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ORIGINAL ARTICLE

Transcutaneous tibial nerve stimulation to treat urgency urinary incontinence in older women: 12-month follow-up of a randomized controlled trial

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Abstract

Introduction and hypothesis Urgency urinary incontinence (UUI) is highly prevalent in elderly individuals and has a great impact on quality of life. Transcutaneous tibial nerve stimulation (TTNS) can be an effective treatment option for UUI in older women.

Methods This is a single-center randomized clinical trial with a 12-month follow-up involving 106 women > 60 years of age. Kegel exercises and bladder retraining were performed alone or in combination with TTNS, which consisted of using a transcutaneous electrical nerve stimulator for 30 min once a week for 12 weeks with the following settings: continuous mode, 10 Hz, 200 ms, and 10 to 50 mA (according to hallux mobilization). Responders to therapy who experienced failure during follow-up were invited for a 3-week protocol with the same parameters as those used for the initial therapy. Patients were evaluated at baseline, 4 weeks after the 12-week protocol, and every 3 months for 12 months, through subjective satisfaction questionnaires, a 3-day bladder diary and the International Consultation on Incontinence Questionnaire-Short Form. King's Health Questionnaire was applied pretreatment and 4 weeks after the last session of the 12-week protocol.

Results A total of 101 women completed the initial 12-week protocol. TTNS patients reported 66.7% subjective global satisfaction vs. 32.0% in the control group ($p < 0.001$). The TTNS group showed statistically significant improvement in quality of life (QoL) and UUI parameters compared with the control group. Forty-eight patients were satisfied after the 12-week protocol and completed the 12-month follow-up (32 in the TTNS group and 16 in the control group). A total of 80.5% of responders to TTNS were still satisfied at the end of the 12-month follow-up vs. 30.8% in the control group ($p = 0.009$).

Conclusion TTNS is effective at the 12-month follow-up for the treatment of UUI in elderly women.

Keywords Urgency urinary incontinence · Elderly · Electrical stimulation

Introduction

The prevalence of urgency urinary incontinence (UUI) increases throughout life. Several therapeutic options are available to manage urinary incontinence in elderly individuals [1, 2]. Electrical stimulation with nonimplanted devices is one therapeutic alternative for patients with overactive bladder (OAB), with limited evidence showing that it is effective and safe. The aim is to inhibit contractions of the detrusor muscle and reduce urinary frequency and urgency [3, 4]. The most common points used for electrical stimulation are the bladder, vagina, perineum, sacrum and tibia [5].

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Medication is often used to treat OAB, and the most commonly used drugs are anticholinergics; however, these often have side effects such as dry mouth, constipation, increased heart rate and even impaired cognitive function in elderly individuals [2, 5]. Tibial nerve stimulation is less invasive than other modalities, and several studies have reported good results, including improvement in quality of life (QOL) and urodynamic findings [6–10].

Many therapies used to treat urinary incontinence, despite good initial results, fail over time, which may compromise their use. Therefore, the durability of and need for reintervention with a proposed therapy are fundamental factors in the indication and situation of the patients in the treatment of UI [6–10].

This study evaluated the immediate and 12-month efficacy of TTNS in the treatment of UUI in elderly women.

Materials and methods

The patients were recruited from the Ambulatory Urogynecology Clinic of the São Lucas Hospital of the Pontifical Catholic University of Rio Grande do Sul, in accordance with the established inclusion and exclusion criteria.

Considering the 33% superiority in the tibial group according to our previous paper, a power of 90% and an alpha of 0.05, we calculated a total sample size of 86 women. We invited 106 women to participate, taking possible losses into consideration [10].

The inclusion criteria were women > 60 years of age with complaints of urinary incontinence and a uroculture with no bacterial growth in the past 7 days. The exclusion criteria were previous surgery for urinary incontinence, history of genito-urinary neoplasia, previous pelvic irradiation, exclusive or predominant stress incontinence complaints, genital prolapse > Baden-Walker grade 2, inability to perform pelvic-floor muscle training, presence of a cardiac pacemaker and use of anticholinergic medications in the last 4 weeks.

Consecutive patients who fulfilled the criteria and agreed to participate in the study completed a consent form, urogynecologic examination, questionnaire regarding demographic data, questionnaire regarding subjective satisfaction, 3-day bladder diary, the International Consultation on Incontinence Questionnaire-Short Form and King's Health Questionnaire. They were then randomized using an electronic random number generator. All evaluations were performed by a blinded researcher.

All patients were instructed to perform contractions of the pelvic floor musculature (15 contractions 3 times a day) and bladder retraining (or adequacy of the voiding habit) for 12 weeks. They underwent three clinical consultations (one per month) during the initial therapy period with gynecologists and urogynecologists to receive guidance regarding perineal muscle-strengthening exercises and voiding habits according to the initial standard treatment routine [4].

In the treatment group, 12 sessions (once a week) of unilateral transcutaneous electrostimulation were performed on the tibial nerve. The electrodes were placed as follows: the negative electrode was placed on the medial malleolus of the right ankle, and the positive electrode was placed 10 cm proximal to it, both connected to a conventional electrostimulator producing pulses varying from 10 to 50 mA (according to the sensitivity and mobilization of the patient's hallux during therapy). Each session was 30 min, with a pulse duration of 200 ms and a frequency of 10 Hz, in the continuous mode [10].

At the end of the initial therapies, patients who reported subjective satisfaction (evaluated with a yes/no question) with no desire for additional therapy at that time and a reduction > 50% in UUI episodes according to a 3-day bladder diary started a 12-month follow-up period including the ICIQ-SF and a subjective satisfaction questionnaire on urinary continence every 3 months. The remaining patients were excluded from the follow-up and referred for other therapies.

During follow-up, patients who had objectively worsened (1-point increase in the ICIQ-SF score) and/or reported subjective dissatisfaction related to urinary symptoms (subjective questionnaire) were invited to a reinforcement therapeutic cycle with three sessions of electrostimulation for the tibial group and reorientation regarding Kegel exercises and bladder retraining 1×/month for 3 months for the control group.

Statistical analysis was performed using the statistical program SPSS version 17.0. A descriptive analysis was performed through frequencies, means and standard deviations. For comparisons between groups, the following tests were used: chi-square test or Fisher's exact test when an expected value < 5 on the chi-square test occurred for categorical variables; Student's *t*-test for independent samples to verify the difference between means. For comparisons of the means before and after the intervention, in each group, Student's *t*-test was used for paired samples. Associations were considered statistically significant if the p value was ≤ 0.05. Additionally, the number needed to treat (NNT) was calculated according to intention-to-treat analysis after the initial randomization, and the follow-up was evaluated through per-protocol analysis. We performed the Kaplan-Meier test to assess therapy failure throughout follow-up.

The study was approved by the Research Ethics Committee of the Pontifical Catholic University of Rio Grande do Sul and registered in the Brazilian Platform for Clinical Trials with the following code: RBR-64S9TS.

Results

One hundred six women were studied between January 2012 and January 2018. Five left the study before completing the course of therapy and were excluded from the analysis (in the TTNS group, 1 patient moved from the city during the treatment, and 2 had health problems unrelated to the therapy; in the control group, 2 had health problems unrelated to the therapy). Three patients in the electrostimulation group reported discomfort at the point of placement of the electrode, posterior to the medial malleolus. They showed spontaneous improvement and continued to undergo electrostimulation.

One hundred one women had ages between 60 and 84 years, with a mean of 69.4 years and standard deviation of 6.2 years, with no significant difference in age between the study groups. The mean number of years of education was 5.6; the mean body mass index was 29.8 kg/m^2. There was no significant difference between the groups before initiation of therapy. After treatment, there were no significant changes in patient weight. Sixty-eight patients (67.3%) had previously undergone physiotherapy or drug treatment prior to being invited to participate in the study.

Prior to initiation of treatment, mixed urinary incontinence was present in 72 (71.3%) patients, and 74 (73.3%) were using incontinence pads; there was no significant difference between groups. After treatment, 51% of the women who underwent electrostimulation and 64.0% of those who did not perform this intervention continued using the incontinence

Table 1 Mean voiding frequency and number of urinary losses before and after therapeutic intervention, according to the study group, in 101 women with urgency or mixed urinary incontinence

Variable	Group 1 (n = 51) With EE mean ± SD	Group 2 (n = 50) Without EE mean ± SD	P[a]
Micturitions per day			
Before	7.8 ± 3.1	7.9 ± 2.5	0.647
After	6.0 ± 1.4	7.5 ± 2.3	
P[b]	0.020	< 0.001	
Difference	1.7 ± 2.9	0.4 ± 0.9	0.003
Nocturia			
Before	3.5 ± 1.6	3.0 ± 1.1	0.191
After	1.6 ± 1.5	2.3 ± 1.3	
P[b]	< 0.001	< 0.001	
Difference	1.8 ± 1.4	0.7 ± 1.1	< 0.001
Episodes of SUI (BD-72 h)			
Before	3.9 ± 4.3	5.4 ± 5.0	0.100
After	2.4 ± 3.3	3.7 ± 5.0	
P[b]	0.003	< 0.001	
Difference	1.5 ± 4.2	1.7 ± 2.5	0.827
Episodes of UUI (BD-72 h)			
Before	7.2 ± 4.5	6.2 ± 2.9	0.072
After	1.8 ± 2.7	4.9 ± 3.6	
P[b]	0.004	< 0.001	
Difference	5.3 ± 4.2	1.4 ± 1.6	< 0.001

EE transcutaneous electroestimulation of tibial nerve

Mean ± SD mean ± standard deviation

SUI Stress urinary incontinence

UUI Urge urinary incontinence

BD Bladder diary

[a] P value calculated by Student's t-test for independent samples

[b] P value calculated by Student's t-test for paired samples (before and after)

Table 2 Mean of International Incontinence Questionnaire (ICIQ-SF) score before and after therapeutic intervention, according to the study group, in 101 women with urge incontinence or mixed urinary incontinence

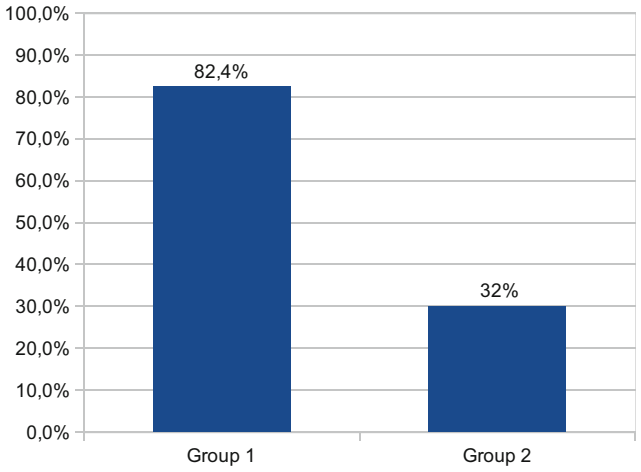
Moment	Group 1 (n = 51) With EE mean ± SD	Group 2 (n = 50) Without EE mean ± SD	P[a]
Before	15.7 ± 3.3	15.0 ± 3.0	0.238
After	8.3 ± 4.6	11.9 ± 5.0	
P[b]	0.026	< 0.001	
Difference	7.3 ± 4.7	3.0 ± 4.2	< 0.001

EE transcutaneous electrostimulation of tibial nerve

Mean ± SD mean ± standard deviation

[a] P value calculated by Student's t-test for independent samples

[b] P value calculated by Student's t-test for paired samples (before and after)



Group 1 – Transcutaneous Tibial Nerve Group.

Group 2 – Control Group.

P < 0.001 calculated by Pearson's chi-square test.

Fig. 1 Proportion of patients with a reduction in the number of urgency urinary incontinence episodes > 50% (efficacy), after the intervention, for each study group, in 101 women with urinary incontinence

pads ($P = 0.131$). None of the patients were on systemic hormone therapy, and there was no significant difference in the use of topical hormonal therapy between groups. The sociodemographic characteristics and clinical history prior to therapy were similar in the two groups.

Bladder diary

There was no difference between groups (before the intervention) regarding the frequency of micturition per day, nocturia and the number of urinary losses with urgency (Table 1). In both groups, there was improvement of these parameters; the results were significantly better in the group treated with electrostimulation than in the group treated with standard treatment alone. In both groups, there was a significant reduction in the number of SUI episodes, and this improvement was not significantly better in either group.

Questionnaires

The groups had similar pretreatment mean ICIQ-SF scores. Both groups showed improvement in the scores of this questionnaire; however, group 1 had a significantly greater improvement than group 2 (Table 2). The pretreatment King's Health Questionnaire score was similar in the two groups, except for the higher scores of group 1 in the impact domain for incontinence. Group 1 showed significantly better improvement than group 2 in all domains.

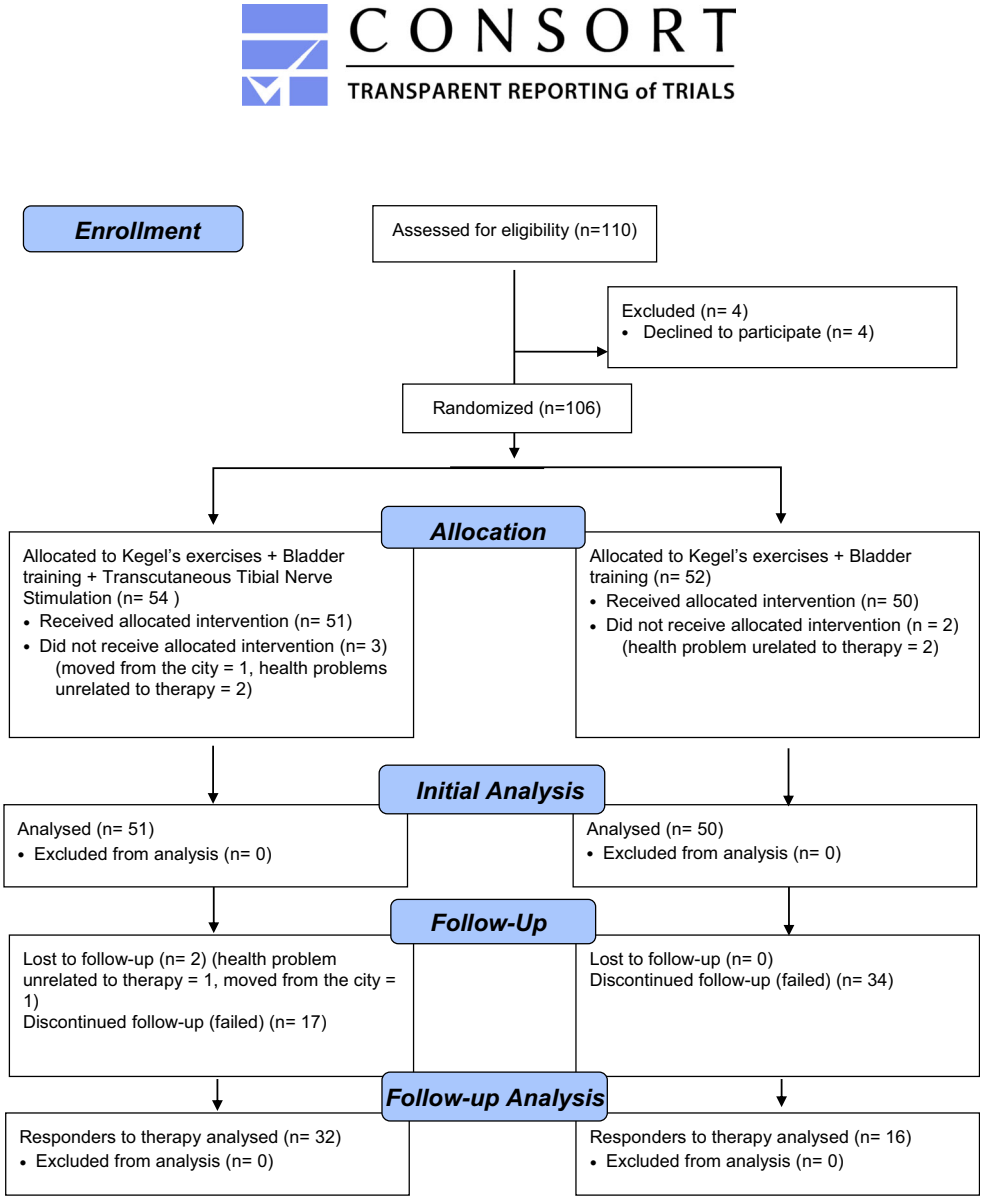


Fig. 2 Consort 2010 flow diagram

Subjective satisfaction and effectiveness

Regarding the overall subjective satisfaction associated with urinary incontinence, characterized by the absence of desire for a new therapy when responding to a specific subjective question, 34 patients (66.7%) in group 1 reported overall satisfaction at the end of therapy, while 16 patients (32.0%) in group 2 reported overall satisfaction.

The efficacy of the therapy was defined as a > 50% reduction in the number of losses reported by the patient in the voiding diary (posttreatment versus pretreatment). There was no difference in the reduction of stress urinary incontinence symptoms between the groups. Electrical stimulation was effective in the treatment of urge incontinence (according to the above criteria) in 42 (82.4%) patients, whereas standard therapy showed efficacy in 30 (30.0%)(16 (32%) patients (Fig. 1). In terms of efficacy in the treatment of urgency, approximately one out of every two patients treated benefited from electrostimulation of the tibial nerve (NNT = 1.9).

Follow-up

At the end of the initial intervention, of the 101 women who completed the study, 50 women (34 patients from the electrostimulation group and 16 from the nonelectrostimulation group) were satisfied (i.e., had no desire for new therapies according to a subjective questionnaire and a reduction of > 50% in episodes of urinary loss according to the 3-day voiding diary) and started follow-up. Two patients in the electrostimulation group were excluded from follow-up (one patient had a stroke and another moved to a distant city), and 48 women completed the 12-month follow-up period.

Patients whose symptoms recurred (worsening of the ICIQ-SF score by > 1 point in relation to the final evaluation) and/or reported subjective dissatisfaction with urinary incontinence during follow-up were considered initial recurrences, and the patients were counseled regarding the possibility of repeating the same therapy or starting another treatment.

During follow-up of the responders to therapy in the tibial group, 22 out of 32 (68.7%) patients met the criteria for recurrence. Of these, 19 out of 22 (86.4%) chose to repeat the electrostimulation of the tibial nerve, and 16 out of 19 (84.2%) of them were satisfied again after retreatment with TTNS for urinary incontinence. During the follow-up of the control group, 10 out of 16 (62.5%) required a new intervention, and none of them chose to repeat a conservative program with exercises and retraining (Fig. 2).

At the end of the 12-month follow-up of the 48 patients who responded to therapy, 81.2% (26/32) of those in the electrostimulation group were satisfied (including those who had a recurrence but re-established satisfaction after a second tibial nerve stimulation protocol). In contrast, of those who underwent standard treatment, only 37.5% (6/16) were satisfied at the end of the follow-up ($P = 0.009$).

There was no significant difference in the survival curves of the therapies because we did not consider the patients who underwent reinforcement therapy during follow-up ($p = 0.373$) (Fig. 3).

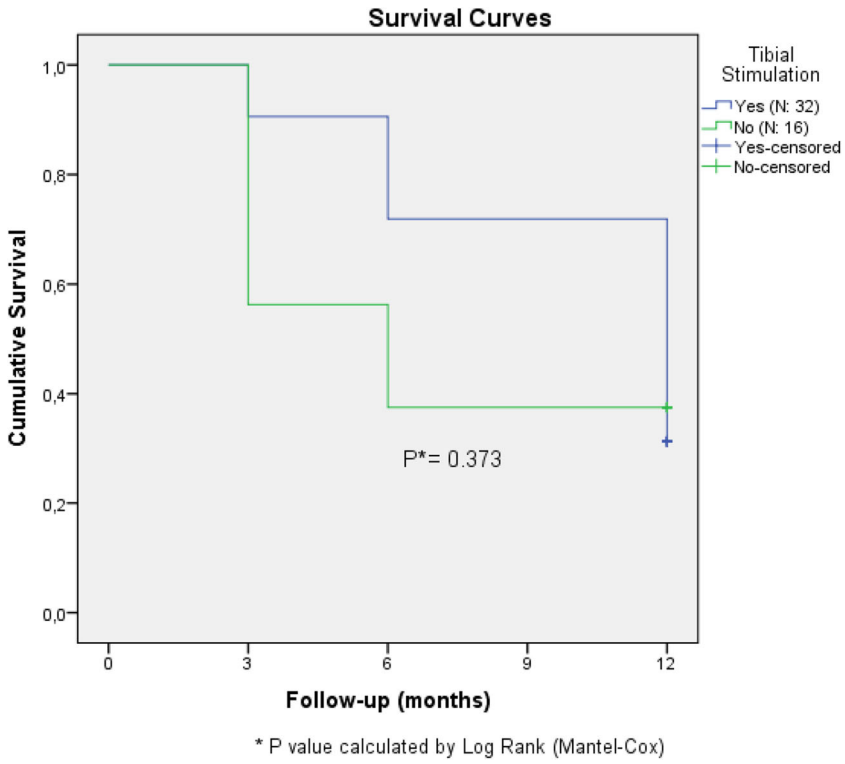


Fig. 3 Survival curve (Kaplan-Meier) of the efficacy of therapies over time in 48 women with urgency or mixed urinary incontinence who responded to initial therapy with or without electrostimulation (re-treatments are not included)

Discussion

The initial standard therapy showed good results for the symptoms of SUI and less efficacy for the urgency symptoms. The inclusion of electrostimulation led to a significant improvement in urgency symptoms, which are often considered those that most interfere with patient quality of life [11, 12].

UI in older women is different from UI in young women. Physiological changes, comorbidities, medications and especially functional deficits characterize incontinence in elderly individuals and should be considered when choosing the therapy to use with these patients [4, 11]. Elderly patients are more prone to comorbidities. In this study, for example, 70.3% of the patients had systemic arterial hypertension, and 23.8% had diabetes. Associated pathologies may make it difficult or even impossible to use medications and surgery for urinary UI [5, 12].

In elderly patients, getting up at night after bedtime can be catastrophic. The combination of tibial nerve electrostimulation with standard treatment significantly reduced episodes of nocturia. This is very important, especially in the elderly population, as it not only allows a better night's sleep (and consequently a better subsequent day) but can prevent falls and their many consequences [4, 5].

The study strengths include the randomized design, collection of validated objective outcomes and 12-month follow-up. The limitations include nonvalidated subjective measures (as none are available in the local language) and a lack of urodynamic data and longer-term follow-up.

A Cochrane review showed that electrical stimulation is promising for treating OAB compared to no active treatment, placebo/sham treatment, PFMT and drug treatment [4]. Several studies have considered that a treatment for UUI is effective if it reduces the episodes of urinary loss by at least 50% [13–15]. Using this definition, the efficacy of electrostimulation was proven in this study, since 82.4% of the patients fulfilled this criterion. The role of retreating patients with recurrent symptoms is still unknown, and this article shows that it can be beneficial.

The technique most often used for electrostimulation of the tibial nerve is percutaneous stimulation (with a needle). Although it would be interesting to compare percutaneous and transcutaneous stimulation, under the principle of minimally invasive treatment, this study used transcutaneous therapy (surface application of electrodes) and obtained good results, which had been observed in the short term in our previous study [10].

It is critical that elderly patients and the healthcare professionals involved in their care recognize UI as a treatable problem and not as an inevitable part of aging. Despite the high prevalence of UI in the elderly population, few studies have been performed on patients in this age group. It is essential that more work be focused on this growing population group. This is the first randomized trial showing 12-month follow-up results with TTNS for urinary incontinence in older women.

Martinson et al. studied the costs of sacral electrostimulation and percutaneous stimulation of the tibial nerve. Percutaneous stimulation proved to be much more affordable than sacral stimulation, costing $4867 versus $24,342 for the sacral technique in patients who responded to therapy [16]. Transcutaneous electrical stimulation has an even lower cost than the percutaneous electrical stimulation: a TENS-type electrostimulator costs < $500 compared to the $1500 for a percutaneous stimulator; in addition, surface electrodes for transcutaneous electrostimulation are reused for all sessions with the same patient in contrast to the disposable needles and the higher-cost percutaneous technique. Ramirez-Garcia et al. published a study showing that the transcutaneous technique is not inferior to the percutaneous technique [17].

Older people are considered a special population for clinical trials. Sham therapy is a good option when studying electrical stimulation therapies; however, we considered that bringing older women to the hospital to use an unplugged apparatus was an unnecessary risk (transportation, falls, etc.). In the future, a tibial nerve trial in women receiving home care could be a way to include sham therapy in this population.

If we consider the reduction in episodes of UUI and nocturia, the improvement of quality of life and the absence of adverse effects (often seen in the use of anticholinergic drugs in elderly individuals), we can propose TTNS as an initial therapy, combined with Kegel exercises and bladder retraining in elderly patients with urinary incontinence.

TTNS is effective and durable over time as long as stimulation reinforcement sessions are conducted at the time of relapse and patients show a good response to repeat therapy.

Compliance with ethical standards

Financial disclosure None.

Conflicts of interest None.

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