ADJUSTABLE SLING (TRT REMEEX FEMALE SYSTEM®): A SALVAGE PROCEDURE FOR RECURRENT FEMALE STRESS URINARY INCONTINENCE

Hypothesis / aims of study

The tension free mid-urethral sling either retropubic or transobturator has become the procedures of choice for stress urinary incontinence. Repeat surgery is requested one in six transobturator slings and one in 16 retropubic/suprapubic slings. [1] We feel the TRT Remeex Female System ® (Neomedic International, S.L. Barcelona, Spain) could become the procedure of choice for recurrent stress incontinence. The surgeon has very few options when faced with managing patients that have failed previous anti-incontinence procedures. The Modified Marshall-Marchetti-Krantz procedure has been reported and remains an excellent salvage procedure [2]. The procedure and management of any complications of such a procedure is not minimally invasive. The only other option would be placement of a new sling which is adjustable only at the time of placement and regardless of technique remains a best guess situation. The TRT Remeex Female System® allows adjustment under real life circumstances. The patient is awake with a full bladder and in a standing position. Readjustment is possible with local analgesia without associated morbidity of placing a new sling and if needed can be carried out multiple times and years later. We review our experience with the adjustable sling system as a salvage procedure, highlighting the learning curve of proper placement, lessons learned in the adjustment and management of complications.

Study design, materials and methods

This is a retrospective review of five years use of the TRT Remeex Female System®. All patients had preoperative urodynamics. Patients that were not satisfied with their continence following placement of the system underwent formal urodynamics to determine if readjustment was needed. Preoperative and postoperative urodynamics included Uroflow, complex CMG/EMG, Valsalva Leak Point Pressures, Urethral Pressure Profile, Pressure Transmissions Ratios and complex Pressure Flow Studies. Patients that had persistent stress incontinence underwent tightening. Patients with urge incontinence, idiopathic or neurologic detrusor overactivity had treatment tailored for these issues.

<u>Results</u>

Sixty-eight patients underwent the adjustable sling placement for recurrent stress incontinence after previous anti-incontinence procedure (1-4 procedures). The average age was 66.4 (SD 11.4) years with a range of 48-91. Forty-three patients (63%) had Valsalva Leak Point Pressures (VLPP) less than 60 cm H₂O. Forty-one patients (60%) had preoperative mixed urinary incontinence. The majority of mixed incontinence patients (n=30) demonstrated idiopathic detrusor overactivity, and the rest had known neurologic detrusor overactivity. Sixty-six patients (97%) had resolution of their stress incontinence. The remaining two required explant of the TRT Remeex Female System® to correct refractory retention. Twelve patients (17.6%) required readjustment-tighten. Seven patients (10.2 %) required loosening, which included the two above which required explantation. Six of the retention patients occurred early during our first 25 adjustable slings. Two infections occurred in the suprapubic site. Fifiteen patients (22%) had concurrent surgical procedures. Six of the 41 patients (8%) with preoperative mixed incontinence had resolution of their symptoms. Eight patients (11%) developed de novo urge incontinence with idiopathic detrusor overactivity. These patients all had preoperative VLPP less than 60 cm H₂O. Ten patients (14%) required addition therapy of sacral neuromdulation or detrusor muscle Botox® injections.

Interpretation of results

Meta-analysis of 33 randomized controlled trials revealed TVT and pubovaginal sling complications are similar. The surgical technique for placement of the TRT Remeex Female System® is similar to the pubovaginal sling. A study evaluated 125 patients who had placement of the TRT Remeex system®. After a mean follow-up of 38 months 108 patients were cured based on UDS and clinical evaluation. 13% patients remain incontinent. 10 or 8% developed de novo detrusor overactivity. [3] We found the TRT Remeex Female System® provides a minimally invasive system that can achieve very good results without any of the technical difficulties encountered with other salvage procedures. The TRT Remeex Female System® allows adjustment in the immediate postoperative period and years later. The following are technique suggestions for the use of the TRT Remeex Female System®.

1. The surgeon should place the sling in a very loose fashion (4-6cm of space between the adjustable spool and the rectus fascia). Add more space for increasing BMI. When the sling is adjusted the next day the only goal is to prevent the loss of urine in the standing position. We find allowing the patients bladder to fill is easier than filling the bladder especially when dealing with a patient population that has a high pre-existing rate of lower urinary tract symptoms.

2. Adjustable does not mean the patient will be able to void immediately and may need a temporary foley catheter or self cathing. As with all anti-incontinence procedures patients may have temporary retention that resolves without any complications.

3. If infection of the suprapubic site occurs (site of the adjustable spool- called "varitensor"), the sling can be retained. Infections were handled by explanting the varitensor, debridement of the wound, securing the sling arms to the rectus fascia and allowing the supra-pubic wound to heal by secondary intension with a negative pressure wound device.

4. The majority of retention requiring intervention occurred in our early experience with the sling system. When retention does persist, we find that doing a urethral dilation along with loosening the sling system is helpful. Two patients had persistent retention following removal of the adjustable spool and sling arms. The retention did not resolve until we removed the suburethral mesh. In these cases it appeared the mesh had been pulled and become fixed in the retroperitoneal space.

5. The dimensions of the varitensor may limit use in the extremely thin patient.

6. The clinician that deals with these types of patients recognizes that he will need to utilize all therapeutic means to help these patients. Simple eliminating stress incontinence is not the necessarily all that is required. Adjuvant therapy of anticholinergics,

pelvic floor physical therapy, sacral and tibial neuromdulation and use of injectable chemodenervation medications such as Botox® are still required.

<u>Concluding message</u> The TRT Remeex Female System® is an excellent salvage procedure for recurrent or persistent stress incontinence. These patients commonly have other lower urinary tract symptoms that will require therapy. We feel that the correction of the stress component allows the physician to maximize effect of other therapy. Unlike previous salvage procedures, the system placement, adjustment and explantation remain minimally invasive. We do not suggest the use of the TRT Remeex Female System® in patients with primary incontinence; however, it is increasingly common that patients are requesting the adjustable sling.

References

- 1. Latthe PM: Foon R; Toosx-Hobson P. TOT and Retropubic Tape Procedures In Stress Incontinence: A Systematic Review and Meta-analysis of Effectiveness and complications BJOG 2007;114:522-531
- 2. Lee RA et al. Surgical Complications and Results of Modified Marshall-Marchetti-Krantz for Urinary Incontinence OB/GYN 1979 April;53 (4):447-450
- 3. Errando C et al. A Re-adjustable Sling for Female Recurrent Stress Incontinence and Sphincteric Deficiency: Outcomes and Complications in 125 patients Using the Remeex Sling System Neurourlolgy and Urodynamics DOI 10.100002/nau

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