

A prospective multicentre study to investigate percutaneous tibial nerve stimulation for the treatment of faecal incontinence

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Abstract

Aim Percutaneous tibial nerve stimulation (PTNS) is a minimal invasive treatment that can be performed in the outpatient clinic. This is a pilot study to investigate PTNS in the treatment of faecal incontinence.

Method Percutaneous tibial nerve stimulation was performed by insertion of a needle electrode near the posterior tibial nerve. Patients were treated twice a week. Evaluation of faecal incontinence and quality of life was performed at baseline, 6 weeks, 3 months, 6 months and 1 year. Quality of life was estimated using SF-36 and FIQL questionnaires.

Results A total of 22 patients were included. The mean age was 60.4 ± 11.7 years. After 6 weeks, 18 continued

the treatment; 13 patients had a $> 50\%$ decrease in incontinence episodes. Overall incontinence episodes fell from 19.6 ± 21.0 at baseline to 9.9 ± 15.5 ($P = 0.082$) at 6 weeks and to 3.6 ± 4.8 ($P = 0.029$) at 1 year. Postponement time and quality of life increased significantly during follow up.

Conclusion Percutaneous tibial nerve stimulation is simple and can be used in the outpatient setting. Good results can be obtained and sustained during maintenance treatment.

Keywords Faecal incontinence, neuromodulation, posterior tibial nerve stimulation, nerve stimulation

Introduction

Faecal incontinence (FI) is the involuntary loss of flatus, liquid or solid stool. It is under-reported by patients and under-recognized by providers. Its true prevalence is therefore unknown [1]. Estimates of population based prevalence vary from 0.5% to 28%, with a female/male ratio of six to eight times [2,3].

There are variable treatment options (medical and surgical) depending on the patient and the aetiology of the incontinence [4].

Sacral nerve modulation (SNM) first described by Matzel *et al.* [5], is highly successful in 70–80% of patients [6,7]. It is minimally invasive, but involves implantation of a neurostimulator with the risk of infection.

An alternative is to stimulate similar nerves a less invasive and simpler technique using. The posterior tibial nerve originates from the sacral plexus [8] and by

stimulating it at the ankle, it may be possible to produce an effect similar to SNM. Posterior tibial nerve stimulation (PTNS) was first undertaken for treatment of urinary incontinence and has been shown to be safe and well tolerated, with almost no morbidity [9,10]. An improvement in symptoms and quality of life has been demonstrated. In FI this technique has shown an improvement of up to 78% in symptoms with no side effects [11], but there are no data on quality of life.

This is the first prospective, multicentre study evaluating the efficacy and effect on quality of life of PTNS for faecal incontinence.

Method

From August 2007 to January 2009, a multicentre (three institutions), prospective trial was performed, in which patients with FI were recruited. Inclusion and exclusion criteria are shown in Table 1. Every patient served as his or her own control.

At baseline, all patients underwent physical examination, endo-anal ultrasound, anal manometry and PTNS test stimulation. The study protocol and evaluation

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intervals are shown in Fig. 1. Every patient provided written informed consent.

FI was assessed by 3 week bowel habit diaries at baseline before the first treatment session and during follow up at 6 weeks and 1 year. The primary outcome measure was the reduction of incontinence episodes per 3 week period. The global rating of improvement as measured by the Cleveland Clinic Florida Faecal Incontinence Score (CCF-FI score) and the severity of FI [12] by the CCF-FI score.

Quality of life was assessed by the standard short form health survey quality of life questionnaire (SF-36) and FI quality of life questionnaire (FIQL) [13,14]. Both questionnaires were completed by the patient at baseline, 6 weeks and 1 year follow up. The SF-36 questionnaire rates quality of life in eight domains (physical functioning, physical role, bodily pain, general health, vitality, social functioning, role emotional and mental health) on a scale of 1–100. The FIQL questionnaire is disease specific for FI and measures quality of life in four domains (lifestyle, coping/behaviour, depression and embarrassment) on a scale of 1–4.

Procedure

Treatment was standardized. PTNS was performed using the Urgent PC Neuromodulation System (Uroplasty, Geleen, the Netherlands). This includes a 34-gauge needle electrode, surface electrode, lead wire and hand-

Table 1 Study in- and exclusion criteria.

Inclusion criteria
Patient aged 18 years or more
Faecal incontinence with solid or liquid stool causing disruption of lifestyle
Psychological stability and suitability for intervention as determined by the investigator
Willing to commit to a rigid follow-up schedule
Failed conservative therapy
Intact peripheral neuro sensory nervous system as determined by clinical investigation
Adequate motor and/or sensory response during treatment
Able to read and write
Exclusion criteria
Major internal and/or external sphincter defect (>120 degrees of circumference)
Faecal impaction
Implanted pacemaker, defibrillator, cardiopathy or bleeding disorders
Pregnancy or intention to become pregnant
Neurogenic or congenital disorders resulting in faecal incontinence (Multiple Sclerosis and Spina Bifida)
Unable to travel to the hospital to receive the treatment

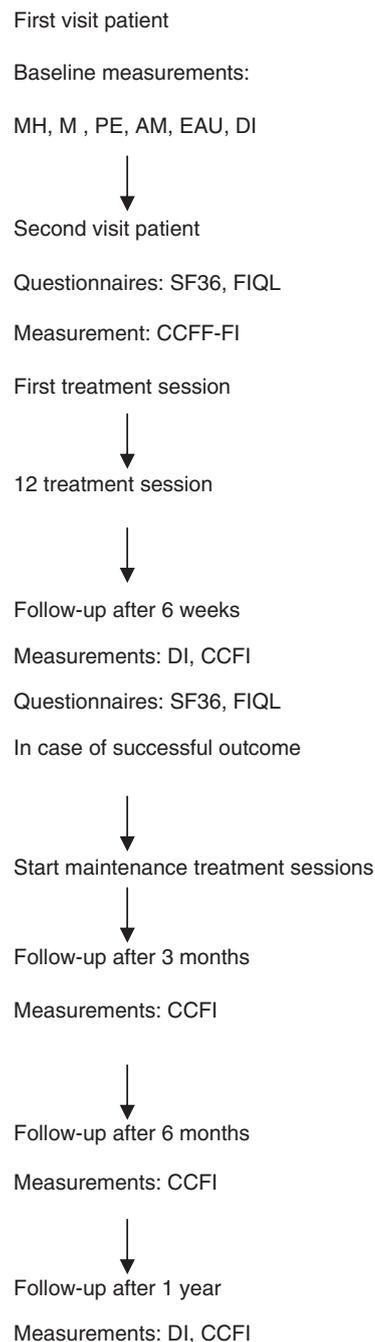


Figure 1 Study flow chart. MH, medical history; M, medications; PE, physical examination; AM, anal manometry; EAU, endo-anal ultrasound; DI, bowel habit diary; SF36, Short Form 36 quality of life questionnaire; FIQL, faecal incontinence quality of life questionnaire; CCF-FI, Cleveland Clinic Florida – Faecal Incontinence score.

held pulse generator. The low voltage stimulator powered by a 9 V battery has an adjustable current setting ranging from 0 to 9 mA, a fixed pulse width of 200 microseconds and a fixed frequency of 20 Hz.

Treatment was performed in the outpatient clinic. Every treatment session started with needle insertion on either the right or left leg. Patients were in the supine or sitting position for easy access and correct site was located approximately 5 cm cephalad to the medial malleolus and approximately 2 cm posterior to the tibia. The electrode was inserted in a 60° angle and was gently advanced until approximately half of the tip had penetrated the skin. The surface electrode was then attached near the medial aspect of the calcaneus on the same leg. Both the electrodes were connected to the stimulator (Fig. 2). Correct needle placement was confirmed by slowly increasing the current until sensory and/or motor responses were evident. Typical responses included foot sole sensation and great toe flexion or extension of the entire foot. If the incremental adjustment of amplitude failed to elicit a correct response, repositioning of the needle was needed. This was performed by gently advancing or retracting the needle electrode or by insertion of a new electrode. After confirming correct position, stimulation was carried out for 30 min at the amplitude level that elicited the optimal response. The total time for every treatment session including patient preparation was approximately 35 min. The treatment protocol consisted of 12 sessions twice per week. At 6 weeks, the outcome was assessed and in patients with a sufficient subjective reduction in symptoms, maintenance therapy was started. The frequency of sessions was then slowly reduced from six sessions weekly to six sessions every 2 weeks and, finally, six sessions monthly. If symptoms reappeared or increased in



Figure 2 Percutaneous tibial nerve stimulation. PTNS stimulation. Needle electrode in place in a 60° angle, approximately 5 cm cephalad to the medial malleolus and approximately 2 cm posterior to the tibia. This is connected to a surface electrode near the medial aspect of the calcaneus. Both are attached to the stimulation device.

frequency during maintenance treatment, the frequency of the sessions was increased to the last effective treatment schedule.

Statistical analysis

With reference to previous studies, we estimated that approximately 18 patients would be necessary to detect an improvement of FI in 50% with a power of 80% at a significance level of 5% [11].

Continuous metric variables were tested for normality of distribution by the Kolmogorov–Smirnov test. Normally distributed data were expressed as mean and standard deviations and nonparametric as presented, if not, median and range. Paired tests were used to compare data at baseline and each follow-up interval. The level of significance was set at $P < 0.05$.

Results

Twenty-two patients were enrolled. All patients had persisting FI after conservative treatment. The patient's characteristics are shown in Table 2. All had a positive response during the first PTNS session and completed 12 sessions in the first 6 weeks. The bowel diaries, QOL questionnaires and CCF-FI scores were complete in all cases. Of the 22 patients, 18 (81.8%) had a subjective improvement and started maintenance treatment

Table 2 Patient's characteristics.

	<i>n</i> = 22
Baseline demographics	
Age (years)	60.4 ± 11.7
Gender (male/female)	6/16
Years of incontinence (years)	7.4 ± 7.8
Cause of faecal incontinence	
Idiopathic	13
Obstetric trauma	7
Anal surgery	2
Previous surgery	
Anal repair	1
Fistula surgery	1
Haemorrhoidopexy (PPH)	1
Anorectal examinations	
Anal manometry	
Resting pressure (mmHg)	45.1 ± 16.4
Squeeze pressure (mmHg)	103.0 ± 46.1
Endoanal ultrasound	
Intact sphincter complex	16
External sphincter defect	6

Patient's characteristics. Data are shown as mean and standard deviation if applicable.

sessions. At the time of this report, 14 patients had completed 1 year follow up. Two had no improvement after 6 weeks and did not continue. They now have an implanted sacral nerve stimulator with good result. Two patients did have subjective improvement but found travel to the hospital too difficult. Neither received an alternative treatment according to their wish. During maintenance treatment, one patient stopped treatment after 3 months. This patient had recurrence of symptoms and did not want to continue.

Clinical outcome

Of the 22 patients, 14 (63.4%) had a greater than 50% reduction in incontinence episodes at 6 weeks of follow up, and 13 of 14 patients had > 50% reduction of incontinence episodes at 1 year. The mean number of incontinence episodes per 3 weeks decreased from a baseline of 19.6 (SD 21.0; 95% CI 5.5–33.8) to 9.9 (15.5; -1.42 to 23.8; *P* = 0.082) at 6 weeks and decreased significantly to 3.6 (4.8; 0.3–6.8; *P* = 0.029) at 1 year. Defecation postponement time was significantly improved at 6 weeks and 1-year follow up (Fig. 3).

The mean CCF-FI-scores decreased from a baseline mean of 11.6 (3.5; 9.5–13.6) to 8.2 (2.5; 6.7–9.7; *P* < 0.001) at 6 weeks and to 5.9 (2.5; 4.5–7.4; *P* < 0.001) at 3 months, 5.4 (4.2; 2.9–7.8; *P* < 0.001) at 6 months and to 5.9 (3.9; 3.7–8.2; *P* = 0.001) at 1 year (Fig. 4).

Quality of life

The SF-36 assessment improved significantly in all domains, apart from vitality, at 1 year (Fig. 5). The

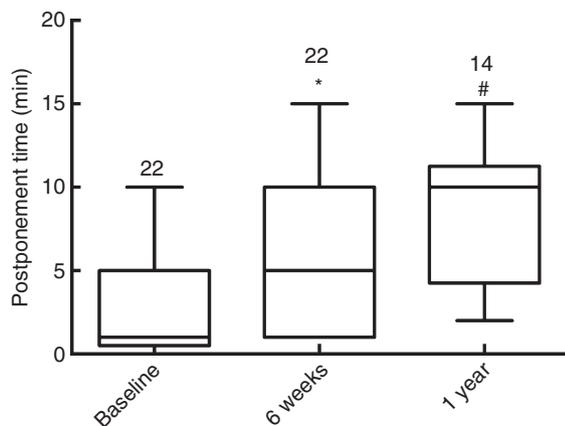


Figure 3 Defecation postponement time. **P* = 0.005, *P* = 0.007, number above each boxplot indicating the number of patients available for follow up.

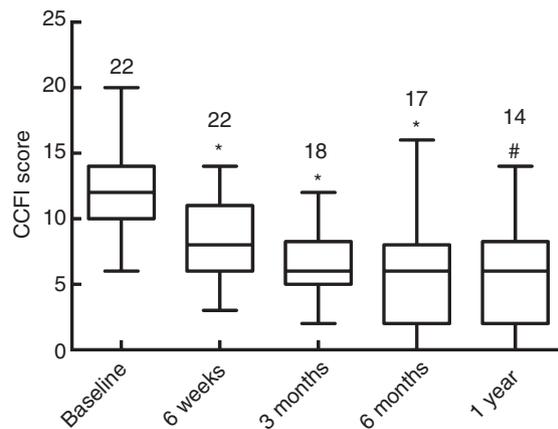


Figure 4 Cleveland Clinic Florida – Faecal Incontinence Score. **P* < 0.001, *P* = 0.001, number above each boxplot indicating the number of patients available for follow up.

domains of role, emotion, and vitality showed statistical significant improvement at 6 weeks.

The disease-specific QOL assessment with the Rockwood FIQL score showed statistically significant improvement in coping/behaviour and embarrassment at 6 weeks and statistical significant improvement in lifestyle and coping/behaviour at 1 year (Fig. 6). During the study, three patients experienced three mild adverse events. All were procedure related including gastrodynia in two approximately 2–3 hours after treatment sessions and lasting for several hours. One patient reported numbness in the leg, lasting for 2 hours. This only occurred after the first treatment session.

Discussion

This study showed improvement in FI in patients treated with PTNS. Tibial nerve stimulation was first used in urology to treat urge-incontinence and overactive bladder syndrome [15,16]. Several reports have been published describing PTNS treatment for FI using various methods

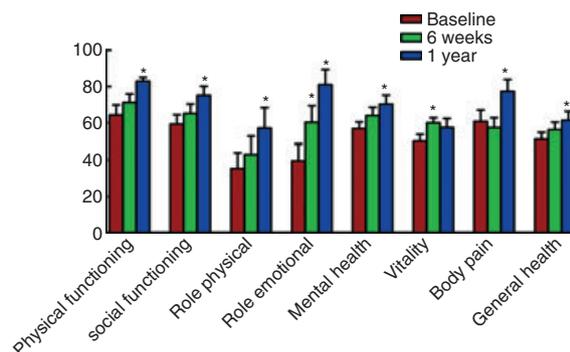


Figure 5 SF-36. **P* < 0.05 compared with baseline.

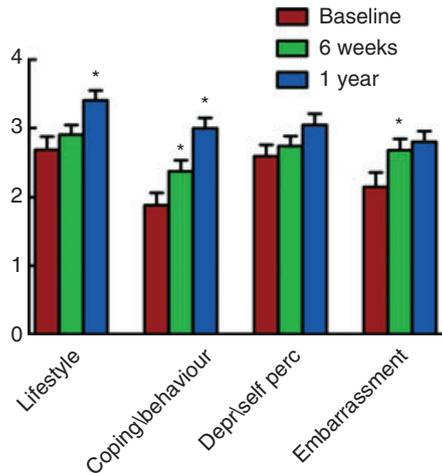


Figure 6 FIQL Rockwood. * $P < 0.05$ compared with baseline.

of stimulation. The first report using a needle electrode showed success in 78% of patients based on assessment by the incontinence score [11]. PTNS with a needle electrode was also reported to be successful after partial spinal injury [17]. Adhesive surface electrodes delivering transcutaneous stimulation is an alternative technique and appears to achieve a similar effect [18]. Queraltó *et al.* [18] described this method in 10 patients, with improvement in Wexner incontinence scores in eight. A recent report describes the use of an adhesive surface electrode in patients FI with inflammatory bowel disease. Five (42%) of 12 patients reported symptomatic improvement [19]. So far, there has been no comparison of these techniques. However, it has been suggested that PTNS is more effective than surface stimulation probably because the needle electrode is closer to the tibial nerve [15].

The exact mechanism of PTNS is unknown. The tibial nerve derives from the same sacral nerve roots as stimulated by SNM [8]. Cortical changes during continuous stimulation in SNM treatment have been described suggesting an important role for the central nervous system [20,21]. In PTNS, similar cortical changes have been discovered in patients with overactive bladder syndrome. These occurred only after PTNS treatment and did not occur after sham stimulation. They were present up to 24 hours after treatment, supporting the observation of sustained improvement [22].

The optimal treatment protocol for FI is not known. Various different frequencies have been described in the literature varying from daily for 3 months to every other day for 4 weeks [11,19]. In the treatment of urinary incontinence, a treatment protocol with weekly sessions for 12 weeks is described [10]. By using the scheme of gradually reducing the frequency in this study, it was

possible to gauge the frequency of sessions during the follow up treatment. Based on our data, we conclude that after a successful initial treatment the effects of treatment lasts for 1 year using monthly maintenance sessions.

A limitation of this study is that of a possible placebo effect due to the needle insertion not being taken into account. Every therapy has a potential placebo effect. A recent study described acupuncture to treat FI [23] with an improvement in FI after multiple acupuncture sessions, using multiple needle insertions in the umbilical, lumbar, sacral regions and leg. The authors explain the working mechanism as a reflex mechanism between the skin and internal organ but acupuncture is not comparable to our study because no electrical stimulation is used and therefore no direct nerve stimulation was applied. The rate of objective improvement was seen in 64% of patients in the present study. This suggests that this is more than a placebo effect.

Percutaneous tibial nerve stimulation is a simple method to treat FI after failure of conservative treatment. We have shown that good results can be obtained and sustained during maintenance treatment. The treatment can be performed in the outpatient clinic or at home.

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