

Percutaneous Peripheral Neuromodulation in the Treatment of Fecal Incontinence

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Key Words

Uninhibited rectal contraction · Uninhibited anal sphincter relaxation · Rectometry · Posterior tibial nerve · Percutaneous access

Abstract

Background/Aims: To assess the results of peripheral neuromodulation for the treatment of fecal incontinence (FI) resulting from uninhibited rectal contraction (URC) or uninhibited anal sphincter relaxation (UASR). **Methods:** The work comprised 32 patients (age 38.2 ± 6.7 years; 22 women) with FI in whom conventional therapy had failed before enrollment in the study. Twenty-six had URC and 6 UASR. Peripheral neurostimulation was effected by posterior tibial nerve stimulation using a Stoller Afferent Nerve Stimulator (UroSurge, Coralville, Iowa, USA). The needle was introduced into the skin cephalad to the medial malleolus. Stimulation (parameters: 0.5–10 mA, 200 μ s, 20 Hz) was performed every other day for 4 weeks. Functional assessment was done by a questionnaire (incontinence score: 0–20) and physiologic studies. **Results:** Group 1: 17 patients (13 URC, 4 UASR) had FI improvement, recording a mean score of 1.7 of 20. Group 2: 10 patients (8 URC, 2 UASR) had fair improvement (score 8.6). Group 3: 5 patients had poor results (score 14.8). Rectometric recording showed improvement in groups 1 and 2. Recurrence of symptoms oc-

curred in 8 patients; 6 improved after retreatment. **Conclusions:** A percutaneous access to the S₃ spinal region was achieved through the posterior tibial nerve. Improvement of FI was achieved in 78.2%. The technique is simple, easy, without complications and cost-effective. It can be done as an outpatient procedure or by the patient at home. The results need to be reproduced on a large number of patients.

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Introduction

Fecal incontinence (FI) is a common defecation disorder of variable causes. It may be of traumatic origin, including obstetric trauma [1–7], or due to neurologic diseases, or it may be idiopathic [8–13]. In previous studies, we demonstrated that FI might be due to uninhibited rectal contractions [14, 15] or anal sphincter relaxation [16]. In the former, the 1st rectal sensation was not felt, and urge was perceived at the time of balloon expulsion, which could not be prevented by voluntary sphincter squeeze. In the uninhibited anal sphincter relaxation, the external anal sphincter did not contract either reflexively or voluntarily on rectal distension, leaving the relaxing internal anal sphincter unprotected and uncontrolled [16].

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Biofeedback has been used in the treatment of FI with variable results [17–20]. Electric stimulation or neuromodulation of the pelvic floor has also been used in the treatment of idiopathic FI. Neuromodulation may be achieved through the transanal or transvaginal route using surface electrodes [21–24]; however, these routes are not highly specific. More specific approaches comprise transcutaneous stimulation of the afferent bundles of the pudendal nerve and sacral root nerve stimulation [25–29]. Anal dynamic graciloplasty is also used in the treatment of FI [30–32]. However, these techniques are elaborate and invasive.

The skin of the lower limb is innervated by the nerves of the segments from which it is derived, i.e. T₁₂–S₃ [33]. The posterior tibial nerve arises from the ventral branches of the ventral rami of the fourth and fifth lumbar and the first, second and third sacral nerves [33]. It contains sensory and motor fibers. As the nerve contains fibers from the sacral nerves, stimulation of its peripheral fibers which reach the ankle area transmits impulses to the sacral nerves and reflexly neuromodulates the rectum and anal sphincters.

In this communication, we assessed the results of peripheral neuromodulation for the treatment of patients with FI due to uninhibited rectal contractions or anal sphincter relaxation. A percutaneous access to the S₃ spinal region was achieved through the posterior tibial nerve. The technique uses the same principle of sacral root stimulation, but instead of activating the sacral root itself, we used one of its peripheral branches which is the posterior tibial nerve.

Subjects and Methods

The study comprised 32 patients with idiopathic FI (22 women and 10 men; mean age $\pm$ SD 38.2 $\pm$ 6.7 years; range 28–44). Mean duration of FI was 8.6 $\pm$ 2.7 years (range 6–11). The patients were incontinent to solid stools. Inclusion criteria comprised patients who had FI with normal EMG activity of external anal sphincter, puborectalis and levator ani muscles as well as normal anorectal sensitivity, anal pressure, defecography and anal endosonography. Prior to enrollment in the study, the patients had all had conventionally used therapies, including medical therapy, pelvic floor stimulation, Kegel exercise and biofeedback, however, with no improvement. Informed consent was given by the patients and the study was approved by our Faculty Review Board and Ethics Committee.

Physical examination and laboratory work were normal. Proctoscopy, colonoscopy, barium enema and rectal and colonic biopsy studies as well as intestinal transit time were also normal. Physiologic studies, comprising anal and rectal pressure measurements, EMG recording of the external anal sphincter and puborectalis muscle, as well as the rectoanal inhibitory reflex were performed after previously mentioned methods [34–39]. Rectometry, by which the rectal vol-

ume, pressure and compliance at the first rectal and at urge sensation are estimated, was carried out as described earlier [40].

Of the 32 patients, 26 had uninhibited rectal contractions as shown by rectometry (fig. 1, 2); their anal pressures recorded a mean of 66.3 $\pm$ 3.8 cm H₂O (range 62–72), which was similar to that of normal volunteers in our laboratory. The EMG activity of the external anal sphincter and puborectalis muscle as well as the rectoanal inhibitory reflex were also normal. In 18 of the 26 patients, the 1st rectal sensation was not felt, and the urge sensation was perceived at the time of balloon expulsion (fig. 1). 8/26 patients did not feel either of the 1st rectal or the urge sensation (fig. 2). The cause of FI is apparently sensory, but the cause of this sensory disturbance is hitherto unknown. Physical examination and investigations were unremarkable, as already mentioned. The remaining 6 patients of the 32 had uninhibited anal sphincter relaxation. They had normal anal pressure. EMG of external anal sphincter and puborectalis muscle and rectometry recordings. The only positive finding was an abnormal rectoanal inhibitory reflex. The external anal sphincter did not contract on rectal distension. The patients could not oppose the urge to defecate if the conditions were inappropriate, with a resulting urgency and fecal soiling.

Twenty patients with FI who matched the treated group in age, duration of symptoms and investigative results acted as controls. Fourteen were women and 6 men. Seventeen had uninhibited rectal contractions and 3 had uninhibited anal sphincter relaxation.

Methods (Technique)

The Stoller Afferent Nerve Stimulator (SANS; UroSurge, Coralville, Iowa, USA) consists of a stimulator which is attached with a connecting lead to a 34-gauge needle and a neutral surface electrode (fig. 3). The subject lay supine under no anesthesia. The needle was inserted into the skin at 3-finger breadth cephalad from the medial malleolus, approximately 3–4 cm behind the tibia, and was directed towards the ankle joint (fig. 3). The needle was connected to a 9-V AC monopolar generator (the Stoller stimulator). Stimulation ranged from 0.5 to 10 mA with a pulse width of 200 μ s and a frequency of 20 Hz. Proper stimulation parameters were recognized by flexion of the big or the other toes. Unilateral stimulation was performed.

Stimulation was done every other day, each time for 30 min. The total period of stimulation was 4 weeks. In case of symptom recurrence, stimulation was repeated twice per week for 4 weeks. For the control group, the above-mentioned technique was applied to the patients, but without stimulation.

Functional assessment was performed by a questionnaire reporting on the frequency of incontinence to solid stool, liquid stool and flatus, as well as the frequency of pad usage and the extent of social inconvenience. Each category was scored from 0 to 4, resulting in a composite score where 0 was perfect continence and 20 complete incontinence. The patients started recording these data for 2 weeks prior to the 1st day of neurostimulation and continued during the treatment and the follow-up period, which ranged from 16 to 30 months (mean $\pm$ SD 22.3 $\pm$ 4.6). The rectometrograms were performed for all the patients 1 and 12 months after treatment termination.

To ensure reproducibility of the results, the recordings and measurements were repeated at least twice in the same subject, and the mean value was calculated. The results were analyzed statistically using Student's *t* test. significance was ascribed to $p < 0.05$ and values were given as the mean $\pm$ SD.

Fig. 1. Rectometrogram of a patient with uninhibited rectal contractions. The patient did not perceive the 1st rectal sensation, but felt the urge sensation as represented by a dash below the rectometrogram.

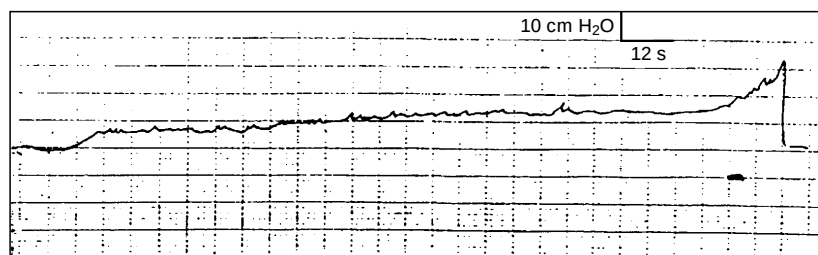
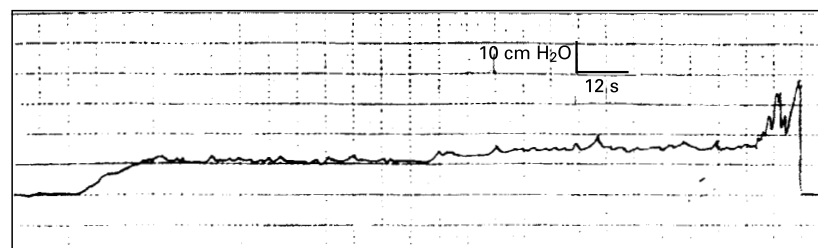


Fig. 2. Rectometrogram of a patient with uninhibited rectal contractions. The patient did not perceive either the 1st rectal or urge sensation.



Results

No adverse side effects were encountered during or after the study and all subjects completed the treatment. 17/32 patients (group 1; 13 with uninhibited rectal contractions and 4 of the uninhibited sphincter relaxation group) reported good results and had an improvement in the incontinence score from a mean of 17.4 ± 2.3 of 20 (range 14–20 of 20; pretreatment) to a mean of 1.7 ± 0.6 of 20 (range 0–4 of 20; posttreatment; $p < 0.001$). Of the remaining 15 patients, 10 (group 2; 8 with uninhibited rectal contractions and 2 with uninhibited sphincter relaxation) considered their outcome as fair; they had a pretreatment score of 18.2 ± 2.6 (range 17–20) and posttreatment score of 8.6 ± 1.2 (range 4–10; $p < 0.05$). The remaining 5 of the 32 patients (group 3; all of the uninhibited rectal group) had a poor incontinence score; they had a mean pretreatment score of 18.6 ± 2.1 (range 17–20) and a posttreatment score of 14.8 ± 3.8 (range 13–20; $p > 0.05$). We did not find a correlation between the results and the age of patients, duration of symptoms or the length of follow-up.

Physiologic Assessment

Group 1 showed normal rectometrogram (fig. 4). The patients felt the 1st rectal and urge sensation and this was maintained up to the rectometric recording, which was done at the 12th posttreatment month. In group 2, the 1st rectal sensation was reported in all the patients, while the urge sensation was not recorded in some patients (fig. 5).

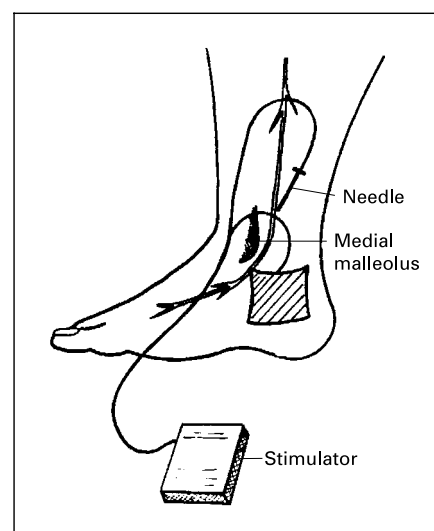


Fig. 3. Diagram illustrating the site of application of the needle cephalad to the medial malleolus. It also shows the posterior tibial nerve and the Stoller Afferent Nerve Stimulator.

The posttreatment rectometric findings in group 3 were similar to those before treatment.

Recurrence

During the follow-up period, recurrence of the symptoms occurred in 8 of 27 patients who had shown improvement in the incontinence score: 3 of group 1 and

Fig. 4. Rectometrogram of the same patient of figure 1 after neuromodulation. The patient perceived both the 1st rectal and urge sensations as marked by 2 dashes below the rectometrogram.

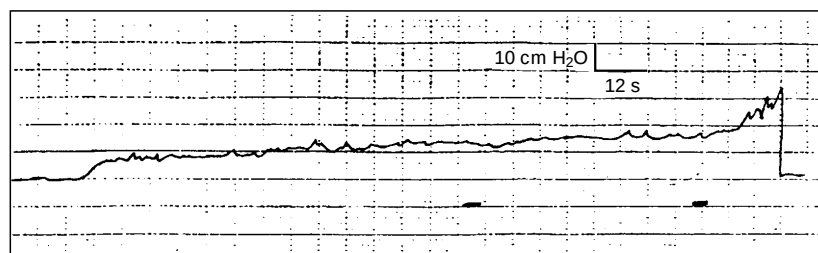
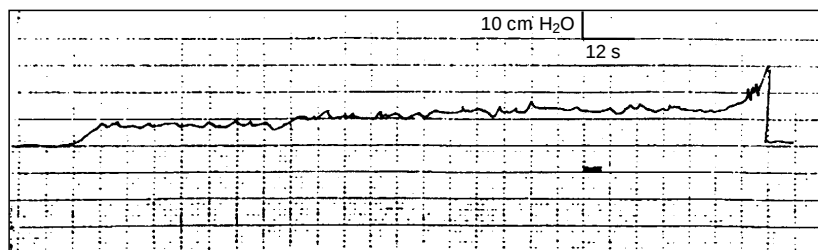


Fig. 5. Rectometrogram of the same patient of figure 2 after neuromodulation. The patient felt the 1st rectal but not the urge sensation as represented by a dash below the rectometrogram.



5 of group 2. After retreatment, 6 improved from a pretreatment mean score of 17.6 ± 1.8 to a posttreatment score of 2.2 ± 0.7 . The remaining 2 patients as well as the patients of group 3 refused retreatment.

Sham stimulation of the control group effected no clinical improvement of the FI or a change in the investigative results.

Discussion

The current study utilizes peripheral stimulation of the posterior tibial nerves for transcutaneous access to the S₃ spinal region. It appears that this route effects reflex neuromodulation of the muscles involved in FI using the same principle of sacral root stimulation but by the percutaneous route. Neural stimulation of the pudendal nerve reflex loop seems to improve innervation and thus reflexly suppress the uninhibited rectal contractions or sphincter relaxations. Both sides of action could be targeted by posterior tibial nerve stimulation.

FI in the current study improved by 78.2%. Symptomatic improvement was associated with rectometric improvement. We do not know the cause of failure in 21.8%. A relation to the patients age, duration of symptoms or the length of follow-up could not be found. Failure could be related to the performance of the technique such as the improper location of the stimulating needle in the leg or inadequate stimulation parameters. Alternatively, it could be related to a disordered pudendal nerve reflex

loop. Upon recurrence of the symptoms, retreatment achieved a success rate of 75%. The improvement was long-lasting; it was continuous during the follow-up period.

Comparing the current technique with other neuromodulatory methods, there is the sacral root stimulation which also activates the S₃ reflex [27–29]. However, in contrast to the sacral root stimulation in which the symptoms recur almost immediately after deactivation, the current technique has a long-lasting improvement and is less invasive. Neuromodulation through the transvaginal or transanal route using surface electrodes [21–24] may not be as highly specific. The present technique is less elaborate and complicated compared with transcutaneous stimulation of the pure afferent bundles of the pudendal nerve [25–26]. It only needs proper selection of the site of the needle application, and thus patients can even perform the technique at home by themselves. However, we believe that this technique should be performed only after failure of the conventional treatment.

It may be argued that, in order to diminish the patients inconvenience, surface instead of needle electrodes should be used. A noninvasive method would definitely be better than an invasive one. However, we think that the needle electrode is getting closer to the nerve fibers and would thus achieve a better therapeutic effect. Nevertheless, surface electrode application remains to be tried.

In conclusion, the current technique using peripheral neuromodulation effected significant improvement in

cases of FI due to uninhibited rectal contractions and anal sphincter relaxation. The technique is simple, easy, without complications and cost-effective. It can be done as an outpatient procedure or by the patient at home. However, the results need to be reproduced with FI of different etiologies.

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