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Outcome and complications of adjustable continence therapy (ProACT™) in the treatment of urinary incontinence after transurethral resection of the prostate: A multicenter study

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Abstract

Aim: To evaluate the outcome of adjustable continence balloons in the treatment of stress urinary incontinence (SUI) after transurethral resection of the prostate (TURP).

Methods: In two tertiary centers, adjustable continence balloons were implanted in 29 patients with post-TURP SUI between 2007 and 2018. Endpoints of this retrospective multicenter study were patient-reported changes in pad count and complications. Dry was defined as no pad or one security pad.

Results: Preoperative urinary incontinence was mild in 7 (24%), moderate in 12 (41%), and severe in 10 (35%) patients. The median follow-up duration was 21 (interquartile range [IQR], 11-43) months. Within 30 days postoperatively, a Clavien-Dindo grade less than or equal to II complication occurred in 24% of the patients. Reintervention rate was 24%. Six and 12 months after implantation, the International Prostate Symptom Score (IPSS) quality-of-life item improved significantly from 5 (IQR, 5-6) preoperatively to 3 (IQR, 1-4.5) and 1 (IQR, 0-3), respectively. At last visit (median 21 months after implantation), the outcome on continence had improved in 76% of the patients, including, 45% dry patients. After a median follow-up of 28 months (IQR, 13-63; N = 23), all but one patient reported improvement on the Patient Global Impression of Improvement (PGI-I) scale. In

Abbreviations: IQR, interquartile range; ICI, International Consultation on Incontinence; PGI-I, Patient Global Impression of Improvement; SUI, stress urinary incontinence; TURP, Transurethral Resection of the Prostate.

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[Correction added on 13 Mar 2019, after first online publication: Table 1 color coding has been changed and Table 2 months to be changed to mo]

detail, 10 patients reported "very much better" condition compared with before the implantation, 10 patients "much better," two patients "a little better," and one patient "no change." Daily pad use decreased from three (IQR, 2-5) to one (IQR, 0-2) pads/day ($P < 0.001$).

Conclusions: This is hitherto, the first study reporting results of adjustable continence balloons in the treatment of post-TURP SUI. The therapy was found to be safe and efficient. The majority of our study population reported improvement on their condition and greater than or equal to 50% reduction in daily pad use.

KEYWORDS

minimally invasive surgical procedures, personal satisfaction, postoperative complications, stress urinary incontinence, transurethral resection of prostate

1 | INTRODUCTION

A transurethral resection of the prostate (TURP) is currently the standard surgical procedure in the treatment of a bladder outlet obstruction caused by benign prostate enlargement.[1,2] A rare but unfortunate complication is post-TURP urinary incontinence.[3] Post-TURP urinary incontinence can be due to damage to the sphincter, pre-existing bladder dysfunction, or new onset bladder dysfunction.[3] According to the International Consultation on Incontinence (ICI), the incidence of post-TURP stress urinary incontinence (SUI) is about 1%, irrespective of the TURP techniques used (ie, monopolar, bipolar, or laser).[3]

Urinary incontinence after prostate surgery can significantly alter a person's quality of life.[4,5] In cases of male SUI secondary to sphincter deficiency, conservative treatment may be tried for periods up to 6 to 12 months in advance of a surgical treatment.[3-5] When conservative treatment fails, several surgical implants are available, such as the artificial urinary sphincter, male sling, and adjustable continence balloons.[3-5] The latter device consists of two periurethrally placed balloons (ProACT™) whose volumes can be adjusted to achieve the optimal balance between voiding pressure and continence.[6] Reported long-term dry rates (no pad or one security pad) range from 45% to 66% with a follow up of 56 to 58 months.[7-9] The majority or all patients included in these studies were treated for SUI after radical prostatectomy. Patients with post-TURP SUI are a different population in view of a different mechanism of injury. Usually, it is damage to the proximal part of the external striated urethral sphincter distal to the verumontanum.[4]

The aim of this retrospective multicenter study was to evaluate the efficacy of adjusted continence balloons in patients with post-TURP SUI. Efficacy and safety were evaluated in terms of achieving continence, changes in pads use, complications, re-interventions and patient-reported estimates of improvement assessed with the Patient Global Impression of Improvement (PGI-I) scale.

2 | PATIENTS AND METHODS

We retrospectively evaluated data prospectively collected from all patients who had the ProACT™ (Uromedica Inc, Plymouth, MN) device implanted as surgical treatment of post-TURP SUI after May 2007 in two tertiary centers: Erasmus University Medical Center in Rotterdam, the Netherlands and Policlinico Tor Vergata in Rome, Italy. Conservative treatment with pelvic floor exercises had failed in all patients. Urethrocystoscopy and urodynamic study were performed to rule out urethral strictures and to evaluate the bladder function. Exclusion criteria were a history of radiotherapy, neurogenic bladder dysfunction, and a male sling or an artificial urinary sphincter (AUS) in situ. The local ethics committee of Erasmus University Medical Center in Rotterdam approved this study (MEC-2017-05 and MEC-2018-1287). The Comitato Etico Policlinico Tor Vergata in Rome gave a general permission to anonymously collect data for scientific purposes.

Preoperative assessment included medical history, anamnestic daily pad count, voiding diary, and International Prostate Symptom Score (IPSS). The preoperative severity of urinary incontinence was determined by the anamnestic daily pad count, classified as mild (1-2 pads), moderate (3-4 pads), or severe (≥5 pads). In each institution, one experienced surgeon had implanted the adjustable continence balloons using the technique described by Hübner and Schlarp.[6] In brief, two

ProACT™ balloons were implanted via two incisions in the perineum, at either side of the bladder neck. Most of the patients were under general anesthesia and some under spinal anesthesia during the procedure. Intravenous cefazolin and metronidazole were given perioperatively as antibiotic prophylaxis. After removal of the transurethral catheter and a successful voiding trial, patients were discharged from the hospital on the day of surgery or the day after. Within a period of 6 months after the implantation, the balloon volume was adjusted at the outpatient clinic by needle puncture of the subcutaneous port in the scrotum. Postoperative assessment included anamnestic daily pad count, IPSS, and complications.

All patients in Rotterdam received an information letter, a three-item questionnaire and a return envelope by post. In Rome, those three questions were asked during the last scheduled outpatient visit. The three questions asked were:

1. "Would you recommend adjustable continence balloons to someone else?" to be answered by yes or no.
2. Which number describes how your condition is now compared to before the adjustable continence balloons: (1) "very much better," (2) "much better," (3) "a little better," (4) "no change," (5) "a little worse," (6) "much worse," (7) "very much worse" (PGI-I scale).
3. How many pads do you use daily?

Other relevant patient characteristics were retrospectively retrieved from the medical charts. Treatment outcome on continence was assessed by the change in preoperative and postoperative anamnestic daily pad use. The definition of "dry" was no pad or a single security pad /day. "Improvement" was defined as a daily pad reduction of greater than or equal to 50% compared with the preoperative situation. "Little/no improvement" was defined as no or less than 50% reduction of daily pad use compared with preoperative. Perception of improvement on condition was assessed with the PGI-I (7-points) scale; a lower score corresponds with a better condition. Complications within 30 days were classified by the Clavien-Dindo Classification of Surgical Complications.[10] Failure of the interventions was defined as explantation with or without revision of adjustable continence balloons, or as an additional surgical procedure because of persistent incontinence, or as acceptance of the situation with persistent incontinence.

Statistical analyses were performed using SPSS version 24.0 (IBM Corp, Armonk, NY). Descriptive statistics are presented as percentages for qualitative variables and median and interquartile range (IQR) for quantitative variables. The Wilcoxon signed-rank test was used to compare preoperative and postoperative quantitative variables. Pearson's χ^2 test was used to compare categories. Time to adjustable continence balloons failure is distributed in a Kaplan-Meier curve. A two-sided $P < 0.05$ was considered statistically significant.

3 | RESULTS

Twenty-nine of 31 eligible patients were included; 26 patients in Rotterdam and five in Rome. Reason for exclusion in two patients was a nonfunctional male sling in situ, both patients were included in Rotterdam. Urinary incontinence was classified as mild in 7 (24.1%), moderate in 12 (41.4%), and severe in 10 (34.5%) patients. Median preoperative anamnestic pad use per day was 3.5 (IQR, 2.3-5.3). The median time between TURP and balloon implantation was 2.2 (IQR, 1.3-3.6) years. TURP had been performed because of lower urinary tract symptoms secondary to benign prostate enlargement. Two patients had prior anti-incontinence surgery with bulking agents. Preoperative assessment of the external urethral sphincter with urethrocystoscopy showed normal findings in 15 (51.7%) patients; three out of 15 patients had severe incontinence. The sphincter remained open in 14 (48.3%) patients; severe incontinence was seen in seven of 14 patients. More severe incontinence was seen in patients with abnormal urethrocystoscopy findings (50.0% vs 20.0%; $P = 0.09$). Patient characteristics are shown in Table 1.

3.1 | Continence outcome

The median number of balloon volume adjustments after implantation was five (Table 1). Six months after implantation, the median pad use per day was 1.0 (IQR, 1.0-1.9); after 1 year it was 1.0 (IQR, 0.0-2.5). The IPSS quality of life score had improved significantly from preoperative 5.0 (IQR, 5.0-6.0) to 3.0 (IQR, 1.0-4.5) 6 months after implantation and to 1.0 (IQR, 0.0-3.0) 1 year after implantation. The median time between implantation and the last outpatient visit was 20.9 (IQR, 10.5-43.4) months. The daily pad use reported at the last visit was 1.0 (IQR, 0.0-2.0). At the last visit, 75.8% (22 of 29) of the patients reported greater than or equal to 50% reduction in daily pad use against the preoperative, including, 44.8% (13 of 29) who had become dry. The seven patients with preoperative mild incontinence were all dry at last visit. In the 12 patients with preoperative moderate incontinence, the outcome at last visit was: dry in four, improved in three, and little or no improvement in five patients. Two of ten patients with preoperative

TABLE 1 Patient and clinical characteristics presented as number (%) or median (interquartile range)

Characteristics (n = 29)[a]	
Age, y	70.5 (66.7-77.7)
Weight, kg	82.0 (75.5-94.0)
BMI, kg/m^2	27.5 (24.8-30.0)
Type of TURP	
Monopolar or bipolar	24 (82.8)
Laser	5 (17.2)
ASA score	
I	3 (10.3)
II	18 (62.1)
III	8 (27.6)
Type of anesthesia	
General	20 (69.0)
Spinal	9 (31.0)
Operating time, minutes (n = 28)	33.0 (26.8-38.5)
Number of adjustments	5.0 (2.0-5.5)
Volume left balloon, mL	5.0 (2.0-6.5)
Volume right balloon, mL	5.0 (2.0-6.5)
Complications within 30 days	
No complication	22 (75.9)
Clavien-Dindo grade I	6 (20.7)
Clavien-Dindo grade II	1 (3.4)

[a]Unless stated otherwise.

severe incontinence were dry, six patients were improved, and two patients had little or no improvement. In the whole study population, one patient needed a single readjustment of the balloons (0.5 mL) more than 5 years after the last adjustment. The other patients had no additional adjustments. Table 2 provides details on daily pad use, the postoperative outcome on continence, and IPSS.

3.2 | Questionnaire

After a median follow-up of 28.1 (IQR, 12.8-62.9) months, 23 patients had completed the three-item questionnaire (response rate 79.0%). Two patients did not respond and four patients (minimal 4 months after the end of follow-up) had died at the time the questionnaire was sent. The reason for death was not related to the surgical procedure. Results are presented in Table 3. All patients would recommend adjustable continence balloons to someone else. Daily pad use improved significantly from 3.0 (IQR, 2.0-5.0) to 1.0 (IQR, 0.0-2.0) pads/day ($P < 0.001$). The outcome on continence had improved in 15 (65.2%) of the patients, including six (26.1%) dry patients. Twenty-two (95.7%) patients reported improvement on the PGI-I scale. In detail, the condition now compared with the condition before the adjustable continence balloons was reported "very much better" in 10 (43.5%) patients, "much better" in 10 (43.5%) patients, "a little better" in two (8.7%) patients, and "no change" in one (4.3%) patient.

3.3 | Complications

In one patient an intraoperative complication occurred, that is, a perforation of the urethra during positioning of the right balloon. The balloon was still placed just lateral to the perforation. In contrast to the other patients, this

TABLE 2 The outcome on daily pad usage, continence, IPSS total, and IPSS QoL, presented as number (%) or median (IQR)

	Preoperative	6 mo after implantation	1 y after implantation	Last visit median FU 20.9 (10.5-43.4) mo
Anamnestic pads/d	n = 29	n = 28	n = 21	n = 29
Median (IQR)	3.5 (2.3-5.3)	1.0 (1.0-1.9)	1.0 (0.0-2.5)	1.0 (0.0-2.0)
P (difference from preoperative)[a]	–	< 0.001	0.004	< 0.001
Postoperative outcome on continence		n = 28	n = 21	n = 29
Dry, n (%)	–	9 (32.1)	6 (28.6)	13 (44.8)
≥50%-99% reduction in daily pad use, n (%)	–	12 (42.9)	7 (33.3)	9 (31.0)
Little or no improvement, n (%)	–	7 (25.0)	8 (38.1)	7 (24.1)
IPSS total	n = 20	n = 25	n = 15	
Median (IQR)	13.0 (10.3-16.0)	7.0 (4.0-14.5)	6.0 (3.0-10.0)	–
P (difference from preoperative)[a]	–	0.001	0.007	
IPSS QoL	n = 20	n = 25	n = 15	
Median (IQR)	5.0 (5.0-6.0)	3.0 (1.0-4.5)	1 (0.0-3.0)	–
P (difference from preoperative)[a]	–	0.001	0.005	–

Abbreviations: FU, follow-up; IPSS, International Prostate Symptom Score; IQR, interquartile range; QoL, quality of life.
[a]The Wilcoxon signed-rank test was used to compare preoperative and postoperative results.

TABLE 3 The outcome on the three-item questionnaire presented as number (%) or median (IQR)

Results of prospective follow-up	
Postoperative follow-up in months	28.1 (12.8 – 62.9)
Recommend balloons to someone else?	
Yes	23 (100)
No	–
PGI-I scale	
Very much better	10 (43.5)
Much better	10 (43.5)
A little better	2 (8.7)
No change	1 (4.3)
A little worse	–
Much worse	–
Very much worse	–
Daily pad use	
Preoperative	3.0 (2.0-5.0)
Postoperative	1.0 (0.0-2.0)
Postoperative outcome on continence	
Dry	6 (26.1)
50%-99% reduction in daily pad use	9 (39.1)
Little or no improvement	8 (34.8)

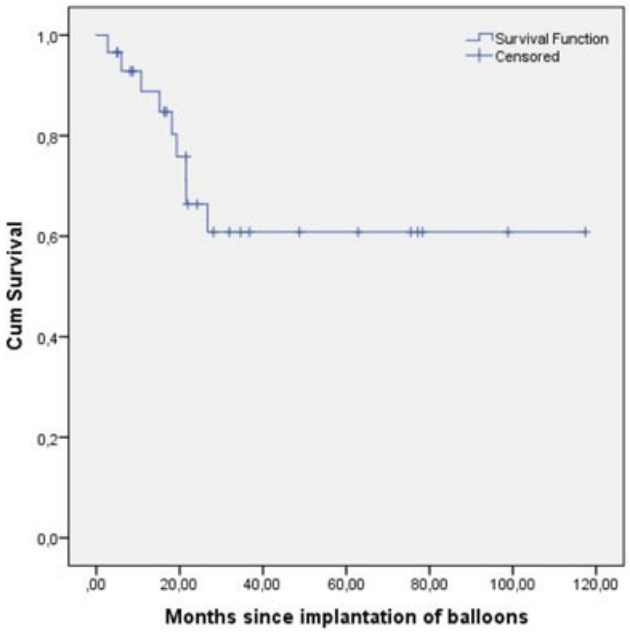

FIGURE 1 Failure-free survival after implantation of balloons distributed in a Kaplan-Meier curve

patient was discharged from the hospital with a transurethral catheter. Five days postoperatively, prophylactic antibiotics were started and the transurethral catheter was removed. At 6 and 12 months postoperative, his pad use was improved from 6 pads/day preoperative to 2.5 and 1.5 pads/day, respectively.

Twenty-two (75.9%) patients were complication-free within 30 days postoperatively. The remaining seven patients had acute urinary retention. The balloon volume was reduced in one patient, which resulted in a successful voiding trial. In the other six patients, the transurethral catheter was replaced and removed at day 5 or 7 with oral antibiotics started at approximately the removal time. In one of these patients, epididymitis was treated with oral antibiotics 3 days after removal of the transurethral catheter.

Failure of the intervention was seen in nine (31.0%) patients after a median follow-up of 18.1 (IQR, 8.4-21.6) months. The failure-free survival curve is presented in Figure 1. Four patients had unchanged urinary incontinence of whom two accepted the situation. The other two patients had additional surgery with bulking agents. At last visit, the outcome on continence was improved in both patients. One or more replacements were performed in five patients; in two on account of malposition of the balloon and in three on account of a defective of the balloon. A second replacement was necessary in two patients because of erosion of one of the balloons through the urethra. The outcome on continence at last visit was in three patients little or no improvement, and in two patients improvement, including one dry patient. Preoperative severe incontinence was seen in six (66.7%) of the nine patients in whom the intervention had failed vs four (20.0%) of the 20 patients in whom the intervention was successful ($P = 0.014$).

4 | DISCUSSION

The aim of this study was to evaluate the efficacy of adjustable continence balloons in the treatment of post-TURP SUI. After a median follow-up of 21 months, two-thirds (22 of 29) of the patients reported to use fewer pads daily, and 13 of the 29 patients were even dry. All but one patient reported improvement on the PGI-I scale. Within 30 days postoperatively, a Clavien-Dindo grade less than or equal to II complication had occurred in 24% of the patients.

Male postsurgical SUI can be caused by direct surgical injury to the external urethral sphincter or its innervation, though this may coexist with bladder dysfunction.[4,5] Post-TURP SUI is most likely the result of damage to the proximal part of the external urethral sphincter distal to the verumontanum.[4] Several additional mechanisms of sphincteric injury after radical prostatectomy have been suggested, like: ischemia and immobilization by scar, atrophy due to incomplete recovery, direct pudendal nerve injury or shortening of urethra below critical functional length.[11] Regarding the different etiologies of male SUI, presumably, this can have an influence on the outcome of surgical treatment.

A recent systematic review addressed functional outcome and complications in the treatment of male postsurgical SUI with adjustable continence balloons.[12] Eleven studies were included, of which six studies included as well patients with post-TURP SUI in the study population. In one of the excluded studies (because of a patient population of <20) post-TURP SUI patients were included as well. An overview of those seven studies with post-TURP SUI patients is given in Table 4.[6-8,13-16] Nevertheless, none of these studies differentiated outcome after radical prostatectomy and post-TURP. Reported dry rates varied between 4.5% and 67% and reintervention rates varied between 14% and 46% (Table 4). The dry rate (45%) at last outpatient visit and reintervention rate (24%) found in the present study fall within the respective ranges. Additionally, the previously published results of adjustable continence balloons in patients with SUI postradical prostatectomy implanted by one of the surgeons of this study[9] were added to Table 4 to compare with the present study. Overall, results in the literature are slightly similar but important to note, besides the etiology, the size, and duration of follow-up of study populations differ. In short, studies are hard to compare because the etiology of SUI, history of adjuvant radiotherapy, duration of follow-up, different centers and surgeons, and definitions of outcome used in the literature are heterogeneous. Our study is hitherto the first reporting results of adjustable continence balloons in the treatment of post-TURP SUI.

The median postoperative daily pad use remains stable during follow-up (see Tables 2 and 3). Remarkably, we observed a decline of the dry rate at the time the PGI-I scale was answered. The efficacy of the balloons could have been reduced. Another possible explanation for this decline in dry rate could be that continent patients will become much more active in time compared than they were preoperative which can result in more "stress" and a decline in dryness. Furthermore, not all patients responded or could response and, therefore, the decline could also partly be explained by selection bias. Despite the decline of dry rate, the majority experienced improvement on PGI-I.

If conservative treatment fails, the standard in the surgical management of male SUI is AUS.[4,17,18] However, alternatives to AUS, such as male sling and adjustable continence devices, are available. These devices do not require manual manipulation to void. Implantation of adjustable continence balloons is less invasive and has the advantages of adjusting the volume or removing the balloons in the outpatient setting. Besides, opting for more invasive procedures is still possible after removal. The working mechanism of adjustable continence balloons with a successful outcome is contributed by an increase in urethral resistance and increased maximum urethral closure pressure.[19,20]

The ICI reviewed the literature with results of AUS in the treatment of male SUI. Most of the studies included men with post-prostatectomy incontinence related to benign and malignant disease. Success rates range from 59% to 90%, defined by no or 1 pad/day, with a follow-up ranging from 1 to 7.7 years.[3,21] To our knowledge, studies with results of AUS in exclusively post-TURP SUI patients are missing.

Regarding the male sling in the treatment of post-TURP SUI, a few studies are published. Recently a systematic review was published which identified 23 post-TURP patients described in six studies who had undergone a male sling. A successful outcome was described in 78% of the patients with divergent definitions of success (total continence, <2 g loss of urine, ≥50% pad reduction, and subjective improvement in continence).[22] Another study (not included in the above review), reported results of 15 post-TURP patients treated with a male sling with a median follow-up of 70 months.[23] The outcome on continence after implantation of the male sling was improved with a greater than or equal to 50% pad reduction in 60% of the patients, including, 47% dry patients.[23]

It would be interesting to perform trials, preferably randomized, comparing adjustable continence balloons in the treatment of male SUI with other devices, such as a male sling or AUS. To prevent mixed patient populations, future studies should differentiate between patients who have post-radical prostatectomy SUI and those who have post-TURP SUI. Besides, future research to define outcome predictors of adjustable continence balloons could be helpful in clinical practice.

Strengths of our study are the multicenter design and the specific study population. The etiology of the SUI was in all patients post-TURP SUI. These patients are a different population with a different mechanism of injury compared with patients with postradical prostatectomy SUI. Both tertiary centers have around one decade of experience in this type of surgery (10-15 procedures/year in Rome and 25 procedures/year in Rotterdam). Still, the study population was relatively small which hindered defining outcome predictors. Another limitation is inherent to the retrospective design of our study. For example, due to the retrospective design, we used the IPSS in the evaluation of the adjustable continence balloons. The IPSS is widely used in our clinical practice and this data was available. This measure focuses on lower urinary tract symptoms, the IPSS total score and IPSS quality fo life (QoL) item improved significantly after implantation. For this patient population, a condition-specific questionnaire would be more interesting,

TABLE 4 Overview of the current literature on studies which included adjusted balloon therapy in post-TURP stress urinary incontinence

Study	Number of patients	Post-TURP patients, N (%)	Type of TURP specified, N	Post-TURP results reported separately	History of radiotherapy, N (%)	Median/mean months of FU	Definition of dry	Dry, N (%)	≥50%-99% improvement on pads/day, N (%)	Reintervention rate, N (%)	Balloon reimplantation rate, N (%)
Hübner et al[6]	117	6 (5)	6 TURP	NR	2 (2)	13	No or one security pad	78 (67)	NR	54 (46)	54 (46)
Kocjancic et al[13]	64	3 (5)	3 TURP, including HIFU (n = ?)	NR	11 (17)	20	No or one security pad	43 (67)	10 (15)	11 (17)	10 (16)
Gilling et al[14]	37	7 (19)	7 Laser TURP	NR	4 (11)	24	No pads	20 (62)	NR	5 (14)	1 (3)
Giammò et al[15]	18	6 (33)	6 TURP	NR	2 (11)	18	No or one security pad	NR	NR	7 (39)	7 (39)
Roûpret et al[7]	128	8 (6)	8 TURP	NR	30 (23)	56	No or one security pad	85 (66)	NR	23 (18)	17 (13)
Kjaer et al[8]	114	38 (33)	29 TURP 2 Laser TURP 7 Palliative TURP	NR	4 (4)	58	0-1 pad/day or daily leakage <8 g	46 (50)	26 (30)	31 (27)	31 (27)
Venturino et al[16]	22	4 (18)	4 TURP	NR	3 (14)	57	No pads	1 (4.5)	NR	24 procedures	16 (73)
Noordhoff et al[9]	143	0 (0)	–	Only post-RP patients	None	56	No or one security pad	51 (45)	21 (19)	55 (38)	43 (30)
Current study	29	29 (100)	24 TURP 5 Laser TURP	Only post-TURP patients	None	21	No or one security pad	13 (45)	9 (31)	7 (24)	5 (17)

Abbreviations: FU, follow-up; HIFU, high-intensity focused ultrasound; NR, not reported; RP, radical prostatectomy; TURP, transurethral resection of the prostate.

such as the Urogenital Distress Inventory (UDI-6),[24] or the Incontinence Impact Questionnaire (IIQ-7),[24] or the International Consultation on Incontinence Questionnaire (ICIQ).[25] However, the use of these questionnaires is not widely spread and the minimal critical values have not been established.

5 | CONCLUSION

Currently little is known about the efficacy of adjustable continence balloons in the treatment of post-TURP SUI. Adjustable continence balloons seem to be safe and efficient in the treatment of post-TURP SUI. The majority of our study population experienced improvement on their condition and needed fewer pads than before the implantation of adjustable continence balloons. Future research is needed to compare different devices and determine outcome predictors.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

TN, JS, EA, and BB were involved in the study design; TN and EA were responsible for data collection; TN and BB for data analysis and interpretation; TN and BB for manuscript writing; and JS, EA, and BB for critical review of the final script. All authors provided the final approval of the version published.

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