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OUTCOMES AND COMPLICATIONS OF THE REMEEX® SYSTEM IN WOMEN WITH RECURRENT STRESS URINARY INCONTINENCE AND SPHINCTERIC DEFICIENCY

Hypothesis / aims of study

Stress urinary incontinence (SUI) is a prevalent illness that represents a serious impact in the quality of life of patients who suffer from it. Its treatment includes lifestyle modifications, pelvic floor exercises and surgical procedures (suburethral tension free slings).

The issue is what to do with SUI recurrence after surgery and dealing with cases of intrinsic sphincteric deficiency (ISD), taking into account that the presence of a fixed urethra is a risk factor for failure of tension-free slings. For these patients, retropubic tapes have shown better results and the Remeex® system could be a good option. It consists of an adjustable tension-free sling with a suburethral tape which is connected through two non-absorbable sutures to an abdominal subcutaneous prosthesis (Varitensor). It allows for sling tension adjustment at the moment of insertion giving the possibility to personalize the mesh tension and also readjust it later on with ambulatory surgery, which makes it a good option for refractory cases.

Another advantage of the Remeex® is that it is a dynamic pressure transmission system. This means that when the patient makes a Valsalva maneuver and the abdominal muscles contract, the Varitensor is pushed forward pulling up the mesh. This movement of the Varitensor closes the urethra correcting the sphincter's insufficiency.

The aim of this study is to evaluate the outcomes and complications of adjustable tension-free sling Remeex® in patients with ISD or recurrent SUI.

Study design, materials and methods

We present a cohort study that includes all patients with SUI, due to ISD or post surgical recurrence confirmed either on physical examination and urodynamic study, operated on with Remeex® System, between 2000 and 2011.

Preoperative assessment included clinical history, ICI-Q-SF and Sandvik questionnaires, urogynecologyc evaluation and urodynamic study.

Follow up visits where scheduled one month after surgery, 6 months and annually from the date of discharge.

Postoperative evaluation stratified the patients into 3 groups: cured, improved and failed. This classification was made based on the patient's subjective opinion and physical exam (stress test). Additional tests were performed if the patient reported any problem.

Results

A total of 85 patients underwent a Remeex® system procedure, between 2000 and 2011.The mean age at surgery was 57 years (19-77). Mean follow up is 60.4 months (1-141).

Thirty-eight of the 85 patients had previous anti-incontinence procedures (44%), 8 of which had been operated on more than once.

On physical examination: 70 patients (82%) had some degree of pelvic organ prolapse and 28 (33%) had urethral hypermobility.

On the urodynamic evaluation SUI was confirmed in 60 patients (70%), 8 patients (9%) had detrussor overactivity, and 25 (29%) experimented increased bladder sensation.

Mean operating time was 47 minutes. The mean hospital stay was 3 days (1-11). The longer stays were caused mainly by urinary retention, and one due to a vulvar hematoma. The mean time of catheterization needed was 3 days (1-24). Some patients were discharged from the hospital with intermitent catheterization that resolved in all cases the initial voiding dysfunction.

78 patients (91.8%) are considered cured, with a negative stress test and good subjective impressions of the procedure, 2 improved and 5 cases were considered a failure of the procedure.

Intra operative complications were reported in 7 patients (8%). Five bladder perforations that were solved during the intervention and two hematomas (one vulvar and one in Retzius space) that resolved spontaneously.

Postoperative complications were reported in 34% of our patients.

Sling post-operative problems:

Extrusion was reported in 12 patients (14%). Two of these extrusions were small and asymptomatic or resolved spontaneously and 7 cases required set-up for correction.

Sling excision was necessary in 6 cases (7%), 4 of them because of serious extrusion and the other 2 due to voiding problems after removing the varitensor.

One patient presented spontaneous drainage of purulent material through the colporraphy and received antibiotic treatment resolving without sequels.

Abdominal post-operative problems:

Five seromas and one subcutaneous hematoma that resolved with antibiotic treatment.

Eight patients had cellulites around the Varitensor (6%) and most of them were treated with antibiotic and resolved completely, except 2 which required Varitensor removal.

Seven patients had cutaneous fistula (5%). Five of them underwent fistulectomy.

Finally, in total, 7 Varitensors were removed (8%). Two because of pain, one because the whole system had to be removed after an important extrusion of the mesh, and 4 because the patients presented other abdominal wall problems (abscess, persisting fistula...).

Readjustment of the mesh tension was needed only in three patients (1, 2 and 3 years after Remeex® placement). After the adjustment the patients were completely dry.

After undergoing surgery 19 patients (22.4%) presented *de novo* urgency symptoms.

Forty-six of 85 patients (54.2%) were followed up for more than 5 years, among this long term follow-up group, 70% were subjectively satisfied.

Interpretation of results

The long term results of this study seem to demonstrate that the Remeex® system is an effective option for complicated cases of incontinence, recurrences of SUI or ISD.
Among its advantages, this system allows the personalization of the tape tension and the eventual readjustment through minimally invasive surgery, enabling to convert failures or recurrences into cures.
This technique is not free of complications. There are abdominal problems due to the Varitensor, which being a foreign body predisposes to wound problems. It also has the intrinsic risk for extrusion like any other mesh and possibly an added risk because it is a dynamic system.
Despite complications it seems to be a good option for these difficult cases where other techniques have failed or are not likely to succeed.

Concluding message

The Remeex® system is an effective tool to treat stress urinary incontinence for those selected difficult patients, assuming a moderated increase in complications, usually with a straightforward resolution.

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