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ORIGINAL ARTICLE

Short-term Uresta efficacy (SURE) study: a randomized controlled trial of the Uresta continence device

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Abstract
Introduction and hypothesis An intravaginal device (Uresta) is currently available for the treatment of stress urinary incontinence (SUI). Case-series data on its effectiveness exist; however, controlled data are lacking. The objective of this study is to determine the short-term efficacy of the Uresta device using a randomized placebo controlled trial. The hypothesis is that the Uresta device might significantly reduce urinary loss.
Methods A single blind randomized controlled trial was conducted among women with urodynamic SUI recruited from a single urogynecology unit. Participants were randomized to receive the Uresta device or a placebo vaginal silastic ring placed high in the vagina for the duration of a pad test. Pad tests were performed before and after device placement. The primary outcome was the achievement of a 50 % or greater reduction in pad weight after device placement, in a comparison of the two groups. Sample size calculation showed a need for 18 subjects per group. Fisher's exact test was used to analyze the primary outcome. Research Ethics Board approval was obtained.
Results Eighteen subjects per group completed the study protocol. The percentage of patients who achieved the primary outcome was 66.7 % in the Uresta group and 22.2 % in the placebo group ($p = 0.01$). The baseline demographic data were similar in the two groups. There were no adverse events during the test period.
Conclusions The Uresta intravaginal continence device significantly reduces the short-term objective measures of urine loss due to SUI. Further study to assess subjective outcomes and long-term patient satisfaction is required.

Keywords Stress urinary incontinence · Uresta continence device

Introduction

Stress urinary incontinence (SUI) is a common problem in women that can have a significant impact on the quality of life. Almost 30 % of women develop urinary incontinence at some point in their lifetime, and SUI is the most common subtype [1]. Approximately 11 % of women undergo surgery for either pelvic organ prolapse (POP) or SUI by the age of 80 and up to one third will require repeat procedures [2]. The most commonly utilized treatments for SUI include either pelvic floor (Kegel) exercises or surgery. Many women find Kegel exercises unsatisfactory, but are reluctant to undergo a surgical procedure. Also, women who are poor candidates for surgery have limited options if Kegel exercises are unsuccessful. Over the years, there have been numerous attempts to develop effective nonsurgical alternatives for treating SUI, but the results have been variable and the data available on efficacy are limited [3, 4]. Such treatments include periurethral bulking agents, intraurethral devices, alpha-adrenergic medications, and intravaginal incontinence pessaries.

Another intravaginal continence device (Uresta) has been developed for treating SUI, and is currently available for use. The self-positioning device is designed to be easily inserted into the vagina and spontaneously fall into position, providing

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support beneath the urethra. The bell-shaped lower end of the device allows it to be seated just above the introitus and at the level of the urethra, thus providing the urethra with supportive pressure at the moment of stress. It is usually first fitted by a healthcare provider, but can be subsequently placed by the patient as needed or desired, for example, during exercise. A single, uncontrolled study of 21 women showed that the Uresta significantly reduces urinary incontinence, with no reported complications [5]. Using questionnaires, Farrell showed a 47 % reduction in self-reported SUI symptoms. Pad weight following a pad test demonstrated a 50 % reduction in leakage. Sixteen out of 21 (76 %) women who were successfully fitted with an Uresta were satisfied, and were still using the device at 1 year. Without a control group, this study was open to bias owing to co-interventions such as Kegel exercises, bladder training, modification of fluid intake, weight loss or any other placebo effect that could affect satisfaction or a sense of well-being.

This trial is intended to be a short-term assessment of the efficacy of the Uresta device, using a placebo arm to remove any of the possible sources of patient biases cited above. The placebo ("sham") group was obtained by placing a flexible silastic ring high in the vagina where it did not alter the urethral forces. The aim was to unequivocally determine whether the Uresta device provides the necessary urethral support to stop urine leakage from SUI using a blinded randomized design.

Materials and methods

This study was a single, blinded, randomized, controlled trial of patients with urodynamically proven SUI recruited between February 2011 and March 2013. Women presenting to a tertiary center with the complaint of urinary incontinence underwent a standard evaluation, including urogynecological history, pelvic examination including assessment for POP, and multi-channel urodynamic assessment. Urodynamic evaluation included measurement of post-void residual urine volume by urethral catheterization or bladder scan, uroflowmetry, subtracted filling cystometry, and urethral pressure profilometry. The trial was registered with ClinicalTrials.gov (NCT01284244).

Women with urodynamically proven SUI were approached to enter the study, and written informed consent was obtained. These patients had SUI subjectively described as having a moderate to severe impact on lifestyle, such that they would consider surgical treatment. Some of the patients were awaiting a surgery booking for SUI, but wished to participate in the study until surgery could be arranged. Randomization was performed with the use of an internet-based randomization service, assigning patients to receive either the Uresta (Resilia, Shediac, NB, Canada) or the vaginal silastic ring. The attending staff urogynecologist or clinical fellow approached patients for enrollment. The clinical fellow performed randomization and group allocation. Randomization and group allocation were performed immediately before pad testing and device or placebo placement. Exclusion criteria were: mixed incontinence where urgency incontinence was the predominant symptom, a cystometric bladder capacity less than 300 mL, prolapse of any vaginal compartment beyond the level of the hymen, post-void residual urine volume greater than 100 mL, hematuria, undiagnosed vaginal bleeding, current pregnancy, a past history of surgery for incontinence or prolapse, failed use of an incontinence pessary, or those physically unable to perform the activities included in the pad test.

Demographic and baseline characteristics of the participants were recorded, including age, menopausal status, parity, type of previous deliveries (vaginal or Cesarean), number of caffeinated beverages consumed per day, previous hysterectomy, previous reconstructive pelvic/incontinence surgeries, symptoms of urinary urgency, medical conditions including chronic cough, BMI, medications, and current use of local or systemic estrogen therapy. Women of childbearing age who could be pregnant received a urine pregnancy test before randomization.

The Uresta pessary is made of medical grade rubber that has been extensively tested for safety. It is bell-shaped, with a narrow tip that allows for easy insertion into the vagina in a similar fashion to a tampon. The device was designed to be easily inserted, positioned, and removed by a patient for use when needed. A complete set of Uresta pessaries includes three sizes (size 3, 4, and 5) that can be fitted by a healthcare provider, or by the patient.

Before placing any device, a baseline pad test was performed. The bladder was filled in a retrograde fashion with 300 mL of sterile saline, with each participant then completing five repetitions of the following physical activities: coughing, step climbing, heel bounce, standing from a sitting position, and walking 50 yards. Women randomized to the control group then had a flexible silastic ring inserted high into the vagina. The silastic ring was the equivalent of a nonmedicated Estring (Prizer™) with no estradiol. The silastic ring was placed high in the posterior fornix to ensure that it was well away from the urethra, and would thus not affect the urethral forces. Patients randomized to the Uresta group had the Uresta size determined first. To fit the Uresta, the smallest size was placed first, and the patient was asked to cough in a semi-recumbent position. If leakage was still observed, then the next size of Uresta device was placed until either the largest size was reached, the patient was uncomfortable due to the size (in which case the next smaller size was replaced), or stress leakage was not observed. If the Uresta fell out or descended to the vaginal introitus, a larger size was placed. A drape was used to conceal from the patient whether the

Uresta device or silastic ring had been placed in the vagina. The identical pad test protocol was conducted, and the difference in pad weight before and after device placement was calculated.

The primary outcome variable was the achievement of a 50 % reduction in pad weight following device placement. This figure was obtained from the study by Farrell, where pad weight decreased from 20 grams to 9 grams with the use of the Uresta [5]. Sample size calculation was performed as follows. It was hypothesized that 75 % of the Uresta group would have the desired 50 % reduction in pad weight, and only 25 % of the control group would have such a reduction. With this prediction, using a Chi-squared test, two-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.

Categorical variables were analyzed using Fisher's exact test, and continuous variables using the *t* test. Ethics approval was received from the hospital Research Ethics Board (reference # 10-0131-A). The costs of purchasing the Uresta devices, in addition to minor incidental costs, such as paper and printing, were internally funded by the hospital department. Other than reimbursement for parking and a free Uresta device after study completion, the study subjects did not receive any financial incentives. The researchers did not have any affiliation with the supplier or inventor of the Uresta device. The study design and conduct was at the sole discretion of the researchers without any input by the supplier or inventor of the Uresta device.

Results

Baseline characteristics (Table 1) of the 36 women who were randomized were similar in the Uresta and placebo groups. All subjects completed the study protocol. Table 2 shows the intention to treat analysis with the proportion of each group that achieved the primary outcome of at least a 50 % reduction in pad weight after placement of either the Uresta or placebo silastic ring. The percentage of patients who achieved the primary outcome was 66.7 % (12 out of 18) in the Uresta group and 22.2 % (4 out of 18) in the control group ($p = 0.01$).

Table 1 Baseline characteristics of the study participants

Characteristic	Uresta ($n = 18$)	Placebo ($n = 18$)
Age (mean ± SD)	52.1 ± 11.0	49.8 ± 7.5
Parity (mean ± SD)	1.9 ± 1.0	1.8 ± 1.0
BMI (mean, kg/m^2)	26.5	25.1
Menopausal status		
Pre-menopausal	10	14
Post-menopausal	8	4
Previous hysterectomy	4	2

SD standard deviation, *BMI* body mass index

Table 2 Pad test results

	Uresta ($n = 18$)	Placebo ($n = 18$)	p*
ITT analysis	12/18 (66.7 %)	4/18 (22.2 %)	0.01
Second analysis[a]	12/14 (85.7 %)	4/17 (23.5 %)	0.01
Third analysis[b]	9/14 (64.3 %)	2/17 (11.8 %)	0.007

ITT intention to treat

*Fisher's exact test

[a] Proportion of participants who achieved a 50 % or greater reduction in pad weight among those with loss at baseline pad testing

[b] Proportion of participants who were completely dry among those with loss at baseline pad testing

Despite being urodynamically diagnosed with SUI before recruitment, 4 women in the Uresta group and 1 woman in the control group did not leak urine during the baseline pad test before placement of the Uresta or placebo. Therefore, a repeat analysis without these subjects was performed, using the same primary outcome measure (Table 2). In this subset, the primary outcome of at least a 50 % reduction in pad weight was achieved in 85.7 % (12 out of 14) of the Uresta subjects and only 23.5 % (4 out of 17) of the control subjects ($p = 0.01$). A final analysis of this subset was performed for the proportion of participants who were completely dry after device placement (Table 2), showing that 64.3 % (9 out of 14) of the Uresta subjects were completely dry, compared with only 11.8 % (2 out of 17) of the control subjects ($p = 0.007$).

There were no documented adverse events, and no patients reported significant discomfort with device placement.

Discussion

Our study has shown objective unbiased evidence that the Uresta continence device is effective in treating SUI using a short-term outcome measure. Pre-existing studies of the Uresta continence device were uncontrolled case series, and were therefore open to various biases. Our study of the Uresta device used a placebo control group to reduce any effects of bias or co-intervention. Blinding of the study subjects was also important in reducing bias. Although the investigator was not blinded, the fact that the primary outcome measure was objective and precise reduced the chance of bias on the part of the investigator.

The intention to treat analysis (Table 2) showed that the Uresta was effective, and that the results were statistically significant. However, there was an unexpected finding that some of the study subjects (4 in the Uresta group and 1 in the control group) did not have any leakage during the baseline pad test before placement of the Uresta or placebo, even

though they all had urodynamically proven SUI before study enrolment. It is possible that the bladder volume during urodynamics was greater than the 300 mL volume used for the standardized pad test. Another explanation for the discrepancy could be that the urodynamics nurse provoked a very strong cough and Valsalva, which was greater than the provocative maneuver used for the pad test. It is also possible that study subjects had undertaken a course of pelvic muscle exercises during the interval between urodynamics and study enrolment. Further unplanned data analysis was performed after removing these patients (Table 2), as it was felt that useful information could be obtained, even though the unplanned analyses were not performed on an intention to treat basis. It was reassuring that all three analyses were in agreement, showing a statistically significant improvement with the Uresta device.

The study subjects were selected to be fairly consistent and representative of patients presenting with symptoms of SUI. Exclusion criteria were used to eliminate complicated cases such as previous failed surgery for SUI. The subjective severity of symptoms was such that this population of patients attending a tertiary urogynecology clinic would likely be seeking significant intervention or surgery. Therefore, it was felt that this study is generalizable to the population at large and applicable to most healthcare providers who see women with SUI.

This study used a short-term outcome measure to design a feasible trial where the study intervention (Uresta) could be tested against a placebo control. As discussed above, it was felt that this was an important issue that was lacking in pre-existing studies on the Uresta device. However, there is a limitation to this study that long-term efficacy and real-world effectiveness were not assessed. It is difficult to extrapolate the results from this study to a patient who may be fitting an Uresta device herself with limited involvement by a healthcare provider. Further study to assess subjective outcomes and long-term patient satisfaction is required.

In summary, the Uresta continence device was shown to be effective in treating SUI using a short-term outcome measure. This provides a useful management option for women who prefer to use a nonsurgical form of treatment for SUI.

Compliance with ethical standards

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Conflicts of interest The authors declare that they have no conflicts of interest.

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