

C R PALMA P¹, L Z RICCETTO C¹, DAMBROS M¹, THIEL M¹, DE FRAGA R¹, PALADINI M², GROSSI O², COLAÇO J³, RETTO H³, CASTRO-DIAZ D⁴, RODRIGUES NETTO JUNIOR N¹

1. UNIVERSIDADE ESTADUAL DE CAMPINAS-UNICAMP, 2. ARGENTINA, 3. PORTUGAL, 4. SPAIN

SAFYRE: A NEW CONCEPT FOR READJUSTABLE MINIMALLY INVASIVE SLING FOR FEMALE URINARY STRESS INCONTINENCE - THE IBEROAMERICAN SAFYRE STUDY GROUP

Aims of Study

Safyre Sling is a new technique to create a support to mid-urethra, in order to restore the continence in women with stress urinary incontinence (SIU). According to the integral theory, the medial and distal third regions of the urethra are the most important regions in urinary continence because of the puburethral ligament and the pelvic muscle floor (1). Safyre consists of a polypropylene mesh that acts as a urethral support, held between two self-anchoring tails which are made of an implant grade polydimethylsiloxane polymer. These tails are the basis of the self fixing system, for minimum surgical damage of pelvic floor natural support structures. A specially designed insertion needle permits both suprapubic or transvaginal approach, according to the surgeon best skills, by changing the needle holder between it is extremities.

Methods

Since February 2001, 128 patients (mean age - 63 years) underwent a SAFYRE implant to treat SUI. Preoperatively, all patients underwent a complete clinical history, physical and pelvic examination, including an objective assessment of urinary leakage during stress maneuvers and a urodynamic study. Patients were reviewed at 1 week, at 1, 6, 12, 18 and 24 months after the procedure. At each visit, detailed history concerning voiding symptoms and urine leakage and physical exam were undertaken, including direct assessment of urinary leakage during stress maneuvers. Dystopia repair was performed whenever necessary, during the same procedure (patients who presented severe pelvic prolapse as grade 3 or 4, were excluded from the study). Most patients (55%) in this group had previously undergone an anti-incontinence procedure. Urethral hypermobility was diagnosed in 43% of the patients (Mean Valsalva Leak Point Pressure was 98cmH₂O) and 57% suffered from intrinsic sphincter insufficiency (Mean Valsalva Leak Point Pressure was 62cmH₂O). Cure was defined by complete continence without symptoms of bladder dysfunction or residual persistent leakage with minimal patient discomfort. Unsuccessful outcome was defined as unchanged or worsened urinary incontinence. The sling was applied through a 1 cm longitudinal vaginal incision at midurethra using a specially designed insertion needle that permits both suprapubic or transvaginal approach.

Results

The average follow up period was 9 months (60 patients have an average follow up period of 18 months). The mean operative time was of 20 minutes and the average hospital stay was 24 hours. In 2,3% of the implants, bladder perforation occurred. Postoperative urinary retention occurred in four patients (3,1%) who were subjected under local anesthesia to readjustment of sling tension and urinated spontaneously after the procedure. Transient irritative voiding symptoms were reported by 25 patients (20%) during the immediate postoperative period (up to 4 postoperative weeks). During the initial follow up period, 90,6% (116 patients) were found to be cured of incontinence, 2,3 % (3 patients) reported an improvement and 5,5% (7 patients) were dissatisfied with the procedure.

Conclusions

SAFYRE is a safe and quick procedure that allows for postoperative readjustment under local anesthesia. This technique may be an attractive alternative if the good result obtained so far prove to be long lasting.

References

1. Petros P, Ulmsten U: Na integral theory and its method for the diagnosis and management of female urinary incontinence. Scand J Urol Nephrol, 153: 1-93, 1993.