

Percutaneous Tibial Nerve Stimulation as Neuromodulative Treatment of Chronic Pelvic Pain

Michael R. van Balken^a, Vera Vandoninck^a, Bert J. Messelink^b, Henk Vergunst^c,
John P.F.A. Heesakkers^a, Frans M.J. Debruyne^a, Bart L.H. Bemelmans^{a,*}

^aDepartment of Urology, University Medical Center Nijmegen, Geert Grooteplein 10, P.O. Box 9101, Nijmegen 6500 HB, The Netherlands

^bDepartment of Urology, Academic Medical Center Amsterdam, Amsterdam, The Netherlands

^cDepartment of Urology, Canisius-Wilhelmina Hospital Nijmegen, Nijmegen, The Netherlands

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Abstract

Purpose: Neuromodulative therapies have been used with moderate success in patients with chronic pelvic pain. Intermittent Percutaneous Tibial Nerve Stimulation (PTNS) is a new, minimally invasive treatment option, which has shown to significantly decrease accompanying pain complaints in patients with lower urinary tract dysfunction, such as urge incontinence or urgency/frequency. In our study, we evaluate the objective results of PTNS in patients with chronic pelvic pain as their main complaint.

Materials and Methods: In a prospective multicentre trial PTNS was evaluated in 33 patients with chronic pelvic pain. Effects were recorded by Visual Analogue Scale (VAS) for pain diaries, the McGill pain questionnaire and the SF-36 general quality of life questionnaire at baseline and after 12 weeks of treatment. Subjective (patients' request to continue chronic treatment to keep the obtained success) and objective responses (decrease in mean VAS >50% and VAS <3 after treatment) were evaluated.

Results: A subjective response was seen in 42% of all patients. In seven patients (21%) mean VAS decreased >50%, in six cases (18%) the decrease was >25%. After 12 weeks of treatment, seven patients (21%) ended up with a mean VAS <3. In all patients quality of life (SF-36) significantly improved, as did the total pain rate intensity (McGill).

Conclusions: Despite very modest overall success rates and the need for placebo-controlled studies, PTNS may have a place in the treatment of patients with chronic pelvic pain who have already tried many other therapies and are left with no further option.

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Keywords: Chronic pelvic pain; Therapy; Neuromodulation; Percutaneous stimulation posterior tibial nerve; PTNS

1. Introduction

Chronic pelvic pain is a common problem with a high impact on patients' quality of life. Unfortunately, pelvic pain is hard to measure, assess or localise, causing great difficulties in diagnosis and treatment [1], as well as frustration in both patients and physicians. The use of descriptive 'diagnoses' and the high referral rate amongst medical specialties covering only certain

aspects of the pelvic region furthermore illustrate our difficulties coping with this complex problem.

As aetiology and pathophysiology are mostly unknown, treatment is often empirical and polypragmatic. Non-steroidal anti-inflammatory drugs, steroids, benzodiazepines, anti-depressants, anti-convulsants, α -blockers, local anaesthetics, GABA- and NMDA-receptor agonists [2] and antibiotics all have been described to have some effect. When faulty pelvic floor behaviour is suspected physiotherapy may be of use. Neuromodulation has been reported in reducing pelvic pain by means of sacral nerve stimulation [3,4], while there are also reports on positive effects of neuromodulation in pain

* Corresponding author. Tel. +31-24-361-3920; Fax: +31-24-354-1031.
E-mail address: b.bemelmans@uro.umcn.nl (B.L.H. Bemelmans).

complaints accompanying conditions like interstitial cystitis (TENS [5], vaginal stimulation [6] or maximal electric pelvic floor stimulation [7]).

Recently, Percutaneous Tibial Nerve Stimulation (PTNS) has come to use for the treatment of lower urinary tract dysfunction, e.g. urge incontinence, urgency/frequency and non-obstructive retention [8–11]. Although accompanying pain complaints were reported to decrease [9,10], this minimally invasive treatment option has not yet been described for the use in distinct pelvic pain syndromes. In our study, we evaluate the objective results of PTNS in patients with chronic pelvic pain as their main complaint.

2. Materials and methods

Between November 1999 and August 2000, 33 patients (22 men, 11 women) with chronic, therapy-resistant pelvic pain were enrolled in a prospective clinical multicentre trial after approval by the Institutional Review Boards. All patients were evaluated for chronic pelvic pain by history, Visual Analogue Scale (VAS) for pain and physical as well as urological examination.

Chronic pelvic pain was defined as complaints of pain for at least 6 months in the bladder, groin, genitals or lower abdomen and/or perineal or (peri)anal pain without clear abnormalities on urological examination. On the Visual Analogue Scale for pain (0–10), the score should be over 5. The use of analgesics should have been stopped two weeks or longer prior to Percutaneous Tibial Nerve Stimulation (PTNS) or had to be continued without dose changes during the entire study. Physiotherapy or electrotherapy like Transcutaneous Electrical Nerve Stimulation (TENS) should have been stopped for at least 3 months prior to the PTNS treatment. Specific exclusion criteria for this study are given in Table 1.

2.1. Patients

Twenty-two men and 11 women with a mean age of 51.6 years (range 25–79 years) were treated for chronic pelvic pain (see Table 2).

Table 1

Exclusion criteria

Age under 18
Symptoms existing for less than 6 months
Pregnancy or the intention to become pregnant during the course of the study
Active urinary tract infection or recurrent urinary tract infections (recurrent infections: ≥ 5 during the last 12 months)
Bladder or kidney stone
Bacterial prostatitis, sexually transmitted disease
Carcinoma in situ, bladder malignancy, interstitial cystitis
Uncontrolled diabetes or diabetes with peripheral nerve involvement
Severe cardiopulmonary disease
Neurological disease like MS, M. Parkinson, CVA, bifid spine or spinal cord lesion
Concomitant use of Elmiron or bladder installations like DMSO, BCG, Chloropectin or Heparin
Change in analgesics within 2 weeks prior to or during the study
Physiotherapy at the same time as the study
Electrotherapy (for example TENS) at the same time as the study

These patients had their complaints for a median period of 5 years (range 2–30 years). Twenty-eight of 33 patients (85%) reported unsuccessful previous medical therapies, mostly analgesics and α -blockers, with a mean number of drug types used of 2.3 (range 1–4). Eight patients (24%) underwent up to two surgical procedures like (partial) epididymectomy, bladder neck incision, Sachse urethrotomy, transurethral resection of the prostate or transurethral microwave therapy for their complaints. Other unsuccessful therapies included physiotherapy and/or biofeedback in 17 (52%), electrical stimulation like TENS in 8 (24%) and alternative therapies like local injection therapy, corsets, sexual evaluation, acupuncture, aura-therapy and hot water baths in 18 patients (55%). Physical examination did not show overt (neuromuscular) abnormalities in any of the patients.

2.2. Method of treatment

PTNS was applied according to Stoller [8] and Govier et al. [10]. Patients lie in supine position with the soles of the feet together and their knees abducted and flexed (frog position). A 34-gauge stainless steel needle is inserted for approximately 3–4 cm cephalad to the medial malleolus, between the posterior margin of the tibia and the soleus muscle tendon. A stick-on electrode is placed on the same leg near the arch of the foot. Both needle and electrode are connected to a stimulator (Urgent PC[®], CystoMedix, Anoka, MN, USA) with an adjustable pulse intensity (0–10 mA). Fixed parameters are a pulse width of 200 μ s and a frequency of 20 Hz. The stimulator contains a battery of 9 V. The amplitude is slowly increased until plantar flexion of the large toe or fanning of the other toes occur. If this response cannot be obtained or pain occurs near the insertion site, the stimulation device is switched off and the procedure is repeated. In most patients the motor response was accompanied by a sensory response as a radiating sensation spreading in the sole of the foot. The current was set at a well-tolerable level. Elevation of the current was allowed whenever fading of this sensation was experienced due to adaptation. Patients underwent 12 weekly outpatient treatment sessions, each lasting for 30 minutes. In case of a good response patients were offered chronic treatment.

2.3. Evaluation of results

After informed consent, all patients had to fill out pain diaries as well as general and disease-specific quality of life questionnaires at study entry and at completion of treatment at 12 weeks. Pain diaries consisted of seven Visual Analogue Scales for pain, one for every day of the week, recording the maximum pain felt during the day. The lowest, highest and mean VAS were calculated from these diaries. General and disease-specific quality of life was evaluated using the SF-36 questionnaire [12] and the McGill Pain Questionnaire (Dutch Language Version), respectively [13,14]. The SF-36 questionnaire consists of 36 items covering eight distinct health status concepts and one item measuring self-reported health transition: physical function, role physical, pain, general health, emotional well being, role-emotional, social functioning, energy/fatigue and change in general health. The maximal score of each domain is 100. A higher score relates to a better quality of life. The McGill Pain Questionnaire uses 20 sets of descriptive words for pain, which can either be sensoric, affective or evaluative. One is allowed to choose maximal one word out of every set, resulting in a 'number of words chosen' score and a 'pain rate intensity' score. The higher the scores, the worse the condition.

Subjective success was defined as the request of the patient to continue chronic treatment to keep the obtained outcome, objective success as a decrease in mean Visual Analogue Scale for pain of

Table 2
Patient characteristics

Patient number	Sex	Age	Main localisation pain	Surgical procedures (abdomen, pelvis, genitals) prior to PTNS
1	Male	33	Lower abdomen	None
2	Male	34	Lower abdomen, scrotum	None
3	Male	39	Scrotum, groin (left)	None
4	Male	54	Lower abdomen, scrotum (left)	Epididymectomy ^a
5	Male	34	Perineum	None
6	Male	34	Scrotum, groin (left)	Vasectomy, epididymectomy ^a
7	Male	40	Scrotum, groin (left)	Varicocele correction
8	Male	43	Perineum, perianaly, suprapubic/bladder region	TW ^a , TURP ^a
9	Male	43	Perineum, scrotum	Inguinal hernia repair, varicocele correction
10	Male	46	Perineum, scrotum	Dorsal penile vein ligation, partial epididymectomy
11	Male	48	Suprapubic/bladder region	Vasectomy, inguinal hernia repair, TUMT ^a
12	Male	49	Suprapubic/bladder region, perineum	Vasectomy, Nephrectomy
13	Male	49	Perineum, scrotum	None
14	Male	50	Suprapubic/bladder region	Appendectomy, inguinal hernia repair, varicocele correction, TW ^a , Otis ^a
15	Male	50	Scrotum, groin (left)	Inguinal hernia repair
16	Male	53	Perineum, lower abdomen	Vasectomy, chemonucleolysis L5-S1
17	Male	56	Suprapubic/bladder region	Cholecystectomy, Sachse urethrotomy ^a
18	Male	62	Perineum, perianaly	TUMT ^a
19	Male	67	Suprapubic/bladder region	None
20	Male	70	Perineum, perianaly	Inguinal hernia repair, TURP ^a
21	Male	77	Perineum, scrotum	TURP
22	Male	79	Suprapubic/bladder region	Appendectomy, TURP
23	Female	30	Vagina	None
24	Female	54	Groin (left)	None
25	Female	66	Vagina	None
26	Female	72	Lower abdomen, vagina	None
27	Female	25	Lower abdomen, groin (right)	None
28	Female	41	Suprapubic/bladder region	Hysterectomy, Mitrofanoff
29	Female	50	Perineum, vagina	None
30	Female	55	Suprapubic/bladder region	None
31	Female	60	Suprapubic/bladder region	None
32	Female	61	Perineum, vagina	None
33	Female	79	Perineum, vagina	Hysterectomy, excision coccyx, ileocaecal resection ^a , rectal prolapse repair ^a

^a Operations were performed after the complaints had already started.

over 50%. A decrease of over 25% was considered to be a partial response. Moreover, the number of patients with a VAS below 3 after 12 weeks of treatment was recorded. Within-group comparisons of parametric results at baseline and 12 weeks of treatment were conducted using the paired-samples *t*-test (5% level statistical difference). Statistical analysis was performed using SPSS 9.0 software (SPSS, Chicago, USA).

3. Results

After 12 weeks of PTNS, 14 (10 men, 4 women) out of 33 patients (42%) were considered subjective responders, as these patients requested continuation of therapy. An objective response occurred in seven patients (21%) of all patients and almost only in the subjective responder group (see Table 3). Mean VAS for pain changed from 6.5 (range 5.3–7.7) at baseline to 5.4 (range 4.2–6.8) after 12 weeks of treatment (95% Confidence

Interval (CI): -0.2 , -2.0 , $p < 0.05$). Seven patients (21%) ended up with a mean VAS below 3. In the subjective responder group, mean VAS decreased from 5.9 (range 4.5–7.3) at baseline to 3.8 (range 2.7–5.2) after 12 weeks of treatment (95% CI: -0.5 , -3.7 , $p < 0.05$). No changes were seen in the subjective non-responders.

Table 3
Decrease of mean Visual Analogue Scale for pain (1 week) after 12 weeks of PTNS

	All patients (<i>N</i> = 33)	Subjective responders (<i>N</i> = 14)	Subjective non-responders (<i>N</i> = 19)
≥50%	7 (21)	6 (43)	1 (5)
≥25%, <50%	6 (18)	3 (21)	3 (15)
No improvement	20 (61)	5 (36)	15 (80)

The values in parentheses are percentages.

Table 4Characteristics in patients with and without a $\geq 25\%$ decrease of the mean VAS for pain

	$\geq 25\%$ decrease	No response
Sex	6 female (46%) 7 male (54%)	8 female (40%) 12 male (60%)
Mean age in years (range)	55.2 (25–79)	49.1 (33–79)
Median duration of symptoms in years (range)	4 (2–15)	5.5 (2–30)
Mentioned localisation's of pain ^a		
Groin/scrotum	2 (15%)	10 (50%)
Lower abdomen/suprapubic/bladder region	5 (38%)	11 (55%)
Perineal/(peri)anal/vaginal region	8 (62%)	7 (35%)
Mean VAS before PTNS	65 (range 60)	65 (range 77)
Mean number of drug types used (range)	2.82 (1–4)	2 (1–4)
Number of patients having had an operation for pain complaints	1 (8%)	7 (35%)
Number of patients having used physiotherapy	5 (38%)	12 (60%)
Number of patients having used electrotherapy	3 (23%)	5 (40%)
Number of patients having used alternative therapy	5 (38%)	12 (60%)

^a More than one localisation per patient possible.

In patients with an objective improvement of $\geq 25\%$ as well as in patients without an objective response certain patient characteristics were recorded that may have an influence on treatment outcome (see Table 4). Although we did not try to statistically identify prognostic factors, a high number of previously tried treatment modalities, a long period of complaints and a more superficial localisation of the pain seem to have a negative influence on PTNS results.

The SF-36 quality of life questionnaire showed statistically significant changes in the domains 'physical functioning' (51.5–57.1 (95% CI: +0.9, +10.3, $p < 0.05$)), 'role physical' (15.2–28 (95% CI: +0.1, +25.6, $p < 0.05$)), 'pain' (37.4–47.8 (95% CI: +2.3, +18.5, $p < 0.05$)) and 'change of health' (37–57 (95% CI: +7, +33, $p < 0.05$)) as well as in the total score (46.1–52.7 (95% CI: +2.6, +10.5, $p < 0.05$)).

In the McGill Pain Questionnaire (MPQ), eight domains were evaluated: Number of Words Chosen (NWC) sensoric, affective, evaluative and total, and Pain Rate Intensity (PRI) sensoric, affective, evaluative and total. Changes after 12 weeks of PTNS were not significant with the exception of PRI total: a decrease was seen from 21.5 to 17.2 (95% CI: –0.3, –8.3, $p < 0.05$).

4. Discussion

Posterior tibial nerve stimulation was first described in 1983 by McGuire et al. [15] in 22 patients with incontinence, using a transcutaneous electrode over the

common peroneal or posterior tibial nerve and a contralaterally placed ground electrode over the same nerve. Later on, Stoller [8] adjusted this method by using a percutaneous needle electrode and placing the ground electrode on the ipsilateral extremity. Since then, several publications report promising early results regarding urge incontinence, urgency/frequency and non-obstructive urinary retention [9–11]. As a positive side-effect, pain reduction has been described in a group of 15 patients, with a decrease in VAS from a mean (standard deviation) of 7.6 (5–10) to 3.1 (1–7) ($p < 0.0005$) [9], as well as in a group of 53 patients, with a reduction in pelvic pain intensity of 30% ($p < 0.05$) [10]. This decrease in pelvic pain as a symptom accompanying urgency/frequency or urge incontinence is also well known in sacral neuromodulation: in many reports there is, alongside relief of other symptoms, a significant decrease in Visual Analogue Scale for pain or likewise pelvic pain scores [16–18].

When looking at neuromodulation in patients with chronic pelvic pain as their main symptom, only a few reports can be found. In a prospective, non-randomised feasibility study sacral nerve stimulation resulted in a substantial clinical benefit in 6 of 10 patients with chronic, intractable pelvic pain [4]. Everaert et al. [3] describe the implantation of a sacral neuromodulator in 11 of 26 PNE tested patients with therapy-resistant pelvic pain syndromes. Nine patients were satisfied and one needed an explantation because of infection of the prosthesis, reducing the success rate to 8 out of 11 and the intention to treat percentage to 31%. At a follow-up of 36 ± 8 months no further failures were seen. Other

neuromodulation modalities reported are intrarectal or vaginal electrostimulation in deep pelvic pain syndromes and TENS in superficial pelvic pain. Results are very modest and fail to reach statistical significance. The same treatment options [5,6] as well as maximal electric pelvic floor stimulation [7] are described for the more specific cases of interstitial cystitis, in which pain cure rates vary between 26 and 54%.

The mechanism of action of neuromodulation is still unknown, although many theories exist. In lower urinary tract dysfunction neuromodulation most probably causes rebalancing of inhibitory and excitatory impulses that govern bladder function in the central nervous system [19]. For pain it can be suggested that, according to the gate control theory, stimulation of large somatic fibres could modulate/inhibit the thinner afferent A-delta or C fibres, thus decreasing pain perception [20]. Another mode of action may be the elevation of endorphins at a spinal level, as can be seen in TENS and acupuncture [21,22]. However, the most important evidence of effects of neuromodulation on nociceptive pathways in the spinal cord comes from Chang et al. [23]: after instillation of acetic acid in rat bladders, a rise in c-fos, a neurotransmitter for pain in the central nervous system, was seen in the sacral micturition centre. Rats that underwent acetic acid installation as well as PTNS showed a significant lower c-fos expression.

In our study, PTNS had a positive effect in 39% of 33 pelvic pain patients (objective success and partial response together), who were refractory to all other previous treatments. A subjective response was seen in 42% of all cases. As can be suspected, most patients with objective changes considered themselves a subjective success as well (69%). Not all patients with an objective response were satisfied enough to continue treatment after the initial 12 weeks. On the other hand, five patients, with no objective response on pelvic pain whatsoever, considered themselves a therapeutic success. All had experienced some pain relief after several PTNS sessions, which disappeared at the end of the course.

To minimise the effects of regression to the mean, only patients who had complaints for over 6 months (median 5 years) were included in our study. On the other hand, cyclic changes in pain patterns could not completely be ruled out, although quick changes were met by keeping diaries during 1 week and recording not only highest and lowest VAS, but also the mean VAS over 7 days. To prevent interference by other treatment modalities, concomitant physiotherapy was not allowed as was the case with starting probable influencing medication. When drugs were already in use, patients had to stop 2 weeks

prior to PTNS or to continue this medication during the entire 12 weeks. As our study was not placebo-controlled, a placebo effect cannot be ruled out. Percutaneous stimulation of the tibial nerve is prone to these effects because of a great deal of personal attention and care within many outpatient clinic visits. Unfortunately, it is most likely that a good placebo-controlled PTNS study is not feasible. We found patients with years of medical history and many failed therapies very well informed on new treatment techniques, making any placebo too different from PTNS useless. Also, placement of a percutaneous needle alone, without electrical stimulation may already have some effect. Maybe placebo acupuncture needles will provide a future possibility for placebo-controlled studies [24].

An important way to improve treatment results in the future is the determination of clear selection criteria. Although 33 patients is too small a number to reliably determine prognostic factors, evaluating some characteristics in patients with or without a $\geq 25\%$ objective improvement of the mean VAS for pain seems to reveal that age, sex or mean VAS for pain prior to PTNS is not of great importance. Patients with a shorter period of complaints and less failed therapies in the past tend to do better. Also, in patients with an objective improvement, deep pain (perineal, (peri)anal and vaginal) seemed to be the most present feature, whereas patients without objective improvement primarily seemed to suffer from more superficial pain (suprapubic region, groin, scrotum). This seems not surprising as the visceral organs neurologically overlap better with stimulated level S3 than the superficial regions do.

Furthermore, the technique may be improved by changing the treatment schedule. In patients with an overactive bladder, Klingler et al. [9] stimulated 12 times at a rate of four per week, obtaining much better results than other authors stimulating once a week for 12 weeks [10,11]. And, as in sacral nerve stimulation bilateral stimulation seems to improve results [25,26], stimulating both posterior tibial nerves concomitantly is an interesting future study objective.

5. Conclusions

Although success rates found in our study are very modest, they are comparable with what has been found in other forms of neuromodulative treatment. Nevertheless, there is a clear need for placebo-controlled data, however difficult a placebo study design. Furthermore, research is needed on the mode of action, optimal treatment scheme, long-term effects of the treatment and selection criteria, to increase the benefit

of Percutaneous Tibial Nerve Stimulation in patients with chronic pelvic pain. In our study, PTNS was found to be minimally invasive and easy applicable in pelvic

pain patients. In this patient group PTNS might be effective, but the lack of a controlled study cannot allow any larger assessment.

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Editorial Comment

J.L.H.R. Bosch, Rotterdam,
The Netherlands

The authors are to be commended for their attempts to explore treatment options for chronic pelvic pain patients. Their study on the use of PTNS (Stoller Afferent Nerve Stimulation), however, has many weaknesses precluding a final conclusion. Among others these problems include the following: there is no clear formulation of a hypothesis that is going to be tested, the study is not placebo controlled which is a capital sin in the evaluation of pain treatments, the authors did not

account for cyclical changes in pain severity that occur even without treatment.

The criterion for objective success: a >50% decrease on the VAS scale is on average not achieved. In spite of this, the paper tries to convey a positive message: PTNS is “minimally invasive”, “easily applicable”, “might be effective”. Fortunately, the valid conclusions are also to be found in the paper and in the authors’ own words these are two-fold:

1. A placebo effect cannot be ruled out.
2. The number of patients is too small to reliably determine prognostic factors.