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Percutaneous posterior tibial nerve stimulation (PPTNS) in faecal incontinence associated with an anal sphincter lesion: Results of a prospective study

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ABSTRACT

Purpose: Establish the efficacy of posterior tibial nerve stimulation in treating faecal incontinence associated to sphincter defect.
Methods: Prospective study that included patients with faecal incontinence associated to sphincter lesions between 90 and 180°. Clinical anamnesis, physical examination, reverse visual analogic scale, incontinence diary and Wexner score were recorded at baseline and 6 months. Anal manometry was realized at baseline and 6 months.
Subjects underwent one 30-min session every week for 12 consecutive weeks and was continued with 6 additional sessions every 2 weeks.
Results: Sixteen patients were analysed, 15 women and 1 men, with a mean age of 56.5 years. The incontinence were obstetric origin (50%) and perineal surgeries (50%). Four patients who did not continue with the second stage.
Referring to the retention time, at baseline 12 patients (75%) did not bear even 1 min. At 6 months the retention time was <1 min in only 2 patients ($p = 0.008$).
Median Wexner baseline values were 10; at 6 months decrease to 5 ($p = 0.006$). The visual analogical scale (VAS) increased from 6 to 7.5 ($p > 0.05$). After 6 months, maximum resting pressure increased from 40.9 to 51 mmHg ($p < 0.001$) and maximum squeeze pressure from 82.5 to 94 mmHg ($p < 0.001$).
Conclusion: PTNS is an effective treatment for faecal incontinence associated to sphincter lesions because the number of incontinence episodes per week, the Wexner Score, the ability to defer defaecation and the manometric determinations improved significantly.

1. Introduction

Faecal incontinence (FI) is a prevalent and important condition, with a wide range of treatment options. An anal sphincter lesion (ASL) is the most common cause of faecal incontinence.[1,2] In these cases with ASL, when conservative therapy that include dietary modification, constipating medications, suppositories, physiotherapy/pelvic floor exercises and biofeedback has failed, the traditional surgical approach to this disabling condition is sphincter repair. However, long-term follow-up has shown that initial success tends to worsen over time with the reappearance of FI symptoms and decrease of satisfaction in approximately half the patients.[3,4]

Recently, sacral nerve stimulation (SNS) has been proposed as an effective therapeutic option for FI in patients with an anal sphincter lesion. However, SNS therapy has a high cost, requires an operating theatre and carries with it the risk of potentially significant complications.[5–7]

For this reason, posterior tibial nerve stimulation (PTNS) has been started using as an alternative or the first step before the utilization of the SNS. As it happened initially with the use of SNS, PTNS has been used only for FI associated with a neurogenic lesion or idiopathic, and evidence of trauma of the external anal sphincter (EAS) was an exclusion criterion.[8]

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In our knowledge, the use of PTNS in this specific group of patients with ASL has not been reported and could be a good option. The aim of this prospective study was to establish further the efficacy of PTNS in treating faecal incontinence associated to sphincter defect.

2. Methods

We performed a prospective interventional study. Patients with faecal incontinence of diverse causes, who were refractory to medical treatments, were included in the study. We selected patients that endoanal ultrasonography showed sphincter lesions between 90 and 180°. Exclusion criteria included inability to communicate (e.g., patients with Alzheimer's disease, among others), acute anatomical problems with possible surgical resolution (less than 3 months) and unwillingness to consent to participating in the study. Gravity stages or Wexner scale degrees were not considered exclusion criteria.

The patients were evaluated by surgeons who were members of the coloproctology unit at the General University Hospital of Elche and Reina Sofia Hospital of Murcia. The patients were interviewed and underwent a physical examination (examination of the anal canal, determination of weakness of the sphincter, scars or overview features). Complementary tests included anal manometry and anal ultrasonography. We determined the Wexner scale. According to the data obtained from the incontinence diary, the patients were divided into the following three groups: patients with fewer than 3 episodes of faecal incontinence per week (mild), patients with 3 and 7 episodes per week (moderate) and patients with more than 7 episodes per week (severe). Their perception of the degree of incontinence was quantified with a visual analogic scale (VAS). A reverse scale was used, with 0 being the worst and 10 the best.

After determining the initial diagnosis, the first 12 sessions of the percutaneous tibial neurostimulation (PTNS process were performed weekly and the next 12 every 2 weeks.

2.1. Manometry

Anorectal manometry was performed with a device from Albyn medical, Palex, with 8 channels and a poly-isoprene balloon, which was 4.9 mm in diameter (Serial MS4 1401, Ross-Shire, Escocia). The transductor was placed across the anal canal into the rectum. Manometric measures included sphincter pressures at rest and during squeeze time and at different distances from the anal canal.

A low resting pressure of the anal canal was used as the baseline measure for relaxation and tonic activities of both internal anal sphincter (IAS) and external anal sphincter (EAS). Squeeze pressure was measured while asking the patient to contract the EAS. We determined the tonic activities during relaxation (resting) and contraction (squeeze) at 6, 5, 4, 3, 2 and 1 cm from the anal border to identify the sphincter. The values were measured in millimetres of mercury (mmHg). The same tests were repeated after 6 months of treatment.

2.2. Anal ultrasonography

A high-frequency panoramic ultrasound scan within the anal canal was performed using the Pro Focus, Ultrasound Scanner Class I, Type B. Ref: 2002 SN1880355, BK Medical, model. Herlev, Dinamarca.

2.3. Posterior tibial nerve stimulation (PTNS)

The PTNS was performed by surgeons who were members of the coloproctology unit at the General University Hospital of Elche and Reina Sofia Hospital of Murcia. The urgent PC 200 Neuromodulation System® (Uroplasty, Minnetonka, MN, USA) was used. Subjects underwent one 30 min session every week for 12 consecutive weeks. Afterwards, we compared the values before and after treatment and repeated the treatment for an additional 6 sessions every 2 weeks in all patients that had shown any clinical improvements after the first stage.

Subjects were placed in the supine position without anaesthesia. PTNS was delivered using a needle electrode that was inserted 3–4 cm cephalad and 2 cm posterior to the medial malleolus at a 60° angle towards the ankle joint to a depth of approximately 0.5–1 cm. Successful placement was confirmed by the presence of electric sensation 5 cm above and below the insertion site or a digital plantar flexion. PTNS was undertaken at the highest amplification (0–20 mA) at a frequency of 20 Hz causing neither a motor response nor pain.

2.4. Variables

Data from clinical anamnesis, the physical examination, incontinence diary, VAS and Wexner score were recorded at baseline and after 3 and 6 months. Anal manometry was realized at baseline and 6 months.

2.5. Statistical analysis

Statistical analysis was performed using SPSS® software v.17.0 (SPSS, Chicago, IL, USA). We used Student's *t*-test and ANOVA to compare paired variables (when following a Gaussian distribution) and Mann–Whitney and Kruskal Wallis tests for variables without a normal distribution. The chi-square test was used to compare discrete variables. Pearson's correlation test was used to compare quantitative variables. A P-value <0.05 was considered significant.

3. Results

Sixteen patients were analysed, 15 women and 1 men, with a mean age of 56.5 ± 10.9 years. The incontinence causes can be summarized in obstetric origin (50%) and secondary to perineal surgeries (50%). Faecal incontinence antecedents are described in Table 1.

The time between the initiation of the symptomatic incontinence and the moment of first medical visit before the first year was only 18.75% (3 patients) (Table 2). More than 60% (10 patients) have waited over 10 symptomatic years. Associated symptoms to faecal incontinence were sexual dysfunction in 4 patients (25%), urinary incontinence in 2 (12.5%) and perineal pain in 2 (12.5%).

At the beginning of the study, median values of visual analogical scale (VAS) were 6 (Range:0–8), and Wexner scale degree was 10 (Range: 3–19).

The defecator diary showed 50% of the patient with fewer than 3 episodes of faecal incontinence per week (mild), 43.8% with 3–7

Table 1
Faecal incontinence antecedents.

Diabetes mellitus	18.8%
Radicular pathology	18.8%
Arterial hypertension	18.8%
Haemorrhoidectomy	18.8%
Anal fistulae	25%
Anal fissure	31.3%
Pelvic surgery	42.1%
Episiotomy	35.5%
Multiparous	56.3%

Table 2
Clinical and manometric results before and after treatment.

	Baseline	6 months	*p*
Maximum resting pressure	40.9	51	0.001
Maximum squeeze pressure	82.5	94	0.001
Wexner score	10	5	0.006
Retention time	2	4	0.008
Visual analogical scale (VAS)	6	7.5	0.001

incontinence episodes (moderate) and 6.3% with more than 7 episodes per week (severe).

Finally, the 75% of the patients had not any possibility of prolonging the retention time more than 1 min.

Four patients discontinued therapy by choice not because of clinical impairment.

3.1. Manometric determinations

Baseline manometric determinations were: maximum resting pressure (MRP) of 40.9 ± 26.2 mmHg, and maximum squeeze pressure (MSP) 82.5 ± 34.6 mmHg. After 6 months, MRP increased to 51 ± 31.2 mmHg ($p < 0.001$) and MSP to 94 ± 52 mmHg ($p < 0.001$).

3.2. Delay capability

Referring to the retention time, at baseline 12 patients (75%) did not bear even 1 min. At 6 months the retention time was <1 min in 2 patients, between 1 and 5 min in 3 patients, and >5 min in 7 patients ($p = 0.008$).

3.3. Wexner scale

Median baseline values were 10. At 6 months, median Wexner values decrease to 5 ($p = 0.006$).

The visual analogical scale (VAS) increased from 6 to 7.5, but statistical significance was not achieved.

4. Discussion

PTNS is a recently appeared therapy for the treatment of FI. A meta-analysis conducted by Thomas et al., in 2012 showed an improvement of 63–82% of the episodes of incontinence, improve of the Wexner scale and an improvement of the urgency symptoms in a total of 273 patients included. However, these studies are not comparable between them, because methodology of PTNS and evaluation systems were different in each group. Moreover, this studies also excludes patients with sphincter injury as from the start of therapy has been questioned as an exclusion criterion, or at least don't identify patients with sphincter injury.[8]

In our knowledge, our study is the first one that analysed the efficacy of PTNS in treating faecal incontinence associated to large sphincter defect. Our results suggests that PTNS is an effective treatment for FI in the presence of an ASL as shown on anal ultrasound because the number of incontinence episodes per week, the Wexner Score, the ability to defer defaecation and the manometric determinations improved significantly.

Hotouras et al. published a study of 88 patients of whom 37 had sphincter injury. They observed that patients with damaged anal sphincter complex had a higher mean incontinence score than those with intact sphincter complex prior to neuromodulation. PTNS resulted in improved incontinence scores, deferment time and weekly incontinence episodes for both groups of patients regardless of sphincter integrity. However, the methodology of this study is not defined classification of sphincter injury grades and damaged sphincter complex.[9]

The action mechanism of PTNS is still not completely understood. Stimulation of somatic afferents modulating visceral functions is most likely the main underlying neurophysiological mechanism. PTNS trigger a spinal and supraspinal somatovisceral reflex activating the sympathetic nervous outflow with inhibition of colorectoanal motility, increasing internal sphincter tone and rectal compliance, and also interfering with the rectal sensory thresholds for defecation.[10] It is hypothesized to access, indirectly, the same sacral nerve roots targeted in sacral nerve stimulation via the posterior tibial nerve, containing sensorimotor and autonomic fibres derived from the 4th and 5th lumbar and 1st to 3rd sacral roots.

Moreover it is uncertain how PTNS works in patients with ASL. Faecal incontinence is not merely due to the sphincter disruption. Although defects after childbirth are related to faecal incontinence, traction and damage to the pudendal nerve and rectal sensory and motordysfunction are also contributing factors. Treatment of incontinence is also multi-factorial and is not solely based on repairing the sphincter defect. This is supported by the fact that therapies such as biofeedback or pudendal nerve stimulation or SNS or PTNS, in the present study, can improve faecal incontinence in patients with ultrasound evidence of a sphincter defect.

On the other hand, PTLN has advantages in cost, simplicity of the procedure, risk of potentially significant complications, not requires hospitalization or operating theatre, compared to SNS.

According to a recent study conducted by Leroi et al.[11] on SNS, the calculated costs for the "test procedure," including care and operation time, amounted to 4000 €. The material costs for the permanent implantation procedure with the inclusion of hospital costs were 16.000 €. Taking into account costs at subsequent outpatient visits, the total cost for a patient having a permanent implant amounts to approx. 21.500 €. In comparison, the costs reported for PTNS are considerably less. The hospital and doctor costs for a 20- to 30-min session amount to about 25 €. For a patient needing treatment with 10 weekly sessions and then 5 monthly sessions, the total costs would be about 400 €.[12] Even some groups are working on the possibility that these treatments can be performed in the outpatient clinic by an adequately trained nurse or physiotherapist, and the effects can be maintained by the patients at home, which reduce costs and are convenient for both patients and healthcare providers.[13,14]

Sacral nerve stimulation (SNS) achieves complete continence in 41–75% of patients, with at least a 50% reduction in incontinence in 75–100%. However, in addition to undergoing an anaesthetic and invasive procedure, adverse events are seen in 12.8%, some of which (such as device infection and lead migration) mandate replacement or re-implantation in 6.7%. Furthermore, after approximately 8 years, device batteries must be replaced.[5–7,15] By contrast, a wealth of evidence supports the efficacy, safety and cost-effectiveness of PTNS in treating urinary and faecal incontinence. Technically simple to perform, there is no requirement for anaesthesia or insertion in the operating theatre.[16]

Similar stimulation may be possible with the use of pudendal nerve stimulator. The pudendal nerve supplies skin, organs and muscles of the perineum so is concerned with micturition, defaecation, clitoral erection and parturition. Improvement in the function of the pudendal nerve therefore should lead to improved anorectal physiologic parameters and reduction in symptoms for patients with faecal incontinence, particularly if its aetiology is perineal trauma or dysfunction leading to reduced anal tone. This pudendal nerve stimulator has advantages over similar devices in that it can be applied externally to the base of the clitoris or penis allowing easy application and removal. Frizelle et al.[17] showed a significant reduction in incontinence

symptom score after pudendal nerve stimulator treatment in the 42 patients treated and was accompanied by significant improvements in anal sphincter tone, maximal tolerated rectal volume and the sustained rectoanal inhibitory reflex.

Our treatment strategy for patients with faecal incontinence and an anal sphincter defect has changed as a result of the present study. After the failure of hygienic-dietary measures and biofeedback, we now start with a PTNS regardless of the morphological state of the anal sphincter complex. If this therapy fails, we proceed to asses SNS or surgery.

However, we need randomized clinical trials to prove if PTNS is the first best option and an effective treatment for faecal incontinence in the presence of an anal sphincter defect.

5. Conclusion

PTNS is an effective treatment for faecal incontinence in the presence of an anal sphincter defect because the number of incontinence episodes per week, the Wexner Score, the ability to defer defaecation and the manometric determinations improved significantly.

Ethical approval

Yes. Ethic Comitte of Elche Hospital.

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Author contribution

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Critical revision of manuscript – A Arroyo, P Parra A Lopez.

Conflict of interest

None.

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