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ARTIFICIAL URINARY SPHINCTER (AMS 800) ™ OUTCOME IN COMPLICATED PROSTATE CANCER PATIENTS

Hypothesis / aims of study
The Artificial Urinary Sphincter (AUS) is the gold standard for treating intrinsic sphincteric deficiency (ISD) in post−prostatectomy incontinence. Concerns exist regarding the safety and efficacy of AUS in patients (pts) who received radiotherapy (RT) for prostate cancer (CaP). This study retrospectively evaluates success and failure rates for AUS placement in pts who have received external beam radiation (XRT), brachytherapy (BT), or radical prostatectomy (RP) for CaP.

Study design, materials and methods
We retrospectively evaluated the records of 99 pts (mean age = 72; range 57−93) who underwent AUS placement from 1999−2008 by a single surgeon. Etiologies for ISD included post-RP (80%), post-XRT administered either as monotherapy or salvage treatment (23%) and BT (13%). Fourteen patients (14%) presented with a prior history of a failed AUS placement. A transurethral incision of bladder neck contracture (BNC) was performed in 53% of patients prior to AUS placement. We employed a 4, 4.5 or 5.0cm bulbar cuff with a 61−70 cm H20 Pressure Regulating Balloon. Activation of the device was performed 6 weeks postoperatively. Statistical analysis was performed with a Pearson Chi-Square and T−test. The mean follow-up was 24 months (6−108). No extramural funding was used for this study.

Results
Twenty-three pts (23%) developed complications that required removal of the AUS. The most common reason for removal was cuff erosion (43%). Five pts (5%) developed urinary retention within one week of AUS placement that ultimately resolved, but required temporary atraumatic and uncomplicated short-term catherization. At 3−year follow-up, 80% and 66% of pts had a functional AUS in the post−RP and post−RT/BT groups respectively. Amongst pts with functional implants, satisfaction rates of 93% and 94% were reported respectively. The difference in rates of functionality, explant and satisfaction between post−RP and post−RT/BT did not reach significance. The number of pads decreased significantly (p=<0.001) in all subgroups after AUS insertion (mean=0.66+/−0.93) compared to baseline (mean=5.31+/−1.9). There was no significant difference in pad usage after AUS between the RT/BT and RP groups.

Interpretation of results
Implantation of an AUS is successful even in patients who have received radiation therapy with high patient satisfaction rates in this subgroup. The AUS was equally effective in reducing urinary incontinence, as measured by pad number, regardless of CaP treatment. Although there was a trend for increased complications in those patients receiving some form of radiation therapy, this did not reach statistical significance.

Concluding message
The explant rate in our series can be explained by preoperative risk factors such as prior radiation, BNC and/or history of a prior failed AUS. We did not, however, identify any statistically significant differences in the success or failure rates between the RP and RT groups. A larger cohort of pts with longer follow-up may indicate differences in outcome. Although patients should be warned of possible complication after radiation therapy, implantation of an AUS is an efficacious treatment for ISD after CaP treatment and should continue to be offered as such.

Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Instituional Review Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**