Posterior tibial nerve stimulation: is ultrasound guided needle placement more accurate?

Steven J. Lomax, MD,[1] Daniela A. Haehn, MD,[1] Eric Robinson, PA-C,[1] Rachel Pung Page,[2] Edsel Bittencourt,[3] Mark F.B. Hurdle, MD,[3] Steven P. Petrou, MD[1]

[1]Department of Urology, Mayo Clinic, Jacksonville, Florida, USA
[2]Division of Biomedical Statistics and Informatics, Mayo Clinic, Jacksonville, Florida, USA
[3]Department of Physical Medicine and Rehabilitation, Mayo Clinic, Jacksonville, Florida, USA

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Introduction: *To compare the accuracy of the transcutaneous ultrasound (US) in detecting the tibial nerve (TN) as opposed to digital palpation in the performance of posterior tibial nerve stimulation (PTNS).*

Materials and methods: *After Institutional Review Board (IRB) approval, 25 adults were enrolled to quantify the difference in position of the distal TN by the use of US as opposed to cutaneous palpation. The position of the TN was determined first by the palpation method and then by using a L12-4MHz high frequency Linear Array Transducer. The difference in position between the two methods was determined in both proximal-distal (PD [Knee-Sole]) and anterior-posterior planes (AP). Statistical analysis was completed with numeric variables summarized with the sample median, range, and interquartile range (IQR). Categorical variables were summarized with the number and percentage of patients. Comparisons between AP and PD distances were performed using a nonparametric Wilcoxon signed rank test. Box and whisker plots were used to display individual observations graphically. All analyses and graphics were performed using SAS statistical software (version 9.4M5, SAS Institute Inc., Cary, NC, USA).*

Results: *Twenty-five patients were studied. The median AP distance between US and digital palpation was 2 mm (range, 0-5 mm; IQR, 2-3 mm). The median PD distance between US and digital palpation was 4 mm (range, 0-9 mm; IQR, 3-5 mm). The median difference between the AP and PD distances was 2 mm (range, -3-7 mm; IQR, 0-4 mm, $p < 0.001$).*

Conclusion: *The use of US identifies the nerve with statistically significant greater accuracy than palpation technique along the PD plane.*

Key Words: PTNS, overactive bladder (OAB), ultrasound

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Address correspondence to Dr. Steven P. Petrou, Department of Urology, Mayo Clinic FL, 4500 San Pablo Road South, Jacksonville, FL 32224 USA

Introduction

The treatment of voiding dysfunction (VD) includes a broad spectrum of therapeutic approaches but depending on the final diagnosis, treatment may ultimately involve a form of neuromodulation, such as Percutaneous Tibial Nerve Stimulation (PTNS). Dr. Marshall Stoller first described this concept of Posterior Tibial Nerve (PTN) neuromodulation for the treatment

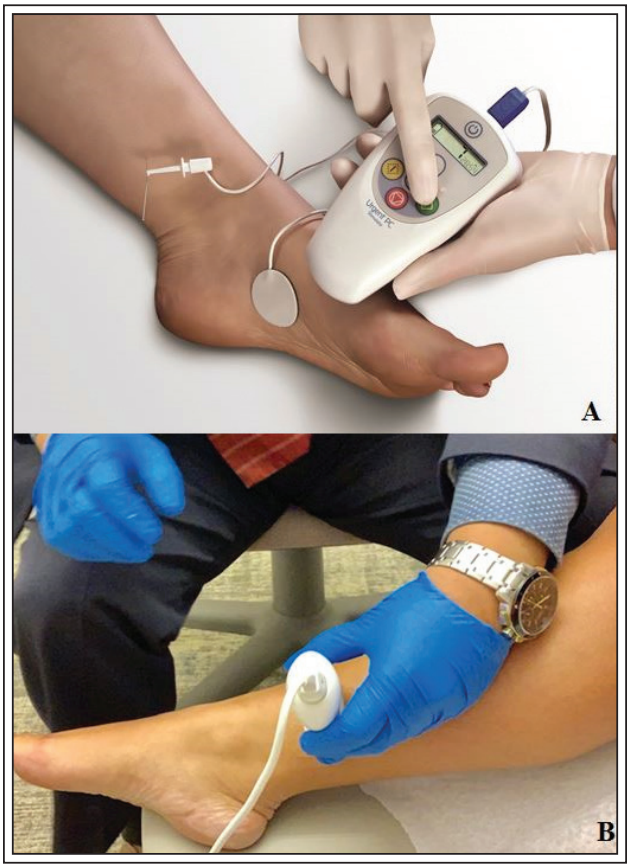

Figure 1. a) Graphic representation of typical needle location for PTNS. Reprinted with permission from Cogentix Medical, Inc. **b)** Localizing tibial nerve with Philips Lumify Mobile App Based ultrasound.

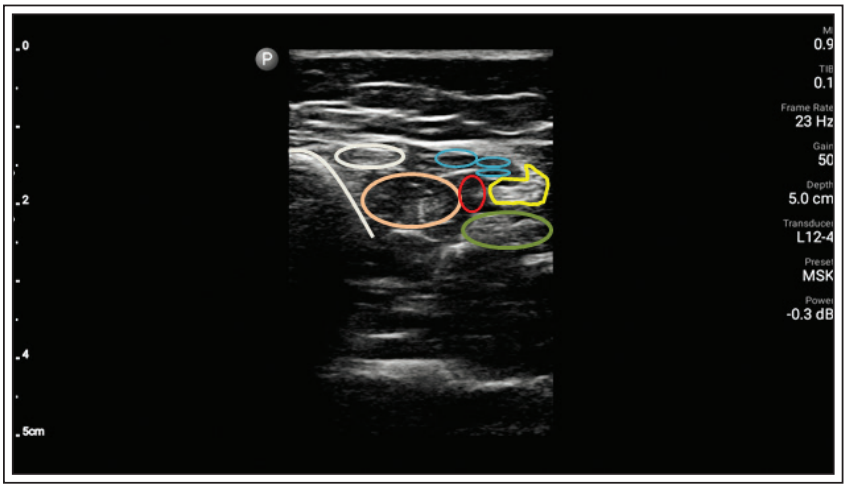

Figure 2. White semi-curved line = medial malleolus of the tibia; white oblong = tibialis posterior; orange oblong = flexor digitorum; light blue oblongs = posterior tibial veins; light red oblong = posterior tibial artery; yellow shape = tibial nerve; light green oblong = flexor hallucis.

of VD in the late 1990s.[1] Traditionally, the placement of the neuromodulation needle is approximately 5 cm superior to the medial malleolus and posterior to the tibia Figure 1a. Treatment efficacy may be impacted by the failure to optimally identify the relative PTN position secondary to individual anatomic variance. Therefore, we hypothesize that the use of ultrasound (US) technology may optimize the identification of the nerve position.

Materials and methods

Tibial nerve identification

Tibial nerve (TN) identification was determined initially by the palpation method. On the lower inner aspect of either leg, the TN was approximated at a location three fingerbreadths (5 cm) cephalad to the medial malleolus and one fingerbreadth (2 cm) posterior to the tibia. A temporary mark was made to identify the location where the treatment needle would be inserted. After identifying the nerve using palpation, the nerve was identified using a L12-4MHz Linear Array Transducer, Figure 1b and 2. The nerve appeared as an ovoid shape structure in the short axis with the classic honeycomb appearance. A mark was made on the skin directly superficial to this ovoid structure as well.

Data collection

All procedures performed in this study were in accordance with the Declaration of Helsinki (as revised in 2013) and approved by the Ethics Committee of the Mayo Clinic Hospital, (IRB No. 18-001756). Due to the prospective nature of the study, written consent was obtained. We included 25 consecutive patients to quantify the accuracy in predicting distal TN location via cutaneous palpation versus US-guided nerve visualization. We collected data on the proximal-distal (PD [Knee-Sole]) and the anterior-posterior planes (AP) for both methods. Additionally, the difference in position between the two methods was determined in both PD and AP, Figure 3. Statistical analysis was completed with numeric variables summarized with the sample median, range, and interquartile range (IQR), Table 1. Comparisons between AP and PD distances were performed using a nonparametric Wilcoxon signed-

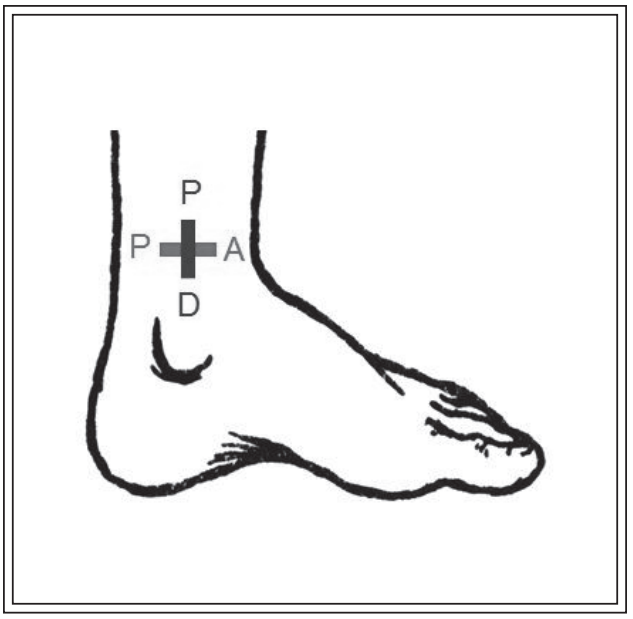

Figure 3. Diagram of anterior-posterior and proximal-distal measurements.

rank test. All analysis and graphics were performed using SAS statistical software (version 9.4M5, SAS Institute Inc., Cary, NC, USA).

Results

Twenty-five patients were studied: 7 (28%) were male and 18 (72%) were female; median age was 37 years (range, 19 to 70; IQR, 31 to 51). The median AP distance between US and digital determination was 2 mm (range, 0 to 5 mm; IQR, 2 to 3 mm). The median PD distance between US and digital determination was 4 mm (range, 0 to 9 mm; IQR, 3 to 5 mm). The median difference between the AP and PD distances was 2 mm (range, -3 to 7 mm; IQR, 0 to 4 mm, p= < 0.001).

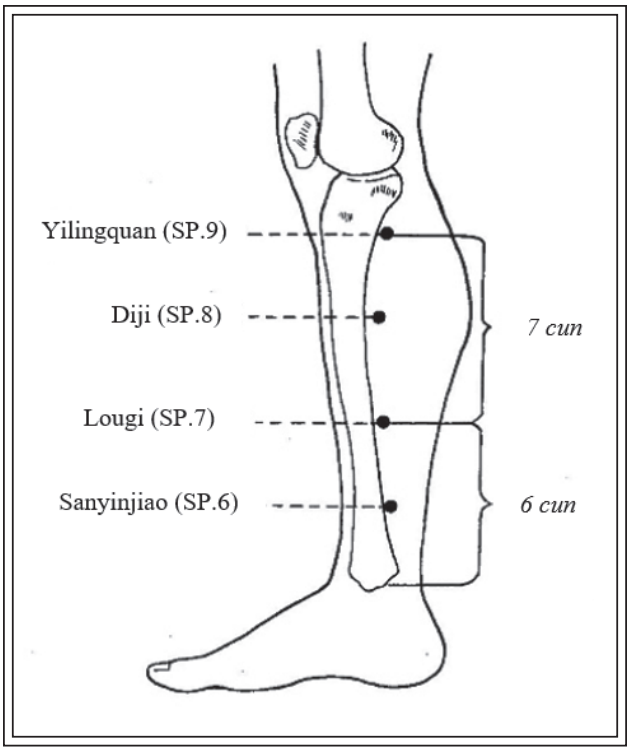

Figure 4. Acupuncture spleen meridian locations.[4]

Discussion

Neuromodulation dates back to early Chinese medicine, with the first historical text describing a medical technique called 'needling' (zhen) written in c. 90 B.C.[2] Many consider this to be the first documented description of what we now refer to as acupuncture. In 1988, Phei L Chang published his findings of increased maximum cystometric capacity and clinical improvement of urinary symptoms in patients who underwent acupuncture at the SP.6 point, Figure 4.[3,4] McGuire et al were the first to describe electrical

TABLE 1. **Summary of results**

	AP distance (mm)	**PD distance (mm)**	**AP-PD distance (mm)**
Mean	2	4	2
SD	1	2	2.47
Median (IQR)	2 (2, 3)	4 (3, 5)	2 (0, 4)
Minimum	0	0	-3
Maximum	5	9	4

AP = anterior-posterior; PD = proximal-distal

stimulation of the TN in 1983 with clinical improvements.[5] Followed closely by Stoller et al who described afferent nerve stimulation in the treatment of overactive bladder.[6] It is now understood that the electrical stimulation of the TN, which contains axons passing through L4-S3 spinal roots, inhibits bladder activity by stimulating somatic afferent fibers leading to central inhibition of the micturition reflex pathway.[7] Despite increased knowledge, the exact mechanism of action has not been fully elucidated. Nevertheless, all the above needle applications are based on anatomic presumptions, palpation, technique, and experience.

In the United States, 16%-28% of women report symptoms consistent with overactive bladder (OAB).[8,9] In response to several new treatments regarding OAB, the American Urological Association (AUA) and Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction (SUFU) released an updated set of guidelines in 2019. These new guidelines are broken down into first, second, third, and fourth line treatments. The third line of therapy includes neuromodulation including in the method of PTNS. The variations in anatomic location of the TN may impact the efficacy of neuromodulation. This prospective study provides clinical data demonstrating that US identifies the PTN with greater accuracy than cutaneous palpation in the PD plane perhaps in a first step to increase the effectiveness and popularity of this technology through more accurate detection.

PTNS is a very well tolerated in-office procedure and we conjecture that the use of US will not affect the ease of application. The adverse events of PTNS are most commonly described as mild and relatively uncommon at 1%-2%, including bruising and bleeding at needle site, tingling and mild pain.[10] The inadvertent placement of the needle through the TN is likely related to increased pain at the time of treatment and may be avoided or mitigated with our described technique via direct needle visualization.

The use of US guidance in anesthesia and pain medicine is not novel and has been well described since 1978.[11] More specifically, studies have been conducted in the use of US to improve the success rate of TN block at the ankle and axillary brachial plexus block showing a better localization of the nerve for sensory block compared with the palpation technique.[12-14] To our knowledge, no formal studies have been conducted utilizing US guided localization of the TN for VD treatment. The challenge of needle placement has led to an interest in the development of implantable TN stimulators.[15-17] There are multiple factors supporting the implementation of transcutaneous US in the identification of the TN. First, treatment efficacy may be impacted by optimal identification of the TN position in the face of individual anatomic variance. Second, the most common side effect documented during PTNS is discomfort at needle insertion. This could be mitigated by accuracy.[18] Efficacy of US guided peripheral nerve stimulation to treat patient symptoms has been reported.[19] Application of accurate US imaging by the urologist or urogynecologist may be limited by baseline training in that technology. This fact has been noted by the appropriate societies and training bodies as evidenced by the AUA in 2012 collaborating with and endorsing the AIUM guidelines in the practice parameters for the performance of US in the practice of Urology.[20] The ultimate value of this technique will be judged by assessing its impact on clinical response as determined by further scientific studies that are currently underway.

The strength of this study is the single provider nature of the palpation technique to eliminate variation as a contributor to outcomes. There are important limitations to this study including its relatively small sample size. In addition, the palpation of the TN is subjective and can be limited by the expertise and experience of the provider mirroring the potential weakness of PTNS as a therapy choice of neuromodulation.

Conclusion

The use of US identifies the nerve with statistically significant greater accuracy than palpation technique along the PD plane. A difference in nerve location was exhibited along the AP plane. The use of US guidance for the application of PTNS is worthy of study with regards to clinical effect and impact. □

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