Neuromodulation for Bladder Conditions and Vivally System

Overactive Bladder (OAB) Condition

Overactive bladder (OAB) is a chronic condition defined by the International Continence Society (ICS) as "urinary urgency, usually accompanied by increased daytime frequency and/or nocturia, with urinary incontinence (OAB-wet) or without (OAB-dry), in the absence of urinary tract infection or other detectable disease."[1] The prevalence of OAB is estimated to be over 16% of the United States adult population, or nearly 44 million patients.[2-3] OAB symptoms can interfere with daily activities, disrupt sleep, reduce quality of life (QoL), and negatively impact mental well-being.[2]

A functional bladder is dependent on the health of the central and peripheral nervous systems. To facilitate functional bladder filling and micturition (bladder emptying), peripheral nerves act as communication pathways between the spinal cord and the urinary system.[4] Dysregulation of these pathways results in a loss of functional bladder, generally experienced by patients as the emergence of lower urinary tract symptoms, such as OAB.

Current OAB Treatment Options

Treatments for OAB are intended to facilitate bladder function, alleviate symptoms, and restore patient quality of life. Current treatment options include behavioral therapies such as timed voiding or pelvic floor muscle training, pharmacotherapies such as anticholinergics and beta-3 agonists, injections of OnabotulinumtoxinA (Botox) into the bladder wall through a cystoscope, and neuromodulation options targeting peripheral nerves, such as the sacral nerves or the posterior tibial nerve (PTN).[5]

Neuromodulation for OAB and Tibial Nerve Stimulation

Neuromodulation is a fast-growing field defined by the International Neuromodulation Society as "the alteration, or modulation, of nerve activity by delivering electrical agents directly to a target area."[6] The field began to grow in the 1960s for epilepsy, cardiac pathophysiology and pain, and in the 1970s for OAB.[6] Neuromodulation is now a well-established and effective treatment for management of OAB symptoms which has been studied in several nerve targets.[5] Devices that target the sacral nerves and the posterior tibial nerve have received Food and Drug Administration (FDA) clearance or approval.

Clinical studies provide evidence supporting tibial nerve stimulation for OAB treatment.[5,7] Although the mechanism of action is not completely understood, neuromodulation appears to modulate bladder pathways, which may be explained by the structural connectivity of the nervous system and urinary system (Bladder, Pudendal Nerve, and Pelvic Nerve). The posterior tibial nerve (PTN) is a distal branch of the sciatic nerve,[4] arising from spinal cord segments L4-S3. Depicted in Figure 1, stimulation of the PTN may provide indirect neuromodulation to the urinary system nerves, which arise from spinal segments S2-S3.[4,8-9]

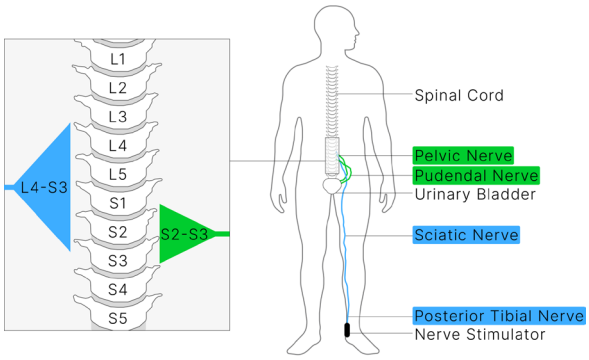

Figure 1. The Structural Connectivity of the Posterior Tibial Nerve, the Spinal Cord, and the Urinary System

The idea of applying therapeutics to neuroanatomical targets originated with ancient acupuncture techniques. Stimulating the PTN for bladder control was investigated in pre-clinical animal studies by McGuire et al, demonstrating that stimulation could modulate bladder dysfunction and they translated the method to treat urinary symptoms in humans by

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applying electrical stimulation to the PTN.[10] A larger study conducted by Govier et al utilized a Stoller Afferent Nerve Stimulation (SANS) device to percutaneously stimulate the PTN on 53 OAB patients, and 71% of patients achieved at least a 25% reduction in mean daytime voiding frequency from baseline to 12-weeks.[11] This was followed by FDA approval of a Percutaneous SANS device in 2000 and two subsequent percutaneous tibial nerve stimulation (PTNS) devices in 2005 and 2013, and later transcutaneous tibial neuromodulation systems such as the Vivally System.

Vivally System – wearable Tibial Neuromodulation with Physiologic Closed-Loop

Vivally System by Avation Medical is a physiologic closed-loop wearable Tibial Neuromodulation (wTNM) System for OAB symptoms, including urinary urgency and urinary urge incontinence. Vivally System (Figure 2) includes a wearable garment with integrated non-invasive stimulation and sensing electrodes, as well as reusable gel cushions to maximize comfort during therapy sessions. A patient mobile app controls therapy sessions and tracks symptoms, and a cloud-based online portal enables clinician monitoring and follow-up.

Figure 2. The Vivally System

The Vivally System is the only FDA-cleared device (K220454) that utilizes physiologic closed-loop control for treatment of OAB symptoms allowing the stimulation to continuously self-adjust and thus provide optimal therapeutic output, even during everyday patient movements and other environmental changes. Vivally complies with FDA special guidelines, which state that "closed-loop systems have the potential to deliver timely, accurate and consistent therapy and can play an important role in minimizing human error and enhancing medical care."[12] Vivally's physiologic closed-loop control uses sensors to record the evoked surface Electromyogram (EMG), a physiological signal generated in response to stimulation. Algorithms filter and interpret the surface EMG signals to adjust stimulation output accordingly (Figure 3).

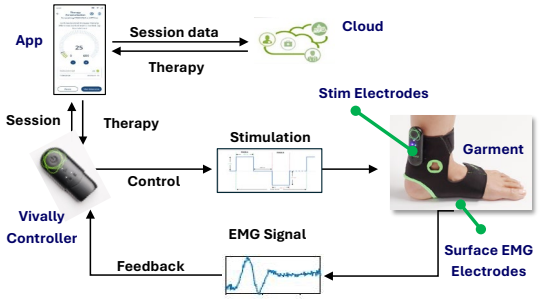

Figure 3. Vivally closed-loop System.

Vivally is calibrated for each patient to personalize therapy parameters, which are individually set for each patient's system and stored in the cloud database. Furthermore, the bi-phasic charge-balanced current-controlled stimulation waveform ensures maximum comfort and consistent therapy output.

The recommended treatment plan is 30-minute sessions, 3 times per week for 12 weeks, with increased sessions up to once per day based on symptom response. After 12 weeks of treatment in a multi-center clinical trial, 84% of patients showed significant improvement in symptoms of urinary frequency, incontinence, or urgency and 99% patients found it easy to use.[13-14] After 12 weeks, the recommended treatment plan is 30-minute sessions 1 time per week, with increased sessions based on symptom response. Given the proven clinical efficacy of tibial neuromodulation and the patient-friendly usability of a wearable, closed-loop system, Vivally is a viable treatment option for the growing population of OAB patients.

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References

1- Haylen BT, de Ridder D, Freeman RM, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *Neurourol Urodyn*. 2010;29(1):4-20. doi:10.1002/nau.20798

2- Reynolds WS, Fowke J, Dmochowski R. The Burden of Overactive Bladder on US Public Health. *Curr Bladder Dysfunct Rep*. 2016;11(1):8-13. doi:10.1007/s11884-016-0344-9

3- Onukwugha E, Zuckerman IH, McNally D, Coyne KS, Vats V, Mullins CD. The total economic burden of overactive bladder in the United States: a disease-specific approach. *Am J Manag Care*. 2009;15(4 Suppl):S90-S97.

4- Fowler CJ, Griffiths D, de Groat WC. The neural control of micturition. *Nat Rev Neurosci*. 2008;9(6):453-466. doi:10.1038/nrn2401

5- Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU Guideline on the Diagnosis and Treatment of Idiopathic Overactive Bladder. *J Urol*. 2024;212(1):11-20. doi:10.1097/JU.0000000000003985

6- Sofatzis T. About Neuromodulation. Neuromodulation.com. Published 2018. https://www.neuromodulation.com/about-neuromodulation

7- Kendall HJ, Schrijvers J, Heesakkers JPFA. Tibial neuromodulation for lower urinary tract dysfunction (idiopathic overactive bladder and non obstructive urinary retention): A review of the literature. *Continence*. 2024;11:101326. doi:10.1016/j.cont.2024.101326

8- Bhide AA, Tailor V, Fernando R, Khullar V, Digesu GA. Posterior tibial nerve stimulation for overactive bladder-techniques and efficacy. Int Urogynecol J. 2020;31(5):865-870. doi:10.1007/s00192-019-04186-3

9- Granger CJ, Cohen-Levy WB. Anatomy, Bony Pelvis and Lower Limb: Posterior Tibial Nerve. StatPearls Publishing; 2023. https://www.ncbi.nlm.nih.gov/books/NBK546623/

10- McGuire EJ, Zhang SC, Horwinski ER, Lytton B. Treatment of motor and sensory detrusor instability by electrical stimulation. *J Urol*. 1983;129(1):78-79. doi:10.1016/s0022-5347(17)51928-x

11- Govier FE, Litwiller S, Nitti V, Kreder KJ Jr, Rosenblatt P. Percutaneous afferent neuromodulation for the refractory overactive bladder: results of a multicenter study. *J Urol*. 2001;165(4):1193-1198.

12- Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology. U.S. Food and Drug Administration. Published December 22, 2021. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-medical-devices-physiologic-closed-loop-control-technology

13- Goudelocke C, Sobol J, Poulos D, Enemchukwu E, Zaslau S, Dhir R. A Multicenter Study Evaluating the FREquency of Use and Efficacy of a Novel Closed-Loop Wearable Tibial Neuromodulation System for Overactive Bladder and Urgency Urinary Incontinence (FREEOAB). *Urology*. 2024;183:63-69. doi:10.1016/j.urology.2023.10.007

14- Goudelocke C, Dhir R, Shapiro E, Cline K, Poulos DE, Hedges P. A Multicenter Prospective Sham-controlled Trial Evaluating a Physiologic Closed-loop Wearable Tibial Neuromodulation System for Overactive Bladder. *Urology*. 2025;195:16-22. doi:10.1016/j.urology.2024.09.018