PATIENT PERCEPTIONS OF TREATMENT OPTIONS FOR OVERACTIVE BLADDER AND THEIR LIKELIHOOD TO TRY A TRANSCUTANEOUS TIBIAL NERVE STIMULATION SYSTEM

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Introduction

Overactive bladder (OAB) is a stressful and disruptive disorder that affects many individuals. The symptoms of OAB cause millions of individuals to suffer from a decrease in their quality of life. It is characterized by four symptoms; urgency, frequency, nocturia, and urge incontinence [1]. In order to be diagnosed, these symptoms or a combination of them must be present without a pathologic or metabolic component causing them [2]. Around 16% of people in the United States are affected by Overactive Bladder [3]. The real number of individuals with OAB is most likely much larger.

The first line of treatments are physical therapy and behavioral modification therapy. behavioral modification therapies include the use of Kegel exercises, timed voiding, and fluid monitoring. All can be highly effective, but many subjects are not compliant [1]. The second line of therapy is pharmacologic treatments. Anticholinergic drugs can be effective in around 60% of subjects but they can produce significant side effects and are cost-prohibitive for many/most [4]. Third line therapies include Botox, percutaneous nerve stimulation (PTNS), and sacral nerve stimulation (SNS). Botox can be effective in up to 70% of cases; however, 39.8% of all who discontinued therapy, did so because of the side effects including urinary retention [1]. The full effect of Botox is temporary and requires additional procedures every 4 to 9 months. PTNS is found to be 70% effective, minimally invasive, and has very few side effects, however patient compliance can be an issue due to the need for frequent visits to the clinic (once a week). Sacral nerve stimulation (SNS) is the most effective at 90% but, it is also the most invasive and can have serious side effects including permanent neurological impairment [5]. In addition to serious side effect, SNS can be very expensive.

Although there are many treatments for OAB, there are significant drawbacks to each leaving a compelling clinical need for a more patient friendly treatment that eliminates the need for both drugs and surgery. We assessed patient interest in using a wearable transcutaneous tibial nerve stimulation system and conducing stimulation in their home setting.

Methods and Materials

This study was designed as a prospective, single visit (2 hours) study to evaluate the effects of a wearable tibial nerve stimulation device on subjects with overactive bladder (OAB) using a commercial TENS device.

After subjects signed the informed consent, they were enrolled in the study. Demographic and baseline measurements were taken including documenting the number of voids per day and the number of frequency events per day. Baseline quality of life will be assessed using an I-QOL incontinence questionnaire, IIQ-7 and Overactive Bladder questionnaire (OAB-q). Subjects were asked a number of questions regarding previous therapies and their understanding of stimulation . After the completion of the interview, subjects were stimulated transcutaneously at the tibial nerve. Stimulation was increased to the highest level tolerable.

After stimulation, all subjects were asked their likelihood of trying a transcutaneous tibial nerve stimulation (TTNS) system on a 5-point Likert scale and the benefit(s) and drawback(s) of it as a treatment option for OAB.

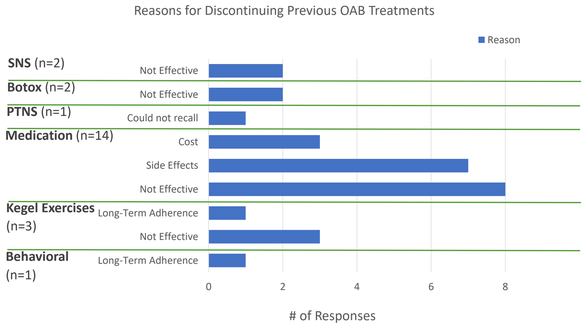

Figure 1. The reasons reported by subjects for discontinuing a previous OAB treatment. Some subjects reported multiple reasons for discontinuing a single OAB treatment.

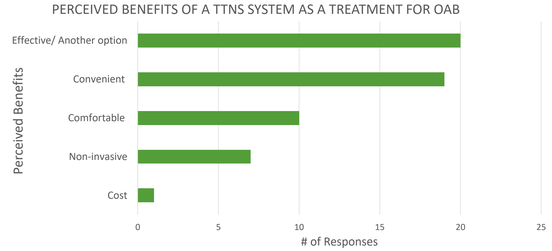

Figure 2. The perceived benefits of a transcutaneous tibial nerve stimulation system for OAB reported by subjects (N=41). Some subjects reported multiple benefits.

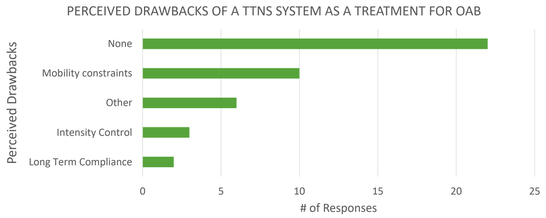

Figure 3. The perceived drawbacks of a transcutaneous tibial nerve stimulation system for OAB reported by subjects (N=41). Some subjects reported multiple drawbacks. 6 unique responses were reported and is represented as "other".

Results

Forty (40) subjects completed the study (10 males; 30 females).

Their mean age was 58.5 years (range 25-73).

The mean duration of OAB symptoms was 8.6 years (range 1-30). 32.5% of the subjects were treating their symptoms by behavioral therapy (25.0%), Kegel exercises (7.5%), and medication (10.0%).

No subject was currently utilizing a third-line therapy. Additionally, 40.0% of the subjects were using incontinence protection.

Mean satisfaction was rated a 3 or lower on a 5-point Likert scale for all current therapies, (2.6 - incontinence protection, 2.4 - behavioral therapy, 3.0 – Kegel exercises, 2.8 – medication).

The discontinued treatments reported by subjects were behavioral therapy (5.0%), Kegel exercises (7.5%), medication (30.0%), PTNS (2.5%), Botox (5%), and SNS (5.0%). 60.0% of the subjects reported no previous treatment.

The reasons for discontinuing the treatments can be found in Figure 1. 57.5% of subjects had never tried a treatment past first-line therapy.

After receiving stimulation all subjects reported that they were likely to try a TTNS therapy as a treatment with 62.5% of the subjects being "extremely likely", 32.5% of the subjects "very likely", and 5.0% of the subjects "moderately likely".

The subjects' initial perception of the benefit(s) and drawback(s) of a TTNS system for OAB can be found in Figures 2 and 3.

Conclusions

OAB subjects are not satisfied with the current treatments and would be willing to try a TTNS system for their OAB.

A long-term study is needed to determine the usability, satisfaction, and efficacy of a TTNS system.

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