

WHEN IS THE MALE SLING ADJUSTABILITY REALLY NECESSARY?

Hypothesis / aims of study

Post radical prostatectomy urinary incontinence (PPI) is the most feared consequence of radical prostatectomy and its occurrence has a major negative impact on quality of life. Around 5% of the patients undergoing radical prostatectomy will have surgical treatment for PPI. The urinary artificial sphincter is the gold standard, but the slings indications have increased due to lower cost, practicality, reproducibility, shorter learning curve and similar results, in mild to moderate incontinence, in short and medium term follow-up. Unlike female slings, failure rates vary, and each male sling should be individually analyzed as a single device. The failure rates can be reduced by sling adjustability, but which are the predictive factors of adjustment? Who is the patient who will benefit from sling adjustment?

This study aims to identify clinical and urodynamic predictive factors for male sling adjustment.

Study design, materials and methods

Seventy two consecutive patients with mild to severe incontinence underwent surgery for PPI, transobturator adjustable sling (Argus-T, Promedon, Cordoba, Argentina), from 2009 to 2016. Open abdominal radical prostatectomy was the procedure in all the patients. Prior to implantation and during follow up, patients were assessed through clinical evaluation, 24 hours pad test, International Index of Erectile Function (IIEF-5), International Consultation on Incontinence–Short Form questionnaire (ICIQ-SF), Global Impression of improvement (GII) and Visual Analogue Scale (VAS) for treatment satisfaction. Urodynamics and terminology followed ICS standardisation^(1,2). All the patients were operated by the same surgeon, through a perineal incision and two crural incisions (4cm lateral to the genitofemoral fold). They received 2g of Ceftriaxone 1 hour before the procedure and remained with Cefuroxime for 7 days. Follow up visits occurred at 14 days, 1, 3 and 6 months and annually thereafter. The sling tensioning was based on urethral retrograde perfusion pressure, reaching between 35 and 40 cmH₂O. Adjustments were done only after one month. Only tightening was required, and the tension was readjusted between 35 and 40cmH₂O. Clinical and urodynamic variables were correlated with outcomes: subjective success (VAS \geq 8 and GII 1 or 2) and objective success (Dry or improvement > 50% on number of pads/day), and the need of adjustments, adjusted to the uni and multivariate logistic regression model.

Results

Median time between prostatectomy and the sling was 48 months (8 - 204). Median follow-up was 14 months (6 - 84), median age 68 (49-81), BMI (body/mass index) 27 (25-34). Salvage radiotherapy in 22 %, previous urethral stenosis 23.5%, diabetes 17%. Patients using 3 or more pads/day, 65%. Median pad test was 400g (20 - 2275g). 27% of the patients presented pad test < 200g, 31% between 200 and 400g, and 42% pad test > 400g. Urodynamic data: Median Bladder Contractility Index (BCI) was 123 (46 - 306), 35% of BCI < 100, 30% BCI 100 to 150 and 35% the BCI was > 150. Complacence < 20 cmH₂O was observed in 39%. Detrusor overactivity in 16%. Median Valsalva leak point pressure was 43 cmH₂O (0 - 213). Objective success was achieved in 52 patients (72%, cure in 64% and improvement 8%). Subjective success in 56 (78%, cure in 70% and improvement 8%). Infection occurred in 3 patients (4%). Sling was removed in one patient (1.4%). At last follow up, IIEF pre and post implantation were similar. ICIQ-SF scores decreased from 18 to 4.5 (p < 0.001). Patients with Pad test \leq 475g were 4 times more likely to have subjective success (ROC analysis, AUC 0.7922). There was no clinical or urodynamic variable with significant correlation to objective success. The only variable that almost reached significance in the correlation with objective success was pad test, as continuous variable, with p = 0.066. Twenty individuals (28%) underwent first adjustment, and a second adjustment was done in 6 (8.3%). Mean time to first adjustment was 11 months (1 - 36). Only tightening was required. Radiotherapy (OR 5.5 95%CI 1.3 - 26, p = 0.01), urethral stenosis (OR 7.5 95%CI 1.8 - 35, p = 0.001), 3 or more pads/day (OR 7 95%CI 1.4 - 70, p = 0.01) and BCI < 110 (OR 8.4 95%CI 1.7 - 58.6, p = 0.003) were risk factors for adjustment in univariate analysis, and only the BCI, as continuous variable (OR 0.97 95%CI 0.94 - 0.99, p = 0.007, for each additional point in BCI) and Radiotherapy (OR 16.2 95%CI 1.88 - 303.8, p = 0.02) were independent risk factors for adjustment in multivariate analysis model.

Interpretation of results

The success rates of the male sling should be analyzed according to each device specifically, and not generically as in the female sling. The success rates in this study are similar to those previously published for this device, however, the complications and adverse events are lower, especially regarding infection rates and sling removal. Probably due to some surgical details to prevent infection, such as distancing the crural incisions of the genitofemoral fold, and the medial and anterior path of the subcutaneous hidden excess silicone arms, preventing their passage under this fold. As far as we know, this is the first study to determine the risk factors for sling adjustment. Of the irradiated patients, 76% and 69% achieved subjective and objective success respectively, however, 62% were submitted to sling adjustment. Thus, there was no correlation between radiotherapy and success rates solely because of the adjustability of the sling. The same can be said about detrusor hypocontractility, number of pads, and urethral stenosis. Thus, patients with pad test \leq 475g are more likely to be satisfied with this sling. However, irradiated patients, and those with detrusor hypocontractility will require adjustment more frequently, which will allow the maintenance of success rates similar to those without these characteristics.

Concluding message

Sling adjustment benefits more than 20 % of the patients who were treated for PPI and more than a half of those with previous radiotherapy or detrusor hypocontractility.

References

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Disclosures

Funding: None. **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Comitê de Ética em Pesquisa (CEP) em seres humanos da Santa Casa de São Paulo. **Helsinki:** Yes **Informed Consent:** Yes