678 Surgical and patient reported outcomes of artificial urinary sphincter implantation- a multicentre prospective observational study

Yasuhiro Kaiho1, Hitoshi Masuda2, Mineo Takei3, Takahiro Hirayama4, Takahiko Mitsui5, Minato Yokoyama2, Naoki Kawamorita1, Haruo Nakagawa1, Masatsugu Iwamura4, Nobuo Shinohara5 and Yoichi Arai1

1. Department of Urology, Tohoku University Graduate School of Medicine
2. Department of Urology, Tokyo Medical and Dental University
3. Harasanshin Hospital
4. Department of Urology, Kitasato University School of Medicine
5. Department of Renal and Genitourinary surgery, Hokkaido University Graduate School of Medicine

Hypothesis / aims of study

The AMS 800™ artificial urinary sphincter (AUS) remains the gold standard for the treatment of stress urinary incontinence in men. However, there have been few prospective observational studies using validated classifications of complications or standard questionnaires to assess changes in continence status and quality of life (QOL) after surgery. We conducted a multicenter, prospective, observational study to assess short-term outcomes, including QOL, after AUS implantation.

Study design, materials and methods

A total of 135 patients who underwent primary AUS implantation at 5 institutions between 2011 and 2015 were prospectively registered. The patients' clinical characteristics are described in Table 1. Perioperative complications that occurred within 90 days after surgery were classified according to the Clavien-Dindo classification. The number of patients who underwent AUS revision surgery during the observation period and the of patients who did not undergo revision surgery (revision-free rate) were estimated. Cox regression analysis was performed to evaluate potential risk factors for revision surgery.

Eighty-one patients in four of the five institutions were also assessed for changes in continence status and QOL preoperatively and at 1, 3 and 12 months after surgery. Patients who finally underwent AUS revision surgery were excluded. To objectively estimate continence status, the number of pads needed per day was assessed. For subjective estimation of continence status, the first two questions from the International Consultation on Incontinence Questionnaire-Short form (ICIQ-SF), i.e. 'frequency of leakage' and 'usual amount of leakage', were assessed. To estimate the patients' QOL, the third question from the ICIQ-SF, 'interference with everyday life', and all nine questions from the King's health questionnaire (KHQ) were assessed. Additional estimation of the continence status and QOL that especially focused on patients who did not need pads at the last follow-up (no-pad group, n=26) was performed. All research protocols were approved by the ethics committee of our institution.

Table 1. Patient clinical characteristics

Preoperative Status			**Operative parameters**		
Age	73 years (mean)	30-84 (range)	Operative time	115 min (mean)	55-262 (range)
BMI	24.3	24.3-30.4	Blood loss	10 ml	3-142
60min pad test	107 ml	15-580			
24h pad test	520 ml	35-2400	**Complications**		
Major Comorbidities			Intraoperative Complication (n=4)	Vascular injury	2 (1.5%)
	Hypertension	36 (27%)		Peritoneal injury	2 (1.5%)
	Diabetes mellitus	19 (14%)			
	Cerebrovascular disease	11 (8%)	Perioperative complications (n=13)	Wound infection	5 (4%)
	Angina pectoris	10 (7%)		Urinary retention	4 (3%)
ECOG-PS	Grade 0	122 (90%)		Hematoma	2 (1.5%)
	Grade 1	13 (10%)		Others	2 (1.5%)
	Grade 2-4	0			
ASA-PS	Class 1	78 (58%)	Clavian-Dindo classification		
	Class 2	50 (37%)		Grade 1	3 (2%)
	Class 3	7 (5%)		Grade 2	2 (1.5%)
	Class 4-6	0		Grade 3a	3 (2%)
Reason for surgery	Radical prostatectomy	126 (96%)		Grade 3b	5 (4%)
	Urethral injury	2 (1.5%)		Grade 4-5	0
	Neurogenic bladder	2 (1.5%)			
	Total cystectomy	1 (1%)			
Past history	Radiation therapy	25 (19%)			
	Internal urethrotomy	16 (12%)			
	Urethroplasty	2 (1.5%)			

Table 2. Potential risk factors for revision surgery

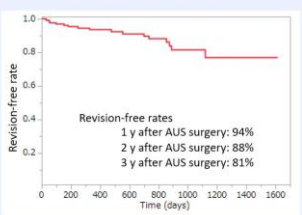
	Univariate		Multivariate	
	HR (95% CI)	P-value	HR (95% CI)	P-value
Age (years)	0.984 (0.908-1.016)	0.129	1.049 (0.954-0.153)	0.312
BMI (kg/m²)	0.946 (0.771-1.161)	0.595	1.030 (0.772-1.373)	0.841
Radiation therapy	1.648 (0.517-4.550)	0.373	1.581 (0.314-7.535)	0.561
Internal urethrotomy	0.549 (0.030-2.722)	0.527	0.580 (0.027-4.038)	0.633
ECOG-PS	1.000 (0.999-1.001)	0.964	9.270 (0.535-182.4)	0.121
ASA-PS	2.293 (0.808-7.416)	0.121	38.45 (3.281-1032.2)	0.002*
Operative time	0.998 (0.982-1.013)	0.838	1.012 (0.987-1.039)	0.342
Blood loss (ml)	0.984 (0.949-1.005)	0.174	0.992 (0.961-1.024)	0.625
Perioperative complication	0.196 (2.388-2.388)	0.418	0.000 (0.000-1.977)	0.144
Diabetes mellitus	2.588 (0.105-0.802)	0.105	10.73 (1.215-94.99)	0.034*
Hypertension	0.361 (0.056-1.312)	0.132	0.846 (0.036-7.409)	0.892
Angina pectoris	0.000 (2.222-2.222)	0.180	0.000 (0.000-40.74)	0.623
Cerebrovascular disease	0.000 (1.703-1.703)	0.128	0.000 (0.000-27.89)	0.599

BMI: body mass index, PS: performance status, ECOG-PS: Eastern cooperative oncology group performance status, ASA-PS: American society of anesthesiologists physical status, * P<0.05

Results

- Perioperative complications were equal to or less than grade 3b in the Clavien-Dindo classification (Table 1).
- The revision-free rate at 3 years was 81% (Figure 1).
- Diabetes mellitus and poor preoperative ASA physical status were significant risk factors for revision surgery (Table 2).
- AUS surgery markedly decreased the number of pads needed and improved scores for every question in both the ICIQ-SF and KHQ (Figures 2, 3, 4).
- However, the number of pads needed, the scores of the first two items in the ICIQ-SF and several items in the KHQ ('impact on life', 'physical limitation score' and 'incontinence severity measure') showed slight, but significant, deterioration at 12 months after surgery compared with those at 1 month after surgery (Figures 3, 4).
- Reductions in continence status and QOL were observed even in the no-pad group (Figure 3).

Figure 1. Artificial urinary sphincter survival curve



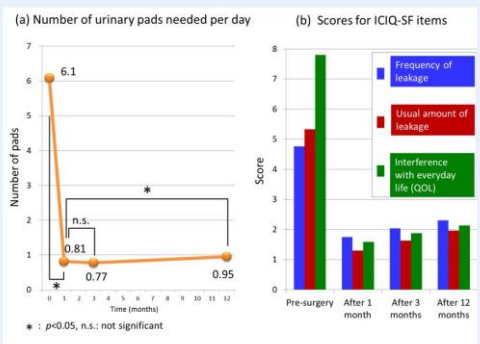
Median observation period : 24 months (range, 3-53)
Revision surgery: 16 (11.9%)
Mechanical failure: 8 (6%)
Infection: 4 (3%)
Erosion: 3 (2%)
Erosion with infection: 1 (1%)
Urethral atrophy: 0

Interpretation of results

Though AUS implantation was safe and durable surgery, revision surgery was needed in a certain percentage of patients.

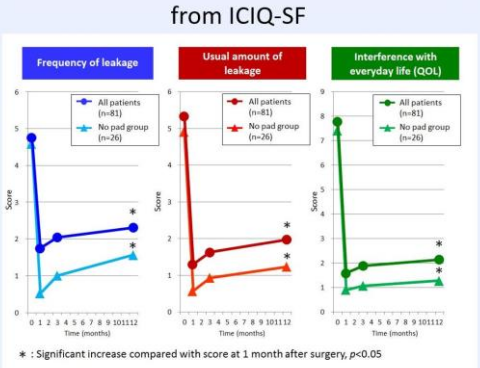
AUS implantation substantially improves pad numbers needed per day and scores of ICIQ-SF and KHQ soon after surgery, however, they showed slight but significant deterioration from relatively early after surgery.

Figure 2. Continence status and QOL



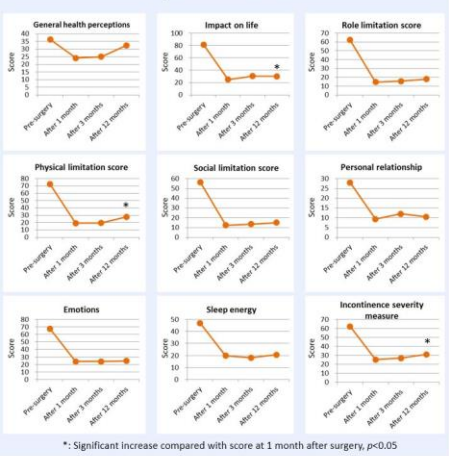
＊ : p<0.05, n.s.: not significant

Figure 3. Changes in the first three questions from ICIQ-SF



＊ : Significant increase compared with score at 1 month after surgery, p<0.05

Figure 4. Changes in King's health questionnaire



*: Significant increase compared with score at 1 month after surgery, p<0.05

Concluding message

- AUS implantation is a safe and durable surgery that substantially improves patient continence status and QOL soon after surgery.
- However, patients start to experience slight, but noticeable, deterioration in continence status and QOL from relatively early, within one year, after surgery.
- One possible reason for this may be urethral atrophy.
- This finding might be helpful in appropriate counselling of patients undergoing AUS implantation.