

A TWO-YEAR FOLLOW-UP OF A NEW READJUSTABLE TRANSOBTURATOR APPROACH FOR SURGICAL TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

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 after surgery.

The self-anchoring SAFYRE (Promedon) sling has recently been added to the existing systems. This is a tension-free, synthetic sling, placed at the mid urethra so that urethral erosion is unlikely it is a re-adjustable, self-anchoring synthetic sling that allows the tension to be re-adjusted after surgery should there be urinary leakage or retention. The Safyre system is based on the integral continence theory. Aim of our study is to report urodynamics and clinical results of a new readjustable sling (Safyre-t) (2) after two year follow-up.

Study design, materials and methods

We implanted 84 TOT between January 2004 to February 2006 in 84 women affected by urodynamic stress urinary incontinence without any vaginal prolapse. Mean age of women was 52 (range 47-64) Tab.1. Mean Q max at diagnosis was 28 ml/sec and no patients reported overactive bladder signs at urodynamic assessment.

Tab.1 Patients characteristics

- Patients
- Mean age 52 years (range 47-64)
- Parity 2,5 (range 0-4)
- Menopause 18 patients(46,6%)
- Previous surgery procedure 16,6%(6 cesar. Sec., 8-ab. Hyst.)
- Post-menopausal pts were taking systemic or local estrogen therapy
- QoL based on the International Consultation on incontinence Questionnaire, short form, ICIQ-SF

Tab.2 - Urodynamics parameters before and after surgery

	DIAGNOSIS	1 Year	2 Year
Mean Q-max at free uroflowmetry (ml/sec)	28.3±0.2	18.2±1.2	17.5±1.2
Mean detrusorial pressure at max flow (cmH2O)	15.4±2.2	19.3±3.2	22.3±3.2
Mean max flow rate (ml/sec)	23.1±1.6	16.3±3.1	19.1±0.2

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 maneuver 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

The main complication after surgery was the novo instability which occurred in 16 patients (19%); this symptoms occurred immediately after surgery and no specific treatment was used. 2 patients (2.3%) presented vaginal erosion of the tape. The protruding part of the tape was removed and the tape was covered by an advanced vaginal flap. Six patients (7.1%) needed to readjust the sling tension thanks to silicon columns remaining in the majora labra because persisting stress incontinence. Remaining 78 pts (92.8 %) was considered cured at two year follow up. (mean Q-max at urodynamic evaluation 18.1 ml/sec). The ICQ-SF showed significantly better scores on all questions than before surgery (90% of patients reported that they had fewer urinary symptoms after surgery).

Interpretation of results

The transobturator approach creates a suburethral support zone and increases urethral resistance and descending movement of the urethra is avoided when abdominal pressure increases.

Concluding message

The Safyre self-anchoring system is unique in allowing readjustment after surgery. This procedure is a promising step forward in the surgical treatment of SUI.

References

1. Urinary incontinence as a worldwide problem. International journal of Gynecology & Obstetrics 2003;82:327-338.
2. Pubovaginal Safyre: A new readjustable minimal/y invasive sling for female urinary stress incontinence. The Iberoamerican Safyre study group. Urologia Panamericana, 2002. 14(4)

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DISCLOSURES: NONE

HUMAN SUBJECTS: This study did not need ethical approval because no necessary and did not follow the Declaration of Helsinki - with approval by the ethics committee - in the sense that no necessary Informed consent was obtained from the patients.