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INCONTINENCE
Invited Review

Post-prostatectomy incontinence: Etiology, evaluation, and management

Nirmish Singla[1], Ajay K. Singla[2]

ABSTRACT

Urinary incontinence after prostatectomy or radiation is a devastating problem in men and remains the most feared complication following the treatment of localized prostate cancer. With an increasing number of radical prostatectomies performed globally for prostate cancer, the impact of urinary incontinence on quality of life assumes an even greater importance. With the advent of male sling procedures, more men are now seeking treatment for incontinence. Since the introduction of the artificial urinary sphincter almost four decades ago, several surgical procedures have emerged to manage post-prostatectomy incontinence, including the male sling for milder forms of incontinence. Several of the newer procedures have shown promise in the United States; many others have been developed and utilized in other parts of the world, though they have not yet gained FDA approval in the United States. The present review seeks to illuminate the etiology, evaluation, and management of post-prostatectomy incontinence. An effort has been made to provide an algorithm to clinicians for appropriate surgical management. The surgical techniques of commonly performed procedures and their outcomes are described.

Key words: Artificial urinary sphincter; male sling; prostatectomy; urinary incontinence.

Introduction

In 2013, approximately 238,590 new cases of prostate cancer were projected to arise in the United States alone, with an estimated 29,720 deaths secondary to the disease process.[1] Approximately 40% of men with localized prostate cancer elect to undergo radical prostatectomy.[2] Persistent and bothersome urinary leakage following prostatectomy is a commonly reported side effect of the surgery, with reports ranging from a 1% to 40% incidence[3-5], depending on how incontinence is defined. Although refinement in surgical techniques has helped reduce the incidence of post-prostatectomy incontinence[6], the overall prevalence continues to rise due to an increase in the total number of prostatectomies performed worldwide.

The approach to evaluating and managing post-prostatectomy incontinence relies on defining the extent of urinary leakage and degree of subjective bother to the patient. Leakage is often quantified by the number of pads used per day, which in turn can affect patients' health-related quality of life. Furthermore, there is considerable variability among patients' thresholds to elect further management of their incontinence. Approximately half of patients seek some form of treatment for incontinence following prostatectomy[7], while anywhere between 6% and 9% of men ultimately elect for surgical approaches.[7-14] Thorough evaluation consists of a detailed history, including baseline status, prior use of prostate- or bladder-based medications, and previous interventions on the prostate or genitourinary tract, and physical examination. Urinalysis, uroflowmetry, and a bladder diary from the patient are also quick and useful tools. Urethroscopy/cystoscopy and urodynamics have additional utility in directing the approach to management.

Approaches to treating post-prostatectomy incontinence include both conservative and surgical approaches. Effective non-surgical approaches include lifestyle modifications and pelvic floor exercises, which should be attempted prior to surgical considerations. Surgical approaches should be deferred for at least 12 months following prostatectomy[15] and include male slings for mild intrinsic sphincter deficiency (ISD) or artificial urinary sphincters – the gold-standard treatment and last resort – for severe ISD. The present review

[1]Department of Urology, University of Texas Southwestern, Dallas, TX, USA

[2]Department of Urology, University of Toledo Medical Center, Toledo, OH, USA

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Correspondence: Nirmish Singla, MD, 2429 Ellis St, Apt 920 Dallas, TX 75204, USA
Phone: +1 248 761-2452
E-mail: nirmish.singla@phhs.org

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Etiology

Despite improvements in surgical approaches, changes in urinary function inevitably occur following radical prostatectomy, with urinary incontinence being a frequently reported adverse effect. The definition or degree of incontinence is subject to considerable variability and often resolves within the first postoperative year. Nonetheless, 95% of men with post-prostatectomy urinary leakage to any degree tend to describe symptoms consistent with stress urinary incontinence (SUI) that are documented on urodynamic studies.[16,17]

Risk Factors

Several risk factors have been proposed to increase one's predisposition to developing incontinence following surgery for prostate cancer, including preoperative comorbidities, patient anatomy, and intraoperative technique. Examples of such preoperative comorbidities include pre-existing voiding dysfunction such as ISD[18,19] or neurogenic detrusor overactivity, as in Parkinson's disease or spinal cord injury.[20] Furthermore, advancing age has been shown to be an independent risk factor for the development of post-prostatectomy incontinence[10,21-26], with older men having a higher likelihood of needing eventual lower urinary tract symptoms (LUTS) implantation.[27] This effect is possibly explained by a progressive decrease in the striated muscle cells within the external urinary sphincter with age.[28] Body mass index (BMI), particularly a BMI above 30 kg/m^2, is also associated with increased peri-operative complications, including incontinence rates that are three times higher than in patients with a lower BMI.[29] Lastly, surgery performed as salvage therapy in those who have previously undergone radiotherapy or cryotherapy tends to be associated with higher rates of incontinence.[30] Nearly half of the patients within this group ultimately elect to undergo AUS implantation.[31-34]

Patient anatomy has also been shown to influence the development of incontinence following prostatectomy. For example, the presence of an anatomic stricture[35,36] or larger prostate volume[37] is associated with higher rates of incontinence. Membranous urethral length has also been shown to have a direct relationship with continence rates, including both anatomic length (based on MRI findings) and functional length (shown on urodynamic studies).[18,38-40]

Lastly, intra-operative techniques may play an important role in predicting continence outcomes. Several studies have shown that bilateral neurovascular bundle sparing techniques may preserve continence[18,41-42], although some large cohort studies have demonstrated no significant effect on continence.[43,44] Surgeon experience may also play a role.[17] Several surgical maneuvers have been proposed to improve continence, including bladder neck preservation, sparing of seminal vesicles, urethral suspension, and bladder neck mucosal eversion.[21,38,42] Several studies have investigated the effect of surgical approach, though none have demonstrated significant differences in continence rates between the perineal and retropubic approaches[45,46] or among the open, laparoscopic, and robotic approaches.[12,13,47-49]

Pathophysiology

Multifactorial etiologies have been proposed to account for the development of incontinence following prostatectomy. Broadly, these include detrusor over- and underactivity, decreased vesical compliance, ISD, and bladder outlet obstruction, as in the case of anastomotic strictures.[16,50] The presence of these factors pre-operatively must also be considered. Most cases of incontinence are a result of intraoperative damage to the native urinary sphincteric mechanisms[11], particularly the intrinsic sphincter component.[16,50,51] Bladder denervation during prostatectomy is also a frequent cause of incontinence after the operation, resulting in impaired detrusor contractility and poor bladder compliance.

Evaluation

The evaluation of patients with post-prostatectomy incontinence should begin with a comprehensive history, including the onset, duration, description of the type and severity of incontinence, and precipitating events. It is important to quantify the severity of leakage based on the number of pads used or pad weight. It is important to assess how the incontinence affects daily activities and whether it is bothersome. A history of adjuvant radiation increases the probability that detrusor overactivity or poor compliance may exist. A voiding diary can be helpful to quantify the fluid intake and functional bladder capacity.

Physical examination is performed with emphasis on the neurological evaluation assessing the S2-S4 spinal segments, including anal sphincter tone, perineal sensation in the S2-S4 segments and bulbocavernosus reflex. Abdominal examination is performed to detect a distended bladder with overflow incontinence.

The primary role of urodynamic evaluation is to differentiate the various causes of post-prostatectomy incontinence and rule out poor bladder compliance, high pressure detrusor overactivity during filling, and any bladder obstruction during the pressure flow study. Urodynamic bladder capacity is also assessed, as most patients with severe incontinence have low functional capacity because of poor storage. Patients with poor compliance are at a particularly high risk for complications after AUS implantation and should be treated with anticholinergics before anti-incontinence procedures.

The role of abdominal leak point pressure (ALPP) in predicting the degree of urinary incontinence is unclear, and studies have failed to show any correlation of ALPP with the severity of sphincter damage. Walker et al. prospectively evaluated 14 patients complaining of post-prostatectomy incontinence and found no correlation between ALPP and the severity of incontinence.[52]

Patients with obstructive symptoms should be evaluated with office cystoscopy before any surgical treatment to rule out anastomotic strictures. Endoscopic evidence of urethral coaptation may indicate the degree of sphincter insufficiency.

Management

Conservative approaches

Prior to instituting surgical approaches in managing post-prostatectomy incontinence, a trial of conservative measures is warranted. In particular, measures that have demonstrated benefit include pelvic floor exercises (Kegel exercises) and behavioral modifications, such as limiting the intake of fluids or bladder irritants such as alcohol and caffeine. Additional non-surgical approaches have been studied, including biofeedback, pelvic floor stimulation, pharmacotherapy, and urethral bulking agents, though there is limited evidence to support the clinical utility of these measures in managing post-prostatectomy incontinence.

Pelvic floor exercises entail repetitive voluntary contraction and relaxation of the urethral sphincter, performed multiple times per day for a course of at least a few months initially. Studies have demonstrated a quicker return of continence in patients who perform Kegel exercises consistently. In a randomized controlled trial by Van Kampen et al.[53], 88% of men who performed pelvic floor exercises were completely continent at 3 months following prostatectomy, in contrast to only 56% of men who did not engage in such exercises, with a difference that was statistically significant. Of note, at 12 months, the difference in continence rates was less dramatic. In another randomized controlled trial with 300 patients, Filocamo et al.[54] showed similar results, with a statistically significant difference in the continence rate at 3 months following surgery (74% in men who performed Kegel exercises versus 30% in men who did not), though the continence rates at 12 months were not significantly different between the two groups (98.7% versus 88%).

Likewise, behavioral modifications have demonstrated benefit in reducing post-prostatectomy incontinence. In a multi-institutional randomized controlled trial, Goode et al.[55] demonstrated the benefit of implementing bladder control strategies, such as limiting the intake of fluids or bladder irritants, including caffeine, in addition to pelvic floor exercises in reducing persistent post-prostatectomy incontinence beyond one year following surgery. They found this effect to be statistically significant at 8 weeks and durable to at least 12 months after implementation. They also investigated the effects of biofeedback and pelvic floor stimulation therapy, which although beneficial over no intervention at all, showed no additional benefit over implementing behavioral measures and pelvic floor exercises alone.[55]

Surgical approaches: artificial urinary sphincter

Surgical intervention for incontinence is typically deferred for at least one year following prostatectomy.[15] Traditionally, the AUS has been the gold standard surgical treatment for SUI after prostatectomy since its introduction several decades ago, offering the advantage of both durability and effectiveness for even severe degrees of incontinence. Initially conceptualized by Foley in 1947[56], the modern AUS design has evolved over several iterations, with closer resemblance to designs introduced in the 1970s by Scott[57] and Rosen.[58] The present models are fashioned on the concept of using an inflatable fluid-filled cuff surrounding the urethra to control continence in addition to a hydraulic pressure-regulating balloon reservoir and control pump. In the resting "activated" state, the cuff is inflated, thereby occluding the urethra. When the control pump, implanted in the scrotum, is squeezed manually, the cuff is deactivated. This pumps fluid out of the cuff into the reservoir, thereby depressurizing the cuff and enabling the patient to void. Unless locked in the deactivated state, the cuff automatically reactivates over the subsequent 45 to 90 seconds following deactivation to prevent further flow of urine through the urethra.

Prior to AUS implantation, a number of pre-operative factors must be considered to ensure appropriate candidacy. The determination of patient comprehension and dexterity is crucial, given the need for active patient participation in controlling the AUS. Urinary tract infections must be adequately treated with documented eradication prior to the implantation of a foreign body. Caution should be exercised in patients with conditions requiring indwelling catheterization, given the associated higher rate of complications following AUS implantation, or in those with vesicoureteral reflux or low bladder capacity. Furthermore, patients with pre-existing lower urinary tract obstruction and those predisposed to obstruction, including patients with a history of pelvic irradiation or trauma, urethral strictures, or bladder neck contractures should undergo further evaluation or interventions to help reduce the higher associated risk of AUS-related complications[59,60], such as urinary retention or cuff erosion.

Surgical access is traditionally obtained via a longitudinal midline perineal incision over the urethra with subsequent dissection through the bulbospongiosus muscle, although alternative approaches have been employed as well, including the penoscrotal and retropubic approaches. Typically, the cuff is placed at the bulbar urethra for post-prostatectomy patients, with

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options of either single or double cuff placement. The control pump is implanted within the scrotum, and the balloon reservoir is placed either intra-abdominally or in an extraperitoneal prevesical space of Retzius.

There is an abundance of long-term follow-up data supporting the central role of AUS in the surgical management of incontinence. In a retrospective study spanning an 11-year mean follow-up in 100 patients with AUS, Venn et al.[61] reported 10-year overall continence rates of 84%. In another study, Montague et al.[62] evaluated the rates of dryness and subjective patient satisfaction following AUS implantation over a 7-year mean follow-up in 113 patients. In their cohort, 4% were completely dry, and 60% had mild degree of leakage (0 to 1 pad per day); subjectively, 28% were very satisfied with the outcome, 45% satisfied, 18% neutral, 6% dissatisfied, and 4% very dissatisfied.

Despite its long-term durability, the AUS remains susceptible to a number of complications, including the development of postoperative hematoma, urinary retention (arising in the context of periurethral edema or stricture), AUS infection, cuff erosion, urethral atrophy, and mechanical failure. Cuff erosion has been reported as a complication in up to 5% of patients[63-67], most commonly due to infection or iatrogenic causes. Infection rates have generally ranged between 1 and 3%.[63-66] Patients presenting with AUS infection may complain of scrotal pain, erythema, edema, or purulence, and they must undergo cystoscopic evaluation to assess cuff erosion. Device explantation is traditionally necessitated in cases of erosion or infection, as device infections generally do not respond to antibiotic therapy alone, and all AUS components must be removed. Device replacement is generally considered after a delay of 3-6 months[68-70] with appropriate antibiotic treatment. Atrophy of the urethral tissue can also contribute to cuff erosion from persistent urethral compression and result in incontinence. The incidence of this complication may be mitigated by nocturnal cuff deactivation or the use of narrow-backed cuffs. Management entails increasing cuff pressure, decreasing cuff size, or implanting a second cuff. Mechanical failure is another potential complication that can result in incontinence and may require replacement of either the failed component or the AUS entirely.

Surgical approaches: male slings

In recent years, various novel surgical treatments have been introduced as alternatives to the AUS. Anti-incontinence procedures can be classified into non-adjustable male slings (bulbourethral sling, bone anchored male sling and transobturator male sling), adjustable male slings (Reemex and Argus), and adjustable balloon devices (ProACT). Unlike the AUS, which compresses the urethra circumferentially, thereby interfering with venous blood flow and predisposing the patient to urethral atrophy and even erosion, the male sling compresses only the ventral aspect of the bulbar urethra, leaving the dorsal and lateral blood flow intact. Moreover, tissue, including the bulbospongiosus muscle, is left intact over the urethra, serving as a cushion between the urethra and the sling and further minimizing the risk of erosion.

Non-adjustable male slings

Slings act to decrease urinary leakage by providing direct urethral compression. A variety of urethral compression procedures have been applied in an attempt to control urinary incontinence over the last several years. Most notable were the Kaufman procedures, which included a crural crossover[71] and were later modified to use a synthetic mesh tape that joins the crura in the midline.[72] A silicone gel device is attached to the corpora cavernosa to compress the ventral urethra. However, an insurgence of various sling procedures has occurred in the last decade.

Based on the Kaufman principles, Schaeffer et al.[73] introduced a bulbourethral sling procedure in 1998, which uses a series of 3 tetra-fluoroethylene bolsters placed beneath the bulbar urethra through a perineal incision. The sling increases resistance to abdominal pressure excursions without affecting resting urethral pressure or causing obstructive voiding. Clemens et al. reported the results of this technique in 64 men with severe postprostatectomy incontinence.[74] At a mean follow-up period of 18 months, 56% of patients were dry, and 8% were significantly improved. However, despite the excellent results, sling revision was required in 21% of patients, and bolster removal was necessary secondary to infection in 6%. Moreover, 52% of patients had perineal numbness or pain, with 26% rating this problem as moderate or severe. Stern et al. reported the long-term results of the bulbourethral sling in 71 patients.[75] At a mean follow-up period of 4 years (range: 0.27 to 6.55), 68% of patients required 2 or fewer pads per day, and only 36% were completely dry, requiring no pads. The sling was removed in 7 cases.

The first series of the bone-anchored perineal male sling was presented by Jacoby in 1999.[76] The use of bone anchors obviates the need for the blind transfer of sutures suprapubically to achieve bulbourethral compression and eliminates any abdominal incision. Unlike the AUS, the perineal male sling has the advantage of allowing spontaneous physiological voiding without manipulation. Optimal cure rates have been reported with the bone-anchored perineal sling and generally range from 39% to 90%, depending on the method of evaluation and definition of success.[77-84] As more experience is gained with this procedure, the importance of patient and material selection is emphasized, as it greatly impacts outcome. In a study of 46 men with a mean follow-up period of 18 months, the procedure was successful in 76%, resulted in improvement in 35%, and failed in 24% of patients due to the use of absorbable graft material.[80] The success rates were significantly greater in patients

receiving synthetic mesh either alone or as a composite graft compared with the use of absorbable material alone (75% and 97% versus 0%, respectively, p<0.05). Sling failure correlated well with the type of material and severity of incontinence. Since the introduction of this procedure, it is now established that it is suited for patients with mild to moderate incontinence only. In another study, the bone anchored male sling provided efficacy for mild to moderate incontinence comparable to that of the AUS at a mean follow-up period of 22 months (90% versus 80%, respectively).[85] However, the AUS was superior to the sling in patients with severe incontinence (72% versus 58%, respectively). In another retrospective study, the dry rates were 68% for men receiving prostate adjustable continence therapy and 64% for those treated with bone anchored male slings at mean follow-ups of 18 months and 36 months, respectively.[86] The results were better for moderate to severe incontinence in the adjustable balloon devices (ProACT) group. Partial compression of the ventral aspect of the urethra by a male sling is adequate for patients with mild to moderate incontinence, as they have adequate sphincter function. However, patients with severe incontinence have severe damage to the sphincter mechanism, which requires circumferential compression by an AUS. Furthermore, placement of a male sling does not preclude AUS implantation at a later date. In a recent study[87], Fisher et al.[87] concluded that AUS placement after a failed bone-anchored male sling is technically feasible and does not affect the short-term efficacy of the AUS, with results comparable to those after naïve AUS placement.

Encouraged by the results of transobturator tape in women, a new transobturator male sling system was approved by the United States Food and Drug Administration (FDA) in 2006. The degree of tension applied is based on retrograde leak point pressure, and the tension helps restore the proximal posterior urethra back into position toward the pelvic outlet. The tape is self-anchoring due to the woven nature of the material. In a recent study, Gozzi et al. reported their experience in a series of 67 patients.[88] The cure rate (no pad usage) was 52%, and the improvement rate (1 to 2 pads per day) was 38%. The median pad usage decreased from 4.42 to 1.0 at 3 months. Of their patients, 11 had urinary retention requiring suprapubic tube drainage.

Adjustable balloon device (ProACT)

ProACT, developed by Uromedica Inc., is not approved for use in the United States. It consists of 2 silicone elastomer balloons placed paraurethrally at the bladder neck. A similar device, ACT (adjustable continence therapy), is currently available for women. Hubner and Schlarp reported their results with ProACT in 117 men.[89] At a mean follow-up period of 13 months (range: 3 to 54) and with a mean of 3 adjustments (0 to 15), 67% of men were dry, 92% were significantly improved, and 8% had no improvement. Reimplantation was required in 32 patients, with a success rate of 75%. The pad count decreased from a mean of 6 to 1 per day.

Adjustable male slings

The Argus System, an adjustable male sling, was developed in Argentina and is currently not approved for use in the United States. First described by Moreno Sierra et al.[90] in 2006, the sling comprises a 4.2x2.6x0.9 cm-thick silicone foam pad for bulbar urethral compression. The results of this procedure were reported in a multicenter trial by Romano et al.[91] Of 48 patients with a mean follow-up period of 7.5 months (range: 1 to 17.5), 73% were dry (no pads), and 10% improved (occasional leakage). The procedure failed in 17% of patients, and the sling was removed in 5 patients secondary to urethral erosion and infection. Readjustment was required in 3 patients. Urinary retention developed in 15% of patients, while urethral perforation was noted intraoperatively in 3 cases, and perineal pain was a minor problem in 21% of patients.

The Male Remeex System, another adjustable male sling, was introduced in Spain and consists of a suburethral sling made of monofilament polypropylene mesh that is connected to a suprapubic regulator called a varitensor through 2 monofilament traction sutures. The varitensor is placed over the rectus fascia and allows adjustment of suburethral pressure from outside the body using an external manipulator. In a multicenter European prospective trial, Sousa-Escandon et al.[92] reported results in 51 patients with moderate to severe incontinence. At a mean follow-up period of 32 months, 64.7% of patients were cured (no pads), and 19.6% had significant improvement. The procedure failed in 15.7% of patients. Almost all patients required at least 1 readjustment. The sling had to be removed from 3 patients due to urethral erosion (1) or an infected varitensor (2). Bladder perforation occurred in 5.5% of cases, and perineal hematoma developed in 3. Almost all patients experienced perineal discomfort.

Newer therapies are currently underway, including the virtue sling and approaches utilizing stem cell therapy. The virtue sling device is a new modified sling with four arms. Two lateral arms are placed via the transobturator approach from outside to in, using a curved needle. The other two arms are passed superiorly in the prepubic space. Polypropylene mesh is placed under the bulbar urethra, and tension is added by pulling all four arms. The sling is approved by the FDA, and clinical trials are currently being conducted at various centers throughout the United States and Canada. Much interest has also been generated in tissue engineering and stem cell therapy for SUI. The first results of autologous myoblast and fibroblast injections in 63 patients with post-prostatectomy incontinence were published by Mitterberger et al.[93] in 2008. The authors reported a continence rate of 65% and an improvement rate of 27%. Other

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groups were not able to confirm these data. The entire treatment involves a complicated and time-consuming process.

Conclusion

Urinary incontinence continues to gain increasing importance in affecting the post-operative quality of life in men treated surgically for prostate cancer. Herein, we have reviewed the most relevant contemporary literature concerning the etiology, evaluation, and management of post-prostatectomy incontinence. While conservative methods, such as pelvic floor exercises and behavioral therapy, are preferred within the first post-operative year, various surgical options are available for those with persistent bothersome incontinence. The AUS has gained a role as the gold standard treatment for post-prostatectomy incontinence since its introduction several decades ago. However, the emergence of male sling procedures in more recent years has provided men with alternative satisfactory treatment options for milder forms of incontinence. Sound clinical judgment must be exercised in the context of patient-related factors to determine an appropriate approach to surgically evaluating and treating patients with post-prostatectomy incontinence. With the advent of novel techniques and newer technologies, the management of these patients continues to evolve.

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