Outcomes of Artificial Urinary Sphincter Implantation in Patients with Detrusor Underactivity and **Postprostatectomy Incontinence**

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Purpose: There is insufficient evidence for postoperative outcomes of artificial urinary sphincter (AUS) implantation for postprostatectomy incontinence (PPI) with detrusor underactivity (DU). Thus, we assessed the impact of preoperative DU on the outcomes of AUS implantation for PPI.

Materials and Methods: Medical records of men who underwent AUS implantation for PPI were reviewed. Patients who had bladder outlet obstruction surgery before radical prostatectomy or AUS-related complications that required revision of AUS within three months were excluded. Patients were divided into two groups based on the preoperative urodynamic study including pressure flow study, a DU group, and a non-DU group. DU was defined as a bladder contractility index less than 100. The primary outcome was postoperative postvoid residual urine volume (PVR). The secondary outcomes included maximum flow rate (Qmax), postoperative satisfaction, and international prostate symptom score (IPSS).

Results: A total of 78 patients with PPI were assessed. The DU group consisted of 55 patients (70.5%) and the non-DU group comprised 23 patients (29.5%). Omax was lower in the DU group than in the non-DU group and PVR was higher in the DU group as per a urodynamic study before AUS implantation. There was no significant difference in postoperative PVR between the two groups, although the Qmax after AUS implantation was significantly lower in the DU group. While the DU group showed significant improvements in Qmax, PVR, IPSS total score, IPSS storage subscore, and IPSS quality of life (QoL) score after AUS implantation, the non-DU group showed postoperative improvement in IPSS QoL score.

Conclusion: There was no clinically significant impact of preoperative DU on the outcome of AUS implantation for PPI; thus, surgery can be safely performed in patients with PPI and DU.

Keywords: artificial urinary sphincter; underactive bladder; urinary stress incontinence

INTRODUCTION

adical prostatectomy may improve bladder func-Ntion by resolving bladder outlet obstruction (BOO), which is one of the main pathophysiologies of male lower urinary tract dysfunction. However, radical prostatectomy may worsen lower urinary tract symptoms (LUTS) owing to changes in the neural circuit of the lower urinary tract, including the urethral sphincter. ⁽¹⁾ Radical prostatectomy can cause urethral sphincter deficiency and detrusor function changes such as detrusor underactivity (DU) or detrusor overactivity (DO).⁽²⁾ Postprostatectomy incontinence (PPI) is known to have a significant impact on patients' quality of life (QoL). It is most severe in the first two months post-surgery, but improves over time.⁽³⁾ Unfortunately, some patients only recover partially, which influences their QoL and self-esteem. Surgical management of PPI can be offered to patients who still have incontinence after one year of conservative treatment. One retrospective analysis showed that approximately 3.3% of PPI cases received

anti-incontinence surgery within two years after prostatectomy.⁽⁴⁾ A variety of methods and devices are available for patients undergoing anti-incontinence surgery, including bulking agents, male slings, and artificial urinary sphincters (AUS). AUS has been the gold standard for surgical intervention in PPI, as the literature shows high satisfaction and success rates.⁽⁵⁻

The prevalence of DU after radical prostatectomy has been reported in 14%-51% of patients, and PPI with DU was observed in 44% of patients after radical prostatectomy.⁽⁸⁻¹⁰⁾ One important concern that may arise after bladder outlet procedures for PPI in patients with DU is the possible aggravation of voiding problems, such as urinary retention. A previous study reported that a male sling for PPI did not affect residual urine volume and can be safely used in men who have DU but void normally.⁽¹¹⁾ However, a single report is not sufficient to represent the results of all bladder outlet procedures for PPI with DU, and male slings are sometimes considered a contraindication for patients with DU because of possible urinary retention.⁽¹²⁾ AUS implantation has

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Variables	Total (N = 78)	DU group (N = 55)	Non-DU group (N = 23)	P-value
Age, year	70.2 ± 0.8	69.6 ± 0.9	71.7 ± 1.3	.212
BMI, kg/m ²	24.4 ± 0.3	24.1 ± 0.3	24.7 ± 0.5	.298
History of radiation	24 (30.8)	19 (34.5)	5 (21.7)	.297
Diabetes	15 (19.2)	12 (21.8)	3 (13.0)	.532
Hypertension	44 (56.4)	32 (58.2)	12 (52.2)	.803
Medication on anticholinergics	41 (52.6)	29 (52.7)	12 (52.2)	.964
IPSS total	16.9 ± 1.8	17.5 ± 2.2	15.8 ± 2.9	.658
IPSS storage subscore	8.5 ± 0.8	8.8 ± 0.9	7.8 ± 1.3	.539
IPSS voiding subscore	8.5 ± 1.1	8.7 ± 1.4	8.0 ± 1.9	.782
IPSS QoL score	4.6 ± 0.2	4.7 ± 0.3	4.2 ± 0.4	.335
Urodynamic parameters				
Qmax, mL/s	12.2 ± 0.9	8.6 ± 0.5	20.8 ± 1.6	<.001*
Voided volume, mL	242.1 ± 12.9	224.5 ± 16.3	283.7 ± 18.1	.036*
PVR, mL	49.8 ± 10.6	66.9 ± 14.4	9.9 ± 4.2	< .001*
Maximum cystometric capacity, mL	293.4 ± 11.7	295.4 ± 14.9	288.7 ± 18.1	.798
VLPP, cmH2O	83.4 ± 3.5	81.5 ± 4.4	87.9 ± 5.7	.412
Compliance				1.000
< 20 mL/cmH2O	8 (10.3)	6 (10.9)	2 (8.7)	
≥ 20 mL/cmH2O	70 (89.7)	49 (89.1)	21 (91.3)	
PdetQmax, cmH ₂ O	18.5 ± 2.1	17.7 ± 1.9	20.4 ± 5.4	.637
BCI	79.5 ± 4.1	60.7 ± 2.7	124.2 ± 5.1	< .001*
MUCP, cmH2O	38.4 ± 2.9	39.0 ± 3.4	37.1 ± 5.9	.765
BOO index	7.8 ± 1.8	7.4 ± 1.5	8.6 ± 4.9	.277
Detrusor overactivity	8 (10.2)	7 (12.7)	1 (4.3)	.097

Table 1. Baseline clinical	characteristics and	urodynamic parameters	of enrolled patients

Data are presented as mean \pm standard error of mean or number (%)

Abbreviations: DU, detrusor underactivity; BMI, body mass index; IPSS, International Prostate Symptom Score; QoL, quality of life; Qmax, maximal flow rate; PVR, post-void residual; MUCP, maximal urethral closure pressure; PdetQmax, detrusor pressure at maximal flow; BOO, bladder outlet obstruction; BCI, bladder contractility index; VLPP, Valsalva leak point pressure * Statistically significant.

generally been performed for such patients in clinical practice, but there is a lack of sufficient evidence on postoperative outcomes. As urethral catheterization for urinary retention after AUS implantation is associated with device survival and urethral erosion, it is important to ensure that AUS can be safely used in patients with DU.(13

Here, we compared the outcomes of AUS for PPI between patients with and without DU patients. This study aimed to determine whether AUS can be applied in patients with and without DU without postoperative complications related to voiding function.

MATERIALS AND METHODS

A retrospective review was conducted in patients with PPI who underwent AUS implantation from January 2010 to December 2019 and were followed up for longer than three months post-surgery. The patients' preoperative urodynamic study (UDS) results, including a pressure-flow study, were reviewed. Exclusion criteria included patients who had bladder outlet obstruction surgery before radical prostatectomy or AUS-related complications that required revision of the device within three months of implantation. AUS implantation was performed by one of the two experienced urologists (JCK and WJB). The AMS800TM (American Medical System, Inc., Minnetonka, MN, USA) urinary control system was implanted through a perineal or penoscrotal incision. All patients received single bulbar urethral cuffs (3.5-4.5 cm), had a balloon reservoir placed in the right lower quadrant of the preperitoneal space through a separate lower abdominal incision and had a pump in the scrotum. The cuff size was determined by measuring the periurethral circumference with a cuff sizer enclosed in the AMS800 kit after careful dissection of the urethra. The implanted cuff was tested under urethroscopy before closing the wound to ensure that the urethra was open and closed with adequate pressure from the cuff. The device was activated six weeks after implantation. This study was approved by the ethics committee and the institutional review board of our center. (HIRB-20211221-016)

Preoperative evaluation included age, body mass index, International Prostate Symptom Score (IPSS), and UDS results. UDS was performed in accordance with the Good Urodynamic Practice standards recommended by the International Continence Society (ICS).⁽¹⁴⁾ Investigated postoperative results were maximum flow rate (Qmax), postvoid residual urine volume (PVR), IPSS, stress urinary incontinence (SUI) status, and patient satisfaction. These factors were evaluated three months after AUS implantation. The enrolled patients were divided into two groups, DU and non-DU groups, based on preoperative urodynamics. DU was defined as a bladder contractility index (BCI) less than 100.⁽¹⁵⁾ Surgical method of AUS implantation was the same for every patient, regardless of which group the patient was allocated. Preoperative factors and postoperative results were compared between the two groups. The primary outcome was postoperative PVR. Secondary outcomes included postoperative treatment satisfaction, SUI status, changes in Qmax, changes in IPSS, and complications. Subjective patient outcomes were defined as follows: 'cured' was defined as one or less pad per day for use in social situations, 'improved' was defined as more than a 50% decrease in frequency and amount of urine leakage, and all other outcomes were regarded as 'failed'. Treatment satisfaction was analyzed according to patient responses as 'satisfied', 'neutral', and 'dissatisfied'.

Numerical variables are reported as means with standard errors of the mean. Nominal variables are expressed as counts and percentages. The variables were statisti-

	Total (N = 78)	DU group (N = 55)	Non-DU group (N = 23)	P-value
Postoperative SUI status				.887
Cured	44 (56.4)	32 (58.2)	12 (52.2)	
Improved	31 (39.7)	21 (38.2)	10 (43.5)	
Failed	3 (3.8)	2 (3.6)	1 (4.3)	
Satisfaction				.662
Satisfied	46 (58.9)	33 (60.0)	13 (56.5)	
Neutral	28 (35.9)	19 (34.5)	9 (39.1)	
Dissatisfied	4 (5.1)	3 (5.5)	1 (4.4)	

Table 2. Treatment outcomes between DU group and non-DU group

Data are presented as number (%)

Abbreviations: DU, detrusor underactivity; SUI, stress urinary incontinence.

cally compared using the Student's t-test, paired t-test, Mann-Whitney U test, or Wilcoxon's signed-rank test for continuous variables and the chi-square or Fisher's exact tests for categorical variables. Statistical analyses were performed using IBM SPSS Statistics for Windows (version 20.0; IBM Corp., Armonk, NY, USA). A P-value of < .05 was considered significant.

The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was performed in accordance with the Declaration of Helsinki (as revised in 2013) and the Ethical Guidelines for Clinical Studies. The study protocol was reviewed and approved by the institutional review board of The Catholic University of Korea Bucheon St. Mary's Hospital (approval No. HIRB-20211221-016), and individual consent for this retrospective analysis was waived.

RESULTS

Of the 93 patients who underwent AUS for PPI in our center, 78 were included in the analysis. The DU and non-DU groups consisted of 55 (70.5%) and 23 (29.5%) patients, respectively. The mean follow-up period was

41.2 months. **Table 1** shows the baseline clinical characteristics and preoperative urodynamic results of the two groups. Qmax was lower in the DU group than in the non-DU group (P < .001), while PVR was higher in the DU group than in the non-DU group (P < .001) in the urodynamic study before AUS implantation. The preoperative BCI was significantly lower in the DU group than in the non-DU group (P < .001).

There was no significant difference in postoperative PVR between the DU group and non-DU group (18.7 \pm 3.8 versus 18.9 \pm 3.4, P = .986). Although Qmax after AUS implantation was significantly lower in the DU group (18.2 ± 1.5 versus 27.6 ± 2.6 , P = .002), the subjective cure rates were 58.2% in the DU group and 52.2% in the non-DU group (P = .887) and the satisfaction rates were 60% in the DU group and 56.5% in the non-DU group (P = .662) (**Table 2**). In total patients, the IPSS total score $(16.9 \pm 1.8 \text{ to } 12.2 \pm 1.3, P = .022)$ and QoL score (4.6 \pm 0.2 to 2.6 \pm 0.2, P < .001) were significantly lower postoperatively than the baseline scores. However, postoperative IPSS scores did not differ between the two groups (Figure 1). While the DU group showed significant improvements in Qmax, PVR, IPSS total score, IPSS storage subscore, and IPSS

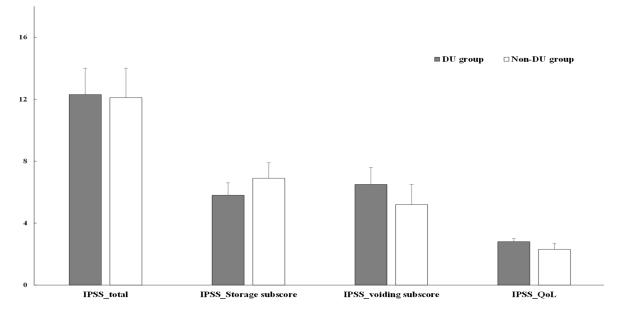


Figure 1. Comparison of postoperative IPSS between DU and non-DU group. IPSS, International Prostate Symptom Score; DU, detrusor underactivity; QoL, quality of life.

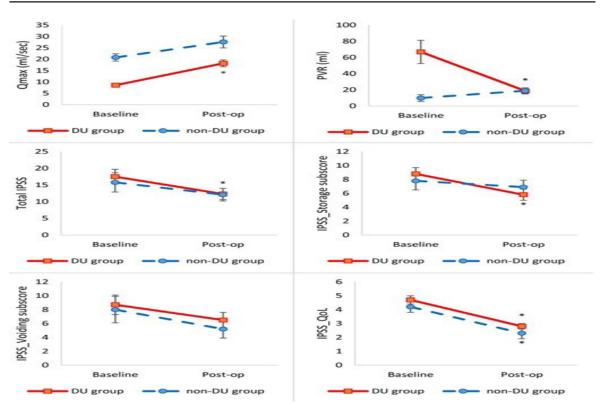


Figure 2. Changes in urodynamic parameters and IPSS after AUS implantation in DU and non-DU group. Qmax, maximum flow rate; PVR, postvoid residual; IPSS, International Prostate Symptom Score; QoL, quality of life; DU, detrusor underactivity. * Statistically significant.

QoL score after AUS implantation, the non-DU group showed postoperative improvement in IPSS QoL score (Figure 2).

One patient in the DU group required clean intermittent catheterization for temporary poor post-obstructive voiding. None of the patients in the non-DU group required catheterization. Urethral stricture or erosion occurred in five patients: four in the DU group and one in the non-DU group (P = 1.000). Mechanical dysfunction occurred in a total of two patients, one in each group (P = .505).

DISCUSSION

Our study showed that voiding function after AUS implantation did not differ significantly regardless of the presence of DU before surgery. Postoperative Qmax was significantly lower in patients with DU than in those without non-DU; however, this did not lead to significant differences in postoperative PVR and satisfaction rates between the two groups.

Voiding or storage function outcomes of AUS implantation for urinary incontinence with concomitant lower urinary tract dysfunction after prostatectomy have been reported since AUS has been used for the management of PPI. Mild bladder dysfunctions, such as small bladder capacity, low compliance, and non-neurogenic bladder overactivity, can sometimes be improved after AUS implantation, and they are not considered contrain-dications to AUS implantation for PPI.⁽¹⁶⁾ There have been reported to depend on whether a patient voided by straining with minimal detrusor contraction, which can reflect decreased detrusor contractility during the voiding phase after prostatectomy. Those reports showed

that about 30%-50% of PPI patients voided by straining, and this voiding pattern did not negatively affect the results of AUS implantation. There were no differences in PVR and pad usage compared with those in patients with normal detrusor voiding patterns.^(17,18) At present, there have been only a few studies on the influence of the cuff on urethral closure pressure in the deactivation or open state of the device. Bentellis et al. reported no significant difference between the preoperative maximum urethral closure pressure (MUCP) and postoperative MUCP in the open-state cuff.⁽¹⁹⁾ We can infer that AUS implantation itself does not negatively influence voiding function, which is well supported by our results showing improved and no difference in postoperative PVR in the DU and non-DU groups, respectively. Queissert et al. suggested that small cuff size (3.5 cm) is a risk factor for urethral erosion.⁽²⁰⁾ This would make surgeons consider complications related to the cuff itself if patients have lower urinary tract dysfunction before the insertion of an AUS. Further studies are needed to elucidate the influence of the cuff on the urethra and associated voiding function.

One of the main mechanisms of DU after radical prostatectomy is detrusor denervation due to pelvic nerve injury during dissection of structures around the semi-nal vesicles.^(21,22) Severe neurological changes or accumulation of neurological damage during radical prostatectomy can cause urinary retention; however, in our study, the average PVR in the DU group before AUS implantation was approximately 67 mL. This was not to the extent that urethral catheterization was required, although the average PVR in the DU group was higher than that of the non-DU group. Previous studies also showed that PVR before AUS implantation was less

than 150 mL, even when voiding functions were impaired in patients with PPI.^(11,17) In the case of PPI, even if bladder function is significantly degraded, a considerable amount of urine can leak out through a weakened urethral sphincter before voiding. Voiding efficiency appears to be preserved by Valsalva voiding or abdominal straining. Therefore, PVR measured before AUS implantation may not be used to evaluate the severity of DU.

In all patients, the subjective cure and satisfaction rates were 56% and 60%, respectively, with significant improvement in the postoperative IPSS total score and QoL score in this study. The presence of DU did not affect postoperative outcomes. Lai et al. also demonstrated that preoperative voiding dysfunction did not negatively affect incontinence outcomes after AUS implantation.⁽²³⁾ A possible reason why DU did not affect the subjective cure rate is that the cuff was selected and applied according to consistent criteria during AUS surgery, regardless of the presence of DU. Additionally, there was no negative effect on storage symptoms such as increased DO after surgery. We believe that DU did not affect satisfaction after surgery because there was no significant difference in PVR between the two groups. The Qmax in each group improved after AUS implantation, although there was a difference in Qmax between the groups.

Sphincteric incompetence has been suggested to be an important cause of PPI, and constant incontinence may lead to bladder dysfunction.^(16,21,24) AUS not only prevents urine leakage but also stabilizes the urethra and bladder. Functional recovery of the bladder may have led to improvements in Qmax and PVR in patients with DU.

This study has several limitations. First, the retrospective and nonrandomized nature of our study should be noted. Second, there is currently no consensus on a standardized urodynamic methodology to diagnose DU with SUI. The main concept underlying DU is voiding dysfunction of the bladder due to low detrusor pressure. Urologists have used surrogate measurements from UDS to quantitatively evaluate detrusor functions, such as Qmax, detrusor pressure at the time of Qmax (PdetQmax), and BCI.⁽²⁵⁾ Jura and Comiter suggested using isometric detrusor contraction pressure (Piso) as a more appropriate measurement of detrusor contractility in patients with PPI due to intrinsic sphincter deficiency, since conventional PdetQmax can be underestimated in such patients.⁽²⁶⁾ However, as there is insufficient data on Piso, it seems too understudied to be used in practice. BCI has been devised to assess the bladder function of males in 'standard' situations, i.e., males with prostate cancer. Unfortunately, we do not have urodynamic data of patients before prostatectomy, therefore we do not know whether the patients had DU or not in the 'standard' situation. However, vesicourethral anastomosis after prostatectomy involves surgical techniques to reduce incontinence. Comparing BCI among postprostatectomy patients may have a role in assessing bladder function and predicting the outcomes of AUS implantation.

Moreover, because we did not perform UDS after AUS implantation, we could not accurately evaluate the change in DU after AUS. In reality, it is not easy to recommend invasive UDS to patients unless there is a serious change in the LUTS after AUS implantation.

In addition, objective evaluations, such as postoperative voiding diaries or pad tests for incontinence, were also insufficient. However, the purpose of this study was to evaluate whether DU negatively affects voiding symptoms after AUS implantation by investigating the representative parameters: Qmax, PVR, and patients' voiding symptom questionnaire.

CONCLUSIONS

DU is relatively common in post-radical prostatectomy patients, and preoperative urodynamic data show differences in some parameters, such as Qmax and PVR, between DU and non-DU patients. However, the postoperative results suggest that AUS implantation could be safely recommended for PPI patients with DU without concerns about urinary retention or voiding dysfunction.

CONFLICT OF INTERESTS

The authors have no conflicts of interest to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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