MP40-12: USE OF ISOTONIC CONTRAST SOLUTION IN PRESSURE REGULATING BALLOON DOES NOT IMPACT ARTIFICIAL URINARY SPHINCTER LONGEVITY

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Background

Incontinence rates following prostatectomy range from 2% to 87%. The artificial urinary sphincter (AUS) remains the gold standard treatment. Surgeons may use normal saline (NS) or isotonic contrast to fill the device. Contrast helps diagnose mechanical failure such as fluid leak and sub-cuff atrophy with just a plain KUB (see below).

Contrast is not routinely used due to concerns of increased mechanical failure and resulting decreased device longevity. We sought to use industry data to thoroughly analyze the effect of contrast on the longevity of the AUS.

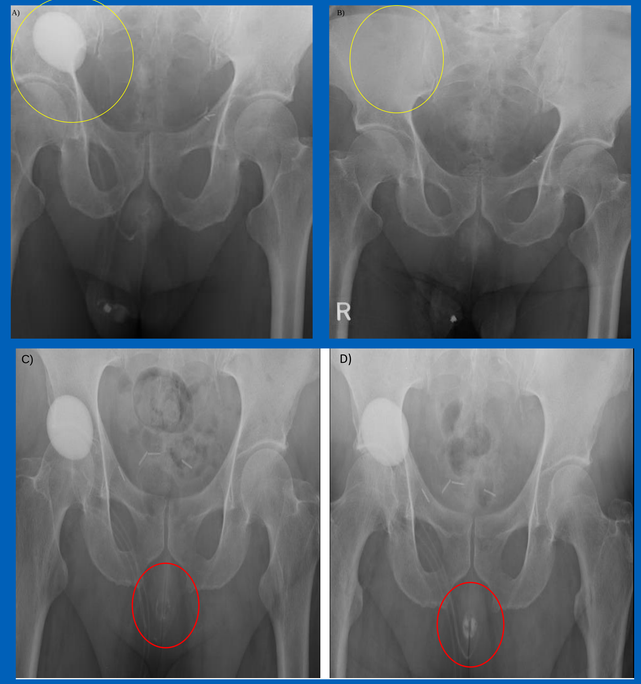

Figure 1 Fluid leak is evident when comparing postop and KUB when patient has recurrent incontinence (A, B). There is contrast on the postoperative imaging but not upon followup when patient had recurrent incontinence. Sub-cuff atrophy can be diagnosed postoperatively when the cuff appears much fuller on followup imaging (C,D).

Methods

We included all men who underwent AUS implantation from 2001 to 2016 in the Boston Scientific database.

Patients divided into two groups:
- AUS filled with NS
- AUS filled with contrast.

Patient demographics, reason for reoperation, type of reoperative surgery, time to removal were abstracted.

Survival of device was time from implantation to reoperation.

T-test was used for continuous variables. A Kaplan Meier curve was created to compare device survival between AUS with NS and AUS with contrast. Significance defined as $p < 0.05$.

Patient Demographics

		Filling Solution	
Variables	Total* (N=39363)	NORMAL SALINE (N=34674)	CONTRAST (N=4689)
Gender			
Male	39363 (100.0%)	34674 (100.0%)	4689 (100.0%)
Reoperative Surgery			
No	29735 (75.5%)	26386 (76.1%)	3349 (71.4%)
Yes	9628 (24.5%)	8288 (23.9%)	1340 (28.6%)
Removal Surgery Type			
Reimplantation	3 (0.0%)	3 (0.0%)	0 (0.0%)
Removal	1343 (3.4%)	1162 (3.4%)	181 (3.9%)
Removal and replacement	3860 (9.8%)	3338 (9.6%)	522 (11.1%)
Revision	4422 (11.2%)	3785 (10.9%)	637 (13.6%)
Missing	29735 (75.5%)	26386 (76.1%)	3349 (71.4%)
Days to removal (mean ± SD)	1107.3 ± 1111.0 (n=9628)	1053.0 ± 1066.9 (n=8288)	1443.0 ± 1303.2 (n=1340)
Years to removal (mean ± SD)	3.0 ± 3.0 (n=9628)	2.9 ± 2.9 (n=8288)	4.0 ± 3.6 (n=1340)

Table 1 represents demographic data along with information regarding reoperative surgeries. All reoperative surgeries were included: Reimplantation surgery (surgery to replace components removed in a prior surgery), Removal surgery (surgery to remove all components without replacement), Replacement surgery (surgery to remove and replace all components), and Revision surgery (surgery to remove, replace, and/or add part but not all of the device components).

Reason for Reoperation

		Filling Solution	
Reason for Reoperation	Total (N=9628)	NORMAL SALINE (N=8288)	CONTRAST (N=1340)
ATROPHY	916 (9.5%)	769 (9.3%)	147 (11.0%)
EROSION	1688 (17.5%)	1467 (17.7%)	221 (16.5%)
FLUID LOSS	1496 (15.5%)	1271 (15.3%)	225 (16.8%)
INCONTINENCE	3963 (41.2%)	3433 (41.4%)	530 (39.6%)
INFECTION	728 (7.6%)	621 (7.5%)	107 (8.0%)
MALFUNCTION	448 (4.7%)	387 (4.7%)	61 (4.6%)
PAIN	151 (1.6%)	126 (1.5%)	25 (1.9%)
PATIENT DISSATISFACTION	216 (2.2%)	205 (2.5%)	11 (0.8%)
OTHER	1701 (17.7%)	1508 (18.2%)	193 (14.4%)
NOT SPECIFIED	913 (9.5%)	779 (9.4%)	134 (10.0%)
UNKNOWN	795 (8.3%)	684 (8.6%)	111 (8.3%)

Table 2. Reasons for AUS reoperation (n = 9628). Due to presumed heterogeneity between the groups (different patient populations, different surgeons), comparative statistics were not performed.

AUS Survival

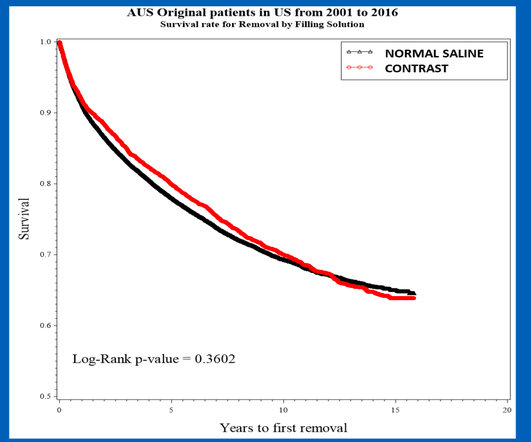

Figure 2. Kaplan Meier Curve of Freedom from Reoperation among Contrast Filled vs Saline Filled AUS Devices. The curve demonstrates no statistical significant difference in survival between AUS filled with saline and AUS filled with contrast.

Conclusion

The use of contrast in the AUS does not change rates of device malfunction, fluid loss, and need for reoperation. Since the use of contrast does not affect longevity and may help in future troubleshooting of the device, we feel this should be considered a safe tool for the implanting surgeon.