

Incontinence after Prostate Treatment: AUA/SUFU Guideline



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Purpose: Urinary incontinence after prostate treatment (IPT) is one of the few urologic diseases that is iatrogenic, and, therefore, predictable and perhaps preventable. Evaluation of the incontinent patient, risk factors for IPT, the assessment of the patient prior to intervention, and a stepwise approach to management are covered in this guideline. Algorithms for patient evaluation, surgical management, and device failure are also provided.

Materials and Methods: This guideline was developed using a systematic review from the Mayo Clinic Evidence Based Practice Center with additional supplementation by the authors. A research librarian conducted searches from 2000 to December 21st, 2017 using Ovid, MEDLINE, Cochrane Central Register of Controlled Trials, and Cochrane Databases of Systematic Reviews. Additional references through 12/31/2018 were identified.

Results: This guideline was developed by a multi-disciplinary panel to inform clinicians on the proper assessment of patients with IPT and the safe and effective management of the condition in both surgical and non-surgical contexts. Statements guiding the clinician on proper management of device failure are also included.

Conclusion: Most patients who undergo radical prostatectomy (RP), and some patients who undergo radiation therapy (RT) or surgery for benign prostatic hyperplasia (BPH), will experience IPT. Although non-surgical options, such as pelvic floor muscle exercises (PFME), can hasten continence recovery, patients who remain incontinent at one-year post-procedure, or have severe incontinence at six months, may elect to undergo surgical treatment (e.g. artificial urinary sphincter). Prior to IPT surgery, the risks, benefits, alternatives, and additional likely procedures should be discussed with the patient.

Key Words: prostate, urinary continence, prostatectomy, radiotherapy, transurethral resection of prostate

Abbreviations and Acronyms

AUA = American Urological Association
AUS = artificial urinary sphincter
BMI = body mass index
BNC = bladder neck contracture
BPH = benign prostatic hyperplasia
ED = erectile dysfunction
IPT = incontinence after prostate treatment
MRI = magnetic resonance imaging
PFME = pelvic floor muscle exercise
PFMT = pelvic floor muscle training
RP = radical prostatectomy
RT = radiation therapy
SUI = stress urinary incontinence
TURP = transurethral resection of the prostate
UDS = urodynamic testing
VUAS = vesicourethral anastomotic stenosis

BACKGROUND

IPT causes emotional and financial distress by delaying patient's re-entry into society, inhibiting relationships, and carrying an economic burden. Since IPT is caused by treatment of the prostate, it is, by definition iatrogenic and perhaps preventable or predictable. Understanding the nature of IPT

will allow clinicians to accurately identify which patients will likely experience further symptom recovery versus those that will not, and allows them to set clear and reasonable expectations regarding the short, medium, and long-term sequela of IPT. Although most clinicians are familiar with the term "post-prostatectomy

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incontinence,” this guideline uses the term IPT, a more inclusive nomenclature given that the management of patients who have incontinence after RP, RT, and treatment of BPH is covered.

GUIDELINE STATEMENTS

Please see table 1 in the supplementary unabridged guideline (<https://www.jurology.com>) for more information on the American Urological Association (AUA) nomenclature system that was used to arrive at statement type and body of evidence strength.

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 identified as risk factors for IPT. Advanced patient age,¹ larger prostate size,² and shorter membranous urethral length (measured by MRI)³ have been consistently associated with increased risk of IPT. Surgical approaches to prostatectomy do not seem to impact rates of IPT; there is no current evidence that any surgical maneuvers, beyond bilateral neurovascular bundle preservation, results in improved continence recovery.⁴ 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.⁵

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

Climacturia (also known as orgasm-associated urinary incontinence) can occur in up to 30% of men following RP.⁶ The main risk factor for climacturia is time since surgery, prior transurethral resection of the prostate (TURP), shorter functional urethral, and penile length following RP. It does not appear that age, preoperative erectile function, or nerve sparing status significantly affect the risk of sexual arousal or orgasm-related incontinence.⁷

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).

Most men undergoing RP are not continent at the time of catheter removal⁸ and should be informed that continence is not immediate, although most men achieve continence (i.e. not requiring a pad or protective device to stay dry) within 12 months of surgery.⁹

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 and should be started three to four weeks prior to surgery to allow for neuromuscular adaptation.¹⁰ Pelvic floor muscle training (PFMT) is a practitioner-guided training program specific to the pelvic floor muscle group, while PFME are self-guided programs. While effectiveness of PFMT/PFME has not been definitively shown in the preoperative period, potential benefits outweigh any potential risks.¹¹

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 following brachytherapy or external beam radiation has been associated with incontinence rates of up to 70%,¹² and though there is little to no published evidence discussing post-TURP outcomes with patients who have undergone other forms of local therapy, it is the opinion of this Panel that these patients have high risks of incontinence similar to post-TURP radiated patients. Regardless of the operative approach to RP, salvage RP is associated with high rates of urinary incontinence rates (ranging from 20-70%) as compared to standard RP.¹³

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).

PFME/PMFT after catheter removal has been shown to improve time-to-achieving continence compared to control groups¹⁴ and should be offered to all patients upon removal of the urethral catheter. Continence recovery can occur as early as three to six months with PFME/PMFT,¹⁵ 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.¹⁶

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 maximum continence improvement by 12 months, patients with severe stress urinary incontinence (SUI) who

show no significant improvement after six months may be candidates for early intervention. Patients who report a lack of symptom improvement, or those experiencing more severe incontinence, at six months can or should be offered early treatment and consider surgical interventions.

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).

The natural history of IPT shows that the clear majority of patients will reach their maximum continence improvement by 12 months;^{17,18} with only a small minority of patients with bothersome SUI demonstrating continued improvement from 12-24 months.^{17,18} Withholding surgical treatment after 12 months in these patients is unlikely to result in improved patient symptoms and will delay restoration of continence.

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).

Taking a history and performing a physical examination should be the first step in the assessment of anyone with urinary incontinence and should focus on characterization of incontinence, the severity of incontinence, the progression or resolution of incontinence over time, and degree of bother (fig. 1). Patients should be questioned on which activities causes incontinence; this can help differentiate between SUI (caused by sphincteric insufficiency) and urgency incontinence (caused by bladder dysfunction). In the event that the clinician cannot definitively confirm the nature of the incontinence, he or she may choose further testing such as urodynamics or pad testing.

Evaluation Algorithm

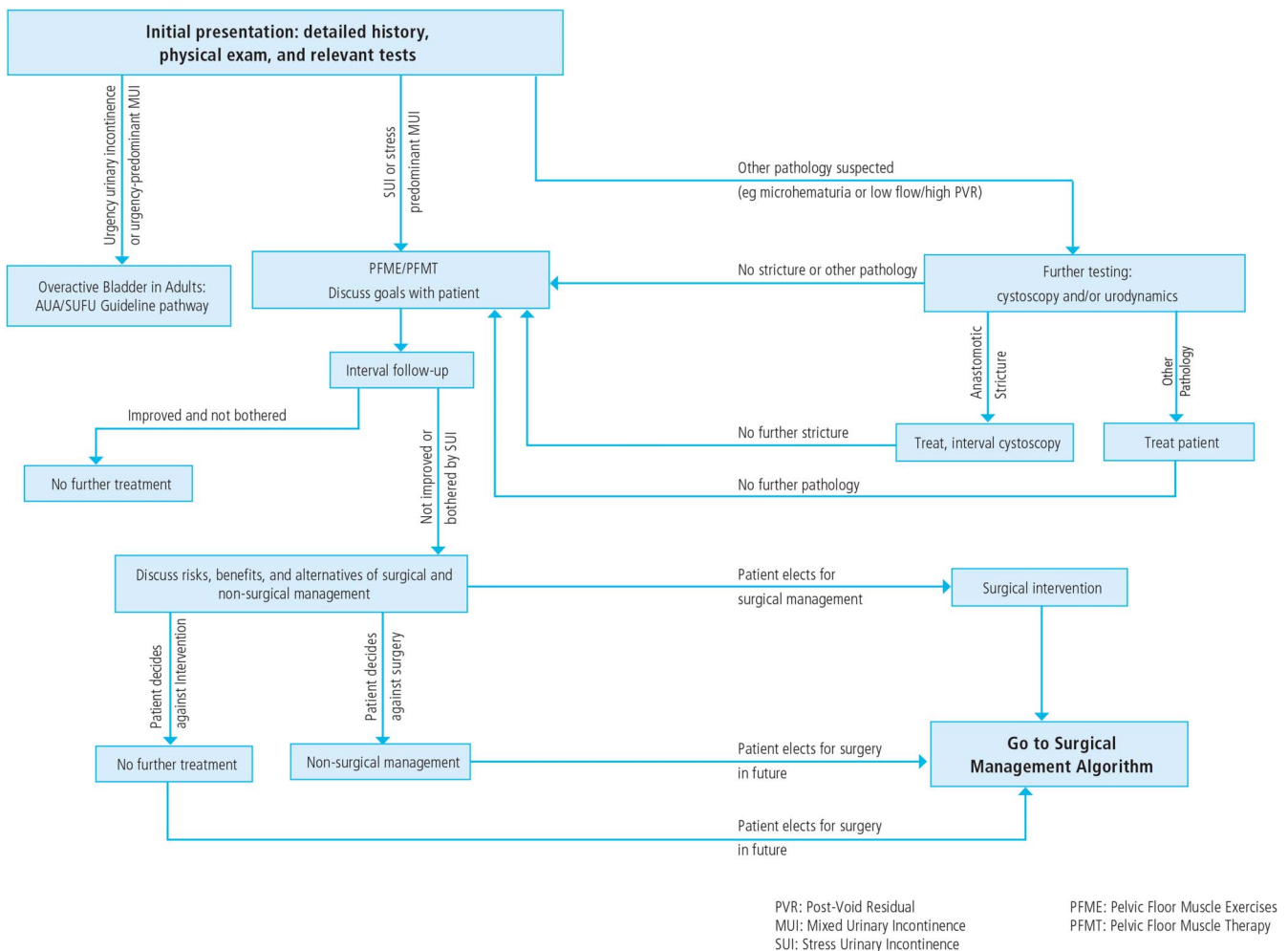


Figure 1.

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.¹⁹ Clinicians should be aware of the prevalence of overactive bladder, which has been described as high as 48%,²⁰ 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.²¹

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

While evidence has not definitely shown whether or not the objective demonstration of SUI predicts surgical outcomes after prostate cancer treatment,

clinicians should take all reasonable measures to confirm SUI on physical exam with or without provocative testing (fig. 2). Urodynamic testing (UDS) may be performed if there is any doubt as to whether the patient has SUI. The assessment of post-void residual may alert the physician to the potential for incomplete bladder emptying and may prompt further diagnostic evaluation.

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 with any active or invasive form of therapy, patients must be made aware of conservative options, such as absorbent pads, penile compression devices (clamps), and catheters as a first-line approach to manage urinary incontinence. Most patients will start with absorbent pads, but these may be associated with skin irritation and dermatitis. Occlusive devices may function as a stand-alone therapy or as an

Surgical Management for IPT

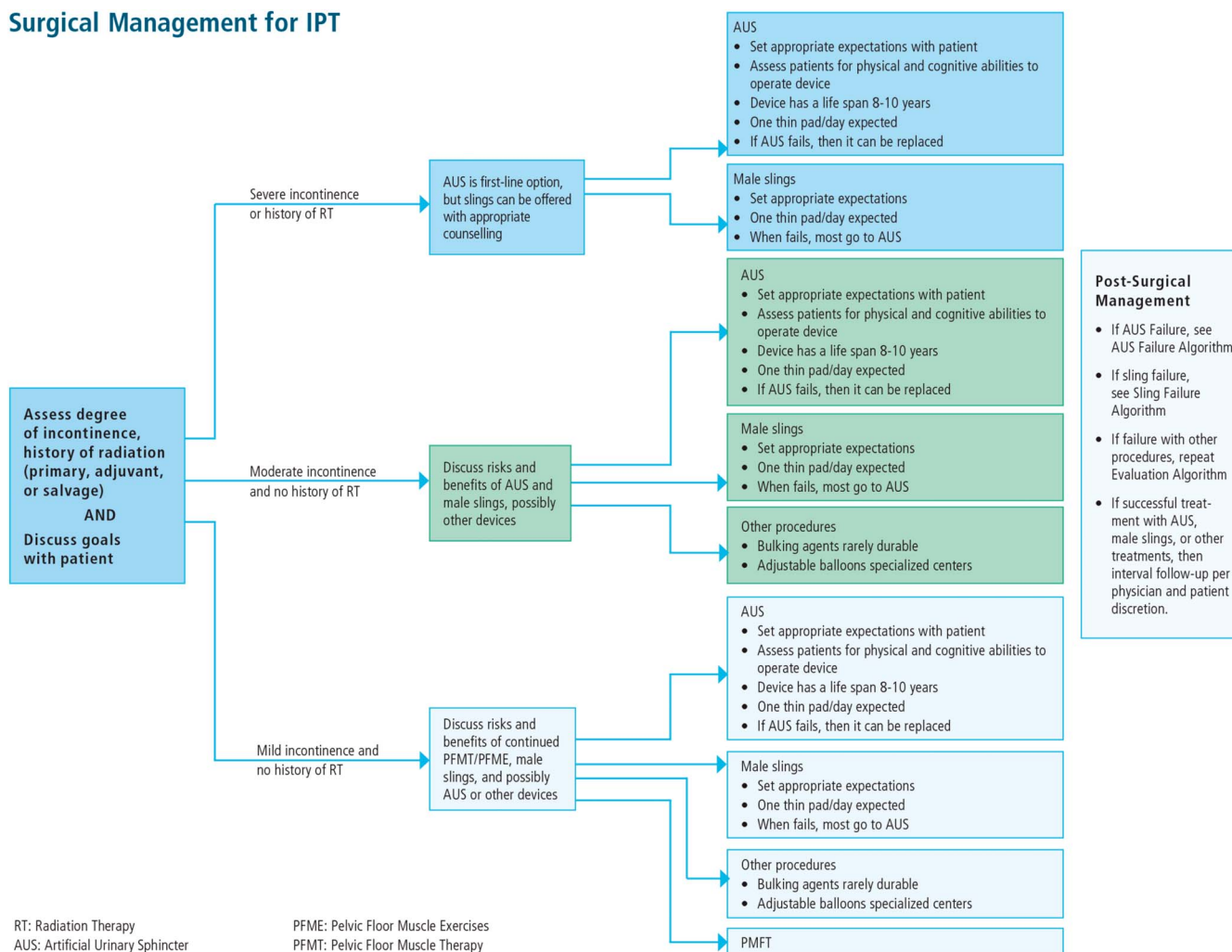


Figure 2.

adjunct to absorbent products, while catheter and drainage systems (i.e. condom-type/urinary sheaths, external, urethral, and suprapubic catheters) may be utilized for patients with severe or total incontinence.

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 and providers should engage patients in shared decision-making during evaluation, treatment, and follow-up. Evidence suggests that patient participation improves patient satisfaction by producing better health outcomes, decreasing anxiety, promoting faster recovery, and improving compliance.

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 (stricture, bladder neck contracture, urethral lesions) may affect the outcome of surgery for SUI and an assessment to rule out significant urethral pathology is recommended. In addition, preoperative cystourethroscopy of the urethra, including the membranous urethra, prostatic urethra (if present), and bladder neck will help clarify expectations and maximize patient satisfaction.

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 and can determine if IPT is caused by sphincter dysfunction, bladder dysfunction, a combination of both, and assess bladder contractility or the presence of bladder outlet dysfunction. If the clinician is unsure if sphincteric or bladder dysfunction is the cause of incontinence, or if there is unexplained poor bladder emptying, then UDS may be helpful in providing that additional information.

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).

PFMT and PFME are safe treatments for IPT, have minimal side-effects, and provide patients with

an opportunity to participate in, and have some control over, their health outcomes. Although the literature does not definitely demonstrate the differential benefit of PFMT versus PMFE, it is believed that both modalities are valuable in restoring pelvic floor muscle function and assisting with continence recovery by supporting muscle strength and enhancing blood flow to the sphincter to promote healing.¹⁵

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 artificial urinary sphincter (AUS) produces long-term continence and high patient satisfaction in men with any level of bothersome SUI.²² Patients should be informed regarding inherent risks of AUS placement including persistent leakage, mechanical failure, erosion, and infection.²²

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 a mechanical device and requires manual dexterity and cognitive ability for the patient to use it properly. Patients must demonstrate the cognitive ability to know when, where, and how to use the device. There should also be some assurance that patients can physically pump a device that is in a normal position in the scrotum.

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. The introduction of transverse scrotal incision and tandem cuff placement have been shown to have decreased efficacy, likely due to a more distal cuff placement, increased complications,²³ and an increased rate of revision surgery.²⁴ While there are equivalent continence outcomes between both tandem cuffs and single cuffs, there is an increased risk of complications in the tandem cuff group compared to a single cuff placement.²⁵

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 evaluating the efficacy of male slings in patients with mild to moderate IPT is marked by insufficient follow-up, different definitions of incontinence prior to treatment, variable

characterizations of “cure” and “improvement” following treatment, and inconsistent use of validated and non-validated outcome measures, making it difficult to accurately evaluate male slings currently available. However, literature that has examined continence improvement (defined as at least a 50% improvement in pad weight or pad use) and cure (zero pads to one pad daily use) in patients with IPT after sling implantation shows that a majority of patients achieved cure or at least 50% improvement in leakage.^{26–29}

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 should consider an AUS over male slings, which have been shown to have poor efficacy compared to an AUS.³⁰ 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.

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 RP or TURP. While they have been shown to improve incontinence, providers should be aware of an increased incidence of intraoperative complications and need for explant within the first two years compared to the male sling and AUS.³¹ 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).

The rate of persistent SUI in patients undergoing open laparoscopic or endoscopic surgical management of BPH ranges between 0–8.4%,^{32,33} and evaluation of these patients should be similar to those who have undergone RP. Patients with BPH who fail conservative measures to control their SUI should be offered sling³⁴ or AUS,³⁵ however, it should be noted that literature on surgical outcomes in this patient population is limited.

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).

Patients with IPT following primary, adjuvant, or salvage RT who fail conservative measures should

be offered surgical management, preferably placement of AUS. Male slings are not recommended given the lack of compelling evidence of their effectiveness in this subgroup.³⁶

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).

While the use of urethral bulking agents to treat SUI, such as collagen, silicone implants, carbon-coated beads, and Polydimethylsiloxane, are considered off-label, they remain the most commonly used procedure,³⁷ likely because they are the least invasive technique available. Despite the fact that they are also the least effective surgical technique in the treatment of SUI, injectable therapies are a consideration in patients who are unable tolerate or refuse more invasive surgical therapy. In male patients, the best success rates have been described in patients with a high Val-salva leak point pressure, unscarred vesicourethral anastomosis, and no RT history.³⁸

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 male 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 intervention³⁹ and penile vibratory stimulation,⁴⁰ but data in larger cohorts are needed to better understand these treatment’s durability. Stem and regenerative cell injections also offer a potential new form of intervention for treating IPT, however patients should be counseled that this is considered investigational.

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).

The failure rate of AUS increases with time, with failure rates of approximately 24% at 5 years⁴¹ and 50% at 10 years.⁴² A malfunctioning AUS can be explanted and a new one replaced in the same operative setting provided the patient is healthy (fig. 3). However, if an AUS device is infected, it should not be replaced for at least three months to allow the infection to clear and inflammation to subside, and preferably placed at a different location along the urethra. In the event of cuff erosion, the AUS should be explanted with the urethral catheter left in place for a few weeks to allow the urethral defect to heal.

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 to ascertain if the patient has deactivated or inadequately cycled the device. Cystoscopy may be used to evaluate cuff coaptation and cross sectional imaging can be used to rule out acute fluid loss. Recurrent incontinence after years of normal function suggests either device failure due to development of a fluid leak within the AUS, which can be assessed by measuring volume of fluid in the reservoir on cross sectional imaging (e.g. ultrasound or computerized tomography), or urethral atrophy (with or without erosion).⁴³ In a patient with a normally functioning AUS, leakage due to elevated storage pressures or detrusor over activity should be suspected.

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, erosion, or patient dissatisfaction with continence recovery (fig. 4). Rates of infection or

erosion after male slings are thought to be very low with almost no long-term series of outcomes after male slings reporting these events. However, if a male sling is thought to be infected or eroded, the management is similar to that of an infected or eroded AUS. 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.⁴⁴

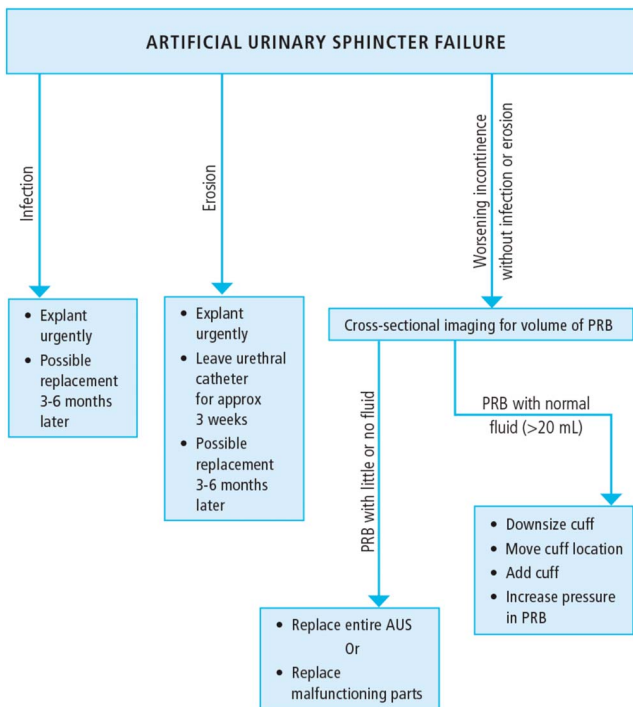
30. In patients with persistent or recurrent stress urinary incontinence after artificial urinary sphincter, revision should be considered. (Strong Recommendation; Evidence Level: Grade B).

Patients with persistent or recurrent incontinence or those dissatisfied with their continence recovery after AUS placement should undergo evaluation. The original operative report should be revisited to note surgical approach, size of urethral cuff, location, and pressure of the pressure-regulating balloon. In patients with a distally located cuff, or those with a larger cuff, proximal relocation or downsizing of the cuff will likely lead to better continence. Tandem cuff placement has also been shown to be effective as a salvage procedure for patients with persistent incontinence.

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).

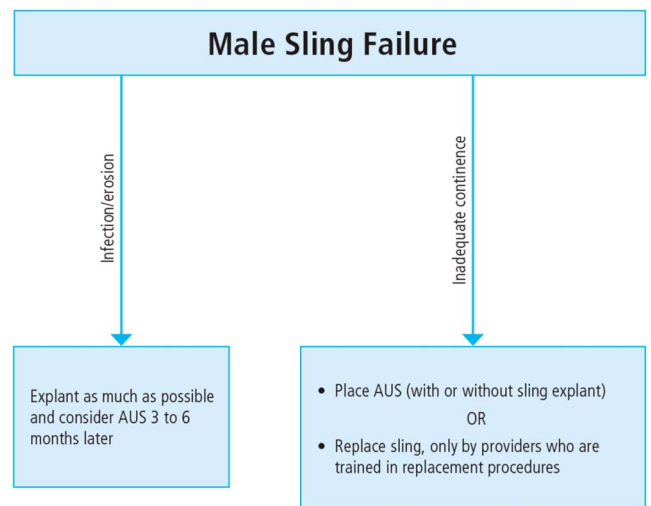
Explantation is indicated for infected AUS or infected male sling and should be performed as soon as possible. Timing of removal is usually influenced



PRB: Pressure Regulating Balloon

AUS: Artificial Urinary Sphincter

Figure 3.



AUS: Artificial Urinary Sphincter

Figure 4.

by severity of the infection and by the associated signs and symptoms (e.g. purulent drainage, erythema, tenderness, fever, chills, etc.). With an 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. For patients seeking a replacement device of AUS or male sling after infection and/or erosion, a waiting period of three to six months is recommended.

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).

Urinary diversion +/- cystectomy may be an option in patients who are unable to obtain a long-term satisfactory quality of life with an AUS due to multiple device failures, intractable bladder neck contracture, or severe detrusor instability. 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).

For patients with climacturia, conservative management, such as emptying the bladder prior to sex, wearing condoms to catch the urine, using a penile variable tension loop, and implementing PFME/PMFT¹¹ should be the initial treatment. Surgical treatment such as implanting an inflatable penile prosthesis for erectile dysfunction (ED),⁴⁵ an AUS, or male sling⁴⁶ have been reported as successful in controlling climacturia, but trials included patients who were operated on for other indications.

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).

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. Transcortical placement of the AUS might be beneficial in some cases due to concerns about alterations in urethral blood supply.⁴⁷ 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 in patients who are considering surgical management of both ED and SUI. However, men should be counseled of the possible increase risk of complications.^{48,49}

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 bladder neck contracture (BNC) should have treatment of their obstruction prior to surgical correction of their incontinence. Although a VUAS or BNC will not necessarily cause SUI, treatment of them may worsen SUI. Patients with a VUAS or BNC have decreased success rates when undergoing male slings and therefore an AUS would generally be considered a better option in this group.³⁰

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. Funding of the Panel

was provided by the AUA and SUFU. Panel members received no remuneration for their work. Each member of the Panel provides an ongoing conflict of interest disclosure to the AUA. 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 intended 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.

CONFLICT OF INTEREST DISCLOSURES

All panel members completed COI disclosures. Disclosures listed include both topic- and non-topic-related relationships.

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

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