Making Education Easy

Issue 67 - 2025

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Abbreviations used in this issue:

 ${\bf aOR}={\bf adjusted}$ odds ratio; ${\bf CI}={\bf confidence}$ interval; ${\bf HR}={\bf hazard}$ ratio; ${\bf LSM}={\bf least}$ -squares mean;

mpMRI = multiparametric magnetic resonance imaging; OR = odds ratio;
OS = overall survival; RCT = randomised controlled trial; RR = relative risk;
TURP = transurethral resection of the prostate; UTI = urinary tract infection.



Welcome to Issue 67 of Urology Research Review.

The FUTURE study, investigating the role of urodynamics in women with refractory overactive bladder, has shown that urodynamics may not be beneficial nor cost-effective in this group. In an Australian study, supervised resistance and aerobic exercise improved erectile function and intercourse satisfaction in men with prostate cancer previously or currently undergoing treatment, but the addition of psychosexual education resulted in no additional improvements. We conclude this issue with a study from Japan investigating a novel portable urine-measuring device for nocturia.

We hope you find our selection of articles for this review interesting and welcome your feedback. Kind Regards,

Professor Eric Chung

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Invasive urodynamic investigations in the management of women with refractory overactive bladder symptoms (FUTURE) in the UK: A multicentre, superiority, parallel, open-label, randomised controlled trial

Authors: Abdel-Fattah M et al.

Summary: The British, multicentre, parallel-group, open-label, randomised controlled FUTURE trial compared clinical- and cost-effectiveness of urodynamics plus comprehensive clinical assessment (CCA) versus CCA alone in 1099 women with refractory overactive bladder symptoms. After 15 months, participant-reported "very much improved" or "much improved" success rates that did not differ between urodynamics plus CCA and CCA alone (22.7% vs 23.6%; aOR; 1.12; 95% CI 0.73-1.74). The incremental cost-effectiveness ratio modelled over the participant lifetime was £42,643 per quality-adjusted life-year (QALY) gained. Cost-effectiveness acceptability suggested that urodynamics had a 34% probability of cost-effectiveness using a threshold of £20,000 per QALY gained, and this probability was reduced when extrapolated over the patient's lifetime.

Comment: The FUTURE study is probably the largest randomised controlled trial world-wide to investigate the role of urodynamics in women with refractory overactive bladder. Concerns had been raised previously in the literature about the effect of the quality of urodynamic studies on the reliability of diagnostic results. In this trial, the participant-reported success rates following treatments in women who underwent urodynamics and CCA were not superior to those who underwent CCA only. Significantly more women who underwent CCA only report earlier improvement in their symptoms. Women in the urodynamics plus CCA group received more tailored treatments, but with no evidence of superiority in participant-reported outcomes or fewer adverse events. Urodynamics is not cost-effective at a threshold of $\mathfrak{L}20,000$ per QALY gained in this cohort. Extrapolating the estimated 24-month results using final treatment designations and published long-term success rates reduces the probability of urodynamics being cost-effective to 23%. Perhaps the FUTURE study has shown that women can experience earlier improvement in their quality of life with initiation of therapy and avoidance of unnecessary invasive investigations.

Reference: Lancet 2025;405(10484):1057-1068

Abstract

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Exercise and psychosexual education to improve sexual function in men with prostate cancer: A randomized clinical trial

Authors: Galvão DA et al.

Summary: This single-centre, three-arm, parallel-group, randomised clinical trial assessed supervised, resistance and aerobic exercise plus a brief psychosexual education and self-management intervention (PESM) on sexual function in 112 men with prostate cancer. After 6 months, the mean adjusted difference in International Index of Erectile Function (IIEF) score favoured exercise versus usual care (3.5; 95% Cl 0.3-6.6; p=0.04); mean adjusted difference for intercourse satisfaction did not differ between treatments (1.7; 95% Cl 0.1-3.2) and the addition of PESM did not provide improvement. Exercise also improved the mean adjusted difference in fat mass (-0.9 kg; 95% Cl -1.8 to -0.1 kg; p=0.02), chair rise performance (-1.8 seconds; 95% Cl -3.2 to -0.5 seconds; p=0.002), and upper (9.4 kg; 95% Cl 6.9-11.9 kg; p<0.001) and lower (17.9 kg; 95% Cl 7.6-28.2 kg; p<0.001) body muscle strength.

Comment: Sexual dysfunction is a common sequelae of prostate cancer treatment and poses a major survivorship issue for patients and their partners. Exercise has been shown to improve patient-reported outcomes and is recommended in various cancer survivorship guidelines. This RCT showed that supervised resistance and aerobic exercise improved erectile function and intercourse satisfaction in men with prostate cancer previously or currently undergoing treatment, but the addition of psychosexual education resulted in no additional improvements. Based on the findings of this study, exercise should be considered as an integral part of treatment to improve sexual function in men with prostate cancer. The low-intensity psychoeducation intervention had no additional effect on sexual function outcomes in the present study. One wonders whether psychosexual support delivered by the exercise physiologist as part of this brief psychosexual education and self-management intervention adjunctive component may not have been powerful enough to improve outcomes above the exercise intervention effect. While exercise alone can improve physical and mental well-being and promote improved feelings of masculinity, multimodal psychosocial interventions coupled with sexual rehabilitation are more likely to improve mental health outcomes and quality of life, as well as increase overall sexual satisfaction.

Reference: JAMA Netw Open 2025;8(3):e250413

<u>Abstract</u>

Bowel disorder incidence and rectal spacer use in patients with prostate cancer undergoing radiotherapy

Authors: Folkert MR et al.

Summary: This US, retrospective cohort study used data from four medical datasets to compare the incidence of bowel disorders in 261,906 patients with prostate cancer receiving radiotherapy with (n = 25,167) or without (n = 236,739) a polyethylene glycol-based hydrogel rectal spacer (PHS). After 4 years, PHS recipients had a 25% lower risk of bowel disorders (HR 0.75; 95% CI 0.72-0.78; p < 0.001) and a 46% lower risk of related procedures (HR 0.54; 95% CI 0.47-0.62; p < 0.001) than non-recipients. Non-PHS recipients also had higher risk than an age-matched general population for bowel disorders (17.1% vs 10.3%; HR 1.35; 95% CI 1.32-1.37; p < 0.001) and related procedures (2.0% vs 0.7%; HR 1.92; 95% CI 1.79-2.06; p < 0.001). PHS recipients did not differ from the age-matched general population for bowel disorders (12.4% vs 10.3%; HR, 1.00; 95% CI 0.98-1.05) or related procedures (1.1% vs 0.7%; HR 1.11; 95% CI 0.96-1.29).

Comment: Radiation therapy invariably causes urinary and rectal complications. Improved understanding of long-term bowel toxic effects in the post-approval setting could guide clinical decision-making regarding the use of rectal spacers when attempting to mitigate radiotherapy-related adverse events. In this cohort study of 261,906 patients with prostate cancer, a rectal spacer (PHS) was associated with a lower incidence of bowel disorders and related procedures over 4 years. Incidence of disorders and procedures among patients who received a PHS was similar to the age-matched general population without prostate cancer and radiotherapy. Evidence from clinical practice data suggests that rectal spacer use improves patient outcomes and reduces the likelihood of bowel disorders and related procedures, in concordance with clinical trial data. While the study attempted to understand the difference in specific bowel disorders and procedures by spacer status, it was not feasible to understand how the spacer use might have been associated with the severity of bowel dysfunction. Perhaps, rectal spacers should be adopted as a standard of care in patients with prostate cancer undergoing radiation therapy.

Reference: JAMA Netw Open 2025;8(3):e250491

Abstract

Has active surveillance for prostate cancer become safer? Lessons learned from a global clinical registry

Authors: Bangma C et al.

Summary: This analysis of a multinational database assessed the safety and acceptability of active surveillance (AS), and treatment outcomes in 14,623 patients with low- and intermediate-risk tumours. Over 4-year time blocks between 2000 and 2016, there were no changes in OS; however, metastasis-free survival (MFS) rates improved after the second 4-year period to >99%. Treatment-free survival rates in the earlier time periods showed a more rapid transition to radical treatment. There was a consistent proportion of men (5%) where anxiety was the reason for treatment alteration, a subset (10-15%) where a treatment change was for no apparent reason, while in another 10-15% group, tumour progression was the reason for treatment. Among those opting for radical treatment, surgery was the most common modality. After radical treatment, 90% of patients were free from biochemical recurrence at 5 years.

Comment: Recent studies, including those leveraging global clinical registries, indicate that AS for prostate cancer has become a safer and more effective treatment option, particularly for low- and intermediate-risk cancers. Improvements in diagnostic tools and risk stratification, coupled with careful patient selection, have led to better outcomes and reduced the need for immediate, potentially more invasive treatments. Specifically for Australia and New Zealand, the rates of AS have increased over time, from 54% in 2015 to 74% in 2018, correlating with a fall in surgery for low-risk prostate cancer (39% vs 24%). The shift towards transperineal saturation template biopsy and judicious use of mpMRI contributed to increased rates of AS. While the worldwide GAP3 registry is unique in size and duration of follow-up in AS, such a registry can suffer from confounders, known and unknown. Nonetheless, advances in radiogenomics and molecular biomarkers will improve the detection and confidence in AS. Long-term trends indicate that, over time, intervention rates have decreased, and eligibility has expanded, supporting AS as the standard of care for low-risk prostate cancer management.

Reference: Eur Urol Oncol. 2025;8(2):324-337 Abstract

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Abbreviations: ADT: androgen deprivation therapy; HR: hazard ratio; mHSPC: metastatic hormone-sensitive prostate cancer; OS: overall survival; PBS: Pharmaceutical Benefits Scheme. References: 1, PBS Schedule of Pharmaceutical Benefits, 2023. Available at: https://www.pbs.gov.au/pbs/home 2, Chi KN et al. N Engl J Med 2019;381:13—24, 3, Chi K et al. J Clin Oncol 2021;39:2294—2303. Further information is available on request from Janssen-Cilag Pty Ltd, ABN 47 000 129 975, 1-5 Khartoum Road, Macquarie Park NSW 2113, Ph: 1800 226 334. ERLYAND® is a registered trademark of Janssen-Cilag Pty Ltd, CP-387406 EMVERL0367 Date of preparation: May 2025

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Effectiveness of Y-V-plasty for refractory bladder neck stenosis after transurethral prostate surgery

Authors: Masumoto H et al.

Summary: This small retrospective study reviewed five patients who underwent Y-V-plasty for refractory bladder neck stenosis (BNS) after transurethral prostate surgery. After a median 13-month follow-up, all procedures were considered successful with cystourethroscope passage without resistance through the anastomosis and no additional procedures required. Median postoperative maximum flow rate was 26.6 mL/s, and median postvoid residual urine volume measurement was 12 mL. Postoperatively, two patients were pad-free, and three patients used one to two pads daily. Three patients were 'very satisfied,' one 'satisfied,' while one was 'dissatisfied.'

Comment: Bladder neck contracture (BNC) was reported to occur up to 5% following TURP. Different risk factors have been proposed, including smaller prostate size, pervasive cauterisation, extensive scarring process and extended resection of the bladder neck. After failure of the second endoscopic attempt, patients with BNC are considered resistant to endoscopic management and are usually offered a more radical solution, including open reconstruction versus urinary diversion. The Y-V-plasty is an effective surgical option for refractory bladder neck contracture that uses a healthy bladder flap to replace the stenotic bladder neck. In this retrospective study, all five patients had a "successful" Y-V-plasty, although three patients became incontinent postoperatively. In recent times, the adoption of robotic-assisted Y-V-plasty has been reported to provide better visualisation and dexterity, potentially leading to better outcomes and faster recovery. It would be interesting to evaluate whether other injectables (steroid, mometasone etc.) or technology (such as laser, Optilume®) could prevent the need for more radical reconstruction

Reference: Int J Urol. 2025;32(4):434-440

Abstract

Efficacy of a clinical decision support tool to promote guidelineconcordant evaluations in patients with high-risk microscopic hematuria: A cluster randomized quality improvement project

Authors: Matulewicz RS et al.

Summary: This multicentre, two-arm, cluster randomised, quality improvement project assessed implementation of a clinical decision support (CDS) tool changed the number of patients with microscopic haematuria (MH; n = 917) classified as American Urological Association (AUA) "highrisk" who received guideline-concordant evaluations. The proportion of eligible patients where an automated CDS alert including recommendations for imaging and cystoscopy was correctly triggered was 83%. The primary outcome, patient received imaging and cystoscopy within 180 days, was achieved by 0.6% of patients in the intervention arm and 0.9% of patients in the control arm (RR 0.69; 95% Cl 0.15-3.10). Patients in both arms had similar rates of completed imaging (17.7% vs 14.7%) and cystoscopy (1.5% vs 0.9%). The intervention increased the likelihood of a CT urogram order (5.5% vs 1.1%; p = 0.003), but not of urology evaluation (11.1% vs 7.5%.

Comment: Roughly 3% to 10% of patients with "high-risk" MH can harbour an occult kidney or bladder cancer. This randomised quality improvement project evaluates the efficacy of a CDS tool embedded in the electronic health record to help clinicians better identify and evaluate patients with high-risk MH. Despite the alert triggering correctly for 83% of patients and being opened by 74% of clinicians, there was no statistically significant difference in the proportion of patients who completed a guideline-concordant evaluation between study arms. There was a significant increase in completion of a "gold standard" CT urogram in patients in the intervention arm relative to usual care. Similarly, when considering an alternative primary outcome which included imaging and urology consultation (with or without cystoscopy), there was a nonsignificant improvement in evaluations completed in the intervention arm. Taken together, these findings suggest a modest potential change in clinician behaviour prompted by the intervention. There remain significant gaps in the evaluation of patients with high-risk MH, even after the implementation of an electronic health record-embedded alert and clinical decision support tool. This may be driven by competing clinical priorities, fragmentation in the multistep MH evaluation process, or a lack of awareness of the guideline recommendations for the evaluation of patients with MH. The implementation of these types of alerts must also be balanced with "alert fatigue," particularly in the primary care setting, where there are many other competing clinical priorities. The associated order set that was provided as part of the alert was nearly never used, which was a surprise finding of this study. Perhaps the inclusion of specific high-risk criteria for each patient, highlighting the association of prior tobacco use and bladder cancer, would further emphasise the importance of evaluation for "high-risk" patients.

Reference: J Urol. 2025;213(5):558-567

Abstract

Multi-institutional analysis of surgery for lichen sclerosus-induced penile urethral stricture: Establishing single-stage urethroplasty as a primary treatment option

Authors: Hengel R et al.

Summary: This multicentre study compared single-stage urethroplasty (SSU) with oral mucosal graft (n = 127), staged urethroplasty (n = 44), and perineal urethrostomy (PU; n = 60) for treatment of lichen sclerosus (LS)-induced penile urethral strictures (PUS). After a median 53-month follow-up 1-, 5-, and 10-year stricture-free estimates were 90%, 80%, and 75% with no difference in recurrence between techniques; 5-year stricture-free estimates were 82% with SSU, 76% with staged urethroplasty, and 75% with PU. There were no differences in 90-day complications (7.1%, 16%, 8.3%), erectile dysfunction (7.1%, 4.5%, 3.3%), chordee (5.5%, 6.8%, 1.7%), or urethrocutaneous fistula (2.4%, 6.8%, 0%). Stricture recurrence was associated with obesity (BMI ≥35; HR 2.31; 95% CI 1.28-4.17; p = 0.006).

Comment: Ideal treatment of LS-induced PUS remains elusive. At the heart of the debate lies the issue of whether a SSU should be preferentially used over a staged reconstruction. This study compared multi-institutional outcomes of SSU with oral mucosal graft, staged urethroplasty, and PU for treatment of LS-induced PUS. In 231 men at nine centres undergoing SSU, staged urethroplasty, or PU, overall 1-, 5-, and 10-year stricture-free estimates were 90%, 80%, and 75%, with no difference in stricture recurrence or 90-day complications. Although this study represents the largest multi-institutional analysis of outcomes specific to surgery for LS-induced PUS, there are some limitations. The nonrandomised nature of the study incurs a risk of selection bias regarding the selection of surgical techniques. A randomised trial comparing these techniques is unlikely to be feasible because of patient preference for single-stage surgery and the emotionally charged nature of genital surgery. The lack of a consensus definition for success after urethroplasty renders it challenging to standardise the reporting of outcomes.

Reference: J Urol. 2025;213(5):628-637Abstract



Independent commentary by Professor Eric Chung

Professor Eric Chung is a consultant urological surgeon at the AndroUrology Centre for Sexual, Urinary, and Reproductive Excellence and holds a professorial academic appointment at the University of Queensland in Brisbane. He is the current Chair of the Male LUTS section and Past Chair of the Andrology section within the Urological Society of Australia and New Zealand (USANZ) and serves in executive positions in various international organizations such as the Member-at-Large and Chair of the Surgical Committee at the International Society of Sexual Medicine (ISSM) and Chair of the Peyronie's disease, Male Genitalia Trauma and Reconstructive Surgery committee at the International Consultation on Sexual Medicine (ICSM). He has been invited as a speaker and surgeon mentor at many national and international meetings and has authored more than 200 peer-reviewed papers and book chapters.

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A contemporary estimate of vasectomy failure in the United States: Analysis of US claims data

Authors: Ha A et al.

Summary: This analysis used data from the Merative MarketScan (2007-21) Commercial Database to characterise trends in vasectomy utilisation, delivery, and failure in 489,277 vasectomised men (mean age 38 years). Most (n = 344,319) procedures were performed by urologists and the 6 month post-procedure pregnancy rate was 1.97 per 1000 persons per year (PY), a pregnancy rate of 0.58%. There were annual declines in post-vasectomy pregnancy (p = 0.03) and birth (p = 0.04) rates, especially in more recent years. Reduced odds of failure were observed with older age and recent vasectomy years, while an increased failure rate was associated with the absence of a post-vasectomy semen analysis (a0R 1.14; 95% Cl 1.03-1.25; p < 0.001). Higher odds of repeat procedures were associated with vasectomies performed by non-urologists (a0R 1.56; 95% Cl 1.40-1.74; p < 0.0001) and vasectomies in office-based settings (a0R 1.25; 95% Cl 1.08-1.44; p < 0.01).

Comment: Vasectomy failure is rare and current data on failure rates remain limited, with most estimates derived from historical cohorts. Based on a large US insurance claims database of 489,277 vasectomised men, an annual decline in post-vasectomy pregnancy and birth rates was observed, with the overall post-vasectomy pregnancy rate being 0.58%. Logistic regression analysis demonstrated that older male and partner age, as well as more recent years in which the vasectomy was performed, were associated with reduced odds of failure, while the absence of a post-vasectomy semen analysis was associated with increased failure. Vasectomies performed by non-urologists and in office-based settings were associated with increased odds of a repeat vasectomy. While this study provides a contemporary failure rate, its retrospective study design and reliance on administrative claims data, coupled with the lack of granular clinical data, may have provided an incomplete capture of pregnancies. These findings underscore the importance of patient counselling and education. Nonetheless, compared to other modes of contraception, vasectomy remains superior in its efficacy.

Reference: J Urol. 2025;213(5):638-647

Abstract

Gene therapy with URO-902 (pVAX/hSlo) for the treatment of female patients with overactive bladder and urge urinary incontinence: Safety and efficacy from a randomized phase 2a trial

Authors: Enemchukwu EA et al.

Summary: This placebo-controlled, randomised phase II trial examined the use of an investigational gene therapy expressing the large-conductance Ca^{2+} -activated K^+ channel (URO-902) administered by intradetrusor injection via cystoscopy in 80 women with overactive bladder (OAB). After 12 weeks, URO-902 doses of 24 and 48 mg were associated with improvements in daily micturitions versus placebo (LSM change -2.3 and -2.4 vs -0.8; p 0.017). The 48 mg dose of URO-902 was also associated with improvements versus placebo in urgency episodes (-3.4 vs -1.1; p = 0.016) and Patient Global Impression of Change responders (58% vs 31%; p = 0.026). One of more treatment-emergent adverse events (TEAE) were experienced by 46% of URO-902 24mg, 54% of URO-902 48 mg, and 54% of placebo recipients, most commonly UTI (0%, 15%, 4%) and haematuria (6%, 8%, 8%).

Comment: The URO-902 (pVAX/hS/o) is a novel gene therapy under investigation for the treatment of OAB in patients who are refractory to oral treatment and is delivered using intradetrusor injection under local anaesthesia. In this phase IIa dose-escalation trial, treatment with URO-902 48 mg was associated with significant and clinically relevant improvements in OAB symptoms of micturition frequency and urgency, as well as improvements in patient-reported overall symptoms as measured by the Patient Global Impression of Severity. In addition, promising numeric improvements were observed in the proportion of participants achieving ≥50% and ≥75% reductions in daily urge urinary incontinence episodes and OAB Questionnaire scores. URO-902 was generally safe, with no regional or systemic manifestations of toxicity, TEAE rates comparable with placebo, and no TEAE-related discontinuations. Expanded clinical studies are warranted to further elucidate the efficacy and safety of URO-902, possibly at higher doses, as a potential safe and durable treatment of refractory OAB. However, this study was limited by a relatively small sample size. Although safety follow-up continued for 48 weeks, the primary efficacy analysis occurred at week 12, and participants were permitted to use additional OAB treatments after week 24, limiting interpretation of long-term efficacy. Further studies are warranted to assess URO-902, possibly at higher doses, as a potential treatment for refractory OAB.

Reference: J Urol. 2025;213(4):417-427

Abstract

Analysis of nocturia determinants using a novel portable urine-measuring device

Authors: Yamasue K et al.

Summary: These authors investigated the relationship between nocturia and values measured using a novel multifunctional portable urine-measuring device among 35 older men (mean age among 33 men included in the analysis was 75.2 years) with nocturia and/or highnormal or high blood pressure. A semi-conical cup was used to collect the urine and measurements were undertaken on one full day (24 hours) and two nights using the portable device. Analysis of the nocturnal urination frequency, including the first urination after waking, revealed a mean of 2.1 voids. Nocturnal urine frequency was found to significantly increase with nocturnal urine volume (r = 0.65, p < 0.001) and salt content (r = 0.57, p < 0.001), but not with 24-hour urine volume and salt content. There was a decrease in void frequency with nocturnal urine temperature (r = -0.37, p < 0.05) and there was a high correlation between night-time urine volume and salt content (r = 0.73, p < 0.001). There was no correlation between morning blood pressure and nocturnal urination frequency.

Comment: Joint research with Zeo System Co. Ltd. (Yokohama, Japan) led to the development of a device applying the principle of water clocks and Trichilly's theorem to develop a novel multifunctional portable, urine measuring device that could measure urinary volume, salt content, and temperature immediately after urination, and the urination rate. The accuracy of urine volume measured using the novel device was inferior to that of the gravimetric method, although it was close (r = 0.95), and the accuracy of salt concentration measured was near that of the ion electrode method (r = 0.92). There was a high correlation between nocturnal urine volume and salt content (n = 31, r = 0.73, p < 0.001), whereas there was no significant relationship between nocturnal urine volume and salt concentration (r = -0.08, p = 0.67). The trial results indicated that nocturnal urine volume, nocturnal urinary salt content, and urine temperature (corresponding to core body temperature) correlated with nocturia, whereas daily urine volume and salt content did not. Monitoring urine temperature could aid in the early detection of infections and heat stroke, and urination rate could help identify urination disorders such as prostatic hyperplasia. Using the device at home for several weeks could facilitate nocturia management by monitoring night-time urinary volume, salt content, and temperature, as well as by enabling informed counselling related to diet, beverage intake, exercise, and sleeping environmental temperature.

Reference: Neurourol Urodyn. 2025;44(4):722-727 Abstract

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