

Review Article

Prostate diseases and male voiding dysfunctions

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How to Prevent and Manage Post-Prostatectomy Incontinence: A Review

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Purpose: To provide an overview of the currently available evidence relating to the prevention and management strategies of urinary incontinence (UI) after radical prostatectomy (RP).

Materials and Methods: A comprehensive research was carried out on MEDLINE/PubMed database to identify pertinent studies concerning post-RP UI. The search strategy included these words: urinary continence; urinary continence recovery; urinary incontinence; radical prostatectomy; and prostate cancer.

Results: Post-RP UI still represents a challenging issue for both urologic patients and clinicians. A complete preoperative assessment of the risk factors associated with post-RP UI aids both in counseling those patients with a higher estimated likelihood of postoperative UI and in identifying those who would probably benefit from preventive strategies in the preoperative and in the intraoperative settings. Over the last decades different surgical strategies based on either the “preservation” or the “reconstruction” of the anatomical elements responsible for urinary continence (UC) led to an overall improvement of postoperative functional outcomes. Finally, several therapeutic strategies should be evaluated for the postoperative UI management. Artificial urinary sphincter implantation represents the gold standard for treatment, notwithstanding its wide adoption is limited due to high costs and significant risk of surgical revision. In this context, male sling positioning seems the most promising strategy, in particular in mild and moderate post-RP UI.

Conclusions: To enhance the likelihood of obtaining an optimal UC recovery after RP, it is here strongly suggested to intervene throughout the overall clinical management process thus including the pre-, intra- and postoperative settings.

Keywords: Prostatectomy; Prostatic neoplasms; Robotic surgical procedures; Urinary incontinence

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INTRODUCTION

Radical prostatectomy (RP) is effective for treating prostate cancer [1]. Despite significant surgical progresses, achieving optimal post-RP functional outcomes is still troublesome. Along with oncological outcomes,

urinary continence (UC) and erectile function are classically reported as post-RP ‘trifecta’ [2]. Urinary incontinence (UI) after RP is the most feared postoperative issue because of its huge negative effect on quality of life [3]. As RP remains an established option, the prevalence of post-RP UI is still significant [4]. Depending on

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both the UC's definition and the length of the follow-up, 1% to 40% of patients may experience persistent UI after RP [4]. Several post-RP UI risk factors have been recognized, and identifying higher-risk patients is of major interest. Indeed, prevention of UI in the preoperative, intraoperative and postoperative setting may be applied to enhance UC recovery [5]. If conservative strategies would fail, patients should be properly counselled for UI treatment.

In this narrative review we aimed at providing an overview of the currently available evidence relating to the prevention and management strategies of post-RP UI.

MAIN BODY

1. Materials and methods

A comprehensive search strategy was performed on MEDLINE/PubMed database to identify relevant studies dealing with post-RP UI. Publications from the past 10 years (2010 to January 2020) were typically selected,

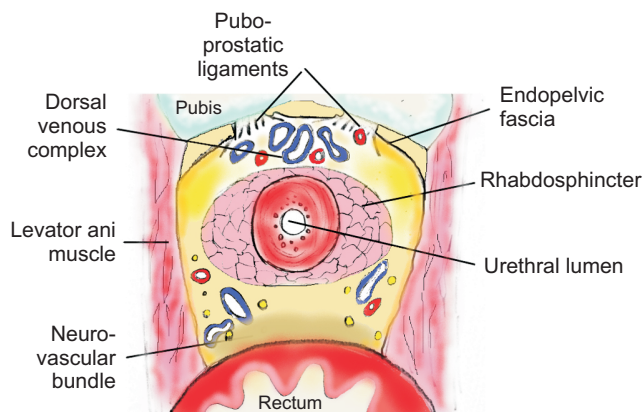


Fig. 1. Axial section depicting external sphincter and its surroundings.

but highly-regarded older publications were included as well. We only included published articles in English in peer-reviewed journals. The search strategy included the following terms: urinary continence; urinary continence recovery; urinary incontinence; radical prostatectomy; and prostate cancer. Resulting abstracts were scrutinized for relevance; the relevant studies were then summed-up after an interactive peer-review process.

2. Pathophysiology of post-radical prostatectomy urinary incontinence

Postoperative UI presents with a multifactorial aetiology, thus including both anatomical and functional factors. Indeed, the primary reason for post-RP UI is the incompetence of the external sphincter leading to stress urinary incontinence (SUI) [6]. However, some patients can also develop overactive bladder (OAB) after surgery, which may often require pharmacotherapy [6,7]. Porena et al [8] found some degree of detrusor overactivity (DO) in up to 77% of cases after RP. Surgical-related damage to anatomic structures or nerves, leading to levels of impairment of the urinary sphincters, is a crucial aetiological factor in post-RP UI. The external sphincter is a striated muscle that is found above the membranous urethra (Fig. 1). Its fibres insert on the anterior prostate, and are under voluntary control [9]. In addition, the internal sphincter is located at the level of the bladder neck (BN) and is made of smooth muscle fibres. The internal sphincter depends upon involuntary control; its function consists of maintaining UC under exertion [6]. As for females, a supportive system aids UC in men as well [10]. Its function is analogue to an hammock, as reported for women [11], since it provides a supplemental occlusive influence on the urethra, triggered by risen intra-abdominal

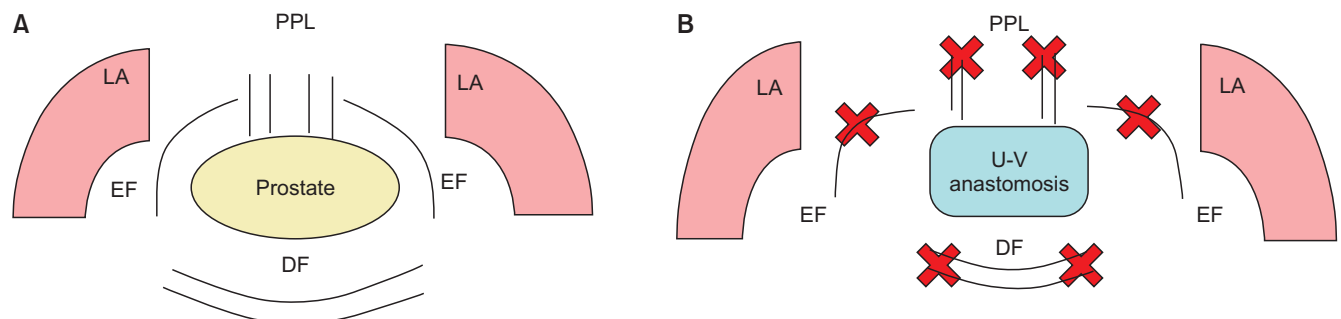


Fig. 2. Male pelvic supportive complex before (A) and after (B) radical prostatectomy. PPL: pubo-prostatic ligaments, EF: endopelvic fascia, LA: levator ani muscles, DF: Denonvilliers fascia, U-V anastomosis: urethro-vesical anastomosis.

pressure (Fig. 2). The male anterior supportive system includes the puboprostic and pubovesical ligaments and the so-called tendinous arch of the endopelvic fascia (EPF), which represents a thickened band of the EPF [12]. The posterior support comprises the perineal body, the Denonvillier's retroprostatic fascia, the rectourethralis muscle, and the pelvic diaphragm muscles complex [6]. The pudendal nerve supplies innervation to the external sphincter [6]. Although it mainly follows an extrapelvic route, anatomical evaluations have also revealed a limited intrapelvic track through the neurovascular bundles (NVBs) which may contribute in innervating the rhabdosphincter [13]. Indeed, a damage to the NVB could be responsible for postoperative UI and NVB preservation during RP can lead to earlier UC recovery [14].

3. Preoperative setting

1) Identification of the risk factors

Identifying preoperative predictors of UI in RP candidates is crucial. This can provide a data-driven method to counsel patients about their expected time to UC recovery and may guide the clinician to apply preventative strategies even before surgery, and certainly in the intraoperative setting. Hence, there may now be sufficient evidence to build solid clinical models predicting UI after RP.

(1) Age

A large number of studies recognized age as a fundamental factor for estimating the risk of UI. Mandel et al [15] analysed data from 8,295 RP patients, finding that the 1-year UC rates worsened in older patients. These findings were confirmed in robot-assisted RP (RARP) series [16,17]. The higher likelihood of developing UI may be due to some specific features of the older subset of RP population, thus considering a pre-existing benign prostate enlargement (BPE) and some functional or structural impairment of the bladder, urethra and supportive system [6].

(2) Body mass index

Higher body mass index (BMI) values have been extensively associated to worse postoperative UI outcomes. Although a specific explanation for the relation between post-RP UI and obesity is not available [18], increased visceral adiposity has been associated

with lower urinary tract symptoms (LUTS) in BPE-patients, thus obese RP-candidates have a higher likelihood of being affected by pre-existing LUTS, which are related to post-RP UI outcomes [6]. The visceral fat-cells secrete adipocytokines, which have a detrimental effect on the lower urinary tract due to both their potential to directly cause an increased sympathetic tone and their proliferative influence on prostatic cells [19]. Among 2,849 RP patients, high BMI levels were predictors of poorer UC outcomes at 6- and 12-month follow-up [20]. Worst UC-outcomes were identified for obese (BMI>30 kg/m²) men undergoing RARP at both 12 and 24 months after surgery [21]. Conversely, Xu et al [22] showed comparable UC outcomes between obese (BMI>30 kg/m²) and non-obese RARP patients, arguing that RARP seemed to promote good functional outcomes even in obese men.

(3) Comorbidities

General health impairment has demonstrated a negative influence on UC recovery. However, only few studies focused on this issue. Teber et al [23] showed a significant association between diabetes and lower rates of both early (*e.g.*, 0–3 months) and late (*e.g.*, 12–24 months) postoperative UC recovery. Likewise, the Charlson comorbidity index was an independent predictor of 12-month UC rate in a cohort of 308 RARP patients [16]; with overall well-being having been described as an independent predictor of immediate UC recovery after RP [24].

(4) Prostate surgery before radical prostatectomy

RP-candidates with a history of previous prostatic surgery were hypothesised to have a higher likelihood of developing post-RP UI, due to both pre-existing LUTS [6] and the challenging RP procedure in this category of patients [25]. Although several studies showed that previous transurethral resection of the prostate (TURP) did not influence post-RP UC outcomes, Tienza et al [26] showed a 6-fold higher risk of postoperative UI in those who had already received TURP. In a RARP cohort, Gupta et al [27] found a 14% UI rate *vs.* 11.8% after 6 months, and 25% *vs.* 8% after 1 year for patients with or without previous TURP, respectively. The post-RARP UC outcomes after holmium laser enucleation of the prostate (HoLEP) were evaluated as well. Abedali et al [28] identified 27 RARP patients who previously underwent HoLEP who were matched

1:1 to RARP patients without any history of transurethral surgery; of HoLEP cohort, 27% patients reached strict UC (*i.e.*, leak free, pad free) in contrast with 64% of matched controls; this comparison, however, did not reach significance ($p=0.07$). Suardi et al [25] investigated the functional outcomes of nerve-sparing open radical prostatectomy (ORP) following HoLEP. In their 1:1 matched study, they failed to describe any significant difference on UC recovery between patients treated with RP after either HoLEP, TURP, or open simple prostatectomy.

(5) Prostate volume

The role of prostate volume (PV) on UC outcomes is controversial. Worst UC outcomes are expected with larger prostates because RP requires substantial urethral damage or because postoperative UI can be associated with antecedent LUTS. In a cohort of 5,447 RP patients, Mandel et al [15] showed that postoperative short- (1 week–3 months) and long-term (6–12 months) UC was adversely affected by higher PVs. Conversely, in 3,067 men PV was identified as an irrelevant factor on 12 months post-RP UC recovery [29]. A number of other studies failed to identify any correlation between PVs and UC outcomes [30,31].

(6) Membranous urethral length

The membranous urethral length (MUL), typically measured with magnetic resonance imaging (MRI), may be correlated with post-RP UC recovery. A recent systematic review concluded that larger levels of preoperative MUL were related with a prompt return to UC [32]. In analyzing a large cohort of patients, preoperative MUL levels were found to be predictors of faster UC recovery post-RARP [31].

2) Preoperative preventative strategies

The typical strategy to prevent UI in RP-candidates is pelvic floor muscle exercise (PFME), this strengthens the pelvic floor muscles, hence possibly improving the urinary sphincters and/or the supportive system. It can be associated with biofeedback, which assists patients' muscles contraction whilst being provided with either a sound or a visual feedback of the correct exercise. Chang et al [33] performed a meta-analysis including 739 patients: they identified a significantly lowered UI-ratio 3 months post-RP for those who received preoperative PFME. No benefit was however observed

at the 6-month assessment. A recent 22-trial-meta-analysis showed significantly better outcomes for those trials where a preoperative PFME was performed [34]. A finer comprehension of its usefulness will however only be available when studies including standardized protocols of PFME will be carried out.

4. Intraoperative setting

Aiming at improving the postoperative UC outcomes, a range of surgical strategies have been proposed, and they are here summarized.

1) Bladder neck preservation

BN includes the internal sphincter which, as previously discussed, contributes to ensure UC. Different approaches have been described to obtain optimal BN preservation (BNP), including an anterior, lateral or antero-lateral approach [5], and all of them aim at carefully dissecting the bladder from the base of the prostate, allowing the preservation of the circular BN fibres (Fig. 3) [35]. RP-outcomes with and without BNP were compared in an randomized controlled trial (RCT): post-RP UC rates (*e.g.*, wearing 1 safety pad or no-pad at all) at 12 months were 74.8% *vs.* 94.7% for those in

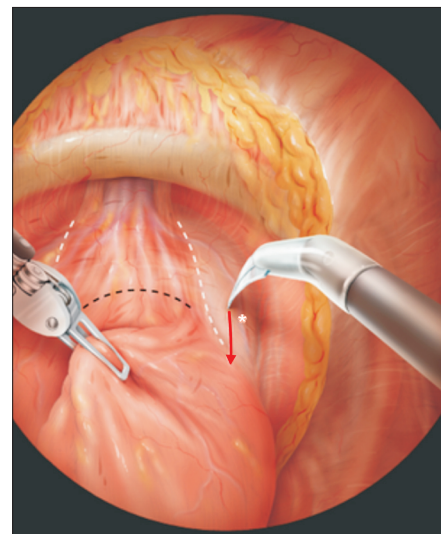


Fig. 3. Lateral-approach bladder neck preservation technique, according to Asimakopoulos et al [35]. The black line represents the estimated position of the bladder neck, whilst the white lines indicate the lateral limits of the detrusor apron. The arrow represents the lateral dissection incision which is used to expose the bladder neck. A combination of blunt and sharp dissection is used to separate the detrusorial fibres from the prostate. *Anastomotic vein used as a landmark for the initial lateral dissection. Illustration by Stephan Spitzer, www.spitzer-illustration.com. Data from Asimakopoulos et al (BJU Int 2012;110:1566-71) [35] with original copyright holder's permission.

the control *vs.* the BNP group, respectively [36]. Long-term (*e.g.*, mean 3.9 years) follow-up from the same cohort confirmed such trend [37]. Likewise, in a series of 791 and 276 RARP patients respectively treated with and without BNP, the authors identified a significant association between BNP and time to UC recovery [38]. Finally, Ma et al [39] analyzed 13 trials, including 1,130 cases and 1,154 controls, confirming that BNP facilitated the occurrence of early recovery levels and better 1-year UC outcomes. However, other studies did not confirm these data, thus hampering to draw a final conclusion on this approach [40].

2) Nerve-sparing approach

The penile innervation derives from the pelvic plexus, through the NVBs that run close to the prostate (Fig. 1). Some branches of the NVBs supplying the rhabdospincter may be damaged during RP [9]. A systematic review including 13,749 patients concluded that significantly higher rates of UC recovery up to 6 months after surgery were observed in men submitted to a NS approach as compared with those treated with a non-nerve sparing (NNS) approach. However, at the 12-month follow-up this difference was not significant any longer [41]. Another 20-study-meta-analysis addressed the issue of functional outcomes after intrafascial or inter-fascial NS technique [42]. If compared with the inter-fascial technique, the intrafascial approach was found to be associated with faster UC re-

covery at the 1-, 3-, and 6-month assessments, but not at the 12-month follow-up. Michl et al [43] compared long-term UC outcomes in 18,427 patients who had received a primary bilateral NS (BNS) procedure; a primary NNS procedure; or a BNS intervention with subsequent resection of NVBs for positive surgical margins. This latter group was associated with better 12-month UC rates compared to the NNS group, possibly suggesting that a meticulous surgical approach, rather than solely the intent of sparing the NVBs, is associated with UC recovery.

3) Maximal urethral length preservation

An increased urethral length, arguably associated with higher levels of muscle tissue sparing, can possibly aid in rhabdospincter's functional rehabilitation. Schlomm et al [44] analysed 691 RP patients (*e.g.*, 285 treated without, and 406 with the maximal urethral length preservation [MULP] technique). Continence rates were respectively 50.1% in the MULP group and 30.9% in the control group 1 week after catheter removal, but no statistically significant difference was identified 12 months later. The group of Hakimi et al [45] intraoperatively measured the urethral stump length in 75 MULP technique-treated patients; a urethral stump length of >2 cm significantly predicted time to pad-free state. With the help of pre- and postoperative MRI, Kadono et al [46] recorded the location of the distal membranous urethra in 185 patients. These records,

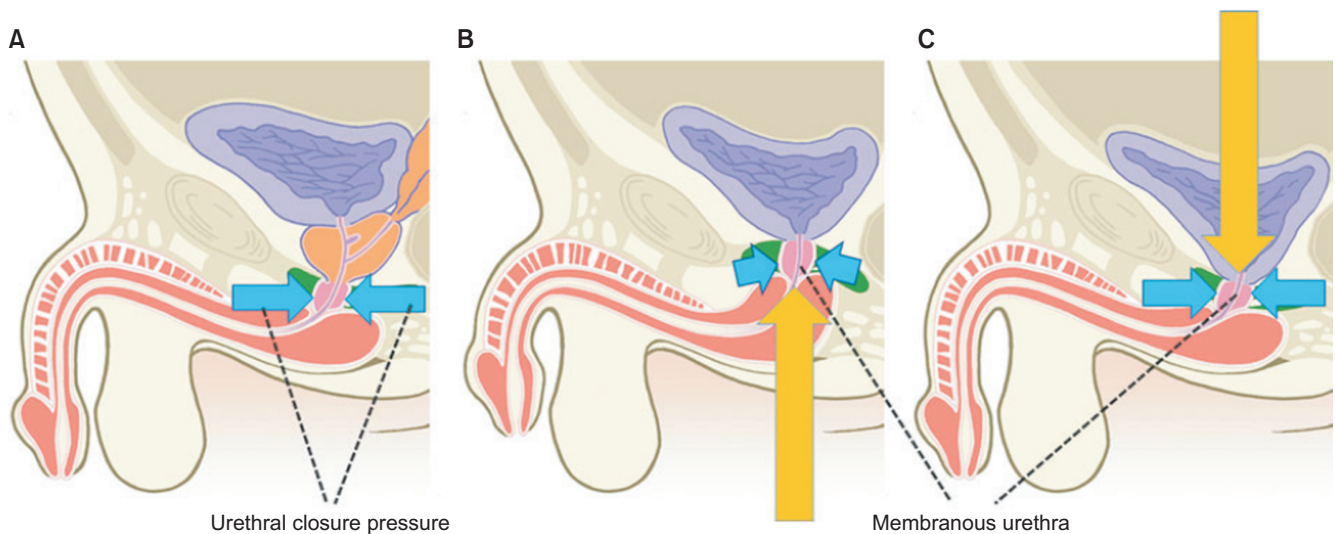


Fig. 4. Chronological changes in terms of urethral positioning and length after radical prostatectomy [46]. (A) The figure represents the physiologic preoperative membranous urethral positioning. The external sphincter is positioned towards a more cephalad position at 10 days (B) vs. 1 year after surgery (C). Data from Kadono et al (BJU Int 2018;122:456-62) [46] with original copyright holder's permission.

in terms of urethral positioning and length, were then analyzed taking into account the chronological changes in UC recovery. It was found that the distal membranous urethra shifted proximally soon after RP and went back to the usual pre-RP location 1 year after RP (Fig. 4) [46]. In parallel, the sphincter's function worsened 10 days after RP, but recovered 12 months later. Maximal preservation of the urethral stump's length was associated with the entity of displacement of the membranous urethra and impacted positively on UI after RP.

4) Endopelvic fascia preservation

The connective tissue sheet between the pelvic wall and organs is named EPF, which must be incised to approach the paraprostatic space [47]. This area, which is located laterally to the apex of the prostate and the rhabdosphincter, is crucial for UC, thus EPF-preservation was hypothesized to influence UC recovery (Fig. 5). Takenaka et al [47] extensively described the EPF anatomical features on fresh cadavers and eventually assessed the clinical implications of EPF-preservation in 23 ORP patients. The one-, three-, six-, and nine-month-post-RP-UC rates using the new technique were 44%, 83%, 96%, and 100%, respectively. The influence of EPF-preservation in 151 RARP patients was assessed as well [14], with the level of EPF-preservation having emerged to be the best predictor of UC recovery at 6- and 12-month postoperatively. In another trial, 138

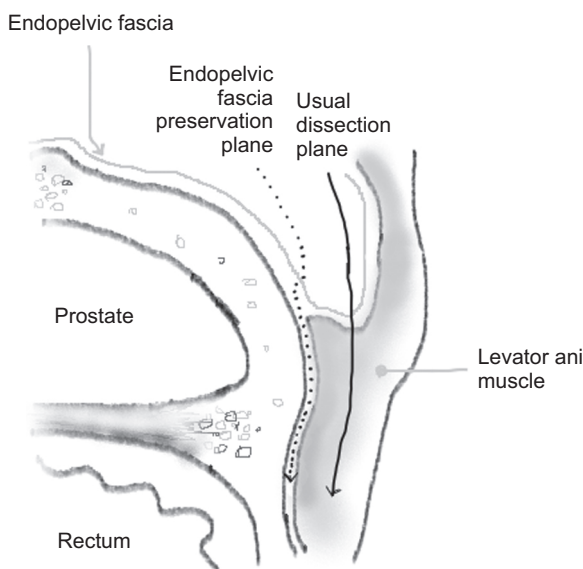


Fig. 5. Endopelvic fascia anatomy. The solid line represents the usual dissection plane, the dotted arrow shows the endopelvic fascia sparing plane.

RARP patients were subdivided in two groups with regards to the adoption of the fascial sparing technique [48]. At the 12-month post-RP follow-up, UC rates were 88.4% and 97.1% in the control group and the experimental group, respectively ($p=0.049$). At the multivariate analysis, EPF-preservation was found to be the only significant predictor of UC recovery.

5) Retzius-sparing approach

The Retzius-sparing approach allows the entire RP completion via the Douglas's pouch, aiming at minimizing surgical trauma whilst preserving regional anatomy (Fig. 6). Hence, the bladder is not dropped and the EPF and pubo-prostatic ligaments are preserved, thus improving urethral support [49]. In a recent RCT, 120 patients were randomized to receive either Retzius-sparing or standard RARP [50]. One week after catheter removal, UC recovery was observed in 71% of subjects undergoing Retzius-sparing variant *vs.* 48% in the standard RARP arm ($p=0.01$). A recent RCT confirmed the same findings [51]. A systematic review concluded that early UC recovery when using this technique as opposed to conventional RARP, is significantly enhanced [52].

6) Selective ligature of dorsal venous complex

Optimal dorsal vascular complex (DVC) management, hence avoiding any damage to the rhabdosphincter's fibres, could influence UC recovery (Fig. 7) [53]. The standard "ligate and cut" technique can result in an accidental sphincter's damage, whilst the "cut and ligate" technique is instead thought to provide better anatomical control [54]. Therefore, to obtain prompt

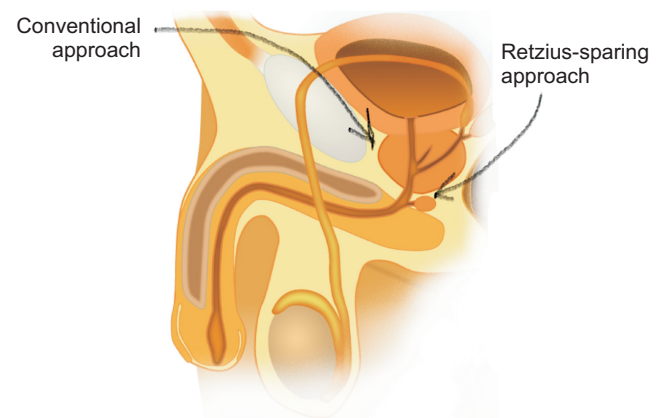


Fig. 6. Retzius-sparing technique; the prostate is approached from below the bladder, *via* the Douglas's pouch.

UC recovery, the venotomies' suture can be performed after DVC section, and in a selective way. Porpiglia et al [54] identified 60 patients who were divided into two groups; a standard ligation of DVC (e.g., ligation and subsequent section) was performed in group A; a selective DVC-ligation after its division was carried out in group B. A significant difference in terms of UC outcomes was recorded between the 2 groups, e.g., 53% in group A vs. 80% in group B, after 3 months. In another trial, UC outcomes of 303 patients receiving DVC ligation

and eventual section were compared with those of 240 patients who received a selective DVC division with sequent ligation [55]. With respect to the whole ligation, the selective ligation technique was associated with earlier UC-recovery (61.4% vs. 39.6%, $p < 0.001$).

7) Pubo-prostatic ligament preservation

The pubo-prostatic ligament is the most important supportive element between the pubis and the prostate; in supporting the urethra the ligament concurs in maintaining UC (Fig. 8) [56]. Hence, the ligament section is expected to worsen the lack of urethral sta-

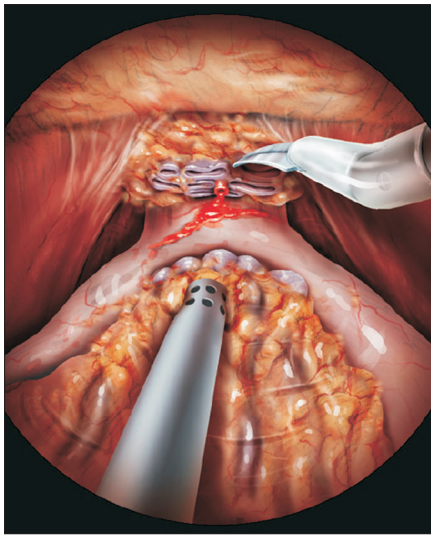


Fig. 7. Image depicting the division of the dorsal venous complex without its initial ligation in a robot-assisted laparoscopic prostatectomy [53]. Illustration by Stephan Spitzer, www.spitzer-illustration.com. Data from Power et al (BJU Int 2011;108:930-2) [53] with original copyright holder's permission.

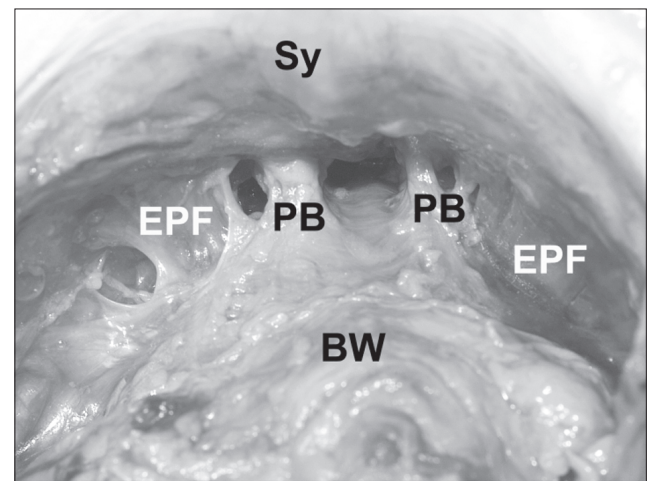


Fig. 8. Puboprostatic ligaments anatomy [56]. Data from Wimpissinger et al (BJU Int 2003;92:681-4) [56] with original copyright holder's permission. BW: bladder wall, Sy: pubic symphysis, PB: puboprostatic ligaments, EPF: endopelvic fascia.

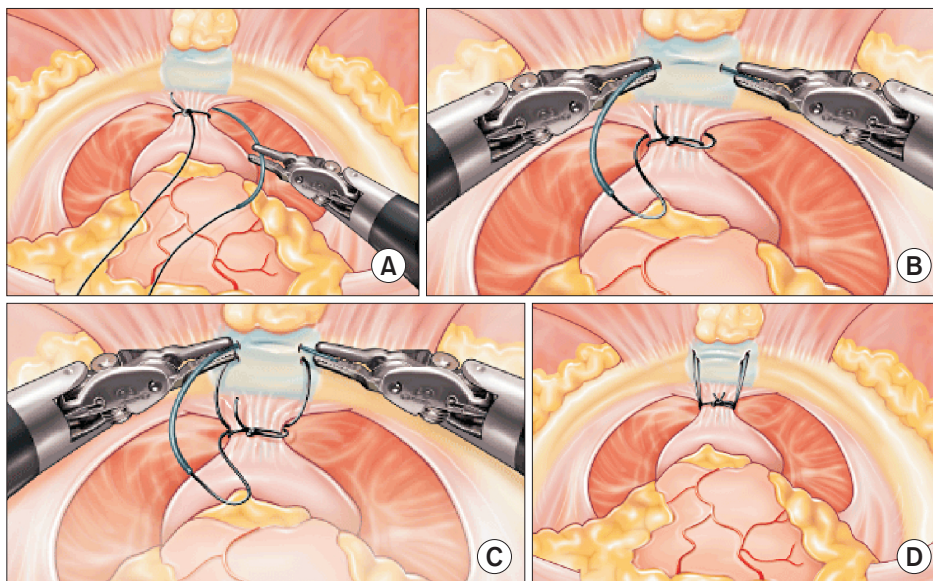


Fig. 9. Anterior reconstruction [60]. (A) After ligating the dorsal venous complex, the same stitch is used to perform the anterior suspension. (B) The needle is then secured to the pubic periosteum. (C) The suture is passed again through the urethra and then through the pubic periosteum. (D) Anterior reconstruction is eventually performed. Data from Hurtes et al (BJU Int 2012;110:875-83) [60] with original copyright holder's permission.

bility, thus negatively influencing UC-outcomes. Pubo-prostatic ligament preservation was therefore proposed to hasten UC recovery, with some authors reporting an associated improvement of postoperative UC [57,58]. Indeed, data of 30 RARP patients treated with pubo-prostatic ligament preservation showed an impressive 80% UC recovery rate after catheter removal, and 100% one month after surgery [58].

8) Anterior reconstruction

Walsh et al [59] proposed a technique based on arranging an anterior suspension stitch running through the urethra and then secured to the pubic periosteum (Fig. 9) [60]. In their cohort of 331 RARP patients, Patel

et al [61] found that anterior reconstruction (AR) could improve functional outcomes at the 3-month assessment in those who underwent AR-RARP; continence rates were however similar to those identified in the control group at the 6- and 12-month follow-up.

9) Posterior reconstruction

Rocco et al [62] described a technique based on the reconstruction of the posterior area of the rhabdosphincter, thus allowing the positioning of the sphincter in a more natural fashion. The tissue included in this area extends from the retrovesical peritoneum to the central tendon of the perineum (Fig. 10). Several RCTs investigated the role of posterior reconstruction (PR) regard-

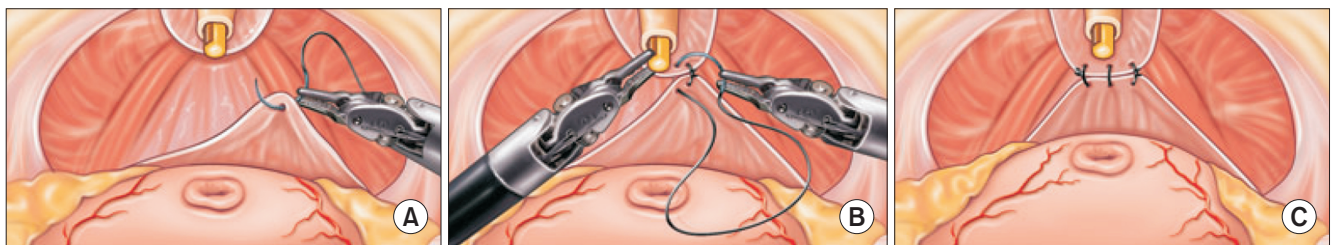


Fig. 10. Posterior reconstruction [60]. (A) The stitch is passed through the Denonvilliers' fascia. (B) The suture is passed through the fascial planes around the rhabdosphincter. (C) The posterior aspect of the external sphincter is finally re-constructed, ready to perform the anastomosis. Data from Hurtes et al (BJU Int 2012;110:875-83) [60] with original copyright holder's permission.

Table 1. RCTs comparing functional outcomes after reconstructive techniques

Study (year)	Patient's number	Study design	Surgical approach in the intervention arm	Continence definition	Evaluation of continence	UC rates (intervention arm/control arm)	Level of evidence
Jeong et al (2015) [65]	PR: 50 Control: 50	RCT	PR RARP	Complete: 0 pad Social: 0-1 pad	EPIC	2 wk: Complete: 24.0%/8.9% Social: 58.0%/37.8%	1b
Sutherland et al (2011) [66]	PR: 47 Control: 47	RCT	PR RARP	0-1 pad	EPIC and IPSS	3 mo: 63%/81%	1b
Koliakos et al (2010) [67]	AR+PR: 23 Control: 24	RCT	AR+PR RARP	0 pad	ICIQ-SF	7 wk: 65.2%/33.3%	1b
Menon et al (2008) [68]	AR+PR: 59 Control: 57	RCT	AR+PR RARP	0/0-1 pad	Pad weighing	1 wk: Complete: 20%/16% Social: 54%/51%	1b
Hurtes et al (2012) [60]	AS+PR: 39 Control: 33	RCT	AS+PR RARP	0/0-1 pad	UCLA-PCI	1 mo: 26.5%/7.1% 3 mo: 45.2%/15.4%	1b
Ogawa et al (2017) [64]	3 layers-2 step PR: 24 Control: 24	RCT	3 layers-2 step PR RARP	Urine leakage of <5 g in the 1-hour pad test	Pad weighing	1 mo: 57%/26%	1b
Sammon et al (2010) [69]	AR+PR: 46 Control: 50	RCT	AR+PR RARP	0-1 pad	EPIC	1 mo: 42%/47%	1b

RCT: randomized clinical trial, UC: urinary continence, PR: posterior reconstruction, AR: anterior reconstruction, AS: anterior suspension, RARP: robot-assisted radical prostatectomy, EPIC: Expanded Prostate Cancer Index Composite questionnaire, IPSS: International Prostate Symptom Score questionnaire, ICIQ-SF: International Consultation of Incontinence Questionnaire – Short Form, UCLA-PCI: University of California-Los Angeles Prostate Cancer Index.

ing UC recovery (Table 1) [60,63-69]. In a 21-study meta-analysis, typical data showed a significant advantage associated with the PR in terms of postoperative UC at different time intervals (*e.g.*, 3, 7, 30, and 90 days after catheter removal), but not at later follow-ups [70]. In another recent meta-analysis, PR-treated patients demonstrated significantly improved UC recovery rates at 1–4, 28–42, 90, 180, and 360 days following catheter removal [63]. The original technique reported by Rocco et al [62] was a 2-layer/2-step, in which reconstruction was performed in two layers. Afterwards, some PR surgical variations have been suggested. A recent RCT examined the usefulness of a 3-layer/2-step RARP technique being carried out using peritoneum, in comparison with the standard RARP technique [64]; 48 patients were subdivided into 2 groups, being treated with either the standard or the 3-layer technique. Four weeks after surgery, UC rates were higher in the experimental (57%) *vs.* the standard RARP group (26%).

10) Combined anterior and posterior reconstruction

In an extensive prospective trial, Tan et al [71] reported significant advantage for a complete reconstruction (CR) approach as compared with both AR and standard approaches. These results were confirmed in 2 RCTs showing better outcomes for the CR compared to a standard technique (26.5%–65% *vs.* 7.1%–33%) at 1-month follow-up (Table 1) [60,67]. Conversely, in a RARP series comparing patients treated with either CR, AR, or PR, no significant difference was observed at 1-month follow-up [68]. In their meta-analysis, Ficarra et al [40] showed a meaningful favour for CR at both 1- and 3 months after RARP, although no difference was detected 6 months after surgery. A novel CR approach was proposed by Porpiglia et al [72]: they reinforced the anastomosis using three posterior and two anterior tissue's layers, in order to re-establish the peri-urethral tissue's anatomy. Results were encouraging, with UC rates of 94.4%, and 98.0% at 12, and 24 weeks post-RARP, respectively. Based on the results of the RCTs [60,67-69], it seems that CR is associated with better UC outcomes 1 and 3 months after RARP, whereas long-term outcomes are scarcely supported by solid evidence.

11) Comparison of open *vs.* robotic radical prostatectomy

Although the robotic technique has allowed the surgeon to face a more detailed anatomical perspective, recent data would not seem to support RARP-superiority. Indeed, while previous series have shown a RARP-associated shorter time-to-UC-recovery [5], recent randomized and prospective studies did not confirm those findings. The first RCT comparing RARP *vs.* ORP failed to observe any benefit of one procedure over another in terms of UC recovery at 6 and 12 weeks [73]. The eventual update on mid-term functional outcomes at 6, 12, and 24 months confirmed such a trend [74]. Specifically, UC scores based on the Expanded Prostate Cancer Index Composite did not differ significantly between RARP and ORP at 6 (88.68 *vs.* 88.45), 12 (90.76 *vs.* 91.53) and 24 months post-RP (91.33 *vs.* 90.86) [69]. Herlemann et al [75] compared 755 RARP *vs.* 1,138 ORP patients and found better UC outcomes for ORP 1 year post-surgery but not beyond. Similarly, Ranasinghe et al [76] analyzed data from 10 online cancer support groups comparing 5,157 RARP *vs.* 579 ORP, and reported no differences in UC outcomes. Finally, Haese et al [77] failed to show any clinically significant improvement in terms of UC rates at 1-year assessment after RARP.

5. Postoperative setting

1) Role of postoperative length of catheterization

A number of studies [78-81] have associated a longer duration of postoperative catheterization with worst UC outcomes, with this conclusion resulting from non-randomized, potentially biased studies. Hence no definitive conclusions can be drawn regarding this issue.

2) Diagnostic work-up

History should identify possible features of urgency- or mixed-type UI and should include a bladder diary consisting in frequency of micturition; number of UI episodes; voided volumes; and 24-hour urinary output collection of related data. Validated tools, such as the OAB questionnaire, are considered reliable and useful to evaluate postoperative UC [82]. Due to its replicability, the 24-hour pad test is the most accurate to quantify UI [83]. A urinalysis test should also be performed in order to rule out any infection. Although its routine adoption is considered controversial [84], urodynamic

investigation had been habitually used in the past to assess DO in candidates for corrective treatment.

3) Conservative strategies

Conservative care should be appraised before moving to invasive options; in this context patients should be examined on a regular basis to evaluate the improvements. Indeed, UI status can last for more than 1 year after RP [85]. Fluid intake reduction, timed voiding and reduction of bladder irritants (e.g., coffee, hot spices) have been associated with improvement of post-RP urinary symptoms and UC [86].

(1) Pelvic floor muscle exercise

The most established conservative option for dealing with post-RP UI is PFME. However, drawing a definitive conclusion about the advantage of PFME for surgery-related UI may be difficult due to the conflicting results provided by current evidences. In this context, there is large heterogeneity between trials regarding both PFME content/delivery (e.g., biofeedback, muscles targeted, and time of commencement of the training)

and UC definition (e.g., 1 hour pad test, 24 hour pad test, International Consultation on Incontinence Questionnaire (ICIQ), bladder diary, and number of pads/d) (Table 2) [34]. Over the past decade, several RCTs have been conducted to evaluate the effectiveness of PFME. Whilst some RCTs supported the benefits of PFME, a recent meta-analysis including 45 RCTs [87] did not support PFME as first line rehabilitative approach for UC recovery after RP. It is here suggested that the approach of deconstructing the details of PFME protocols, as described in a recent review by Hall et al [34], can aid in getting a better understanding of the usefulness of this strategy. In their analysis, preoperative PFME, use of biofeedback, and UC defined as no leakage were features associated with successful patient outcomes. We aim at this point to summarize the most recent RCTs on this topic. In a recent RCT, UC outcomes were evaluated in 60 patients after RP, 30 received PFME whilst the 30 controls did not receive any treatment [88]. The number of pads used during the first and in the six months after surgery was significantly lower in the experimental *vs.* the control group [88]. Another

Table 2. Outcomes of pelvic floor muscle exercise after RP in relation to specific trial's features [34]

Trial feature	Total number of patient	Trial's number	Cumulative analysis of findings (RR, 95% CI)
Preoperative PFME	PFME: 165 Control: 166	5	0.76 (0.63–0.92)
Postoperative PFME only	PFME: 664 Control: 658	10	0.90 (0.79–1.02)
PFME only	PFME: 457 Control: 462	5	0.94 (0.88–1.00)
PFME+BFB	PFME: 372 Control: 362	10	0.73 (0.58–0.91)
Instructions focused on anal region only	PFME: 190 Control: 197	5	0.64 (0.38–1.08)
Instructions involved urethral and anal region	PFME: 626 Control: 617	9	0.90 (0.86–0.96)
Control group received no PFME instructions	PFME: 514 Control: 512	7	0.85 (0.72–0.99)
Control group received some PFME instructions	PFME: 315 Control: 312	8	0.84 (0.70–1.00)
Included all men postoperatively	PFME: 509 Control: 500	11	0.84 (0.74–0.94)
Included only men with post-RP UI	PFME: 320 Control: 324	4	0.82 (0.57–1.17)
Continence definition- no loss of urine allowed	PFME: 374 Control: 369	7	0.85 (0.72–0.99)
Continence definition- some loss of urine allowed	PFME: 455 Control: 455	8	0.82 (0.67–1.00)

RP: radical prostatectomy, RR: risk ratio, CI: confidence interval, PFME: pelvic floor muscle exercise, BFB: biofeedback, UI: urinary incontinence.

RCT allocated 97 men undergoing RP to a control group (n=47) in which a limited rehabilitation was performed, or to a PFME group (n=50) [89]. In the experimental group, interventions started 5 weeks before and were sustained for a 12-week period after RP. Controls showed a slower UC-recovery and encountered significantly extra urinary leakage, as quantified by one-day pad weight, *vs.* the experimental group.

(2) Pharmacological treatment

DO may be a contributing factor to post-RP UI [90], hence the attempt to improve UC with antimuscarinics. Over the last few years, several studies investigated their efficacy on post-RP OAB symptoms. One small RCT (n=27) found a significant decrease in urge UI with tolterodine 2 mg in comparison with no treatment in the early period after catheter removal [91]. Additionally, two large RCTs demonstrated earlier return to continence with solifenacin [92,93]. Two RCTs showed a significant effect of duloxetine, an antidepressant, in improving SUI after RP [94,95]. Although off-label in many European countries, duloxetine is currently recommended by the European Association Guidelines panel as an effective drug for postoperative SUI, although its side effects should be adequately explained to the patient [96]. Gandaglia et al [97] prospectively assessed a large cohort of RP patients, finding that those who were taking phosphodiesterase type 5 inhibitors (PDE5Is) presented with better UC recovery rates as compared with those left untreated. Conversely, other studies failed to show any benefits after PDE5Is in RP patients [98].

4) Surgical treatments

Surgical therapy for post-RP SUI is an option for patients with unsatisfactory improvements after conservative management (Table 3).

(1) Male slings

Male slings (MS) are considered a feasible alternative to artificial urinary sphincter (AUS) in a number of cases of mild to moderate post-RP UI [96]. Different types of slings are available, and all of them are meant to appropriately reposition the urethra. A clear advantage over AUS is that slings do not require patient's manual dexterity and they are also cheaper [99]. Overall, slings are classified into adjustable and non-adjustable types. Furthermore, depending on the method of insertion, slings can be divided into retropubic and transobturator categories. Currently, there is a range of adjustable MS commercially available; therefore, it is difficult to express an opinion regarding the superiority of one MS against another, due to significant heterogeneity of the available data and lack of long-term follow-up RCTs. In a recent meta-analysis [100], the recovery rate for the fixed slings varied between 8.3% and 87%. Although the overall complication rates were assessed in only a minority of studies, they were significantly more frequent for adjustable *vs.* fixed slings. In both the fixed and the adjustable varieties, pain was regarded as the commonest issue, followed by urinary retention for fixed slings, and infection for adjustable slings [100]. In considering the complications associated with this surgery, it is important to identify their possible predictors. Among them, a history of previous pelvic radiotherapy, an increased UI severity, obesity, and previous UI surgery were all considered crucial to estimate the likelihood of complications [100]. Men failing sling treatment can eventually undergo salvage AUS placement [101].

(2) Artificial urinary sphincter

The AUS, with the most popular being the AMS800, is based on a pressure-regulating balloon located in the pre-vesical space and connected to an inflatable cuff which acts as an all-round urethral compression device, hence regulating urine passage. The control unit

Table 3. Outcomes of AUS and slings for urinary incontinence after radical prostatectomy [4]

Surgical procedure	Number of trial	Overall number of patient	Continence outcome
AUS	16	991	59%–96% (0–1 pad/d)
Slings			
InVance	15	677	16%–87% (cured)
AdVance	4	416	9%–74% (cured)
Others (Remeex, Argus, TOMS)	16	903	17%–79% (cured)

AUS: artificial urinary sphincter.

of this system is placed in the scrotum, allowing the patient to void the bladder. The AUS remains the most established surgery for dealing with post-RP UI, presenting with the largest body of evidence and reporting long-term success ranging from 20% to 89%, hence being currently regarded as the best available option for patients suffering from moderate to severe UI [102]. However, due to the relatively high costs, the non-negligible complication rates and the requirement for appropriate manual dexterity, the AUS may represent an unfeasible option for every single case with post-RP UI [99]. Another possible drawback is that occasional revisions may be required in some patients, with revision and explantation rates varying considerably in the range of 8% to 45% [4,102]. A large retrospective single-institution study found a 5.5% rate of device infection [103]; prompt device removal is the standard management of this complication [4]. Urethral erosion occurs in up to 8.5% (3.3%–27.8%) of implants [104]. As with any device, its components are susceptible to malfunction; the survival expectation of the AUS drops over time, with a 68-month median overall device's longevity [103].

5) Alternative options

(1) Urethral bulking agents

Urethral bulking is a minimally invasive option based on increasing the juxtaposition of the tissues in both the internal and external sphincters. Several different agents (*e.g.*, collagen, teflon, silicone, autologous tissues, hyaluronic acid) have been used. In a recent meta-analysis of 25 studies, the success rates varied widely from 13% to 100% [105]. Due to poor clinical evidence base, further research is required and this approach should therefore be considered when other more established treatments are contraindicated.

(2) Adjustable balloons

The Pro-Act system depends upon the compression force which is provided by two balloons that are located bilaterally to the BN. Adjustable balloons appear to be a valid alternative for patients with mild to moderate post-RP UI; however only small case series evaluated its outcomes in post-surgical setting. A recent retrospective single-institution study [106] focusing on 143 patients who received a post-RP Pro-Act implantation showed that, after a median follow-up of 56 months, 64% of patients showed levels of improvement, with

daily pad use reduced by $\geq 50\%$, and 45% of patients either did not wear any pad or used only one “security” pad per day. The treatment was considered safe, as 90.2% patients showed no complications.

(3) Intravesical onabotulinum toxin A injections

This treatment had been approved for OAB in 2014, following the results of several RCTs. However, there are limited data relating to their use in the post-RP population. In a retrospective series of 11 patients with post-RP OAB, Habashy et al [107] observed a resolution of urgency-UI in 45% after onabotulinum toxin A intradetrusorial injection. Further clinical trials should be carried out to shed more light on the usefulness of this approach.

CONCLUSIONS

RP remains a major cause of UI in men; therefore, during the preoperative assessment patients must be counselled concerning the risk of post-RP UI. Patient's individual features should be well kept in mind, with the aim of better assessing the individual risk of UI. Over the last decade, the advances of surgical technique opened the way to the progress of multiple intraoperative techniques to improve UC outcomes after RP. PFME and pharmacotherapy are reasonable conservative approaches for post-RP UI, even if success rates using these techniques have been inconsistent. Several surgical procedures are currently available to treat post-RP UI. Out of these, AUS showed the longest record of safety and efficacy for patients with moderate to severe UI. MS are an alternative approach, with intermediate data supporting their efficacy. Other less popular options, such as injectable agents or adjustable balloons, should only be considered when more established options are contra-indicated. Further randomized trials should be carried out to compare the different options, and innovation in the field should continue to refine current techniques and produce novel, and possibly more effective, treatment approaches.

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Conflict of Interest

The authors have nothing to disclose.

Author Contribution

Conceptualization: PC, NS. Methodology: PC, AS. Supervision: AS, FM. Writing – original draft: NS, PC. Writing – review & editing: FD, MT.

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