

uresta[®] Clinical Studies

A Compilation of Studies & References

Pivotal uresta® Research

Reference:

1. Farrell SA, Baydock S, Amir B, Fanning C. Effectiveness of a new self-positioning pessary for the management of urinary incontinence in women. Am J Obstet Gynecol 2007; 196:474e.1-474.e.

Method:

- A pilot research study consisting of 32 women
- 7-day log of urine loss; validated Incontinence Q's: IIQ-7 and UDI-6; POP-Q evaluation; Q-tip test; pelvic exam of vaginal epithelium
- Pad test measured urine loss with activity before & after pessary fitting
- Follow up at 2 wks, 3 and 6 months; 1-yr final follow-up visit

Discontinuations:

- 5 women:
 - pessary failed to work satisfactorily, or pessary fell out
 - one person felt incontinence was resolved while using device and Kegels exercises
- 6 women:
 - lost to follow-up: tired of research, travel, could not contact

Pivotal uresta[®] Research

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1. Farrell SA, Baydock S, Amir B, Fanning C. Effectiveness of a new self-positioning pessary for the management of urinary incontinence in women. Am J Obstet Gynecol 2007; 196:474e.1-474.e.

Results:

- 21/32 were satisfied and chose to continue use of uresta[®]
- 10 reported uresta[®] stopped leaking; 11 noted sig ↓ in leaking
- Sig ↓ scores on UI Q's, QOL measures, pad wts, # of leaks on urolog
- 66% of women observed improvement or stoppage of SUI
- 77% pessary found uresta[®] ok or easy to insert,
- 57% were more confident in public usually or always
- 72% would recommend it to a friend

Pivotal uresta[®] Research

Reference:

2. Lovatsis D, Best C, Diamond P. Short-term uresta[®] efficacy (SURE) study: a randomized controlled trial of the Uresta continence device. Int Urogynecol J. 2017; 28(1):147-150.

Method:

- 36 women
- RCT of uresta[®] pessary vs placebo device (silastic ring)
- Pad test measured urine loss before/after device placement
- Primary outcome 50% reduction in pad weight with device in place

Results:

- 66.7% achieved primary outcome using uresta[®]
- Clinically significant treatment effect

Pivotal uresta® Research

Reference:

3. Gallagher L, Woodcock D, Massey L. Product Reviews. Journal of Pelvic, Obstetric and Gynaecological Physiotherapy. 2019; 124: 63-66.

Method:

- 3 physios - specialist pelvic health team in UK
- Compared 3 devices: uresta®, Contiform & Contrelle Activgard
- Used devices themselves

Results:

- 2/3 had sensation of bladder urgency on initial insertion of uresta®
- 1 felt heaviness/discomfort after wearing uresta® for several hrs
- All 3 able to empty their bladders with uresta® in place
- Generally, found uresta® comfortable to wear, and simple to insert
- Thought uresta® superior to Contiform, largely due to its easy insertion and removal

Non-Pivotal Pessary-Specific Research

Reference:

1. Farrell SA, Singh B, Aldakhil L. Continence pessaries in the management of UI in women. J Obstet Gynaecol Can. 2004; 26(2):113-117.

Method:

- A retrospective chart review of 100 women who chose to use pessary to tx SUI

Results:

- At a mean follow-up time of 11 months (range, 2-42 months), 59 women continued to experience a complete resolution or decrease in their incontinence.
- Urinary incontinence pessaries are effective for SUI
- More than 50% of women who try a continence pessary will continue to use it.

Non-Pivotal Pessary-Specific Research

Reference:

2. Richter et al. Continence pessary compared with behavioral therapy or combined therapy for stress incontinence: A randomized controlled trial. *Obstet Gynecol.* 2010; 115(3): 609-617.

Method:

- Continence pessary compared with behavioral therapy or combined therapy for stress incontinence (SUI)
- Did not use **uresta**[®] pessary in research, but did demonstrate effectiveness of pessaries for tx of SUI
- 446 women, multi-centre RCT

Results:

- Combined therapy not better than single modality
- 12 mos – 91% pessary users satisfied with tx
- Pessaries s/b offered to women wishing to defer or avoid surgery for SUI, not interested in behavioural therapy

Non-Pivotal Pessary-Specific Research

Reference:

3. McIntosh L, Andersen E, Reekie M Conservative treatment of stress urinary incontinence in women: A 10-year (2004-2013) scoping review of the literature. *Urologic Nursing*, 2015; 35 (4): 179-203.

Method:

- Review of conservative tx of SUI
- 10-yr lit review (2004-2013) by 3 urology nurses
- Focused on Pelvic Floor Muscle Exercise (PFME) and intravaginal support devices
- Included **uresta**[®] pessary in review

Results:

- Found use of devices could be enhanced if women given option to handle and care for the pessary themselves, especially with education

Non-Pivotal Pessary-Specific Research

Reference:

4. Oliveira PDA, Somense CB, Barros NA, Gregghi EFM, Alexandre NMC, Dantas SRPE, Silveira NI. Vaginal pessaries in urinary incontinence: integrative review. ESTIMA, Braz. J. Enterostomal Ther. 2019; 16: e0419.

Method:

- Sought to analyze types of pessaries, indications & impact of these on treatment
- 8 studies included in review
- Pessaries included: **uresta**[®] pessary, incontinence dish, incontinence ring, Contiform device.

Results:

- Pessaries found to be economically viable, easy to insert, fit and withdraw, with low risk of complications and generally successful in treating SUI (resolution or reduction)
- Some potential predictors of failure included smaller vaginal length, smaller vaginal introitus, greater parity, advanced prolapse and previous gynecological surgeries

Conservative Tx of SUI

Reference:

1. Glazener CMA. Co-ordinating Editor, Cochrane Incontinence Group Cochrane Database of Systematic Reviews 2015(7): [10.1002/14651858.ED000101](https://doi.org/10.1002/14651858.ED000101)

Recommendation from Experts, Clinical Guidelines:

“The essential message is that women with urinary incontinence must be aware of all the options available to them including their chance of success and risk of adverse effects, and explore conservative options first, before considering invasive surgery.”

Conservative Tx of SUI

Reference:

2. Society of Obstetricians and Gynaecologists of Canada (SOGC). Clinical Practice Guideline No. 186, 2006. (Reaffirmed: February, 2018)

Recommendation from Experts, Clinical Guidelines:

“Pessaries should be offered as effective, low-risk treatment for SUI.”



Conservative Tx of SUI

Reference:

3. Dessie et al. Effect of vaginal estrogen on pessary use. *Int. Urogynecol J* 2016; 27 (9): 1423-1429.

Recommendation from Experts, Clinical Guidelines:

- Pessaries often first line treatment for SUI as they are non-invasive and simple to use
- 67% to 92% of women report satisfaction with pessary use
- Typical complications include vaginal discharge, foul smell, bleeding, pain and erosions
- Vaginal atrophy may predispose women to complications
- Use of vaginal estrogen has been shown to help vaginal epithelium to improve dryness and atrophy.
- Estrogen users less likely to discontinue their pessary use than those who did not use estrogen (30.6% vs 58.5%, $p < 0.001$)
- Those who used estrogen were less likely to develop increased vaginal discharge (hazard ratio of 0.31).

Diagnostic Tools: QUID Questionnaire

The Questionnaire for Urinary Incontinence Diagnosis

Development:

Brown JS, Bradley CS, Subak LL, Richter HE, Kraus SR, Brubaker L, Lin F, Vittinghoff E, Grady D. The sensitivity and specificity of a simple test to distinguish between urge and stress urinary incontinence. *Ann Int Med* 2006; 144:715-23.

- Designed for use by Family doctors to quickly assess the patient's UI type
- 6 simple questions to ask your patient about her urine loss

Clinical Use:

Farrell SA, Bent A, Amir-Khalkhali B, Rittenberg D, Zilbert A, Farrell KD, O'Connell C, Fanning C. Women's ability to assess their urinary incontinence type using the QUID as an educational tool. *Int Urogynecol J.* 2013; 24:759-62.

- Results of this questionnaire have been shown to correlate very closely to the diagnosis made by a urogynaecologist

Diagnostic Tools: QUID Questionnaire

Questionnaire

Please complete all questions. Do not leave any questions blank. For each question, mark the box that accurately describes how often you experience your symptoms.

Do you leak urine (even small drops), wet yourself, or wet your pads or undergarments...

	None of the Time 0	Rarely 1	Once in a While 2	Often 3	Most of the Time 4	All of the Time 5
1. When you cough, laugh or sneeze?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. When you bend down or lift something up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. When you walk quickly, jog, or exercise?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
STRESS INCONTINENCE SUBSCALE SCORE TOTAL:						<input type="text"/>
4. When you are undressing to use the toilet?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Do you get such a strong and uncomfortable need to urinate that you leak urine (even small drops) or wet yourself before reaching the toilet?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Do you have to rush to the bathroom because you get a sudden, strong need to urinate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
URGE INCONTINENCE SUBSCALE SCORE TOTAL:						<input type="text"/>