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ORIGINAL ARTICLE

Percutaneous tibial nerve stimulation (pTNS): success rate and the role of rectal capacity

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Abstract
Purpose Percutaneous tibial nerve stimulation (pTNS) was originally developed to treat urinary incontinence. Recently, some case series have also documented its success in the treatment of fecal incontinence. Nevertheless, the mechanism underlying this effect remains unknown but may be related to changes in rectal capacity. The aim of this study was to investigate the success of pTNS for the treatment of fecal urge incontinence and assess the influence of rectal capacity on treatment efficacy.
Methods All patients undergoing pTNS for fecal incontinence between July 2009 and March 2014 were enrolled in a prospective, observational study consisting of a therapeutic regimen that lasted 9 months. Therapy success was defined as a reduction in the CCI (Cleveland Clinic incontinence) score of ≥50% and patient-reported success. Furthermore, quality of life (Rockwood's scale) and changes in anorectal physiology were recorded.
Results Fifty-seven patients with fecal urge incontinence were eligible, nine of whom were excluded. The success rate was 72.5%. Incontinence events and urge symptoms were significantly reduced after 3 months and at the end of therapy. The median CCI score decreased from 12 to 4 ($P < 0.0001$), and the quality of life was significantly improved. However, rectal capacity was not significantly related to treatment success before or after therapy. No adverse events were observed.
Conclusions These results demonstrate that pTNS can improve the symptoms and quality of life of patients with fecal urge incontinence. However, the study fails to demonstrate a correlation between treatment success and changes in rectal capacity.

Keywords pTNS · Percutaneous tibial nerve stimulation · Fecal incontinence · Rectal capacity · Neuromodulation

Introduction

The peripheral stimulation of the posterior tibial nerve has shown promise in the treatment of fecal incontinence. Today, two forms of tibial nerve stimulation are performed: transcutaneous tibial nerve stimulation (tTNS) applied over an adhesive electrode and percutaneous tibial nerve stimulation (pTNS) applied over a fine-needle electrode [1]. Previous case studies and a small randomized controlled trial (RCT) suggested that pTNS is more effective than tTNS [2, 3], and some data suggest that pTNS is more effective for patients suffering from urge and mixed incontinence than patients suffering from purely passive incontinence [4].

Similar to sacral nerve modulation (SNM), the mechanism by which pTNS improves fecal incontinence is not fully understood, and most authors believe the mechanisms of pTNS and SNM are similar [1] with multifactorial effects that

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involve the modulation and stimulation of efferent and afferent nerves. Some studies investigating SNM or pTNS have shown modified afferent rectal sensory inputs, pelvic striate muscle activation, and rectal and anal relaxation/contractions [5, 6]. Moreover, an impressive increase in rectal capacity and lower sensitivity to distension were demonstrated in patients undergoing SNM [6, 7].

Fecal incontinence is a major health issue that affects approximately 2–4% of the general population, and its incidence is thought to be underreported because of the shame associated with the condition [8, 9]. Affected patients suffer from a decreased quality of life (QoL) [10]. The standard surgical treatments are sphincteroplasty and SNM. The former is associated with a risk of severe complications, whereas the latter is cost intensive and is associated with a surgical revision rate of up to 26.3% in the long term (excluding the necessary battery replacements) [11, 12]. Therefore, pTNS might represent a good alternative treatment because it is less invasive and cheaper.

The aim of this study was to assess the success of pTNS in a cohort suffering from fecal incontinence with an urge component. Furthermore, rectal capacity and sensitivity were investigated to clarify the influence of these parameters on the efficacy of pTNS.

Material and methods

A prospective, observational analysis was performed of all patients undergoing pTNS therapy for fecal incontinence at a pelvic floor unit of a tertiary hospital in Switzerland. All patients suffering from fecal incontinence with an urge component (mere urge or mixed incontinence, a minimum of one urge episode per week (with or without concomitant loss of stool)) were offered pTNS treatment. Additional inclusion criteria were age over 18 years and unsuccessful conservative therapy consisting of pelvic floor exercises and loperamide medication for more than 3 months. Exclusion criteria were pregnancy, neurological lesions in the legs, and external sphincter defects >120°. Patients receiving oral anticoagulants or who were otherwise prone to bleeding and patients with severe cardiac illness, a pacemaker, or defibrillator were excluded for safety reasons.

The alternative treatments offered were SNM or sphincteroplasty, with the latter only offered to younger patients with a documented anal sphincter defect. All patients provided informed consent after receiving a full explanation of the therapy and the study. The study protocol was reviewed and accepted by the local ethics board and published under www.clinicaltrials.gov, identifier NCT01162525.

Treatment protocol

All included patients were examined at the outpatient clinic by obtaining a history and performing a clinical examination. The CCI (Cleveland Clinic incontinence) score [13], urge symptoms, a QoL questionnaire (Rockwood's Fecal Incontinence Quality of Life Scale (FIQL)) [14], and a visual analogue scale (VAS) score (0–10) of patient well-being in the context of fecal incontinence were collected. Furthermore, a gastroenterologist not involved in the treatment performed an in-depth anorectal physiological investigation. This investigation included the squeezing pressure, pressure at rest, and several other parameters, such as the rectal capacity measured at different sensitivity thresholds using a balloon. The treatment consisted of an initial therapy phase, a consolidation phase, and a weaning phase and was performed according to a slightly modified Stoller's scheme used to treat pelvic floor dysfunction [15]. The initial phase consisted of 12 weekly treatment sessions, and the consolidation phase consisted of four to six treatments approximately every other week. The therapy concluded with the weaning phase, which consisted of three treatments at intervals increasing from 3 to 4 weeks. Overall, 21 treatments were performed over a period of 9 months. A clinical follow-up and a reassessment of the scores and scales were performed at 6 weeks, after the initial phase at approximately 3 months, and at the end of the therapy (9–11 months). A second anorectal physiological assessment was performed at 3 months.

pTNS therapy

All patients were treated at the pelvic floor unit by a specialized nurse. A 34-gauge needle (0.1842 mm) was inserted approximately 5 cm above the medial malleolus 1.5 cm posterior to the tibia. An additional adhesive electrode was positioned over the plantar arch. The correct positioning of the needle was verified by inducing plantar flexion or abduction of the big toe (Fig. 1). A pulsating electrical stimulus was applied for 30 min (amplitude 9 V, pulse width 200 μs, frequency 20 Hz). The intensity (0–10 mA) was adjusted to a constant sensation of stimulation but below the level of discomfort. Treatment was performed using an Urgent® PC system (Uroplasty Limited, Netherlands) (FDA-approved for urinary incontinence treatment but not yet formally approved for fecal incontinence treatment). During each visit, the effect of therapy, VAS, and adverse events was documented.

Definition of outcome variables and statistical analysis

Success was defined as a reduction in the CCI score of at least 50% and patient-reported subjective success. To evaluate the

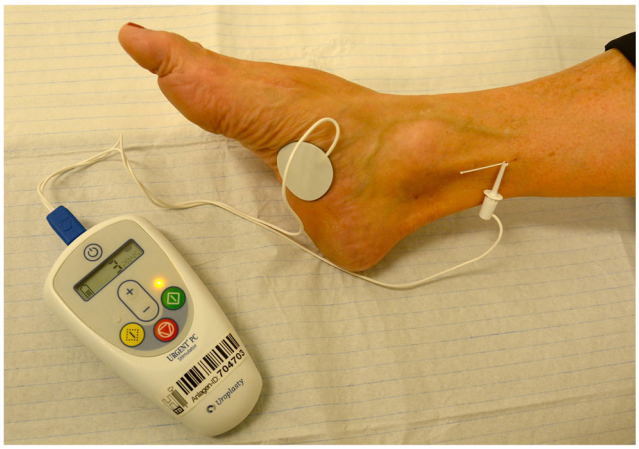

Fig. 1 Setup for pTNS therapy. The needle was inserted approximately 5 cm above and 1.5 cm behind the medial malleolus; an adhesive electrode was applied to the sole of the foot

influence of rectal capacity on the outcome, the patients were divided into two groups: a "success" group and a "no success" group, with the latter consisting of patients who did not achieve success after 3 months of treatment. Overall and within-group changes in rectal capacity were then analyzed. Furthermore, patients with a reduced capacity before therapy were investigated in a subgroup analysis. Urge episodes were evaluated with a score from 0 to 4, where 0 is less than one urge episode per day, and 1, 2, 3, and 4 are 1–2, 3–5, 5–9, and >9 episodes per day, respectively. Continuous outcome variables are reported as median and range or as mean and standard deviation, as appropriate. The Wilcoxon rank test was used (paired for comparisons of the same patients at different times, unpaired for the comparison of subgroups) to statistically analyze continuous data, and Fisher's exact test was applied for categorical data. A two-sided P value <0.05 was considered significant. The analysis was performed using IBM SPSS Statistics for Windows, version 20.0. (Armonk, NY: IBM Corp. 2011).

Results

Patients

Between July 2009 and March 2014, 57 patients suffering from fecal incontinence with urge symptoms were eligible for the study, 56 of whom were enrolled. One patient revoked his already-given informed consent before starting the therapy. Most of the patients who decided to participate in the trial were those who did not want to undergo a more invasive procedure. Eight patients had to be excluded from the

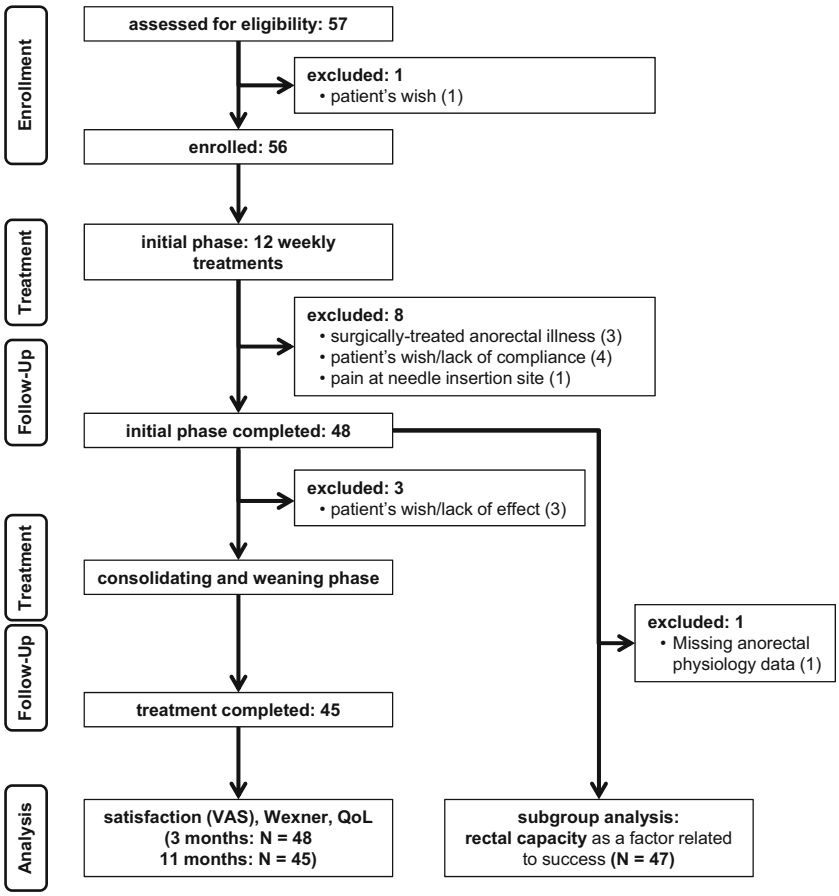

Fig. 2 Patient flow

Table 1 Main causes for fecal incontinence (in most patients, the cause was multifactorial)

	Number of patients (N = 48)	Percent
Obstetric injury	12	25
Rectal surgery (LAR[a] for rectal cancer 7; IPAA[b] for ulcerative colitis 1)	8	17
Anorectal surgery (STARR[c] 7; haemorrhoidectomies 2; fistula operations 2; tailgut cyst operation 1)	12	25
Rectal prolapse (previously surgically corrected)	4	8
Radiation injury (because of anal cancer 1; because of cervical cancer 1)	2	4
No apparent main cause	10	21
Total	48	100

[a] Low anterior resection

[b] Ileal pouch-anal anastomosis

[c] Stapled transanal rectal resection

analysis; an anatomical problem with the anorectum that required surgical treatment during the study period prevented the inclusion of three of these patients (one progressive stenosis after low anterior resection, two newly evident rectal prolapses). The remaining five excluded patients stopped treatment early (after 2–7 treatments). One patient suffering from leg pain after a fall experienced increasing pain when the stimulus was applied, and the remaining four patients withdrew from the study because they experienced an insufficient effect or because treatment was too inconvenient for them. After completing the initial phase of the therapy, three additional patients withdrew because of an insufficient effect on their incontinence (Fig. 2).

The 48 patients who completed the initial treatment phase had a median age of 63.9 years (range 23–87); 44 patients (91.7%) were female, and four patients (8.3%) were male. Table 1 summarizes the causes of their incontinence.

Effect of pTNS treatment on fecal incontinence and QoL

Success, which was defined as a reduction in the CCI score by at least 50% and subjective success, was observed in 17 (38.6%) of 44 patients after 3 months of treatment. Because of ambiguous communication, the subjective success at 3 months was not reported by four patients and, consequently, could not be assessed. At the end of treatment, success was documented in 29 (72.5%) of the 40 patients with complete data. The approximate intention-to-treat success rate was 60.4% (calculated by adding the eight patients who withdrew from therapy to the group of patients analyzed).

The frequency of incontinence events significantly decreased from a mean of 1.4 ± 2.1/ week to 0.6 ± 1.1/week after 3 months to 0.2 ± 0.4/week at the end of treatment ($P < 0.00001$). Correspondingly, the CCI score decreased from a median (range) of 12 (3–19) to 7 (1–19) after 3 months and ultimately decreased to a final score of 4 (0–15) ($P < 0.0001$) (Fig. 3). Moreover, the VAS scores for well-being significantly increased from a mean of 4.3 ± 2.2 to 6.7 ± 1.9; the final score was 8.0 ± 1.4 ($P < 0.0001$). The urge score decreased from a median (range) of 3 (0–4) to 1 (0–4) ($P < 0.0001$) (Fig. 4). The number of patients having only 1 min or less to reach the toilet decreased from 36 to 4.

After 3 months and at the end of therapy, the QoL had significantly improved compared to the QoL before treatment, as shown in detail in Table 2.

Sphincter pressure and rectal capacity

The resting sphincter pressure was not significantly different before and after pTNS therapy (mean 38 ± 14 vs. 40 ± 14 mmHg ($P = 0.46$)) nor was the increase when squeezing (60 ± 34 vs. 65 ± 29% ($P = 0.35$)). Additionally, the rectal volumes measured in the anorectal physiology tests did not significantly change. The volume of first rectal perception changed from 33 ± 31 to 37 ± 54 ml ($P = 0.85$), the volume

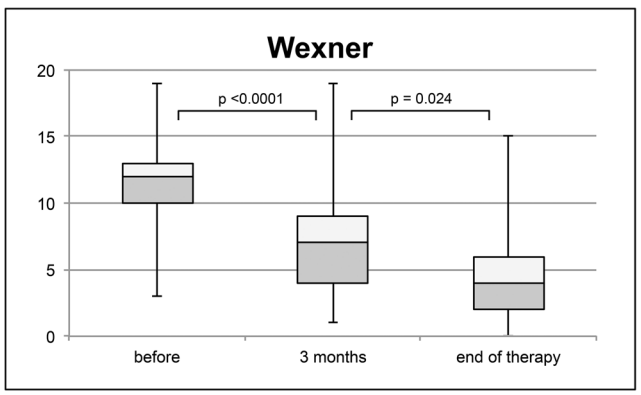

Fig. 3 The effect of pTNS therapy on the CCI score (best 0; worst 20). Box plots before, at 3 months, and at the end of treatment. The distribution of scores is shown as *box plots*, with the *darker box* representing the second quartile and the *lighter box* representing the third. The *line within the box* represents the median, and the *whiskers* represent the minimum and maximum scores; the same applies for the box plots in other figures

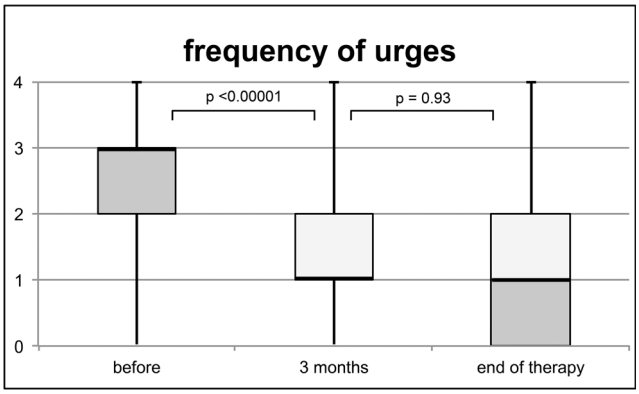

Fig. 4 The effects of pTNS on stool urge episodes (with or without concomitant incontinence), as evaluated using a score from 0 to 4, where 0 is less than one urge episode per day, and 1, 2, 3, and 4 are 1–2, 3–5, 5–9, and >9 episodes per day, respectively. The distribution of urge scores is demonstrated using *box plots* before, at 3 months, and at the end of therapy

of constant perception changed from 108 ± 67 to 107 ± 70 ml ($P = 0.60$), and the maximum tolerable volume changed from 179 ± 83 to 185 ± 94 ml ($P = 0.65$). The 37 patients with a less-than-normal constant volume perception (<130 ml) before therapy had a higher success rate than the 10 patients with a normal constant volume perception (43 vs. 10%); however, this difference was not significant ($P = 0.07$).

The rectal capacity values after therapy did not significantly differ between patients who experienced treatment success and patients whose treatment was not successful. In the "success" and "no success" groups, the respective mean volumes at first perception were 30 ± 17 and 26 ± 20 ml ($P = 0.46$), the respective mean volumes at constant perception were 99 ± 41 vs. 91 ± 36 ml ($P = 0.36$), and the mean respective maximum tolerable volumes were 172 ± 68 vs. 169 ± 85 ml ($P = 0.77$). Furthermore, after pTNS, these volumes did not significantly differ between the "success" and the "no success" groups in the subgroups with reduced first perception, reduced constant perception, and reduced maximum volumes before therapy (Fig. 5).

Adverse events

No adverse events were observed in the study population. The patient excluded due to pain in the thighs had already been suffering from that pain due to trauma to the pelvis; thus, the two sessions of pTNS were likely not the primary cause of pain.

Discussion

The present study shows that pTNS therapy is effective in patients suffering from fecal incontinence with an urge component. The CCI score decreased from 12 to 4, and the QoL clearly improved. Anorectal manometry did not reveal significant differences in the sphincter pressure or rectal capacity before and after pTNS treatment. Furthermore, changes in rectal capacity were not related to success.

The success rate at the end of treatment was 72.5%, which corroborates the 63–82% success rate reported in a recent systematic review of pTNS [2]. In that review, success was defined as a 50% reduction in lost stools per week, whereas in this study, it was patient-reported success and a 50% reduction of the CCI score, with the latter usually being more difficult to reach. Furthermore, all four domains of the FIQL markedly improved after pTNS, exceeding the improvements observed in the large case series published by Hotouras et al. in 2014 [16]. pTNS seems to be more effective in patients with urge fecal incontinence [4], which may explain the success observed in our cohort because only patients with an urge component were included. Until recently, all published data indicated that pTNS was an effective therapy for fecal incontinence [2]. However, a multicenter, double-blind RCT published in 2015 reported that pTNS failed to demonstrate a significant improvement in the primary endpoint compared to a sham control. The primary endpoint was a reduction of 50% in the lost stools per week, which was reached by 38% of patients treated with pTNS and by 31% of patients treated with the sham procedure. Nevertheless, episodes of fecal urge incontinence per week decreased from 3 to 1.5 after pTNS therapy, which was significantly different from the control [17]. Furthermore, a success rate exceeding 70% likely cannot be explained by a placebo effect alone because the success rate of placebo treatment only slightly exceeded 20% in a high-quality multicenter RCT of urinary incontinence and pTNS treatment [18]. Therefore, pTNS is likely effective in treating

Table 2 Quality of life (QoL) measured with Rockwood's Fecal Incontinence Quality of Life Scale (FIQL) [14] before, at 3 months, and at the end of pTNS therapy (median and range in parentheses)

	Pre-treatment	At 3 months	P^a	End of therapy	P^a
Lifestyle	2.7 (1.1–3.9)	3.0 (1.0–4.0)	0.006	3.2 (2.3–4.0)	0.039
Coping and behavior	2.0 (1.0–3.5)	2.3 (1.0–4.0)	0.00004	2.9 (1.3–3.8)	0.004
Depression and self-perception	2.6 (1.3–3.8)	2.8 (1.4–3.8)	0.007	3.3 (1.5–3.9)	0.005
Embarrassment	2.0 (1.0–4.0)	2.3 (1.0–4.0)	0.0002	3.2 (1.0–4.0)	0.001

[a] Two-sided paired Wilcoxon rank test, compared to pre-treatment

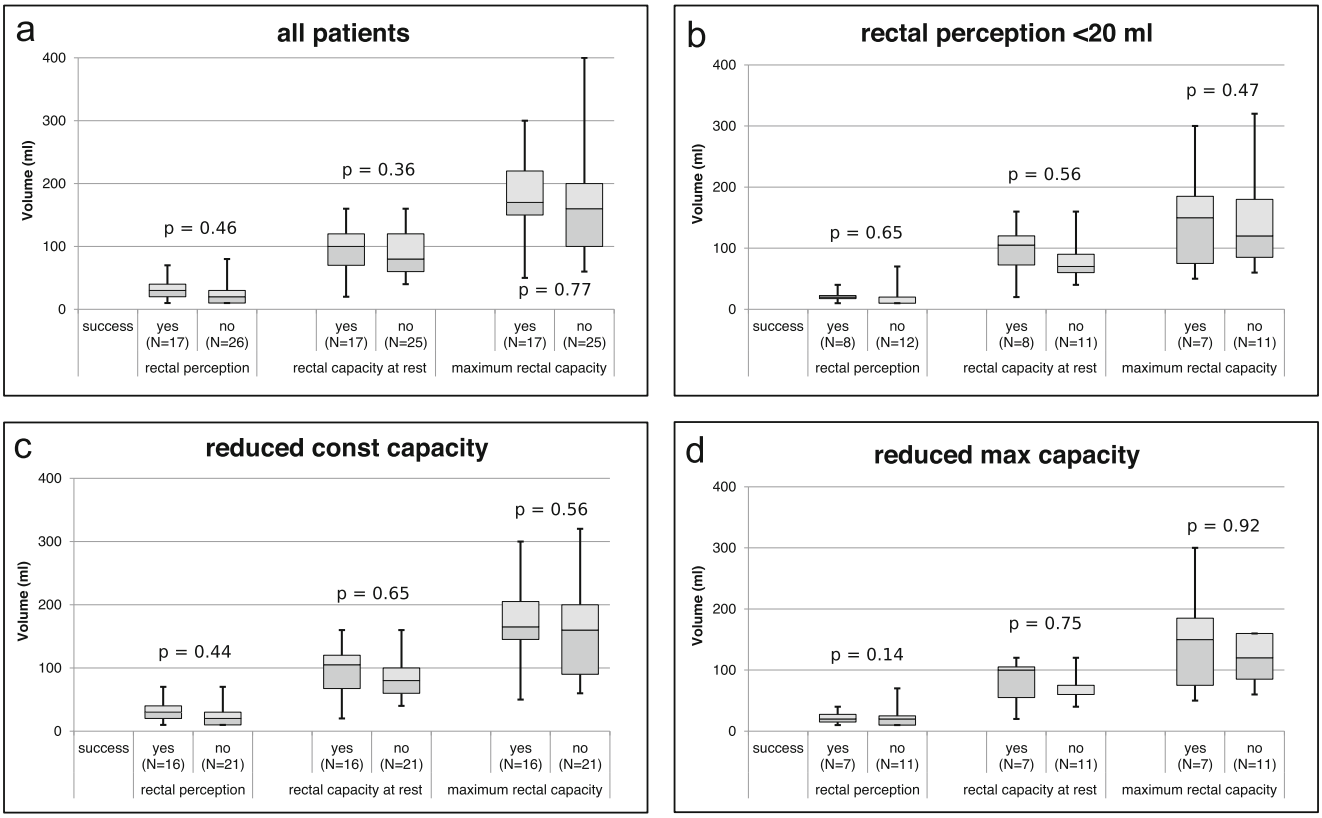

Fig. 5 Rectal capacity after 3 months of pTNS. Comparison of the capacity values of the "success" and "no success" groups. **a** The rectal volumes at first perception, constant perception, and the maximum tolerable volume of all patients (no subjective success information was available for four patients, and they were therefore excluded from the analysis). **b** Rectal volumes of patients with initial volume <20 ml at first perception. **c** Rectal volumes of patients with a low initial volume for constant perception. **d** Rectal volumes of patients with low initial maximum tolerable volume

urge fecal incontinence, and the lack of significant success in the new RCT [17] might be explained by the inclusion of patients with purely passive incontinence.

Other than the unrelated leg pain of the excluded patient, adverse events were not noted in this study. Many other publications also reported no severe adverse events; the most severe adverse event described to date was a temporary sensitivity loss in parts of the cutaneous branches coming from the tibial nerve. This adverse event occurred in two women treated for overactive bladder, and the symptoms completely resolved. Thus, pTNS can be considered a safe procedure [2, 17, 18].

The 72.5% success rate of pTNS does not seem to be inferior to that of SNM, which was approximately 80% in a recent systematic review [19]. Although SNM was more effective than pTNS in a direct comparison in a small RCT [20], SNM is associated with a higher rate of complications (approximately 10%), which sometimes even required device removal [21]. Furthermore, pTNS is cheaper than SNM. The cost of treatment for one patient in this study was approximately 1750 € and consisted mainly of the specialist nurse's salary, disposable materials, and the stimulation device. In comparison, the device and the two operations for SNM cost more than 18,450 €. This cost discrepancy has already been discussed in a previous report [22].

The mechanism underlying the efficacy of pTNS remains unclear, and the sphincter pressure and rectal capacity measurements did not elucidate this mechanism. Other studies showed a slight improvement in the sphincter pressures [23, 24], whereas most other authors did not comment on this issue [16, 25] or did not observe changes in the sphincter pressures [26, 27]. Thus, the efficacy of pTNS likely is not due to improved sphincter pressure. Although an increase in rectal capacity is at least partly responsible for the efficacy of SNM [6, 7], no such effect was found in the patients treated with pTNS in this study, which may be due to the use of sensitivity thresholds instead of a barostat device for volumetric assessment. However, a recent small RCT using a barostat also did not demonstrate significant changes in rectal compliance after tTNS compared to the sham treatment [28]. Shafik et al. investigated a special group of patients suffering from too late or not felt first rectal "sensations" or urge "sensations" during rectal distension and showed an improvement in these parameters in response to pTNS [5]. Therefore, the mechanism of action of pTNS seems to be linked to rectal volume and

sensation, but this mechanism is likely more complex than a simple change in rectal capacity or compliance.

Moreover, the rectal capacity did not significantly change in patients with a hypersensitive rectum, as documented by decreased volumes at first sensation or constant perception, or patients with a low maximum tolerable volume before treatment. pTNS therapy remained successful in this subgroup of patients, as also reported in another case series [29]. Therefore, hypersensitive patients do not seem to respond especially well or poorly to pTNS therapy, and the normalization of these volumes is consequently not considered to be responsible for success in these patients.

Finally, some limitations of this study should be discussed. First, this study lacked a control group receiving placebo, sham, or alternative therapy because it was an observational trial for the therapy introduction. Furthermore, the patients were informed about alternative treatments, such as SNM or sphincteroplasty, before enrollment, and they were free to decide whether they wanted to participate in the pTNS study or receive such treatment, which may have introduced selection bias. Furthermore, the success rate was calculated for patients with complete data at the end of follow-up, which may result in an overly optimistic impression because it does not take into account the patients who dropped out due to insufficient efficacy. Nevertheless, other studies do not provide intention-to-treat success rates at the end of follow-up, and the calculated approximate intention-to-treat success of 60.4% is in accordance with similar studies reporting values from 40 to 59.1% [16, 23, 25].

Conclusion

Although conflicting data have been published regarding the efficacy of pTNS for fecal incontinence in the literature, the results of our study are promising. The patients were satisfied with the therapy, severe adverse events were not observed, and the treatment was relatively inexpensive. Thus, pTNS is worthwhile to pursue, especially for patients with urge components and those not fit or ready for surgery.

The initial rectal capacity and the change in rectal capacity did not seem to significantly influence the efficacy of pTNS and should not be used as a criterion for patient selection. Further research should aim to identify the mechanism of action of pTNS to help identify patients who would benefit most from pTNS therapy.

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Compliance with ethical standards The study protocol was reviewed and accepted by the local ethics board and published under www.clinicaltrials.gov, identifier NCT01162525.

Conflict of interest The work presented here did not receive direct or indirect funding. L.M. received some funding for an educational fellowship 7 years ago from Medtronic, and F. H. was a consultant for Medtronic. Medtronic produces stimulators for SNM but not for pTNS therapy. For research/teaching on unrelated topics conducted by L.M., his institution received some financial support from Covidien-Medtronic, Medtronic, AMI, and Fumedica. The mentioned relationships may have influenced the work presented, although the authors are not aware of such an influence.

Ethical approval All procedures performed in the study presented involving human participants were performed in accordance with the current version of the Declaration of Helsinki, good clinical practice guidelines, and local legislation. Prior to the inclusion of the first patient, the study had been approved by the ethics committee of the Canton St. Gallen.

Informed consent Informed consent was obtained from all individual participants included in the study.

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