Do larger cuff sizes with artificial urinary sphincter placement increase the risk of leakage after placement?

Samuel Otis-Chapados, MD, Thomas de los Reyes, MD, Ahmad Mousa, MD, Gagan Fervaha, MD, Sidney B. Radomski, MD
Department of Surgery, Faculty of Medicine, University Health Network, Toronto, Ontario, Canada

OTIS-CHAPADOS S, DE LOS REYES T, MOUSA A, FERVAHA G, RADOMSKI SB. Do larger cuff sizes with artificial urinary sphincter placement increase the risk of leakage after placement? *Can J Urol* 2023; 30(1):11419-11423.

Introduction: *To determine whether larger artificial urinary sphincters (AUS) cuff sizes of ≥ 5.0 cm have an impact on urinary incontinence after AUS implantation as compared to cuff sizes ≤ 4.5 cm.*
Materials and methods: *A retrospective chart review of AUS implants performed at our institution from 1991 to 2021. Medical records were reviewed for demographics including body mass index (BMI), cause of incontinence, pelvic radiation, valsalva leak point pressure (VLPP), degree of leakage preoperatively and at 1-year post-AUS surgery, AUS revisions, erosion rate and the need for adjunct medication postoperatively.*
Results: *A total of 110 patients were included in the analysis. Of these, 44 patients had an AUS cuff size of ≥ 5.0 cm and 66 patients had a cuff size ≤ 4.5 cm. After AUS implantation at 1 year both groups had a median pad use of 1 pad per day. Lastly, the erosion rate was higher in the ≤ 4.5 cm cuff group (7.7% vs. 2.4%) but this was not statically significant. In all cases (6 patients) of cuff erosion, each patient had been radiated.*
Conclusion: *AUS cuff sizes of ≥ 5.0 cm do not appear to have a negative impact on the degree of incontinence at 1-year post AUS as compared to those with cuff sizes ≤ 4.5 cm. The erosion rate was higher in those with cuffs ≤ 4.5 cm but was not statistically significant. This would suggest that at AUS implantation, the surgeon should choose a larger cuff if there is any doubt especially in those with radiation.*

Key Words: artificial urinary sphincter, incontinence, cuffs, erosion

Introduction

Stress urinary incontinence (SUI) is defined by the International Continence Society as "the complaint of any involuntary loss of urine on effort or physical exertion (i.e. sporting activities) or on sneezing or coughing".[1] In men, this is commonly due to sphincteric injury due to radical prostatectomy (RP).[2] Radiation treatment can worsen this stress incontinence.[3] In the last two decades, despite the increased adoption of active surveillance, the burden of disease from post-RP or post radiation remains high.[4]

Worse SUI is a negative predictor of quality of life in men after RP.[5] There are several non-surgical approaches to SUI including wearing pads or protection, using a condom catheter or a penile clamp. However, many patients are not satisfied with these options and request a more definite treatment to improve their quality of life on a day-to-

Accepted for publication January 2023

Address correspondence to Dr. Sidney B Radomski, Department of Surgery, University Health Network – University of Toronto, Toronto, ON M5T 2S8 Canada

day basis. They can be much improved by surgical treatment such as bulbar urethral slings and artificial urinary sphincters (AUS). In the "incontinence after prostate treatment" guidelines by AUA/SUFU, the AUS remains the gold standard for the treatment of moderate to severe SUI in males because of the long term durability and effectiveness.[6]

During AUS surgery, there is a great deal of variability in the bulbar urethral circumference between patients. To better fit all patients, there are several cuff sizes of the device that are available. As stated in the literature, patients with radiation are more at risk of failure, leakage after the surgery and erosion.[7,8] In these studies, there is also good evidence that those patients radiated with a smaller cuff size (3.5 cm) are at greater risk of erosion. However, it is unclear in the literature if leakage after the AUS surgery, erosion rate and need of adjunct treatment are significantly different between other cuff sizes with and without radiation.

The purpose of this study was to determine if larger cuff sizes in AUS implantation increase the risk of leakage after placement. Such findings can give guidance to surgeons when there is any doubt as to which cuff size to use intraoperatively.

Materials and methods

In this study, we reviewed all AUS patient's charts (n = 665) performed by a single surgeon at the University Health Network in Toronto between 1991 and 2021. We specifically looked at patients with 5.0 cm and higher cuffs size. We also looked at patients between 2016 and 2021 for those with 4.5 cm and smaller cuffs. Of all these charts, 66 patients were in the ≤ 4.5 cm group and 44 were in the ≥ 5.0 cm. All patients with missing data or patients without a proper follow up of at least 1 year were excluded from the study. All patients had a bulbar approach, and a 61-70 cm H2O reservoir was placed. Information documented for all patients included: age, body mass index (BMI), time between RP and AUS, radiation prior AUS surgery, valsalva leak point pressure (VLPP), number of pads prior and after AUS insertion, the adjunct need of anticholinergics and revision and erosion rate. All data were compiled, and analyses were performed. The institutional research ethics board approved data collection and the study. The main study outcome was the degree of leakage at 1-year post AUS implantation between two groups. The secondary outcome was the erosion rates between the two groups.

Statistical methodology

The data were analyzed using IBM SPSS Statistics version 28 (IBM Corp, Armonk, NY, USA) and Microsoft Excel (Microsoft, Redmond, WA, USA). Q-Q plots and Shaprio-Wilk tests were conducted to establish normality of the data. Continuous data were analyzed using Student t and Mann-Whitney U tests. Categorical data were analyzed using Pearson chi-square tests, Fisher exact tests, and linear regression.

Results

A total of 110 charts of patients with AUS insertion were reviewed and divided in two groups: Group 1- 4.5 cm and smaller cuffs (n = 66) and Group 2- 5.0 cm and higher cuffs (n = 44), Table 1. The reason for incontinence was RP for prostate cancer in all patients.

In the ≤ 4.5 cm cuff group (n = 66), the median age, BMI and VLPP was 67 years old, 26.8 kg/m^2 and 49 cm H2O respectively. The median time elapsed between

TABLE 1. **Patients characteristic between ≤ 4.5 cm and the ≥ 5.0 cm cuff size groups**

Median characteristics	3.5 to 4.5 cm cuff group (n = 66)	5.0 cm cuff and higher (n = 44)	p value
Age at surgery (years)	67	70	0.024
Body mass index	26.8	29.1	0.046
Valsalva leak point pressure (cm H20)	49	40	0.055
Months between RP to AUS	48.0	43.5	0.24
Radiation prior AUS (%)	56.1	45.5	0.33

RP = radical prostatectomy; AUS = artificial urinary sphincter

TABLE 2. **Patients outcomes between ≤ 4.5 cm and the ≥ 5.0 cm cuff size groups**

Characteristics	3.5 to 4.5 cm cuff group (n = 66)	5.0 cm cuff and higher (n = 44)	p value
Number of pads prior AUS (median)	4	4	0.59
Number of pads post AUS (median)	1	1	0.097
Adjunct treatment after (anticholinergic and/or beta-3 agonist) (%)	32.3	30.8	1
Erosion (%)	7.7	2.4	0.4

RP and AUS insertion was 48 months. In this group, 56.1% of patients had radiation prior AUS insertion. As stated in Table 2, patients used overall 4 pads per day preoperatively in this group. After a minimum of 1 year of follow up, most patients did use a median of 1 pad per day for the leakage. The need for adjunct treatment after the surgery (anticholinergic and/or beta-3 adrenergic) was 32.3%. Finally, five patients had erosion in this group (7.7%) and all of them had prior radiation.

In the ≥ 5.0 cm cuff group (n = 44), the median age, BMI and VLPP was 70 years old, 29.1 kg/m^2 and 40 cm H2O respectively. The median time elapsed between RP and AUS insertion was 43.5 months. In this group, 45.5% of patients had radiation prior AUS insertion. As stated in Table 2, patients used overall 4 pads per day preoperatively in this group. After a minimum of 1 year of follow up, most patients did use a median of 1 pad per day for the leakage. The need for adjunct treatment after the surgery (anticholinergic and/or beta-3 adrenergic) was 30.8%. Finally, one patient had erosion in this group (2.4%) and the patient had prior radiation.

There was no significant difference in the number of pads used preoperatively and time from RP and AUS surgery between the two groups. The median age was slightly higher in the those with cuff sizes ≥ 5.0 cm (70 vs. 67 years old; p = 0.024). The median BMI was slightly higher in those with cuff sizes ≥ 5.0 cm (29.1 vs. 26.8; p = 0.046). Although, the VLPP was higher (49 vs. 40 cm H2O) in the ≤ 4.5 cm cuff group it was not significant clinically or statistically (p = 0.06). There was no difference in rates of radiation between groups (56.1 vs. 45.5%; p = 0.33).

After AUS implantation at 1 year both groups had a median pad use of only 1 per day. The use of overactive bladder medication postoperatively was similar (p = 1) between the groups (32.3% in the ≤ 4.5 cm cuff group vs. 30.8% in those with cuffs ≥ 5.0 cm cuff). Lastly, the erosion rate was not statistically significantly different between groups (7.7% vs. 2.4%; p = 0.4). In all cases of cuff erosion (6 patients) each patient had been radiated.

Discussion

Our study examined differences in characteristics and outcomes in patients with different AUS cuff sizes. We did not identify any significant difference in pad use or erosion rates in those with cuff sizes 5 cm or greater compared to those with smaller cuff sizes. Our findings are consistent with other studies that have examined the relationship between cuff size and outcome, and failed to find a significant relationship on multivariate analyses.[9] Rothschild et al examined whether a difference of 4 mm or more between intraoperative urethral circumference and AUS cuff size can affect postoperative outcomes.[10] They found that there was no statistical difference in pad use or patient satisfaction if there was less than 4 mm or 4 mm or more of free space at 4.5 months follow up. They also found that at long term follow up the 4 mm or more space group had statistically significant better continence and patient satisfaction compared to those with space less than 4 mm. However, they did not compare the cuff sizes themselves. This study suggests, as we have found, that larger cuff sizes may not be a risk factor for persistent incontinence after AUS implantation. In our study, we were able to compare cuff sizes between two group: ≤ 4.5 cm cuffs and ≥ 5.0 cm cuffs. We created these groups because most of the large AUS cohort studies revealed that the most frequent cuff size used in the literature is the 4.5 cm.[11,12] As stated in one of these studies, there is a significant increase of erosion with the 3.5 cm cuffs and they stated that cuffs between 4.0 cm and 5.5 cm are the safest, which is nearly all cuff sizes possible. The goal of our study was to better understand if there is a significant difference in leakage, adjunct treatment, and erosion between smaller and larger cuffs. As we found, the number of pads used, and the need for adjunct treatment was the same in both groups. There was more erosion in the ≤ 4.5 cm cuff group (7.7% vs. 2.4%), however this did not reach statistical significance.

One study found that cuff sizes of 5 cm or greater were associated with greater likelihood of required revision surgery; however, after adjusting of confounding variables on multivariate analysis this relationship was nullified.[9] Similarly, a multi-center study looking at dry rates and revision rates found that cuff size was not a significant predictor in either case.[13]

Our initial goal was to compare individual cuff sizes with one another; however, the sample size in each group precluded meaningful statistical analysis and interpretation. In any case, we found that in the ≤ 4.5 cm cuff group, the 4.5 cm cuff represented 82% of all patients (n = 54). In the ≥ 5.0 cm cuff group, 75% of all patients (n = 33) had a 5.0 cm cuff. These two cuff sizes represent 79% (n = 87) of all patients in our study, of which the 4.5 cm cuff is the most frequently used in the literature. Our study showed that between the most frequent cuff size and the one slightly larger, there is no difference between urinary leakage and the need for adjunct treatment. However, a study published in 2021, stated that a shorter time interval between RP and AUS and a lower VLPP could be predictive for leakage after AUS implantation.[14] In our study there was no difference in VLPP (which was low in both groups) and time from RP to AUS in both groups which did not appear to effect continence after AUS implantation.

In our study we found that age and BMI were statistically significant between the two groups. Median age and BMI were slightly higher in the ≥ 5.0 cm cuff group as compared to the ≤ 4.5 cm cuff group (70 vs. 67 years old; BMI of 29.1 vs. 26.8). We believe the difference for both age and BMI between the groups is not clinically significant. Furthermore, despite the differences in age and BMI between the groups, there was no difference in incontinence rates between the two groups examined. This would suggest, that at least in our study, age and BMI are not factors that affect incontinence rates. Queissert et al, found in their study that persistent incontinence occurred with cuff sizes ≥ 5.0 cm.[9] However, in this study BMI was not a factor examined in relation to cuff sizes. Viers et al, showed that those patients with an AUS with higher BMI's had a decreased risk of erosion and that those with a BMI > 30 had statistically less pads per day.[15]

AUS insertion can create, over the long term, complications like leakage, erosion, and urethral atrophy. In the literature, there are conflicting studies about the risk of erosion with the 3.5 cm cuff without radiation.[16,17] Our study showed that smaller cuffs seem to have a higher rate of erosion, although not statistically significant, in comparison with large cuffs. All six patients with erosion in our study previously underwent radiation. This finding fits other studies conclusions about the correlation between AUS and diverse complications after radiation.[11,18] This is important data for all urologists performing AUS implantation in radiated patients since erosion rates are higher. At the time of surgery, when it is unclear which cuff size is appropriate, our data suggests that choosing a larger cuff size does not increase the risk of leakage postoperatively and potentially may reduce the risk of erosion. Bentellis et al, in a recent publication, found that for AUS nonmechanical failures (urethral atrophy or recurrent or persistent stress leakage) the only risk factor for revision was larger cuff sizes.[19] However, this article excluded patients where the AUS was removed or there was a revision due to erosion or infection. Hence, no direct correlation could be made concerning erosion and incontinence rates with different size cuffs.

There are limitations to the conclusions that can be drawn from our study and the data presented. Since it was a retrospective study, the degree of satisfaction and improvement was not documented prospectively using questionnaires pre and postoperatively. Also, we examined complications at 1 year, this may have affected the number of long term complications, like erosion, that may have occurred more than 1 year after AUS implantation. The other limitation that exists is examining two different groups from different time intervals (≤ 4.5 cm cuff group from 2016-2021 and ≥ 5.0 cm cuffs from 1991-2021). Cuffs sizes ≥ 5.0 cm are not as commonly placed as the ≤ 4.5 cm cuff. Hence, a longer time interval was needed to accrue adequate numbers of patients in those with cuff sizes ≥ 5.0 cm. This longer time interval may possibly affect the results of our study (i.e change in surgical technique, complexity of the patients etc.).

Conclusion

AUS cuff sizes of ≥ 5.0 cm do not appear to have a negative impact on the degree of incontinence at 1-year post AUS insertion as compared to those with cuff sizes ≤ 4.5 cm. In our cohort, all patients that experienced erosion had a history of radiation. This would suggest that at AUS implantation, the surgeon should choose a larger cuff size if there is any doubt especially in those with radiation. □

References

1. Haylen BT, de Ridder D, Freeman RM et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *Neurourol Urodyn* 2010;29(1):4-20.
2. Shamliyan TA, Wyman JF, Ping R, Wilt TJ, Kane RL. Male urinary incontinence: prevalence, risk factors, and preventive interventions. *Rev Urol* 2009;11(3):145-165.
3. Das AK, Kucherov V, Glick L, Chung P. Male urinary incontinence after prostate disease treatment. *Can J Urol* 2020;27(S3):36-43.
4. Chen J, Oromendia C, Halpern JA, Ballman KV. National trends in management of localized prostate cancer: A population based analysis 2004-2013. *Prostate* 2018;78(7):512-520.
5. Sacco E, Prayer-Galetti T, Pinto F et al. Urinary incontinence after radical prostatectomy: incidence by definition, risk factors and temporal trend in a large series with a long-term follow-up. *BJU Int* 2006;97(6):1234-1241.
6. Sandhu JS, Breyer B, Comiter C et al. Incontinence after prostate treatment: AUA/SUFU guideline. *J Urol* 2019;202(2):369-378.
7. Guillaumier S, Solomon E, Jenks J et al. Radiotherapy is associated with reduced continence outcomes following implantation of the artificial urinary sphincter in men with post-radical prostatectomy incontinence. *Urol Ann* 2017;9(3):253-256.
8. Mamane J, Sanchez S, Lellouch AG et al. Impact of radiation therapy on artificial urinary sphincter implantation in male patients: a multicenter study. *Neurourol Urodyn* 2022;41(1):332-339.
9. Linder BJ, Rivera ME, Ziegelmann MJ, Elliott DS. Long-term outcomes following artificial urinary sphincter placement: an analysis of 1082 cases at Mayo Clinic. *Urology* 2015;86(3):602-607.
10. Rothschild J, Chang Kit L, Seltz L et al. Difference between urethral circumference and artificial urinary sphincter cuff size, and its effect on postoperative incontinence. *J Urol* 2014;191(1):138-142.
11. Hird AE, Radomski SB. Artificial urinary sphincter erosion after radical prostatectomy in patients treated with and without radiation. *Can Urol Assoc J* 2015;9(5-6):E354-E358.
12. Queissert F, Huesch T, Kretschmer A et al. Artificial urinary sphincter cuff size predicts outcome in male patients treated for stress incontinence: results of a large central European multicenter cohort study. *Int Neurourol J* 2019;23(3):219-225.
13. Tutolo M, Cornu JN, Bauer RM et al. Efficacy and safety of artificial urinary sphincter (AUS): results of a large multi-institutional cohort of patients with mid-term follow-up. *Neurourol Urodyn* 2019;38(2):710-718.
14. Shin D, Ahn J, Kwon HJ et al. Impact of preoperative factors on recovery of continence after artificial urinary sphincter implantation in postprostatectomy incontinence. *Prostate Int* 2021;9(4):176-180.
15. Viers BR, Linder BJ, Rivera ME et al. The impact of diabetes mellitus and obesity on artificial urinary sphincter outcomes in men. *Urology* 2016;98:176-182.
16. McKibben MJ, Shakir N, Fuchs JS, Scott JM, Morey AF. Erosion rates of 3.5-cm artificial urinary sphincter cuffs are similar to larger cuffs. *BJU Int* 2019;123(2):335-341.
17. Loh-Doyle JC, Hartman N, Nazemi A et al. Mechanical failure rates of artificial urinary sphincter components: Is the 3.5-cm urethral cuff at higher risk? *Neurourol Urodyn* 2019;38(1):187-192.
18. Ravier E, Fassi-Fehri H, Crouzet S, Gelet A, Abid N, Martin X. Complications after artificial urinary sphincter implantation in patients with or without prior radiotherapy. *BJU Int* 2015;115(2):300-307.
19. Bentellis I, El-Akri M, Cornu JN et al. Prevalence and risk factors of artificial urinary sphincter revision in nonneurological male patients. *J Urol* 2021;206(5):1248-1257.