W13 WEBINAR: Current surgical management of postprostatectomy incontinence – workup, options and decision making

Workshop Chair: Ralf Anding, Switzerland

Topic	Speakers
Introduction	Ralf Anding
Pathophysiology	Craig Comiter
Diagnostics	Vincent Tse
Fixed slings	Vincent Tse
Adjustable devices	Wilhelm Hübner
Classic sphincter	Craig Comiter
Adjustable sphincters	Wilhelm Hübner
Decision making	Ralf Anding

Faculty:

Ralf G. Anding, Urologist
Ass. Professor of Urology at the University of Basel, Switzerland
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Bio:
Subspecialty in Neurourology. Broad experience in male incontinence therapy for 20+ years. 60+ publications and book chapters. Research and development of novel devices and alternative sling techniques.
Board Certifications: Specialist of Urology (1998), Advanced Urologic Surgery (2004), Urologic Oncology (2011)
Residencies: Staedtische Kliniken Dortmund, Kreiskrankenhaus Luedenscheid, Otto-von-Guericke-University Magdeburg, Klinikum Osnabrueck, Friedrich-Wilhelms-University Bonn
Medical Education: Ruhr-University Bochum, Graduation (1992), M.D. (1993)
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Bio:
Board Certification: American Board of Urology (2001), Female Pelvic Medicine and Reconstructive Surgery (2013)
Fellowship: University of California Los Angeles (1999)
Residencies: Brigham and Women's Hospital Harvard Medical School (1994), Harvard Program in Urology (1998)
Medical Education: Harvard Medical School, M.D. (1992)
A.B., Harvard College, Biology (1988)
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Vincent Tse, Urologist
Clinical Associate Professor at the University of Sydney, Australia
Consultant Urologist at Concord Hospital and Macquarie University Hospital, Sydney
Department of Urology, Suite 101 Hospital Rd, Concord West NSW 2137, Australia
Bio:
Dr Tse has special interest in the investigation and management of all types of urinary incontinence, bladder functional disorders, urethral strictures and pelvic organ prolapse surgery. He is a past working member of the Standardisation and Terminology Committee of the International Continence Society (ICS), immediate past chair of Continence Foundation of Australia (CFA)-NSW, and scientific co-chair of ICS Melbourne 2021. He has co-edited two books on urinary incontinence and the pelvic floor and authored over 50 papers and abstracts in this area.
Residencies: Prince of Wales Hospital and Community Health Services (2001), University of California Davis Medical Center, Sacramento, USA (2002), Concord Repatriation General Hospital (2003), Macquarie University Hospital (2011)
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Bio:
Great experience in minimal invasive treatment in male urinary incontinence. Pioneer in developing alternative surgical treatment modalities for male incontinence. Prof Hubner has successfully led several ICS male incontinence workshops.
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Aims of Workshop
Delegates will acquire a current overview of surgical options and limits of postprostatectomy incontinence therapy. Various sling devices have been developed over the last 15 years and can now be evaluated with long-term studies. Adjustable devices offer the opportunity of adaptation to a changing degree of incontinence during follow-up. The specific role of fixed and adjustable slings as well as balloons in this field will be defined. The mainstay of treatment of more severe stress incontinence is still the AMS 800 sphincter prosthesis. However, new and also adjustable implants have been introduced in recent years and will be covered. Case discussions will give practical views of complex aspects and troubleshooting.

Learning Objectives
Provide attendants with up-to-date information of surgical options and techniques of male incontinence therapy

Target Audience
Urology

Advanced/Basic
Advanced

Suggested Learning before Workshop Attendance

- Huebner WA, Schlarp OM. Treatment of incontinence after prostatectomy using a new minimally invasive device: adjustable continence therapy. BJU Int. 2005;96(4):587-594
- Huebner WA, Schlarp OM. Adjustable continence therapy (ProACT): evolution of the surgical technique and comparison of the original 50 patients with the most recent 50 patients at a single centre. Eur Urol 2007;52(3):680-686
- Bauer RM, Gozzi C, Huebner W, Nitti VW, Novara G, Peterson A, Sandhu JS, Stief CG. Contemporary Management of Postprostatectomy Incontinence. Eur Urol 2011;59(6):985-996
- Jura YH, Comiter CV. Urodynamics for postprostatectomy incontinence: when are they helpful and how do we use them? Urol Clin North Am. 2014;41(3):419-427
- Bretterbauer KM, Huber ER, Remzi M, Huebner W. Telephone-delivered quality of life after 365 male stress urinary incontinence (SUI) operations. Int Braz J Urol. 2016;42(5):986-992
- Kretschmer A, Huesch T, Thomsen F, Kronlachner D, Obaje A, Anding R, Pottek T, Rose A, Olianas R, Friedl A, Huebner W, Homberg R, Pfitzenmaier J, Grein U, Queissert F, Naumann CM, Schweiger J, Wotzka C, Nyarangi-Dix JN, Hofmann T, Seiler R, Haferkamp A, Bauer RM. Complications and Short-Term Explantation Rate Following Artificial Urinary Sphincter Implantation: Results from a Large Middle European Multi-Institutional Case Series. Urol Int. 2016;97(2):205-211
- Sahai A, Abrams A, Dmochowski R, Anding R. The role of male slings in post prostatectomy incontinence: ICI-RS 2015. Neurourol Urodyn 2017;36(4):927-934
- Kretschmer A, Huesch T, Thomsen F, Kronlachner D, Obaje A, Anding R, Pottek T, Rose A, Olianas R, Friedl A, Huebner W, Homberg R, Pfitzenmaier J, Grein U, Queissert F, Naumann CM, Schweiger J, Wotzka C, Nyarangi-Dix JN, Hofmann T, Seiler R, Haferkamp A, Bauer RM. Targeting Moderate and Severe Male Stress Urinary Incontinence with Adjustable Male Slings and the Perineal Artificial Urinary Sphincter: Focus on Perioperative Complications and Device Explantations. Int Neurourol J. 2017;21(2):109-115
- Huesch T, Kretschmer A, Thomsen F, Kronlachner D, Kurosch M, Obaje A, Anding R, Pottek T, Rose A, Olianas R, Friedl A, Huebner W, Homberg R, Pfitzenmaier J, Grein U, Queissert F, Naumann CM, Schweiger J, Wotzka C, Nyarangi-Dix JN, Hofmann T, Ulm K, Bauer RM, Haferkamp A. Antibiotic Coating of the Artificial Urinary Sphincter (AMS 800): Is it Worthwhile? Urology 2017;103:179-184
- Huesch T, Kretschmer A, Thomsen F, Kronlachner D, Kurosch M, Obaje A, Anding R, Pottek T, Rose A, Olianas R, Friedl A, Huebner W, Homberg R, Pfitzenmaier J, Grein U, Queissert F, Naumann CM, Schweiger J, Wotzka C,

Nyarangi-Dix JN, Hofmann T, Ulm K, Bauer RM, Haferkamp A. Risk Factors for Failure of Male Slings and Artificial Urinary Sphincters: Results from a Large Middle European Cohort Study. Urol Int. 2017;99(1):14-21
- Habashy D, Losco G, Tse V, Collins R, Chan L. Mid-term outcomes of a male retro-urethral, transobturator synthetic sling for treatment of post-prostatectomy incontinence: Impact of radiotherapy and storage dysfunction. Neurourology and Urodynamics 2017;36(4):1147-1150
- Toia B, Leung LY, Saigal R, Solomon E, Malde S, Taylor C, Sahai A, Hamid R, Seth JH, Sharma D, Greenwell TJ, Ockrim JL. Is pre-operative urodynamic bladder function the true predictor of outcome of male sling for post prostatectomy incontinence? World J Urol 2020 Jun 6. doi: 10.1007/s00345-020-03288-8. Online ahead of print.

Handouts

Pathophysiology - Craig Comiter

Risk factors for Incontinence —

- Preoperative continence status – Preoperative incontinence is the most reliable predictor of incontinence after prostate treatment (IPT).
- Nerve-sparing versus non-nerve-sparing surgery Patients who had non-nerve-sparing surgery had a 2.2-fold increased risk of incontinence compared with patients who had a bilateral nerve-sparing dissection at one year postoperatively.
- Age – Older age is an independent predictor of worsened continence status after RP. There is increased apoptosis of the striated muscle cells (and associated decreased function) of the external sphincter with age.
- Urethral length – Preoperative membranous urethral length is correlated with continence rates, with a small but significant improvement with each additional millimeter of length. Similarly, longer postoperative functional urethral length is also associated with improved continence.
- Radiation – Radiation therapy to the prostate, following surgery for either benign or malignant prostate disease, is associated with substantially higher rates of IPT.
- Obesity – While patients with an elevated body mass index (BMI) are more likely to have incontinence in the short term, BMI does not necessarily predict incontinence at 12 months postoperatively.

PATHOPHYSIOLOGY — Incontinence after prostate treatment can result from either bladder or sphincter dysfunction, or a combination of the two.

Bladder dysfunction

Overactive — The development of de novo irritative symptoms after prostate treatment is common, with approximately one-third of incontinent patients having at least some component of overactive bladder symptoms. However, the majority of men with UUI following prostate cancer surgery have concomitant SUI, with only 6 to 7 percent manifesting pure UUI.

Underactive — Up to 33 percent rate of detrusor underactivity in patients who had undergone radical prostatectomy (RP), typically presenting as the complaint of requiring abdominal straining to urinate after the procedure, possibly due to denervation of the trigone.

Intrinsic sphincter deficiency — ISD is the most common cause of IPT. Following RP, as an example, the vast majority of incontinent men (88 to 100 percent) have ISD as the main cause of their incontinence. ISD is likely a direct result of the surgery, with injury to the external striated sphincter during ligation of the dorsal venous complex, damage to the smooth muscle of the urethra caused by the anastomotic sutures, and/or denervation due to dissection of the urethra and prostate.

Diagnostics - Vincent Tse

At the conclusion of this presentation, the delegate should be able to understand the importance of the diagnostic method in post-prostatectomy incontinence (PPI), as accurate diagnosis will lead to the most effective management option being chosen to improve patient's quality of life. It is vital to understand that PPI is not always due to intrinsic sphincter deficiency. Up to 50% of PPI cases may be secondary to storage dysfunction such as detrusor overactivity or reduced bladder compliance. Each of these may be antecedent to the radical prostatectomy or arise de novo as a result of the pelvic cancer operation. Therefore, it is strongly advised that a multichannel urodynamic study be performed prior to surgery to correct PPI as surgery will only raise urethral resistance via increasing the leak point pressure but it will not correct pre-existing bladder overactivity or reduced compliance. An accurate history and physical examination are also required to identify whether the patient may need salvage radiation later, have cognitive, mobility or eye-hand coordination issues. An MSU and post-void residual volume and bladder diary are essential, as is 24 hour pad-weights. Number of pads has been shown not to correlate with incontinence bothersomeness or capacity. Transperineal ultrasound is useful in assessing the component pelvic floor muscles which may be weak and requires training to better target of the relevant muscles by physiotherapists. It may also assist in the diagnosis of why a sling may fail. This presentation will show ultrasound images on its utility to diagnosis such as fixed bladder neck opening and in diagnosing causation of male sling failure and how it may change management. Cystoscopy is indicated to evaluate the external sphincter muscle and the anastomotic region after radical prostatectomy and if a stenosis or stricture is expected or encountered.

Fixed slings - Vincent Tse

Male slings have been a treatment option for post-prostatectomy incontinence (PPI) now for more than 10 years. The most widely used type of slings is the fixed sling, although there are also adjustable slings as well as artificial urinary sphincters. This presentation will focus on the fixed sling, with the two-arm Advance sling (from Boston Scientific) being more commonly used, and also the Virtue sling (from Coloplast) which is a four-arm sling. After this presentation, the delegates should be able to describe the 2 different types of slings, their mechanisms of action, clinical indications, the nature of the surgery, results and complication profile. Prior pelvic radiation as well as overactive bladder may reduce the long-term success rate of male sling.

Adjustable devices - Wilhelm Hübner

The most commonly used adjustable sling systems are the Argus sling system (Promedon Argentina), the ATOMS system (AMI, Austria) and the Remeex System (Neomedic, Spain). The aim of adjustable sling systems is to support the postoperatively reduced baseline continence provided by the smooth muscle system by a minimal increase of the urethral resistance (10-15 cmH_2O). These slings are positioned suburethrally on top of the bulbospongiosus muscle
The *Argus sling* (Promedon, Argentina) consists of a radiopaque cushioned system with a silicone foam pad for soft compression of the bulbar urethra. Two silicone columns are attached to the silicone foam and allow system readjustment while two radiopaque silicone “washers” allow regulation of the desired tension. The Argus sling can be implanted via a retropubic (Argus classic) or a transobturator (ArgusT) approach.
The sling is fixed with “washers” in the suprapubic (Argus classic) or inguinal (ArgusT) region on the fascia. In patients with moderate to severe SUI and a mean follow-up of 2.1 years a dry rate of 79.2% (pad test of 0–1 g) was reported. Another study with patients with severe SUI showed success rates of up to 67%. Re-adjustments are required in approximately one third of the patients. Complications of the Argus sling include acute urinary retention and erosion, sling removal is seen in up to 12%. In irradiated patients equal success rates compared to non-irradiated patients can be achieved. Tha Argus sling has shown to be safe and effective.

The *Adjustable Transobturator Male System* (ATOMS) consists of a silicone cushion and a pre-attached fully silicone-covered scrotal port as well as mesh arms which are placed around the inferior rami of the pubic bone. The volume of the cushion can be adjusted any time postoperatively. The all-time adjustability in the outpatient setting and the fixed anchoring around the obturator foramina are the main characteristics of this device. Short follow-up series have shown promising results for the precursor generations (inguinal port) with reported success rates of between 61% and 63%, and revision rates of between 5% and 16%. Risk factors for treatment failure were identified in a multicentre study [12]. In a larger multicenter study Friedl et al found a dry rate of 64% was found, however 20% of the devices were removed within a median time to explantation of 11 (4–25) months. The influence of radiation therapy on the results is rated differently in the literature. The ATOMS device appears to be safe and shows good treatment efficacy.
The *Remeex system* (Neomedic, Spain) consists of a mesh connected via two monofilament traction threads to a suprapubic mechanical regulator. This "varitensor" is implanted over the abdominal rectum fascia. Adjustment is conducted via an external manipulator. The manipulator is left in place at end of implantation, on day 1 the sling will be adjusted using the manipulator until the patient is dry during coughing. In an average follow-up of 32 months, success rates (no or one small pad per day) of up to 65 % can be achieved in patients with mild to moderate SUI. Most of the patients need at least one readjustment. The main complications are intraoperative bladder injuries (up to 11%) and removal of the device (up to 12%). Many patients report perineal discomfort or even pain after implantation. No data exist concerning second line treatment after failed Remeex sling implantation.

Classic sphincter - Craig Comiter

Artificial urinary sphincter — The AUS is the most predictably reliable treatment for SUI for men with all degrees of incontinence.

The AUS is composed of a circumferential urethral cuff, a pressure-regulating balloon reservoir, and a scrotal pump. It should be placed via a two-incision technique, using a perineal incision for cuff placement and an inguinal incision for balloon reservoir and scrotal pump placement. The cuff opens after manual compression of the scrotal pump and automatically closes after a period of two to three minutes.

The literature is replete with studies demonstrating the efficacy of the AUS in both the short and long term with satisfaction rates generally greater than 90%. Prior to AUS placement, patients must be informed of the risks of mechanical failure, erosion, infection, and persistent incontinence.

Device explantation is indicated for infection or erosion. Device revision is indicated for recurrent incontinence due to ISD, with options including cuff repositioning or downsizing, transcorporal cuff placement, typically with removal and replacement of the balloon reservoir and scrotal pump if the device is more than 2 years old.

Adjustable sphincters - Wilhelm Hübner

For more than 30 years the AMS 800 has been the gold standard of hydraulic sphincters. In spite revision rates of 10-41% (depending on FU) and social continence rates of 79% most patients would have had their sphincter put in again 94,4%). Certain points of improvement have been raised repeatedly:
a possibility to change the intra-device pressure postoperatively, a ready made implant to avoid connecting components during the operation, a pump less challenging to use for patients with impaired dexterity, and increasing the intra-device pressure during maneuvers with high intraabdominal pressure.
Two alternative commercially available hydraulic implants are on the market today and will be discussed addressing these points - the ZSI375 artificial urinary sphincter, and the Victo/Victo plus sphincter.

ZSI 375 artificial urinary sphincter:

The ZSI 375 consists of a cuff and a pump, which covers both the function of a pressure regulating reservoir as well as the opening activation. The regulation unit involves two hydraulic compartments, one to fill the cuff and a second one regulating the pressure in the system. Implantation can be performed through a trans scrotal approach or via two incisions (perineal and inguinal).
The ZSI 375 provides adjustability by percutaneous filling any time after implantation. It is a „one piece implant", thereby facilitating implantation. Improvement concerning challanges for dexterity over the AMS 800 is limited. A possibility of increasing the intra-device pressure during maneuvers with high intraabdominal pressure is not provided.
Ostrowski et al published a success rate of 78% associated with a revision rate of 22%, in a cohort of 50 pts. Afzer a FU of 21 mts., Kretschmer et al found less favourable results.
The Victo sphincter consists of a cuff, a pump and optionally an additional intraabdominal balloon for conditional pressure increase. The pressure within the system can be adjusted any time after implantation by punction of the self-sealing port. Implantation is performed through a perineal and inguinal incision.

The Victo device is a one-piece implant and provides adjustability, Victo plus includes a smart self-acting adjustment system, that covers sudden pressure rises by pressure transfer from the intraabdominal stress - balloon to the cuff. This allows decreasing the resting pressure in the cuff to a minimum. The pump is similar to the AMS 800, however, it has a self-sealing port for adjustment of the volume in the system.

Decision making - Ralf Anding

The process of decision-making for optimal therapy planning and favorable results in post prostatectomy incontinence implies various dimensions. Important factors concerning the patient are the severity of symptoms, age and health condition, comorbidities, in particular those that affect mental capabilities and dexterity, eg neurological diseases, and also patients' expectations.
Important aspects of treatment of the underlying prostate disease that affect further continence therapy are the type of prostate surgery, radiation therapy, time span from prostate treatment to continence therapy, status of cure, other pathologies, and current diagnostic findings.
Furthermore, the skills of the surgeon and individual product preference are increasingly in the focus. Lastly, product availability is also a major factor when comparing therapy concepts in different countries.
With respect to symptom severity there is still limited objectivity due to the lack of a generally accepted classification of male incontinence. Some proposals define mild, moderate, and severe incontinence as urine loss of <100g, 100-400g, and >400g in 24 hours, respectively. Other authors specify 200g of urine loss/24h as a better threshold for severe incontinence because of less favorable results of fixed slings in this category [Collado et al. World Journal of Urology 2019;37:195–200]. A simple pad count is a poor measure of urinary incontinence severity because of the poor correlation with actual urine loss [Tsui et al. J Urol. 2013;190:1787-1790]. Also, little changes in daily activity have a significant impact on 24h pad weight [Malik et al. Int Braz J Urol. 2016;42:327-33].
Today, as we are increasingly confronted with elderly patients, the decision for an implant that needs patient activation (AUS pump) can be difficult. The group from Munich just presented 7 years data and found that age at surgery is not a prognostic factor for AdVance-XP male sling efficacy [Mumm et al. Neurourology and Urodynamics. 2021;40:1616-1624]. Various tools for the mental/dexterity assessment of elderly or otherwise limited patients are available like the Mini Mental Status Test (MMST), Clock Completion Test (CC), Pen Test, Timed Up and Go Test (TUGT), and should be used eg when the appropriate handling of the AUS pump is doubtful. When the decision is in the balance the majority of patients favors a non-mechanical device. When the choice is theirs only a small minority desired the more definitive procedure (AUS) with a proven track record [Kumar et al. J Urol 2009;181:1231-1235]. Also, psychological aspects in decision-making must be considered. In a recent study 20% of patients with male SUI reported decisional regret, particularly among those electing conservative treatment pointing out the underutilized surgical option to treat male SUI. Depression and

higher incontinence scores were associated with more regret, shared decision-making was associated with less regret [Hampson et al. MP56, AUA Meeting 2021].
With respect to prostate treatment multiple studies have demonstrated that continence rates after open and robotic prostatectomies are equal [MacKenzie et al. Neurourology Urodyn 2019;38:1353-1362]. Moreover, neither degree of nerve sparing nor surgery type proved to be reliably related to urinary functioning [Strassberg et al. Curr Urol 2017;11:16–20]. A substantial difference in continence rates can be observed after previous radiotherapy. The risk for failure of both male slings and AUS is significantly higher with a history of pelvic irradiation [Husch et al. Urol Int. 2017;99:14-21]. In case of local PCA recurrence incontinence surgery should be accomplished before radiation therapy. The decision for surgery should not be determined by the status of cure as quality of life matters equally in a palliative setting. Other concomitant diseases play a greater role for the decision between an AUS and an adjustable sling (eg Atoms). In high-volume centers the decision for an AUS was made significantly more often after urethral stricture disease, radiation therapy, and prior incontinence surgery [Grabbert et al. Urol Int 2020;104:902–907].
Also, surgeon preference and experience are important factors in decision-making. When comparing high- and low-volume centers, the decision for a double cuff (compared to single cuff) and for a perineal access (compared to penoscrotal) was made significantly more often in high-volume centers, with respect to AUS. The rate of both explantations and urethral erosions was significantly lower in the high-volume centers [Queissert et al. Neurourology and Urodynamics 2020;39:1856–1861]. Lastly, product availability in various local markets often decides which product is utilized.