How I Do It: Transcutaneous tibial nerve stimulation TENSI+ system

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Overactive bladder (OAB) is a common condition that significantly impacts the quality of life (QoL), well-being and daily functioning for both men and women. Among various treatments, peripheral tibial nerve stimulation (PTNS) emerges as an effective third-line treatment for OAB symptoms, with options for either a percutaneous approach (P-PTNS) or by transcutaneous delivery (T-PTNS). Recent studies have shown negligible differences between P-PTNS and T-PTNS efficacy in alleviating urinary urgency and frequency and QoL improvement and, overall no difference in efficacy over antimuscarinic regimens. The TENSI+ system offers a cutting-edge transcutaneous approach, allowing patients to self-administer treatment conveniently at home with electrical stimulation delivery through surface electrodes. It stands out for its ease of preparation, tolerability, and high levels of patient satisfaction. Prospective multicentric data highlights TENSI+ to be an effective and safe treatment for lower urinary tract symptoms with high treatment adherence at 3 months. This paper aims to familiarize readers with the TENSI+ system, current studies, device assembly, operation, and treatment recommendations.

Key Words: OAB, PTNS, T-PTNS, TENSI+

Introduction

Overview of procedure/technology

Overactive bladder (OAB) is a chronic condition affecting 11.8% of individuals worldwide.[1,2] Its significant impact on quality of life, economic burden, and daily activities has amplified the need for effective, minimally invasive treatments.[3] Emerging data highlighting the limitations and adverse effects of antimuscarinic therapies have pivoted attention towards non-pharmacological solutions. Among these, electrical nerve stimulation techniques are gaining prominence as increasingly attractive, minimally invasive alternatives.[4,5]

In this context, peripheral tibial nerve stimulation (PTNS) has gained prominence. PTNS operates by delivering electrical stimuli to the sacral micturition center via the S2–S4 nerve roots.[2] Although the exact

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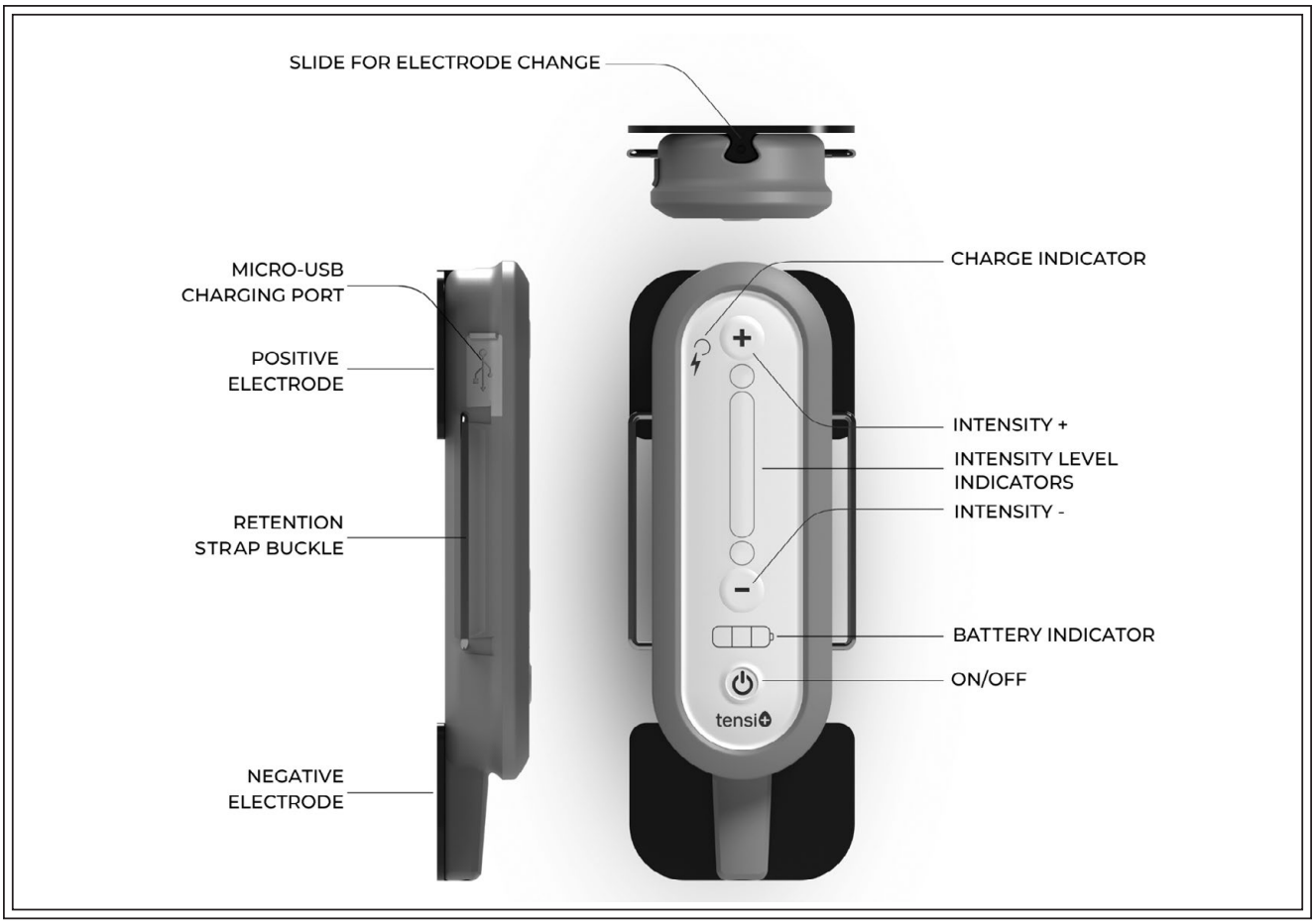

Figure 1. TENSI+ device components.

mechanism of nerve stimulation and bladder control is yet to be clearly defined, it is thought to work similarly to sacral neuromodulation by regulating spinal reflexes and ultimately balancing the excitatory and inhibitory components, thereby modulating bladder function.[1,3,6] PTNS can be administered through two main avenues: percutaneous tibial nerve stimulation (P-PTNS) and transcutaneous tibial nerve stimulation (T-PTNS). P-PTNS uses the delivery of electrical impulses through a fine 34-gauge needle,[7] whereas T-PTNS delivers stimuli through surface skin electrodes positioned at the same anatomical level.[2,7,8] Both interventions have shown significant symptomatic relief for OAB patients, with T-PTNS providing a more accessible alternative, as it reduces invasiveness, preparation time, and travel expenses without forfeiting its efficacy.[3,7,9] Moreover, major urological associations have recognized T-PTNS as a viable, effective, and attractive option for OAB treatment.[2,10,11] This has led to the development of T-PTNS devices with unique features and advantages.

The TENSI+ (Stimuli Technology, Boulogne Billancourt, France) is a one-piece transcutaneous tibial nerve stimulator designed as an ankle band with integrated electrodes, battery, and stimulator, Figure 1. The TENSI+ device is strategically positioned directly along the peripheral tibial nerve as it passes through the medial malleolus. This device administers controlled, low-level electrical impulses through skin electrodes in the ankle and offers adjustable current intensities ranging from 0 to 50 milliamps (mA). The device's streamlined one-piece construction allows for ease of use and mobility. Additionally, it features built-in safeguards to ensure appropriate intensity modulation, correct positioning, and adherence to treatment guidelines, setting it apart from other devices in the market.[8]

Historical significant studies

Tibial nerve stimulation as a potential treatment option for OAB, was first introduced by Stoler in 1999, alongside other methods of electrical stimulation delivery.[12] P-PTNS became one of the

most promising techniques by showing its safety and efficacy, eventually gaining approval from the FDA and endorsed to selected patients by NICE in 2019.[3,11] However, the formal endorsement of P-PTNS as a guideline-approved treatment for OAB was solidified with the publication of the multicenter SUmiT trial. This was a 3-year, multicenter, randomized, controlled trial that showed significant symptom relief for OAB patients who underwent PTNS treatment instead of placebo intervention.[13] Years later, transcutaneous tibial nerve stimulation would gain traction as a more accessible non-invasive alternative for P-PTNS as meta-analysis data surface proving both variants yielded similar outcomes in terms of symptom, and quality of life improvement, while also highlighting the smaller side effects and discontinuation percentage in the transcutaneous group.[14] More recently, T-PTNS has been added as a first-line treatment for female non-neurogenic OAB and UUI with a strong level of recommendation in the latest version of the European Association of Urology guidelines.[2] This modality is also endorsed as third-line therapy for selected patients by the AUA guidelines.[10] Recognizing this technology, not only as an equivalent to P-PTNS but also as a superior treatment to some pharmacological regimens.[2]

Moreover, T-PTNS could be a robust alternative to P-PTNS for OAB. A qualitative study by Daly et al suggests that in-home T-PTNS treatments offer patients both flexibility and empowerment, aspects that are often missing in traditional clinical settings.[15] The convenience of administering T-PTNS therapy at home not only aligns well with individuals' lifestyle and work commitments but also provides them with a greater sense of control over their OAB symptoms. By eliminating some of the logistical and psychological barriers to care, in-home TENS treatments may offer a convenient, effective, and patient-preferred approach to managing OAB symptoms.

Recently, a 2023 study by Cornu et al focused on the efficacy and safety of the TENSI+ device in treating lower urinary tract symptoms. Conducted in France between September 2021 and February 2022, this retrospective multicenter study involved 103 patients—17 men and 86 women. All subjects underwent a 12-week, 20-minute daily treatment regimen with TENSI+. The study aimed to assess overall improvement, using the Patient's Global Impression of Improvement (PGI-I) score as the primary endpoint. The findings were promising: 70.8% of participants reported some level of symptom improvement. Specifically, 52.4% experienced "significant" improvement, while 18.4% reported a slight improvement. Additional outcomes, such as treatment adherence and side effects, were also encouraging; adherence stood at an impressive 68%, and only one case of minor pelvic pain was reported, which subsided shortly after discontinuation of treatment.[8]

Method and technique

Patient selection and assessment

For patients presenting with urinary symptoms, a comprehensive evaluation should be conducted in alignment with current urological guidelines. This may encompass a detailed medical history, physical examination, non-invasive urodynamic studies, and the administration of standardized questionnaires like the International Consultation on Incontinence Modular Questionnaire (ICIQ-FLUTS, ICIQ-OAB etc.) or the Overactive Bladder Questionnaire (OAB-q). Patients should be encouraged to first-line treatments which include lifestyle interventions, behavioural therapies, and pelvic floor physiotherapy, followed by standard pharmacological treatments with anti-muscarinic and beta-3 agonists. For adults with idiopathic or neurogenic OAB who either do not respond fully to or are resistant to pharmacological treatments, cannot tolerate medication, or are interested in a non-invasive option, we suggest using TENSI+.

Device is contraindicated for patients with:

- Cardiac pacemakers, defibrillators, electronic implants, or metal implants near the stimulated area. This may cause interference or burns.
- Pregnancy, ankle joint problems, or dermatological conditions where electrodes are to be placed.

Assembling and positioning

The device comes pre-assembled with two electrodes and two adjustable textile straps. We strongly recommend that physicians and patients attempt a trial placing of the ankle to ascertain a proper fit before continuing. Adjusting the device follows a simple process.

- Simply pull on one of the straps until it hugs the ankle. If the device remains too loose, it is possible to remove the shorter strap and subsequently adjust the longer one to encircle the ankle by securing its free end to the remaining plastic buckle.

Once a comfortable fit is achieved, you are ready to position the TENSI + for treatment. For proper positioning follow these steps:

1. Treatment can be performed on either (right or left) leg. Clean the inner ankle and Achilles area with a damp cloth; it is unnecessary to dry the area as humidity facilitates the transmission of electrical impulses.

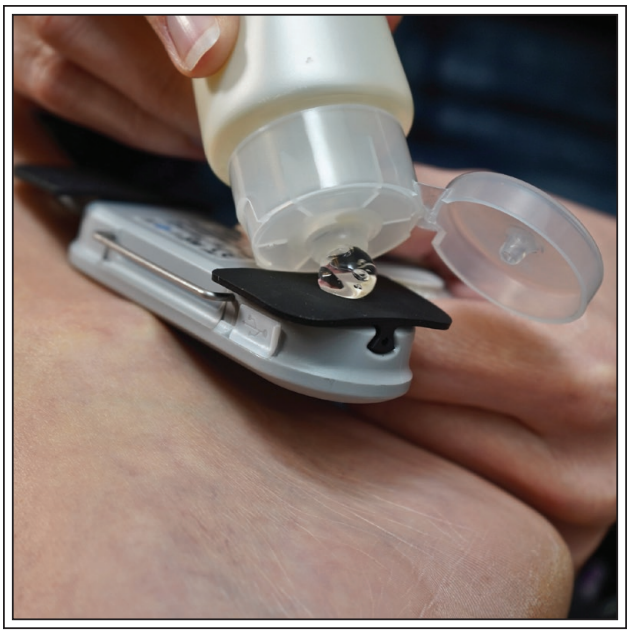

Figure 2. First steps for assembly and positioning of the device.

Figure 3. TENSI+ should be placed over the ankle with the lower electrode placed below and behind the medial malleolus.

2. Optionally, apply a drop of gel on each electrode to enhance electrical transmission, Figure 2.
3. Place the device on the ankle, ensuring the lower electrode is just below and behind the medial malleolus. Align the device's vertical axis parallel to the ankle, Figure 3.
4. Positioning is crucial: always place the device with the on/off button facing downward to ensure proper operation.
5. Once positioned correctly, secure the free strap around the ankle.

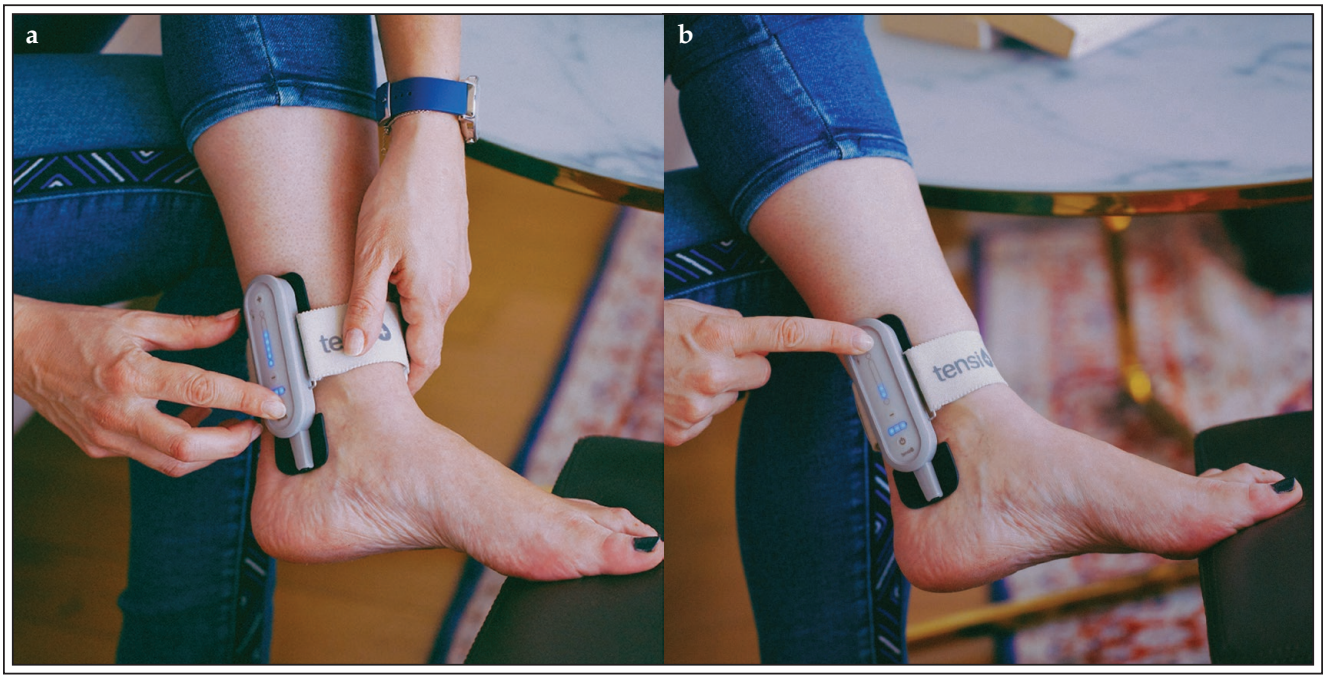

Figure 4. a) Press and hold down the ON/OFF buttom. **b)** Press the (+) buttom, this will activate the program.

Operating the TENSI+

To initiate the device, press and hold the on/off button for a duration of 1 second, Figure 4a. You will hear a prolonged, gentle beep, confirming that the device is now powered on. To begin treatment, simply press the (+) button, this will activate the program at LED 1 which corresponds to the lowest intensity treatment of 0.5 to 5 mA, Figure 4b.

Calibration of stimulation intensity is achieved by pressing the (+) or (-) buttons and modifying the intensity in 0.5 mA increments. This is a good time to check the device's placement if you have any uncertainty while positioning. To do so simply increase the stimulation intensity until you observe hallux (big toe) contraction (flexion). Absence of this response requires repositioning (review of steps 3 and 4 in the positioning section). Once you are confident in the placement start tailoring the intensity level of the stimulation to the patient's comfort. Raise the stimulation until a subtle tingling or tapping sensation is detected at the sole. If discomfort occurs, reduce the intensity to the comfort range just before the sensation dissipates. When the device crosses the 10-mA threshold, two short beeps will sound as an alert.

Once you have set the device to the patient's comfort range they can move around as they wish. To mitigate inadvertent alterations to the stimulation the device will enter a locked state if no interaction with its settings is detected for more than 30 seconds. Additionally, if the device's electrodes lose contact with the skin for more than one second, the stimulation level will revert to zero, and all six LEDs will flash as a safety measure. A simple readjustment will suffice to continue the treatment.

The TENSI+ is programmed to run for a 20-minute session and will automatically shut down thereafter. To manually terminate the session earlier, a one-second press of the on/off button will suffice. Following deactivation, the device can be safely removed, cleaned, and stored. For optimal treatment outcomes, patients should adhere to daily 20-minute sessions over a 12-week period.

Treatment expectations and follow up

If physicians and patients adhere to the provided guidelines for treatment administration, they should anticipate an initial improvement of OAB symptomatology by the end of the sixth week of treatment. By week twelve, the initial phase concludes, and patients should be experiencing the full therapeutic benefits. For sustained results, ongoing treatment sessions are advised with 3 sessions weekly for the following 12 weeks followed by an individualized treatment plan to target patients' treatment goals. To maximize therapy success, we advocate for an initial training consultation. This can be successfully monitored by physician assistants, nurses, or allied health care professionals. Where patients will be allowed to voice any concerns, learn the device's operation, and resolve any technical barriers.

We suggest following patients at 1-, 3-, 6- and 12-month post TENSI+ initiation. The 1-month follow up is encouraged to address any emerging concerns during device adaptation. Three-month and consecutive clinic visits allow adequate time for conclusion of the initial 12-week period to assess overall treatment effectiveness and discuss the possibility of treatment progression and adjunct therapy re-adjustment/discontinuation.

Presently, it remains inconclusive whether extended therapy will offer additional benefits for those who initially respond positively or whether non-respondents may eventually gain from prolonged treatment. Based on T-PTNS available data, we recommend that patients experiencing symptom relief should continue with maintenance sessions of 3 sessions a week for the following 12 weeks and tapered individualized to patient's response and treatment goals. Conversely, those unresponsive to the initial 12-week regimen can be counselled for alternative therapeutic options.

TENSI+ safety and precautions

The manufacturer recommends the following safety precautions that all physicians should be aware of before prescribing the TENSI+ device and counselling their patients:

- Avoid using TENSI+ in tandem with high-frequency surgical devices, as this could lead to burns under the area where the TENSI+ electrodes are placed.
- Never place the electrodes on other body areas besides the ankle.
- Advise patients to avoid environments with strong electromagnetic interference as it may alter the stimulation settings.
- Keep TENSI+ at a safe distance (at least 1 meter or 3 feet) from devices that emit microwave, short-wave or ultra-short-wave frequencies. This includes microwave ovens, Wi-Fi terminals or modules, mobile phones, and Bluetooth systems.

In terms of adverse effects, TENSI+ has demonstrated a strong safety profile. Minor transient pelvic pain and localized discomfort at the stimulation site have been reported but typically resolve quickly upon treatment cessation. The decision to continue or discontinue treatment is ultimately patient-driven, and as such,

clinicians should be prepared to offer alternative therapeutic options when needed.

Discussion and conclusions

The TENSI+ device is a transcutaneous tibial nerve stimulator system that offers a highly effective and minimally invasive therapeutic solution for managing OAB from the comfort of one's home. The encouraging results from previous clinical trials further reinforce our commitment to promoting state-of-the-art medical technologies such as TENSI+. Its exceptional attributes in terms of design, convenience, and efficacy render it a promising option for both patients and healthcare providers. Moreover, this technology holds the potential to address some of the concerns associated with current OAB treatments, including safety, discontinuation rates, invasiveness, and accessibility.

Notably, the utility of TENSI+ is not limited to academic settings or clinical trials; it holds practical, real-world applications as a viable first- or second-line treatment for OAB/LUTS. This is particularly relevant for patients who are not suitable candidates for more invasive approaches, those who experience no or partial response to medical therapy, or those who are unable to tolerate such treatments. These patients could gain significant benefits from neurostimulation. Therefore, TENSI+ enriches our array of treatment options and provides new opportunities for comprehensive, patient-centred care in pelvic floor health.

Disclosures

Drs. Roseanne Ferreira and Valentina Garcia Perez have no disclosures. All other authors are medical advisors to Stimuli Technology. □

References

1. Sayner AM, Rogers F, Tran J, Jovanovic E, Henningham L, Nahon I. Transcutaneous tibial nerve stimulation in the management of overactive bladder: a scoping review. *Neuromodulation* 2022;25(8):1086-1096.
2. Harding CK, Lapitan MC, Arlandis S et al. EAU guidelines on management of non neurogenic female lower urinary tract symptoms;2023.
3. Booth J, Connelly L, Dickson S, Duncan F, Lawrence M. The effectiveness of transcutaneous tibial nerve stimulation (TTNS) for adults with overactive bladder syndrome: a systematic review. *Neurourol Urodyn* 2018;37(2):528-541.
4. Veenboer PW, Bosch JLHR. Long-term adherence to antimuscarinic therapy in everyday practice: a systematic review. *J Urol* 2014;191(4):1003-1008.
5. Schreiner L, Dos Santos TG, Knorst MR, Da Silva Filho IG. Randomized trial of transcutaneous tibial nerve stimulation to treat urge urinary incontinence in older women. *Int Urogynecol J* 2010;21(9):1065-1070.
6. Monga AK, Tracey MR, Subbaroyan J. A systematic review of clinical studies of electrical stimulation for treatment of lower urinary tract dysfunction. *Int Urogynecol J* 2012;23(8):993-1005.
7. Sonmez R, Yildiz N, Alkan H. Efficacy of percutaneous and transcutaneous tibial nerve stimulation in women with idiopathic overactive bladder: a prospective randomised controlled trial. *Ann Phys Rehabil Med* 2022;65(1):101486.
8. Cornu JN, Klap J, Thuillier C et al. Efficacy and safety of the TENSI+ device for posterior tibial nerve stimulation: a multicenter, retrospective study. *Prog En Urol* 2023;33(11):541-546.
9. Agost-González A, Escobio-Prieto I, Pareja-Leal AM, Casuso-Holgado MJ, Blanco-Diaz M, Albornoz-Cabello M. Percutaneous versus transcutaneous electrical stimulation of the posterior tibial nerve in idiopathic overactive bladder syndrome with urinary incontinence in adults: a systematic review. *Healthcare* 2021;9(7):879.
10. Lightner DJ, Gomelsky A, Souter L, Vasavada SP. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline amendment 2019. *J Urol* 2019;202(3):558-563. 000309
11. Urinary incontinence and pelvic organ prolapse in women: management. National Institute for Health and Care Excellence;2019. Accessed October 30, 2023. Available from: https://www.nice.org.uk/guidance/ng123/chapter/Recommendations#non-surgical-management-of-urinary-incontinence.
12. Barış Nuhoğlu Æ Vecihi Fidan Æ Ali Ayyıldız Erim Ersoy Æ Cankon Germiyanoğlu. Stoller afferent nerve stimulation in woman with therapy resistant over active bladder; a 1-year follow up. *Int Urogynecol J Pelvic Floor Dysfunct* 2006;17(3):204-207.
13. Peters KM, Carrico DJ, Perez-Marrero RA et al. Randomized trial of percutaneous tibial nerve stimulation versus sham efficacy in the treatment of overactive bladder syndrome: results from the SUmiT trial. *J Urol* 2010;183(4):1438-1443.
14. Yang DY, Zhao LN, Qiu MX. Treatment for overactive bladder: a meta-analysis of transcutaneous tibial nerve stimulation versus percutaneous tibial nerve stimulation. *Medicine (Baltimore)* 2021;100(20):e25941.
15. Daly CME, Loi L, Booth J, Saidan D, Guerrero K, Tyagi V. Self-management of overactive bladder at home using transcutaneous tibial nerve stimulation: a qualitative study of women's experiences. *BMC Womens Health* 2021;21(1):374.