

SIX MONTH FOLLOW-UP OF A NEW READJUSTABLE AND AUTOFIXATING TOT : SAFYRE T

Hypothesis / aims of study

Urinary incontinence (UI) remains a worldwide problem affecting women of all ages and across different cultures and races, with a severe economic and emotional impact .(1)

There are only 2 procedures that are proven to have effective long-term cure rates for the treatment of stress urinary incontinence (SUI). These procedures are the abdominal Burch Colposuspension and the sling procedure that is completed vaginally.

After TVT procedure, TOT has been appreciated for its lower operating time and cost as it doesn't need cystoscopy evaluation after surgery.

Aim of our study is to report urodynamics and clinical results of a new readjustable TOT (SAFYRE T) (2) after six months

Study design, materials and methods

We implanted 34 TOT between January and August, 2004 in 34 women affected by urodynamic stress urinary incontinence without any vaginal prolapse. Mean age of women was 52 (range 47-64). Mean Q max at diagnosis was 28 ml/sec and no patients reported overactive bladder signs at urodynamic assessment.

Any patient reported previous surgery for stress incontinence

The procedure was performed with the patient in the lithotomy position under spinal anesthesia. A 2 cm long vertical vaginal incision was performed at 0.5 cm from the urethral meatus. Minimal vaginal dissection was performed laterally toward the inferior ramus of the pubic bone; this minimal dissection avoided damage to the urethral innervations and allowed for the passage of the needle and the anchoring tails.

Skin punctures were made bilaterally in the genitofemoral folds at the level of the clitoris. The needle passed around and under the ischiopubic ramus through the skin, obturator membrane and muscles, finally exiting through the vaginal incision. This was accomplished by introducing the needle vertically in the previously made skin incision until the obturator membrane and muscle were perforated. Next, the needle was brought to an horizontal position with the tip heading to the surgeons index finger in the vaginal incision. This maneuver allows for the surgeon to bring the needle safely to the vaginal incision.

SAFYRE sling was hooked by the tip of the needle and brought to the previously made incision. The same maneuvers were repeated on the other side. A Metzenbaum scissors was placed between the tape and the urethra during intra operative adjustment, avoiding any tension of the tape. The exceeding columns were cut leaving 5 cones over the skin. This extra length was introduced in the subcutaneous tissue, toward the labia majora for safety and to facilitate the anchoring tails identification should it be necessary. The skin and vaginal incisions were closed in the usual manner.

Accordingly, no cystoscopy was necessary and a Foley catheter was left in place overnight.

Results

After six months only three patients (8,8 %) needed to readjust the sling tension thanks to silicon columns remaining in the majora labra because persisting stress incontinence. Remaining 31 (91 %) was considered cured at six months follow up (mean Q-max at urodynamic evaluation 17,5 ml/sec).

Interpretation of results

The possibility to access to the previous incision with only local anaesthesia make this procedure sure and modifiable every time is needed

Concluding message

Safyre T associates the advantages of the transobturator approach with the readjustability.

References

1. Urinary incontinence as a worldwide problem. International journal of Gynecology & Obstetrics 2003;82:327-338.
2. Pubovaginal Safyre: A new readjustable minimally invasive sling for female urinary stress

incontinence. The iberoamerican Safyre study group. Urología Panamericana, 2002, 14(4): 22-25.