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IS THE ANTERIOR VAGINAL WALL SLING A GOOD ALTERNATIVE FOR INTRINSIC SPHINCTERIC INSUFFICIENCY?

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ABSTRACT

Objectives: We present our experience with the anterior vaginal wall sling, in the treatment of patients with stress urinary incontinence (SUI) due to urethral intrinsic sphincteric deficiency.

Material and Methods: Forty-five women (mean age 53.4 years) with urodynamically proven intrinsic sphincteric deficiency (Valsalva Leak Point Pressure below 60cm H_2O) were studied, prospectively. Coexisting bladder neck hypermobility was assessed using transperineal ultrasound. Patients with severe pelvic prolapse (grade 3 or 4) were excluded. Multivariable logistic regression was used to identify the variables that influenced the outcome (statistical significance was established for $p<0.05$). Follow-up ranged from 26 to 61 months (mean 40 months).

Results: Complete SUI cure was achieved in 14 women (31.1%) and 17 other women (37.8%) described SUI improvement and were satisfied with the outcome. Statistical analysis showed that factors such as age below 35 years ($p=0.0251$), and preoperative bladder neck hypermobility ($p=0.0176$), were strongly related to postoperative continence.

Conclusions: We concluded that the vaginal wall sling has a high rate of failure in the treatment of patients with intrinsic sphincteric deficiency. This technique should not be proposed if hypermobility is not associated, especially in the case of elderly patients.

Key words: urinary incontinence; stress; surgical technique; vagina; sling
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INTRODUCTION

The main goal of the sling procedure is to correct stress urinary incontinence (SUI) resulting from intrinsic sphincteric deficiency. Recently, slings have also been proposed for patients with associate or exclusive urethral hypermobility (1). In this procedure, continence is restored because of improved pressure transmission ratio in the urethra, obtained through the support provided by the sling (2). A wide variety of materials have been proposed to be used in slings, e.g. autologous materials (rectus fascia, fascia lata, and anterior vaginal wall), biological homologous or heterologous material (cadaveric fascia, unepithhelized dermal grafts, bovine pericardium, porcine intestinal submucosa), or synthetic material (expanded polytetraflouroethylene or polypropilpropylene) (1).

Modern concepts of female pelvic anatomy and physiology have resulted in a new approach for treating SUI (3) that involves the complete anatomical restoration of the pelvic fascial and muscular structures of the continence mechanism, especially those related to suburethral support of the midurethra. Anterior vaginal wall sling has evolved from vaginal wall sling, which has been previously described by Raz et al. (3). In the vaginal wall sling first described, a rectangular graft of vaginal epithelium anchored with

polypropylene sutures in both extremities was suspended to suprapubic area in the same way as in a classical aponeurotic sling. The main purpose of anterior vaginal sling is to strengthen urethropelvic ligaments using sutures applied from lateral aspect of midurethra to ligament insertion in the tendineous arc of obturator fascia. A formal Raz bladder neck suspension is also performed simultaneously. According to Raz et al. experience, the anterior vaginal wall sling can play a major role in anterior pelvic reconstruction and is expected to cure all pathophysiologic components of SUI with a high rate of success, regardless of the urodynamic diagnosis (3). Our experience with the anterior vaginal wall sling in treating female intrinsic sphincteric deficiency was distinct, and is presented below.

PATIENTS AND METHODS

All patients with urinary stress incontinence resulting from intrinsic sphincteric deficiency, defined as having Valsalva leak point pressure (VLPP) below 60cm H_2O, attended at our institution from 1993 to 1996, were initially selected for this study. After careful evaluation, 45 patients were prospectively studied. Patients who presented severe pelvic prolapse (grades 3 or 4), VLPP above 60cm H_2O, or detrusor instability, were excluded from the study. Preoperatively, all patients underwent a complete physical and pelvic examination, including an objective assessment of urinary leakage during stress maneuvers. Pelvic prolapse was graded according to Baden et al. (4). Urodynamic evaluation was performed with 2 urethral catheters (one 8F for filling and another 4F for bladder pressure measurement). A rectal saline filled 8F catheter-balloon was placed above the anal sphincter to obtain abdominal pressure. The test included medium filled water cystometry, VLPP assessment, and pressure-flow study. Patients with VLPP below 60cm H_2O were diagnosed as having intrinsic sphincteric deficiency, based on McGuire's criterion (5). Urethral mobility was evaluated in all patients using transperineal ultrasound. Urethral hypermobility was considered as partly a cause of SUI in cases where urethral descent on transperineal ultrasound was above 10mm. All examinations were performed by the same senior radiologist.

All operations were performed by the same senior surgeon. After spinal or epidural anesthesia, the patient was placed in dorsal lithotomy position. The vagina, perineum, and lower abdomen were prepared in usual fashion and draped. A urethral 16F Foley catheter was inserted and the balloon was filled with 10mL of sterile saline, emptying thus the bladder and providing a landmark for the bladder neck. The posterior vaginal wall was retracted with a weighted vaginal speculum. Submucosal saline injections were used to ease the dissection of vaginal wall. Two paramedian oblique incisions were made from the bladder neck to the midurethra. Dissection proceeded just under the vaginal epithelium until exposing pubocervical fascia. Endopelvic fascia was bilaterally perforated by laterally inserting Metzembaum scissors in bladder neck, close to the urethropelvic ligament insertion in the obturator's tendinous arch. This maneuver allowed the surgeon to reach the retropubic area (Figure-1). The urethropelvic ligament was bluntly dissected from the tendinous arch and, when necessary, urethrolysis was performed during this step, by dissection of all adherences between the urethra and surrounding tissues, until it became completely free of scar tissue. The vaginal wall sling was fashioned by placing 2 number 0 polypropylene helical sutures on each side of the urethra and bladder neck. The first pair of sutures was bilaterally applied to the midurethra, and included medial and lateral edges of the perforated urethropelvic ligament, the pubocervical fascia, and the vaginal wall without the epithelium. The second pair was bilaterally placed at the bladder neck, and included the medial stump of urethropelvic ligament, the pubocervical fascia, and the vaginal wall without the epithelium. (Figure-2). A 1cm midline transverse suprapubic incision was made, and the sutures were transferred towards this incision with a Stamey suspension needle. Cystoscopy was performed to rule out bladder or urethral perforation. The sutures were tied with the cystoscope inside the urethra and parallel to the vaginal axis, without any tension. Suprapubic cystostomy was not performed in any patient. The abdominal incision was closed with interrupted 4-0

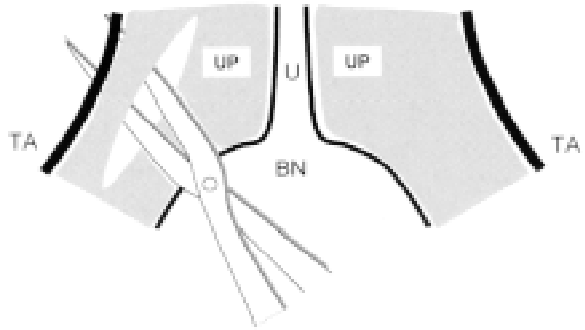

Figure 1 *- Two oblique incisions are made in the vaginal wall from just proximal to the urethral meatus to the bladder neck. Uretropelvic ligament and endopelvic fascia are perforated using a Metzembaum scissors and retropubic area is reached. TA = tendineous arc; UP = urethropelvic ligament; U = urethra; BN = bladder neck.*

nylon stitches, and the vaginal wall was sutured with 2-0 chromic interrupted stitches. An antibiotic-soaked vaginal pack was placed to be retrieved in 24 hours. A Foley catheter was left indwelling for 48 hours, when residual urine volume was measured. If residuals exceeded 100mL, or 30% of total bladder capacity, the catheter was reinserted and the patient was re-evaluated after 4 days, and then weekly, until the aforementioned criteria were met, and catheter withdrawal was possible. If after a month, the patient still did not have the catheter removed, clean intermittent self-catheterization was implemented for 3 postoperative months, after which vaginal urethrolysis was proposed if infravesical obstruction was diagnosed.

Patients were reviewed at 1 week, at 1, 3 and 6 months, and annually thereafter. At each visit, detailed history concerning voiding symptoms and urine leakage plus a physical and pelvic exam were undertaken, including direct assessment of urinary leakage during stress maneuvers (Bonney–Marshall test). All visits were supervised by the head researchers.

Success was defined by complete continence without symptoms of bladder dysfunction or residual persistent leakage with minimal patient discomfort (i.e., important improvement from previous state). Unsuccessful outcome was defined as unchanged or worsened urinary incontinence.

Statistical analysis was carried out using a logistic regression model. If the variable was dichotomic (e.g., presence or absence of urethral hypermobility), logistic transformation was used. Proportional odds ratio was used for trichotomic or polytomic variables. Variables included in multivariate logistic regression analysis were age, associated urge-incontinence, presence of nocturnal enuresis, previous abdominal and/or vaginal surgery for urinary incontinence, associated bladder neck hypermobility, and leakage in resting position. Chi-square analysis and Fischer's exact test were respectively used to assess individual dichotomic or trichotomic variables versus successful or unsuccessful outcome. Statistical significance was established at $p<0.05$.

RESULTS

The patients' ages ranged from 29 to 75 years (mean 53.4 years). Demographic data are summarized in Table-1. Most of the patients presented some degreeof anterior vaginal relaxation (mild cystocele: 19 patients; moderate cystocele: 16 patients). Pre-operative urodynamic evaluations are summarized inTable-2.

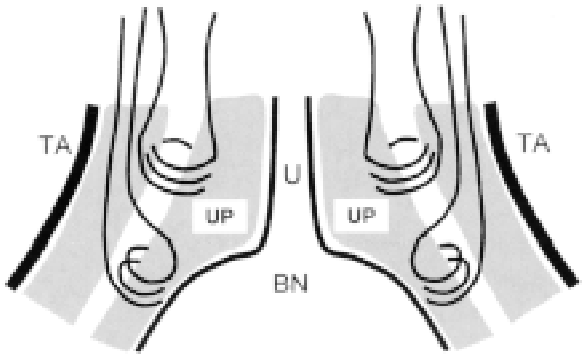

Figure 2 *- Vaginal wall sling is fashioned by placing two number 0 polypropylene helical sutures on each side of the urethra and bladder neck. The first pair of sutures is applied on the midurethra bilaterally and includes the medial and lateral edges of the perforated urethropelvic ligament, pubocervical fascia and the vaginal wall without the epithelium. The second pair is placed on the bladder neck bilaterally and includes the medial stump of urethropelvic ligament, pubocervical fascia, and vaginal wall without the epithelium. TA = tendineous arc; UP = urethropelvic ligament; U = urethra; BN = bladder neck.*

Table 1 *- Demographics data.*

Variable	Mean ± SD (range)
Age	53.4 ± 0.9 years (29-75)
Vaginal deliveries	3.8 ± 2.9 deliveries (0-15)
Previous vaginal anti-incontinence procedures	0.84 ± 0.6 procedures (0-2)
Total anti-incontinence surgeries	1 ± 0.8 procedures (0-3)

The procedure lasted from 40 to 135 minutes (mean=81, standard deviation=12). Three patients bled profusely (>200mL) during vaginal dissection and endopelvic fascia perforation, but the hemorrhage was controlled by manual compression and electro-coagulation without needing blood transfusions. Average hospital stay was 2.3 days (ranged from 2 to 4 days). Sixteen patients (35%) were discharged without bladder catheter. The remainder stayed with urethral catheter for 4 to 25 days (average = 4 days). No patient underwent clean intermittent catheterization. For patients who progressed with urinary retention or significant post-void residual volume, were performed weekly attempts to remove the Foley catheter until voiding improvement. Analgesic requirements were minimal.

Follow-up ranged from 26 to 61 months (median=40). Complete cure of SUI, defined as complete continence without symptoms of bladder dysfunction or residual persistent leakage, and absence of objective leakage during Valsalva's maneuver, was achieved in 14 women (31.1%), and 17 (37.8%) presented improvement from SUI and were satisfied with the outcome. Therefore, according to the criteria above, the outcome was successful in 31 women (68.9%). However, SUI symptoms persisted or urine leakage worsened in the remaining 14 patients (31.1%). Up to present, surgery had failed in 8 patients who underwent aponeurotic sling implant using the rectus fascia.

Finally, multivariate logistic regression revealed that only 2 variables, namely age above 35 years (p=0.0251), and lack of urethral hypermobility (p=0.0176), negatively influenced the outcome. The cure probability and the odds ratio involving these variables are demonstrated in Tables-3 and 4.

DISCUSSION

Stress urinary incontinence resulting from intrinsic sphincteric insufficiency occurs more frequently in patients who have previously undergone surgery to treat incontinence, or who have pelvic irradiation, trauma of ischiopubic region or urethral dysfunction of neurological origin (3). Treating sphincteric insufficiency implies increased urethral resistance, which can be achieved with a sling, submucosal injection of different substances or implantation of an artificial urinary sphincter (6).

Table 2 *- Results of preoperative urodynamic evaluation (n = 45).*

Parameter	Mean ± SD (range)
Maximum cystometric capacity (ml)	360.00 ± 110.3 (200-700)
Valsalva leak point pressure (cm H_2O)	30.9 ± 11.5 (5-55)
Peak flow (ml/sec)	22.4 ± 2.1 (17-27)
Detrusor pressure at peak flow (cm H_2O)	21.4 ± 9.4 (10-58)
Residual volume	6.1 ± 1.5 (0-30)

Table 3 - *Age and urethral mobility related to patients' outcome; p-values derived from multivariate logistic regression.*

Variable	Intercept*	P	Odds Ratio	Confidence Interval (0.95)
Age = 35 years	-0.0783	0.0251	0.925	0.864; 0.990
Hypermobility**	1.9234	0.0176	6.844	1.339; 33.472

** Intercept positive values indicate better responses with increasing values, and intercept negative values indicates worsening response with increasing values.*

*** Urethral descent on transperineal ultrasound ≥10mm.*

Slings made from autologous material have been used since the technique was first described by Aldridge in 1942 (7). Recently, other synthetic materials have been proposed in order to diminish the potential morbidity related to the harvest of aponeurotic or fascial grafts (1). However, the main problem of synthetic material is a greater risk of erosion and infection than biological grafts (8).

The urethral fascial support depends on pubo-urethral and urethropelvic ligaments (9). Pubo-urethral ligaments support the urethra against the inferior branch of pubic symphysis, which has a band of prepubic fibers (more tenuous), and another more robust band of retropubic fibers. They divide the urethra into 3 distinct functional regions. The proximal region, also called intra-abdominal region, is related to passive continence secondary to transmission of abdominal pressure variations that act in conjunction with the bladder neck. The intermediate region includes the midurethra, which is responsible for the active sphincteric mechanism. The function of the region that is distal to the pubo-urethral ligament is related to urinary conduction only, with no involvement of continence mechanism (10). The thickness of anal levator muscle fascia is due to the urethropelvic ligaments that extend parallel to urethra from midurethra to the bladder neck, corresponding to 3 and 9 o'clock positions, and are laterally inserted into the tendinous arch of pelvic fascia. It provides an increase in urethral resistance and supports the urethra and bladder neck. Increased abdominal pressure causes reflexive contraction of anal levator muscle, which increases the tension of urethropelvic ligaments, which results in suspension and compression of the urethra (11). The vaginal wall sling is based on these concepts and aims at restoring the natural elements of urethral support by plication of urethropelvic ligaments with the tendinous arch, so that the urethra is stabilized using available natural tissues (3). The bladder neck support is obtained by applying helicoidal sutures, according to the technique previously described by the same author for the endoscopic suspension of the bladder neck. In a study conducted with 160 patients, of which 95 (59.3%) presented intrinsic sphincteric insufficiency, patient's subjective report demonstrated a success rate of 93%

Table 4 - *Odds ratio values for likelihood for cure or improvement versus unchanged or worsened factoring age and the presence or absence of preoperative hypermobility.*

	Odds Ratio	
Age (years)	**Hypermobility**	**No Hypermobility**
29 - 34	23.675	3.459
35 - 49	14.8	2.162
50 - 74	4.573	0.668
> 75	0.646	0.094

(12). In the same study, 9% of the patients reported urinary urge associated with urine leakage during postoperative period. Stratified analysis did not demonstrate significant differences in relation to the etiology of incontinence, although patients with intrinsic sphincteric insufficiency have shown relatively long periods of postoperative urinary retention. Complications described were uncommon, and were related to vaginal suture infection, suprapubic pain, and in 5% of the cases, to prolonged urinary retention (more than 30 days). Despite the good preliminary results obtained, the author did not report on long-term progression of these patients. A trend towards late recurrence of incontinence among patients with sphincteric deficiency was also described, similarly in the present study.

In this study, only 31.1% of the patients had favorable outcome. Those patients who progressed to incontinence recurrence underwent an aponeurotic pubovaginal sling implant, during which intense periurethral fibrosis - often verified - required ample urethrolysis before implanting the new sling. Fibrosis and urethral fixation were considered to have resulted because of the sutures in the midurethra and the urethral pressure against the pelvic wall. This very same mechanism may be considered a possible cause for worsening of incontinence referred by some patients.

We consider that the lack of objective parameters (other than direct observation of urinary leakage and patient interview) applied for recent incontinence assessment may not be very important, regarding the results obtained. Statistical analysis has shown that both young age and presence of hypermobility are related to success. It can be argued that better collagen synthesis or better collagen turnover, theoretically found among younger individuals, could have a positive impact on the outcome (13). Recently other prospective study in 373 patients presented comparative results of vaginal wall sling, either in women with urethral hypermobility or in those with intrinsic sphincteric deficiency (14). Despite the favorable results presented in both group of patients, the technique described is based on the use of a rectangular shape graft of vaginal wall as suburethral support for the bladder neck and proximal urethra, as the technique first described by Raz *et al*. in 1989 (3). We considered this procedure technically comparable with that of the aponeurotic sling, and thus, similar results would be expected. Otherwise, this technique has important conceptual differences from the procedure discussed in our study, and so we are not able to compare the results.

CONCLUSION

We concluded that the vaginal wall sling has a high rate of failure in the treatment of patients with intrinsic sphincter deficiency. This technique should not be used for patients with stress urinary incontinence due to intrinsic sphincteric deficiency without associated hypermobility, especially in the case of elderly patients.

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EDITORIAL COMMENT

The authors present a retrospective review of their experience using an anterior vaginal wall sling in the treatment of female urinary incontinence secondary to intrinsic sphincter deficiency (ISD).

Findings included a cure rate of 31.1% and an improved rate of 37.8%. Variables associated with success included age of less than 35 years and preoperative diagnosis of urethral hypermobility.

The authors should be applauded for their candid thoughts and results in the use of the anterior vaginal wall sling. The importance of this manuscript is in its contribution to the discussion of the efficacy of various approaches to treatment of female stress urinary incontinence from ISD as well as the notation of the importance of the physical examination (e.g. urethral hypermobility) in predicting success or failure with this approach. Key points for the reader to ponder is the contrast of results in reports in the literature regarding the anterior vaginal wall sling (1,2), the tendency of the anterior vaginal wall sling to fail in the presence of severe ISD (2), and the use of the preoperative Marshall test before selecting this technique. It is hoped that the authors will reexamine their study population in 3 to 5 years to establish or disprove the durability of results in this operation.

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