UROGYNECOLOGY

Effectiveness of a new self-positioning pessary for the management of urinary incontinence in women

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OBJECTIVE: The objective of the study was to evaluate the effectiveness of a new self-positioning women's incontinence pessary.

STUDY DESIGN: Thirty-two women were enrolled and followed up for 12 months. Evaluation included baseline questionnaires, physical examination including pelvic organ prolapse quantification (POP-Q) scores, cotton swab testing, and assessment of Kegel strength. A pad test and 7 day urolog were also performed before and after pessary fitting.

RESULTS: Incontinence questionnaire scores were all significantly reduced as percent of baseline: stress incontinence, 7 of 15 (47%) ($P = .000$); urge incontinence, 5 of 14 (36%) ($P = .002$); the urogenital distress inventory (short form); 2 of 6 (33%) ($P = .002$); and incontinence impact questionnaire (short form), 4 of 8 (50%) ($P = .002$). Leaking episodes decreased by 4 (7 day urolog) ($P = .028$) and pad weights by 11 g ($P = .006$). Among women successfully fitted at 2 weeks, 16 of 21 or 76% continued using their pessary at 1 year. There were no complications with pessary use.

CONCLUSION: The Uresta incontinence pessary significantly reduces urinary incontinence and is easy for women to use.

Key words: conservative management, pessaries, urinary incontinence

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Urinary incontinence is an international problem of significant proportion.[1,2] Although surgical management of this problem is effective,[3] access to surgery is limited by a triage system, used in many countries, which requires initial evaluation by a general practitioner before referral to a specialist such as a gynecologist or a urologist. Wait times to see specialists for continence care can be lengthy, and many general practitioners are reluctant to discuss urinary incontinence with the patients.[4-6] Less than one third of women with newly diagnosed incontinence receive treatment in the first year for their incontinence.[7] Among women who have had surgical treatment of urinary incontinence, the cure rate is as low as 28%, and only 66% feel that surgery meets or exceeds their expectations.[8]

Research has shown that women with urinary incontinence are able to accept and normalize their incontinence if they can take charge of the problem by developing and implementing a management plan which prevents loss of self-esteem.[9] Many women prefer to self-manage their incontinence and prefer conservative management options.[10] Incontinence pessaries are an effective treatment for urinary incontinence.[11,12] Incontinence pessaries are an alternative to pads in the self-management category. Unfortunately this option is currently underutilized because the majority of medical professionals do not realize that pessaries can be used to treat urinary incontinence and rarely offer them as a treatment option. Up to 50% of women who are offered this option continue to use their pessaries over the longer term.[11,12]

Current incontinence pessaries, although effective, are difficult for some women to insert, position correctly, and remove.[13] These difficulties undoubtedly affect the long-term use of incontinence pessaries. In an effort to overcome these limitations a new incontinence pessary, Uresta (EastMed Inc, Halifax, Nova Scotia, Canada), was designed to be easily inserted and removed and to be self-positioning once inserted. In this paper we report the results of a pilot study of this new incontinence pessary.

Materials and Methods

One hundred twenty-seven women with urinary incontinence applied and were screened for participation in this study. Exclusion criteria included unexplained pelvic bleeding or vaginal discharge, a history of incontinence surgery, failed use of an incontinence pessary, and a symptom history dominated by urgency symptoms. The most common reasons for exclusion were a history of previous surgery and significant symptoms of urge incontinence by patient self-report. Thirty-two women were enrolled following a consent process approved by

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In a potential conflict of interest, Dr Farrell is president and principal shareholder of EastMed Inc, a start-up company established to develop, manufacture, and distribute Uresta.

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FIGURE 1
The Uresta incontinence pessary

the local research ethics board. Participants completed a 7 day urolog recording their incontinence episodes before coming to the first study visit. Each woman completed an author-compiled incontinence questionnaire, which consisted of 19 questions, 6 questions for stress incontinence and 13 questions for urge incontinence, scored on a 5 point Likert-type response scale ranging from 0 (never) to 4 (always). The maximum possible stress incontinence score was 24. The maximum possible urge incontinence score was 52.

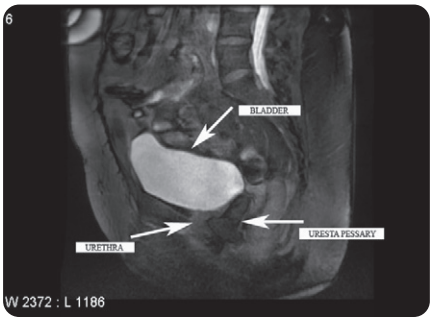
In addition, participants completed the incontinence impact questionnaire (IIQ-7) and the urogenital distress inventory (UDI-6).[14] The evaluation of enrolled women included a medical history and physical examination, a urinalysis, and a urine culture. The pelvic examination included a POP-Q quantification of pelvic prolapse[15]; classification of vaginal epithelial thickness as normal, thin, or atrophic based on a visual assessment; and cotton swab testing both at rest and with straining using a goniometer to measure the angles. Kegel assessment was based on the Oxford subjective scale, which ranged from 0 (no palpable contraction) to 5 (very strong contraction).[16] Pad testing was performed by inserting a catheter and filling the bladder in a retrograde fashion until the participant was symptomatically full. Each participant then completed 5 repetitions of the following activities: coughing, step climbing, heel bounce, and standing from a sitting position as well as walking 50 yards. Pad weights were measured in grams, and a weight of less than 2 g was considered normal.

Uresta is a bell-shaped pessary with a handle at its base for easy insertion and removal (Figure 1). The narrow tip allows for easy insertion into the vaginal introitus. Uresta is inserted directly into the vagina like a tampon and positions itself so that the wide base provides support to the urethra (Figure 2). The pessary is made of a medical grade rubber that has been extensively tested for biocompatibility and safety in medical applications and meets the criteria for use in class II medical devices.

In phase I (participants 1-15), after the pad test was completed, each participant was fitted with a size 3, 4, or 5 Uresta pessary, the size determined by the examining physician. In phase II (participants 16-32), after the initial pad test was completed, the participants were given brief instructions on pessary insertion and then allowed to select and insert the pessary themselves. During this phase the ability of participants to insert their own pessary was assessed. If the pessary was uncomfortable, a smaller size was substituted. If the pessary did not stop the leaking, a larger size was inserted.

In both phases of the study, if the pessary was comfortable, did not dislodge with coughing and appeared to stop bladder leaking, the pad test was immediately repeated. After completion of the second pad test, if the pessary size was satisfactory, the woman was given further instruction on pessary handling and she was provided with a complete set of Uresta pessaries (sizes 3, 4, 5), a second 7 day urolog and a pessary utilization log. Participants were asked to keep a record of the times of pessary insertion and removal and to record any difficulties and general observations. Participants were advised to adjust the pessary size as indicated by symptoms using 1 of the 3 pessaries provided to them. Four scenarios were reviewed with participants: the pessary descends to the vaginal introitus or falls out; the pessary does not stop bladder leaking; the pessary feels too large and is uncomfortable; or the patient is unable to void. In the first 2 scenarios, it was recommended that a larger-sized pessary should be substituted and in the second 2, a smaller-sized pessary should be substituted. Before leaving the clinic,

FIGURE 2
Magnetic resonance imaging study of Uresta showing support of the bladder neck



the ability of each participant to void with the pessary in place was tested and instructions concerning pessary cleaning and care were provided. Whereas daily removal and washing of the pessary before sleep was encouraged, a minimum of twice-weekly removal and cleaning was recommended.

At the first follow-up visit at 2 weeks, the pessary was removed and a vaginal speculum exam performed to look for abrasions or other abnormalities. The second 7 day urolog was reviewed along with the pessary utilization log. Adjustments in pessary size were made if indicated.

Women who were satisfied with the Uresta pessary at the 2 week visit were considered successfully fitted. A second set of incontinence questionnaires reflecting their experience while using Uresta were completed along with an author compiled pessary use questionnaire (Figure 3). Subsequent follow-up visits occurred at 3, 6, and 12 months. At these visits a speculum examination of the vagina was repeated. At the final visit, the incontinence questionnaires and pessary use questionnaire were repeated. For the duration of the study, participants did not receive instructions in Kegel exercises, guidelines on lifestyle modification, or any other therapeutic intervention. Women who chose to withdraw from the study were offered the opportunity to see a urogynecologist for assessment and treatment. None of the participants had significant functional limitations or medical comorbidities.

FIGURE 3
Pessary use questionnaire

Please answer the following questions concerning your experience with the Uresta™ incontinence pessary

1. **With the pessary in place my bladder leaking is:**

0	1	2	3	4
not changed	slightly improved	improved	greatly improved	stopped

2. **Inserting my pessary is:**

0	1	2	3	4
very difficult	somewhat difficult	okay	easy	very easy

3. **Removing my pessary is:**

0	1	2	3	4
very difficult	somewhat difficult	okay	easy	very easy

4. **Using the Uresta™ pessary has made me more confident about not leaking in public:**

0	1	2	3	4
never	rarely	sometimes	usually	always

5. **I plan to continue using the Uresta™ pessary to stop my bladder leaking:**

0	1
no	yes

6. **I would recommend this form of treatment to a friend:**

0	1
no	yes

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) (version13, SPSS Inc, Chicago, IL). Parametric data were evaluated using independent-samples *t* tests for between-group comparisons and paired-samples *t* tests for changes in variables within groups. Nonparametric data were examined with χ^2 tests. Correlations were performed using Pearson's correlation coefficient. Backward-conditional logistic regression was performed.

RESULTS

Thirty-two women were enrolled in this study, 15 in phase 1 and 17 in phase 2. The characteristics of the study group are shown in Table 1. POP-Q stages were: stage 0, 10 (31%); stage 1, 20 (63%); and stage 2, 2 (6%). The vaginal epithelium was normal in 27 (84%) and thin in 5(16%). Mean cotton swab angles at rest were +11 (SD 10) and straining +40 (SD 14). The mean Kegel strength was 3 (SD 1.2, range 0-5) and the mean pad test weight (grams) at baseline was 20 (SD 23, range 0-95) and after pessary fitting, 9 (SD 18, range 0-85). Pessary sizes fitted

TABLE 1
Characteristics of the women enrolled in a study of the Uresta pessary (n = 32)

Age (y)*	50 (SD 9; range 33-69)
BMI*	28 (SD 5; range 18-42)
Parity*	1.9 (SD 1.1; range 0-5)
Menopausal, n (%)	14 (44)
Hormone replacement, n (%)	7 (22)
Prior hysterectomy, n (%)	13 (41)
Vaginal deliveries*	1.6 (SD 1.0, range 0-4)
Cesarean deliveries*	0.3 (SD 1.0; range 0-5)
Number of caffeinated beverages per day*	3 (SD 2.5; range 0-10)
Using medications affecting bladder, n (%)	3 (9)
Urgency to void	
≤50% of voids, n (%)	23 (72%)
>50% of voids, n (%)	9 (28%)
Leaks associated with urgency	
≤50%, n (%)	25 (78%)
>50%, n (%)	7 (22%)
Cotton swab angle (degrees)	
Resting	10.9 (SD 9.7, range −6 to 40)
Straining	39.7 (SD 13.9, range 10-60)

* Mean value.

at the initial visit included 4 (12%) small-size 3; 23(72%) medium-size 4; and 5 (16%) large-size 5.

Figure 4 is a flow diagram illustrating pessary usage over the 12 month period of the study. The left-hand side of the figure shows the outcomes for the overall study group, whereas the right-hand side shows the outcomes for the group of women who were successfully fitted at their 2 week visit (pessary stopped or significantly reduced their incontinence). At the 2 week visit, 21 of 32 of the women (66%) were satisfied with the Uresta pessary and chose to continue using it. Of these women 10 (47%) reported that Uresta stopped their leaking, and 11 (53%) noted a significant decrease in leaking. One woman did not return for the 2 week visit but was subsequently contacted by phone. At the time of contact she was using the pessary and was satisfied with it. She indicated that she did not wish to return for study follow-up visits. Between the visit at 2 weeks and the final 12 month visit, 5 participants withdrew: 3 because the pessary failed to control their leaking satisfactorily; 1 because the pessary fell out and 1 who, when contacted, indicated she had used the pessary for a period of time during which she did Kegel's exercises and her urinary incontinence resolved. At completion of the study, 16 (50%) participants continued to use their pessary. Among the group of women who were successfully fitted at week 2, 16 (76%) completed the study and indicated on their pessary use questionnaire their intention to continue using the pessary after the 12 month follow-up visit.

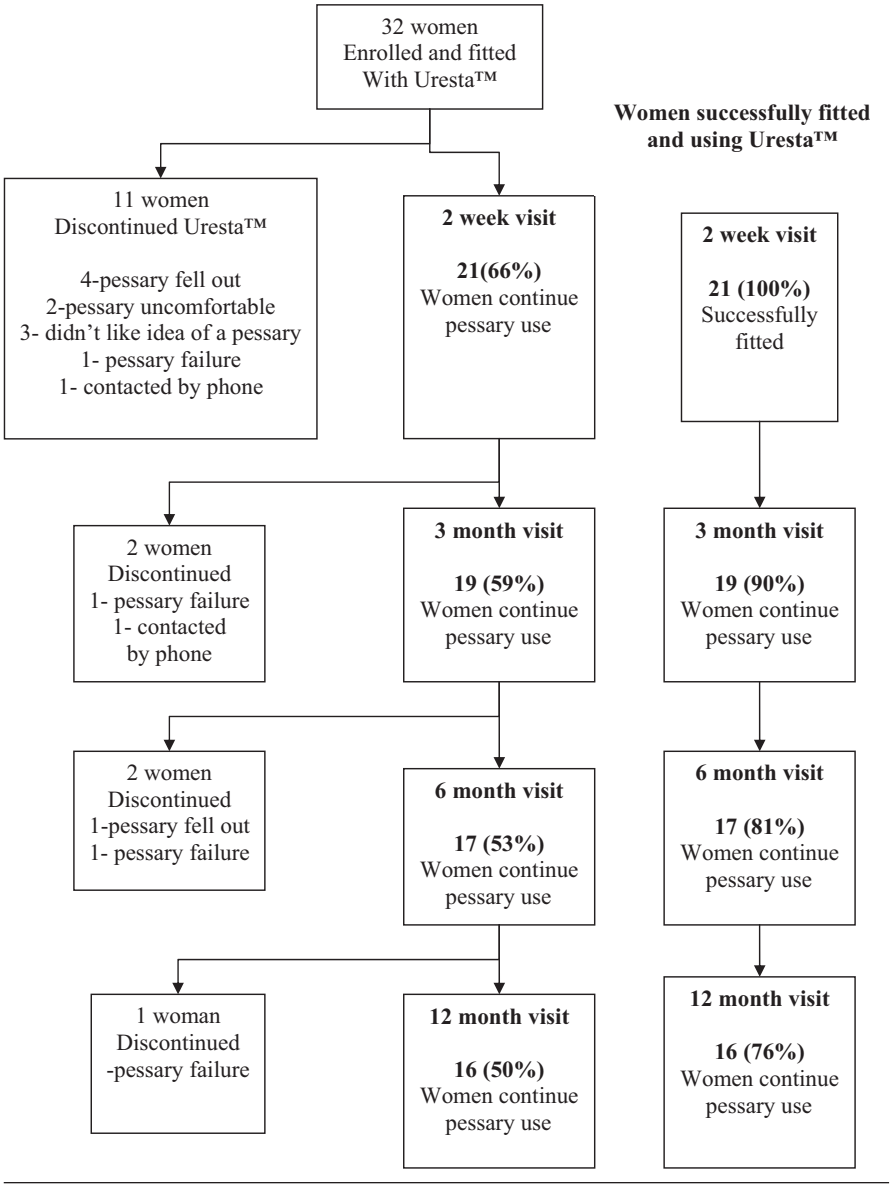
Table 2 shows the effect of Uresta pessary fitting on objective measures of incontinence. Use of Uresta resulted in significant decreases in the mean scores on the incontinence questionnaires, quality-of-life measures, pad weights, and number of leaking episodes on a 7 day urolog. Correlations between the author-compiled incontinence questionnaires and the previously validated UDI-6 and the IIQ-7 were calculated. The stress incontinence score showed correlations of r = 0.455 (P = .01) for the IIQ-7 and r = 0.519 (P = .01) for the UDI-6. The urge incontinence score showed correlations of r = 0.560 (P = .01) with the IIQ-7 and r = 0.529 (P = .01) with UDI-6.

In Table 3 risk factors (with numerically discrete data) for pessary fitting failure at 2 weeks are examined. Mean parity was significantly lower in the successfully fitted group (1.6, SD 0.9) when compared with the unsuccessfully fitted group (2.5, SD 1.2, P = .03). Kegel strength was inversely related to pessary fitting success. Women experiencing a successful fitting had a lower mean Kegel contraction score (2.9, SD 1.3), compared with those who failed fitting (3.7, SD 0.8, P = .026). In Table 4, the nonparametric risk factors are examined. None of these variables had a significant effect on outcomes.

In Table 5, the results of the pessary use questionnaire administered at the last study visit of each participant are shown. Sixty-six percent of women observed that their urinary incontinence was improved, greatly improved, or stopped. The majority of women (79%) found the pessary okay or easy or very easy to insert, and 69% found it okay or easy or very easy to remove. Fifty-seven percent were more confident in public usually or always, and 66% planned to continue using their pessary. Seventy-two percent would recommend it to a friend. Not surprisingly, the overall mean pessary use score was significantly higher among those who were successfully fitted (13, SD 2.2) when compared with those not successfully fitted (6.86, SD 5.6, P = .027). There were no complications or adverse events with pessary use.

Backward-conditional logistic regression was used to identify predictors of successful pessary fitting at 2 weeks. The variables selected for inclusion in the regression analysis were those that were considered most clinically relevant: age, body mass index (BMI), parity, Kegel strength, duration of incontinence, and

FIGURE 4
Study flow diagram



number of vaginal deliveries. No factors were found to be predictive.

Comment

Urinary incontinence has a significant impact on quality of life and is a pervasive problem among women. Most women with this problem seek a solution that allows them to pursue as normal a lifestyle as possible with the least inconvenience or risk.[9] Many women prefer to self-manage the problem, and the most commonly used self-management option is absorbent pads and garments.[10] Although these products provide a means of hiding the problem and thereby allow successful avoidance of public embarrassment, they do not stop the incontinence. Most women find that Kegel's exercises do not resolve their incontinence. This lack of efficacy of Kegel's exercises is consistent with long-term follow-up studies.[17] Surgery is perceived by the general public to be highly effective and most likely to allow a return to normal activities. Research has clearly demonstrated, however, that there is a significant recurrence of urinary incontinence following surgery for stress incontinence and that many women are not fully satisfied with the outcomes of surgery.[8]

Incontinence pessaries offer an alternative to surgery with a similar mechanism of action, mechanical support of the urethra. There is a paucity of literature on the outcomes of incontinence pessary treatment of urinary incontinence. To date, 2 retrospective reviews with mean follow-ups of 6 and 11 months[12,13] and 1 prospective observa-

TABLE 2
The effect of the Uresta pessary on incontinence measures*

Outcome measure	Mean at baseline	Mean after pessary fitting	Difference	*t*	Significance (*P* value)
Stress incontinence score (maximum = 24)	15	8	7	6.43	.001
Urge incontinence score (maximum = 52)	14	9	5	3.40	.002
UDI-6 score (maximum = 16)	6	4	2	3.36	.002
IIQ-7 score (maximum = 24)	8	4	4	2.90	.008
Leaking episodes (urolog)	20	4	16	2.38	.028
Pad weight (g)	20	9	11	2.95	.006

* Paired-samples *t* test.

TABLE 3
Risk factors for incontinence pessary failure*

	Successful fitting (21)	Failed fitting (11)	
Factor	Mean ± SD	Mean ± SD	*P* value (significance†)
Age	48 ± 8	52 ± 12	.224
BMI	29 ± 5	26 ± 4	.078
Parity	1.6 ± 0.9	2.5 ± 1.2	.031†
Duration of incontinence (y)	7 ± 6	8 ± 6	.722
Cotton swab angle			
Resting	12 ± 11	8 ± 7	.403
Straining	40 ± 14	40 ± 15	.986
Kegel strength	2.9 ± 1.3	3.7 ± 0.8	.026†
Baseline pad weight (g)	20 ± 27	19 ± 14	.964
Number of caffeinated beverages per day	2.8 ± 2.6	4.3 ± 2.1	.105
Total fluid intake (cups)	11.8 ± 8	11 ± 3.2	.765
Number of vaginal deliveries	1.4 ± 1.0	2.0 ± 1.1	.112
Baseline incontinence scores			
SUI	15 ± 3.8	13 ± 4	.260
UUI	15 ± 8.5	14 ± 8	.814
UDI-6	6.4 ± 2.5	6.2 ± 3.7	.789
IIQ-7	8.4 ± 6.3	7.0 ± 4.2	.519
Leaking episodes per 7 days (urolog visit 1)	21 ± 36	7 ± 8	.223

SUI, stress urinary incontinence; *UUI*, urge urinary incontinence.

* Independent samples *t* test.

† Significant results.

tional trial with 12 month follow-up[18] have been published. These studies have evaluated the effectiveness of currently available incontinence pessaries. The 2 retrospective studies did not utilize any specific outcome measures other than patient satisfaction and willingness to continue pessary use. The prospective study by Robert et al[18] included a pad test, 7 day voiding diary, and the IIQ as objective outcome measures. In Robert's study only 24% of women were successfully fitted with an incontinence pessary, and none of the objective outcome measures in this small group were significantly changed by the use of a pessary. Robert et al[18] utilized two incontinence pessaries, 1 of which has not been widely utilized or tested. Their low success rate may have been due to difficulties with fitting and efficacy of this pessary. Their patient population may be similar to ours because women with significant urinary urgency were eliminated by urodynamics testing. In the current study, use of the Uresta pessary resulted in a significant reduction in all of the objective parameters of urinary incontinence for the entire study group. This is the first study to demonstrate that incontinence pessaries change objective measures of urinary incontinence.

TABLE 4
Risk factors for incontinence pessary failure

	Successful (21) number (%)	Unsuccessful (11) number (%)	*P* value*
Menopausal	8 (38)	6 (55)	.373
Taking HRT	5 (24)	2 (18)	.715
Hysterectomy	9 (43)	4 (36)	.202

* χ^2 test.

Previous studies have not identified any demographic variables that affect fitting success. In this study, age and BMI did not have any significant effect on fitting success, but higher parity was associated with higher rates of fitting failure. Although we are not aware of any research associating higher parity with failure of stress incontinence surgery, there are a number of studies that have linked higher parity with higher rates of urinary incontinence. It might be hypothesized that higher parity, particularly vaginal parity, results in greater degrees of injury to pelvic structural supports and neuromuscular function, thereby affecting likelihood of successful treatment of the

TABLE 5
Results of pessary use questionnaire administered at last study visit (32 women enrolled and fitted with Uresta)

Likert score*	0	1	2	3	4
1. Leaking with pessary	6 (19)	2 (6)	7 (22)	10 (31)	4 (13)
2. Inserting pessary is	1 (3)	3 (9)	7 (23)	14 (44)	4 (13)
3. Removing pessary is	0 (0)	7 (22)	6 (19)	13 (41)	3 (9)
4. More confidence in public	4 (13)	1 (3)	5 (16)	11 (35)	7 (22)
5. Plan to continue use	7 (22)	21 (66)	[4 (13) did not answer question]		
6. Would recommend pessary to a friend	3 (9)	23 (72)	[6 (19) did not answer question]		

Values are given as number and percent in brackets. Some participants did not complete all of the questions.

* See Figure 3 for details of Likert scale categories.

incontinence, regardless of the treatment mode used.

In a previous study, we found that women with a history of incontinence surgery were at greater risk of incontinence pessary fitting failure.[11] This group was intentionally excluded from the current study. Donnelly et al[12] found in their study that women with a history of pelvic prolapse surgery or hysterectomy were more likely to fail pessary treatment of their incontinence. In our study the rates of hysterectomy were not significantly different in the successfully and unsuccessfully fitted groups. We intentionally excluded any patients who had undergone pelvic prolapse surgery. The finding by Donnelly et al[12] of an effect of hysterectomy may be due to the fact that concomitant procedures were performed that would affect pelvic anatomy and reduce the effectiveness of incontinence pessaries.

We examined a wide variety of risk factors for pessary failure. Variables that might intuitively suggest more severe degrees of stress incontinence such as the duration of incontinence, baseline pad weights, number of leaking episodes on a 7 day urolog, and baseline incontinence questionnaire scores did not predict the outcome of pessary fitting in our study. This lack of influence of urinary incontinence severity on incontinence pessary success suggests that incontinence pessaries may be effective for all degrees of incontinence severity. The finding that Kegel strength was inversely related to pessary fitting is difficult to explain. Whereas it would not be surprising to find that Kegel strength had no effect on fitting success, given that pessaries work on the support aspect of the continence mechanism rather than intrinsic function that presumably is improved with Kegel exercises, the finding that Kegel strength was inversely related may be artifactual in this small group of women. Logistic regression to predict success of fitting at 2 weeks was performed and no factors were found to be predictive. This pilot study involved relatively small numbers of participants. Future studies with larger numbers should permit further analysis of factors affecting fitting success.

No previous studies have examined the ease of incontinence pessary use. The Uresta pessary is designed to be inserted much like a tampon, directly into the vagina and to fall into place beneath the urethra naturally without any manipulation. The pessary is removed simply by exerting some valsalva effort and grasping the handle to pull it directly out. The tapered end of the pessary fits in the upper vaginal axis, which is more horizontal, and this has the effect of rotating the wider bell-shaped portion of the pessary under the urethra to provide better support. This is evident from the magnetic resonance imaging scan showing the pessary in place in the vagina (Figure 2). The majority of women found this pessary easy to insert and remove, and the effect was to improve quality of life by giving them greater confidence in public. As illustrated in Figure 4, of women who were successfully fitted with the Uresta pessary at the 2 week visit, 76% completed the 12 month follow-up and planned to continue using their pessary after the study period was completed.

At the beginning of enrollment in this study, the screening process did not emphasize the practical aspects of pessary care. It became evident to us early in the study that some women, although interested in a nonsurgical solution to their incontinence, were not very comfortable with the process of using and caring for a pessary. At least 3 of the 11 women who dropped out of the study during the first 2 week period were in this category. As the study progressed we took greater care, during this screening process, to provide prospective enrollees with a detailed explanation of the pessary, how it worked, and what would be necessary to use it. This elaborated explanation helped eliminate women who were not comfortable with pessaries before they were enrolled and may have contributed to the higher success rate in the latter half of the study.

This study is the first prospective evaluation of an incontinence pessary that used objective outcome measures to clearly demonstrate the effectiveness of incontinence pessaries on a variety of measures including patient experience with pessary use. Although regular follow-up visits were scheduled to ensure safety, no complications occurred with the pessaries and most participants felt physician visits for reassurance were probably not necessary. During this study, once properly fitted, women removed and inserted their pessaries themselves and none required a physi-

cian visit for help with pessary management. The greater ease of use involved with this pessary may mean that greater numbers of women will find this conservative option acceptable.

Because this is pilot research that involved small numbers of women, larger prospective trials are needed to confirm these findings. Also, the study did not involve a group to control for placebo effect. A recent study examining the relative effects of duloxetine, Kegel's exercises, and placebo on episodes of stress urinary incontinence found a placebo effect of 29%.[20] Ultimately, larger comparative trials will be needed to control for placebo effect and to evaluate more fully the place of incontinence pessaries in the armamentarium of urinary incontinence treatment options.[19] ■

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