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INTONE: A NOVEL PELVIC FLOOR REHABILITATION DEVICE FOR URINARY INCONTINENCE

Hypothesis / aims of study

Biofeedback (BF) and electrical stimulation (ES) are used as adjunctive measures to pelvic floor exercises for the management of urinary incontinence. They typically require multiple visits to a therapist's office. InTone (InControl Medical) is a non-implanted vaginal device providing biofeedback (BF) and electrical stimulation (ES) of the pelvic floor muscles that can be used at home. The purpose of this study is to assess the efficacy and usability of InTone for the treatment of urinary incontinence.

Study design, materials and methods

Women with urinary incontinence (stress, urge, mixed) were recruited for this single-center, prospective, IRB-approved pilot trial. The type of incontinence was determined by patients' answers to questions describing SUI (leaking with coughing, sneezing, exercise/activity), UUI (leaking with strong urge) and MUI (both SUI and UUI). Patients with MUI were asked which type of incontinence (SUI or UUI) was predominant. All patients completed standardized symptom questionnaires (Urogenital Distress Inventory, UDI6: Incontinence Impact Questionnaire, IIQ7), 48 hour bladder diaries and 24 hour pad weight tests prior to study entry. A minimum of 1 incontinent episode per day documented on diary and 10g of leakage on 24 hour pad weight testing was needed for study eligibility. Patients with pelvic organ prolapse greater than stage 2, recurrent urinary tract/vaginal infections, or an underlying neurologic/neuromuscular disorder were excluded. InTone was used 5-6 days a week for 12 weeks. Each session is 12 minutes in duration: 7 minutes of BF-assisted pelvic muscle contractions and 5 minutes of ES. Efficacy was assessed by comparing the 12 week results to the baseline values using Chi-square and Wilcoxon Rank-Sum tests. Usability was assessed with a device usage log and the System Usability Scale (SUS) which evaluates patient global impression of usability [1].

Results

Thirty-three women were enrolled. Five patients withdrew and were excluded. Twenty-eight patients completed the 3 month trial and are included in the analysis. Median age was 50 years (range 35-69). Fourteen patients (50%) were post-menopausal and 8 (28.6%) were using some form of estrogen replacement (4 SUI patients, 4 UUI patients). Twenty-three of 28 patients (82.1%) had previously performed PFME (18 SUI patients, 5 UUI patients) and 10 (35.7%) had also completed some form of pelvic floor PT and/or tried some type of vaginal incontinence device (6 SUI patients, 4 UUI patients). Five patients (17.9%) had previously undergone suburethral sling. Five patients (17.9%) had used OAB medications prior to the trial and 2 remained on the medication during the trial (both UUI patients). One patient with SUI continued her pre-trial duloxetine during the trial.

Table 1 shows baseline and 3 month subjective and objective results with comparisons between SUI and UUI patients. After 3 months of InTone use, significant improvements in UDI6, IIQ7, pad weights, pad usage, daily incontinent episodes and PFM strength were noted for the entire group. Thirteen patients (46.4%) were using 1 or fewer pads per day with the majority (12) having had predominantly SUI. 68% of patients achieved a >50% reduction in daily pad usage and pad weights. Device usability was good with a median SUS of 86.3 (range 22.5 - 100.0) and a median percent of expected use of 107% (33-140%).

Five patients experienced UTI during the trial and 5 had vaginitis (1 Gardnerella, 4 Candida). One of the Candida infections occurred in the patient who received antibiotic treatment for Gardnerella. Most infections occurred within the first month of use and appeared to resolve with additional patient instruction regarding proper cleaning procedures.

Table 1. Baseline vs 3 Month Data (Wilcoxon rank-sum test)

Variable	Baseline	3 Month	Change	P
UDI 6				
Entire Group	50.0 (0-66.7)	29.2 (0-75.0)	-12.5 (-62.5-15.0)	<0.001
SUI	50.0 (0-66.7)	22.9 (0-62.5)	-20.8 (-62.52-12.5)	<0.001
UUI	58.3 (25.0-66.7)	37.5 (25.0-75.0)	0 (-20.8-15.0)	0.625
IIQ 7				
Entire Group	42.9 (9.5-90.5)	14.3 (0-81.0)	-23.8 (-90.5-38.1)	<0.001
SUI	50.0 (9.5-90.5)	9.5 (0-76.2)	-23.8 (-90.5-19.0)	<0.001
UUI	38.1 (14.3-81.0)	23.8 (4.8-81.0)	-9.5 (-42.9-38.1)	0.563
24 Hr Pad Weight				
Entire Group	35.5 (10.1-634.0)	4.6 (0-274.6)	-28.6 (-359.4-21.3)	<0.001
SUI	34.1 (10.1-279.6)	3.7 (0-212.0)	-30.0 (-268.5-18.3)	<0.001
UUI	108.0 (17.1-634.0)	38.4 (0-274.6)	-24.7 (-359.4-21.3)	0.078

24 Hr Pad Use Entire Group SUI UUI	 4.0 (1.0-9.0) 4.0 (1.0-9.0) 4.0 (2.0-6.0)	 2.0 (0-6.0) 1.0 (0-6.0) 3.0 (0-4.0)	 -2.0 (-5.0-0) -3.0 (-5.0-0) -2.0 (-4.0-0)	 <0.001 <0.001 0.031

Results presented as median (range).
There were no significant differences between SUI and UUI patients except for UDI6: 3 month UDI6 and change in UDI6 were significantly lower and higher, respectively, in SUI patients

Interpretation of results

Women who used intone, particularly for SUI, experienced significant reductions in incontinence based on 24 hr pad weight testing and pad usage. Symptom scores also showed significant improvements although to a lesser degree than the objective measures. It is possible that with more time, further improvement in the symptom scores could occur.
The device was perceived to be easy to use as noted by the median SUS score of 86.3 (an average SUS score is 68) and there was excellent compliance with device usage (>100%). This compares favourably with the 45% patient compliance for the addition of ES to PFME noted by Bidmead et al [2].
Our study is limited by the lack of a comparison group doing PFME alone. Most of the women in the trial had done or were currently doing PFME at the time of trial entry, and approximately 1/3 had already done some form of pelvic floor physical therapy and/or used a vaginal device previously. Nevertheless, the demonstration, in a randomized trial, of superiority of InTone over a comparison group undergoing a supervised regimen of PFME, with at least monthly visits, would make the findings much more significant. Our pilot trial provides preliminary data on InTone that justifies such a trial.

Concluding message

Twelve weeks of InTone usage resulted in significant objective and subjective reductions in urinary incontinence. Device usability was very good.

References

1. Burke J (2013) SUS: A Retrospective. Journal of Usability Studies 8:29-40
2. Bidmead J MJ, Cardozo L, Hextall A, Boos K. (2002) Home electrical stimulation in addition to conventional pelvic floor exercises: a useful adjunct or expensive distraction? Neurourology and Urodynamics 68:372-373

Disclosures

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