802

Srivastava A[1], Joice G[1], Manka M[1], Sopko N[1], Wright E[1]
1. *Johns Hopkins*

SIZE OF ARTIFICIAL URINARY SPHINCTER CUFF RELATIVE TO URETHRAL CIRCUMFERENCE AND ITS IMPLICATIONS FOR DEVICE EFFICACY OVER TIME

Hypothesis / aims of study

The artificial urinary sphincter (AUS) is the gold standard therapy for stress urinary incontinence. The device, using an occlusive cuff placed at the bulbar urethra, provides urethral coaptation in the setting of intrinsic sphincter deficiency. Cuff sizes range from 3.5cm to 11cm and are selected based on urethral circumference. An overly large cuff may provide insufficient urethral coaptation, whereas a cuff too small may cause urethral erosion, urethral atrophy, or urinary retention. However, there is no standardized method of cuff selection and the implications of cuff size relative to urethral circumference are poorly understood. By tabulating the difference between urethral circumference and cuff circumference (UCC = urethral circumference – cuff circumference) and conducting survival analysis we aim to better understand the implications of cuff selection. To the authors' knowledge this is the first study to examine the association of UCC and AUS failure using time-to-event survival analysis.

Study design, materials and methods

We report a series of 168 patients who received AUS placement and/or revision by one surgeon from 2008 – 2016. During initial placement, the surgeon measured and noted urethral circumference and cuff size. Patients requiring explant or revision of their AUS were identified as having the event of interest. Upon presenting for revision, intraoperatively, the surgeon systematically evaluated the device for mechanical failure as well as the urethra, for signs of erosion or atrophy. Patients not requiring revision were assumed to have a fully functional AUS without any urethral compromise. We conducted retrospective chart review to collect baseline characteristics, intraoperative findings, and post-operative outcomes. Kaplan Meier estimates and Cox proportional hazards models evaluated the impact of UCC on all causes of AUS failure and urethral complication (urethral atrophy or erosion). In survival analysis, patients were stratified by UCC into 3 categories: 0-1.5cm, >1.5-2.5cm, and >2.5cm; higher UCCs indicated a more tightly fitting cuff.

Results

All 168 patients received an AMS 800 device with a 61-70mL reservoir filled with 27cc of isotonic contrast or saline and had a median follow up of 2.7 years (IQR: 1.1, 5.9). Cuff sizes ranged from 3.5 to 5.5cm, with 4.5cm selected in 119/168 cases (75.0%). Median urethral circumference was 7.0cm (IQR: 6, 7.2) and the median difference between urethral circumference and cuff size (UCC) was 2.0cm (IQR: 1.5, 2.5). 63 of the patients required AUS correction (37.5%). Reservoir leak constituted 36.5% (23/63) of failures, followed by urethral atrophy (22.2%), and urethral erosion (19.0%). Table 1 and Figure 1 display the output from survival analysis. Notably, on multivariable analysis tighter fitting cuffs demonstrated no differences in overall AUS durability and rates of urethral complication.

Interpretation of results

In general, patients with larger UCCs (i.e. more tightly fitting AUS cuffs) do not experience statistically different AUS efficacy over time and do not experience increased rates of urethral complication. Kaplan Meier estimates and log rank testing suggest a slight improvement in AUS efficacy over time with larger UCC; however, this association was not statistically significant. Similarly, unadjusted Cox proportional hazards models demonstrated that those with UCC>2.5cm had lower rates of all-cause failure, relative to patients with UCC <1.5cm. Yet this association did not maintain statistical significance in multivariable models. Additionally, more tightly fitting cuffs (UCC>1.5cm and >2.5cm) do not appear to experience higher erosion and atrophy rates, when looking at failure secondary to urethral complication.

Concluding message

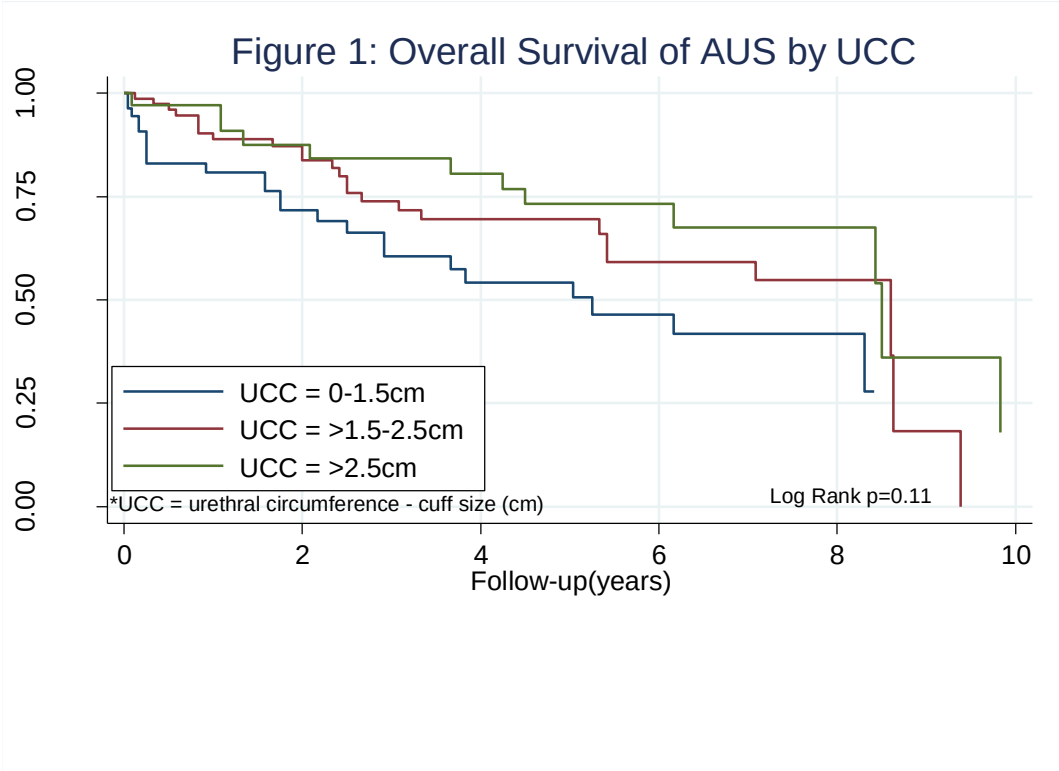
Patients with large UCCs, or tightly fitting cuffs, do not appear to experience comprised AUS efficacy on survival analysis. Furthermore, previously it was presumed that choosing a relatively small cuff (i.e. high UCC) may predispose a patient to urethral erosion or atrophy. However, our results do not demonstrate that patients with relatively smaller cuffs experience increased urethral complications.

Table 1: Survival Analysis by UCC Category

	Univariable				*Multivariable*[1]			
UCC Category	**HR**	**95% CI**		**p value**	**HR**	**95% CI**		**p value**
All-Cause Failure								
0 - 1.5cm	REF	-	-	-	-	-	-	-
>1.5 - 2.5cm	0.67	0.38	1.18	0.16	0.95	0.48	1.90	0.89
>2.5 cm	0.51	0.26	1.00	0.05	0.57	0.24	1.31	0.18
Failure due to Urethral Complication								
0 - 1.5cm	REF	-	-	-	-	-	-	-
>1.5 - 2.5cm	0.99	0.42	2.38	0.99	1.19	0.38	3.73	0.77
>2.5 cm	0.42	0.13	1.43	0.17	0.25	0.04	1.55	0.14

[1]Adjusted for pads/day, history of bladder neck contracture, history of urethral surgery, and history of external beam radiation

UCC = (urethral circumference - AUS cuff size (cm)); HR = hazard ratio; 95% CI = 95% confidence interval; REF = reference



References

1. Rothschild, J., Chang Kit, L., Seltz, L., Wang, L., Kaufman, M., Dmochowski, R., & Milam, D. F. (2014). Difference between Urethral Circumference and Artificial Urinary Sphincter Cuff Size, and its Effect on Postoperative Incontinence. The Journal of Urology, 191(1), 138–142. https://doi.org/10.1016/j.juro.2013.06.052

Disclosures

Funding: Institutional funding from Johns Hopkins School of Medicine **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Institutional Review Board **Helsinki:** Yes **Informed Consent:** Yes