

Posterior tibial nerve stimulation in the treatment of fecal incontinence: a systematic review

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ABSTRACT

Fecal incontinence severely impacts on quality of life, causing stigmatization and social exclusion. Posterior tibial nerve stimulation (PTNS) is one technique used for treatment. This systematic review aims to assess the effectiveness of PTNS for the treatment of fecal incontinence.

A literature review was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) declaration. Pubmed, Scopus, Web of Knowledge and PEDro databases were searched for both randomized clinical trials and cases series. The outcome variables were treatment effectiveness, severity of incontinence and quality of life; all were measured in the short, mid and long-term after performing both percutaneous and transcutaneous PTNS. Twenty-three studies met the selection criteria. Two clinical trials found significant differences in treatment effectiveness compared to the placebo response. Fifteen cases series observed significant differences in terms of effectiveness, severity and quality of life. All clinical trials achieved a reduction in the number of incontinence episodes and an increase in the deferral time for defecation. Optimal results were achieved by interventions consisting of one or two weekly sessions of a 30-60 minutes duration and the use of pulse widths of 200 μ s and frequencies of 10-20 Hz. Percutaneous stimulation did not demonstrate better results compared to transcutaneous application. PTNS is an effective technique for the treatment of fecal incontinence, although long-term interventions are required in order to prolong its effects in the long-term.

Key words: Transcutaneous electrical nerve stimulation. Percutaneous electrical nerve stimulation.

INTRODUCTION

Anal incontinence is defined by the International Continence Society as "any involuntary loss of fecal material and/or gas" and can be classified as fecal incontinence (FI) or gas incontinence (1). The prevalence is 10-15% in the gen-

eral population (2-4), causing a significant impact on quality of life, and leads to stigmatization and social exclusion on occasions (5). The etiology of FI is usually multifactorial. Physiopathologic mechanisms can be classified into four categories (6): structural abnormalities (muscular, neurological and/or visceral); physiologic abnormalities (changes in anus-rectum sensitivity, fecal impaction); characteristics of feces (changes in their consistency, volume or frequency; presence or absence of irritants) and other mechanisms.

A wide array of techniques are available for the treatment of FI (1). Following the failure of standard measures (diet changes, rehabilitation of pelvic floor, biofeedback, pharmacological treatment), the next line of treatment includes neuromodulation (1). This technique uses low-frequency electric currents for the direct or indirect stimulation of the spinal nerves (7). This includes neuromodulation of the sacral nerve (8) and posterior tibial nerve stimulation (PTNS) (8,9). PTNS is more economical (10) and does not require the surgical implantation of permanent devices. There are two modalities for PTNS application: a percutaneous route using a needle electrode and a transcutaneous route via a surface electrode (9).

Previous reviews (5,11,12) have concluded that PTNS is an effective technique for the treatment of FI. However, none have specified the optimal parameters for the application of the current, such as scheduling and the frequency of sessions. Furthermore, there is a lack of published randomized clinical trials (RCTs). Thus, meta-analysis to compare different controlled PTNS interventions in order to produce a quantitative synthesis cannot be performed.

The aim of this systematic review was to assess the usefulness of PTNS for the treatment of FI in terms of effective-

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ness, severity of incontinence and quality of life, as well as to identify any differences in protocols and/or outcomes that result from the type of electrostimulation used.

MATERIALS AND METHODS

This review was conducted in accordance with the PRISMA declaration (13). A literature search of Pubmed (Medline), Scopus, Web of Knowledge and PEDro databases was performed in order to identify scientific articles published up to March 2017 in Spanish, English, French, Italian or Portuguese. Bibliographic references from relevant articles were examined to identify articles that had not been identified in the primary search but met the inclusion criteria. The key words used for the search included: "fecal incontinence" OR "faecal incontinence" OR "anal incontinence"; AND "electrical stimulation" OR "tibial nerve stimulation" OR "Stoller stimulation" OR "PTNS".

The criteria for inclusion included: a) subjects: patients diagnosed with FI; b) study type: randomized controlled trials (RCTs) or prospective observational studies (also referred to as cases series); c) intervention type: PTNS programs (transcutaneous and percutaneous); and d) outcome variables: treatment effectiveness, severity of incontinence and quality of life. The criteria for exclusion included: a) studies with sample sizes of < 10 subjects; b) studies including subjects of < 18 years of age; c) intracavitary stimulation studies; d) surgical procedures for treating FI; and e) articles that did not provide specific data on any of the outcome measures previously mentioned.

Two reviewers (RAF and AFM) carried out the search, selection and evaluation of the methodological quality of the articles independently, as well as the data extraction. Possible discrepancies were resolved by a consensus. For each of the selected articles, the two reviewers independently extracted the following data: a) characteristics of subjects (sample size and age); b) treatment's characteristics (type and parameters); c) treatment planning (duration and frequency); and d) outcome variables (type of test, time points of evaluation and outcome measurements).

The Physiotherapy Evidence Database (PEDro) scale was used in order to evaluate the methodological quality of articles. This is based on the Delphi list and its reliability to assess the quality of RCTs has been validated (14). On the other hand, the methodological quality of observational studies was rated via the Quality Assessment for Cases Series scale, by the National Institute for Health and Care Excellence (NICE) (15).

RESULTS

The initial keywords search identified a total of 287 studies. After excluding duplicates and articles that did not meet the inclusion criteria, a total of 23 articles were selected for the review, five from the manual search (Fig. 1).

Characteristics of studies

The characteristics of the 23 studies included are described in tables 1 and 2. Table 1 shows the RCTs (8,9,16-19) and table

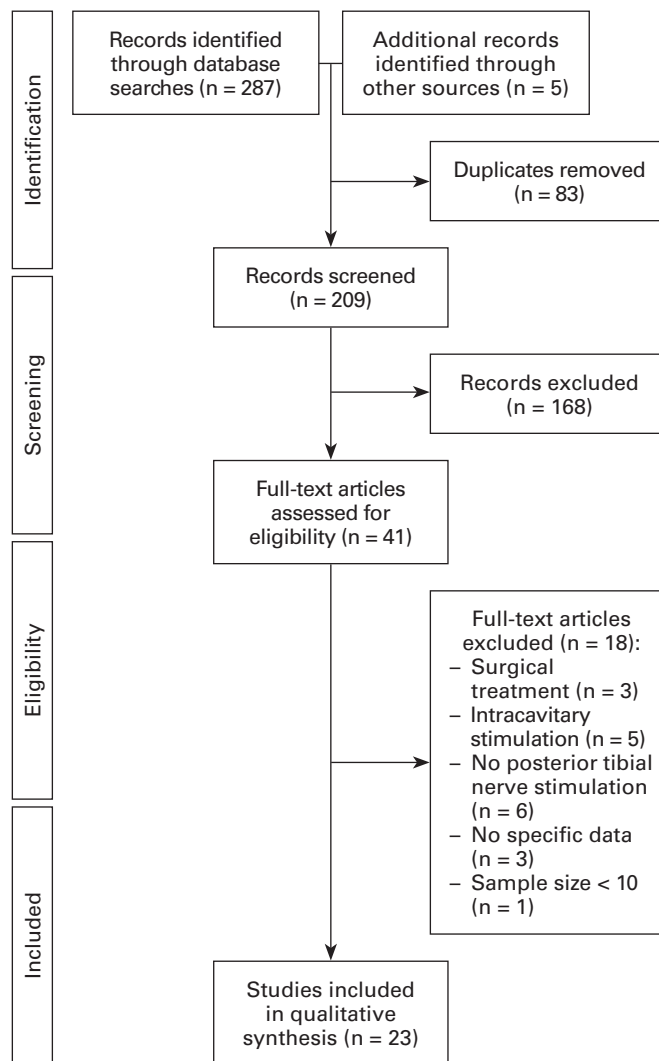


Fig. 1.

2, the descriptive longitudinal prospective studies (20-35). Of the six RCTs, only three included a sham stimulation (8,9,16). Transcutaneous PTNS was performed in four of the studies (9,16-18) and percutaneous PTNS, in three (8,9,19). One study (9) included three arms in order to compare percutaneous and transcutaneous stimulation with a placebo group. Therefore, this article was selected for both stimulation modalities. The length of treatment varied between 1.5 and 6 months, with a wide variability in the frequency of sessions that ranged from two daily sessions at the beginning of treatment to one weekly session. There was also a wide variability in the current frequency, which was either 10 or 20 Hz (Table 1).

With regard to prospective studies, stimulation was performed transcutaneously in six interventions (20,22,24,27,30,34) and percutaneously in eleven (10,21,23, 25,26,28,29,31-33,35). The duration of the intervention treatment was 1.5 to 26 months. The variability found in the frequency of the current application and current parameters was similar to that of RCT (Table 2).

The RCTs that were included in this review obtained a mean score on the PEDro scale of 6.83 (SD = 1.17, maximum = 11), whereas the 17 prospective studies obtained an average of 4.29 (SD = 0.92, maximum = 8) points on the Quality Assess-

Table 1. Characteristics of randomized clinical trials

Study	Study groups	n	Current parameters and intervention protocol	Follow-up (months)	Methodological quality* (0-11)
	G1: PPTNS	115	200 µs; 10 Hz; 30 min; 1 session/week; 12 weeks	3	8
	G2: Placebo	112	Placebo stimulation; 12 weeks		
	G1: TPTNS	11	200 µs; 20 Hz; 30 min; 2 sessions/week; 6 weeks	1.5	8
	G2: EPNTP	11	200 µs; 20 Hz; 30 min; 2 sessions/week; 6 weeks		
	G3: Placebo	8	Placebo stimulation; 6 weeks		
	G1: TPTNS	73	200 µs; 10 Hz; 20 min; 2 sessions/day; 12 weeks	3	7
	G2: Placebo	71	Placebo stimulation; 12 weeks		
	G1: TPTNS	15	200 µs; 10 Hz; 30 min; 1 session/day; 6 weeks	1.5	5
	G2: TPTNS	15	200 µs; 10 Hz; 30 min; 2 sessions/week; 6 weeks		
	G1: TPTNS	22	200µs; 10Hz; 60min; 2sessions/week; 6 weeks	1.5	7
	G2: TPTNS	21	200µs; 10Hz; 240min; 2sessions/week; 6 weeks		
	G1: SNS	23	14 sessions	6	6
	G2: EPNTP	17	200 µs; 20 Hz; 30 min; session/week; 12 weeks + 3 sessions/2 months		

TPTNS: transcutaneous posterior tibial nerve stimulation; µs: microseconds; Hz: hertz; min: minutes; PPTNS: percutaneous posterior tibial nerve stimulation; SNS: sacral nerve stimulation.
*Physiotherapy Evidence Database (PEDro) scale.

ment for Cases Series scale. Contrary to transcutaneous treatments, the methodological quality of trials was a decisive factor for the effectiveness of percutaneous interventions. The RCT that obtained the lowest quality score also obtained the highest therapeutic effectiveness (19) (main bias in masking of subjects and therapists). In agreement with this, the case series with the lowest quality (25,26) obtained a greater reduction in incontinence episodes compared to the best quality series.

A total of 1,262 subjects diagnosed with FI participated in the studies (131 males and 1,131 females), with an average age of 58.48 (SD = 3.32) years. The average sample size of the groups was 50.52 (SD = 55.05) (Tables 1 and 2).

Measurement tools

The studies mainly assessed treatment effectiveness via a one-week diary for a self-reported stool data (8-10,16-19,21,23,25,26,28-32,35), which international associations recommend for the evaluation of bowel habits (36). This allows data of the total number of depositions, number of incontinence episodes (solid, liquid or gas), number of urge episodes or deferral time for deposition to be obtained.

The severity of FI focuses on two aspects: loss of fecal material and the mechanisms used for coping with it (37).

The Wexner Scale (20-22,27,31,33-35), Cleveland Clinic Incontinence Scale (CCIS) (10,16,18,19,23,24,26,28,29,32) and St. Mark's continence Score (8,9,17,30) were used for the evaluation, all of which are validated (38-40).

Quality of life was measured using three types of validated scales (41-47):

- *Generic:* Short Form 36 Health Survey (SF-36) (8,9,17-19,26,30,34) and European Quality of Life-5 Dimensions Questionnaire (EQ-5D) (8,18,19).
- *Specialized:* KESS Score (24), Anxiety Depression Score (24) and Hospital Anxiety and Depression Scale (HADS) (25).
- *Specific:* Fecal Incontinence Quality of Life Scale (FIQOL) (8,9,16,17,19,21,24-26,29,30,32-35), Gastrointestinal Quality of Life Index (GIQLI) (8) and International Consultation on Incontinence Questionnaire-Bowel Symptoms (ICIQ-BS) (8,18,25).

Outcome evaluations were conducted in the short-term (< 3 months) (8-10,16-18,22,28-30), mid-term (3-6 months) (19,20,23-25,31,33) and long-term (> 6 months) (21,26,27,32,34,35). The average follow-up time was 26.43 (SD = 23.95) weeks.

A qualitative review was performed, as the lack of homogeneity in therapeutic interventions and outcome measures

Table 2. Characteristics of case series

Study	Study group	n	Intervention protocol	Follow-up (months)	Methodological quality* (0-8)
Hotouras et al. (10)	PPTNS	146	200 µs; 20 Hz; 30 min; 1 session/week; 12 weeks	3	3
Queralto et al. (20)	TPTNS	10	200 µs; 20 Hz; 30 min; 1 session/day; 4 weeks + 1 session/day; 8 weeks in case of improvement	4	3
De la Portilla (21)	PPTNS	16	200 µs; 20 Hz; 30 min; 1 session/week; 12 weeks + 1 session/week; 8 weeks in case of improvement + 1 session/3 weeks; 8 weeks in case of improvement + 1 session/month in case of improvement	14	4
Vitton et al. (22)	TPTNS	12	200 µs; 10 Hz; 20 min; 1 session/day; 12 weeks	3	4
Boyle et al. (23)	PPTNS	31	200 µs; 20 Hz; 30 min; 1 session/week; 12 weeks + 2 sessions/2 weeks + 1 session/month	5	4
Eleouet et al. (24)	TPTNS	32	200 µs; 10 Hz; 20 min; 2 sessions/day; 4 weeks	6	5
Findlay et al. (25)	PPTNS	13	? µs; 20 Hz; 30 min; 1 session/week; 12 weeks	4	4
Govaert et al. (26)	PPTNS	22	200 µs; 20 Hz; 30 min; 2 sessions/week; 6 weeks + 1 session/week; 6 weeks in case of improvement + 1 session/2 weeks; 12 weeks in case of improvement	12	5
Vitton et al. (27)	TPTNS	24	200 µs; 10 Hz; 20 min; 1 session/day; 12 weeks + 1 session/day; 12 weeks in case of improvement + 1 s/month; 24 weeks in case of improvement	15	6
Hotouras et al. (28)	PPTNS	88	200 µs; 20 Hz; 30 min; 1 session/week; 12 weeks + 1 session/2 weeks; 4 weeks in case of improvement + 1 session/month in case of improvement	3	5
Hotouras et al. (29)	PPTNS	100	200 µs; 20 Hz; 30 min; 1 or 2 sessions/week; 12 or 6 weeks	3	4
Thomas et al. (30)	TPTNS	17	200 µs; 10 Hz; 30 min; 1 session/day; 6 weeks	1,5	4
Arroyo et al. (31)	PPTNS	16	? µs; 20 Hz; 30 min; 1 session/week; 12 weeks + 1 session/2 weeks; 12 weeks in case of improvement	6	3
Hotouras et al. (32)	PPTNS	115	200 µs; 20 Hz; 30 min; 1 or 2 sessions/week; 12 or 6 weeks + 1 session/month; 24 weeks in case of improvement	26	4
López et al. (33)	PPTNS	24	? µs; 20 Hz; 30 min; 1 session/week; 12 weeks	6	5
Jiménez et al. (34)	TPTNS	27	200 µs; 10 Hz; 20 min; 1 session/day; 4 weeks + 1 session/day; 8 weeks in case of improvement	12	4
Peña et al. (35)	PPTNS	55	200 µs; 20 Hz; 30 min; 1 session/week; 12 weeks + 1 session/2 weeks; 12 weeks	12	6

TPTNS: transcutaneous posterior tibial nerve stimulation; µs: microseconds; Hz: hertz; min: minutes; PPTNS: percutaneous posterior tibial nerve stimulation. * Quality Assessment of Cases Series in accordance with the National Institute for Health and Care Excellence (NICE).

among the different authors did not allow a quantitative review (meta-analysis) to be performed.

Treatment effectiveness

Incontinence episodes

Only two clinical trials (8,9) performed interventions that obtained significant improvements in the short-term. Transcutaneous PTNS obtained a greater reduction in the number of weekly FI episodes (6.4) compared to percutaneous PTNS (2.3) or sham stimulation (1.8) ($p = 0.044$) (9), whereas percutaneous PTNS obtained a greater reduction compared to sham stimulation (2.5 vs 2.1, $p = 0.021$) (8) (Table 3). Three prospective studies (29,30,32) achieved significant results at 1.5 and 3 months post-intervention; one reported a total absence of urge FI episodes (29) (Table 4). Only two prospective series observed significant results in the mid-term (23,25); both achieved a complete lack of stool escape (Table 4).

In the long-term, only three prospective studies (26,32,35) reported significant improvements. However, none of the patients attained a complete FI control (Table 4).

The success rate for a treatment is defined as a reduction of $\geq 50\%$ in FI episodes as reported in the stool diary (12). In this sense, only one RCT obtained significant short-term outcomes via transcutaneous stimulation (9).

Capability to delay the deposition

In the short-term, only one RCT (9) achieved significant improvements in the number of minutes of stool delay; transcutaneous PTNS was 4.8, percutaneous PTNS was 1.9 and sham stimulation was 0.4, $p = 0.010$ (Table 3), whereas three prospective studies (20,30,32) obtained significant delays of up to five minutes following the defecating stimulus (Table 4). In the mid-term, two non-randomized trials (23,31) obtained significant improvements by delaying deposition by four and two minutes respectively, compared to baseline values (Table 4). Finally, in the long-term, three cases series (26,32,35) obtained significant defecation delays of 9, 3, and 9 minutes, respectively (Table 4).

Severity of FI

Overall, none of the included RCT had statistically significant outcomes with regard to the severity scales of FI.

Table 3. Treatment effectiveness, severity of incontinence and quality of life in randomized clinical trials

Study	Effectiveness				Severity		Quality of life (LS/C/D/E)	
	FI episodes		Deferral (min)		Ini	FU	Initial	FU
	Ini	FU	Ini	FU				
Short-term follow-up								
Knowles et al. (8)								
G1: PPTNS	6.0	3.5	-	-	*14	14	[§] 2.7/1.7/3.1/2.0	3.0/1.9/3.1/2.7
G2: Placebo	6.9	4.8	-	-	*16	15	[§] 2.5/1.6/2.6/2.0	2.9/1.7/2.6/2.3
George et al. (9)								
G1: TPTNS	8.2	1.8	1.9	6.7	*19	12	[†] 2.1/1.6/2.3/1.6	2.7/2.2/3.0/2.0
G2: PPTNS	7.4	5.1	2.5	4.4	*18	14	[†] 2.3/1.6/2.5/1.5	2.4/2.0/2.7/1.8
G3: Placebo	6.5	4.7	2.2	2.6	*16	14	[†] 2.1/1.8/2.6/2.1	2.7/2.1/2.9/2.7
Leroi et al. (16)								
G1: TPTNS	1.7	1.0	1-5	1-5	[†] 11	8	[†] 2.7/2.0/2.7/1.7	3.0/2.5/3.2/2.0
G2: Placebo	2.9	1.6	1-5	1-5	[†] 11	9	[†] 2.5/2.1/2.8/1.7	2.9/2.2/3.0/2.0
Thomas et al. (17)								
G1: TPTNS (1 session/day)	5.0	3.5	-	-	*18	18	[†] 2.2/1.8/2.4/1.7	2.6/1.8/2.4/2.2
G2: TPTNS (2 sessions/week)	6.5	3.0	-	-	*21	17	[†] 2.7/1.7/2.6/1.9	2.8/1.8/2.9/1.9
Rimmer et al. (18)								
G1: TPTNS (1 h)	3.5	1.0	2.0	2.0	[†] 15	11	-	-
G2: TPTNS (4 h)	9.0	3.0	0.5	5.0	[†] 14	12	-	-
Mid-term follow-up								
Thin et al. (19)								
G1: SNS	11.4	4.9	-	-	[†] 16.2	10.4	-	-
G2: PPTNS	10.6	6.3	-	-	[†] 15.1	12.1	-	-

Values in italics have a $p < 0.05$ intra-group. FI: fecal incontinence; min: minutes; LS: lifestyle; B: behavior; D: depression; E: embarrassment; Ini: initial; FU: follow-up; PPTNS: percutaneous posterior tibial nerve stimulation; TPTNS: transcutaneous posterior tibial nerve stimulation; SNS: sacral nerve stimulation. *St. Mark's scale. [†]Wexner scale. [§]GIQL scale. [¶]GIQI scale.

Table 4. Treatment effectiveness and severity of incontinence in case series

Study		Effectiveness				Severity	
		FI episodes		Deferral (min)		Wexner scale	
		Ini	FU	Ini	FU	Ini	FU
Short-term follow-up							
<i>Transcutaneous application</i>							
Queralto et al. (20)		-	-	-	-	11.4	5.4
Vitton et al. (22)		-	-	-	-	13.3	12.3
Eleouet et al. (24)		-	-	-	-	14.5	11.1
Thomas et al. (30)		6	2	3	5	*20	*19
Jiménez et al. (34)	U	4.1	0	-	-	11	7
	P	1.2	0	-	-		
<i>Percutaneous application</i>							
Hotouras et al. (10)		4	1	1	5	12	10
De la Portilla et al. (21)		-	-	-	-	13.2	9.0
Govaert et al. (26)		19.6	9.9	1	5	11.6	8.2
Hotouras et al. (28)		5	1	1	5	12.2	9.1
Hotouras et al. (29)	P	4	3	5	12.5	11.5	9.41
	U	4	0	1	5	11.0	8.3
Hotouras et al. (32)	M	5	1	1	5	12.8	9.1
		5	1	1	5	12.0	9.4
López et al. (33)		-	-	-	-	15	14
Mid-term follow-up							
<i>Transcutaneous application</i>							
Eleouet et al. (24)		-	-	-	-	14.5	10.2
<i>Percutaneous application</i>							
Boyle et al. (23)		4	0	1	5	13	7
	G	6	0	-	-	-	-
Findlay et al. (25)	L	10	0	-	-	-	-
	S	18	0	-	-	-	-
Arroyo et al. (31)		-	-	2	4	10	5
López et al. (33)		-	-	-	-	15	10
Long-term follow-up							
<i>Transcutaneous application</i>							
Vitton et al. (22)		-	-	-	-	14	12
Jiménez et al. (34)		4.1	0	-	-	11	9
		1.2	0	-	-		
<i>Percutaneous application</i>							
Govaert et al. (26)		19.6	3.6	1	10	11.6	5.9
Hotouras et al. (32)		5	1	1	4	12.0	10.0
Peña et al. (35)		4	1	2	11	9.98	4.55
Summary							
Short-term	Transcutaneous	3.8	0.7	3	5	14.0	11.0
	Percutaneous	6.7	2.4	1.6	6.1	12.4	9.6
Mid-term	Transcutaneous	9.5	0	-	-	14.5	10.2
	Percutaneous	-	-	1.5	4.5	12.7	7.7
Long-term	Transcutaneous	9.5	1.9	-	-	12.5	10.5
	Percutaneous	2.7	0	1.3	8.3	11.2	6.8

Values in italics have a $p < 0.05$ intra-group. FI: fecal incontinence; min: minutes; Ini: initial; FU: follow-up; *St. Mark's scale; P: passive; U: urge; M: mixed; G: gas; L: liquid; S: solid.

In the short term, seven prospective studies (20,21,24,26,28,29,32) obtained significant values on the Wexner scale and one reduced severity of FI to half of the baseline values (20). Hotouras et al. (29) achieved a similar improvement for urge and mixed incontinence, but not for passive incontinence (Table 4). In the mid-term, seven cohort studies (20,21,24,31-34) managed to significantly reduce FI levels and one (20) obtained an improvement of > 75% compared to baseline values of FI severity (Table 4). In the long-term, four cases series (26,27,34,35) reported substantial improvements; this reached 50% in two cases (26,35) compared to the pre-intervention scores (Table 4).

Quality of life

Overall, no RCT obtained statistically significant results with regard to the quality of life scales specific for FI. In the short-term, seven prospective studies (21,24,26,29,30,32,34) observed significant increases in quality of life. However, only four (21,24,29,32) achieved this in the four dimensions assessed by the scale: lifestyle, behavior, depression and embarrassment (Table 5). On the other hand, two studies (24,25) found statistically significant improvements in quality of life in the mid-term. However, only in the dimensions of behavior and embarrassment in the first case and life-

Table 5. Quality of life in case series

Estudio	Escala Fecal Incontinence Quality of Life										
	Inicial					Seguimiento					
	E	C	D	V	Total	E	C	D	V	Total	
Short-term follow-up											
<i>Transcutaneous application</i>											
Eleouet et al. (24)	2.4	1.8	2.5	1.6	8.3	3.0	2.2	2.9	2.4	10.5	
Thomas et al. (30)	2.1	1.3	2.1	1.3	6.8	2.5	1.5	2.4	1.7	8.1	
Jiménez et al. (34)	3.0	1.6	3.2	2.0	9.8	3.6	2.8	3.2	2.7	12.3	
<i>Percutaneous application</i>											
De la Portilla et al. (21)	2.7	1.7	3.1	1.8	9.3	2.9	2.1	3.2	2.3	9.5	
Govaert et al. (26)	2.7	1.9	2.6	2.1	9.3	2.9	2.4	2.7	2.7	10.7	
Hotouras et al. (28)	P	3.0	2.3	2.9	2.2	10.4	3.1	2.6	3.2	2.3	11.2
	U	1.9	1.4	2.4	2.2	7.9	2.4	1.9	2.9	2.3	9.5
	M	2.4	1.7	2.9	2.0	9.0	2.9	2.4	3.3	2.6	11.2
Hotouras et al. (32)	2.4	1.6	2.7	2.0	9.7	3.3	2.2	3.5	2.4	11.4	
Mid-term follow-up											
<i>Transcutaneous application</i>											
Eleouet et al. (24)	2.4	1.8	2.5	1.6	8.3	2.9	2.4	2.8	2.3	10.4	
<i>Percutaneous application</i>											
Findlay et al. (25)	*	2.6	1.5	1.0	1.0	6.1	3.0	1.8	1.1	1.0	6.9
Long-term follow-up											
<i>Transcutaneous application</i>											
Jiménez et al. (34)	3.0	1.6	2.7	2.0	9.3	3.8	3.2	3.1	3.0	13.1	
<i>Percutaneous application</i>											
Govaert et al. (26)	2.7	1.9	2.6	2.1	9.3	3.2	3.0	3.1	2.8	12.1	
Hotouras et al. (32)	2.4	1.6	2.7	2.0	8.7	3.0	2.3	3.2	2.7	11.2	
Peña et al. (35)	2.4	2.3	2.6	2.5	9.8	3.5	3.2	3.1	3.0	12.8	
Summary											
Short-term	Transcutaneous	2.5	1.6	2.6	1.6	8.3	3.0	2.2	2.8	2.3	10.3
	Percutaneous	2.5	1.8	2.8	2.1	9.1	2.9	2.3	3.1	2.4	10.8
Mid-term	Transcutaneous	2.4	1.8	2.5	1.6	6.1	3.8	3.2	3.1	3.0	6.9
	Percutaneous	-	-	-	-	-	-	-	-	-	-
Long-term	Transcutaneous	3.0	1.6	2.7	2.0	9.8	3.8	3.2	3.1	3.0	13.1
	Percutaneous	2.5	1.9	2.6	2.2	10.0	3.2	2.8	3.1	2.8	12.0

Values in italics have a $p < 0.05$ intra-group. LS: lifestyle; B: behavior; D: depression; E: embarrassment; P: passive; U: urge; M: mixed. *ICIQ-BS scale.

style in the second case (Table 5). Finally, five interventions (21,26,32,34,35) concluded their follow-up with significant outcomes in the long-term. Only three (21,32,35) achieved this in all the quality of life dimensions (Table 5).

Adverse effects

Of the 23 studies included in this review, seven did not report about adverse effects (10,22,27,28,30,31,33) and six stated that there were no reported complications (17,20,21,23,24,34). The remaining studies reported a series of secondary effects that did not stop the treatment, with the exception of one case of thrombophlebitis and cellulitis (35). Irrelevant adverse effects included: local symptoms at the needle insertion point (light bleeding [9,29,32], irritation [18], itching and stinging [16], discomfort [19], or pain [8,25]); local symptoms in the lower limb (paresthesia [19] or tingling [26]) and remote symptoms in the abdomen (constipation [16], cramps [9], or stomach pain [26]).

DISCUSSION

Even if the effectiveness of PTNS for the treatment of an overactive bladder has been demonstrated (48), its applicability for the treatment of FI is still under question (5,11). Overall, the reviewed studies reported positive outcomes in terms of the reduction of the number of incontinence episodes, increasing deferral time for deposition and improvements in FI severity and quality of life scales. However, only two RCTs achieved statistically significant changes (8,9) in terms of treatment effectiveness and none achieved this in terms of FI severity or quality of life.

Treatment effectiveness

The success rate of the treatment is an outcome measure that few studies provide. This review shows slightly discordant results. While observational studies report improvements in ~60% of subjects after six weeks (26,30), which further increased in the mid (23) and long-term (26), RCT studies conclude otherwise. Among the RCTs, only the study by George et al. (9) obtained significant differences using transcutaneous PTNS compared to sham stimulation; 81.8% of subjects experienced improvements in $\geq 50\%$ of their symptoms. Neither of the two RCTs (8,9) that assessed reductions of $\geq 50\%$ of the symptoms reported significant changes with percutaneous PTNS.

The session frequency was one or two times per week, with the exception of Thomas et al. (30) and Leroi et al. (16), who used one and two daily sessions, respectively. No significant differences were found when varying the frequency of sessions for the application of the technique.

On the other hand, studies show that PTNS reduces the number of incontinence episodes recalled in the stool diary. Prospective studies show several cases series with a considerable reduction in the weekly stool frequency (10,23,25,29,30,32,34,35). Only two studies did not observe a significant improvement (10,34). Along these lines, two RCTs obtained substantial improvements using both trans-

cutaneous (9) and percutaneous (8) PTNS compared to placebo intervention, unlike the trial by Leroi et al. (16), who used surface electrodes. Furthermore, the evidence to determine whether the use of longer electrostimulation sessions (18) or a higher frequency of application (16,49) were more beneficial for the subject was inconclusive. In terms of deferral time for deposition, the outcomes achieved are in agreement with the reduction of incontinence episodes. In particular, those studies with significant reductions in the number of involuntary losses also achieved longer deferral lapses (9,23,26,29,30,32,35).

Severity of FI

The FI level, measured on both the Wexner and St. Mark's scales, decreased in clinical trials and non-controlled interventions. However, statistically significant differences were only found in prospective studies (20,21,24,26-29,31-35) and some intra-class comparisons in RCTs (16,17). Thus indicating the effectiveness of PTNS for the treatment of FI but not its superiority over sham stimulation in terms of severity scales.

Quality of life

Similarly to the FI severity outcome, both RCT and prospective studies obtained improvements in the quality of life scales, but statistical significance was only reached in non-controlled studies (21,24-26,29,30,32,34,35). Under equal conditions, lifestyle, behavior and embarrassment were the most frequently experienced improvements. The worst results were seen with the level of depression.

Current parameters for electrostimulation

While there appears to be an agreement on adjusting the pulse width to 200 μ s, this is not the case for the current frequency, which varies between 10 and 20 Hz. All the included studies on percutaneous PTNS employed 20 Hz with one exception (8), whereas transcutaneous PTNS uses 10 Hz currents, so that all study arms are equally treated, with the exception of two studies that used 20 Hz (9,20). It must also be noted that all studies on percutaneous PTNS, except for Knowles et al. (8), used an Urgent PC® current generator. This only allows for the application of frequencies of 20 Hz, while transcutaneous PTNS used electrostimulation devices that allow frequency modulation. Knowles et al. (8) showed that when using a 10 Hz frequency for percutaneous PTNS, this significantly reduced the number of incontinence episodes. George et al. (9) also observed this whilst using 20 Hz currents for transcutaneous PTNS. In view of this, we consider that conducting controlled clinical trials will be of interest to compare the effectiveness of different frequencies of electrostimulation and determine their optimal values. For the same treatment effectiveness, a 10 Hz frequency is preferable over 20 Hz. The former produces a subtetanic contraction in the muscles innervated by the posterior tibial nerve and the latter, a tetanic contraction. It is important to remember that the purpose of this technique is neuromodulation at the level of the spinal cord and not boosting the flexor and abductor digitorum muscles.

Technique safety

The absence of reports on severe adverse effects corroborates the safety of PTNS for the treatment of FI. Furthermore, in its transcutaneous modality, this technique can be self-applied by patients at home. PTNS is objectively less invasive and more economical (10) compared to other neuromodulation techniques, such as sacral nerve stimulation. Thus, many authors recommend it as the first choice for the treatment of FI (50).

This review included a greater number of RCTs and cases series than previous reports, which implies a greater sample size. On the basis of the studies reviewed, it also specifies the ideal parameters and scheduling in order to attain the best outcome. Nevertheless, the heterogeneity found in RCTs between the intervention and control groups does not allow for a quantitative synthesis of the results. Since a meta-analysis was not possible, the statistical assessment of the publication bias via an Egger test was not viable. This is important when valuing the outcome of this review. If such a bias existed, there would be a predominance of publications with favorable outcomes at the expense of less favorable ones. This would imply the overestimation of positive PTNS results.

The limitations of the present review include the heterogeneity among different studies, which hindered the perfor-

mance of a meta-analysis. On the one hand, no homogeneity was found between researchers in terms of their choices for measuring and presenting outcomes or between intervention and control groups in RCTs. Finally, PTNS should be considered as the first choice for the treatment of FI instead of being used as a specialized treatment (1). This is due to the positive results of PTNS in patients where previous conservative treatments have failed and also to its effectiveness and lack of adverse effects. Possible future lines of research should focus on the comparison of standard techniques *versus* neuromodulation as the initial FI treatment.

CONCLUSIONS

PTNS is an effective technique for the treatment of FI. Clinical trials and cases series achieved a reduction in the number of incontinence episodes and an increase in the deferral time for deposition. Improvements in the FI severity and quality of life scales were also achieved. A substantial superiority of transcutaneous *versus* percutaneous applications has not been observed. Interventions consisting of one or two weekly sessions of a 30-60 minute duration are optimal in order to obtain these results. Long-term treatments are required to achieve prolonged treatment effects.

Annex 1

METODOLOGICAL PROTOCOL OF THE REVIEW: STIMULATION OF THE POSTERIOR TIBIAL NERVE FOR TREATING FECAL INCONTINENCE: A SYSTEMATIC REVIEW

The review will be conducted in accordance with the guidelines of the PRISMA declaration.

Search strategy

A bibliography search in Pubmed (Medline), Scopus, Web of Knowledge, and PEDro databases will be performed.

The search will be limited to articles published in Spanish, English, French, Italian and Portuguese up to the date of the search. A manual search of the bibliographic references of the included articles will then be performed in order to identify articles meeting the selection criteria that were not identified in the primary search. If necessary, the researchers will contact authors to ask for information that is missing in the articles.

Selection of studies

Criteria for inclusion: a) subjects: patients diagnosed with fecal incontinence; b) study type: randomized controlled trials (RCTs), controlled clinical trials, or prospective observational studies; c) intervention type: posterior tibial nerve stimulation programs (transcutaneous and percutaneous); and d) outcome measures: treatment effectiveness, severity of incontinence and quality of life.

Criteria for exclusion: a) studies with sample sizes of < 10 subjects; b) studies including subjects < 18 years of age; c) studies using intracavitary stimulation or surgical procedures for treating FI; and d) articles not providing specific data on any of the outcome measures previously mentioned.

Data extraction

Two reviewers will independently perform the search and selection of articles as well as data extraction. Possible discrepancies will be resolved by a consensus. Finally, the information obtained by each reviewer from the reviewed literature will be combined.

For each of the selected articles, the reviewers will independently extract the following data: a) subject characteristics (sample size and age); b) treatment characteristics (type and parameters); c) treatment scheduling (duration and frequency); and d) outcome variables (type of test, time points of evaluation and outcome measures).

(Continue in the next page)

Assessment of methodological quality

The methodological quality of the selected clinical trials will be independently assessed by the two reviewers via the Physiotherapy Evidence Database (PEDro) scale. The reliability of this method for evaluating randomized clinical trials has been determined. Even though it includes eleven items, the authors only recommend using items 2-11, for which the maximum score is 10. Item 1 refers to external validity and hence is omitted in order to obtain the final score.

The methodological quality of case series will be measured via the Quality Assessment for Case Series scale by the National Institute for Health and Care Excellence.

Data analysis

The odds ratio (OR) and 95% confidence intervals (CI 95%) will be calculated for the data obtained. A fixed-effects model will be used to combine the results of the selected studies, based on the Mantel-Haenszel or random effects method, depending on whether statistically significant heterogeneity is reached ($p < 0.05$) or not. The EPIDAT software, version 4.2, will be used for the statistical analysis.

Heterogeneity assessment

The Cochran's Q and I^2 statistical tests will be used to estimate and quantify heterogeneity among the studies, so that 25%, 50%, and 75% values will correspond to low, moderate and high levels of heterogeneity, respectively.

Sensitivity analysis

A sensitivity analysis of the global outcome will be performed to check its reliability and robustness. For this, the meta-analysis will be replicated after omitting one of the included studies at each step and thereby assessing its influence on the global results.

Publication bias

The presence of publication bias will be determined via a funnel plot and Egger test.

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