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ELECTRICAL STIMULATION OF SOMATIC AFFERENT NERVES IN THE FOOT IMPROVES OVERACTIVE BLADDER SYMPTOMS

Hypothesis / aims of study

The International Continence Society (ICS) defines the overactive bladder syndrome (OAB) as urgency, with or without urge incontinence, usually with frequency and nocturia [1]. Treatments for OAB patients that have failed behavioral and anti-muscarinic or beta-3 agonist therapies include intradetrusor injection of onabotulinumtoxinA, sacral neuromodulation, or tibial neuromodulation. Yet, a non-invasive and convenient OAB treatment with no major adverse effects would be very attractive to many patients. Previous studies in the cat have demonstrated inhibited reflex micturition and increased bladder capacity with transcutaneous electrical stimulation of somatic afferent nerves in the foot using skin surface electrodes. We previously showed that foot stimulation in healthy human subjects without OAB delayed bladder filling sensations and significantly increased bladder capacities [2]. We sought to determine if electrical stimulation of somatic afferent nerves in the foot can improve bladder storage symptoms in humans with OAB.

Study design, materials and methods

Thirteen OAB subjects (ages 40-84 with 12 female and 1 male) were recruited onto the study. Of those 13 patients 10 had urge urinary incontinence (UUI) and 3 had urgency-frequency without incontinence. If applicable, subjects on OAB drug therapy underwent a 2 week pre-study OAB drug 'wash out' period. Patients with implanted electrical stimulators were excluded. Subjects completed a 3-week voiding diary during which foot stimulation was applied during the second week. Each subject underwent 3 hours of foot stimulation every evening for a week using skin surface electrodes connected to a transcutaneous electrical nerve stimulator. The electrodes were attached to the bottom of the foot to activate the lateral and medial plantar nerves (Figure). Each voiding diary included the time and urine volumes per void, the number of urge urinary incontinence (UUI) episodes per day, and the number of urinary urgency episodes per day during the 3-week period. Stimulation parameters included a pulse frequency of 5 Hz, a pulse width of 0.2 ms, and an intensity of 2-4 times the minimal stimulation current necessary to induce a toe twitch. The stimulation intensity was maximally set by the subjects themselves to ensure comfort.

Results

The mean number of daytime voids per day decreased from 9.05±0.29 to 7.31±0.31 after a week of foot stimulation, p=0.03 (Table). The mean number of daily urge urinary incontinence (UUI) episodes per day increased from 2.17±0.27 to 1.37±0.19 after a week of foot stimulation, p=0.02. The mean volume per daytime void increased from 161.2±9.2 ml to 193.8±11.1 ml after a week of foot stimulation, p=0.02. The mean number of daily urgency episodes decreased from 7.09±0.31 to 6.11±.03 after a week of foot stimulation, p=0.03. The mean number of night-time voids decreased from 1.48±0.13 to 1.09±0.14 after a week of foot stimulation, p=0.04. The mean volume per night-time void decreased from 206.8±18.4 ml to 151.8±17.9 ml after a week of foot stimulation, p=0.03. There were no adverse events. Specifically, there was no skin irritation, redness, rash, or foot cramp seen in any of the patients with foot stimulation.

Interpretation of results

Foot stimulation for 3 hours every evening for a week in 13 OAB patients resulted in statistically significant ($p<0.05$) decreases in UUI episodes/day, daytime voids/day, urgency episodes/day, night-time voids, volume/night-time void. In addition, foot stimulation resulted in a statistically significant increase in volume/daytime void. The decrease in mean volume/night-time void can be explained with the reduction in the number of night-time/voids.

Concluding message

Foot stimulation reduced # of daily UUI episodes, # day-time voids/day, # urgency episodes/day, # night-time voids, and volume/night-time void, and it significantly increased volume/daytime void in 13 OAB subjects. Although this study group was small, our results support moving forward with further clinical trials of foot stimulation in OAB patients. We plan to next perform hand stimulation in OAB patients as a control arm to confirm that the foot stimulation results are effective in the treatment of OAB.

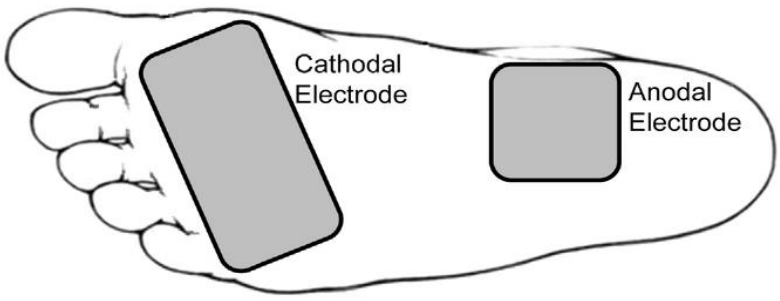

Figure:Sites on right foot where 2 pad electrodes were placed to stimulate somatic afferent nerves of foot.

	Before foot stimulation	After foot stimulation	p value
# Day-time voids/day	9.05 ± 0.29	7.31 ± 0.31	0.03
# UUI episodes/day	2.17 ± 0.27	1.37 ± 0.19	0.02
Volume/daytime void	161.2 ± 9.2 ml	193.8 ± 11.1 ml	0.02
# Urgency episodes/day	7.09 ± 0.31	6.11 ± 0.03	0.03
# Night-time voids	1.48 ± 0.13	1.09 ± 0.14	0.04
Volume/night-time void	206.8 ± 18.4 ml	151.8 ± 17.9 ml	0.03

Table: Results of Foot Stimulation on OAB parameters.

References

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Disclosures

Funding: Wallace H Coulter Foundation at the University of Pittsburgh **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** University of Pittsburgh Institutional Review Board **Helsinki:** Yes **Informed Consent:** Yes