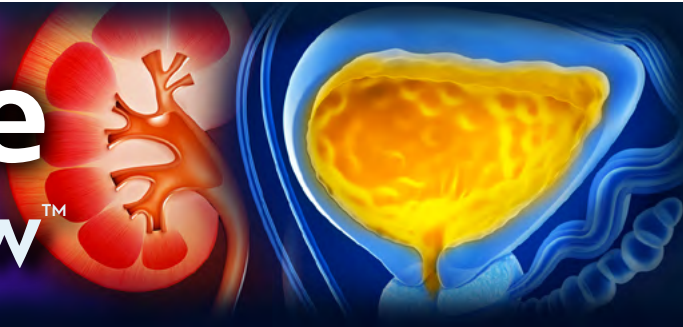


# Continence Research Review™



Making Education Easy

Issue 12 - 2023

## In this issue:

- > Short-term benefits and potential harms of therapeutic modalities for OAB
- > The reduction of male lower urinary tract symptoms and a lower death risk
- > Food insecurity and urge incontinence
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- > Safety and efficacy of intravesical sustained release system of lidocaine and oxybutynin
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- > The efficacy of intravaginal electrical stimulation in women with idiopathic OAB
- > Follow-up after tension-free vaginal tape for stress urinary incontinence

### Abbreviations used in this issue:

**AUA** = American Urological Association; **BPH** = benign prostatic hyperplasia;  
**EUI** = external ureteral stents; **HR** = hazard ratio;  
**MUI** = mixed urinary incontinence; **SUI** = stress urinary incontinence;  
**OAB** = overactive bladder syndrome; **SNS** = sacral nerve stimulation.

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## Welcome to issue 12 of Continence Research Review.

We open this month's issue with a *Eur Urol* study on the short-term benefits and potential harms of therapeutic modalities for overactive bladder syndrome (OAB). This study aimed to provide a contemporary overview of the treatment options for women with OAB. This is followed by a *J Urol* study on the reduction of male lower urinary tract symptoms and its association with a decreased risk of death. This study included 3,046 patients with a median age of 62 years. We feature two studies in this review that should be read in combination with each other; they both examine the Optilume benign prostatic hyperplasia (BPH) catheter system's effectiveness for treating lower urinary tract symptoms due to BPH. The first of the two studies is on food insecurity and its association with urge urinary incontinence, and the second is a review of the results from the PINNACLE study. Finally, we conclude this month's issue with a 10- to 20-year follow-up study after tension-free vaginal tape for stress urinary incontinence. This study from *Int Urogynecol J* included over 200 women who were successfully treated for stress urinary incontinence with vaginal tape.

We hope that you enjoy the studies featured in this month's issue. As always, we look forward to hearing your feedback.

Best regards,

Associate Professor Bill Lynch

[bill.lynch@researchreview.com.au](mailto:bill.lynch@researchreview.com.au)

## What are the short-term benefits and potential harms of therapeutic modalities for the management of overactive bladder syndrome in women?

**Authors:** Farag F et al.

**Summary:** This study aimed to provide a contemporary overview of treatment options for OAB in women, assessing their short-term effectiveness, safety, and potential side effects. Antimuscarinic drugs and beta-3 agonists were significantly more effective than placebos, although beta-3 agonists were superior in reducing nocturia episodes. However, antimuscarinics had a higher rate of adverse events. Onabotulinumtoxin-A (Onabot-A) was more effective than a placebo, but it came with a significantly higher risk of acute urinary retention and urinary tract infections. Onabot-A outperformed antimuscarinics in curing urge urinary incontinence but not in reducing the number of episodes. Sacral nerve stimulation (SNS) showed higher success rates compared to antimuscarinics, with similar adverse event rates. SNS and Onabot-A had similar efficacy outcomes. Patient satisfaction was higher with Onabot-A but was associated with a greater risk of recurrent urinary tract infections. SNS had a 9% removal rate and a 3% revision rate.

**Comment:** This is a timely review for all urologists. The undoubted benefit of treatment modalities to many patients is presented in a progressive manner. More importantly, it puts the side-effect profiles of the various management options into perspective - little more to be said.

**Reference:** *Eur Urol*. 2023;84:302-12

[Abstract](#)

## The reduction of male lower urinary tract symptoms is associated with a decreased risk of death

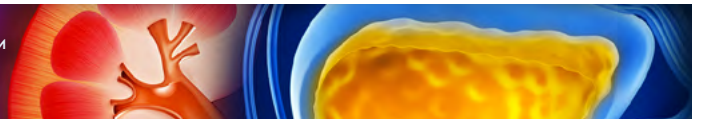
**Authors:** Welk B & McClure JA

**Summary:** This secondary analysis of the MTOPS study included 3,046 men with a median age of 62 years. Researchers assessed the relationship between improvements in the American Urological Association (AUA) Symptom Score and the risk of death. They found that for every 1-point improvement in the AUA Symptom Score, there was a significant reduction in the hazard ratio for death (HR 0.96), indicating a lower risk of mortality. This association was held for men who received active treatment but not for those in the placebo group. The results remained consistent after accounting for factors like transurethral prostate resection, potential confounders, and a shorter observation period after the study visit. The study also found that similar reductions in the risk of death were associated with 1-point improvements in the storage and voiding subscales of the AUA Symptom Score. The study findings suggest improvements in urinary symptoms, as measured by the AUA Symptom Score, may be linked to a reduced risk of death, particularly in men receiving active treatment.

**Comment:** This is potentially a very important paper. If untreated LUTS, independent of the degree of bother, is truly associated with an increased risk of death, then our duty of care to our male patients with LUTS would need to be re-examined. This study definitely indicates further investigation is necessary in this group of patients – especially as there has been little attention to LUTS and mortality to date. In the meantime, it may behoove all of us to consider the earlier introduction of therapy to men with lower urinary tract symptoms.

**Reference:** *J Urol*. 2023;210:670-77

[Abstract](#)



## Food insecurity is associated with urge urinary incontinence

**Authors:** Okada C et al.

**Summary:** This analysis of the 2005-2010 national health and nutrition examination survey included 14,847 participants with a mean age of 50.4±17.9 years. 22.4% of participants experienced urge urinary incontinence. Notably, individuals who reported food insecurity had a 55% higher likelihood of having urge urinary incontinence compared to those without food insecurity. This association was statistically significant (odds ratio=1.55, 95% confidence interval=1.33-1.82,  $P < .001$ ). Food-insecure participants consumed fewer bladder irritants like caffeine and alcohol than food-secure participants. When the data was analysed by food insecurity status, caffeine consumption did not differ between those with and without urge urinary incontinence. Additionally, alcohol consumption was lower among participants experiencing urge urinary incontinence compared to those without this condition. The study concluded that these findings may suggest a link between food insecurity and urge urinary incontinence, highlighting the potential impact of dietary factors on this health issue.

**Comment:** This is an intriguing paper which, at its simplest level, makes us re-think the usual cautions we give to patients concerning coffee and alcohol consumption if they are suffering from symptoms of urgency incontinence. On a deeper level, it starts to examine the social determinants as they apply to health in the community, and in particular, the socioeconomic factors (and their surrogates) that may affect incontinence. It will be most interesting to see what future investigations are triggered to help us understand the complex interplay factors involved in incontinence.

**Reference:** *J Urol.* 2023;210:481-91

[Abstract](#)

## The PINNACLE Study

**Authors:** Kaplan SA et al.

**Summary:** This double-blind, randomised, sham-controlled study included men aged 50 and above with symptomatic BPH and prostate sizes between 20 and 80 grams; a randomised trial was conducted comparing treatment with Optilume BPH to a sham surgical procedure, with blinding maintained for both subjects and evaluators up to one-year post-procedure. The trial included 148 participants, with 100 receiving Optilume BPH treatment and 48 undergoing the sham procedure across 18 United States and Canada centres. Results indicated that participants who received Optilume BPH experienced a substantial reduction in their International Prostate Symptom Score, with a reduction of 11.5±7.8 points at one-year post-treatment, compared to a reduction of 8.0±8.3 points at three months in the sham group. Additionally, the flow rate significantly improved in the Optilume BPH group, showing a remarkable increase of +10.3 mL/s from baseline to one year, representing a 125% improvement. The study concluded that Optilume BPH treatment may offer significant benefits to individuals with symptomatic BPH, particularly in terms of symptom relief and urinary flow rate enhancement.

**Comment:** Optilume is a balloon device that is coated with Paclitaxel, which is an anti-proliferative agent. The theory is that the gains made by balloon dilatation are rendered long-term through the action of the Paclitaxel. The first study compares the dice to a sham, with a positive response. The second study looks at 2-year outcomes with significant improvements in symptoms (IPSS 22.3 to 8.2) as well as objective/obstructive parameters (flow improved by 10.9ml/s from baseline). This is potentially one of the genuinely minimally invasive therapies that offers effective improvement in LUTS, especially when compared with the plethora of devices that seem to be offered more because they “can be” rather than genuinely provide a better alternative to the tried and true TURP in its various modern forms.

**Reference:** *J Urol.* 2023;210:500-9

[Abstract](#)

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## Aquablation therapy in large prostates (80-150 mL) for lower urinary tract symptoms due to benign prostatic hyperplasia

**Authors:** Bhojani N et al.

**Summary:** This study included the final WATER II 5-year clinical trial results. The study effectively achieved its safety and efficacy objectives, as assessed based on outcomes commonly associated with transurethral resection of the prostate, even in cases of larger prostate volumes, at the 3-month mark. Patients reported significant improvements in their symptoms, as evidenced by a substantial reduction in the mean International Prostate Symptom Score (IPSS), decreasing from 22.6 (with a standard deviation of 6.4) at baseline to 6.8 (with a standard deviation of 4.6) at the 5-year follow-up, resulting in a change score of 15.9 (with a standard deviation of 7.7). Uroflowmetry measurements also demonstrated improvements, with the mean maximum urinary flow rate increasing from 8.6 mL/s (with a standard deviation of 3.4) to 17.1 mL/s (with a standard deviation of 9.8) at the 5-year follow-up, resulting in a change score of 9.2 mL/s (with a standard deviation of 11.1) at five years ( $P < 0.001$ ). Additionally, a prespecified subgroup analysis considered a baseline prostate volume cutoff of 100 mL showed no variance in efficacy outcomes over the five years.

**Comment:** This study reports good, durable results for *aquablation* therapy – both symptoms (IPSS: 22.6 to 6.8) and flow rate (8.6ml/s to 17.1ml/s) when treating larger glands, up to 150ml. What the study does ignore for the practising Urologist is the fact that the technique still requires standard endoscopic haemostasis control at the end of the “*aquablation*”. The cynic in me questions why one would go to the expense of the Aquablation when you still had the expense and time of the endoscopic procedure anyway – why not just perform a “saline-based” endoscopic procedure from the start?

**Reference:** *J Urol.* 2023;210:143-53

[Abstract](#)



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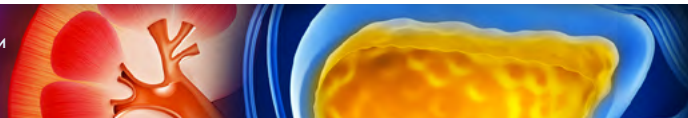
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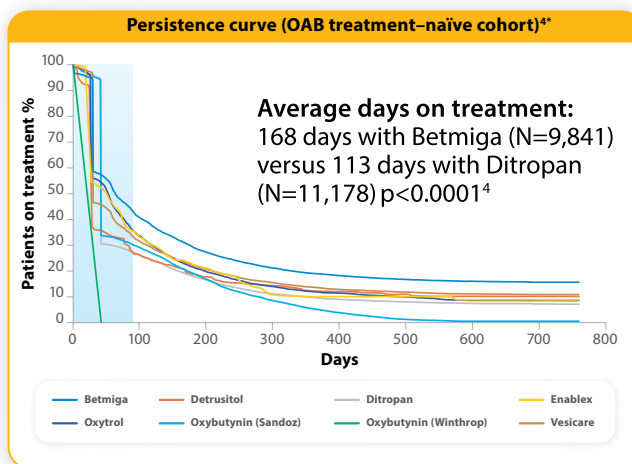


Figure adapted from IQVIA NostraData LRx<sup>4</sup>

\*Data captures every prescription from over 4,500 pharmacies (approximately 75% of retail pharmacy prescription volume) for the period June 2016 to September 2020. Hospital pharmacies are not covered. All data are presented un-projected, and no national-level extrapolation is included.

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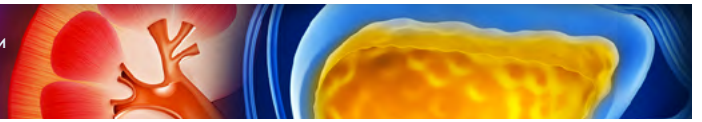
**Abbreviation:** OAB, overactive bladder.

**References:** 1. Betmiga (mirabegron) Australian Approved Product Information, 14th July 2021. 2. Yeowell G, Smith P, Nazir J, et al. Real-world persistence and adherence to oral antimuscarinics and mirabegron in patients with overactive bladder (OAB): a systematic literature review. *BMJ Open* 2018;8:e021889. 3. Conjoint USANZ and UGSA Guidelines on the Management of Adult Non-Neurogenic Overactive Bladder. 2015. Available online: <https://www.usanz.org.au/info-resources/position-statements-guidelines/management-adult-non-neurogenic-overactive-bladder> (accessed March 2022). 4. IQVIA NostraData LRx. December 2020.

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## Open label, pilot evaluation of the safety and efficacy of intravesical sustained release system of lidocaine and oxybutynin (TRG-100) for patients with interstitial cystitis/bladder pain syndrome, overactive bladder and patients with retained ureteral stents following endourological interventions

**Authors:** Raisin G et al.

**Summary:** In this study, 36 patients were divided into three groups: 10 with interstitial cystitis/bladder pain syndrome, 10 with OAB, and 16 with external ureteral stents (EUI). EUI patients received weekly installations until stent removal, while OAB and interstitial cystitis/bladder pain syndrome patients had four consecutive weekly installations. The treatment's impact was evaluated using various measures. For the EUI group, there was a notable 4-point improvement in their visual analog scale score. In the OAB group, there was a significant 33.54% reduction in urination frequency. The interstitial cystitis/bladder pain syndrome group exhibited a substantial mean 3.2-point enhancement in their visual analog scale score, a 25.43% decrease in urination frequency, and an average 8.1-point decrease in O'Leary Sant Questionnaires score. These improvements were all statistically significant, suggesting the efficacy of the treatment in alleviating symptoms across the three patient groups.

**Comment:** This study is exciting in its potential. It seems to offer genuine hope for an effective local treatment for patients with interstitial cystitis/painful bladder syndrome and refractory OAB. Whilst only a pilot evaluation, the potential is both encouraging and significant. Watch this space, as it could be a game-changer!

**Reference:** *Urology*. 2023;178:42-7

[Abstract](#)

## Adjustable continence therapy (proACT) for the treatment of male stress urinary incontinence post-prostatectomy

**Authors:** Tricard T et al.

**Summary:** This systematic review and meta-analysis included 18 studies with 1570 patients. The study had an average follow-up duration of 34.7 months, with a median of 38.5 months and a range from 1 to 128 months. Among the patients, 60.7% experienced mild-to-moderate incontinence, while 40.4% suffered from severe incontinence. The overall rate of achieving dryness, defined as using 0-1 pads per day, was 55.1%, with a mean dryness rate of 53%. In terms of complications, the average overall complication rate was 31.2%, encompassing an explantation rate of 26.5% and a reoperation rate of 22.7%.

**Comment:** This review allows an objective assessment of the minimally invasive proact device for stress incontinence. The adjustable balloon device could be considered a comparator to bulking agents, with the potential for non-operative adjustment. Results can best be described as moderate at best, with just over 50% of patients achieving acceptable levels of continence but at a cost of significant explantation – 26% and re-operation – 23%. A therapy perhaps reserved for the most considered of circumstances.

**Reference:** *World J Urol*. 2023;41:1793-1802

[Abstract](#)



## Continence Research Review™

### Independent commentary by Associate Professor Bill Lynch

Bill Lynch is a consultant urologist based in Sydney. He has a particular interest in functional & reconstructive urology, as well as the practical application of technology within the urological discipline. He has published widely and often speaks internationally in these areas. He is associated with The St George Hospital (University of NSW), Sydney and is a founding member of the world-renowned Pelvic Floor Unit at that institution. He is a Clinical Associate Professor of Urology at Macquarie University.

## Comparison of the efficacy of intravaginal electrical stimulation in women with idiopathic overactive bladder naive and refractory to pharmacological agents

**Authors:** Yildiz N et al.

**Summary:** In this prospective trial, two groups of women were studied: Group 1 consisted of PhA-naive women (n = 24), while Group 2 included women with PhA-resistant idiopathic OAB (n = 24). Both groups underwent intravaginal electrical stimulation three times a week, totalling 24 sessions over an 8-week period, with each session lasting 20 minutes. Various parameters were assessed, including incontinence severity, pelvic floor muscle strength, voiding patterns, symptom severity, quality of life, treatment outcomes, and patient satisfaction. The results showed that both groups experienced statistically significant improvements in all measured parameters at the end of the 8-week intervention compared to baseline values (p < 0.05). Notably, there were no statistically significant differences between the two groups in terms of incontinence severity, pelvic floor muscle strength, incontinence episodes, nocturia, pad usage, quality of life, treatment satisfaction, cure/improvement rates, or positive response rates (p > 0.05). However, Group 1 significantly improved voiding frequency and symptom severity compared to Group 2 (p < 0.05). These findings suggest the potential efficacy of intravaginal electrical stimulation for both PhA-naive and PhA-resistant idiopathic OAB patients, with some differences in specific parameters.

**Comment:** An interesting study with potential in a difficult group of patients. A simple self-directed therapy with minimal potential for side effects. Numbers are low, so further assessment and trials are required before wider adoption could be considered, but if patients are happy in the non-trial setting to use this therapy, then it is definitely a therapy to keep an eye on.

**Reference:** *Int Urogynecol J*. 2023;34:2099-105

[Abstract](#)

## A 10- to 20-year follow-up after tension-free vaginal tape for stress urinary incontinence

**Authors:** Goessens EMV & Cammu H

**Summary:** In this retrospective cohort study of 291 women who underwent a successful transvaginal tape procedure via the retrobulbar bottom-to-top route at a teaching hospital between January 2001 and December 2010, the study aimed to assess the long-term outcomes of transvaginal tape at a 10 to 20-year follow-up. The study revealed that transvaginal tape remains highly effective, with 94% of women experiencing no/or infrequent leakage. Mesh exposure occurred in 2.7% of cases, repeat surgery for SUI in 3.8%, and intermittent self-catheterisation was necessary for 1% of women. However, bothersome OAB symptoms affected 15% of patients, associated with factors like polypharmacy, cardiovascular medication use, and obesity. These findings indicate the enduring efficacy of transvaginal tape in managing SUI over the long term while highlighting the prevalence of overactive bladder symptoms and its connections to various clinical factors.

**Comment:** A paper that every urologist and urogynecologist should read. 20-year data on therapies that have been questioned since the "great mesh debacle". With 94% continence rates, with mesh exposure at 2.7% and repeat surgery at 3.8% at 20 years, it certainly makes one feel for those denied this therapy in the current climate. No other treatment has similar long-term data and success.

**Reference:** *Int Urogynecol J*. 2023;34:2107-114

[Abstract](#)

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