

Safyre. A new concept for adjustable minimally invasive sling for female urinary stress incontinence

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ABSTRACT

INTRODUCTION: SAFYRE is a new readjustable and minimally invasive sling for the treatment of stress urinary incontinence (SUI). Attempts to restore the normal suburethral hammock using an anatomical approach have been made in recent years. The authors report their experience with this device, which associates the efficacy of slings with readjustability.

MATERIAL and METHODS: A total of 100 consecutive patients with clinical and urodynamic diagnosis of SUI underwent SAFYRE sling procedure. The age range was from 40 to 71, mean age 63 years. Seventy-five patients (75%) presented previous failed anti-incontinence procedures. Physical clinical examination, stress test, pad use and a urodynamic study were performed before the surgery. All the patients presented symptoms of SUI and 30 % also reported mild urgency.

RESULTS: The average follow up period was 14 months (12 – 30 months). The mean operative time was of 25 minutes. Dystopia repair was performed whenever necessary, during the same procedure. The average hospital stay was 24 hours. In 3% of the implants, bladder perforation occurred. During the postoperative period, 26 patients developed urgency symptoms. During that follow up period, 92% were found to be continent, 3% reported an improvement and 5% were dissatisfied.

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

KEYWORDS: Stress Urinary Incontinence; Sling; Female; Failure.

INTRODUCTION

Pubovaginal slings date back to the beginning of the last century (1). Nowadays, this technique has been considered to be the most effective for treating Stress Urinary Incontinence (SUI) in patients with lesions in the intrinsic urethral mechanism (2). However, morbidity and convalescence issues have stimulated the search for less invasive procedures such as minimally invasive slings and periurethral injections.

Synthetic tapes have been used with a high success rate, giving strength to damaged tissues. An added benefit of synthetic slings is that they transform major surgeries into minimally invasive procedures and also they reduce operative time, hospital stay and postoperative discomfort as well (3).

Since the marketing and success of the TVT technique, other products have been developed onto the suburethral sling market. The self-anchoring SAFYRE sling has recently been added to the existing tools. It is a tension-free, synthetic sling, placed at the mid urethra that makes urethral erosion unlikely. It is a readjustable, self-anchoring synthetic sling that allows for postoperative tension readjustment should urinary leakage or retention occurs (4).

According to the integral continence theory, the medial and distal third regions of the urethra are the most important. SAFYRE procedure is based on this theory and experimental studies of the female urethral closure mechanism (5).

Slings are now being utilized even more frequently and the SAFYRE, which has imbibed these new concepts is an attractive alternative for the surgical treatment of SUI. The authors present their experience with this readjustable sling, focusing on the safety perioperative and efficacy a medium-term of the procedure.

MATERIAL AND METHODS

Patients

We conducted a prospective, multicenter, single-arm, nonrandomized clinical study involving SUI patients, which received the approval of the Hospital Ethics Committee.

From February 2001 to March 2002, 100 patients with SUI diagnostics underwent the SAFYRE implant. The patients' ages ranged from 40 to 71 years (median age 63 years).

Study design

All patients were given a routine diagnosis for incontinence, including history, followed by impact assessment based on the International Consultation on Incontinence Questionnaire – short form (ICIQ-SF) (6), gynecologic examination, stress test, pad use and urodynamic investigation. Urodynamic evaluation was performed with 2 urethral catheters (one 10F for filling and another 4F for bladder pressure measurement). A rectal 4F catheter-balloon was placed above the anal sphincter to obtain abdominal pressure. The test included water cystometry, Valsalva leak point pressure (VLPP) assessment, which was performed with a intravesical volume of 200ml and Valsalva maneuvers, and pressure-flow study.

The gynecological examination disclosed mild cystocele in 62 patients (62%); 70% of the cases were grade I and the rest grade II. Rectocele grade I was diagnosed in 13 patients and only cases of symptomatic grade II cystocele were repaired (3 patients).

The stress test was positive in all patients. Results related to urodynamic testing are shown in table 1. Patients who presented involuntary detrusor contractions during bladder filling or Maximum flow (Qmax) less than 15ml/s and/or post void residual urine of more than 20% of the volume voided were excluded from the study but those with irritative symptoms without urodynamically proven involuntary contractions were included. Although urodynamically proven detrusor instability does

not have a significant effect on surgical outcome, this decision was based on the concept regarding the postoperative improvement of sensory urgency, as described previously (7). Patients with involuntary detrusor contractions were excluded from this initial study due to the less favorable prognosis regarding post-operative irritative symptoms (8).

Most patients, in this clinical trial, had at least one previously failed anti-incontinence procedures (75%). The one most commonly performed was the anterior vaginal repair (table 2).

Follow-up was performed at 1 month and each 6 months. At these recalls, the patients were questioned about presence of spontaneous voiding, involuntary urinary leakage, bladder irritant symptoms and vaginal and suprapubic pain, followed by a impact assessment, stress test and pad use.

The surgical results were classified according to Blaivas & Jacobs (9) into 3 categories: a) cured – absence of incontinence; b) improved – frequency of incontinence episodes less than once every 2 weeks; c) failure – frequency of incontinence episodes more than once a week.

Material

SAFYRE consists of a polypropylene mesh that acts as a urethral support, held between two self-anchoring columns that are made of an implant grade polydimethylsiloxane polymer. These columns are the basis of the self-fixing system. In order to minimize the surgical damage of pelvic floor natural support structures, a special 3.5 mm in diameter needle, allows for both suprapubic and transvaginal approaches, according to the surgeon best skills (Fig. 1). The versatile needle is assembled for transvaginal approach when the hooked extremity is introduced inside the needle holder, and for suprapubic approach when assembled the other way (needle and sling are made by Promedon, Cordoba, Argentina).

Surgical Technique

The procedure was performed with the patient in the lithotomy position under spinal anesthesia.

Two grams of first-generation of cephalosporin were administered intravenously at the time of anesthesia induction, followed by one gram repeated 6, 12 and 18 hours after the procedure.

Two 0.5 cm transverse incisions are made close to the superior aspect of the pubic bone 5 cm apart. A longitudinal vaginal incision, 1.5 cm in length is made, starting 0.5 cm from the urethral meatus. Notice that this incision is not allowed to encroach on the bladder neck. Dissection is done to create a 1 cm tunnel lateral to the urethra for the introduction of SAFYRE insertion needle. First, the needle is advanced through the vaginal tunnel until the perforation of pelvic floor at the level of the mid-urethra . Then, it is redirected against the back of pubic bone and advanced continuously to the benchmarks in the suprapubic area (transvaginal approach). According to the surgeon's option the suprapubic approach can be used. In this approach the needle is advanced through one of the suprapubic incisions, down the posterior side of the pubic bone towards the vaginal incision. The needle tip remains in contact with the posterior pubic bone until it passes through the endopelvic fascia. Using the index finger of the other hand, the surgeon locates the tip of the needle then guides it through the vaginal incision. Cystoscopy is performed to rule out bladder perforation. After the removal of the holder, SAFYRE is attached to the needle and pulled out to the suprapubic area. The same maneuvers are repeated on the other side. The proper tension of the sling is adjusted maintaining a Metzenbaum pair of scissors between the urethra and the sling, to prevent undue tension. The extremities of the sling are cut and the Metzembraum scissors are removed. No further fixation is needed and the incisions are closed in the usual manner. An indwelling catheter is left in place overnight.

Readjustment technique

The procedure to tight SAFYRE can be performed under local or spinal anesthesia. As the extremities of the polydimethylsiloxane tails can be easily palpable in the subcutaneous tissue, local anesthesia with lidocaine 1% solution seems to be the method of choice. Usually, the readjustment of only one tail is enough, without risk of significant deviation of the urethral axis. A small incision is made over the palpable tail extremity (close to the superior aspect of the pubic

bone) and it is gently dissected and pulled carefully, until the proper tension is achieved (Fig. 2). During this maneuver, a Metzenbaum scissors should be maintained between the mesh and the urethra, to prevent over correction. The bladder is filled with saline solution before the procedure, so the patient can be asked to cough and to do repeated Valsalva maneuvers to check if leakage occurs. Generally, the readjustment is proposed before 30 days postoperative, but theoretically it can be done at any time after the procedure, because of the formation of a fibroblastic pseudocapsule surrounding the polydimethylsiloxane tail of SAFYRE, that permits easy dissection and mobilization of the tails inside this pseudocapsule, whenever it became necessary.

The procedure to loosen the SAFYRE can be performed under spinal, intravenous or local anesthesia. When the local anesthesia is used, both suprapubic area (including urethropelvic fascia) and anterior vaginal wall (including rectus muscle and fascia) have to be anesthetized with lidocaine 1% solution. A longitudinal vaginal incision, 1.5 cm in length is made, starting 1 cm from the urethral meatus, and the polypropylene mesh is dissected from the urethropelvic fascia. The tails are dissected bilaterally, grasped with haemostatic clamps and pulled back, until a Metzenbaum scissors or a right-angle clamp can be interposed between the mesh and the urethra. A Foley catheter is left in place overnight .

RESULTS

Patient characteristics

The basic characteristics and the demographic data of all patients are presented in Table 3.

The follow up period ranged from 12 to 30 months, the mean follow up period was 14 months.

Complications of procedure

The mean duration of the procedure was 25 minutes and the mean period of hospitalization was 24 hours (from 12 to 36 hours). All patients went home the day after the surgery.

The overall complication rate was 34%. Most of the women concerned had more than one complication.

Perioperative complications occurred in 3 cases and included perforation of the upper lateral wall of the bladder in all 3 cases. Foley catheter was kept for 48 hours in those patients and they evolved without complications. There was no bleeding, blood transfusion, urethral or vaginal perforations during the procedure.

The diagnosis of urinary retention was done when the residual volume, obtained by post micturition urethral catheterization, was higher than 100 ml. Patients which could not present spontaneous micturition in the immediate post-operative period were maintained in a clear intermittent catheterization program until 4 weeks post-operatively when a loosening procedure was performed if retention had persisted. All of the patients that presented spontaneous micturition in early post-operative period showed post-void residual less than 100 ml and were considered without retention. Following the above criteria, postoperative urinary retention occurred in 4 patients who had not presented spontaneous micturition after 4 weeks post-operatively. All underwent sling tension loosening under local anesthesia and voided spontaneously, with completed relief of

irritative symptoms and with a mean post void residual volume of 60 ml after the procedure. Tape section was not necessary in any case.

The main postoperative complication was postmicturitional irritation symptoms, which occurred in 26 patients. This symptom was related during the immediate postoperative period (up to 4 postoperative weeks). There were 6 cases of tape infection and the sling needed to be removed in 4 patients.

Six patients underwent later readjustment of the tape to tight the SAFYRE, These patients presented urinary incontinence after the surgery and the readjustment was performed in order to become them continent. We had good results in four patients (cure of pre-operative complaints) and improvement in two. The readjustment was performed under local anesthesia.

Cure rates

According to Blaivas & Jacobs criteria (9) after 14 months mean follow up, 92% of patients were continent, 3% reported significant improvement and 5% were dissatisfied with the procedure and were considered as failures. The impact questionnaire (ICQ-SF) showed significant improvement in all questions compared with pre-operative assessment (90% of patients reported that they had less urinary symptoms after surgery).

At the end of follow up period, the stress test was negative in all the continent and incontinent patients and the incontinent group was using, at most, 1 unit daily of perineal pad.

DISCUSSION

Recent studies agree that pubovaginal slings and the retropubic urethrocytopexies are stress urinary incontinence techniques that produce the best continence results after a long-term follow up (10). The slings, however, imply a considerable period of surgical training and an inconvenient need for a donor site to obtain the fascia to be used in the surgery as well as risks of infra-vesical obstruction and other bladder dysfunction's (9). The retropubic urethrocytopexies, on the other hand, imply an abdominal incision with increased morbidity and hospitalization, high costs when performed using a laparoscopic access and a learning curve (5). Therefore all efforts towards the development of minimally invasive techniques are justifiable.

From a conceptual viewpoint, the SAFYRE corresponds to a sling but the creation of a sub-urethral support zone increases urethral resistance and consequently the rotational as well as the descending movement of the urethra is avoided when abdominal pressure increases. Additionally, it facilitates the coaptation of the urethral lumen at rest and under stress. However, contrary to the classical pubovaginal slings, the SAFYRE is applied in the medial third of the urethra where the pubourethral ligaments responsible for natural stability of the urethra are inserted (11). Sling maintenance in an adequate position is explained by the saliencies and their re-entrances, creating a hook-like effect on the pelvic fascias and the abdominal smooth muscle as well as local inflammatory reactions.

SAFYRE insertion is tension-free and is not restricted by the size of the bladder neck as in conventional slings. Although our study presented 3,1% of urinary retention, SAFYRE allowed for postoperative tension readjustment without difficulties. These patients underwent sling readjustment under local anesthesia and voided spontaneously, with completed relief of irritative symptoms and with a mean post void residual volume of 60 ml.

Our results confirm the feasibility and safety of SAFYRE treatment of urinary incontinence. Since the first report by Ulmsten (12), TVT has become a popular method for genuine stress urinary

incontinence. A recent review of 11 articles with objective endpoints gave a cure rate of 87,3% an average of 17 months after surgery (13). The use of suprapubic and transvaginal approach have been associated with various complications, including bladder perforation, injuries to the obturator, external iliac, femoral, inferior epigastric vessels, nerves and small intestine (14, 15). Following 140 SPARC (Suprapubic Arc) sling procedure, the hematocris was checked on postoperative day 1 in the last 57 patients regardless of blood loss in the operating room. A total of 6 patients required intervention in the early postoperative period, including transfusion in 4 immediately postoperatively for retro pubic bleeding. One patient presented on postoperative day 4 drainage from a suprapubic incision. She had a perforation through a loop of small bowel that required resection of a short segment of the bowel and removal of the sling (16).

Although this study have not compared SAFYRE to other minimally invasive techniques, such as TVT or similar, there are specific and significant differences concerning the biochemical and biomechanical properties of this device. As opposed to TVT or other polypropylene minimally invasive slings, the smooth surface of SAFYRE mesh allows for easy primary adjustment during the implant and even during eventual readjustment, besides keeping its resistance and shape due to its low deformity rate. Moreover, the elasticity of polymetylsyloxane tails can provide fine movements according to the changes of patient's abdominal pressure, acting as a dynamic support. Furthermore SAFYRE self-anchoring system is unique as far as postoperative readjustibility is concerned. The procedure is minimally invasive and no large abdominal incision is required for harvesting fascia, neither to fix the sling to the aponeurosis of the abdominal rectus muscle as in classical slings. Its readjustability allows for late adjustments of sling tension in patients presenting persistent incontinence or urinary retention, avoiding major surgeries such as urethrolisis or the need for another sling insertion, reducing costs.

The coherence of the physiological principles involved in female urinary incontinence, cure indices above 90% and the uncontestable benefits of postoperative tension readjustments indicate that this procedure is a promising step forward in the surgical treatment of SUI.

REFERENCES

1. Goebel R. Zur operativen Beseitigung der Angeborenen Incontinentia Vesicae. Z Gynak Urol 1910; 2:187.
2. McGuire EJ, Fitzpatrick CC, Wan J, Bloom D, Sanvordenker J, Ritchey M et al. Clinical assessment of Urethral Sphincter Function. J Urol 1993; 150:1452.
3. Ulmsten U, Henriksson L, Johnson P, Varhos G: An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J 1996; 7:81.
4. Palma PCR, Riccetto CLZ, Dambros M, Thiel M, Fraga R, Herrmann V, Netto NR Jr. Pubovaginal Safyre: A new readjustable minimally invasive sling for female urinary stress incontinence. The iberoamerican Safyre study group. Urología Panamericana 2002; 14(4): 22.
5. Petros P, Ulmsten U: An integral theory and its method for the diagnosis and management of female urinary incontinence. Scand J urol Nephrol 1993; 153:1.
6. Avery K, Donovan J, Abrams, P. Validation of a new questionnaire for incontinence: The International Consultation on Incontinence Questionnaire (ICIQ). Neurourol and Urodynamics 2001; 4:510.
7. Schrepferman CG, Griebing TL, Nygaard IE, Kreder KJ: Resolution of urge symptoms following sling cystourethropexy. J Urol 2000; 164:1628.
8. Kaplan SA, Te AE, Young GP: Prospective analysis of 373 consecutive women with stress urinary incontinence treated with a vaginal wall sling the Columbia-Cornell University experience. J Urol 2000; 164:1623.
9. Blaivas JG, Jacobs BZ. Pubovaginal Fascial Sling for the treatment of complicated stress urinary incontinence. J Urol 1991; 145: 1214.
10. Norris JP, Breslin DS, Staskin DR: Use of synthetic material in sling surgery: a minimally invasive approach. J Endourol 1996; 10: 227.

11. Ulmsten U, Falconer C, Johnson P, Jomaa M, Lannér L, Nilsson C G, Olsson I: A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. *Int Urogynecol J* 1998; 9:210.
12. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunction* 1996; 7:81.
13. Perchers UM, Tunn R, Buczkowski M, Perucchini D. Tension-free vaginal tape for the treatment of Stress Urinary Incontinence. *Clin Obstet Gynecol* 2000; 43:670.
14. Neuman M. Infected hematoma following tension-free vaginal tape implantation. *J Urol* 2002; 168:2549.
15. Kuuva N, Nilsson CG. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. *Acta Obstet Gynecol Scand* 2002; 81:72.
- 16.** Kobashi KC, Govier FE: Perioperative complications: the first 140 polypropylene pubovaginal slings. *J Urol* 2003; 170(5):1918.

SUBTITLES

Figure 1: SAFYRE sling set; mesh made of polypropylene and two self-anchoring columns made of polydimethylsiloxane polymer; versatile needle that allows a vaginal approach as well as suprapubic approach.

Figure 2: Fibroblastic pseudocapsule surrounding the polydimethylsiloxane tail of SAFYRE. The pseudocapsule should be dissected in order to mobilize the tail and readjust the tape.