Are there clinical predictors or urodynamic parameters related to the efficacy of the adjustable artificial urinary sphincter (VICTO®)?

Lebani B1,2, Sacomani C2, Silva AB 1, Almeida FG, 1, Zequi S2

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1 - Department of Urology, Division of Urology and Voiding Dysfunction Section, AC Camargo Cancer Center
2 - Department of Surgery, Division of Urology, Voiding Dysfunction Section, Federal University of São Paulo, Brazil.

Aims of study

Post-prostatectomy urinary incontinence (PPI) is a challenging complication affecting a significant proportion of men who undergo radical prostatectomy, with severe cases leading to substantial impairment in quality of life due to social embarrassment and psychological distress [1]. The artificial urinary sphincter (AUS) remains the gold standard treatment for severe PPI, providing effective continence control in most cases [2]. However, traditional AUS devices lack adjustability, which can complicate achieving optimal outcomes, particularly in patients with complex conditions such as those with prior radiotherapy or urethral stenosis [3].

The development of the adjustable artificial urinary sphincter (VICTO®) offers a promising advancement in managing PPI, as it allows for postoperative adjustments to optimize continence and patient satisfaction [4], providing the lower pressure in urethra according to the filling volume of the device.

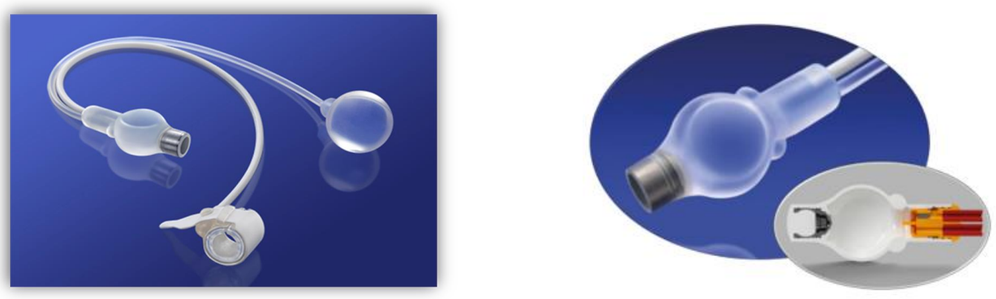

Figure 1 – Victo device and adjustment mechanism

Although preliminary results have shown potential benefits, the relationship between preoperative clinical and urodynamic parameters and the postoperative efficacy of this adjustable AUS device remains poorly understood [5]. Identifying predictive factors could improve patient selection and individualize treatment strategies, enhancing overall outcomes.

This study aims to evaluate the clinical and urodynamic parameters associated with the efficacy of the adjustable AUS in treating severe PPI. We hypothesized that preoperative characteristics, such as abdominal leak point pressure (ALPP) and incontinence severity, may correlate with postoperative outcomes, including patient satisfaction and the final adjustment volume of the device. By exploring these associations, we hope to provide evidence-based recommendations for clinicians managing patients with severe PPI.

Materials and methods

This prospective, single-center study was conducted from April 2022 to May 2023, with a cohort of 19 male patients diagnosed with severe post-prostatectomy urinary incontinence (PPI). All patients provided written informed consent, and the study protocol was approved by the local ethics committee. The inclusion criteria were patients with severe urinary incontinence, defined as grade 3 or 4 on the Male Stress Incontinence Grading Scale (MSIGS – Standing cough test - SCT), more the 4 PADs per day or a 24-hour pad test result greater than 400 grams. Exclusion criteria included ongoing urinary tract infections or severe comorbid conditions contraindicating surgery.

Patients underwent a comprehensive clinical assessment, which included a detailed medical history, physical examination, and assessment of incontinence severity. Severity was measured using the MSIGS, which categorizes stress urinary incontinence into four grades, with grade 4 representing the most severe form. The SCT, number of pads used per day and the 24-hour pad test (weight of pads used in 24 hours) were recorded to quantify the degree of incontinence.

Urodynamic studies were performed according to the guidelines of the International Continence Society (ICS) using a standardized protocol. The procedure included the assessment of bladder capacity, compliance, and sensation, with saline infused at a rate of 50 ml/min. Abdominal leak point pressure (VLPP) was recorded at the point of leakage during standardized coughing maneuvers with a filled bladder.

Follow-up was performed at 3 months using the Patient Global Impression (PGI) questionnaire to evaluate postoperative success. The study was approved by the local ethics committee.

Statistical analysis included T-tests or Mann-Whitney tests for outcome comparisons and correlation analyses (Pearson and Spearman) based on data distribution. All statistical analyses were conducted using JAMOVI software Version 2.6.
A p-value of < 0.05 was considered statistically significant.

Results and interpretation

The mean patient age was 69.4 ± 5.39 years. Demographics are shown in table 1. Prior incontinence surgery was noted in 21%, 52.6% had received radiotherapy, and 21% had a history of urethral stenosis,as shown in figure 2.

	AGE	TIME OF INCONTINENCE	PADs	PAD TEST	NOCTURIA EPISODES	PRE OP UROFLOWMETRY (ml)	VLPP (cmH2O)	LEAK (ml)
Average	69.4	71.9	5.05	459	1.53	19.0	86.2	174
Standard deviation	5.39	57.7	1.90	153	1.68	11.4	49.8	99.8

Table 1 – Demographics

Baseline pad usage was 5 ± 1.90 units/day, and the mean 24-hour pad weight was 459 ± 153 g. Mean abdominal leak point pressure (VLPP) was 86.2 ± 49.8 cmH2O, with an average bladder filling volume of 174 ± 99.8 ml. Patients who had undergone radiotherapy showed lower ALPP values preoperatively (58.3 ± 24.9 vs 117 ± 53.3, $p < 0.05$, CI 19.3 – 98.4), as shown in figure 2.

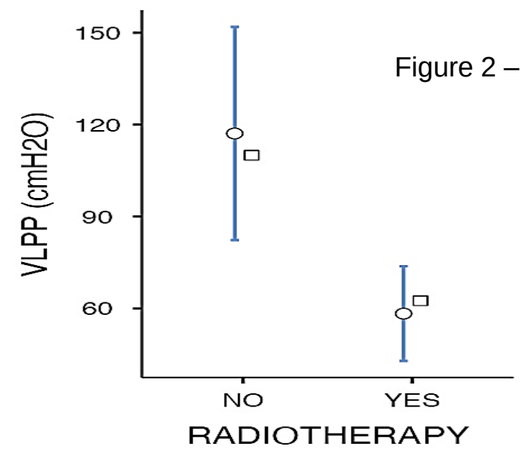

Figure 2 – VLPP vs RT

Post-implantation, the PGI improvement rate was high (89.5%), with a median pressure-regulating balloon (PRB) volume of 19 ml (IQR 17.5 – 20.5). No significant correlation was found between postoperative satisfaction and preoperative parameters, such as VLPP ($p = 0.665$), 24-hour pad test ($p = 0.917$), or daily pad usage ($p = 0.295$). We did not find association between the VLPP, bladder capacity or filling volume at leak and the final volume of the pressure regulating balloon. Although patients underwent radiotherapy had lower preoperative VLPP, this did not correlate with the final adjustment volume or the satisfaction level, as shown in figure 3.

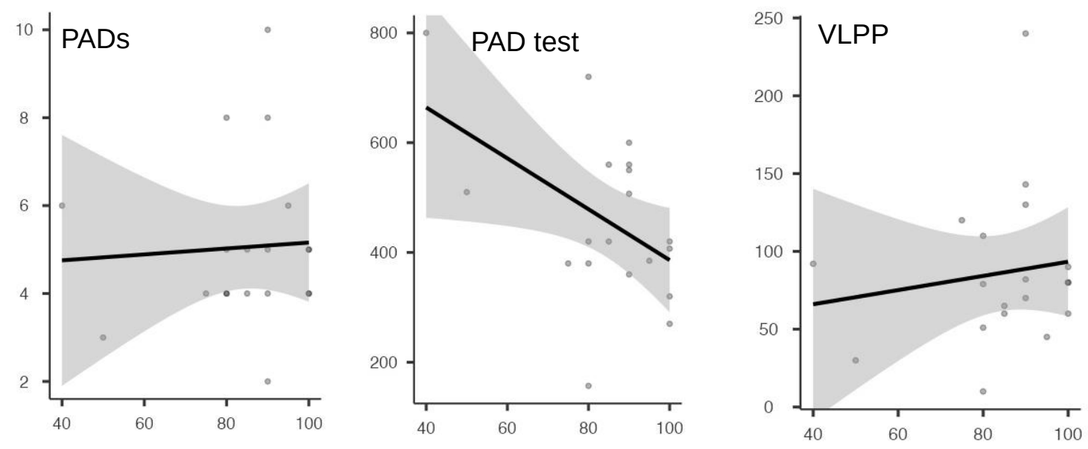

Figure 3 – Satisfaction vs urodinamic and clinical parameters

Conclusions

Neither urodynamic parameters nor other clinical characteristics appear to predict immediate patient satisfaction following AUS implantation. This suggests that the adjustable AUS can be effectively used across diverse PPI profiles without significant differences in outcomes [4, 5]. It is possible that superior results are more closely related to the quality of the medical center and the expertise of the surgeon [7].

References

1.Smith, A. B., Johnson, C., & Miller, R. (2017). *Incidence and risk factors for post-prostatectomy incontinence: A review of the literature.* Journal of Urology, 198(5), 1123-1130.
2.Chen, Z., Wang, X., & Liu, Y. (2019). *Impact of radical prostatectomy on urinary continence: A meta-analysis of cohort studies.* European Urology, 75(2), 129-138.
3.Thompson, R., Barr, S., & Davies, L. (2020). *Quality of life in men with post-prostatectomy incontinence: A systematic review.* BJU International, 125(1), 17-25.
4.Hernandez, D., Perez, M., & Rivera, M. (2018). *Long-term outcomes of artificial urinary sphincter implantation in male patients: A single-center experience.* International Journal of Urology, 25(9), 783-789.
5.Kumar, S., Patel, A., & Desai, M. (2021). *Challenges in managing post-prostatectomy incontinence in patients with a history of pelvic radiation therapy.* Urology Journal, 18(3), 145-152.
6.Garcia-Perdomo, H., Zapata, W., & Gutierrez, R. (2022). *Adjustable artificial urinary sphincter in the treatment of severe urinary incontinence: A systematic review and meta-analysis.* Journal of Clinical Urology, 15(4), 281-290.
7.Johnson, P., Smith, R., & Chan, H. (2021). *Comparison of adjustable and non-adjustable artificial urinary sphincters in complex urinary incontinence cases.* Urology, 145, 53-59.
8.Martinez, A., Sanchez, F., & Lopez, D. (2019). *Predictive factors for success in artificial urinary sphincter implantation.* World Journal of Urology, 37(3), 501-507.
9.Santos, R., De Paula, L., & Silva, M. (2020). *Urodynamic predictors of artificial urinary sphincter outcomes in post-prostatectomy patients.* Neurourology and Urodynamics, 39(5), 1289-1295.