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A READJUSTABLE TRANSOBTURATOR SLING FOR MALE SPHINCTERIC URINARY INCONTINENCE.

Hypothesis / aims of study

Male stress urinary incontinence (SUI) may result as a complication of prostatic surgery for benign or malignant disease. Over the past years, the artificial urinary sphincter has been considered as the gold standard for incontinence treatment; however, the male sling has become increasingly popular in the last decade due to its efficiency, lower cost and easier and reproducible surgical technique, besides, it doesn't need patients intervention to void. The drawbacks associated with the retropubic sling technique are related to the possibility of bladder perforation and injuries to other intra abdominal organs (vessels, intestine and others) during the procedure when the needles go through this area. An alternative to these surgical techniques is the transobturator approach, where the device is attached to the muscular aponeurotic membranes that cover the obturator foramen, avoiding perforation of the bladder and of any other intra abdominal organ. The retropubic adjustable sling "Argus" results have been described[(1,2)].The objective of our study is to present preliminary results of transobturator approach using the adjustable sling "Argus".

Study design, materials and methods

Ten patients underwent the procedure with a spinal block. The sling (Argus T™, Promedon S.A., Córdoba, Argentina) comprised of a 4.2 x 2.6 x 0.9 cm thick silicone foam pad for soft bulbous urethral compression (figure 1). The pad, which is attached to the silicone cone columns, was placed with needles through the obturator foramen and then adjusted with silicone washers to regulate and keep the desired tension against the urethra (figure 2-4). The tensioning was adjusted to 35 cm/H_20 through retrograde urethral perfusion pressure. The pad and washers are radio-opaque, which allows their position to be assessed during follow-up. All patients were fully evaluated, which included a quality of life questionnaire (International Consultation on Incontinence Questionnaire-Short Form, ICIQ-SF, range 0-21), endoscopy, urodynamic evaluation, 24 hours pad test and a follow–up program. Postoperative objective success was defined as absence of any urinary loss during full bladder standing Valsalva maneuver and no need of pads, while subjective success was achieved when the patients considered themselves much better or cured, the level of satisfaction was ≥ 8 (according to a visual analogic scale from 0 to 10) and there was no report of stress incontinence.

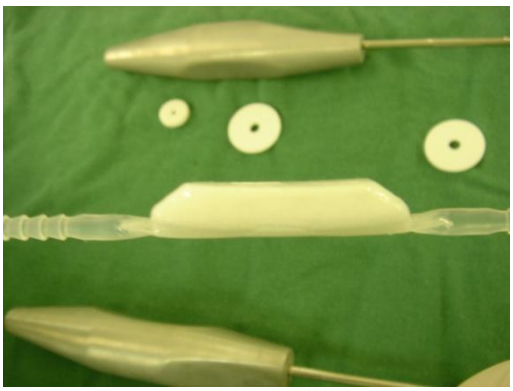

Figure 1) Impermeable silicone foam pad.

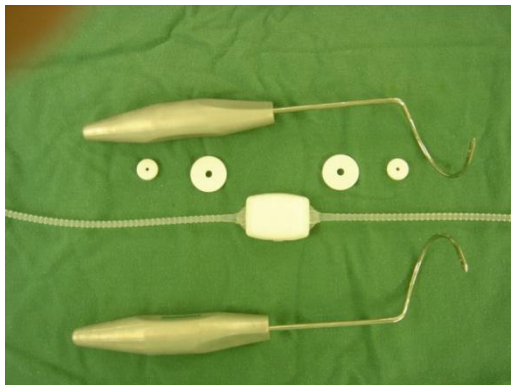

Figure 2) Silicone cone columns.

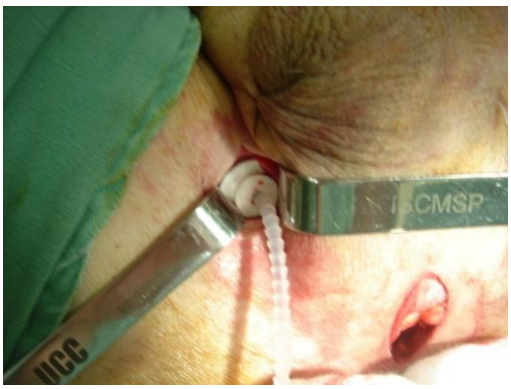

Figure 3) Washers to keep sling tension.

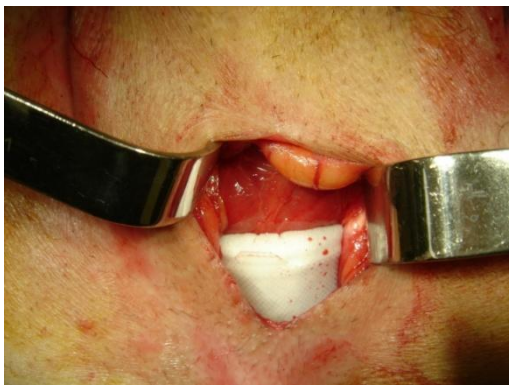

Figure 4) Silicone pad placed outside bulbospongiosus muscle

Results

The mean follow-up time was 6 months (3 to 12 months). Nine patients (90%) achieved complete continence (no-pads), while the remaining patient showed important improvement (1 pad a day), was satisfied and didn't want readjustment.

One patient required readjustment of the sling and became dry, but evolved with an operative site infection treated with antibiotics without success and had the sling taken out after six months of the surgery. All patients were satisfied with the results and considered success subjectively. There was no case of erosion or extrusion.

Interpretation of results

The results are encouraging because they are similar to retropubic slings avoinding intra abdominal complications. A previous doubt was if it would be possible to achieve and keep the desired tension against the bulbous urethra through transobturator approach, but it was easily done with the washers holding the sling against the external obturator muscle fascia. The impermeable silicone foam pad is placed outside of the bulbospongiosus muscle compounding, with the ventral corpus spongiosum of bulbous urethra, a thick and soft tissue compression of the urethra permitting physiologic voinding and blood perfusion (figure 4). Post operative urodynamics will be done to confirm normal voiding. As the sling is totally silicone made, it doesn't integrate but is encapsulated by surrounding tissue, just as artificial sphincter, allowing readjustment but also facilitating infection progression. We had one (10%) case of infection witch ended with sling removal.

Concluding message

This new approach for an adjustable male sling effectively controls sphincter incontinence in men after prostate surgery with a low complication rate. These early results are encouraging making transobturator approach a valid alternative to the retropubic male sling devices.

References

1. Romano SV, Metrebian SE, Vaz F, Muller V, D'Ancona CA, Costa DE Souza EA, Nakamura F. An adjustable male sling for treating urinary incontinence after prostatectomy: a phase III multicentre trial. BJU Int. 2006 Mar;97(3):533-9.
2. Romano SV, Metrebian SE, Vaz F, Muller V, D'Ancona CA, de Souza EA, Nakamura F. Long-term results of a phase III multicentre trial of the adjustable male sling for treating urinary incontinence after prostatectomy: minimum 3 years. Actas Urol Esp. 2009 Mar;33(3):309-14.

Specify source of funding or grant	**Promedon S.A., Córdoba, Argentina provided the slings for the study with no additional funding or grant.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Santa Casa de São Paulo Medical School Ethics Committee.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**