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**Research Article** 

# Impact of preoperative factors on recovery of continence after artificial urinary sphincter implantation in postprostatectomy incontinence



Dongho Shin <sup>a</sup>, Joonho Ahn <sup>b</sup>, Hyeok Jae Kwon <sup>a</sup>, Kyung Jae Hur <sup>a</sup>, Hyong Woo Moon <sup>a</sup>, Yong Hyun Park <sup>a</sup>, Hyuk Jin Cho <sup>a</sup>, U-syn Ha <sup>a</sup>, Sung-Hoo Hong <sup>a</sup>, Ji Youl Lee <sup>a</sup>, Sae Woong Kim <sup>a, c</sup>, Woong Jin Bae <sup>a, c, \*</sup>

<sup>a</sup> Department of Urology, Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Seoul, Korea

<sup>b</sup> Department of Occupational and Environmental Medicine, Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Seoul, Korea

<sup>c</sup> Catholic Integrative Medicine Research Institute, The Catholic University of Korea, Korea

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# ABSTRACT

**Background:** The purpose of this study was to determine the influence of preoperative factors on the recovery of continence after artificial urinary sphincter (AUS) implantation in postprostatectomy incontinence.

**Materials and methods:** Seventy-two patients who underwent AUS implantation between April 2006 and March 2020 were analyzed. The clinical features and preoperative urodynamic parameters were correlated with the postoperative continence rate using linear and logistic regression analysis. The recovery of continence was defined by the patient requiring no use of a protective urine pad during the 24 hours.

**Results:** Of the 72 patients, 57 (79.2%) recovered continence (dry group), while 15 (20.8%) were wearing more than 1 pad per day (wet group) on the last follow-up visit. In the clinical characteristics, only the interval between radical prostatectomy and AUS (in months) showed a statistically significant difference (35.4  $\pm$  26.2 in the dry group, 22.7  $\pm$  12.2 in the wet group, p = 0.009). Other preoperative clinical features such as the underlying disease, surgical methods, size of prostate, tumor stage, and radio nor hormonal therapy did not present statistically significant differences.

Of the preoperative urodynamic parameters, only the abdominal leak point pressure (ALPP) showed statistical significance when related to surgical outcomes by  $88.6 \pm 33.6$  in the dry group and  $66.1 \pm 29.6$  in wet the group (P = 0.024). The number of patients for whom ALPP was higher than 80 cm H<sub>2</sub>O was 61.4% in the dry group and 20% in the wet group (95% confidence interval: 1.612-25.11). Other preoperative UDS features including detrusor underactivity, maximum urethral closure pressure, and others were not statistically significant.

**Conclusions:** The interval between RP and AUS, as well as the preoperative ALPP, can be possible predictive factors for the surgical outcomes of AUS implantation. In addition, an ALPP of >80 cm H<sub>2</sub>O has a high degree of predictability for success of AUS surgical outcomes in post-RP incontinence.

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# 1. Introduction

Urinary incontinence after radical prostatectomy (RP) is a devastating complication and limits the patient's quality of life.<sup>1</sup> About 15%-20% of men who underwent RP present with urinary

incontinence which persists longer than a year.<sup>2</sup> An artificial urinary sphincter (AUS) placement surgery has been the gold standard treatment for the surgical correction of post-RP incontinence (PPI).<sup>3</sup>

Traditionally, the urodynamic testing before AUS implantation is done to assess the cause of PPI and to detect factors that can affect surgical success.<sup>4</sup>

Studies show that adverse preoperative UDS features such as poor bladder compliance, presence of detrusor overactivity, early sensation of bladder filling, and reduced cystometric capacity before AUS insertion did not negatively affect the post-AUS continence results.<sup>5,6</sup>

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<sup>\*</sup> Corresponding author. Department of Urology, Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, 222, Banpo-daero, Seocho-gu, Seoul, 06591, Korea.

*E-mail address:* bwoong@catholic.ac.kr (W.J. Bae).

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Even so, some urologists are hesitant to perform AUS surgery on patients with PPI who show adverse preoperative UDS features. Patients are carefully selected and only those in the intrinsic sphincter deficiency (ISD) group are likely to receive the AUS treatment.<sup>7,8</sup> ISD, hypermobility of the urethra, and instability of the bladder were commonly considered the causes of PPI, but recent research has called these ideas into question.<sup>9-12</sup> By interpreting UDS features, we aim to determine the underlying causes and mechanisms of PPI post-AUS.

The purpose of this study was to determine the influence of preoperative factors on the recovery of continence after AUS implantation in PPI. Determining whether there are positive preoperative UDS features will help urologists better choose eligible patients likely to have positive AUS surgical outcomes.

# 2. Materials and methods

After approval by the institutional review board, we analyzed a retrospective review of 72 patients with PPI who underwent implantation of the AMS 800<sup>TM</sup> (American Medical System, Inc.) from April 2006 to March 2020. All patients underwent one of the following procedures due to prostate cancer: robot-assisted radical prostatectomy (RARP), laparoscopic radical prostatectomy (LRP), or perineal radical prostatectomy (PRP). The urodynamic studies were performed during preoperative visits. Only virgin AUS (bulbar single-cuff) implantation cases were included. All patients had a balloon reservoir placed in the lower quadrant preperitoneal space and the AUS was activated 4 to 6 weeks after surgery. Exclusion criteria included a lack of preoperative urodynamic study, follow-up less than 3 months after AUS insertion, or revision of AUS due to complications within 3 months.

We compared post-AUS surgical outcomes with the base clinical characteristics and preoperative UDS measurements using linear and logistic regression analysis. Treatment success (recovery of continence) was defined by the patient not requiring the use of urine pads within 24 hours after the follow-up visit.

Multichannel urodynamics (Laborie Medical Technologies Inc.) were performed with patients in a seated position and saline administered into bladder via urethral catheter at 50 ml/min. A dual lumen 6Fr. urodynamic catheter (Sar-Med, Italy) was used for bladder filling and pressure monitoring. For abdominal pressure, a 7.5Fr. rectal balloon catheter (Sar-Med, Italy) was used.

The detrusor pressure was defined as vesical pressure minus abdominal pressure. The abdominal leak point pressure (ALPP) was defined as the Valsalva abdominal pressure which induced urethral leakage. When ALPP was higher than 80cmH<sub>2</sub>O, it was thought to be normal urethral function in accordance with PUB (pelvic support, urethral function, bladder function) classification system.<sup>1</sup> Detrusor overactivity (DO) was characterized as involuntary bladder contractions during the filling phase, both spontaneous and provoked. Bladder compliance was calculated by dividing the volume change by the change in detrusor pressure during the change in bladder volume. Loss of compliance was defined as less than 10 ml/cm H<sub>2</sub>O. Maximum urethral closure pressure (MUCP) was measured as the maximum difference between urethral pressure and intravesical pressure. Maximum flow rate (Qmax) was the maximum measured value of urine flow rate. Pressure at maximum flow (pdetQmax) was the lowest pressure recorded at the maximum measured flow rate. Postvoid residual was defined as the volume of urine left in the bladder at the end of micturition. All definitions conformed to the recommendations of the International Continence Society.<sup>14</sup>

All data analyses were performed using SAS software version 9.4 (SAS Institute, Cary, NC, USA). Student t-tests and Pearson Chisquare tests were used for comparisons of preoperative clinical features and urodynamic measures, respectively. Multivariate analysis was performed using a logistic regression model to evaluate the predictive value of preoperative UDS features associated with post-op continence. Data were considered significant at P < 0.05.

# 3. Results

The patient's demographic data are summarized in Table 1. Of the 72 patients, 34.7% had undergone adjuvant pelvic radiotherapy before AUS surgery. Before patients underwent RP, the mean prostate size was  $36.9 \pm 13.8$  grams. The mean age at RP was  $65.8 \pm 7.4$  while the mean age at AUS implantation was  $69.9 \pm 6.9$  years, so the mean interval between RP and AUS implantation was  $32.8 \pm 24.4$  months. Mean follow-up until last appointment after AUS insertion was  $48.0 \pm 36.3$  months. Of 72, 53 (73.6%) men received LRP, 17 (23.6%) RARP, and 2 (2.8%) PRP. Nervesparing was performed in 12 (16.7%) patients and 11 (15.3%) patients had adjuvant hormone therapy after having RP. The staging of tumors was T2 in 39 (54.2%), T3 in 30 (41.7%), and T4 in 3 (4.2) patients. Median cuff size at last follow-up was  $3.99 \pm 0.39$  cm.

Treatments for incontinence before AUS implantation included the use of anticholinergics in 58 (80.5%) patients and the injection of urethral bulking agents in 9 (12.5%) patients.

As preoperative urodynamic findings described in Table 2, 17 (23.6%) men presented with DO, 8 (11.4%) had loss of compliance, and 22 (30.6%) had pre-op LUTS. The mean bladder capacity was 296.9  $\pm$  110.3 cc and the mean MUCP was 43.1  $\pm$  34.8 cm H<sub>2</sub>O. The mean preoperative ALPP was 83.9  $\pm$  34.9 cm H<sub>2</sub>O, while 38 (52.8%) patients had an ALPP > 80. The mean bladder contractility index was 85.7  $\pm$  43.9 and the mean bladder outlet obstruction index was  $-2.9 \pm 9.2$ . The means of pre- and post-AUS daily pad use were 3.6  $\pm$  2.4 and 0.5  $\pm$  0.2, respectively.

Table 1
Patients demographic features

Variable	n	%
Patients	72	
DM	16	22
HBP	42	58
Height (cm)	$168.1 \pm 5.45$	
Weight (kg)	$68.9 \pm 8.1$	
BMI	$24.4 \pm 2.6$	
Prostate size (g)		
Mean age at RP (y)	$65.8 \pm 7.4$	
Mean age at AUS implantation (y)	$69.9 \pm 6.9$	
Interval between RP and AUS (mo)	$32.8 \pm 24.4$	
Mean follow-up (mo)	$48.0 \pm 36.3$	
Radical prostatectomy	72	100
LRP	53	73.6
RARP	17	23.6
PRP	2	2.8
Nerve-sparing	12	16.7
RT	25	34.7
HT	11	15.3
T stage		
2	39	54.2
3	30	41.7
4	3	4.2
AUS cuff size (cm) at last follow-up	$3.99 \pm 0.39$	
3	1	1.4
3.5	17	26.6
4	39	54.2
4.5	14	19.4
5.5	1	1.4

AUS, artificial urinary sphincter; LRP, laparoscopic radical prostatectomy; RARP, robot-assisted radical prostatectomy; PRP, perineal radical prostatectomy; RT, radiation therapy; HT, hormone therapy.

As shown in Tables 3 and 4, of the 72 patients, 57 (79.2%) recovered continence (dry group), whereas 15 (20.8%) were wearing more than 1 pad per day (wet group) on the last follow-up visit. In the clinical characteristics, only the interval between RP and AUS surgery showed a statistically significant difference ( $35.4 \pm 26.2$  months in the dry group,  $22.7 \pm 12.2$  months in the wet group, p = 0.009). Other preoperative clinical features including the underlying disease, BMI, surgical methods (including nerve-sparing), prostate size, age of RP, age of AUS, adjuvant radiation therapy or hormone therapy, T stage of cancer and the sphincter cuff size did not present statistically significant differences.

Of the preoperative urodynamic parameters, only the ALPP showed statistical significance when related to surgical outcomes by 88.6  $\pm$  33.6 in the dry group and 66.1  $\pm$  29.6 in wet the group (odd ratio: 1.028, confidence interval (CI): 1.004-1.052; P = 0.024). The number of patients for whom the ALPP was higher than 80 cm H<sub>2</sub>O was 61.4% in the dry group and 20% in the wet group (95% confidence interval: 1.612-25.11).

Table 5 shows the logistic regression model of post-AUS dry rate associates with preoperative UDS features (adjusted by age). The ALPP has significant association with post-op continence rate (adjust OR: 1.028; 95% CI: 1.004-1.052). Whereas the patient with higher ALPP than 80cmH<sub>2</sub>O had higher post-op continence rate (adjust OR: 6.364; 95% CI: 1.612-25.11).

# 4. Discussion

The ability of preoperative UDS to predict the outcomes of AUS surgery for patients with PPI is uncertain; most previous studies reported no significant correlation between preoperative UDS parameters and AUS surgical outcomes.<sup>5-7,15</sup> However, our study showed improvements in surgical outcomes when ALPP is higher than 80 cm  $H_2O$ . These data suggest that incontinence after RP was due to the hypermobility of the urethra.

Unlike our outcome, most of the prior studies, PPI is mainly the result of an intrinsic sphincter deficiency resulting from damage while undergoing RP.<sup>12,16</sup> More recent studies suggest that PPI is caused by both anatomical and functional alteration in the sphincteric mechanisms and surrounding supporting pelvic

Tal	ble	2

Preoperative urodynamic features

Urodynamic features	n	%
Presence of DO	17	23.6
Loss of compliance	8	11.4
Pre-op LUTS	22	30.6
Capacity (cc)	296.9 ± 110.3	
MUCP ( $cmH_2O$ )	43.1 ± 34.8	
ALPP ( $cmH_2O$ )	83.9 ± 34.9	
ALPP>cmH <sub>2</sub> O	38	52.8
Qmax (cc/sec)	12.1 ± 7.7	
PdetQmax (cmH <sub>2</sub> O)	22.8 ± 19.7	
PVR (cc)	47.4 ± 30.5	
BCI	85.7 ± 43.9	
BOOI	$-2.9 \pm 9.2$	
Volume of first sensation (cc)	136.9 ± 82.1	
Volume of first urge (cc)	247.3 ± 108.7	
Daily pad use		
Before AUS		
Mean	$3.6 \pm 2.4$	
After AUS		
Mean	$0.5 \pm 0.2$	

AUS, artificial urinary sphincter; DO, detrusor underactivity; LUTS, low urinary tract symptoms; MUCP, maximum urethral closure pressure; ALPP, abdominal leak point pressure; Qmax, maximal urinary flow rate; PdetQmax, detrusor pressure at maximal urinary flow rate; PVR, postvoided residual urine volume; BCI, bladder contractility index; BOOI, bladder outlet obstruction index.

#### Table 3

Post-AUS outcomes association with clinical characteristics

	Pad free	1 or more pads	Р
n	57	15	
DM (%)	19.3	33.33	0.245
HBP (%)	61.4	46.7	0.303
Height (cm)	$167.8 \pm 5.6$	169.2 ± 4.8	0.373
Weight (kg)	$68.9 \pm 8.5$	69.1 ± 6.2	0.905
BMI	$24.5 \pm 2.8$	$24.2 \pm 2.1$	0.704
Prostate size (g)	38.0 ± 14.2	32.7 ± 11.7	0.193
Mean age at RP (y)	65.9 ± 7.8	$65.3 \pm 5.6$	0.759
Mean age at AUS implantation (y)	69.3 ± 7.2	$67.3 \pm 5.4$	0.309
Interval between RP and AUS (mo)	$35.4 \pm 26.2$	22.7 ± 12.2	0.009
Radical prostatectomy			
LRP (%)	75.4	66.7	0.493
RARP (%)	22.8	26.7	0.754
Nerve-sparing (%)	14.0	26.7	0.436
RT	35.1	33.33	0.899
HT	10	1	0.523
AUS cuff size (cm) at last follow-up	$3.96 \pm 0.43$	$4.07 \pm 0.18$	0.168
T stage			0.448
2 (%)	56.1	46.7	
3 (%)	38.6	53.3	
4 (%)	5.3	0	

AUS, artificial urinary sphincter; RP, radical prostatectomy; RARP, robot-assisted radical prostatectomy; LRP, laparoscopic radical prostatectomy; RT, radiation therapy; HT, hormone therapy.

#### Table 4

Post-AUS outcomes association with preoperative urodynamic parameters

	Pad free	1 or more pads	Р
N	57	15	
Urodynamic features			
Presence of DO (%)	21	33.33	0.319
Loss of compliance (%)	12.3	6.7	0.538
Pre-op LUTS (%)	28.1	40	0.372
Capacity (cc)	$303 \pm 109$	275 ± 118	0.394
MUCP (cmH <sub>2</sub> O)	42.1 ± 34.1	47.3 ± 38.5	0.609
ALPP ( $cmH_2O$ )	88.6 ± 33.6	$66.1 \pm 29.6$	0.024
ALPP>80cmH <sub>2</sub> O(%)	61.4	20	0.008
Qmax (cc/sec)	$12.1 \pm 8.1$	$12.0 \pm 6.2$	0.969
PdetQmax (cmH <sub>2</sub> O)	$22.5 \pm 20.6$	$24.0 \pm 16.3$	0.802
PVR (cc)	$52.04 \pm 28.7$	34.3 ± 18.3	0.550
BCI	86.2 ± 47.6	$84.0 \pm 26.8$	0.815
Volume of first sensation (cc)	141.3 ± 85.7	$120 \pm 66.8$	0.375
Volume of first urge (cc)	$252.6 \pm 107.3$	227 ± 115.4	0.420

ALPP, abdominal leak point pressure; AUS, artificial urinary sphincter; DO, detrusor underactivity; LUTS, low urinary tract symptoms; MUCP, maximum urethral closure pressure; Qmax, maximal urinary flow rate; PdetQmax, detrusor pressure at maximal urinary flow rate; PVR, postvoided residual urine volume; BCI, bladder contractility index.

structures after RP.<sup>17</sup> Yoshiyuki et al. compared post RARP, LRP, and PRP anatomical structures of women with urinary incontinence which included the sphincteric system and supportive system.<sup>18</sup>

On the other hand, there were studies suggesting a lower Valsalva leak point pressure (VLPP) correlates with a higher degree of incontinence.<sup>15,19</sup> Which might be similar result to our study. Also an author have reported that a VLPP of >100 cm H<sub>2</sub>O has a high predictability for greater success in AdVance male sling placement for the treatment of PPL<sup>8</sup>

Some researchers have hypothesized that PPI is caused by the absence of a prostate along with its fascial and ligamentous structures causing urethral and bladder neck hypermobility,<sup>20,21</sup> which can support present study's result.

At our institution, all laparoscopic and robot-assisted radical prostatectomies were performed via the intraperitoneal retropubic approach. The mobilization of bladder from anterior abdominal wall is performed by making incision to peritoneum from lateral to lateral umbilical ligament on both sides to make the proper plane of

Table 5

The ouds ratio (OK) and 95% connuence interval (CI) of post-AUS dry rate to preoperative ODS reatures from logistic regressi	The odds ratio (OR) and 95% confidence interval (CI) of post-AUS dry rate to preop	perative UDS features from logistic regressio
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	Crude OR (95% CI)	Adjusted OR <sup>a</sup> (95% CI)
Interval between RP and AUS (mo)	1.035 (0.996-1.075)	1.035 (0.995-1.076)
ALPP ( $cmH_2O$ )	1.028 (1.004-1.052)	1.028 (1.005-1.052)
ALPP>80 (cmH <sub>2</sub> O)	6.364 (1.612-25.117)	6.911 (1.680-28.424)

ALPP, abdominal leak point pressure; AUS, artificial urinary sphincter; RP, radical prostatectomy. <sup>a</sup> Adjusting for age.

prostatectomy.<sup>22</sup> This procedure carries the risk of inducing pelvicfloor instability. We believe that the hypermobility of urethra is the reason why our data show improved surgical outcomes when ALPP is higher than 80 cm H<sub>2</sub>O (normal urethral function). Contrarily, Suskind et al found no statistical difference in the bladder neck or urethral position and mobility by evaluating the difference of dynamic MRI feature between continent and incontinent men who underwent RP.23

Most surgeons use intraoperative techniques to reduce urinary incontinence. Common pelvic-floor reconstruction techniques to improve PPI include bladder neck preservation, nerve-sparing, Roccos stitch, Patels stitch, and the maximal urethral length technique.<sup>24</sup> In institutions such as our hospital, where transperitoneal retropubic radical prostatectomies are routinely performed, it would be beneficial to practice additional pelvic-floor reconstruction techniques to prevent PPI. Noguchi et al suggested that the rapid recovery of PPI can be facilitated by preserving the attachment of the prostate ligament to the pubis and suspending vesicourethral anastomosis, thereby fixing the hypermobility of urethra.<sup>21</sup> Because robot-assisted surgery makes it easier to perform additional procedures to reduce PPI, a multicenter study was performed which categorized surgical modifications into three categories: preservation (bladder neck, neurovascular bundle, puboprostatic ligament, pubovesical complex, and urethral length), reconstruction (posterior and anterior reconstruction, reattachment of the arcus tendinous to the bladder neck), and reinforcement (bladder neck plication and sling suspension).<sup>18</sup>

In addition, in present study, interval between RP and AUS insertion showed better continence rate when surgery was performed on mean 35.4 months. Cheryn et al demonstrated that there is a reduction in bladder capacity, detrusor activity, and sphincteric activity immediately after RP. This reduction stabilized thereafter but remained significantly reduced after 3 years.<sup>25</sup> In the Ontario Health Insurance Plan Register, about 3% of patients underwent AUS implantation within a median time of 36 months after RP.<sup>26</sup> There was also a study indicating a higher prevalence of incontinence within the first six months with a tendency to decrease over time.<sup>27</sup> Several studies proved that incontinence does improve with time and most men reach a plateau 1 to 2 years after surgery.<sup>28-30</sup> Stress incontinence of varying degrees also improved with time when evaluated with post-RP UDS.<sup>31</sup> We assume this is because time is required to stabilize the changes in sphincteric activity after RP. Currently there are no guidelines for when AUS surgery should be performed,<sup>2</sup> making our next mission to determine the best time interval between RP and AUS implant.

A multicenter, randomized study comparing functional and oncological outcomes between RARP and LRP at 3 months followup, concluded that patents undergoing robotic prostatectomy had better continence rate than those undergoing laparoscopic surgery by 54% to 46% (p = 0.027).<sup>32</sup> Previous study of our institution (only Seoul St. Mary's Hospital) showed that urinary continence recovered in 77.5% within mean follow-up period of 22.5 months,<sup>33</sup> which were compatible results compared with external studies.

In the present study, there were 10 patients excluded due to complications after AUS surgery. Four patients had their AUS device removed: two due to infections, one because bladder cancer occurred, and one due to malfunction of the device. Six patients underwent revision surgery: four due to re-incontinence, one due to mechanical failure, and one due to infection. These data align with previous studies.<sup>34,35</sup>

While this study was performed with due diligence following appropriate protocols, the relatively small sample size could result in a lack of power to detect more subtle associations. In addition. we did not have UDS data after AUS implantation which represents another limitation in our data. However, these data are available currently, making our next step an analysis of UDS parameters in the post-AUS incontinence group. Which might help us find the reason of surgical failure such as De Novo overactive bladder syndrome in post-AUS incontinence (wet) group.<sup>36</sup>

In conclusion, preoperative ALPP can be predictive factor for surgical outcomes of AUS. And the dry rate of post-AUS improves when the PPI patient has normal urethral function. Also expecting better continence rate by having adequate interval time for sphincteric activity to stabilize.

### Author contributions

DS and WIB contributed to conceptualization and writing-original draft. Data curation was performed by DS, HJK, KJH, HWM, YHP, HJC, SHH, UH, JYL, SWK, and WJB. Formal analysis was performed by DS and JA. Funding acquisition was carried out by SWK and WJB. Writing—review and editing was contributed to DS, **JYL, SWK, and WJB.** 

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## **Conflicts of interest**

The authors declare that there is no conflict of interests for the publication of this article.

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