author for preliminary outcome, when the posttreatment scores were collected. During consultation, patients would report their overall use of S-TENS including any difficulties encountered and daily bowel habits. The physiotherapist was also available during office hours to offer support to these patients if required. If patients expressed no improvement at all despite compliant and correct use of TENS on review at the first month with the physiotherapist, the therapy would be discontinued. However, if improvement was equivocal with S-TENS, then the stimulation parameters would be manipulated and

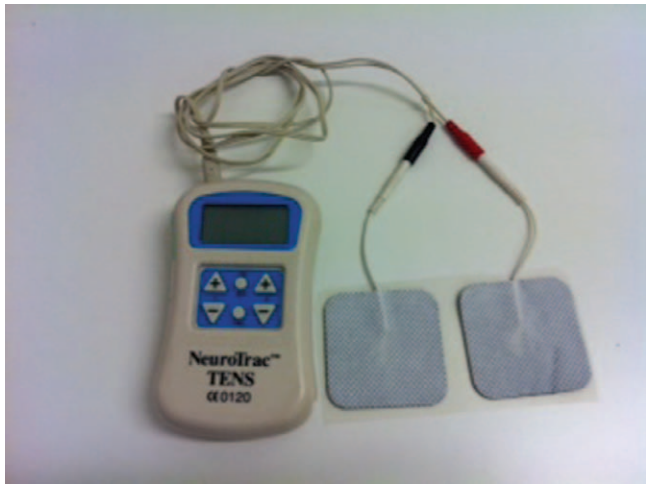

FIGURE 1. Neurotrac TENS machine (approximately 10 cm × 6 cm × 2 cm). TENS = transcutaneous electrical nerve stimulation.

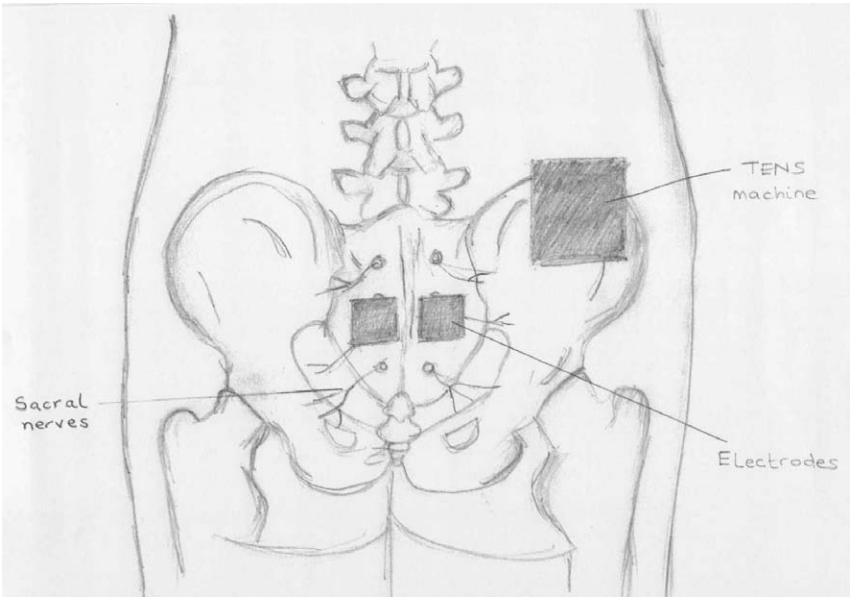

FIGURE 2. Siting of electrode pads during S-TENS therapy. Each pad is 50 mm × 50 mm in size. S-TENS = sacral transcutaneous electrical nerve stimulation.

patients be reviewed again 1 month later. If patients expressed significant improvement, they were advised to reduce the hours per day or days per week of treatment.

Statistical Analysis

The data are expressed as means ± SD or median. The student paired *t* test was used to compare the values before and after treatment with TENS. A *p* value of <0.05 was considered statistically significant.

RESULTS

Twenty female patients were identified. All were compliant to treatment and follow-up. Their ages ranged from 30 to 86 with a median age of 57.5. The median follow-up was 10 months (range, 5–12 months). The patient characteristics are illustrated in Table 2. One patient had a fourth-degree tear during childbirth and immediate repair. Five patients had forceps delivery, but endoanal

TABLE 2. Patients characteristics and their scores pre- and post-TENS therapy

Age	*Follow-up, mo*	*No. of vaginal deliveries*	*Pre-TENS Wexner (/16)*	*Post-TENS Wexner (/16), n (%)*	*Pre-TENS Vaizey (/24)*	*Post-TENS Vaizey (/24), n (%)*	*Other diagnosis*	*Patient impression score (/4)*
57	12	3 (I)	7	3 (57)	13	3 (77)		2
51	11	2 (I)	16	6 (63)	22	6 (73)		3
35	12	1 (I)	5	4 (20)	9	4 (56)	4th tear	3
35	12	2	0	0 (0)	6	2 (67)	neuropathy	1
67	10	4	9	0 (100)	13	4 (69)		3
73	8	2	4	0 (100)	8	0 (100)		4
49	12	3	2	0 (100)	2	0 (100)	SRUS	4
86	10	3	9	4 (56)	15	6 (60)		3
61	6	2 (I)	2	4 (worse)	2	0 (100)		4
53	9	2	12	8 (33)	16	12 (25)		3
67	8	2	11	2 (82)	17	2 (88)		3
54	11	2	8	3 (63)	12	3 (75)		4
58	10	2	14	3 (79)	20	5 (75)		4
69	11	2	12	5 (58)	18	5 (72)		4
65	9	2	8	8 (0)	10	10 (0)	Mucosal prolapse	1
30	6	3	5	1 (80)	9	1 (89)		3
43	5	2 (I)	8	8 (0)	14	14 (0)		1
59	5	2	11	11 (0)	19	19 (0)	Mucosal prolapse	2
30	8	3	10	6 (40)	18	16 (11)		1
64	12	1 (I)	5	3 (40)	11	3 (73)		2

Percentage in bracket under post-Wexner or post-Vaizey score denotes percentage of improvement.
(I) = instrumental delivery; SRUS = solitary rectal ulcer syndrome; TENS = transcutaneous electrical nerve stimulation.

ultrasound did not detect any external sphincter defect. Overall, 10 patients underwent anorectal physiological studies. Their mean resting pressure, squeeze pressure, sensory threshold volume, urge volume, and maximum tolerance volume was 38.4 mmHg ± 14.9, 52.8 mmHg ± 30.3, 68.5 mL ± 32.5, 108.3 mL ± 42.5 and 145 mL ± 46.7. Two of these 10 patients had up to 20% external sphincter defect incidentally detected on endoanal ultrasound. All patients declared good compliance and tolerance to S-TENS treatment. There were no treatment-related complications.

Wexner and Vaizey Scores

Four patients did not record a change in their Wexner score. Two patients were discovered to have mucosal prolapse. However, 2 of these 4 patients recorded an improvement in their Vaizey score. One of these 2 patients was later diagnosed with demyelinating neuropathy. The overall mean Wexner score was 7.9 ± 4.2 before S-TENS treatment in comparison with 4.0 ± 3.1 after S-TENS treatment ($p < 0.0001$, CI = 2.2–5.7, SE = 0.832, 50% improvement). The overall mean Vaizey score was 12.7 ± 5.7 before S-TENS treatment in comparison with 5.8 ± 5.6 after S-TENS treatment ($p < 0.0001$, CI = 4.5–9.4, SE = 1.162, 55.7% improvement).

Patient Impression Score

Four patients indicated that S-TENS did not improve their symptoms of fecal incontinence at all. Of these 4 patients, one had mucosal prolapse and another was the patient who was diagnosed with demyelinating neuropathy. The latter patient had an improved Vaizey score. Both patients with incidental sphincter defect detected on ultrasound reported much improvement after S-TENS treatment, as did the patient who had a fourth-degree tear plus immediate repair. The pretreatment patient impression score was set at a mean of 1 ± 0 in comparison with 2.8 ± 1.1 after S-TENS treatment ($p < 0.0001$, CI = 1.2–2.2, SE = 0.25).

DISCUSSION

Our data have demonstrated significant improvement after S-TENS treatment for fecal incontinence, as illustrated by their Wexner, Vaizey, and patient impression scores. Patients having received percutaneous sacral nerve stimulation (PSNS) for their fecal incontinence treatment generally report favorable outcomes: 88% of patients had more than 50% continence improvement after a 16 months follow-up.[8]

Transcutaneous electrical nerve stimulation potentially offers a cheaper, safer, noninvasive alternative to PSNS. Transcutaneous electrical nerve stimulation is a simple technique and requires minimal patient education. Our TENS machine costs US $48 each, whereas the initial cost of a PSNS implant is in excess of US $16,000 per year per patient.[9] PSNS is the implantation of an electrode; therefore, it is more invasive. Complications of PSNS implantation include infection, lead migration, and pain; treatment of these complications exacerbates the already high running cost of PSNS. Furthermore, the PSNS implant often sets off antitheft-scanning devices in shops and airport security causing a degree of embarrassment to patients.

The techniques of TENS have been widely used for years for urinary incontinence.[10] Until recently, PTN-TENS has been reported to show an overall mean improvement of fecal incontinence just after 4 weeks of neuromodulation.[6] The scientific basis behind the success of TENS in the management of fecal incontinence is poorly understood. TENS activates myelinated sensory α- and β-fibers, thereby inhibiting C-fiber transmission to the thalamus. This potentially has an effect on signal modulation to the pelvic organs. Sacral transcutaneous electrical nerve stimulation may have an advantage over posterior tibial nerve neuromodulation in that the electrode is closer to S3 dermatome, which theoretically has less electrical resistance. However, it is inconclusive that S-TENS is more effective than PTN-TENS. Such comparison at present cannot be made because of the small number of published series.

Several disadvantages of S-TENS therapy were observed. Patients were required to carry the machine with them while under stimulation, which was especially inconvenient during their daily commute or at work. The self-adhesive pads occasionally migrated, requiring readjustment. However, our patients were not particularly discouraged by these drawbacks, and most claimed that the benefits still outweighed the drawbacks. In contrast, the percutaneous sacral nerve stimulation implant, once inserted, would be very convenient.

In our series, 80% (16/20) of patients reported improvement following S-TENS treatment. Two of the 4 patients, who expressed no change in the patient impression score, actually had an improved Vaizey score. One of these 2 patients was subsequently diagnosed with demyelinating neuropathy. The other 2 patients had no improvement in either the Wexner or Vaizey score. One of these 2 patients was found to have mucosal prolapse on flexible sigmoidoscopy. Therefore, only 1 patient did not improve in all scores after S-TENS treatment (5%) without an organic explanation.

All our patients reported good compliance to S-TENS therapy, wearing the TENS machine 8 hours per day. There may be times when the TENS machines are switched off temporarily during the day for reasons such as patients were driving or were in a work meeting. This would only reflect the true benefits of S-TENS therapy because the purpose of treatment was to reintroduce their premorbid lifestyle to the patients. Most patients declared that the inconvenience of wearing the TENS machine was minimal and was easy to adapt to. Consultation with our patients

at the end of the first month gave our physiotherapists insight to whether compliance was adequate and was worthy of continuing with S-TENS treatment.

The 2 patients who had incidental sphincter defect detected both showed significant improvement with S-TENS. These patients would have been denied PSNS, because an intact sphincter is one of the mandatory criteria in accordance to the National Institute of Clinical Excellence guidelines.[11] However, in more recent studies,[12] there is good evidence to support the effective use of PSNS in patients with sphincter defects. Moreover, the mean Wexner score in our series was 7.9, which indicated that our cohort started out with quite a moderate degree of incontinence. This was expected in a secondary referral center, because the patients with less severe disease would normally be managed in primary care. Nonetheless, S-TENS therapy should also be considered in primary care on these patients with less severe disease even though the potential degree of improvement may not be as marked. Perhaps, in the future, patients with more severe incontinence could be managed in primary care with S-TENS therapy.

Our results appear better than another recent study,[13] the only other study to our knowledge: 53% of patients had more than 50% continence improvement after a mean follow-up of 19.7 months. The duration of stimulation in our cohort was much longer, which may be 1 reason of better outcome. The choice of 8 hours was based on the moderate results from studies using transcutaneous posterior tibial nerve stimulation for only 2 to 4 hours.[6] Another potential reason of our better outcome could be that our cohort of patients had only moderately severe incontinence at the outset (mean Vaizey score = 12/24). Therefore, a larger cohort of subjects would represent a better balance of the heterogenous population. The use of placebo machines was considered as control. However, because patients are required to adjust the current amplitude at a level sufficient to produce a background of mild tingling sensation to confirm stimulation, neither the patient nor the physiotherapist would be blinded.

Other limitations of our study include the inability to follow up patients with anorectal physiology measurements as an objective assessment of improvement. As a direct consequence of cost, only some patients had pretreatment anorectal physiology measurements and endoanal ultrasound. Our unit did not have the facilities, and only those with suspicions of sphincter defects from clinical assessment were referred to the Oxford Pelvic Floor Center for further evaluations. Moreover, this was a preliminary study. Our sample size was small, and the patients were not randomly assigned. Patients' diaries on the duration of daily S-TENS usage in relation to bowel activities were not formally recorded in the study, and, therefore, there are no reliable data regarding how many hours per day the patients actually used the device. The median follow-up periods need to be lengthened. Although our series analyzed patients' satisfaction, formal quality-of-life assessment, eg, fecal incontinence quality-of-life scale,[14] needs to be one of the primary outcomes in any future study. Bowel functions may decline over time with S-TENS therapy, as seen with tibial nerve stimulation. It is possible that continuing medical therapy accounts for the positive confounding effects as opposed to the true physiological effects of S-TENS. Nonetheless, such strong significance in patients' satisfaction over a cheap, safe, and noninvasive procedure warrants a larger study to be evaluated, including patients with anatomical sphincter defects.

CONCLUSION

Our preliminary data suggest that S-TENS is an effective, feasible, quick, noninvasive, well-tolerated, and inexpensive modality in the treatment of fecal incontinence. Further larger controlled studies are necessary to evaluate its true physiological effects and its feasibility as an alternative technique to PSNS.

ACKNOWLEDGMENT

The authors thank Rachel Grubb, our physiotherapist, for the data collection.

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