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American Urological Association (AUA)/

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INCONTINENCE AFTER PROSTATE TREATMENT: AUA/SUFU GUIDELINE

Jaspreet S. Sandhu, MD; Benjamin Breyer, MD; Craig Comiter, MD; James A. Eastham, MD; Christopher Gomez, MD; Daniel J. Kirages, PT; Chris Kittle; Alvaro Lucioni, MD; Victor W. Nitti, MD; John T. Stoffel, MD; O. Lenaine Westney, MD; M. Hassan Murad, MD; Kurt Mc Cammon, MD

Purpose

Urinary incontinence after prostate treatment (IPT) is a clinically significant condition that causes a high degree of patient distress. It is one of the few urologic diseases that is iatrogenic, and, therefore, predictable and perhaps preventable. Although most clinicians are familiar with the more commonly known term "post-prostatectomy incontinence," this guideline uses the term IPT, which is more inclusive given that it covers the management of patients who have incontinence after undergoing radical prostatectomy (RP), radiation treatment (RT), and treatment of benign prostatic hyperplasia (BPH). Evaluation of the patient; risk factors for IPT, which should be discussed with all patients prior to treatment; assessment of the patient prior to intervention; and a stepwise approach to management are covered in this guideline. Possible maneuvers to decrease rates of IPT, with specific focus placed on patients with stress urinary incontinence (SUI) are also explored. The multiple treatments that exist for patients with IPT are discussed and evaluated, including physical therapy, medications, and surgery.

Methodologies

The systematic review utilized to inform this guideline was conducted by a methodology team at the Mayo Clinic Evidence-Based Practice Research Program. The scope of the topic and the discussion of the final systematic review used to develop guideline statements was conducted in conjunction with the Incontinence after Prostate Treatment expert panel. A research librarian conducted searches in Ovid MEDLINE (from 2000 to December 21st, 2017), Cochrane Central Register of Controlled Trials (from 2000 to December 21st, 2017) and Cochrane Databases of Systematic Reviews (from 2000 to December 21st, 2017). Searches of electronic databases were supplemented by reviewing reference lists of relevant articles. Panel members identified additional references through 12/31/2018.

Guideline Statements

Pre-Treatment

1. Clinicians should inform patients undergoing radical prostatectomy of all known factors that could affect continence. (Moderate Recommendation; Evidence Level: Grade B)

2. Clinicians should counsel patients regarding the risk of sexual arousal incontinence and climacturia following radical prostatectomy. (Strong Recommendation; Evidence Level: Grade B)

3. Clinicians should inform patients undergoing radical prostatectomy that incontinence is expected in the short-term and generally improves to near baseline by 12 months after surgery but may persist and require treatment. (Strong Recommendation; Evidence Level: Grade A)

4. Prior to radical prostatectomy, patients may be offered pelvic floor muscle exercises or pelvic floor muscle training. (Conditional Recommendation; Evidence Level: Grade C)

5. Patients undergoing transurethral resection of the prostate after radiation therapy or radical prostatectomy after radiation therapy should be informed of the high rate of urinary incontinence following these procedures. (Moderate Recommendation; Evidence Level: Grade C)

Post-Prostate Treatment

6. In patients who have undergone radical prostatectomy, clinicians should offer pelvic floor muscle exercises or pelvic floor muscle training in the immediate post-operative period. (Moderate Recommendation; Evidence Level: Grade B)

7. In patients with bothersome stress urinary incontinence after prostate treatment, surgery may be considered as early as six months if incontinence is not improving despite conservative therapy. (Conditional Recommendation; Evidence Level: Grade C)

8. In patients with bothersome stress urinary incontinence after prostate treatment, despite conservative therapy, surgical treatment should be offered at one year post-prostate treatment. (Strong Recommendation; Evidence Level: Grade B)

Evaluation of Incontinence after Prostate Treatment

9. Clinicians should evaluate patients with incontinence after prostate treatment with history, physical exam, *and appropriate diagnostic modalities* to categorize type and severity of incontinence and degree of bother. (Clinical Principle)

10. Patients with urgency urinary incontinence or urgency predominant mixed urinary incontinence should be offered treatment options per the American Urological Association Overactive Bladder guideline. (Clinical Principle)

11. Prior to surgical intervention for stress urinary incontinence, stress urinary incontinence should be confirmed by history, physical exam, or ancillary testing. (Clinical Principle)

12. Patients with incontinence after prostate treatment should be informed of management options for their incontinence, including surgical and non-surgical options. (Clinical Principle)

13. In patients with incontinence after prostate treatment, physicians should discuss risk, benefits, and expectations of different treatments using the shared decision-making model. (Clinical Principle)

14. Prior to surgical intervention for stress urinary incontinence, cystourethroscopy should be per formed to assess for urethral and bladder pathology that may affect outcomes of surgery. (Expert Opinion)

15. Clinicians may perform urodynamic testing in a patient prior to surgical intervention for stress urinary incontinence in cases where it may facilitate diagnosis or counseling. (Conditional Recommendation; Evidence Level: Grade C)

Treatment Options

16. In patients seeking treatment for incontinence after radical prostatectomy, pelvic floor muscle exercises or pelvic floor muscle training should be offered. (Moderate Recommendation; Evidence Level: Grade B)
17. Artificial urinary sphincter should be considered for patients with bothersome stress urinary incontinence after prostate treatment. (Strong Recommendation; Evidence Level: Grade B)
18. Prior to implantation of artificial urinary sphincter, clinicians should ensure that patients have adequate physical and cognitive abilities to operate the device. (Clinical Principle)
19. In the patient who selects artificial urinary sphincter, a single cuff perineal approach is preferred. (Moderate Recommendation; Evidence Level: Grade C)
20. Male slings should be considered as treatment options for mild to moderate stress urinary incontinence after prostate treatment. (Moderate Recommendation; Evidence Level: Grade B)
21. Male slings should not be routinely performed in patients with severe stress incontinence. (Moderate Recommendation; Evidence Level: Grade C)
22. Adjustable balloon devices may be offered to patients with mild stress urinary incontinence after prostate treatment. (Moderate Recommendation; Evidence Level: Grade B)
23. Surgical management of stress urinary incontinence after treatment of benign prostatic hyperplasia is the same as that for patients after radical prostatectomy. (Moderate Recommendation; Evidence Level: Grade C)
24. In men with stress urinary incontinence after primary, adjuvant, or salvage radiotherapy who are seeking surgical management, artificial urinary sphincter is preferred over male slings or adjustable balloons. (Moderate Recommendation; Evidence Level: Grade C)
25. Patients with incontinence after prostate treatment should be counseled that efficacy is low and cure is rare with urethral bulking agents. (Strong Recommendation; Evidence Level: Grade B)
26. Other potential treatments for incontinence after prostate treatment should be considered investigational, and patients should be counseled accordingly. (Expert Opinion)

Complications after Surgery

27. Patients should be counseled that artificial urinary sphincter will likely lose effectiveness over time, and reoperations are common. (Strong Recommendation; Evidence Level: Grade B)
28. In patients with persistent or recurrent urinary incontinence after artificial urinary sphincter or sling, clinicians should again perform history, physical examination, and/or other investigations to determine the cause of incontinence. (Clinical Principle)
29. In patients with persistent or recurrent stress urinary incontinence after sling, an artificial urinary sphincter is recommended. (Moderate Recommendation; Evidence Level: Grade C)
30. In patients with persistent or recurrent stress urinary incontinence after artificial urinary sphincter, revision should be considered. (Strong Recommendation; Evidence Level: Grade B)

Special Situations

31. In a patient presenting with infection or erosion of an artificial urinary sphincter or sling, explantation should be performed and reimplantation should be delayed. (Clinical Principle)
32. A urinary diversion can be considered in patients who are unable to obtain long-term quality of life after incontinence after prostate treatment and who are appropriately motivated and counseled. (Expert Opinion)
33. In a patient with bothersome climacturia, treatment may be offered. (Conditional Recommendation; Evidence Level: Grade C)
34. Patients with stress urinary incontinence following urethral reconstructive surgery may be offered artificial urinary sphincter and should be counseled that complications rates are higher. (Conditional Recommendation; Evidence Level: Grade C)
35. In patients with incontinence after prostate treatment and erectile dysfunction, a concomitant or staged procedure may be offered. (Conditional Recommendation; Evidence Level: Grade C)
36. Patients with symptomatic vesicourethral anastomotic stenosis or bladder neck contracture should be treated prior to surgery for incontinence after prostate treatment. (Clinical Principle)

Introduction

IPT causes emotional and financial distress to patients afflicted with this condition by delaying patients' re-entry into society, inhibiting relationships, and carrying an economic burden for families and stakeholders. It is a condition that has gained visibility not only due to the extensive use of surgery for prostate cancer but also given to the proliferation of men's continence products available to the lay public.

Since IPT is caused by treatment of the prostate, it is, by definition iatrogenic and perhaps preventable or predictable. Understanding the nature of IPT is crucial for patients and practitioners during recovery and extended survivorship. Practitioners benefit from being able to assess which patient will likely experience further symptom recovery versus those who will not. This allows clinicians to set clear and reasonable expectations regarding the short-, medium-, and long-term sequela of IPT.

Although most clinicians are familiar with the more commonly known term "post-prostatectomy incontinence," this guideline uses the term IPT, which is more inclusive given that it covers the management of patients who have incontinence after undergoing RP, RT, and treatment of BPH. Evaluation of the patient; risk factors for IPT, which should be discussed with all patients prior to treatment; assessment of the patient prior to intervention; and a stepwise approach to management are covered in this guideline. Possible maneuvers to decrease rates of IPT, with specific focus placed on patients with SUI, are also explored. The multiple treatments that exist for patients with IPT are discussed and evaluated, including physical therapy, medications, and surgery. Algorithms for patient evaluation, surgical management, and device failure are provided for practitioners.

Methodology

The systematic review utilized to inform this guideline was conducted by a methodology team at Mayo Clinic Evidence-Based Practice Research Program. Determination of the guideline scope and review of the final systematic review to inform guideline statements was conducted in conjunction with the Incontinence after Prostate Treatment expert panel.

Panel Formation

The IPT Panel was created in 2017 by the American Urological Association Education and Research, Inc. (AUAER). This guideline was developed in collaboration with the Society of Urodynamics, Female Pelvic

Medicine & Urogenital Reconstruction (SUFU). The Practice Guidelines Committee (PGC) of the American Urological Association (AUA) selected the Panel Chair, who in turn appointed additional panel members with specific expertise in this area, in conjunction with SUFU. Funding of the panel was provided by the AUA with contributions from SUFU; panel members received no remuneration for their work.

Searches and Article Selection

A comprehensive search of several databases from 2000 to December 21st, 2017 was completed. Databases included Ovid MEDLINE Epub Ahead of Print, Ovid Medline In-Process & Other Non-Indexed Citations, Ovid MEDLINE, Ovid EMBASE, Ovid Cochrane Central Register of Controlled Trials, Ovid Cochrane Database of Systematic Reviews, and Scopus. The search strategy was designed and conducted by an experienced medical reference librarian with input from the guideline methodologist. Controlled vocabulary supplemented with keywords was used to search for studies on IPT. The search was restricted to studies published in English and available in full text in the peer reviewed literature.

Data Abstractions

Two reviewers independently selected studies and extracted data using standardized, pilot tested forms created in a systematic review software management system (Distiller SR, Evidence Partners, Ottawa, Canada). Disagreements were resolved by discussion between the two reviewers. Two main types of data were abstracted: baseline characteristics (study design, objective, inclusion and exclusion criteria, sample size, age, body mass index [BMI], intervention, period of follow up), and outcome data (number of patients who were incontinent and those with incontinence improvement, mean pads per day, quality of life [QoL], and complications).

Risk of Bias Assessment

The Newcastle Ottawa scale, which evaluates cohort selection, comparability and outcomes assessment, was used for non-randomized controlled trials (RCTs). The Cochrane risk of bias tool which evaluates random sequence generation, allocation concealment, blinding, and attrition was used for evaluation of RCTs.

Data Synthesis

When meta-analysis was appropriate, methodologists utilized the random-effects model *a priori* because of the anticipated heterogeneity across study populations and settings. Otherwise, outcomes were evaluated using narrative and descriptive approaches.

Determination of Evidence Strength

The categorization of evidence strength is conceptually distinct from the quality of individual studies. Evidence strength refers to the body of evidence available for a particular question and includes individual study quality in addition to consideration of study design; consistency of findings across studies; adequacy of sample sizes; and generalizability of samples, settings, and treatments for the purposes of the guideline. Investigators graded the strength of evidence for key comparisons and outcomes for each Key Question, using the approach described in the Agency for Healthcare Research and Quality Evidence-based Practice Center Methods Guide for Comparative Effectiveness and Effectiveness Reviews.[1] Strength of evidence assessments were based on the following domains:

- Study limitations, based on the overall risk of bias across studies (low, medium, or high)
- Consistency of results across studies
- Directness of the evidence linking the intervention and health outcomes
- Precision of the estimate of effect, based on the number and size of studies and confidence intervals for the estimates (precise or imprecise)
- Reporting bias, based on whether or not the studies defined and reported primary outcomes and whether or not we identified relevant unpublished studies (suspected or undetected)

The AUA categorizes body of evidence strength as Grade A (well-conducted and highly-generalizable

RCTs or exceptionally strong observational studies with consistent findings), Grade B (RCTs with some weaknesses of procedure or generalizability or moderately strong observational studies with consistent findings), or Grade C (RCTs with serious deficiencies of procedure or generalizability or extremely small sample sizes or observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data). By definition, Grade A evidence is evidence about which the Panel has a high level of certainty, Grade B evidence is evidence about which the Panel has a moderate level of certainty, and Grade C evidence is evidence about which the Panel has a low level of certainty.

AUA Nomenclature: Linking Statement Type to Evidence Strength

The AUA nomenclature system explicitly links statement type to body of evidence strength, level of certainty, magnitude of benefit or risk/burdens, and the Panel's judgment regarding the balance between benefits and risks/burdens (Table 1). ***Strong Recommendations*** are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/ burdens outweigh benefits) be undertaken because net benefit or net harm is substantial. ***Moderate Recommendations*** are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/ burdens outweigh benefits) be undertaken because net benefit or net harm is moderate. ***Conditional Recommendations*** are non-directive statements used when the evidence indicates that there is no apparent net benefit or harm or when the balance between benefits and risks/burden is unclear. All three statement types may be supported by any body of evidence strength grade. Body of evidence strength Grade A in support of a Strong or Moderate Recommendation indicates that the statement can be applied to most patients in most circumstances, and that future research is *unlikely to change confidence*. Body of evidence strength Grade B in support of a Strong or Moderate Recommendation indicates that the statement can be applied to most patients in most circumstances, but better evidence *could change confidence*. Body of evidence strength Grade C in support of a Strong or Moderate Recommendation indicates that the statement can be applied to most patients in most circumstances, but better evidence *is likely to change confidence*. Body of evidence strength Grade C is only rarely used in support of a Strong Recommendation. Conditional Recommendations also can be supported by any evidence strength. When body of evidence strength is Grade A, the statement indicates that benefits and risks/burdens appear balanced, the best action depends on patient circumstances, and future research is *unlikely to change confidence*. When body of evidence strength Grade B is used, benefits and risks/burdens appear balanced, the best action also depends on individual patient circumstances, and better evidence *could change confidence*. When body of evidence strength Grade C is used, there is uncertainty regarding the balance between benefits and risks/burdens, alternative strategies may be equally reasonable, and better evidence is *likely to change confidence*.

Where gaps in the evidence existed, the Panel provides guidance in the form of ***Clinical Principles*** or ***Expert Opinions*** with consensus achieved using a modified Delphi technique if differences of opinion emerged.[2] A *Clinical Principle* is a statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature. *Expert Opinion* refers to a statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence.

Peer Review and Document Approval

An integral part of the guideline development process at the AUA is external peer review. The AUA conducted a thorough peer review process to ensure that the document was reviewed by experts in the treatment of IPT. In addition to reviewers from the AUA PGC, Science and Quality Council (SQC), and Board of Directors (BOD), the document was reviewed by representatives from

TABLE 1: AUA Nomenclature Linking Statement Type to Level of Certainty, Magnitude of Benefit or Risk/Burden, and Body of Evidence Strength

	Evidence Strength A (High Certainty)	**Evidence Strength B (Moderate Certainty)**	**Evidence Strength C (Low Certainty)**
Strong Recommendation (Net benefit or harm substantial)	Benefits > Risks/ Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/ Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances but better evidence could change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears substantial Applies to most patients in most circumstances but better evidence is likely to change confidence (rarely used to support a Strong Recommendation)
Moderate Recommendation (Net benefit or harm moderate)	Benefits > Risks/ Burdens (or vice versa) Net benefit (or net harm) is moderate Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/ Burdens (or vice versa) Net benefit (or net harm) is moderate Applies to most patients in most circumstances but better evidence could change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears moderate Applies to most patients in most circumstances but better evidence is likely to change confidence
Conditional Recommendation (No apparent net benefit or harm)	Benefits = Risks/ Burdens Best action depends on individual patient circumstances Future research unlikely to change confidence	Benefits = Risks/ Burdens Best action appears to depend on individual patient circumstances Better evidence could change confidence	Balance between Benefits & Risks/Burdens unclear Alternative strategies may be equally reasonable Better evidence likely to change confidence
Clinical Principle	A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature		
Expert Opinion	A statement, achieved by consensus of the Panel, that is based on members clinical training, experience, knowledge, and judgment for which there is no evidence		

AUA and SUFU as well as external content experts. Additionally, a call for reviewers was placed on the AUA website from January 14-28, 2019 to allow any additional interested parties to request a copy of the document for review. The guideline was also sent to the Urology Care Foundation to open the document further to the patient perspective. The draft guideline document was distributed to 49 external peer reviewers. All peer review comments were blinded and sent to the Panel for review. In total, 33 reviewers (9 AUA PGC, SQC, and BOD reviewers; 22 external reviewers; and 2 public reviewers) provided comments. At the end of the peer review process, a total of 476 comments were received. Following comment discussion, the Panel revised the draft as needed. Once finalized, the guideline was submitted for approval to the AUA PGC, SQC and BOD as well as the governing bodies of SUFU for final approval.

Guideline Statements

PRE-TREATMENT

1. Clinicians should inform patients undergoing radical prostatectomy of all known factors that could affect continence. (Moderate Recommendation; Evidence Level: Grade B)

Many patient and surgical based factors have been evaluated to determine their impact on recovery of continence after RP. Younger patient age, smaller prostate size, and longer membranous urethral length (measured by MRI) have been consistently associated with improved recovery of continence after RP. A meta-analysis of studies evaluating age as a risk factor of IPT found that increasing patient age at the time of RP increases risk of incontinence.[3-8] Similarly, increasing prostate size results in increased odds of IPT,[4-6, 9-17] while increasing membranous urethral length results in decreased risk.[4-6, 9, 12, 18-20] Although each of the above are risk factors, their relationship to IPT is complex and nonlinear. Predictive models should account for this nonlinearity and are best represented as nomograms.[9]

Surgical approaches do not seem to impact rates of IPT; in particular, open RP has similar rates of urinary incontinence as robot-assisted RP.[21, 22] There is no current evidence that any surgical maneuvers, beyond bilateral neurovascular bundle preservation, results in improved continence recovery.[23, 24,25, 26] Men receiving bilateral neurovascular bundle preservation were 26% more likely to be continent at six months compared to men who did not;[27-32] however, surgeons should base the degree of nerve sparing on the features of the cancer rather than pre-operative potency. Men with poor pre-operative potency still benefit from nerve sparing in terms of recovery of continence.[33, 34]

BMI may impact IPT in the short-term; however there is little evidence that it is a risk factor for incontinence after RP at one year.[4-6, 9, 11-17]

2. Clinicians should counsel patients regarding the risk of sexual arousal incontinence and climacturia following radical prostatectomy. (Strong Recommendation; Evidence Level: Grade B)

Urologists should inform patients of the risks of sexual arousal incontinence and climacturia. Sexual arousal incontinence is characterized by the inadvertent loss of urine during sexual arousal, foreplay, and/or masturbation. Climacturia (also known as orgasm-associated urinary incontinence) is the involuntary loss of urine at the time of orgasm. This can occur following RP, with or without adjuvant RT, and can even occur in those treated with RT alone. While precise prevalence has not been well-established, several studies report an incidence of sexual arousal incontinence and climacturia following prostate cancer surgery ranging from 20 -93%, with most reporting an overall rate close to 30%.[35]

Such leakage is reported as bothersome by up to half of those patients, and one-third report that they avoid sexual situations due to fear of leakage.[36]

The pathophysiology of climacturia is not completely understood. The mechanism is thought

to relate to removal of the internal sphincter during RP, which is exacerbated by prior transurethral resection of the prostate (TURP). Bladder contraction at the time of orgasms with some degree of external sphincter insufficiency is thought to result in leakage during orgasm.[37]

Although climacturia and SUI are not mutually exclusive, there is some overlap between the conditions. In patients with climacturia, 30% do not experience SUI; conversely, 30% of patients with SUI do not report climacturia.[38] While the risk factors for climacturia are not as well defined as those for SUI, the main risk factor is time since surgery (shorter time from surgery is associated with a higher rate of leakage). Additionally, there appears to be a faster recovery of continence during sexual activity following robotic RP compared to open or pure laparoscopic RP.[39] Improvement can be expected throughout the postoperative period, but it can take several years to resolve, and typically persists in one-third of patients.[35, 40]

Other risk factors include prior TURP, as well as shorter functional urethral and penile length following RP. It does not appear that age, pre-operative erectile function, or nerve sparing status significantly affect the risk of sexual arousal or orgasm-related incontinence.[38]

3. Clinicians should inform patients undergoing radical prostatectomy that incontinence is expected in the short-term and generally improves to near baseline by 12 months after surgery but may persist and require treatment.(Strong Recommendation; Evidence Level: Grade A)

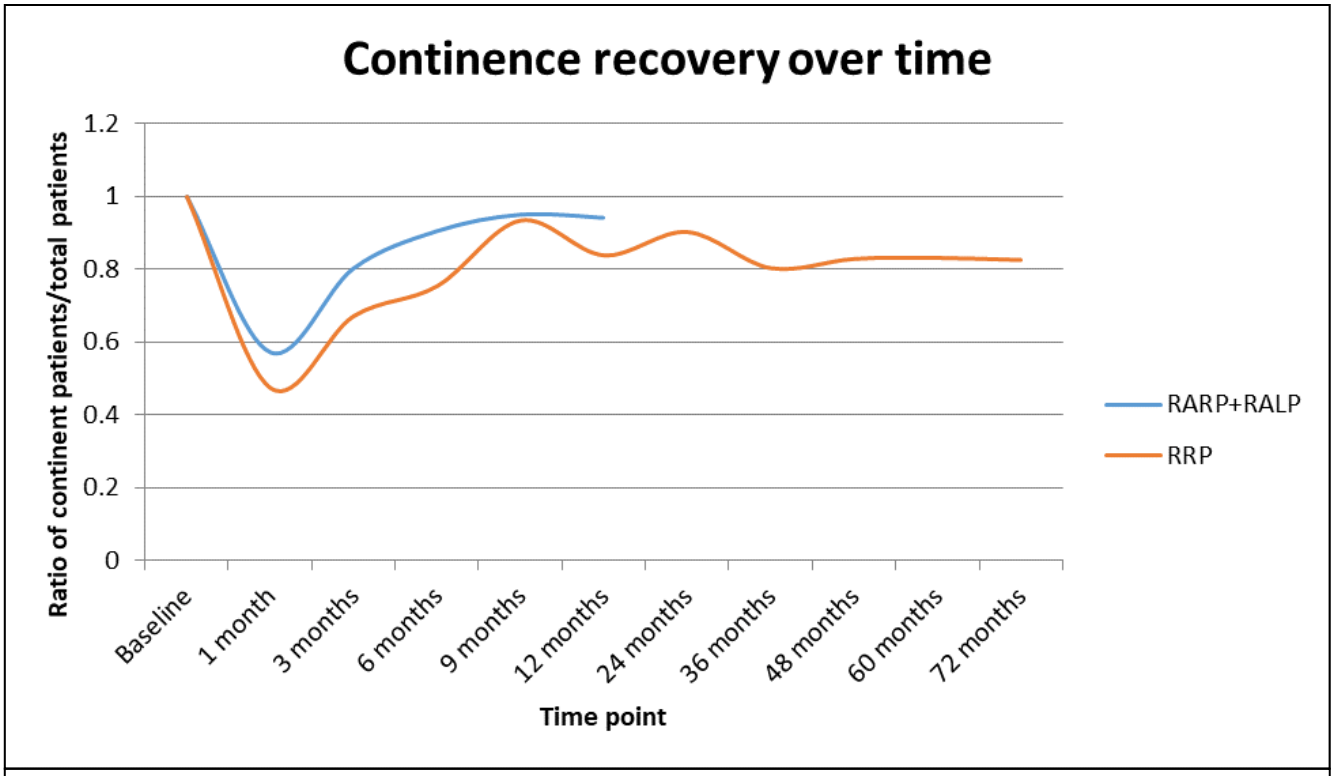
A commonly accepted definition of urinary continence is not requiring a pad or protective device to stay dry (pad-free).[41] Most men undergoing RP are not continent (pad-free) at the time of catheter removal and should be informed that continence is not immediate.[8] Continence after RP improves with time, and most men achieve continence within 12 months of surgery.[8] Men considering RP should be provided with reasonable expectations regarding recovery of continence. Because incontinence is expected in the early phase after surgery, conservative management with regular follow-up during the first year after surgery is recommended to assess patient progress. The spectrum of improvement over time based on procedure is shown in Figure 1.

4. Prior to radical prostatectomy, patients may be offered pelvic floor muscle exercises or pelvic floor muscle training. (Conditional Recommendation; Evidence Level: Grade C)

Voluntarily activating the pelvic floor muscles through an exercise program prior to RP is a common practice. Exercises for the pelvic floor muscle are easier to learn in the pre-operative period since mastery can be difficult postoperatively given muscle inhibition, sensory changes, urinary incontinence, and surgical pain.[42] Typical preliminary goals of a preoperative program include proper patient education regarding pelvic floor muscle anatomy, physiology, awareness, and motor control, which maximize the effectiveness of exercises.

Pelvic floor muscle exercises (PFME) is defined in this guideline as an exercise program specific to the pelvic floor muscle group that is self-guided as a home exercise program only. The patient may have learned the program through patient education literature or with a single basic instruction session from an appropriate practitioner. Pelvic floor muscle training (PFMT) is defined as a training program specific to the pelvic floor muscle group that is practitioner guided. Typically, PMFT will consist of individualized pelvic floor muscle awareness training using verbal, tactile, and/or visual feedback along with a home based PFME program to be progressed during follow-up visits with the practitioner.

Seven trials met inclusion criteria regarding the effectiveness of a pre-operative PFMT program improving post-prostatectomy continence. The robustness of the recommendation is limited by heterogeneous methods of evaluation and comparison among the different studies. The PFMT methods utilized to optimize pelvic floor



RARP: Robotic-assisted radical prostatectomy, RALP: Robot-assisted laparoscopic prostatectomy, RRP: Retropubic radical prostatectomy

muscle awareness included verbal cues,[43-45] tactile cues,[43, 45, 46] visualization of penile movement,[45] surface electromyography biofeedback,[44, 46, 47] pressure biofeedback,[48] and transabdominal ultrasound imaging.[43] Overall, these methods successfully assisted patients in isolating and contracting their pelvic floor muscles. However, it is not clear whether they are truly necessary or which methods are more beneficial.

To allow for neuromuscular adaptation, preoperative PFMT should be started three to four weeks prior to surgery.[43-46] However, the Panel can neither recommend the optimal time frame for initiation of pre-operative PFMT, nor the ideal intensity of the program due to reported variability in start times found in the literature.[47-49] The methods, dosage, and level of follow-up for PFMT and PFME in the post-operative period also varied among trials.

The benefit of starting pre-operative PMFT in not consistent in the outcome data. In one view, pre-operative PFMT has been shown to be effective in hastening continence recovery after surgery,[43, 45, 48, 49] while other efforts have failed to demonstrate a beneficial effect on continence.[44, 46] All trials varied with respect to assigned PFMT/ PFME regimens, definitions of continence, and length of follow-up. It is important to note that formal PFMT is not harmful, and the potential benefits clearly outweigh any potential risks and likely decrease regret.[46]

5. Patients undergoing transurethral resection of the prostate after radiation therapy or radical prostatectomy after radiation therapy should be informed of the high rate of urinary incontinence following these procedures. (Moderate Recommendation; Evidence Level: Grade C)

TURP. TURP following brachytherapy or external beam radiation has been associated with incontinence rates of up to 70%.[50, 51] The urethral fibrosis developing from radiation-related progressive endarteritis decreases the functional capabilities of the external sphincter. Even in the

absence of direct damage to the sphincter, adjacent surgical cautery or laser energy further compromises sphincter function. The need for subsequent resections, patient age, and pre-TURP urgency is correlated with higher rates of incontinence.[52]

There is little to no published evidence discussing post-TURP outcomes with patients who have undergone other forms of local therapy such as high-intensity focused ultrasound and cryotherapy. However, it is the opinion of this Panel that these patients have high risks of incontinence similar to post-TURP radiated patients.

Salvage Prostatectomy. Regardless of the initial form of non-operative therapy or the operative approach, salvage RP is associated with high rates of urinary incontinence rates (ranging from 20-70%) for both open and robotic techniques compared to standard RP.[53-59]

Patients undergoing TURP or salvage RP after primary non-surgical treatment for prostate cancer who seek long-term continence should be informed that they may require an artificial urinary sphincter (AUS).

POST-PROSTATE TREATMENT

6. In patients who have undergone radical prostatectomy, clinicians should offer pelvic floor muscle exercises or pelvic floor muscle training in the immediate post-operative period. (Moderate Recommendation; Evidence Level: Grade B)

Short-term PFMT may be offered to patients who are not able to perform self-directed PFME with appropriate quality and who request additional interventions to hasten the recovery of continence after RP. PFME after catheter removal has been shown to improve time-to-achieving continence compared to control groups in RCTs[60] and should be offered to all patients after RP upon removal of the urethral catheter. Those patients who are committed to a progressive PFMT or PFME program can expect an earlier return to continence than those who are not.[47] The timeframe for this early continence recovery after RP can be as early as three[47, 49, 61-63] to six months.[64] However, longer term assessment suggests that overall continence rates at one year remain similar between men who underwent PFME or PFMT and those who did not.[65]

Long-term assessment is skewed because of highly heterogeneous data and continence rates between men treated with PFME/PFMT are similar to those not treated (57% with urinary incontinence in intervention group versus 62% in control group, RR=0.85 at 12 months, 95% CI=0.60-1.22).[65] Overall these data suggest that if performed in the early post-operative period, PFME or PFMT improve time to continence (thus improving QoL) but not overall continence at 12 months.

7. In patients with bothersome stress urinary incontinence after prostate treatment, surgery may be considered as early as six months if incontinence is not improving despite conservative therapy. (Conditional Recommendation; Evidence Level: Grade C)

While almost all patients have reached their maximum improvement by 12 months, most patients with severe SUI will show no significant improvement after six months and may be candidates for early intervention. A review of the data indicates that 90% of patients will achieve continence at six months after robotic-assisted laparoscopic prostatectomy and only an additional 4% of patients will gain continence afterwards.[8, 66-71] Such data highlight that symptom improvement often plateaus earlier than one year. Patients who report a lack of symptom improvement or those experiencing more severe incontinence at six months may be offered early treatment in the form of surgical interventions with such a treatment decision made using a shared decision-making model.

8. In patients with bothersome stress urinary incontinence after prostate treatment, despite conservative therapy, surgical treatment should be offered at one year post-prostate treatment. (Strong Recommendation; Evidence Level: Grade: B)

Timing of treatment should be optimized to restore QoL as soon as possible without over-treatment. The natural history of incontinence after prostate surgery shows that the clear majority of patients will reach their maximum improvement by 12 months with minimal to no improvement afterwards. While cumulative data[8, 66-71] has shown that 94% of patients achieve continence by 12 months,[69, 72] patients followed for 24 months after robotic-assisted laparoscopic prostatectomy revealed that only an additional 1% of patients had continued improvement from 12-24 months. Withholding surgical treatment after 12 months is unlikely to result in improved patient symptoms and will delay restoration of continence. Patients who are eager to become dry and whose symptom improvement has reached a plateau may desire surgical treatment earlier than one year, and shared decision-making is key in initiating this intervention. Conversely, treatment should be offered with caution in patients who are displaying symptom improvement.

EVALUATION OF INCONTINENCE AFTER PROSTATE TREATMENT

9. Clinicians should evaluate patients with incontinence after prostate treatment with history, physical exam, *and appropriate diagnostic modalities* to categorize type and severity of incontinence and degree of bother. (Clinical Principle)

There is no formal evidence regarding the effects of history and physical exam on outcomes of IPT treatments; however, there is universal agreement that taking a history and performing a physical examination should be the first step in the assessment of anyone with urinary incontinence.[73] There is strong evidence that a history of pelvic RT[74, 75] is associated with the severity of incontinence, especially stress incontinence,[76, 77] after prostate surgery.

The Panel believes that before treating IPT, it is critical to categorize the type of incontinence (stress, urgency, mixed) and the severity and degree of bother of incontinence. The status of prostate cancer also should be known, particularly for men who are candidates for salvage RT, which may impact efficacy of continence treatment.

History is the first step in determining the type of incontinence, which is important because treatments for SUI (caused by sphincteric insufficiency) and urgency incontinence (caused by bladder dysfunction) are very different. In cases of mixed incontinence, it can be important to determine which component is more prevalent and bothersome, though many investigators feel that treatment outcomes for urgency incontinence may be difficult to determine in the face of significant sphincteric insufficiency.

History should focus on characterization of incontinence (stress or activity related versus urgency related), the severity of incontinence, the progression or resolution of incontinence over time, and degree of bother. Specifically, patients should be questioned on which activities causes incontinence. Increases in abdominal pressure such as that caused by straining, walking, cough, and exercise are suggestive of SUI, while the sudden compelling desire to void that is difficult to defer and results in leakage indicates urgency incontinence.[78] Presence of incontinence while asleep as well as nocturia are also important to note, because this may indicate urgency urinary incontinence or severe SUI. Confirmation of SUI can often be determined by history or physical exam alone; however there are times when a clinician may choose advanced testing such as urodynamic studies (UDS).

The severity of incontinence (i.e. volume lost over time) is important to know, especially in the case of sphincteric insufficiency as some treatments (e.g., male slings), clearly have inferior results in severe incontinence. Incontinence severity can be determined by history, or more objectively, by pad testing. It has been shown that careful questioning regarding pad number, size, and degree of wetness correlates well with pad weights and effect on QoL.[79] However, there may be times when a formal one-hour or 24-hour pad test may be helpful in determining incontinence severity.[79, 80] The Panel agrees that it is important to determine the degree of bother of incontinence and effect on QoL since this will

help to determine the type of initial treatment, or no treatment, and guide counselling through a shared decision-making model.

10. Patients with urgency urinary incontinence or urgency predominant mixed urinary incontinence should be offered treatment options per the American Urological Association Overactive Bladder guideline. (Clinical Principle)

The occurrence of urinary frequency, urgency, and urgency urinary incontinence is common after prostate treatment.[81-84] A review of urinary symptoms after RP reveals that 29% of patients will develop one or more symptoms, with 19% developing urinary urgency and 6% complaining of urgency incontinence.[81] Clinicians should be aware of the prevalence of overactive bladder (OAB), which has been described as high as 48% [85] and specifically assess for symptoms after prostate treatment. Evaluation and treatment can be initiated at any time post-prostate treatment and should follow the Overactive Bladder in Adults: AUA/SUFU Guideline.[86, 87] The presence of urgency urinary incontinence should not exclude a patient from surgical treatment of his bothersome SUI.

11. Prior to surgical intervention for stress urinary incontinence, stress urinary incontinence should be confirmed by history, physical exam, or ancillary testing. (Clinical Principle)

Prior to surgical intervention for SUI, clinicians should be certain that a patient truly has sphincteric insufficiency as a cause for his incontinence. History of SUI has a 95% positive predictive and 100% negative predictive value for the presence of SUI on UDS.[88] Evidence has not definitely shown whether or not the objective demonstration of SUI predicts surgical outcomes after prostate cancer treatment. The AUA/SUFU Guideline on the Surgical Management of Female Stress Urinary Incontinence states that the objective demonstration of SUI should be confirmed prior to surgical management (based on panel consensus).[89] Similarly, a recent International Continence Society consensus panel on AUS recommended that every effort should be made to objectively confirm the presence of SUI prior to AUS placement.[90] Clinicians should take all reasonable measures to demonstrate SUI on physical exam with or without provocative testing such as bending, shifting position, or rising from seated to standing position. Stress pad testing can also be performed. Finally, if there is any doubt as to whether the patient has SUI, UDS may be performed. Examples of this may be when the patient has significant mixed incontinence and stress incontinence is not demonstrated, in cases where impaired compliance is suspected and incontinence could be related to high storage pressures without urgency, or if overflow incontinence is suspected. In the case of the latter, a post-void residual (PVR) may be helpful to rule out significant retention of urine.

The presence of microscopic hematuria may warrant additional evaluation with upper tract imaging and cystoscopy. The assessment of PVR may alert the physician to the potential for incomplete bladder emptying; however, the reliability of a single elevated PVR value for predicting emptying dysfunction remains in question, just as a single low PVR value does not rule out the presence of incomplete emptying. Second, the threshold value of a significant PVR is similarly undefined. Finally, a persistently elevated PVR does not characterize the cause of impaired emptying, but rather indicates the need for further evaluation. Additionally, an elevated PVR in the presence of SUI may impact patient counseling regarding surgical interventions and patient expectations. Elevated PVR may be an indication of detrusor underactivity or obstruction (e.g., urethral stricture or bladder neck contracture [BNC]) and thus may prompt further diagnostic evaluation such as uroflowmetry, cystoscopy, or multichannel UDS.

12. Patients with incontinence after prostate treatment should be informed of management options for their incontinence, including surgical and non-surgical options. (Clinical Principle)

Prior to engaging in any active or invasive form of therapy, patients must be made aware of the conservative options for management of urinary incontinence, such as absorbent pads, penile compression devices (clamps), and catheters. These alternatives may be utilized while engaging in PFME/PFMT, considering future options, waiting an appropriate time before surgical intervention, or as an indefinite form of management. Those patients who are candidates for surgical intervention in the future require assistance in handling ongoing leakage in a comfortable, reliable, and cost-efficient manner.[91]

In IPT management, the conservative approach is first-line to control urinary leakage post catheter removal. Absorbent pads, which are available in an array of forms and sizes, are the primary tool of urinary containment. Penile compression devices can be used independently and as an adjunct to reduce daily absorbent product usage. Catheters (condom and urethral), may be necessary in patients with high volume pad usage suffering from skin excoriation, dermatitis, and cellulitis due to urinary leakage.

Absorbent Products – Liners, Guards, Briefs, Underwear. Most patients will start with absorbent pads and make adjustments in type based on the severity of leakage.[91] In general, milder incontinence is managed satisfactorily with shields or lower density guards, while severe incontinence requires briefs or underwear with or without inserts to prevent accidents. From a cost perspective, briefs and underwear systems have been demonstrated to be more effective than pads.[92] Thus, the patient should be advised along these lines if they wish to continue wearing pads as their primary mechanism for urinary containment.

In the individual patient, absorbent products alone may constitute a long-term management strategy. However, it has been demonstrated that the use of even one pad per day is a source of bother and decreased patient satisfaction.[93] Additionally, the use of pads may be associated with skin irritation and dermatitis, especially in the intertriginous areas. In those who need to use more than several pads or garments per day, financial considerations may influence the ability to change pads in a timely fashion. Therefore, it is important to ensure that the patient is utilizing the most effective product based on their degree of incontinence.

Occlusive Devices (Clamps). Occlusive devices may function as a stand-alone therapy for incontinence or as an adjunct to absorbent products. Combination therapy between the two types of devices, such as pads and clamps together, decreases the number of pads required during active periods with a resultant decrease in incontinence products expenditure. Patients must be instructed to release the clamp every two hours to allow for circulation regardless of the need to void. The clamp should not be left on the phallus overnight due to the risks of constant pressure. While successful in decreasing urine loss, compressive devices are associated with decreased penile Doppler flow.[94] Mechanical compression devices are not suitable for patients with memory deficits, poor manual dexterity, impaired sensation, or a significant component of OAB.

Catheters (Condom, Urethral, and Suprapubic). Patients with severe or total incontinence may resort to a catheter and drainage system as the best method to obtain complete control of urinary incontinence. This form of management is also advantageous when the number or frequency of absorbent product changes is disruptive and/or financially prohibitive. Condom type catheters or urinary sheaths are an effective method of urinary containment for men with severe incontinence. In comparison to compressive devices, condom catheter systems are acceptable for patients with any degree of urge incontinence. Theoretically, this approach would also be superior to urethral stricture, poor manual dexterity, or a large glans/ narrow phallus configuration.[95] In the appropriate patient, external catheters have been demonstrated to be superior to absorbent products in patient satisfaction. However, the success of a condom catheter is wholly dependent on proper sizing. The condom or sheath varies based on the material (latex or silicone), length of

adhesive surface, circumference, and overall length.[96] Urethral catheter drainage is a decision of last resort in a patient who is unsuitable for alternative management. Suprapubic catheter drainage is not a solution for the patient with severe intrinsic sphincter deficiency, as urethral leakage will persist.

13. In patients with incontinence after prostate treatment, physicians should discuss risk, benefits, and expectations of different treatments using the shared decision-making model. (Clinical Principle)

The treatment of IPT can be a complex process involving numerous risks and benefits for the patient. Given these inherent complexities, providers should engage patients in shared decision-making during evaluation, treatment, and follow-up. Shared decision-making is a process in which providers and patients work together to make decisions about tests, interventions, and care plans.[97] Shared decisions are made based on clinical evidence that takes into account the risks and benefits and is teamed with patient preferences and values. The approach is predicated on two principles: 1) Patients provide accurate information and can and will participate in the medical decision-making process by asking questions and expressing opinions about their treatment options. 2) Providers will honor patient preferences for goals and treatment and use them to guide recommendations. Evidence suggests that patient participation improves patient satisfaction. Shared decision-making produces better health outcomes by decreasing anxiety, promoting faster recovery, and improving compliance.[98-101]

14. Prior to surgical intervention for stress urinary incontinence, cystourethroscopy should be performed to assess for urethral and bladder pathology that may affect outcomes of surgery. (Expert Opinion)

The presence of urethral pathology (e.g., stricture, BNC, urethral lesions) may affect the outcome of surgery for SUI; therefore some assessment to rule out significant urethral pathology is recommended. The gold standard for this would be a visual assessment of the urethra, including the membranous urethra, prostatic urethra (if present), and bladder neck with cystourethroscopy. Cystourethroscopy has also been recommended prior to placement of transobturator slings to assess urethral function (patients should have visual voluntary contraction of the external sphincter), and luminal closure of the urethra should be demonstrated with bulbar compression and elevation (repositioning test).[102] However, success of the procedure has not been shown to be dependent on these findings in any controlled study. In addition to an evaluation of the urethra, sphincter and bladder neck, pre-operative cystourethroscopy can assess the bladder for any pathology that could affect the decision to perform surgery for stress incontinence. There is, however, no evidence that patients who undergo pre-operative cystourethroscopy have better outcomes for AUS or sling compared to those who do not. With this in mind, the International Continence Society consensus panel of AUS in 2015 stated that preoperative cystourethroscopy should be performed whenever feasible as unrecognized urethral and bladder neck pathology can significantly complicate AUS placement. Unrecognized significant pathology may result in aborting AUS placement in favor of a staged-approach. Having this information preoperatively is beneficial to the patient and the surgeon to clarify expectation and maximize patient satisfaction.[90]

In cases where pre-operative cystourethroscopy is not performed, it may be done at the start of the AUS or sling implantation before any incision is made. In such cases, patients should be made aware of the potential consequences and the possibility of aborting an AUS or sling insertion if significant urethral or bladder pathology is discovered.

15. Clinicians may perform urodynamic testing in a patient prior to surgical intervention for stress urinary incontinence in cases where it may facilitate diagnosis or counseling. (Conditional Recommendation; Evidence Level: Grade C)

UDS allows for a precise evaluation of lower urinary tract function with respect to storage and emptying. It can aid in determining if IPT is caused by sphincter dysfunction, bladder dysfunction, or a combination of both, and also assess bladder contractility and the presence of bladder outlet dysfunction. Thus, UDS can be helpful in situations where this information is not apparent from history, physical, or simple testing.

UDS are not required before surgical intervention for IPT unless the clinician is in doubt of the diagnosis or it is felt that patient counseling will be affected. Unlike for the surgical treatment of SUI in women, there are no controlled studies that assess the value of UDS versus no UDS in men with SUI prior to surgery. In women with uncomplicated SUI, studies show UDS added no value over simple office evaluation,[103] and there is no advantage to UDS-based treatment of abnormalities other than stress incontinence.[104] There are a number of retrospective cohort studies that have shown that the presence of UDS abnormalities of storage (e.g., detrusor overactivity, impaired compliance, small cystometric capacity) do not affect outcomes of AUS or sling surgery in men with SUI.[105-108] Similarly, detrusor overactivity found on UDS has not been shown to negatively impact sling outcomes in men with SUI after prostate treatment.[109] In addition, abdominal leak-point pressure has not been shown to affect outcomes of AUS.[106] Furthermore, abdominal leak-point pressure does not correlate well with the degree of urinary incontinence, as determined by the 24-hour pad test.[110]

Pre-operative UDS may have a role in patient counseling (e.g., which patients may need further treatment of OAB symptoms post implant); however, patient selection for this reason is not well characterized. Finally, if the clinician is unsure of how prevalent sphincteric versus bladder affecting incontinence, or if there is unexplained poor bladder emptying, then UDS may be helpful in providing that additional information.

It is also important that the catheter be removed and stress testing repeated in men with suspected SUI who do not demonstrate stress incontinence with a catheter in place. It has been shown that up to 35% of men with post-prostatectomy SUI will not demonstrate SUI with a catheter in place.[111] This may be due to some scarring at the site of the anastomosis. In such cases, even a small catheter can occlude the urethra and prevent stress leakage. Also, if obstruction is suspected based on UDS criteria, a uroflow should be repeated without the catheter in place due to the possible obstructive effects of the catheter.

The most concerning and potentially most dangerous UDS finding is poor bladder compliance. This finding, however, is rare in IPT, even in patients who have had RT.[112] UDS likely has the highest yield for poor compliance in patients with severe radiation cystitis or those who have advanced neurogenic lower urinary tract dysfunction. Patients with significantly elevated storage pressures can be treated primarily (if no stress incontinence) with anticholinergics or onabotulinumtoxin A to lower such pressures. UDS then can be repeated to document adequate reservoir function. For patients with poor compliance and SUI, the observation that untreated poor bladder compliance did not worsen the AUS continence outcomes must be viewed with caution. It is well known that increasing outlet resistance could potentially expose the upper tracts to even higher intravesical pressures as compliance worsens.[113] Such patients can be treated with anticholinergics or onabotulinumtoxin A and storage pressure can be rechecked prior to treating SUI.

Alternatively, periodic upper tract imaging and/or UDS can be done post- SUI surgery (sling or AUS) to follow "at risk" patients. While the risk damage to the upper tracts in pediatric patients with myelomeningocele is well documented,[114] it is not known if poor bladder compliance and an uncorrected storage pressure are absolute contraindications to SUI surgery in IPT patients. However, the Panel believes that when such patients are identified, they should be carefully followed to avoid upper tract decompensation.

TREATMENT OPTIONS

16. In patients seeking treatment for incontinence after radical prostatectomy, pelvic floor muscle exercises or pelvic floor muscle training should be offered. (Moderate Recommendation; Evidence Level: Grade B)

IPT is caused by damage to the voluntary urethral sphincter. Both injury to striated muscle and nerve fibers of the rhabdo-sphincter can lead to IPT. PFMT is thought to support muscle strength and enhance blood flow to the sphincter to promote healing.[64] PFMT is a safe treatment with minimal side-effects that is readily accepted by patients and provides them with an opportunity to participate in, and have some control over, their health outcomes. Relative downsides to PFMT include time and effort needed by the patient and health care team, and cost of repeated visits, depending on the intensity of the program.[115, 116]

There are numerous RCTs that suggest benefit of undertaking PFMT[47, 49, 61, 115, 117-119] while other studies did not show benefits.[115, 116] Trials differ on the regimen of PFMT employed, with some including biofeedback or electrical stimulation, the amount of caregiver contact,[62, 64] and whether or not the therapy was before or after surgery.[47, 120-122] Further, trials lack a common urinary incontinence definition, making comparison more challenging.

Although PFMT and PFME may both be beneficial in restoring pelvic floor muscle function to assist with continence recovery, there is some evidence that PFMT may be preferred over self-directed PFME potentially due to the practitioner guided support and follow-up instruction offered with PFMT.[62, 64, 118]

17. Artificial urinary sphincter should be considered for patients with bothersome stress urinary incontinence after prostate treatment. (Strong Recommendation; Evidence Level: Grade B)

Multiple studies have demonstrated that AUS produces long-term continence and high patient satisfaction in men with any level of bothersome SUI.[30, 123-132] AUS should be discussed as a treatment option when surgical treatments are being considered.[130] Patients should be informed regarding inherent risks of AUS placement including persistent leakage, mechanical failure, erosion, and infection.[126, 127, 130]

In one study of AUS outcomes with two-year follow-up, complete continence was achieved in 20%, 55% had leakage of a few drops daily, and 22% had leakage of less than a teaspoon.[126] The patients were highly satisfied, with 92% reporting they would do the surgery again, and 96% willing to recommend the surgery to a friend.[126] In another study with follow-up of 2-11 years, a significant pad reduction was seen after AUS placement (4.0 to 0.6 pads per day).[127]

18. Prior to implantation of artificial urinary sphincter, clinicians should ensure that patients have adequate physical and cognitive abilities to operate the device. (Clinical Principle)

While AUS is the most predictable and reliable treatment for SUI after prostate treatment, it is important to remember that it is a mechanical device and that current versions of AUS require manual dexterity and cognitive ability in order for the patient to use it properly. Patients must demonstrate the cognitive ability to know when, where, and how to use the device. Furthermore, there should be some assurance that patients can physically pump a device that is in a normal position in the scrotum. There are no uniform ways to demonstrate such dexterity, but a simple demonstration of strength in the fingers and the ability to squeeze the pump between the index finger and thumb should be minimal requirements.

19. In the patient who selects artificial urinary sphincter, a single cuff perineal approach is preferred. (Moderate Recommendation; Evidence Level: Grade C)

The traditional placement of AUS has been a single cuff via perineal incision.[133] The introduction of new techniques such as the transverse scrotal incision and tandem cuff placement have been evaluated to be inferior

in non-randomized studies and should not be the standard of care for the customary AUS patient.[92, 134-137]

While AUS placement is feasible via a transverse scrotal incision,[92] comparative studies indicate inferior outcomes. A review of complication rates between perineal and scrotal incisions revealed an increase complication rate requiring short-term explantation in 9% versus 19% when comparing the perineal versus transverse scrotal incisions, respectively.[134] In a multi-center cohort study, the transverse scrotal approach demonstrated decreased completely dry rates, increased need for revision surgery due to continued incontinence, and a decrease in number of socially continent patients ($\leq$1 pad/day).[135] Taken together, these studies indicate that the transverse scrotal approach has a decrease in efficacy, likely due to a more distal cuff placement, along with an increase in complications and need for revision surgery.

In regard to placement of a tandem cuff compared to a single cuff placement, a review of the data indicates equivalent continence outcomes but with an increased risk of complications in the tandem cuff group.[136, 137] In a cohort of 124 tandem cuff and 57 single cuff patients, outcomes indicated equal pad weight and total number of daily pads between the two groups, but the tandem cuff group had a 17% risk of explant at 48 months compared to 4% for the single cuff group.[136] In another cohort, overall dry rate and daily pad use between the two groups was similar, but the tandem cuff group had 12 additional surgeries related to complications versus seven in the single cuff group.[137]

These comparative studies continue to support the traditional surgical approach of a single cuff via perineal approach as the standard technique that should be used. Furthermore, it is important to note that meticulous sterile technique needs to employed during this approach, preoperative antibiotics should be always given to cover skin flora as per the AUA Antimicrobial Prophylaxis Best Practice Statement,[138] and surgeons must be able to select the appropriate cuff based on intraoperative measurements, fill the components of the AUS with fluid, connect the tubing to make a watertight system, and test the AUS. If an intraoperative urethral injury is identified during implantation of an AUS, the procedure should be abandoned and subsequent implantation should be delayed.

20. Male slings should be considered as treatment options for mild to moderate stress urinary incontinence after prostate treatment. (Moderate Recommendation; Evidence Level: Grade B)

The literature is replete with both prospective and retrospective cohort studies of male sling placement for IPT. However, insufficient follow-up, different definitions of incontinence prior to treatment, variable definitions of "cure" and "improvement" following treatment, and use of a plethora of validated and non-validated outcome measures limits the ability to accurately compare the various male sling options currently available to patients.

Nine prospective[102, 139-147] and five retrospective cohort studies[148-152] met criteria for inclusion in analysis for this guideline in determining the cure rate for male sling surgery IPT. The 14 studies included 758 patients, 470 of whom were considered cured by the respective investigator. Definition of "cure" varied from zero pads or one pad daily used for protection to a negative one-hour pad weight test. Overall, 62% of patient achieved cure (range 34-91%); 95% CI=0.51-0.72.

Ten studies, eight of which were prospective,[139, 140, 142, 144-147, 153, 154] and two of which were retrospective,[148,151] met criteria for assessment of "improvement" after sling implantation. In general, improvement was defined as at least a 50% improvement in pad weight or pad use and does not include patients who were less incontinent but did not meet the 50% threshold. In the overall group, 518 patients were included, 176 of whom were improved. Overall, 34% of patients achieved at least 50% improvement in leakage, with a range of 4-100%; 95% CI=0.18-0.51. Two trials[153,154] did not separate cured and

improved patients, categorizing all such patients as "improved." When these two studies were omitted, the improvement rate was 28%.

The cohort studies did not include patients with radiation, and some excluded those with severe incontinence, generally considered >500 g urine per day leakage, or >5 pads per day. For those studies that included patients with severe leakage, sling failure was generally highest in that sub-group. Complications are not consistently reported, but in general, complication rates are low, with urinary retention typically resolving within one week, and pelvic and perineal pain and paresthesia resolving within 12 weeks. Erosion of the male sling is exceedingly rare.[155] If this happens, however, removal of the sling is necessary. Prior male sling does not typically interfere with subsequent sling revision or placement of an artificial sphincter in the setting of an unsatisfactory continence outcome.[156]

21. Male slings should not be routinely performed in patients with severe stress incontinence. (Moderate Recommendation; Evidence Level: Grade C)

Men suffering with severe SUI electing treatment should not have a male sling and should consider an AUS. Male slings have been shown to have poor efficacy in comparison to an AUS in this subset of patients.[157, 158] Clinicians might consider a sling in patients who have not undergone radiation, who have minimal incontinence at night, or who would be unable to use the AUS given poor hand function or cognitive abilities. If a sling procedure is done, it would be imperative to counsel the patient regarding appropriate expectations.

22. Adjustable balloon devices may be offered to patients with mild stress urinary incontinence after prostate treatment. (Moderate Recommendation; Evidence Level: Grade B)

In 2017, adjustable balloon devices became available in the United States for treatment of male intrinsic sphincter deficiency after prostatectomy or TURP. At the time of this publication, clinical experience in the United States with this device remains limited.

Patients with mild incontinence and no history of prior RT tend to have better outcomes.[159] Pre-market studies have shown a 60-81% "cure" rate defined as 0-1 pads/day after implantation of the adjustable balloon.[106, 159-163] The success of the device should be weighed against the complication rate. Intraoperative complications and need for explant tend to be higher than other anti-incontinence procedures. Explantation of the device due to complications or failure of treatment was common across all series and ranged from 4-30% during the first two years.[106, 159-162, 164]

In a group of men with severe incontinence (5 pads per day; n=50), implantation of the adjustable balloon led to a significant improvement 12 months after surgery (1.8 pads per day, $p<0.0001$).[162] In a larger series from the same group, 80/101 (79.2%) patients were considered as dry, with a pad test of 0-1g (70 patients, 0g; 10 patients, 1g) at 2.2 years follow-up. Significant improvements in QoL were also reported.[150]

While the adjustable balloon devices have been shown to improve incontinence, providers should be aware of an increased incidence of intraoperative complications and need for explanation within the first two years compared to the male sling and AUS. Given the limited clinical experience of implanters across the United States, providers should obtain specialty training prior to device implantation.

23. Surgical management of stress urinary incontinence after treatment of benign prostatic hyperplasia is the same as that for patients after radical prostatectomy. (Moderate Recommendation; Evidence Level: Grade C)

BPH is one of the main causes of lower urinary tract symptoms in men. Around 30% of men over age 65 are diagnosed with BPH.[165] Transurethral removal of prostate tissue (e.g., TURP, laser TURP, holmium laser enucleation of the prostate) or open simple prostatectomies are offered to

men in whom behavioral and drug therapy fail to relieve symptoms. The rate of persistent SUI in patients undergoing open laparoscopic or endoscopic surgical management of BPH ranges between 0-8.4%.[165, 166] Evaluation of patients with SUI after surgical therapy for BPH should be similar to those who have undergone RP; however care must be taken to rule out a primary bladder pathology such as OAB. Management of SUI after surgical management of BPH should follow the algorithm as that of a patient who underwent RP for prostate cancer. Patients who fail conservative measures should be offered surgical management. However, it should be noted that literature on surgical outcomes in this patient population is limited. Most studies evaluating results of AUS or male sling either combine BPH patients with RP patients or exclude them. There are a few studies that have demonstrated that AUS or male sling are safe and efficacious. A Cochrane review only identified one RCT evaluating surgical management of SUI after BPH surgery.[165] This study compared the efficacy of AUS implantation versus injectable therapy. Men undergoing AUS placement were more likely to be dry with an odds ratio of 5.67. Another study in which 56 patients were undergoing AUS placement after TURP found that continence was significantly improved in 90% of patients with a satisfaction rate of 87%,[167] and 14 patients required surgical revisions of their AUS. A study looking at 18 men undergoing transobturator male sling after TURP[168] found that 47% of men were cured and 60% were cured or improved using a cure definition of 0-5 g in the 24-hour pad test. In another study evaluating the use of the quadripolar male sling, four of eight patients were continent and two were improved at one year follow-up.[169]

24. In men with stress urinary incontinence after primary, adjuvant, or salvage radiotherapy who are seeking surgical management, artificial urinary sphincter is preferred over male slings or adjustable balloons. (Moderate Recommendation; Evidence Level: Grade C)

Over the last decade there has been an increase in the use of multimodal therapy for prostate cancer including adjuvant RT.[170] Radiation causes small vessel obliteration and endarteritis, resulting in ischemic tissue changes such as fibrosis and necrosis that can ultimately affect continence and outcomes following AUS or sling placement.[171, 172] Patients with IPT following adjuvant or salvage RT should be offered the same conservative management as a patient with post-prostatectomy SUI. Patients who fail conservative measures should be offered surgical management, preferably placement of AUS. Radiated patients undergoing AUS placement should be counseled on potentially compromised functional outcomes and an increased risk of complications. Overall 66% of radiated patients will demonstrate significant improvement in their continence after AUS placement. However, when compared to the non-radiated patients, continence in the radiated patient after AUS placement may be compromised. Previous studies evaluating AUS placement in radiated versus non-radiated patients have shown mixed results, with some demonstrating equivalent and some worse outcomes in the radiated group. [105, 124 173, 174] However, a more contemporary cohort study comparing continence outcomes in radiated versus non-radiated patients showed that 89% of non-radiated patients were continent compared to 56% in the radiated group.[128]

Radiated patients may also be at increased risk of complications after AUS placement. Recent meta-analysis demonstrated AUS revision was higher in radiated compared to non-radiated patients with a random effects risk ratio of 1.56 and a risk difference of 16%.[175] The majority of the revisions in the radiated group were secondary to erosion, whereas in the non-radiated group was secondary to urethral atrophy. A recent study evaluated whether temporal improvements in RT technique had an impact on AUS outcomes.[176] Patients undergoing RT prior after 2007 had equivalent outcomes to those undergoing RT prior to 2006. As a result, the Panel recommends that patients with RT for prostate cancer, whether as monotherapy or in combination with surgery be counseled in an equivalent manner regarding the

outcomes, risks, and complications associated with anti-incontinence surgery.

Male slings are not recommended for patients who have undergone adjuvant or salvage RT due to a lack of compelling evidence regarding their effectiveness in this subgroup. The literature suggests that slings are not as successful in patients who have undergone adjuvant or salvage RT compared to those patients who have not. Also, when reviewing the literature, it appears that there is a decline in efficacy over time, which will likely continue to worsen.[74, 75]

Publications looking at RT patients have relatively low numbers and do not look at the efficacy in mild, moderate, or severely incontinent patients. Therefore, it is difficult to determine if male slings work in any level of severity of incontinence. There may be improved efficacy in patients with milder SUI; however there is minimal data in this group. As such, it is still generally recommended that male slings should not be considered even in this group of patients.

25. Patients with incontinence after prostate treatment should be counseled that efficacy is low and cure is rare with urethral bulking agents. (Strong Recommendation; Evidence Level: Grade B)

There are currently no FDA-approved available agents for the treatment of male incontinence, and while the use of bulking agents to treat SUI is considered off-label, they remain the most commonly used procedure.[177] This is likely because urethral bulking agents are the least invasive technique available; however they are also the least effective surgical technique in the treatment of male SUI. The utilization of materials to improve urethral coaptation evolved from initial application in females for intrinsic sphincter deficiency.[178]

Injectable therapy is a consideration in patients who are unable to tolerate or refuse more invasive surgical therapy. In male patients, the best success rates have been described in patients with a high Valsalva leak point pressure, unscarred vesicourethral anastomosis, and no RT history.[15, 179, 180] Data on the efficacy of injectable agents, including collagen, carbon coated zirconium beads, and silicone implants, in male patients are generally limited by the number of reports, patient cohort size, and length of follow-up.

In the largest published study of the utilization of collagen for male SUI, improvement was reported in approximately 50% of patients with a mean duration of 6 months whereas complete continence was achieved in 17% with a mean duration of 9 months. Of note, 1.5% of patients reported an increase in incontinence following collagen injections.[181]

Success with the injection of carbon coated beads in male patients is characterized by transient partial improvement and risk of retention. Efficacy of carbon beads has been studied in the treatment of mild to moderate IPT. In a study of eight patients who had SUI after RP, only three patients reported subjective transient improvement and five patients opted for a more invasive surgical option after injection of pyrolytic carbon microspheres.[182] One patient reported worsening of his incontinence and another had acute urinary retention requiring an indwelling catheter for four days.

Injectable polydimethylsiloxane is a large molecule with a mean diameter of 140 μm that becomes encapsulated in fibrin and collagen, thereby minimizing the risk of migration. However, due to its size and associated viscosity, special equipment is required for particle delivery.[15] Reported efficacy in post prostatectomy patients ranges widely from 10 – 80%. The associated complications rates are variable: urinary retention (6-18%), urinary frequency (0-72%), dysuria (0-100%), and rarely urinary tract infection (0-6%).[183, 184]

26. Other potential treatments for incontinence after prostate treatment should be considered investigational, and patients should be counseled accordingly. (Expert Opinion)

Outside of PFMT, AUS and perineal sling, no other

IPT interventions have vigorous data to support sustained efficacy. There have been some promising results reported in small case series for interventions such as extracorporeal magnetic intervention[185] and penile vibratory stimulation.[186] More data in larger cohorts are needed to better understand these treatment's durability in treating IPT; as such patients should be counseled accordingly regarding the lack of outcome data. Stem and regenerative cell injections also offer a potential new form of intervention for treating IPT. However, there are data currently supporting this intervention and patients should be counseled that this is considered investigational. Patients wishing to pursue this modality should be referred to clinical research trials where safety and outcomes are monitored.

COMPLICATIONS AFTER SURGERY

27. Patients should be counseled that the artificial urinary sphincter will likely lose effectiveness over time, and reoperations are common. (Strong Recommendation; Evidence Level: Grade B)

AUS is an implant used for the treatment of stress -predominant IPT. The current version consists of a hydraulic system composed of three separate parts: a urethral cuff of varying sizes, a pressure regulating balloon reservoir with three available pressure profiles, and a control pump. The device will fail if any of the three parts, the tubing, or connections suffer a micro-perforation with loss of fluid. The rate of device failure increases with time, with failure rates of approximately 24% at 5 years[187] and 50% at 10 years.[132]

A malfunctioning AUS does not necessarily need to be replaced, but if the patient is healthy and requests a replacement, the AUS can be explanted and a new one replaced at the same operative setting. The durability and efficacy of a secondary re-implant in this setting is the same as that of a primary AUS.[187]

Device infection and cuff erosion are also causes of reoperation and should be discussed in detail with the patient prior to implantation of the AUS. Device infection is quite uncommon, with rates in long-term series ranging from less than 1% up to 5%.[132, 188] It is a dramatic presentation with pain at the site of the AUS; fever; scrotal warmth or erythema; or skin changes and necessitates an urgent explantation of the device. An AUS should not be replaced in the setting of infection for at least three months to allow the infection to clear and inflammation to subside. Cuff erosion can be due to unrecognized urethral injury at the time of initial surgery or more likely due to subsequent instrumentation of the urethra including catheterization. Rate of erosion is difficult to obtain due to varying patient populations and techniques but typically range from 1% to 10% on long-term follow-up.[132, 188] A cuff erosion can present insidiously but generally presents with hematuria, dysuria, or difficulty emptying the bladder and is diagnosed with a cystoscopic demonstration of the AUS cuff within the urethra.[189, 190] Management of cuff erosion is via AUS explant with the urethral catheter left in place for a few weeks to allow the urethral defect to heal. Similar to an infection, the AUS should not be reimplanted until at least three months and preferably at a different location along the urethra. In this setting, a transcorporal approach may be used.

Finally, an AUS might need to be replaced over time due to persistent or recurrent incontinence generally due to urethral atrophy, improper cuff sizing, or partial fluid loss. As previously stated, secondary AUS placements generally have similar outcomes to primary AUS placements;[187, 188, 191] however, patient satisfaction is driven by the degree of continence after AUS and not by the number of reoperations.[130, 192]

28. In patients with persistent or recurrent urinary incontinence after artificial urinary sphincter or sling, clinicians should again perform history, physical examination, and/ or other investigations to determine the cause of incontinence. (Clinical Principle)

In the patient with persistent urinary incontinence after AUS placement, a history and physical examination is necessary. In the case of the patient inadvertently deactivating the device or

inadequately cycling the device, re-education must be performed to ensure that the device is being utilized properly. In the event that an acute fluid loss is suspected, the volume in the pressure regulating balloon can be assessed using computerized tomography or ultrasound.[193] Cuff coaptation may be evaluated by cycling the device during cystoscopic visualization. Although rare, poor coaptation in the absence of fluid loss in the early post-operative phase is related to improper cuff sizing or incomplete engagement of the cuff tab. Either situation can only be addressed by operative revision.

Recurrent incontinence after years of normal function suggests either development of a new leak due to wear or urethral atrophy (with or without erosion). A leak can be confirmed by decreased volume in the pressure regulating balloon, which can be assessed by using ultrasound or computerized tomography.[193] The mainstay for evaluation of atrophy and erosion is cystoscopy.

In a patient with a normally functioning AUS, as determined by physical examination and imaging, leakage due to elevated storage pressures or detrusor over-activity should be suspected. UDS may be performed to evaluate filling pressures, capacity, presence of uninhibited detrusor contractions, and effective voiding. As a technical point, the cuff needs to be temporarily deflated and deactivated to allow for safe and atraumatic urodynamic sensor placement. If there are concerns regarding cuff damage, cystoscopy must be performed immediately to evaluate. In all cases of detrusor dysfunction, the underlying abnormalities must be addressed rather than performing any adjustments to the AUS with the exception of deflating and deactivating in the patient experiencing retention.

29. In patients with persistent or recurrent stress urinary incontinence after sling, an artificial urinary sphincter is recommended. (Moderate Recommendation; Evidence Level: Grade C)

Failure of a male sling can be due to infection or erosion, or more likely, due to patient dissatisfaction with continence recovery. Rates of infection or erosion after male slings are thought to be very low with almost no long-term series of outcomes reporting these events. However, if a male sling is thought to be infected or documented to be eroded on cystoscopy, the management is similar to management of an infected or eroded AUS. Specifically, in this setting as much of the sling should be explanted as soon as possible with a catheter left in place in the setting of an erosion.

In patients who are not satisfied with the results of a sling due to inadequate continence recovery, a subsequent AUS is the most efficacious option. While a secondary sling can be performed with cure rate of about 45% and satisfaction rates of approximately 70% in highly experienced centers,[147, 194, 195] most authors recommend an AUS in this setting. A retrospective cohort study of 61 men looked at continence outcomes between salvage AUS and secondary transobrurator slings.[195] Twenty-nine men underwent a repeat sling and 32 underwent an AUS following sling. Repeat sling patients had a failure rate of 55% compared to 6% after AUS. Multiple authors have shown that AUS after sling[196, 197] have similar outcomes to primary AUS, and the Panel recommends and AUS following sling failure.

30. In patients with persistent or recurrent stress urinary incontinence after artificial urinary sphincter, revision should be considered. (Strong Recommendation; Evidence Level: Grade B)

Patients with persistent or recurrent incontinence or those dissatisfied with their continence recovery after AUS placement should undergo evaluation. Inadequate recovery of continence after AUS placement can be due to a host of factors, including suboptimal cuff sizing at the time of original operation or inadequate pressure regulating balloon gradient.

The original operative report should be evaluated to note surgical approach, size of urethral cuff, and location of pressure regulating balloon. In patients with a possible distally located cuff, or

those with a larger cuff, proximal relocation or downsizing of the cuff are both reasonable options and will likely lead to better continence.

Tandem cuff placement is the addition of a cuff to the original cuff and has also been shown to be effective as a salvage procedure for patients with persistent incontinence. Specific additional risks of tandem cuff placement should be discussed with the patient prior to proceeding. Such risks include injury to the urethra during dissection, which would lead to aborting the case and the higher risk of subsequent erosion.

Some authorities have advocated moving the pressure regulating balloon to a different location or replacing it with a higher-pressure balloon.[198, 199] Others have used a transcorporal approach to improve urethral coaptation in patients with small urethral caliber, especially in the setting of prior RT and/or erosion;[200] however there is limited evidence to support either of these approaches.

Any of the above maneuvers can be combined with replacement of an AUS at the time of device failure. It is important to note that, in general efficacy and durability after secondary AUS placement appear to be similar to those after primary AUS placement, except in the setting of erosion.[187, 188, 191]

SPECIAL SITUATIONS

31. In a patient presenting with infection or erosion of an artificial urinary sphincter or sling, explantation should be performed and reimplantation should be delayed. (Clinical Principle)

Similar to other synthetic devices, explantation is indicated in cases of AUS or male sling device infection. Timing of removal is usually influenced by severity of the infection and acuity of the clinical situation as indicated by the associated signs and symptoms (e.g., purulent drainage, erythema, tenderness, fever, chills). In general, explantation should be performed as soon as possible. In the case of the AUS, the most conservative course of action is removal of all components, regardless of whether the infection and any associated reaction are limited to a single component. Even in the absence of purulent fluid and erythema, a wash-out procedure combined with immediate device replacement has not been consistently proven to be reliable or effective.[201] As discussed previously, an infected male sling should be removed as completely as feasible without damaging any adjacent structures.

Often times an infection is secondary to a pre-existing erosion. For AUS isolated cuff infections are rare without an associated erosion. Like infection, erosion requires device explantation. The urethral defect will usually heal by leaving a urethral catheter in place for three weeks. Some authors, however, recommend a urethral repair in cases of larger urethral defects due to decreased rates of stricture.[202]

For patients seeking a replacement device (AUS or male sling) after infection and/or erosion, a waiting period of three to six months is recommended. In the AUS patient, it may be necessary to proceed with transcorporal placement of the cuff.[203, 204] This approach would be recommended in the radiated patient with the prior erosion with thinned spongiosal tissue who has insufficient tissue to obtain a satisfactory fitting cuff. Xenograft tissue buttressed to supplement the urethra (theoretically decreasing risk of erosion) has been associated with significant complications and thus has not been advantageous.[205, 206]

32. A urinary diversion can be considered in patients who are unable to obtain long-term quality of life after incontinence after prostate treatment and who are appropriately motivated and counseled. (Expert Opinion)

In patients who are unable to obtain a satisfactory QoL long-term with an AUS due to multiple device failures, intractable BNC, or severe detrusor instability, urinary diversion with or without cystectomy may be an option. If bladder preservation is feasible, conversion to a Mitrofanoff (e.g. Appendix, Monti), incontinent ileovesicostomy, or suprapubic tube with bladder neck closure may confer an improved QoL. In the event of the "hostile" bladder, cystectomy in

combination with either an ileal conduit or continent catheterizable pouch would best manage incontinence while protecting the upper tracts.

33. In a patient with bothersome climacturia, treatment may be offered. (Conditional Recommendation; Evidence Level: Grade C)

As with post-prostatectomy SUI, for those with sexual arousal incontinence or climacturia, conservative management should be the initial treatment. The complaint may resolve in two-thirds of patients over time.[40] For those with persistent leakage, behavioral management includes emptying the bladder prior to sex, use of condoms to catch the urine, and PFME, which has demonstrated improvement in one small randomized trial.[46]

Anecdotal success has been reported with the tricyclic antidepressant imipramine, but this medication is generally contraindicated in men over the age of 65 years due to the risk of somnolence, falling down, and changes in cognition.[207]

The use of a penile variable tension loop (a soft silicone tube placed around the penis and adjusted to provide pressure on the urethra to physically prevent leaking during sex) has been used with success, decreasing the degree of orgasm-associated leakage in those with mild, moderate, and even severe self-reported leakage. Decreasing distress has been reported in both patients and partners, from 14% to 2% and 61% to 11%, respectively.[208]

Surgical treatment has been reported as very successful, but all trials included patients who were operated on for other indications. For example, implantation of an inflatable penile prosthesis for erectile dysfunction (ED) with a small polypropylene mesh anchored to the medial aspects of the bilateral corporotomies was successful in most of patients, with 93% noting improvement in climacturia postoperatively.[209] The mechanism of action is one where the mesh compresses the bulbar urethra as the inflatable penile prosthesis cylinders expand with inflation. Similarly, both the AUS and the transobturator male sling, when implanted for daytime SUI, are associated with high rates of improvement in climacturia, similar to the rates of improvement in SUI.[153, 210]

34. Patients with stress urinary incontinence following urethral reconstructive surgery may be offered artificial urinary sphincter and should be counseled that complications rates are higher. (Conditional Recommendation; Evidence Level: Grade C)

Urethral strictures of the anterior urethra and urethral stenosis of the posterior urethra can arise after RP, RT, or treatment for IPT.[211] Anterior urethral strictures may be synchronous with prostate-related conditions and persist after treatment, occur *de novo* after therapy for prostate-related conditions or arise after an AUS erosion. Posterior urethral stenosis typically arises after treatment for prostate-related conditions. Urethral reconstructive surgery is often used to treat narrowing in the urethra. Often IPT exists prior to urethroplasty or is caused by urethral reconstruction in rare cases. AUS is the preferred surgical treatment for IPT after urethral reconstruction. Depending on the technique employed (urethra transecting or not) the blood supply to the urethra may be diminished and potentially decrease the life span of an AUS.

Transcorporal placement of the AUS might be beneficial in some cases due to concerns about alterations in urethral blood supply. AUS can be successfully replaced after erosion-related urethral strictures and subsequent reconstruction.[212] Given post-surgical changes related to most types of urethral reconstruction in the posterior and anterior urethra, male slings will not be effective.

35. In patients with incontinence after prostate treatment and erectile dysfunction, a concomitant or staged procedure may be offered. (Conditional Recommendation; Evidence Level: Grade C)

In patients with both IPT and post-prostatectomy

ED, concomitant surgery to treat both conditions should be considered. Though initial investigations showed concern for infection during concomitant surgery, various studies have demonstrated that concomitant surgery is safe and may actually provide significant benefits.[213, 214] In a report of 55 patients undergoing combined penile prosthesis and AUS surgical procedures, combined procedures had a significantly longer operative time;[215] however, the rate of device infection, erosion or malfunction was not increased in combined compared to staged procedures. Another study described similar continence, sexual function, and overall satisfaction in patients undergoing staged versus combined procedures.[216] Despite these positive results of concomitant surgery most recent study using the SPARCS (New York State Department of Health Statewide Planning and Research Cooperative) database found that men undergoing combination of penile prosthesis and AUS placement had a higher rate of reoperation compared to men undergoing penile prosthesis alone.[217] Even though combination surgery is feasible, men considering surgical management of both ED and SUI should be counseled of the possible increase risk of complications.

36. Patients with symptomatic vesicourethral anastomotic stenosis or bladder neck contracture should be treated prior to surgery for incontinence after prostate treatment. (Clinical Principle)

Patients who are diagnosed with a symptomatic vesicourethral anastomotic stenosis (VUAS) or BNC should have treatment of their obstruction prior to surgical correction of their incontinence. Following treatment of VUAS, an interval cystoscopy should be performed at least four to six weeks later to document improvement and stabilization, after which IPT treatment can be considered. Although a VUAS or BNC will not necessarily cause SUI, treatment of them may worsen SUI. This is important because a patient may be considered for a sling procedure if he had "mild" incontinence, but he would likely need an AUS if it worsens after treatment. It is also generally felt that patients with a VUAS or BNC have decreased success rates when undergoing male slings; therefore an AUS would generally be considered a better option in this group.[157]

Treatment of a VUAS or BNC after a sling or AUS could be difficult or might place the patient at a higher risk of complications such as worsening of urinary incontinence, erosion of the AUS cuff, or possible infection. Endoscopic treatment of VUAS/ BNC after AUS has been described using a semi-rigid ureteroscope and holmium laser although this is still not the optimal approach.[218]

FUTURE DIRECTIONS

In the future significant changes are expected in the management of IPT, including enhancements in diagnostics and treatment options that will continue to improve patient continence and decrease the incidence of IPT. Since most papers are single center experiences, the Panel expects and hopes to have increased multicenter research collaboration. Patient reported outcome measures, which are very important in the treatment of QoL surgery have also become more prevalent; as such the Panel expects these to also improve in use and quality, allowing clinicians to fully address patient concerns.

Newer treatments will encompass not only improvements in surgical products such as the AUS and male slings, but also will include continued research into muscle injections, stem cells, and newer treatments for urgency and urge incontinence.

Developments regarding surgical products will likely include improvements to the current AUS, possibly improving the patient's ability to use the pump. It may also include a more automated system controlled from an external device. With newer technologies the Panel hopes to see automatic adjustments in cuff pressures or fluid volumes that would allow increased pressures improving continence with any increase in abdominal pressure.

Male slings have continued to evolve from bone anchored slings to the current products on the

market. As clinicians learn more about etiology, continued development and improvements will increase efficacy of newer products.

Some advances in the treatment of male SUI are expected to parallel those for female SUI. Regenerative medicine will continue to shape future treatments attempting to restore normal function with either autologous muscle-derived cells or multipotent mesenchymal stem cells injected into the sphincter. These cell-based therapies will continue to improve and provide clinicians with increased success rates. Ethical and legal issues associated with these regenerative treatments still need to be clarified.

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ABBREVIATIONS

AUA	American Urological Association
AUAER	American Urological Association Education and Research, Inc.
AUS	Artificial urinary sphincter
BMI	Body mass index
BNC	Bladder neck contracture
BOD	Board of directors
BPH	Benign prostatic hyperplasia
ED	Erectile dysfunction
FDA	Food and Drug Administration
IPT	Incontinence after prostate treatment
MRI	]Magnetic resonance imaging
OAB	Overactive bladder
PFME	Pelvic floor muscle exercise
PFMT	Pelvic floor muscle training
PGC	Practice guidelines committee
PVR	Post-void residual
QoL	Quality of life
RCT	Randomized controlled trial
RP	Radical prostatectomy
RT	Radiation treatment
SQC	Science and Quality Council
SUFU	Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction
SUI	Stress urinary incontinence
TURP	Transurethral resection of the prostate
UDS	Urodynamic testing
VUAS	Vesicourethral anastomotic stenosis

INCONTINENCE AFTER PROSTATE TREATMENT PANEL, CONSULTANTS, AND STAFF

Panel

Jaspreet S. Sandhu, MD (Chair)
Memorial Sloan Kettering Cancer Center

Kurt McCammon, MD (Vice Chair)
Eastern Virginia Medical School

Benjamin Breyer, MD
University of California San Francisco

Craig Comiter, MD
Stanford University

James A. Eastham, MD
Memorial Sloan Kettering Cancer Center

Christopher Gomez, MD
University of Miami

Daniel Kirages, PT, DPT
University of Southern California

Chris Kittle (Patient Advocate)

Alvaro Lucioni, MD
Virginia Mason

Victor Nitti, MD
University of California, Los Angeles

John T. Stoffel, MD
University of Michigan

O. Lenaine Westney, MD
MD Anderson Cancer Center

Consultants

M. Hassan Murad
Mayo Clinic

Staff

Abid Khan, MHS, MPP
Erin Kirkby, MS
Nenellia K. Bronson, MA
Leila Rahimi, MHS
Brooke Bixler, MH
Shalini Selvarajah, MD, MPH

CONFLICT OF INTEREST DISCLOSURES

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Consultant/Advisor: Craig Comiter, Avails Medical, Neuspera, Better Health; **Kurt McCammon,** Boston Scientific.

Employee: O. Lenaine Westney, Boston Scientific; **Kurt McCammon,** Urology of Virginia.

Health Publishing: Benjamin Breyer, World Journal Urology, Sexual Medicine Open Access.

Investment Interest: James Eastham, 3D-Biopsy; **Victor Nitti,** Serenity Pharmaceuticals.

Leadership Position: Kurt McCammon, IVUMed, **John Stoffel**, Journal of Urology.

Scientific Study or Trial: Craig Comiter, Zen-flow, BE Technologies, **Kurt MCCammon,** Allergen, Astellas, Solace, Taris, Cook; **Victor Nitti,** Astellas, Allergen, Medtronic, Amphora; **John T. Stoffel,** Uroplasty, Department of Defense

PEER REVIEWERS

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AUA (Board of Directors, Science and Quality Council, Practice Guidelines Committee, Journal of Urology)
Rodney Breau
Pat Fulgham
David Ginsberg
Anne Gormley
Melissa Kaufman
Louis Kavoussi
John Mulhall
Roger E. Schultz
Anthony Smith

External Reviewers (Non-AUA Affiliates)
William Brant
Stuart Boyd
Anne Cameron
Roger Dmochowski
Bradley Gill
Howard Goldman
Alexander Gomelsky
Sender Herschorn
Michael Kennelly
Laura Leddy
Gary Lemack
Mark Litwin
Joshua Meeks
Allen Morey
Robert O'Connor
Drew Peterson
Phillip Pierorazio
Keith Rourke
Eric Rovner
Beth Shelley
Ajay Singla
Jack Zuckerman

Public Commenters (via public notice on AUA website)
Jordan Dimitrakoff
Kirill Shiranov

DISCLAIMER

This document was written by the Incontinence After Prostate Treatment Guideline Panel of the American Urological Association Education and Research, Inc., which was created in 2017. The PGC of the AUA selected the committee chair. Panel members were selected by the chair. Membership of the Panel included specialists in urology with specific expertise on this disorder. The mission of the Panel was to develop recommendations that are analysis-based or consensus-based, depending on Panel processes and available data, for optimal clinical practices in the treatment of stress urinary incontinence.

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While these guidelines do not necessarily establish the standard of care, AUA seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today these evidence-based guidelines statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases.

Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses ('off label') that are not approved by the Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines and best practice statements are not in-tended to provide legal advice about use and misuse of these substances.

Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices.

For this reason, the AUA does not regard technologies or management which are too new to be addressed by this guideline as necessarily experimental or investigational.