A Personalized, Surgery-free Wearable Bladder Modulation and Digital Therapy System to Treat OAB Shows Comparable Results to More Invasive Treatments

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Introduction

Despite the availability of several different physician-prescribed treatment options to address the symptoms of overactive bladder (OAB) and urge urinary incontinence (UUI), low rates of patient adoption and poor therapy compliance persist. Pharmacologic agents carry unpleasant side effects and interactions with other medications. Injection of botulinum toxin can be effective in up to 70% of cases; however, it requires use of a cystoscope and comes with side effects resulting in up to 40% of patients terminating therapy. PTNS has been shown to be 64-76% effective at reducing symptoms and has few side effects but requires insertion of a needle-electrode and that the patient travel to the clinic weekly. SNS has been shown to be the most effective treatment with 89% reported to be responders, however, this responder rate excludes patients who failed a temporary trial of SNS. Further, SNS is a more invasive therapy, carries a high re-operation rate, and poses the risk of serious adverse events. Although these therapies have shown good effectiveness, they all have drawbacks which have limited their adoption. OAB and UUI patients remain in need of safe and effective therapies that are surgery-free, convenient, and eliminate the side effects of current treatments.

Methods

A surgery-free, wearable bladder modulation and digital health system (Avation Medical, Columbus, OH) has been developed to address these issues. The wearable system uses neuromodulation of the tibial nerve and allows the patient to conduct therapy at home using a mobile application on the patient's own device. The wearable system utilizes closed-loop physiologic sensing to objectively confirm activation of the nerve and adjust the signal to maintain an optimal therapeutic range. The system is also connected with a digital health platform to track symptoms and therapy data in a HIPAA-compliant cloud server available to both patient and physician. A prospective, multicenter study evaluated the safety and effectiveness of the system by comparing subjects randomized into two arms for a total of 12 weeks: therapy for 30 minutes either one-time or three-times per week. Objective confirmation of tibial nerve stimulation was achieved, and a personal therapeutic range was set for each subject. Therapy sessions were performed by the subject at home.

Results

Ninety-six subjects were enrolled with ninety-three evaluable. Three subjects were dropped due to unreliable data at baseline. All subjects found the garment and sensation comfortable. At 12 weeks, the wearable system demonstrated an 84.8% responder rate. Efficacy was similar in both arms. No serious device-related adverse events were reported.

Discussion

A surgery-free, drug-free, wearable bladder modulation and digital therapy system can be an effective and feasible treatment alternative for the treatment of symptoms of OAB and UUI.

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Personalized, Surgery-Free, Wearable

Bladder Modulation and Digital Health System

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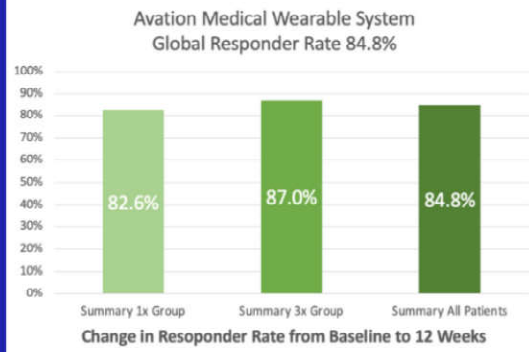
Comparable Results to More Invasive Treatments



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