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ORIGINAL ARTICLE

Efficacy and safety of the TENSI+ device for posterior tibial nerve stimulation: A multicenter, retrospective study

Stimulation du nerf tibial postérieur transcutanée par le dispositif TENSI+ : une étude rétrospective multicentrique

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Summary
Objectives. — Transcutaneous posterior tibial nerve stimulation (TC-PTNS) is a validated option for lower urinary tract symptoms (LUTS) management, with a short-term success rate of around 60% and few adverse events. Our goal was to report the efficacy and safety results of TC-PTNS using the newly issued device TENSI+ for LUTS management.
Patients and methods. — A multicenter, retrospective study was conducted in 7 urology departments in France. All patients treated with TC-PTNS for LUTS using the TENSI+ device between September 2021 and February 2022 were included. All patients received supervised at-home

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training by a specialized nurse. All patients were asked to do daily, 20 minutes sessions of TC-PTNS. Patient demographics, history, initial symptoms and previous treatment were collected at inclusion. A follow-up visit was scheduled at 3 months. Efficacy was evaluated through treatment persistence at 3 months and PGI-I (Patient Global Impression of Improvement) score. Adverse events were recorded.
Results. — One hundred and three patients (86 women and 17 men) were included. All patients had overactive bladder symptoms, 64 suffered from urgency incontinence, and 24 had associated voiding symptoms. Eighteen patients had neurogenic background, and 30 previously received anticholinergics. After a median follow-up of 12 [10—21] weeks, 70 patients were still using the device (68%). PGI-I score reflected an improvement in 70.9% and was 1, 2 and 3 in 28, 26 and 19 patients respectively, while 24 were unchanged and 6 were worse. No clinical baseline parameter was predictive of success. Adverse events included pain at stimulation site (two cases) and pelvic pain (two patients), which rapidly resolved after treatment interruption.
Conclusions. — TC-PTNS with TENSI+ device is an effective option for LUTS management, with results that seem similar to other TC-PTNS approaches. Adverse events were mild and reversible after treatment interruption.
Level of evidence.— 4

MOTS CLÉS
Incontinence urinaire ;
Neuro-urologie ;
Hyperactivité vésicale ;
Stimulation du nerf tibial postérieur ;
Transcutané

Résumé
Objectifs. — La stimulation du nerf tibial postérieur (TENS) transcutanée est un traitement validé pour la prise en charge des symptômes du bas appareil urinaire (SBAU), avec un taux de succès à court terme d'environ 60 % et peu d'effets secondaires. Le but de notre étude était de rapporter les données d'efficacité et de sécurité d'utilisation du dispositif TENSI+ pour le traitement des SBAU.
Patients et méthodes. — Une étude rétrospective multicentrique a été conduite dans 7 centres en France. Tous les patients traités par TENS transcutané pour des SBAU avec le dispositif TENSI+ entre septembre 2021 et février 2022 ont été inclus. Tous les patients ont reçu une éducation spécialisée par une infirmière dédiée à domicile, avec une prescription de 20 minutes d'utilisation par jour à domicile. Les données cliniques démographiques, l'histoire de la maladie, les symptômes initiaux et les traitements antérieurs ont été collectés à l'inclusion. Une visite de suivi était prévue à 3 mois. L'efficacité du traitement a été évaluée par la persistance au traitement (décision de maintenir le traitement à la visite de suivi) et le score PGI-I (Patient Global Impression of Improvement). Les effets secondaires mentionnés par les patients ont été rapportés.
Résultats. — 103 patients (86 femmes et 17 hommes) ont été inclus. Tous les patients avaient des symptômes d'hyperactivité vésicale. Dix-huit patients étaient neurologiques, et 30 avaient déjà pris des anticholinergiques. Après un suivi médian de 12 [10—21] semaines, 70 patients (soit 68 % de l'échantillon) poursuivaient leur traitement. Le PGI-I a montré une amélioration dans 70,9 % des cas avec une valeur égale à 1, 2 et 3 chez respectivement 28,26, et 19 patients, alors que 24 étaient inchangés et 6 étaient moins bien. Aucun paramètre clinique initial n'était prédictif de succès de la thérapie. Les effets secondaires étaient deux cas de douleur au site de stimulation et deux cas de douleurs pelviennes, tous ayant rapidement disparu après la suspension du traitement.
Conclusion. — Le TENS transcutané administré par le dispositif TENSI+ est une option sure et efficace pour le traitement des SBAU, et semble donner des résultats comparables aux dispositifs déjà existants. Les effets secondaires étaient non graves et régressifs à l'interruption du traitement.
Niveau de preuve.— 4

Introduction

Posterior tibial nerve stimulation (PTNS) is a validated option for the non-invasive management of storage lower urinary tract symptom (LUTS) in both sexes [1]. Global success rates depend on the initial clinical picture and stimulation regimen, but efficacy of PTNS varies between 25% and 93% according to the most recent literature depending upon the definition of success and the stimulation regimen used [2]. Because of its low rate of associated adverse events and its few contra-indications (limited to cardiac pace-maker, pregnancy and local skin disorders), PTNS is gaining more and more popularity, and can even been proposed as a first line therapy for overactive bladder (OAB) management [3].

PTNS can be done by two different approaches, either by percutaneous (PC) approach [REF] or transcutaneous (TC) approach [4]. Recent reviews suggest that both options have similar efficacy [5—7]. But conversely to PC-PTNS, TC-PTNS is a home-based, self-administered treatment. The prescription is standardized, with daily session of 20 minutes. TC-PTNS has thus some potential advantages regarding treatment tolerance, costs and adherence. However, efficacy is conditioned by an appropriate patient education, and an optimal adherence to the treatment plan.

TENSI + ™ (Stimuli Technology, Boulogne Billancourt, France) is one-piece TC-PTNS device which has been recently approved on the market. It is designed like an ankle wrist with integrated electrodes, batteries and stimulator. Our objective was to evaluate the efficacy and safety of this device in population of patients with storage LUTS.

Patients and methods

Study design

A retrospective study was conducted in seven urological centers in France. All consecutive patients treated with TC-PTNS with TENSI + ™ device between September 2021 and February 2022 were included. Patients with a contra-indication for PTNS (cardiac pace-maker, pregnancy or local skin diseases) were excluded. Given the retrospective design, and the current clinical practice setting, the principles of the Helsinki Declaration were followed in lieu of a formal ethics committee.

Intervention

All patients were prescribed the same TENSI + ™ device (Stimuli Technology, Boulogne Billancourt, France). TENSI + ™ has been approved for commercial use (CE mark) on Feb 2nd, 2021 as a class IIa medical device [8]. It is a single longitudinal piece with two silicone graphite electrodes, that can be applied to the posterior tibial nerve region after application of a conductor gel (Conductor gel for silicone graphite electrodes ref 3760316090030) (Fig. 1). After the electrodes are properly placed, a strap is put around the ankle to stabilize the device. A single button is used for selecting the on/off position and another one to adjust the level of stimulation. All patients received the same prescription of daily sessions of 20 minutes. The decision to place the device at the right or left ankle was made with the patient on a case-by-case basis. All patients received appropriate and supervised education at home, by a home care nurse employed by external healthcare providers. Patients had the opportunity to contact the nurse during follow-up if needed for technical support. Follow-up visits were scheduled at 3 months.

Figure 1. TENSI+ device.

Data collection and outcome analysis

The patients' characteristics were drawn from medical charts, including age, sex, body mass index, medical history, underlying neurological condition if any, previous use of anticholinergics (including efficacy data and adverse events). Symptoms were assessed by patient interview, Urinary Symptoms Profile (USP) questionnaire and bladder diary, when available. LUTS were categorized as binary variables: OAB, urgency urinary incontinence, chronic pelvic pain, voiding symptoms. Nocturia was retrieved as a categorical variable. The main indication for PTNS prescription was collected. Bowel symptoms (constipation, diarrhea, fecal incontinence) were also assessed before treatment.

Follow-up visit was scheduled at 3 months for all patients. The primary endpoints were, the Patient Global Impression of Improvement (PGI-I) score and the treatment persistence at 3 months. The secondary outcomes included reasons for discontinuation, and adverse events.

Statistical analysis

Descriptive analysis was conducted for every patient characteristic and outcome parameter. Quantitative data were presented as mean values and standard deviation (SD), while categorical variables were presented by crude values and percentages. Potential predictive factors of success were assessed among baseline data (neurogenic bladder, age, BMI, previous use of anticholinergics) using a Mann-Whitney test

Table 1 Patients characteristics

Patient characteristics ($n = 103$)		
Age (mean, SD)	56	6.4
Sex		
Male	17	16.5%
Female	86	83.5%
Body mass index (mean, SD)	25.9	3.2
Neurogenic bladder	18	17.5%
Lower urinary tract symptoms		
Overactive bladder	99	96.1%
Urgency urinary incontinence	64	62.1%
Nocturia		
0	33	32.0%
1	27	26.2%
2	19	18.4%
> 2	24	23.3%
Voiding symptoms	24	23.3%
Bowel dysfunction		
None	65	63.1%
Constipation	19	18.4%
Diarrhea	2	1.9%
Fecal incontinence	2	1.9%
Unknown	15	14.6%
Previous anticholinergic use	30	29.1%
Chronic pelvic pain		
Yes	10	9.7%
No	72	69.9%
Unknown	21	20.4%
Main indication for PTNS		
Predominant OAB	87	84.5%
Predominant voiding LUTS	2	1.9%
Mixed (storage and voiding symptoms)	11	10.7%
Predominant pelvic pain	2	1.9%
Isolated nocturia	1	1.0%

(for continuous variables) or a Chi-square test (for categorical variables). Data were analyzed with SAS 9.2 (Cary, NC, USA).

Results

Patient characteristics

One hundred and three patients (86 women and 17 men) were included with a median follow up of 12 weeks [9—20]. The baseline characteristics are displayed in Table 1. Mean age was 56 ± 6.4 years [16—88], with a slightly overweight population as mean BMI was 25.9 ± 3.2 [18—35]. The main clinical picture for PTNS prescription was OAB, which was mixed with voiding symptoms in 11 cases. Sixty four patients had OAB with urgency incontinence. In five cases, the indication was predominantly voiding symptoms (two cases), pelvic pain (two cases) or isolated nocturia (one case). Bowel dysfunction was present in 23 cases. Thirty patients had been prescribed anticholinergics before, which were mostly interrupted because of lack of efficacy (19 cases) and or adverse events (11 cases). None of the patients used any anticholinergic medication during the study period.

Table 2 PGI-I results.

Very much better	28	27.2%
Much better	26	25.2%
A little better	19	18.4%
Unchanged	24	23.3%
A bit worse	4	3.9%
Much worse	1	1.0%
Very much worse	1	1.0%

Table 3 Discrepancies between persistence rate and PGI-I: treatment interrupted but PGI-I < 4.

PGI-I of 1 (3 cases)
One case switched to UroStim2 by practitioner
One case switched to UroStim2 by patient, bad ergonomy of TENSI+
One case asking for SNM because PTNS is too demanding
PGI-I of 2 (2 cases)
One stopped despite improvement, switched to pelvic floor muscle exercises
One stopped following improvement of symptoms, hoping for stability
PGI-I of 3 (5 cases)
One case asking for SNM because PTNS is too demanding
Three case of too limited efficacy compared to treatment charge
One Was feeling pelvic pain

Efficacy

Of the 103 patients included, 70 were still doing their daily PTNS treatment at last follow-up (68%), whereas 31 patients had interrupted their treatment. Two patients never made the sessions appropriately, and were classified as failures. According to the PGI-I, 54 patients (52.4%) were very much improved or much improved (PGI-I of 1 or 2), while 19 patients (18.4%) were slightly improved (PGI-I score of 3) (Table 2). The discrepancies between PGI-I results and treatment persistence were investigated (Table 3). Some patients stopped treatment because of switch to another device (two cases), were considering rather sacral neuromodulation because they felt PTNS was too burdensome (two cases), found too little improvement compared to treatment's burden (three patients), quit for pelvic floor exercises (one case), or was feeling pelvic pain (one case). One patient stopped because of significant improvement, waiting for further PTNS sessions in case of symptoms recurrence. Conversely, six patients described no significant improvement (PGI-I of 4) but were still doing daily stimulations.

Predictive factors

Success rate of PTNS treatment was not significantly associated with age ($p = 0.78$), sex ($p = 0.37$), history of anticholinergic drug treatment ($p = 0.11$), presence of urge urinary incontinence ($p = 0.12$), or neurogenic background ($p = 0.32$).

Adverse events

All adverse events were mild and rapidly disappeared after treatment interruption. Two patients reported pain at stimulation site, and two female patients complained of pelvic pain.

Discussion

LUTS are highly prevalent in both men and women and heavily impact the quality of life of affected patients [21]. With increasing evidence of the multifactorial pathophysiology underlying LUTS [9] and the inherent need of a large therapeutic armamentarium, along with the rising concerns surrounding LUTS pharmacological treatments in some populations [10], PTNS has gained more popularity over the past few years [11]. Transcutaneous tibial nerve stimulation has been used for a long time in France using the Urostim2® device with transcutaneous electrodes wired to a relatively large stimulator [12]. The present series is the first to assess the outcomes of this new single-piece transcutaneous PTNS device and one of the largest prospective series to report the outcomes of daily home-based transcutaneous PTNS device to date [2]. We observed a high proportion of patients improved at 3 months with an excellent safety profile.

Compared to previous literature, the results of home-based treatment with the TENSI+ device seems similar to those obtained with other transcutaneous devices. Indeed, Leroux et al. previously reported a treatment persistence rate of 71.1% at 3 months with the Urostim2™ transcutaneous device [13]. In case of use of percutaneous PTNS (which is usually scheduled as a weekly session of stimulation for 12 weeks), one year follow-up has been reported a treatment persistence of less than 50% [14,15]. Further studies are thus warranted to estimated medium and long term success of TENSI+ and compare it to other competitors.

This study confirms the satisfactory outcomes obtained with daily sessions home-based transcutaneous PTNS. The treatment regimen used herein differ from most transcutaneous PTNS series in which the treatment was used weekly in the office [2,6,16]. It would be of great interest to compare the treatments' burden from the patients' perspective and the costs of this treatment regimen compared to the other ones described in the literature. It has recently been suggested by small sample randomized controlled trials that weekly transcutaneous and percutaneous PTNS may yield similar outcomes [17,18]. Hence, comparing daily home based transcutaneous PTNS with such a device to percutaneous PTNS weekly would be of interest given that the percutaneous route remained the most widely used in many countries. One may hypothesize that daily transcutaneous stimulation may overperform weekly percutaneous PTNS. The cost-effectiveness of those various PTNS strategies would also be important to consider.

The specific design of TENSI+ presents several potential advantages. The device is a single piece with a single button for activation. It is small, discrete and presented in a user-friendly package, easy to carry on when travelling. Its apparent easiness of use however remains to be established through specific patients and caregivers feedback analysis. But intuitively, one could postulate that the assets described hereabove would increase patient adherence, tolerance of daily use and finally improve observance, which would be the goal of further dedicated studies. Furthermore, the specific design and easiness of use may be an opportunity to simplify patient education at the initiation phase. In this very preliminary study, we decided to have home care nurses covering education, which introduces a specific positive bias. But in the future, teleconsultation or self-education by audio guide or a free video tutorial (e.g. with a QR code in the package) could be tested, with the objective to save costs and get the patient even more autonomous. Potential drawbacks would be misuse by the patients or difficulties in device positioning due to patient morphology (e.g. in obese patients). This happened in one case in our study, but due to rather careful patient selection and implication of the nurses, this issue may be underestimated. Larger trials are mandatory to further investigate those questions.

Interestingly no predictive factors of efficacy were found in the present series. The efficacy of PTNS on voiding dysfunction remains doubtful [19], and same could be said for neurogenic LUTS as recently evidence by the findings of the UROPARKTENS study (NCT02190851). In regard of the existing literature, one would expect that the outcomes would be superior for OAB patients than for neurogenic LUTS or voiding dysfunction. Overall, this lack of predictive factors is certainly due mostly to the relatively small sample size and inherent lack of statistical power. No conclusion can be drawn from the present work on the relative efficacy of PTNS on OAB vs neurogenic LUTS vs voiding dysfunction. Further studies are need to elucidate the role of PTNS with the TENSI+ devices on each of this possible indications.

The present study has several limitations that should be acknowledged. First, it has all the biases inherent to its retrospective design. The population was relatively heterogenous with inclusion of several clinical patterns although the majority of patients were prescribed PTNS for OAB. Another significant shortcoming was the relatively small sample size. Apart from the PGI-I, no other validated questionnaires or patient-reported outcomes was uniformly used by all the centers. Numerous bladder diaries at time of 3-month follow-up were missing, which is another significant drawback. These limitations also preclude comparisons with other studies, where results are mostly reported as quality of life questionnaires or objective items extracted from the bladder diary [20,22,23]. The preoperative work up was very basic and not standardized which may not have ruled out significant confounders such as coexisting bladder outlet obstruction. On the one hand, this could be regarded as an asset as the present results reflect the use of TENSI+ as a first- or second-line treatment for various LUTS in real life. On the other hand, one may see this as a flaw and could hypothesize that the outcomes may have been different—possibly better—with a more stringent patients' selection. Finally, the follow-up was short and further studies will be needed to assess the value of this new device in the long-run.

Conclusion

Transcutaneous PTNS with the newly released TENSI+ device seems a safe and effective treatment for LUTS in both men

and women, with a high persistence rate at 3 months. The outcomes were found overall to be similar to those reported with other TC-PTNS devices. Further well-designed prospective studies with longer follow-up are needed to confirm these preliminary results.

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Disclosure of interest

Authors are investigators for Stimuli Technology. JNC is a consultant for AbbVie, Astellas, BBRAUN, Boston Scientific, Recordati, Coloplast, Cousin Biotech, Medtronic, Stimuli Technology.

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