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Outcome and complications of adjustable continence therapy (ProACT™) after radical prostatectomy: 10 years' experience in 143 patients

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Aims: To evaluate our outcomes of the adjustable continence balloons ProACT™ for the treatment of male stress urinary incontinence after radical prostatectomy.
Methods: Between May 2007-August 2016 the ProACT™ was implanted in 143 patients without a history of radiotherapy. Endpoints were patient-reported changes in pad counts and complications. Treatment was considered successful if no pad or just one "security" pad per day sufficed, and improved if daily pad use was reduced by ≥50%.
Results: Incontinence before implantation was mild in 36 (25%), moderate in 57 (40%), and severe in 50 (35%) patients. Complications within 30 days were classified by the Clavien-Dindo classification; eight (5.6%) grade I, three (2.1%) grade II, three (2.1%) grade IIIb, and 129 (90.2%) patients had no complication. Revision was done in 43 (30%) patients. The IPSS quality of life item improved significantly from 5.0 (IQR 4.0-5.0) preoperative to 2.0 (IQR 1.0-4.0) and 1.0 (IQR 0.0-3.0) 6 and 12 months after implantation, respectively. After a median follow up of 56 months (range 28 to 79, $n = 112$), 72 (64%) patients were improved, including 51 (45%) patients were successful. Daily pad use decreased from 3.0 to 1.0 (67% reduction). The median outcome on the Patient Global Impression of Improvement scale was "much better," and 97 (87%) patients perceived improvement.
Conclusions: The minimally invasive ProACT™ device showed a clear beneficial continence outcome in patients with stress urinary incontinence after radical prostatectomy. The majority of the patients were satisfied and perceived improvement ≥50% on daily pad use on the long term.

KEYWORDS
minimally invasive surgical procedures, personal satisfaction, postoperative complications, prostatectomy, stress urinary incontinence

Abbreviations: ASA, American Society of Anesthesiologists; AUS, artificial urinary sphincter; IPSS, International Prostate Symptom Score; IPSS QOL, International Prostate Symptom Score Quality of Life Item; IQR, interquartile range; OR, odds ratio; PGI-I, Patient Global Impression of Improvement; PPI, post-prostatectomy urinary incontinence; RP, radical prostatectomy; SUI, stress urinary incontinence.

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1 | INTRODUCTION

Post-prostatectomy urinary incontinence (PPI) is a devastating complication after a radical prostatectomy (RP).[1] In most cases this concerns stress urinary incontinence (SUI) caused by intrinsic sphincter deficiency.[2] The prevalence of SUI after is up to 60%, at varying times after the operation.[3] Usually, SUI has a great negative impact on the patients' quality of life.[2,4] Several approved devices for the surgical treatment for male SUI are available. One of these is the ProACT™ device (Uromedica, Inc., MN) which consists of two periurethrally placed volume-adjustable balloons.[1] The volume of the balloons can be adjusted in an outpatient setting to achieve the optimal balance between voiding pressure and continence.[1] Successful outcome after ProACT™ implantation has been correlated with an increase in urethral resistance and increased maximum urethral closure pressure.[5,6]

Several studies reported a significant reduction of daily pad use and improvement on quality of life index scores with the use of ProACT™. Some studies showed dry or daily pad use improvement rates ranging from 60-92% limited to 12-24 months.[1,7–9] Long term outcomes reported in the literature are hardly available. Three studies with a mixed population of patients with PPI and post transurethral resection of the prostate incontinence with a follow up ranging from 56-58 months showed a 50-66% overall dry rate, defined as "no pad or one security pad,"[10,11] or a 4.5% overall dry rate, defined as "no pads."[12]

Quality of life is an important outcome domain in the treatment of urinary incontinence.[13] Multiple-question condition-specific quality of life instruments give access to many components of the condition, but some are extensive and minimally suitable in the standard clinical setting.[13–15] The Patient Global Impression of Improvement (PGI-I) scale is a global index that provides an overall response to an intervention.[13] It is a simple, easy-to-use and easy to interpret tool in clinical practice and research settings.[13–15] The PGI-I scale has been used and/or has been validated for women with SUI,[13] women with urogenital prolapse,[14] men with lower urinary tract symptoms secondary to benign prostatic hyperplasia,[15] and patients with non-urological diseases.[16]

We have been using the ProACT™ device for the treatment of male SUI after RP at our department Urology since May 2007. The aim of this study is to evaluate our results in terms of success, changes in pads use, complications and patient-reported estimates of improvement assessed with the PGI-I scale.

2 | PATIENTS AND METHODS

2.1 | Study population

We included patients with SUI after RP who had the ProACT™ device implanted between May 2007 and August 2016 after conservative treatment with pelvic floor exercises for 1 year had failed. In all patients the possibility of adjustable continence balloons, male sling, and artificial sphincter were discussed. Patients with an artificial urinary sphincter (AUS) or male sling in situ and those with a history of adjuvant radiotherapy after RP were excluded. Severe SUI and a history of failed and removed urinary incontinence devices (AUS, male sling, or ProACT™) were not exclusion criteria. All included patients underwent a cystoscopy (to assess the presence of a stricture) and an urodynamic study.

2.2 | Intervention

Initially, the ProACT™ device was implanted percutaneously with the use of a rigid 19F cystoscope and fluoroscopy in the anterior posterior direction. After April 2014 a flexible cystoscope was used. The flexible cystoscope provides retrospective intravesical examination during implantation and the use of it may decrease the amount of bladder neck perforations. Furthermore, a flexible cystoscope causes less friction in the bladder neck than a rigid cystoscope and results in less chance of increased SUI just after placement of the balloons. Two separate titanium ports are placed in the scrotum and connected to each of the balloons, respectively, via a tube. All procedures were performed by the same surgeon (BB) with the patient in lithotomy position mostly under general anesthesia, otherwise under spinal anesthesia. Perioperative intravenous antibiotic prophylaxis consisting of cefazolin and metronidazole was given. In most cases patients were discharged from the hospital on the day of surgery after removal of the transurethral catheter and a successful voiding trial. If the bladder neck was perforated intraoperatively the balloon was still placed ipsilaterally of the perforation but as a rule more laterally than without a perforation. In these patients, the transurethral catheter was removed at day 5 or 7 and oral antibiotics were started at approximately the removal time. After the implantation, patients visited the outpatient clinic every 3-4 weeks. Balloon volume was adjusted with maximal 1 mL per balloon per visit by needle puncture of the subcutaneous port sited in the scrotum. This was done by a specialized nurse or by the surgeon until continence was achieved.

2.3 | Design

After obtaining approval by the local ethics committee (MEC-2017-05) all eligible patients were sent an information letter and a three-item questionnaire with a return envelope:

1. The dichotomous question: "Would you recommend ProACT™ to someone else?" to be answered by yes or no.
2. The PGI-I scale: check the number that describes how your condition is now compared to before the ProACT™ implantation: 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."

3. The open-ended question: How many pads do you use daily?

Other relevant data were retrospectively retrieved from the individual patients' medical charts. Preoperative evaluation included medical history, anamnestic pad count, voiding diary, American Society of Anesthesiologists (ASA) classes, and International Prostate Symptom Score (IPSS). The severity of urinary incontinence was classified by the anamnestic pad use per day and ranked as mild (one or two pads), moderate (three or four pads), or severe (5 or more pads or use of condom catheter). Postoperative evaluation included anamnestic pad count, IPSS, and complications. Complications within 30 days postoperative were graded using the Clavien-Dindo Classification of Surgical Complications.[17] Failure of the intervention was defined as explantation with or without revision of the ProACT™ device, or as an additional surgical procedure needed because of persistent incontinence (eg, onabotulinumtoxin-A injected in the bladder wall, sacral neuromodulation, bulking agents, male sling, AUS).

Postoperative continence was assessed according to changes in pad counts. The outcome of the treatment was defined as "successful" when the patient was dry (no pad or a single "security pad" per day); as "improved" when ≥50% reduction in daily pad use against preoperative use was reported; and as "little/no improvement" when <50% reduction in daily pad use against preoperative use was obtained. The PGI-I question served to evaluate a patient's perception of improvement on his condition. A lower score on the 7-point scale corresponds with a better condition than before ProACT™ implantation.

2.4 | Statistical analysis

Statistical analyses were performed using SPSS version 21.0 (IBM Corp., Armonk, NY). A two-sided *P*-value <0.05 was considered statistically significant. 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. A student-*t*-test was used to compare change in pad use and outcome on the PGI-I scale. Time to ProACT™ failure is distributed in a Kaplan-Meier curve. A binary multivariate logistic regression analysis was conducted using the backward method. The parameters (age, BMI, preoperative use of >5 pads per day, time between prostatectomy and implantation of ProACT™, and complications) with $P < 0.05$ on univariate analysis were considered in building the model to investigate the association between these variables and a non-successful outcome.

TABLE 1 Patient characteristics of the study population presented as number (%) or median (interquartile range)

Characteristics, $n = 143$[a]		
Age, years (IQR)	69.0 (66.0-73.0)	
Weight, kg (IQR)	83.0 (78.0-89.0)	($n = 142$)
BMI, kg/m^2 (IQR)	26.1 (24.1-28.1)	($n = 142$)
Type of prostatectomy		
-Retropubic radical prostatectomy	65 (45.5)	
-Laparoscopic radical prostatectomy	33 (23.0)	
-Robot-assisted radical prostatectomy	45 (31.5)	
Previous urological surger		
-Urethrotomy	9 (6.3)	
-Male sling	2 (1.4)	
-AUS	5 (3.5)	
-Bulking agents	3 (2.1)	
-AUS and urethrotomy	1 (0.7)	
-Male sling and ProACT™ in different clinic	1 (0.7)	
Incontinence severity before		
-mild: 1-2 pads/day	36 (25.2)	
-moderate: 3-4 pads/day	57 (39.8)	
-severe: 5 or more pads/day	50 (35.0)	
ASA score		
-I	27 (18.9)	
-II	95 (66.4)	
-III	21 (14.7)	
Type of anesthesia		
-Spinal	18 (12.6)	
-General	125 (87.4)	
Operating time, minutes (IQR)	69.0 (60.0-77.0)	($n = 123$)
Number of adjustments, *n* (IQR)	4.0 (2.0-6.0)	($n = 139$)
Volume left balloon, mL (IQR)	4.5 (2.5-7.0)	($n = 134$)
Volume right balloon, mL (IQR)	4.5 (2.5-7.0)	
Died		
-Reason unknown, after follow up	5	
-Malignancy	4	
-Multi organ failure	1	
-Suicide	1	

[a] Unless stated otherwise.

3 | RESULTS

A total of 143 out of 150 patients were included; the median follow up period was 46.0 (IQR 21.0–76.0) months. Seven patients with a sling or AUS in situ were excluded. Patient characteristics are shown in Table 1. The median time between prostatectomy and ProACT™ implantation was 37.0 months (IQR 20.0-87.0 months). Twenty-one (14.7%) patients had undergone prior anti-incontinence surgery with bulking agents, AUS, urethral sling, urethrotomy, and/or ProACT™ in various hospitals. At the time the questionnaires were sent 11 patients were deceased. Overall, the median preoperative anamnestic pad use per day was 3.5 (IQR 2.0-5.0, $n = 143$). Urinary incontinence was classified

as mild in 36 (25.2%), moderate in 57 (39.8%), and severe in 50 (35.0%) patients.

3.1 | Continence outcome

After implantation and a median of four balloon volume adjustments daily pad usage had decreased significantly from a median of 3.5 (IQR 2.0-5.0) pads per day preoperatively to a median of 1.0 (IQR 0.0-2.0) pads per day at 6 months and 0.0 (IQR 0.0-2.0) pads per day at 1 year (Table 2). Six months after implantation 72.9% (97/133) patients had ≥50% reduction in daily pad use against preoperative, including 47.4% (63/133) who had become dry (no pad or one security pad per day). After 1 year 50.6% (48/95) patients were dry (no pad or one security pad per day) of the 77.9% (74/95) patients whose daily pad use was reduced with ≥50%. The score on the IPSS quality of life item (IPSS-QOL) had improved significantly from 5.0 (IQR 4.0-5.0) preoperative to 2.0 (IQR 1.0-4.0) 6 months after implantation and 1.0 (IQR 0.0-3.0) 12 months after implantation (Table 2).

3.2 | Questionnaire

The questionnaires were sent to 132 patients with a response rate of 120 (90.9%). The median time between the implantation of ProACT™ and the questionnaire was 59.0 (IQR 29.0-87.0) months. One hundred and six (88.3%) patients would recommend the ProACT™ to someone else, eight (6.7%) not, and six (5.0%) did not answer this question. In eight (6.7%) patients who responded on the questionnaire, the ProACT™ has been removed; in three patients an AUS was implanted; in two patients a male sling was implanted; two patients accepted the incontinence; and one patient was on the waiting list for the ProACT™. One hundred and twelve (93.3%) patients had the ProACT™ in situ and 32 (28.6%) responders had one or more ProACT™ revisions. The daily pad use of the 112 responders with ProACT™ in situ was significantly reduced from 3.0 (IQR 2.0-4.9) to 1.0 (IQR 0.0-2.9) pads per day after a median follow up of 56.0 (IQR 27.5-79.0) months ($P < 0.001$, Table 2). This corresponds with a 66.7% decrease in pad use. The median outcome on the PGI-I scale in the patients with the device in situ was 2.0 (IQR 1.0-2.0, $n = 111$). Ninety-seven (87.4%) patients reported improvement; 14 (12.6%) no difference or deterioration. The mean difference in pad use before and after the implantation was significantly different in those two groups ($P = 0.03$), namely in the group with improvement on the PGI-I scale mean decrease of 2.5 pad per day (mean pad use pre-operative 3.7) and in the group with no difference or deterioration on the PGI-I scale 0.0 pad per day (mean pad use pre-operative 5.3).

3.3 | Intraoperative complications

Seventeen (11.9%) intraoperative perforations of the urethra occurred. In two cases, there was minimal perforation and patients received antibiotics and the transurethral catheter was removed the same day. The other 15 patients were treated with a transurethral catheter from 5 to 7 days.

TABLE 2 Outcome on daily pad usage, continence, IPSS total, and IPSS QOL, presented as number (%) or median (interquartile range)

	Preoperative	6 months after implantation	1 year after implantation	Median 56 (28-79) months follow-up
	***n* = 143**	***n* = 133**	***n* = 95**	***n* = 112**
Anamnestic pads/day, median (IQR)	3.5 (2.0-5.0)	1.0 (0.0-2.0)	0.0 (0.0-2.0)	1.0 (0.0-2.9)
P-value (difference from preoperative)[a]	-	<0.001	<0.001	<0.001
		n = 133	*n* = 95	*n* = 112
Postoperative outcome on continence				
-Successful, *n* (%)		63 (47)	48 (51)	51 (45)
-≥50-99% reduction in daily pad use, *n* (%)		34 (26)	26 (27)	21 (19)
-Little or no improvement, *n* (%)		36 (27)	21 (22)	40 (36)
	n = 78	*n* = 107	*n* = 65	
IPSS total, median (IQR)	8.5 (4.8-14.0)	6.0 (3.0-10.0)	5.0 (2.0-11.0)	
P-value (difference from preoperative)[a]	-	0.38	0.08	
	n = 81	*n* = 106	*n* = 66	
IPSS QOL, median (IQR)	5.0 (4.0-5.0)	2.0 (1.0-4.0)	1.0 (0.0-3.0)	
P-value (difference from preoperative)[a]	-	<0.001	<0.001	

[a]The Wilcoxon signed-rank test was used to compare preoperative and postoperative results.

TABLE 3 Post-operative complications, <30 days, presented as number, and graded using the Clavien-Dindo classification

	$n = 143$	Cause	Management
No complication	129		
Grade I	8	7 acute urinary retention	Catheter for a week and prophylactic antibiotics around removing the catheter
		1 intraoperative perforation and scrotal hematoma	Catheter for a week and antibiotics
Grade II	3	2 scrotal hematoma and pain	Oral pain medication
		1 infection	Antibiotics
Grade IIIb	3	1 urethral perforation and hematuria	Removed under local anesthetics and new balloons were implanted 2-4 months after removal
		1 infection and intraoperative perforation	
		1 dislocation and pain	

3.4 | Post-operative complications

In Table 3 the short-term (<30 days) post-operative complications and management are summarized. By the Clavien-Dindo classification, three (2.1%) complications were grade IIIb. Two (1.4%) patients had post-operative pain. A total of 129 (90.2%) patients had no complication. On the long term (>30 days), 78 (55.7%) patients had no complication. There were 79 (55.2%) patients without failure of the ProACT™. One or more revisions had been done in 43 (30.1%) patients, mostly because of an unilateral balloon defect (Table 4). Two patients received an AUS after one ProACT™ revision and one patient after two ProACT™ revisions. After balloon failure nine (6.3%) patients accepted the situation. An additional surgery was given to six (4.2%) patients (eg, onabotulinumtoxin-A injected in the bladder wall, sacral neuromodulation, bulking agents). Six (4.2%) patients with failure of the ProACT™ received a different device after removing the balloons (four patients an AUS and two patients a male sling). The failure-free survival after ProACT™ implantation is shown in a Kaplan-Meier curve (Figure 1).

After a median follow up of 56.0 months univariate logistic analysis showed, intraoperative perforation (OR 13.89, $P = 0.012$), short (OR 8.00, $P = 0.001$) and long term (OR 6.83, $P < 0.001$) complication, and the number of adjustments of the balloons (OR 1.47, $P < 0.001$) were significant parameters. Whereas age ($P = 0.431$), BMI ($P = 0.942$), time between prostatectomy and implantation of ProACT™ ($P = 0.889$), and pre-operative >5 reported pads per day ($P = 0.183$) were not significantly parameters and were not considered in building the model. Multivariate logistic regression analysis showed short term complications (OR 8.41, $P = 0.004$) and the number of adjustments of the balloons (OR 1.46, $P = 0.002$) were both independently associated with a non-successful outcome.

4 | DISCUSSION

The aim of this study was to evaluate our results with the implantation of the ProACT™ device, with a focus on the patients' perception of improvement after implantation. After a median follow up of 56 months, 112 patients with ProACT™ in situ reported a 45% dry rate and a 64% improvement of continence rate. The dry rate in our study is within the range (4.5-66%) reported in studies with comparable follow up.[10–12] Venturino et al[12] defined dry as "no pads" versus "no or one security pad" in our study and the studies of Kjaer et al[10] and Rouprêt et al.[11] Further, the decrease in daily pad use (67%) in our study is more beneficial than reported in other studies with comparable follow up, ranging from 34% to 65%.[10–12] However, patient baseline characteristics were not comparable with those in other studies.[10–12] Our study population were men with SUI after RP without a history of adjuvant radiotherapy and we did not include patients with SUI after a transurethral resection of the prostate. A recently

TABLE 4 Reasons of ProACT™ reinterventions, presented in numbers (%)

ProACT™ reinterventions	First redo	Second redo	Third redo	Fourth redo
Defect of the balloon(s)	22 (15.4)	8 (5.6)	1 (0.7)	
Infection	5 (3.5)	1 (0.7)	1 (0.7)	1 (0.7)
Bladder neck perforation	2 (1.4)	2 (1.4)	1 (0.7)	
Erosion	2 (1.4)			1 (0.7)
Persistent incontinence	8 (5.6)			
Migration/dislocation	4 (2.8)	2 (1.4)		
Total	**43 (30.1)**	**13 (9.1)**	**3 (2.1)**	**2 (1.4)**

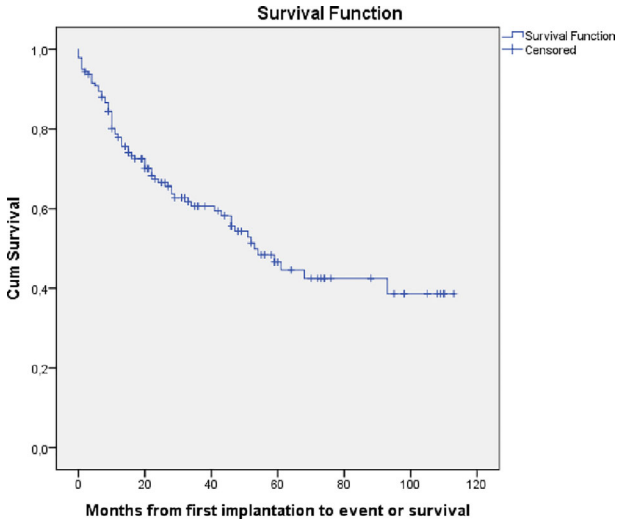

FIGURE 1 Failure free survival after implantation of ProACT™ distributed in a Kaplan-Meier curve

performed systematic review comparing surgical devices for SUI after RP reported an average dry or one safety pad rates of 66%, 48%, and 64% for AUS, male sling, and ProACT™, respectively.[4] Therefore, balloon compression devices like ProACT™ and AUS seem to have similar superior symptom related outcome compared to the male sling, but the AUS was associated with the highest complication rate.[4]

In our study population, revision of ProACT™ was done in 43 (30%) patients. This revision rate is within the range of the literature, ranging from 13% to 73%.[1,10–12] A significant difference was found in the mean number of balloon adjustments between the failure and the failure-free group, 5.4 versus 3.0 adjustments, respectively. This implicates that more tension on the balloon wall results in a higher chance of balloon failure. Another hypothesis could be that patients will become more active with better continence, which gives potentially more traction on the scrotally placed tubes resulting in friction between the balloons and ramus inferior of the pubic bone.

Almost 90% of the patients were satisfied with this treatment, which can be concluded from the scores on the PGI-I scale and the recommendations to others. The median outcome on the PGI-I scale after a median follow up of 56 months was "much better" and 87% perceived improvement. Besides, the change in pad use after the implantation was significantly different between the group with improvement and the group with no difference or deterioration on the PGI-I scale. Experiencing improvement seems to be proportional to improvement on the change in pad use. The PGI-I may be a valuable tool to evaluate a man's overall appraisal of his condition and his response to surgical treatment for SUI in clinical practice and studies. Since many patients are coming from regions outside the direct vicinity of our hospital, they informed themselves via relatives and/or internet on the possibility of the adjustable continence balloons and asked for referral to our hospital. Consequently, almost all patients choose to be implanted with these balloons initially and not with the alternative options. This could give some bias on the satisfaction. Another possible bias could be the time between the question and the operation. The patient could forget how the situation was precisely before the operation. The validity of the PGI-I in men with SUI has not yet been established. However, a good construct validity of the PGI-I has been established in women with SUI and in men with lower urinary tract symptoms secondary to benign prostatic condition.[13,15]

In contrast to Utomo et al[6] severe pre-operative urinary incontinence (>5 pads per day) and longer duration of PPI in the present study were not independently associated with non-successful treatment outcome. This discrepancy is possibly explained by our longer median follow up (56 vs 9 months) and larger number of patients (112 vs 49). Short term complication and the number of balloon adjustments were significantly associated with a non-successful outcome. The intraoperative perforations were included in the short term complications. The majority of the short term complications were due to an intraoperative perforation. A non-successful outcome after a intraoperative perforation might be the result of the more lateral position of the balloon at the site of the perforation and the necessity for more balloon adjustments to achieve continence. It might be concluded not to place the balloon at the site of perforation in the same surgical session but this necessitates an extra operation and results in financial damage due to loss of the balloon.

Limitations of our study are inherent to the retrospective design. Moreover, the individual learning curve of the surgeon involved might have affected the results. As described by Hübner and Schlarp[8] the treatment outcome can be improved with the learning curve.

Strengths of our study are the large number of patients and the relatively long follow up period. In various cohort and feasibility studies the follow up period ranged from 51 to 58 months and the number of patients from 22 to 128.[10–12] The prospectively sent questionnaire provided patient-determined estimates of their outcome and changes in daily pad use, which can be considered a strength.

The results suggest that ProACT™ is the minimal invasive first line surgical treatment for PPI (without stratification of severity of PPI) before opting for a more invasive treatment, such as male sling or AUS. The balloons can be adjusted in the outpatient clinic, in case of failure the device can be easily removed in the outpatient clinic and another treatment or revision can be considered. Further research is needed, however, to determine outcome predictors. A possible outcome predictor could be the anatomy of the bladder neck post-prostatecomy.

5 | CONCLUSION

Our results demonstrate improvement of the continence rate and satisfaction in the majority of patients with SUI after RP without a history of radiotherapy after implantation of adjustable continence balloons. The revision rate should be discussed preoperatively with patients. Future clinical evaluation is, however, necessary to determine outcome predictors.

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CONFLICTS OF INTEREST

The authors declare that they have no conflict of interest.

ETHICAL APPROVAL

The local ethics committee approved this prospective cross-sectional survey study (MEC-2017-05).

AUTHORS' CONTRIBUTION

TN, JS, and BB contributed to study design. TN and BB contributed to data collection. TN, JS, and BB contributed to data analysis and interpretation. TN and BB contributed to manuscript writing. JS and BB contributed to critical review of the final script. Final approval of the version published by all author.

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