644

Chermansky C[1], Shen B[1], Okonski J[1], de Groat W[2], Tai C[1]
1. *Dept of Urology - University of Pittsburgh,* ***2.*** *Dept of Pharmacology and Chemical Biology - University of Pittsburgh*

ELECTRICAL STIMULATION OF AFFERENT NERVES IN THE FOOT WITH TRANSCUTANEOUS ADHESIVE PAD ELECTRODES IN WOMEN WITH OAB: COMPARISON OF DIFFERENT STIMULATION DURATIONS

Hypothesis / aims of study
A non-invasive and convenient overactive bladder (OAB) treatment with no major adverse events would be ideal. We previously showed that stimulation of afferent nerves in the foot for 3 hours daily with transcutaneous adhesive pad electrodes (FootStim) decreased urgency urinary incontinence (UUI) and urgency frequency in women with refractory OAB. Yet, the ideal stimulation duration remains unknown. In this study, we sought to define the ideal stimulation duration in women with refractory OAB who underwent FootStim for either 30 minutes or 3 hours daily for 1 week.

Study design, materials and methods
Women with refractory OAB were recruited onto the study. All these patients with UUI stopped OAB drug therapy 2 weeks prior to study initiation. A 3-week voiding diary was obtained, and FootStim was applied during week 2. The patients underwent FootStim for either 30 minutes or 3 hours daily. Baseline voiding parameters were measured during week 1, and the post-stimulation effect was measured during week 3. Adhesive pad electrodes were attached to the bottom of the foot and connected to a transcutaneous electrical nerve stimulator. Stimulation parameters included pulse frequency of 5 Hz, pulse width of 0.2 ms, and intensity of 2-4 times the minimal stimulation necessary to induce a toe twitch. Responder was defined as having a statistically significant improvement in 1 or more OAB symptoms.

Results
38 women completed the study, of which 19 underwent stimulation for 3 hours and 19 underwent stimulation for 30 minutes. The response rates were 16/19 (84%) in the 3 hour group and 12/19 (63%) in the 30 minute group (Fig 1). In the 3 hour group (Fig 2) UUI frequency decreased from 3.5 to 1.4 leaks/day (p=0.004) and urgency frequency decreased from 8.5 to 6.2 episodes/day (p<0.0001). Also, daytime voiding frequency (n=8) and nocturia (n=7) decreased in the 3 hour group. In contrast, only UUI frequency decreased in the 30 minute group, and this dropped from 5.5 to 3.3 leaks/day (p p<0.0001). In the 30 minute group urgency frequency improved in only 3, nocturia improved in 2, and daytime urinary frequency improved in 2. Mean FootStim intensity was 2.5 times motor threshold in both groups. FootStim effects persisted in both groups for 4 days after treatment ended. There were no adverse events in either group.

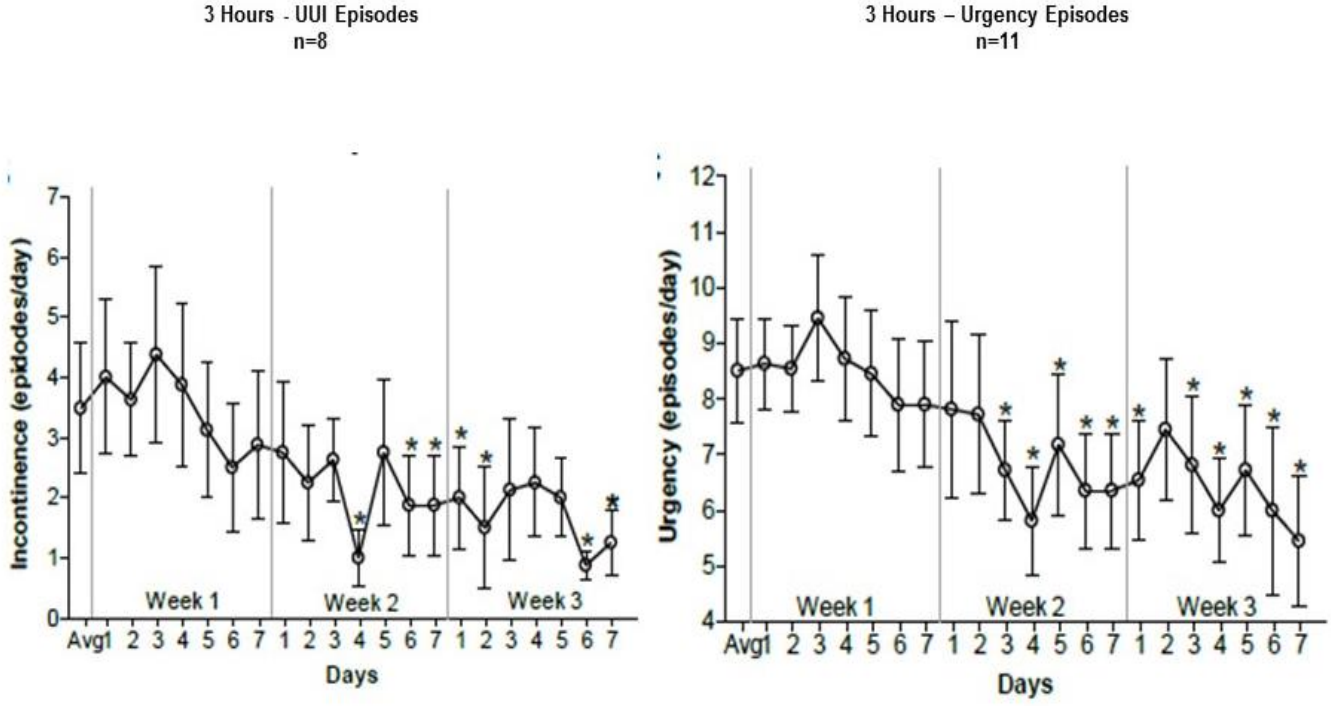
Interpretation of results
Although this preliminary study is neither randomized nor sham controlled, testing different stimulation durations does serve as a test to define the ideal stimulation duration. FootStim for either 30 minutes or 3 hours daily for 1 week decreased UUI episodes in women with OAB; however, FootStim for 3 hours better improved the other OAB symptoms.

Concluding message
FootStim for either 30 minutes or 3 hours daily decreased UUI frequency in women with refractory OAB; however, FootStim for 3 hours better improved the other OAB symptoms. Our results support further testing of FootStim to determine long-term efficacy and stimulation schedule.

Figure 1: FootStim for OAB - Responders

	3-Hour Stimulation 16 responders from 19 subjects (84%)				30-Minute Stimulation 12 responders from 19 subjects (63%)			
	Week 1 (7 days)	Week 2-3 (7 days)	# of Subjects	P value	Week 1 (7 days)	Week 2-3 (7 days)	# of Subjects	P value
Frequency (voids/day)	10.0±0.4	8.5±0.4	8	0.0001*	10.2±0.4	7.9±0.4	2	0.2710
Voided Volume (mL/void)	187±10	217±10		0.0407*	222±18	221±13		0.8840
Incontinence (episodes/day)	3.5±0.4	1.4±0.3	8	0.0035*	5.5±0.3	3.3±0.3	11	<0.0001*
Urgency (episodes/day)	8.5±0.4	6.2±0.4	11	<0.0001*	6.4±0.6	1.6±0.3	3	0.0398*
Nocturia (episodes/day)	1.8±0.1	1.0±0.1	7	<0.0001*	2.6±0.4	1.5±0.3	2	0.1586

Figure 2: Time Course of FootStim Effects on UUI and Urgency in Responders from 3 Hour Group



Avg – average data over week 1 * Indicates significantly ($p<0.05$) different from Average using paired t test

Disclosures
Funding: Colter Foundation University of Pittsburgh **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov, NCT01972061 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** University of Pittsburgh Institutional Review Board **Helsinki:** Yes **Informed Consent:** Yes