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Is artificial urinary sphincter surgery safe and effective in elderly males aged 70 years and above?

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Abstract

Objectives: To evaluate the clinical outcomes and patient satisfaction rate between men aged under and over 70 years who underwent artificial urinary sphincter (AUS) surgery.

Methods: A prospective review of all men who received AUS between January 2008 and January 2018 was undertaken with a minimum 24-month review. All patient demographics and surgical outcomes including data on the Incontinence Impact Questionnaire, Patient Global Impression of Improvement (PGI-I) and National Surgical Quality Improvement Program Frailty Index (NSQIP-FI) scores, as well as patient satisfaction rates, were recorded.

Results: Of the 245 AUS implanted, 60 patients were aged ≥70 years with 45 virgin cases and 15 revision AUS. Reduction in mean pad use and weight over 24 hours were significant at 0.21 (0–1) pads and 8 (0–30) g in both groups with no significant difference ($P = 0.76$). Kaplan–Meier estimates of AUS survival showed no significant difference between men aged ≥ and <70 years at 1 year (98% versus 96%; $P = 0.44$). The multivariate logistic regression model showed that radiation (adjusted odds ratio [OR] 3.8, 95% CI 1.4–6.8; $P < 0.01$) was a significant predictor of AUS revision, while age ≥ 70 years (adjusted OR 1.0, 95% CI 0.8–8.8; $P = 0.14$) and frailty (NSQIP-FI ≥ 0.27 adjusted OR 0.9, 95% CI 0.2–7.6; $P = 0.82$) were not. There were no significant differences in PGI-I scores ($P = 0.43$) and overall satisfaction rate (83% versus 84%; $P = 0.44$) between the two groups.

Conclusions: Men aged ≥70 years reported similar clinical efficacy as men aged <70 years in terms of device survival and satisfaction rates following AUS surgery.

KEYWORDS

artificial urinary sphincter, clinical outcomes, device survival, elderly male, patient satisfaction rates

1 | INTRODUCTION

The AMS 800 (Boston Scientific, Minnetonka, Minnesota) artificial urinary sphincter (AUS) is regarded as the standard of care in men with moderate to severe stress urinary incontinence (SUI).[1,2] The recent MASTER trial comparing AUS and male sling found both devices to have reasonable continence outcomes and high satisfaction rate, although the secondary outcome measures were in favor of AUS in terms of operative and postoperative details, patient-reported measures, and adverse events.[3] Despite the introduction of male slings

and other AUS-like devices in the market, the AMS 800 device accounted for most of 150 000 implants globally.[4,5] Although AMS 800 has a proven clinical efficacy and safety record, there are several drawbacks, such as the need for physical dexterity to manually operate the device to void, a predetermined cuff size, and long-term urethral atrophy secondary to constant urethral cuff compression.[5]

Studies have been published which show that AUS implantation in elderly men could be associated with poorer clinical outcomes due to diminishing functional status.[6] Furthermore, many urologists are hesitant to perform AUS surgery in older men due to perceived higher surgical complications and concerns regarding the future need to deactivate the urethral cuff when the man becomes unwell or has poor manual dexterity.[7] Nonetheless, longer longevity in the aging population coupled with the improved medical care has resulted in an increased healthcare demand to improve the quality of life in older men. In men aged 70 and older, it has been shown that SUI has a significant impact on mental well-being, with restricted physical independence and poorer quality-of-life domains.[8]

The present study examines the clinical outcomes and patient satisfaction rates between men aged 70 years and older and those under the age of 70 years, who underwent AUS surgery. We aim to show that men aged ≥70 years have similar clinical outcomes, AUS mechanical malfunction, and satisfaction rates to that of younger men.

2 | METHODS

Following institutional ethics review board approval, all men who underwent AUS surgery between January 2008 and January 2018 were identified in the prospectively collected database. The decision on the age cutoff for males aged 70 years and above as elderly is based on the definition provided by the recent Royal Commission into Aged Care Quality and Safety report on older Australians by the Australian government.[9] All patient demographics and surgical outcomes, including completion of the validated questionnaires such as the Incontinence Impact Questionnaire-Short Form (SF IIQ-7), National Surgical Quality Improvement Program Frailty Index (NSQIP-FI) and Patient Global Impression of Improvement (PGI-I) scores, as well as the overall patient satisfaction rates (on a 5-point scale with 1 being the least satisfied and 5 being most satisfied following AUS surgery), were recorded. The National Surgical Quality Improvement Program Frailty Index (NSQIP-FI), a validated measure of decreased functional status, was used to assess clinical outcomes relating to AUS use, with an NSQIP-FI of ≥0.27 deemed to be of significance.[6] For the PGI-I score, the patient was asked to check the one response that best described "How is your urinary continence now, compared with how it was before you had AUS surgery" on a scale from 1 to 7 (1 meaning very much worse and 7 meaning very much better). All patients were reviewed with a minimal 24-month follow-up period, and an independent data entry clerk was employed to complete the data collection using telephone interviews and review of medical records on the database to minimize reporting bias.

The exact surgical care has been described in the literature,[10] and all patients received antimicrobial prophylaxis cover. In brief, the AUS implantation was performed using a standard perineal approach for the placement of the bulbar urethral AUS cuff and a separate subinguinal incision for the retropubic pressure-regulating balloon and subdartos pump placement. Social continence was defined as 0 to 1 thin urinary pad use. A Kaplan–Meier (KM) survival curve on AUS mechanical failure analysis was generated using a log-rank test to provide a statistical comparison between men aged ≥70 versus < 70 years. This statistical analysis allowed for the fact that not all AUS continued to function after certain years. Mechanical failure was defined as a malfunction of the AUS with recurrent urinary incontinence that required revision or replacement of at least one component, with the term *AUS survival from mechanical failure* being the same as mechanical failure-free survival. An AUS infection was defined as a device infection requiring surgical removal of the AUS device.

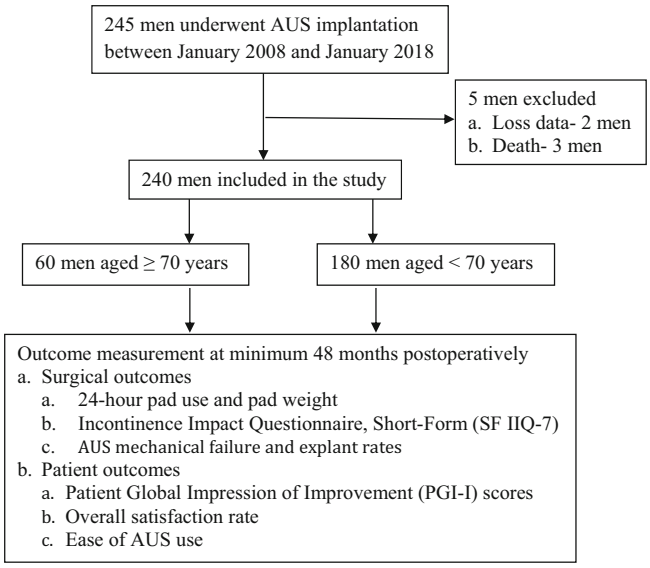

FIGURE 1 Flow diagram of study recruitment. AUS, artificial urinary sphincter

Categorical variables were tested using an independent samples *t* test and a normal distribution of data was observed, while continuous data were reported as means and compared using the Mann-Whitney test. The related clinical factors responsible for AUS revision based on previously published studies[6-8] such as age, history of radiation, hypertension, diabetes mellitus, cardiovascular history, and medical frailty were selected and analyzed by using a multivariate logistic regression model analysis. All statistical analyses were conducted using STATA10 (StataCorp, College Station, Texas), a significance level of $P < 0.05$ was utilized, and all tests were two-sided.

3 | RESULTS

3.1 | Patient demographics

A total of 245 AUS were implanted over the 10 years (Figure 1). Five patients were excluded from the final analysis because data of two

TABLE 1 Baseline characteristics between men aged ≥70 years and < 70 years

	Men aged ≥70 years	Men aged <70 years
Number	60	180
Virgin AUS cases	45 (75.0%)	132 (73.3%)
Revision AUS cases	15 (25.0%)	48 (26.7%)
Mean length of review (mo)	68.2 (±35.5)	76.0 (±26.9)
Cardiovascular risk factors	29 (48.3%)	108 (60.0%)
Neurological disorders	2 (3.3%)	8 (4.4%)
Current ADT use	10 (16.7%)	30 (16.7%)
Causes of SUI (numbers of men)		
a.Radical prostatectomy	a. 28 (46.6%)	a. 88 (48.9%)
b.Radiation therapy	b. 10 (16.7%)	b. 39 (21.7%)
c.Combined surgery and radiation	c. 10 (16.7%)	c. 38 (21.1%)
d.Posttransurethral resection of benign prostate	d. 12 (20.0%)	d. 15 (8.3%)

Note: Values are presented as mean (± standard deviation or percentages).
Abbreviations: ADT, androgen deprivation therapy; AUS, artificial urinary sphincter; SUI, stress urinary incontinence.

TABLE 2 Selected surgical outcomes between men aged ≥70 years and < 70 years

	Men aged ≥70 years	Men aged <70 years
Mean preoperative number of pads used	3.5 (±1.0)	3.8 (±1.3)
Mean postoperative number of pads used	0.29 (±0.5)	0.25 (±0.4)
Mean preoperative 24-h pad weight (g)	478 (±196.3)	435 (±187.5)
Mean postoperative 24-h pad weight (g)	10 (±16.4)	8 (±11.2)
Social continence level (0–1 pad use)	54 (90%)	168 (93%)
PGI-I score	6.8 (5–7)	6.5 (4–7)
Overall satisfaction (score ≥4 out of 5)	50 (83%)	152 (84%)
Reasons for AUS dissatisfaction		
a. Difficulty cycling pump	5	3
a. Persistent SUI or need to wear pad	4	20
a. Surgical-related complications	1	4

Note: Values are presented as mean (± standard deviation or percentages).
Cardiovascular risk factors include hypertension, hyperlipidemia, diabetes mellitus, ischemic heart disease, smoking history; neurological disorders include previous stroke and Parkinson disease; surgical-related complications include revision surgery for cuff erosion or AUS infection.
Abbreviations: AUS, artificial urinary sphincter; PGI-I, Patient Global Impression of Improvement; SUI, stress urinary incontinence.

patients were incomplete, while the other three patients were deceased. We identified 60 patients aged ≥70 years (mean 74.2; 70–85 years old) at the time of the AUS implantation. Of these cases, 45 were virgin AUS cases and 15 revision surgeries. In comparison, there were 132 virgin and 48 revision AUS cases in the group of patients aged <70 years. Complete information was obtained from 240 patients (including 60 men aged ≥70 years). The average length of follow-up for men aged <70 years was 76.0 (24–141) months, and in men aged ≥70 years it was 68.2 (24–138) months. There was no statistically significant difference in medical comorbidities between the two groups (Table 1).

The causes of SUI in men aged ≥70 versus < 70 years were radical prostatectomy (28 versus 88 patients), radiation therapy (10 versus 39 patients), combined prostatectomy and radiation (10 versus 38 patients), and posttransurethral resection of benign prostate (12 versus 10 patients). Twenty-four (40%) men aged ≥70 had failed male sling before AUS implantation, compared to 65 (35%) men aged <70 years. Comparing men aged ≥70 versus < 70 years, there was no statistically significant difference in the mean number of pads used (3.5 versus 3.8; $P = 0.21$) or 24-hour pad weights (478 g versus 435 g; $P = 0.38$).

3.2 | Surgical outcomes

Fifty-six (93%) patients aged ≥70 years and 160 patients (89%) patients aged <70 years achieved social continence following AUS surgery. There was no difference in the cuff size between both groups, with the 4-cm cuff being the most used (65%). Eighteen (7%) patients had transcorporal cuff placement, and 14 (6%) patients received tandem cuffs. There was no documented intraoperative complication in both groups, while minor scrotal hematoma (Clavien-Dindo grade I) was identified in 18 patients (6 men aged ≥70 years and 12 men aged <70 years). Significant decrease in mean pad use over 24 hours (mean 0.21; 0–1 pad) and 24-hour pad weight (mean 8; 0–50 g) were reported in both groups ($P < 0.01$), with no significant difference detected between the two groups ($P = 0.76$) (Table 2). The social continence level was not statistically different between the two groups either (90% versus 93%; $P = 0.41$). Positive changes in SF IIQ-7 domains on physical recreation and social activities were recorded too ($P < 0.01$).

The KM estimates of AUS device survival from mechanical failure showed a minor but nonsignificant difference between men aged ≥ and < 70 years at 1 year (98% versus 96%; $P = 0.44$), with no difference detected in the device mechanical failure rate between the two groups after 36 months (Figure 2). One (2%) patient in the group of men aged ≥70 years and three (2%) in the group <70 years had AUS explant due to cuff erosion. There was one (0.6%) AUS infection reported in the group of men <70 years and none in patients aged ≥70 years.

The NSQIP-FI score was notably greater in AUS revision cases, and 14.5% reported an NSQIP-FI of ≥0.27 (vs 7.6% in primary AUS cases; $P < 0.01$). The multivariate logistic regression model showed

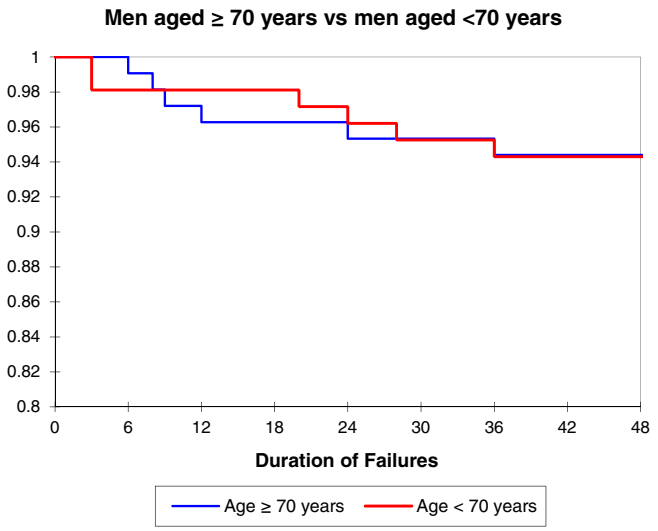

FIGURE 2 The Kaplan-Meier estimates of AUS survival from mechanical failure showed a minor but nonsignificant difference between men aged ≥ and < 70 years at 1 year review (98% vs 96%; $P = .44$), but no difference was detected in the device mechanical failure rate between the two groups (94%) after 36 months. AUS, artificial urinary sphincter

that radiation (adjusted odds ratio [OR] 3.8, 95% CI 1.4–6.8; $P < 0.01$) was a significant predictor of AUS revision, while age ≥ 70 years (adjusted OR 1.0, 95% CI 0.8–8.8; $P = 0.14$) and frailty (NSQIP-FI ≥ 0.27 adjusted OR 0.9, 95% CI 0.2–7.6; $P = 0.82$) were not associated with higher AUS revision rates. During the duration of follow-ups, only two patients (3%) had their AUS devices deactivated due to cognitive decline or loss of manual dexterity.

3.3 | Patient satisfaction

For the PGI-I score in virgin cases, the average score was 6.5, and at least 90% scored 6 or 7. There was no significant difference in the PGI-I scores between the two groups ($P = 0.43$). The overall patient satisfaction rate was not statistically significant between the two groups (83% vs 84%; $P = 0.44$) (Table 2). Most patients (94%) rated the ease of AUS use (on a scale from 1 to 5, with 5 meaning very easy to use) at an average of 4.1, with men aged ≥70 years reporting difficulty manipulating or cycling the pump as commonest reason for dissatisfaction (50%) (Table 2).

4 | DISCUSSION

Due to increasing life expectancy and improved healthcare services, many older men are likely going to require interventions for urinary dysfunction.[11-13] While the AMS 800 device is effective and safe,[1,14] the recent consensus statement reported that AMS 800 surgery can be challenging.[1] Furthermore, there exist some concerns about whether older men are more likely to have complications relating to surgery and associated AUS-specific complications including higher risks of urethral atrophy, difficulty operating the pump, and mechanical revision rates.[6] In our study, there was no statistically significant difference in postoperative reduction in mean pad use over 24 hours and 24-hour pad weight between the two groups, and significant improvement across various SF IIQ-7 domains was reported postoperatively ($P < 0.01$). The Kaplan-Meier estimates of AUS survival from mechanical failure were similar between men aged ≥ and < 70 years at 36 months.

In one study, O'Connor[7] showed that more than 21% of elderly men required cuff deactivation due to deteriorating mental state, physical dexterity, and functional status. More recently, Medendorp[15] reported that men who underwent AUS removal procedures are on average frailer, and the presence of frailty instead of older age is related to higher complication rates. The impact of frailty as measured using the NSQIP-FI has been shown to correlate well with surgical morbidity and mortality.[6,16,17] General frailty is commonly associated with a poorer physiologic reserve and greater vulnerability to adverse events[17] and increases the risks of AUS-related complications secondary to poorer tissue quality, longer wound healing time, and poor nutrition.

In contrast, our study showed that both age ≥ 70 years and frailty were not associated with higher AUS revision rates. Our cohort of men aged ≥70 years may have had better health status as evidenced by the relatively low NSQIP-FI score. Our study found higher NSQIP-FI in men undergoing AUS revision surgery, with 14.5% having an NSQIP-FI of ≥0.27 compared to 7.6% of men with primary AUS surgery ($P < 0.01$). The etiology of SUI in older adults is often multifactorial beyond just direct external sphincteric damage. Elderly people may have multiple age-related lower urinary tract dysfunctions and conditions such as detrusor overactivity, poor compliance, or detrusor underactivity, which can coexist and contribute to the SUI. Mental health, medical comorbidities, physical status, and a supportive network can contribute to or exacerbate SUI too.[18,19] While our study did not capture a full social dataset since this was not the purpose of this study, our patient demographics showed relatively good overall health with reasonable medical comorbidities.

Our study showed that men aged ≥70 years had high satisfaction rates and no issue with AUS use when compared to men aged <70 years ($P > 0.05$). Nonetheless, the difficulty in manipulating or cycling the pump was cited as the commonest reason for patient dissatisfaction (50%), with men aged ≥70 years reporting higher difficulty in manipulating the device for voiding ($P = 0.08$). Unfortunately, our study did not test finger motor strength, sensory proprioception, or manual dexterity, nor was designed to do so. In our study, two patients (3%) had their AUS devices deactivated due to cognitive decline or loss of manual dexterity. Studies have shown that increasing age with declining mental agility and physical activity can result in decreased motor speed, manual dexterity, fingertip responses, and fine precision grip movements.[20,21]

We acknowledge that direct comparison in the surgical outcomes and patient satisfaction rates between men aged < and ≥ 70 years can be biased, and observation may be limited for several reasons. The decision to choose 70 years old as the cutoff for the elderly males in this study rather than 65 years and older is based on the definition of older Australians used by the Royal Commission into Aged Care Quality and Safety[9] and the fact that various countries and societies

consider the onset of old age as anywhere beyond the seventies.[22] Nonetheless, it is important to acknowledge that the aging process is not uniform across the population due to differences in genetics, lifestyle, and overall health.[23] The significantly higher proportion of men aged <70 years potentially biased some of the observations. The NSQIP-FI questionnaire has specific predefined variables and may not account for other confounders such as testosterone level, social support network, and other medical interventions not related to AUS surgery. However, in a relatively matched 1:3 ratio with no statistically significant difference in patient demographics, apart from a higher NSQIP-FI in the older men, our study found that men aged ≥70 years have similar clinical outcomes and patient satisfaction rates to men aged <70 years. The complete data collection coupled with the use of validated instruments and a third-party independent survey in our study adds to the overall strengths of this research.

5 | CONCLUSIONS

Men aged ≥70 years reported similar AUS clinical outcomes and patient satisfaction rates to men aged <70 years in our study. Older age should not be a discriminating factor for AUS surgery in men with SUI.

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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.

DISCLOSURE

The authors declare no conflict of interest.

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