

A RANDOMIZED CONTROLLED TRIAL OF THE URESTA CONTINENCE DEVICE: SHORT TERM URESTA EFFICACY STUDY ("SURE" STUDY)

Hypothesis / aims of study

Stress urinary incontinence (SUI) is a common problem in women that can significantly affect quality of life. Commonly used treatments for SUI include pelvic floor exercises, intravaginal incontinence pessaries and surgery. A new, self-positioning intravaginal incontinence pessary (Uresta) has been developed. An initial, uncontrolled study showed a significant reduction in urinary incontinence with no reported complications (1). The aim of this study was to determine the short-term efficacy of the Uresta intravaginal device in reducing the loss of urine due to stress incontinence. The hypothesis is that the Uresta device will significantly reduce objective measures of urine loss from baseline.

Study design, materials and methods

A single centre randomized controlled trial was conducted. Participants were randomized to receiving either the Uresta device or a sham device (vaginal silastic ring) for the duration of a pad test to objectively assess urine loss with physical activity. All women over 18 years of age with urodynamically proven SUI presenting for evaluation at a tertiary centre were invited to participate. Exclusion criteria included; mixed incontinence, significant pelvic organ prolapse, a post-void residual over 100 mls, hematuria, vaginal bleeding, current pregnancy, previous surgery for prolapse or incontinence, or physically unable to perform a pad test. Randomization was performed with the use of an internet-based randomization service. Before placing any device, a baseline pad test was performed by retrograde filling the bladder with 300 mls of saline and completing physical activities as described previously by Farrell et al. (1) Participants were blinded to the device being inserted using a drape, and a second pad test was performed with a device in place. The difference in pad weight before and after device placement was calculated. The primary outcome was the achievement of a 50% reduction in the pad weight before and after device placement. It was predicted based on a previous study (1) that 75% of the group assigned to the Uresta would have a 50% reduction in urine loss, with a 25% reduction among the sham group. Using a chi square test, 2-tailed alpha of 0.05 and a power of 0.8, the required sample size was 18 patients per group, or a total of 36 participants.

Results

Between February 2011 and March 2013, participants (n=36) were randomized to receive either the Uresta continence device (n=18) or a vaginal silastic ring (n=18). Baseline characteristics including mean age (46.4 vs. 47.9), Parity (2.0 vs. 2.1) and BMI (26.8 vs 25.1) were similar between the Uresta and the placebo groups respectively. With an intention to treat analysis, a significantly higher proportion of the women assigned to the Uresta (12/18, 66.7%) experienced at least a 50% reduction in urine loss in comparison those assigned to the vaginal silastic ring (4/18, 22.2%) p=0.0121. Despite a formal diagnosis of SUI with urodynamics, 4 women in the Uresta group and 2 women in the sham device group did not experience any urine leakage during the baseline pad test. Repeat analysis after excluding these 6 subjects showed a 50% or greater reduction in urine loss for 85.7% (12/14) of those assigned the Uresta device, and 24.5% (4/17) of the silastic ring group (p=0.0068). 64.3% (9/14) of participants were completely dry following Uresta device placement, compared to 11.8% (2/17) receiving the vaginal silastic ring (p=0.0068).

Interpretation of results

The Uresta intravaginal continence device significantly reduces short term objective measures of urine loss due stress urinary incontinence in comparison to placebo.

Concluding message

The Uresta continence device reduces urine loss due to stress urinary incontinence. Further study to assess subjective outcomes and patient satisfaction are required.

References

1. Farrell SA, Baydock S, Amir B, Fanning C. Effectiveness of a new self-positioning pessary for the management of urinary incontinence in women. *AJOG* 2007; 196: 474.e1-474.e8.

Disclosures

Funding: University Of Toronto, Department of Obstetrics and Gynaecology Research Fund **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov Identifier: NCT01284244 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Research Ethics Board, Mount Sinai Hospital, Toronto, Canada **Helsinki:** Yes **Informed Consent:** Yes