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Updates to Incontinence After Prostate Treatment: AUA/GURS/SUFU Guideline (2024)

Benjamin N. Breyer,[1] Sennett K. Kim,[2] Erin Kirkby,[2] Alexis Marianes,[3] Alex J. Vanni,[4] and O. Lenaine Westney[5]

[1]Department of Urology, University of California, San Francisco, San Francisco, California
[2]American Urological Association, Linthicum, Maryland
[3]Tucker, Georgia
[4]Department of Urology, Lahey Hospital and Medical Center, Burlington, Massachusetts
[5]Department of Urology, MD Anderson Cancer Center, Houston, Texas

Purpose: In 2023 the American Urological Association (AUA) requested an Update Literature Review (ULR) to incorporate new evidence generated since the 2019 publication of this Guideline. The resulting 2024 Guideline Amendment addresses updated recommendations to provide guidance for the care of patients with incontinence after prostate treatment (IPT).

Materials and Methods: In 2023, the IPT Guideline was updated through the AUA amendment process in which newly published literature is reviewed and integrated into previously published guidelines. There were 82 studies of interest initially identified in preliminary abstract review. Following full-text review, 17 studies met inclusion criteria and ultimately informed the statements of interest.

Results: The Panel developed evidence- and consensus-based statements based on an updated review to provide guidance for the care of patients who experience IPT. These updates are detailed herein.

Conclusions: As prostate treatments are refined, a decreasing incidence of incontinence is anticipated. This Guideline will require further review as the diagnostic and treatment options for patients with IPT continue to evolve.

Key Words: incontinence, therapy, urinary, stress, treatment, urge, urine, radical prostatectomy, radiotherapy, incontinence after prostate treatment, urinary leakage

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 the proliferation of men's continence products available to the lay public.

Given that IPT is caused by treatment of the prostate, it is by definition iatrogenic. As such, it is perhaps

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Corresponding Author: Benjamin N. Breyer, MD, Department of Urology, University of California, San Francisco, 400 Parnassus Suite A610, San Francisco, CA 94121(Benjamin.breyer@ucsf.edu).

Abbreviations and Acronyms

95% CI = 95% confidence interval
AU = abbreviated urethroplasty
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 = U.S. Food and Drug Administration
GURS = Society of Genitourinary Reconstructive Surgeons
HIFU = high intensity focused ultrasound
IPP = inflatable penile prosthesis
IPT = incontinence after prostate treatment
MRI = magnetic resonance imaging
OAB = overactive bladder
OR = odds ratio
PA = primary urethral anastomosis
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 therapy
SQC = Science and Quality Council
SUFU = Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction
SUI = stress urinary incontinence
TC = transcorporal cuff
TURP = transurethral resection of the prostate
ULR = update literature review
UDS = urodynamic testing
VUAS = vesicourethral anastomotic stenosis

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preventable or predictable. Understanding the nature of IPT is crucial for patients and clinicians during recovery and extended survivorship following prostate treatment. Clinicians benefit from being able to assess which patients will likely experience further symptom recovery vs those who will not. This allows clinicians to set clear and reasonable expectations regarding the short-, medium-, and long-term sequelae of IPT.

Although most clinicians are familiar with the more commonly known term "post-prostatectomy incontinence," this Guideline uses the term "IPT" as a more inclusive term that covers the management of patients who have incontinence after undergoing treatment of localized prostate cancer and benign prostatic hyperplasia (BPH). While no clear convention for severity grading is accepted, for the purposes of this Guideline the following definitions are being used based on patient reported pads per day usage. Patient reported outcome measures, standing cough test, and daily pad weights can also be employed. Social continence is considered one or fewer pads per day that is tolerable to the patient.[1,2] Mild, moderate, severe incontinence is considered 1 to 2, 2 to 4, 5 plus pads per day reported by the patient, respectively.[3-5]

The unabridged version of this Guideline discusses evaluation of the patient, risk factors for IPT that should be discussed with all patients prior to treatment, assessment of the patient prior to intervention, and a stepwise approach to management. 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.

GUIDELINE STATEMENTS

Pre-Treatment

Clinicians should inform patients undergoing localized prostate cancer treatment of all known factors that could affect continence. (*Moderate Recommendation; Evidence Level: Grade B*)

While this statement previously focused on radical prostatectomy (RP), it was determined that there are other localized prostate cancer treatments that may affect continence. RP and radiation therapy (RT) for prostate cancer are both associated with urinary incontinence after treatment,[6,7] with urinary incontinence more common following surgery than radiation. Ten-year data from the CEASAR trial (NCT01326286) shows 14% to 25% of men who had prostatectomy reported bothersome leakage compared to 4% to 11% in the external beam radiation group.[7] Data suggest similar rates of leakage across types of radiotherapy.[8] High intensity focused ultrasound (HIFU) and cryotherapy can also lead to incontinence following treatment.[9] Some data suggest that the differential impacts of the therapies on incontinence diminishes over time and is similar at 15 years post treatment.[10] While surgery patients experience more incontinence initially, the impacts of radiation increase over time, and cases of adjuvant radiation may be particularly harmful to urinary health as SUI and urge incontinence is common.[11] It is noted that data exist to support early return of continence for Retzius sparing RP, although continence rates at 12 months are similar to other techniques.[12]

Clinicians should counsel patients regarding the risk of sexual arousal incontinence and climacturia following localized prostate cancer treatment. (*Strong Recommendation; Evidence Level: Grade B*)

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% to 93%, with most reporting an overall rate close to 30%.[13] Rates of climacturia after RT are lower (4%-5.2%), while other ejaculatory dysfunction, such as anejaculation, is common after radiation (11%-72%).[14,15]

Treatment Options

Clinicians should discuss the option of artificial urinary sphincter (AUS) with patients who are experiencing mild to severe stress urinary incontinence after prostate treatment. (*Strong Recommendation; Evidence Level: Grade B*)

This statement was updated to define the level of SUI after prostate treatment. AUS should be discussed as a treatment option when surgical treatments are being considered.[16] Patients should be informed regarding inherent risks of AUS placement including persistent leakage, mechanical failure, erosion, and infection (see Figure).[16-18]

In one study of AUS outcomes with 2-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.[17] The patients were highly satisfied, with 92% reporting they would do the surgery again and 96% willing to recommend

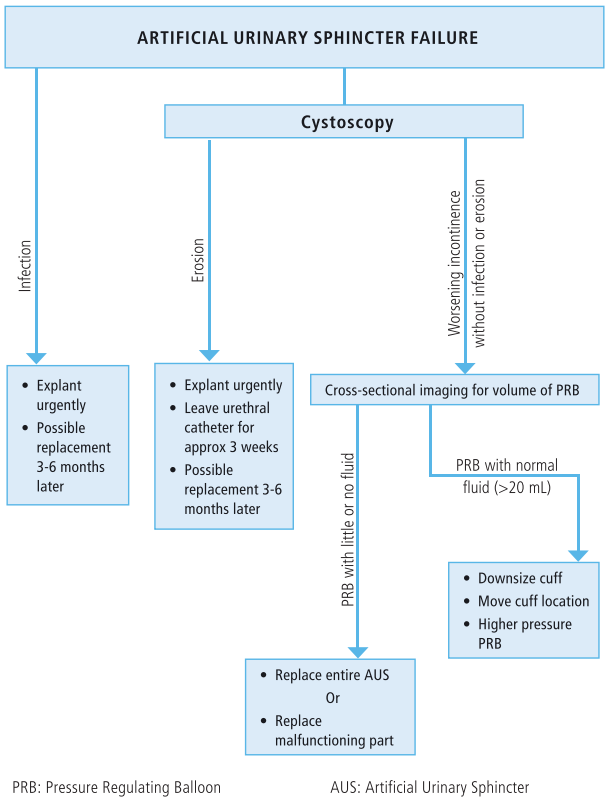

Figure. AUS failure algorithm.

the surgery to a friend. In another study with follow-up of 2 to 11 years, a significant pad reduction was seen after AUS placement (4.0-0.6 pads per day).[18]

Clinicians should not routinely implant male slings 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.[19,20] Clinicians might consider a sling in patients who have not undergone radiation, who have minimal incontinence at night, bothersome isolated climacturia, 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.

Clinicians may offer adjustable balloon devices to non-radiated patients with mild to severe stress urinary incontinence after prostate treatment. (*Conditional Recommendation; Evidence Level: Grade C*)

In 2017, adjustable balloon devices became available in the United States for the treatment of male intrinsic sphincter deficiency after prostatectomy or transurethral resection of the prostate (TURP). There has been a marginal increase in clinical experience in the United States since the initial Guideline publication in 2019. Overall, evidence has been supplemented with longer cohort follow-up and meta-analyses.[21-25]

In pooled data, patients with all degrees of incontinence have cure and improvement rates of 55% (95% confidence interval [CI]: 47-63) and 80% (95% CI: 72-87), respectively.[22] Nash et al[21] presented the 4-year follow-up of a pre-market study that demonstrated an overall > 50% pad reduction of 77.3% in a non-irradiated cohort with comparable improvements in mildly, moderately, and severely incontinent subjects. Other studies with similar follow-up length have reported equivalent results.[25,26] Like slings and AUS, RT negatively affects success and is associated with a higher complication rate.[24,27]

The success of an intervention must be weighed against the revision and complication rate. The intraoperative and early complication rates of adjustable balloons tend to be higher than other anti-incontinence procedures. The most common intraoperative complication is urethral or bladder perforation—5.3% (3.4%-8%).[23] The mean all-cause (ie, erosion, infection, balloon migration or balloon failure) explantation rate is 27% (range: 7%-55%).[24]

While adjustable balloon devices demonstrate efficacy for incontinence, providers should be aware of the unique intraoperative complications and device management. Serial additions of contrast solution to the balloons in the outpatient clinic will optimize efficacy. Adjustable balloons have an advantage in procedure length, less invasive placement, and elimination of the need for patient manipulation. Device removal is more common than AUS.[28] Efficacy, complication rates, and complication types have been proven to be directly linked to case numbers.[29] Thus, obtaining specialty training from an experienced implanter would be beneficial before device implantation.

In patients with stress urinary incontinence after primary, adjuvant, or salvage radiotherapy who are seeking surgical management, clinicians should offer AUS over male slings or adjustable balloons. (*Moderate Recommendation; Evidence Level: Grade C*)

Radiated patients may also be at increased risk of complications after AUS placement. A 2015 meta-analysis demonstrated that AUS revision was higher in radiated patients than in non-radiated patients with a random effects risk ratio of 1.56 and a risk difference of 16%.[30] Most of the revisions in the radiated group were secondary to erosion, whereas they were secondary to urethral atrophy in the non-radiated group. A study evaluated whether temporal improvements in RT technique impacted AUS outcomes.[31] Patients undergoing RT after 2007

had equivalent outcomes to those undergoing RT before 2006. As a result, the Panel recommends that patients with RT for prostate cancer, whether as monotherapy or in combination with surgery, be counseled equivalently regarding the outcomes, risks, and complications associated with anti-incontinence surgery.

Since the original Guideline publication, additional reports have become available regarding sling efficacy and outcomes in the radiated population. Simultaneously, the U.S. field of available and pending devices in the adjustable sub-group continues to evolve with tension adjustment and injectable pillow based products, respectively.[32] In general, radiation has been correlated with decreased efficacy and an accelerated failure rate in all sling types compared to non-radiated cohorts.[33-35] However, there is some evidence that radiated patients with a "normal" cystoscopic appearance and good pelvic floor function may benefit from male slings.[36] In a small 2 center cohort study, Li Marzi et al[36] demonstrated fixed sling results equivalent to non-radiated when the radiated patients had a positive repositioning test, normal compliance, normal capacity, and no bladder neck contracture (BNC).

As previously stated, RT negatively affects the efficacy and complication rate with adjustable balloons. A recent meta-analysis comparing the adjustable balloons and the injectable pillow sling supports the above viewpoint that while sling usage may be a potential in some radiated patients, adjustable balloons are significantly less effective.[22] The majority of literature is in accord with the opinion that usage is optimal in the non-radiated patient.[24]

Complications After Surgery

Clinicians may counsel patients regarding risk factors for AUS erosion. (*Conditional Recommendation; Evidence Level: C*)

Radiation. Radiation causes small vessel obliteration and endarteritis, resulting in ischemic tissue changes such as fibrosis and necrosis, ultimately affecting continence and outcomes following AUS or sling placement.[37,38] Theoretically, these changes result in poor vascular supply, making the urethra more vulnerable to long-term cuff compression. The sentinel paper from Raj et al reported the relative risk for erosion of 2.97 (95% CI: 1.69-5.20) in radiated patients.[39] More recently, a multi-institutional group led by Kaufman et al demonstrated that among patients with idiopathic erosion, radiated subjects had significantly shorter erosion-free device survival in comparison to non-radiated (1.00 year [95% CI: 0.36-3.00] vs 3.15 years [95% CI: 1.95-5.80]).[40] Similarly, Huang et al[41] reported a shorter time to all-cause device failure in radiated AUS patients (eg, erosion, infection, mechanical failure), with a median of 1.4 years vs 3.5 years in non-irradiated control and a higher 5-year cumulative incidence of erosion/infection (25% vs 6%).

Prior Urethral Surgery. In addition to radiation, urethral compromise due to surgical intervention, including urethroplasty, multiple treatments for BNC or stricture, urethral stent placement, and prior AUS erosion is a central component of the high-risk urethra.[42] In a prospective analysis by Sayedahmed et al,[43] patients with prior urethroplasty were shown to have a risk of erosion (odds ratio [OR]: 4.182) and decreased erosion-free survival (40.5 vs 51.1 months). Other investigators have also identified the post-urethroplasty erosion rate to be elevated, with hazard ratios (HRs) ranging from 2.12 to 8.14.[44-46] Currently, there is no evidence whether non-transecting urethroplasty is associated with a decreased erosion risk. Brant et al[42] showed that prior urethral stenting was an independent risk factor for device explantation (OR: 5.75; 95% CI: 1.23-28.8).

Cuff Size. The introduction of the 3.5 cm cuff combined with the structural differences compared to the larger cuffs resulted in evaluation regarding increased risk of erosion. Simhan et al[47] initially reported an increased erosion rate in radiated patients with 3.5 cm cuffs vs non-radiated (21% radiated vs 4% non-radiated). In a longer-term evaluation of the same cohort, a history of RT, prior AUS cuff erosion, prior urethroplasty, and history of inflatable penile prosthesis (IPP) placement were significantly associated with erosion instead of cuff size.[46] Conversely, a large multicenter European study by Queissert et al[48] reported higher erosion rates for smaller cuff sizes and radiated patients.

Technique (Transverse Scrotal, Transcorporal). The transverse scrotal (penoscrotal) technique first popularized in 2003 has been associated with more distal cuff placement, lower dry rates, smaller mean cuff sizes, and higher erosion rates.[48] Thus, practice has deviated from this technique except for specific situations. Transcorporal cuff (TC) placement is utilized as a strategy for supplementing the urethra with tunica albuginea with the goal of decreasing erosion.[49] However, in recent reports, the transcorporal approach has not been protective against future erosion.[50] Other groups focused on erosion risk factors in the high-risk urethra have not identified the TC approach as an independent risk factor for erosion.[44] From a technical standpoint, options may be limited by the atrophic urethra requiring additional soft tissue for appropriate cuff sizing.

After explanting an eroded device, clinicians may manage AUS urethral cuff erosion intra-operatively with urethral catheter alone, in situ urethroplasty, or anastomotic urethroplasty. (*Expert Opinion*)

AUS cuff erosion is a devastating complication that can lead to urine extravasation, infection, abscess formation, and sepsis, and may result in long-term urethral fistula, urethral diverticula, or urethral stricture after AUS explant. The degree of urethral loss with erosion can be highly variable, ranging from a small < 5 mm hole in the urethra, to complete circumferential urethral loss under the 2 cm cuff. During AUS explant, the goal of erosion management is to maximize the chances of urethral healing without developing a fistula or stricture. The decision on how to best manage the erosion takes into consideration the size of the urethral defect, quality of local tissues (there are heterogeneous degrees of inflammation, induration, and fibrosis), and surgeon preference/experience.

A retrospective study analyzing outcomes of 3 different intraoperative AUS erosion management techniques (ie, urethral catheter only, abbreviated urethroplasty [AU], or primary urethral anastomosis [PA]) found that management with PA was more common in patients with severe erosion (erosion > 50% of urethral circumference) than with urethral catheter or AU groups (100% vs 37%; $P < .001$; 100% vs 38%; $P < .001$). In addition, cuff erosions treated with PA were more likely to be severely eroded than cuff erosions treated with urethral catheter or AU (100% vs 35%; $P < .001$; 100% vs 42%; $P < .001$).[51] Additionally, severe erosions treated with urethral catheters were more likely to develop strictures than mild erosions (38% vs 5%; p: .009).

Similarly, Rozanski et al[52] demonstrated a dramatically lower rate of stricture formation (38% vs 85%) and a decrease in the delay of AUS replacement (9 months vs 17 months) in patients receiving an abbreviated in situ urethroplasty with urethral catheter compared to those managed with urethral catheter only.

In another study, patients treated with in situ urethroplasty for urethral erosion who went on to revision AUS were more likely to eventually require urinary diversion if the erosion involved > 33% of the urethral circumference at the initial erosion event.[53] Patients with erosions < 33% of the urethral circumference had lower rates of lower urinary tract complications (ie, urethral fistula, diverticula, urethral stricture) compared to patients with erosions > 33% urethral circumference (17% vs 68% despite both have in situ urethroplasty management of the erosion).[53]

Special Situations

In patients with bothersome incontinence during sexual activity, clinicians should offer treatment. (*Moderate Recommendation; Evidence Level: Grade C*)

For those with persistent leakage, behavioral management includes dehydration and emptying the bladder prior to sex, use of condoms to catch the urine, achieving orgasm while supine, and pelvic floor muscle exercise (PFME), which has demonstrated improvement in one small randomized trial.[54]

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.[55] In patients who also have erectile dysfunction and are undergoing an IPP, a small mesh or autologous graft anchored to the medial aspects of the bilateral corporotomies to improve incontinence during sexual activity, with 93% noting improvement postoperatively.[56] The mechanism of action is one where the mesh compresses the bulbar urethra as the IPP cylinders expand with inflation.

AUS Failure Algorithm

The AUS Failure Algorithm (Figure) was updated to include cystoscopy as the method to determine erosion and worsening of incontinence in a patient. In addition, in patients that have a pressure-regulating balloon (PRB) with normal fluid after cross-sectional imaging, the recommendation to add cuff was removed, and higher pressure PRB replaced increase pressure in PRB for clarity.

FUTURE DIRECTIONS

Looking ahead, refinements to therapies that create IPT will occur, decreasing incidence. The Panel expects continued enhancements in diagnostics and treatment options that will continue to improve patient continence and decrease the prevalence of IPT. Since most papers are single center experiences, the Panel expects and hopes to have increased multicenter research collaboration. Clinical trials of lifestyle interventions, medications, and surgeries will be needed to estimate therapeutic benefit, while comparative effectiveness research can help determine which therapy to use and when. Patient reported outcome measures, which are very important in the treatment of quality of life (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.

Refining which patient populations with SUI and BNC/vesicourethral anastomotic stenosis (VUAS) will benefit from synchronous BNC/VUAS treatment

and AUS placement rather than staged procedures will improve the QoL of many patients.

Newer treatments will encompass not only improvements in surgical products such as AUS and male slings, but will also 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 no manual dexterity needed. 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. Dynamic pressuring could lead to less leakage and less wear on the urethra.

Male slings have continued to evolve from bone anchored slings to the current products on the market, including some that are adjustable. As clinicians learn more about etiology, continued development and improvements will increase efficacy of newer products.

The ATOMS adjustable transobturator sling is currently approved for use in Europe and Canada; however, it is currently under review by the FDA.

Some advances in the treatment of male SUI are expected to parallel those with female SUI. Regenerative medicine may shape future treatments attempting to restore normal function with either autologous muscle-derived cells or multipotent mesenchymal stem cells injected into the sphincter. While cell-based therapies have yet to produce long-term clinical improvement, hope exists that cellular regenerative therapies such as stem cells or low-intensity shockwave will lead to effective non-surgical therapies.

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