PUBOVAGINAL FASCIAL SLING FOR ALL TYPES OF STRESS URINARY INCONTINENCE: LONG-TERM ANALYSIS

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ABSTRACT

Purpose: There is a lack of consensus regarding indications and long-term efficacy of the many surgical techniques for treating stress incontinence. Historically pubovaginal sling has been reserved for cases of intrinsic sphincter deficiency or prior surgical failure. Transvaginal needle and retropubic suspensions have been used mainly for sphincteric incontinence unassociated with intrinsic sphincter deficiency. We report the long-term results of pubovaginal sling for all types of stress incontinence.

Materials and Methods: A total of 251 consecutive women with all types of stress incontinence who underwent pubovaginal fascial sling by a single surgeon were retrospectively and prospectively reviewed. Patients were evaluated preoperatively with history, physical examination, standardized symptom questionnaire, voiding diary, pad test, uroflow, post-void residual urine, video urodynamics and cystoscopy. Postoperatively women with at least 1-year followup were assessed by an independent third party (J. R.) who had no prior knowledge of them, and who recorded the parameters of the questionnaire, examination with a full bladder, voiding diary, pad test, uroflow and post-void residual urine.

Results: Overall stress incontinence was cured or improved in 92% of the patients with at least 1-year followup (median 3.1 years, range 1 to 15). The majority of patients with postoperative incontinence had de novo (3%) or persistent (23%) urge incontinence. Permanent urinary retention developed in 4 patients (2%).

Conclusions: Fascial pubovaginal sling is an effective treatment for all types of stress incontinence with acceptable long-term efficacy.

KEY WORDS: urinary incontinence, stress; urodynamics; bladder

A plethora of surgical procedures have been devised for the treatment of stress urinary incontinence but no single technique has met with widespread acceptance. Historically selection of the operative technique has been based on the 3 types of incontinence, urethral hypermobility and intrinsic sphincter deficiency,[1] and surgeon experience with the procedure.[2,3] Typically patients with type 1 or 2 stress incontinence or urethral hypermobility have undergone retropubic suspension, transvaginal suspension or anterior repair, while those with type 3 or intrinsic sphincter deficiency have undergone sling, periurethral injection or sphincter prosthesis procedures. We present our experience with 251 patients who underwent pubovaginal sling operations for all types of stress urinary incontinence.

MATERIALS AND METHODS

We analyzed retrospectively (before 1991) and prospectively (after 1991) 251 consecutive patients with stress incontinence who underwent pubovaginal sling by a single surgeon. Patients underwent neurourological history, physical examination and video urodynamics preoperatively. Beginning in 1988 patients completed a standardized voiding questionnaire, and starting in 1991 they also completed a validated 24-hour pad test and voiding diary before and after surgery. Video urodynamics were performed with room temperature radiographic contrast material at 75 to 100 ml. per minute with a 10F (before 1991) or 7F (after 1991) dual lumen pressure catheter. For cystometry the patient was instructed neither to try to void nor to inhibit micturition but simply to report sensations to the examiner. Since 1992 Valsalva's leak point pressure was defined at a bladder vol-

ume of 150 ml. as the lowest vesical pressure that caused visible leakage from the urethra when the patient coughed and strained. If no leakage occurred with the urethral catheter in place it was removed. The lowest abdominal pressure recorded during cough and Valsalva's maneuver that produced urine leakage was the abdominal leak point pressure.

Patients were evaluated 1 month, 6 months, 1 year and yearly postoperatively. At each visit a history, focused examination with a full bladder, voiding diary, pad test, uroflow and post-void residual urine were obtained. We examined women in the lithotomy position and asked them to strain to check for recurrent incontinence as well as signs of genital prolapse (cystocele, rectocele and enterocele). Patients were contacted in person at followup or by telephone and asked to complete a validated postoperative voiding questionnaire administered by a blinded third party (J. R.).[4] In 84 patients we also compared the questionnaire with the pad test, voiding diary and surgeon assessment of the outcome of the surgery.

Cases were classified as simple or complex. Complex cases included urge incontinence, "pipe stem urethra" (a fixed, scarred urethra), urethral or vesicovaginal fistula, urethral diverticulum, grade 3 or 4 cystocele or neurogenic bladder. Pipe stem urethra was defined subjectively on the basis of cystoscopic appearance, comparison of free flow and pressure flow, and palpation. Women who had no leakage with the urethral catheter in place but did have leakage without it at low pressure were considered to have a pipe stem urethra if there were other subjective parameters which suggested this diagnosis. Simple cases comprised those that did not meet the criteria for complex incontinence including those of detrusor instability if there was no urge incontinence and those of prior surgical failure.

Surgery results were classified overall and with respect to

stress and urge incontinence. Overall a woman was considered dry only if she was not incontinent under any circumstances. Improved was defined as a 50% or more reduction in incontinence and failure was less than a 50% reduction. Cases of stress incontinence were also stratified as cured—no stress incontinence under any circumstances after the perioperative period as stated by the patient, less than 2 gm. change in pad weight, and no notations of incontinence on the pad test and voiding diary; improved—a decrease in stress incontinence episodes by 50% as stated and confirmed by the diary and pad test, and failed—incontinence not improved by more than 50% as stated and confirmed. If there was a discrepancy between the objective data and patient subjective assessment, patient assessment was used as the final arbiter. Postoperatively women were asked about urge incontinence and divided into the 4 groups of cured—urge incontinence present preoperatively but not postoperatively, improved—urge incontinence occurred less than 50% of the time compared to preoperatively, persistent—no improvement by at least 50% compared to preoperatively and de novo—persistent postoperative urge incontinence that was not present preoperatively.

OPERATIVE TECHNIQUE

Details of the operative technique have been previously reported but subsequently we have made 2 minor modifications.[5,6] A transverse or slightly curved incision rather than an inverted U is made in the anterior vaginal wall. A 2-zero polyester fiber suture is attached to each end of the sling and left long to be tied loosely, without any tension, in the midline over the rectus fascia.

Epidural or spinal anesthesia is used unless there is a contraindication or if it proves technically unsatisfactory. Surgery is performed with the patient in the dorsal lithotomy position with a weighted speculum in the vagina. A transverse incision is made over the vesical neck. The dissection continues laterally just beneath the vaginal epithelium with a Metzenbaum scissors pointed toward the ipsilateral shoulder of the patient. The endopelvic fascia is perforated at its lateral most insertion into the ischiopubic ramus. The retropubic space is entered and the lateral edge of the fascia is separated from the bone for about 4 to 6 cm. In cases of obvious vaginal scarring the bladder base and vesical neck are freed from the vaginal attachments. Pfannenstiel's incision is made and the surface of the rectus fascia is dissected free of subcutaneous tissue. Two parallel horizontal incisions 2 cm. apart are made near the midline in the rectus fascia for the entire width of the wound (approximately 15 cm.). Each end of the fascia is secured with a long 2-zero nonabsorbable suture using a running horizontal mattress, which is placed at right angles to the fascial fibers. The sutures are left long, and the strip is excised and stored in a saline filled basin for later use. The fascial defect is closed. A 1 cm. incision is made in the rectus fascia just above the pubis and lateral to the midline on either side. A long curved DeBakey clamp is inserted into the incision and directed to the undersurface of the pubis. The tip of the clamp is pressed against the periosteum and directed toward the index finger, which palpates the periosteum through the vaginal incision. The index finger is used to guide the clamp into the vaginal wound. When the tip of the clamp is visible, one end of the long suture that is attached to the fascial graft is grasped and pulled into the abdominal wound. The procedure is repeated on the other side.

The fascial sling is now positioned from the abdominal wall on 1 side around the undersurface of the urethra at the junction of the bladder neck and back to the abdominal wall on the other side. Cystoscopy is performed to ensure that there has been no damage to the urethra or bladder neck. A trocar 12F suprapubic tube is inserted percutaneously into

the bladder and its position is visually inspected to be sure that it is well away from the trigone. The vaginal incision is closed before the long sutures attached to the sling are tied loosely together over the rectus fascia using the long suture attached to the end of the fascial graft. The sling is secured to the other side without tension and a vaginal pack is left in place.

The vaginal pack is removed the day after surgery. Voiding trials are begun as soon as the patient is ambulatory. If the patient is unable to void by time of hospital discharge (usually postoperative day 2 to 4), the suprapubic tube is left in place for gravity drainage or preferably she is taught intermittent self-catheterization and seen in about 1 month. The kappa coefficient was used for statistical analysis comparing the questionnaire with the pad test, voiding diary and surgeon assessment of the outcome of the surgery in 84 patients. Kaplan-Meier curves were used to express the long-term results.

RESULTS

There were 63 simple (25%) and 188 complex (75%) cases of stress incontinence. Average patient age was 56 years (range 19 to 80). Figures 1 and 2 show the 3 types of incontinence in both groups. Mean number of prior incontinence surgeries was 0.78 (range 0 to 3) in the simple and 3.1 (range 0 to 19) in the complex group. Mean followup was 3.1 years (range 1 to 15). Operative time ranged between 35 minutes and 4 hours depending on concomitant surgery (cystocele, rectocele and so forth) in the simple group.

All women, except for 1 who died postoperatively, were available for evaluation at 1-year followup. Overall stress and urge incontinence was cured in 183 women (73%) and improved in 48 (19%) with at least 1 year of followup (fig. 3). Overall 92% of women were cured or improved following surgery. Median followup was 3 years (range 1 to 15). Table 1 depicts the success rates at 1 year for simple and complex cases, and table 2 depicts the success rate at 1, 3, 5 and greater than 10 years. After initial cure there were no recurrences of stress incontinence with followup as long as 15 years. Figures 4 and 5 depict Kaplan-Meier curves assessing long-term efficacy of the pubovaginal sling for stress, urge and overall cure. We found a statistically significant difference of success probability between the 2 groups (p <0.05). There was excellent agreement (kappa greater than 0.9) among physician assessment, patient assessment (questionnaire), voiding diary and pad test with respect to cure/improved versus fail rates in the 84 consecutive patients (table 3).

Table 4 lists the surgical complications, the most frequent of which was urge incontinence (persistent 23%, de novo 3%). An 80-year-old woman died of complications from an elective implantation of a cardiac pacemaker. Prolonged unexpected urinary retention occurred in only 4 patients. The rest of the women were able to void within 30 days. Two bladder injuries occurred during the passage of the DeBakey clamp from above, and both were realized immediately. They were managed by re-passing the clamp and leaving the suprapubic tube indwelling for 7 days, and neither required open repair.
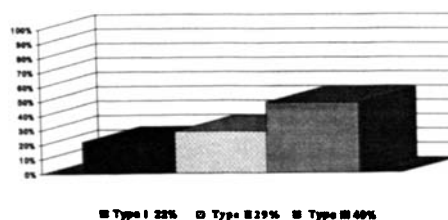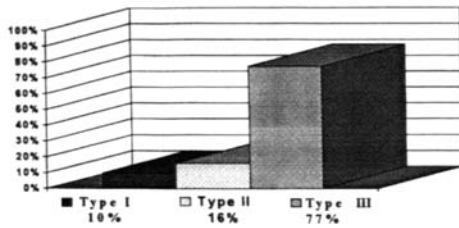

FIG. 1. Types of simple incontinence
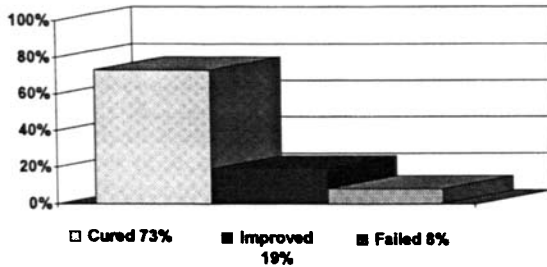
FIG. 2. Types of complex incontinence

FIG. 3. Overall continence results following pubovaginal sling for stress and urge incontinence.

TABLE 1. *Pubovaginal sling results for stress incontinence only*

No. (%)	Simple		Complex	
Pts.	63		188	
Type 1	14	(22)	19	(10%)
Type 2	18	(29)	30	(16%)
Type 3	31	(49)	139	(77)
Previous surgery (range) Mean	0.78 (0–3)		3.1 (0–19)	
Cure	62	(98)*	175	(93)
Improved	0		9	(5)
Failure	0		4	(2)

* One death.

TABLE 2. *Followup by years and success*

	1 Yr.	3 Yrs.	5 Yrs.	More Than 10 Yrs.
No pts.	250	103	47	20
% Stress urinary incontinence (cure)	94	94	96	95
% De novo urinary incontinence	3	5	5	0
% Persistent urinary incontinence	23	26	31	41

The increased success rate for stress incontinence at 5 and 10 years is due to the way the data were calculated. The number of failures was divided by the number of total patients available for followup at each interval. For example if a patient had failure at 1 year but was not yet followed for 3 years, she would be included in the 1 but not the 3-year data.

DISCUSSION

Traditionally type 1 or 2 stress incontinence or urethral hypermobility has been treated with anterior repair, transvaginal bladder neck suspension or retropubic suspension, while type 3 stress incontinence or intrinsic sphincter deficiency has been treated with a sling procedure.[7,8] However, the long-term results of the procedures for less complicated cases have been inferior to those of fascial pubovaginal sling. A recent review of the literature on the surgical management of female stress urinary incontinence revealed a cure rate of only 53 to 79% for transvaginal needle suspension and 47 to 72% for anterior repair compared to 75 to 88% for pubovaginal sling.[2] While retropubic suspension had a success rate of 79 to 88%, comparable to that of the sling operation, the procedure is not indicated in cases of intrinsic sphincter deficiency.[9]

Since the introduction of the sling operation in 1910, the procedure has been associated with a high incidence of per-

TABLE 3. *Comparison of instruments to measure stress and urge incontinence*

	No. (%)			
	Pt.	Physician	Pad Test	Diary
Cure	56 (67)	39 (46)	62 (74)	48 (72)
Cure/improved	78 (93)	80 (95)	79 (94)	53 (79)
Improved	22 (26)	41 (49)	17 (20)	5 (7)
Failure	6 (7)	4 (5)	5 (6)	14 (21)

TABLE 4. *Complications*

Complication	No. Incidence/Total No. Pts. (%)
Unexpected permanent urinary retention	4/251 (2)
De novo urge incontinence	7/251 (3)
Persistent urge incontinence	38/165 (23)
Bladder injury during surgery	2/251 (0.6)
Urethral injury	0/251
Prolonged pain	1/251 (0.3)
Death	1/251 (0.3)

manent urinary retention, de novo detrusor instability and, when synthetic slings are used, urethral erosion.[10] Despite a reported cure rate ranging from 82 to 98%, pubovaginal fascial sling for stress urinary incontinence has never achieved widespread popularity. We believe that the operation lacks popularity because the complication rate, particularly in the hands of inexperienced surgeons, is probably much higher than reported in the literature. Complications are primarily related to placing too much tension on the sling during surgery, which results in urinary retention, refractory detrusor instability or urethral erosion when synthetic slings are used.[11-19] Until recently most of the literature describing the surgical technique depicted 1 or both ends of the fascial graft left attached to the rectus fascia, and the free end passed under the urethra and united with its mate from the other side, or sutured to the fascia or rectus muscle on the other side.[7] With either technique there is a tendency to make the sling too tight because of insufficient length of the fascial strip. Since there is no exact method of determining how much tension to put on the sling during surgery, one must rely on experience to make the judgement. Most patients undergoing pubovaginal sling have had multiple previous failed surgeries. Thus, the surgeon may be overzealous in trying to correct the problem. We believe that the sling should be placed with no tension in all patients. In the large series of Morgan et al, using polyester fiber instead of fascia, the sling is simply positioned as a hammock beneath the urethra and not even sewn in place.[20]

There has been a resurgence in the use of the pubovaginal sling since McGuire and Lytton reported an 80% overall success rate with minimal morbidity using their modification for type 3 stress incontinence.[7] In a subsequent series of McGuire et al the success rate was 82% also with minimal morbidity.[8] We believe that not attaching the sling to the rectus fascia and tying it without any tension at all have had significant impact on lessening the poor outcomes originally associated with this procedure. In addition, as our experience has increased the procedure can be accomplished with a minimal hospitalization (1 or 2 days). Using the modifications described by Blaivas and Jacobs,[5,6] and McGuire and Lytton,[7] Carr et al reported on 96 women who underwent pubovaginal sling for intrinsic sphincter deficiency.[21] In that series 93 patients were cured of stress incontinence, while 1 required permanent catheterization for urinary retention and de novo detrusor instability developed in 10.[21] Zaragoza reported a continence rate of 95% using the pubovaginal sling in 60 women with types 2 and 3 stress incontinence.[22] In addition, there were no patients with permanent urinary retention and de novo detrusor instability developed in only 3 (5%).
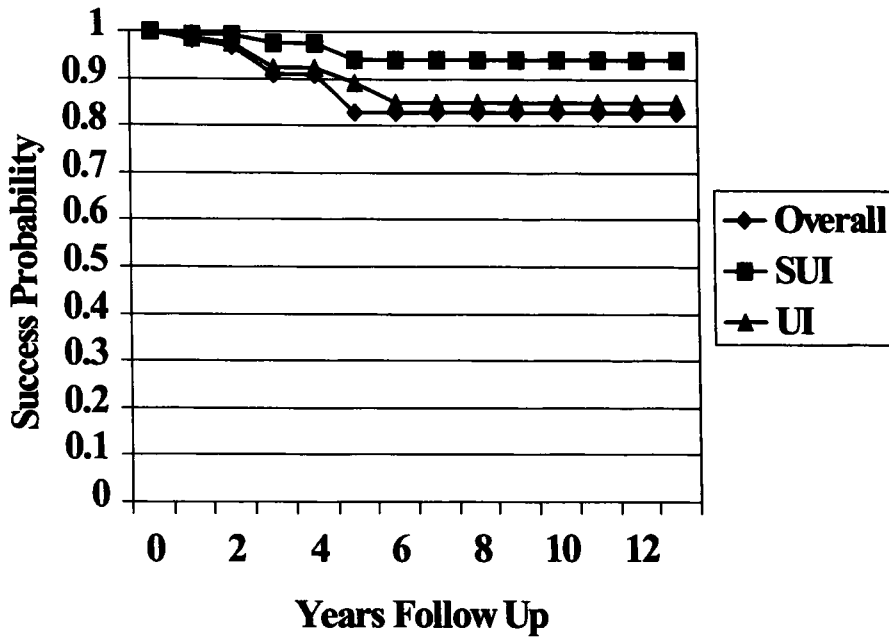
FIG. 4. Kaplan-Meier curve for success rates following pubovaginal sling (overall versus cure for stress [*SUI*] versus cure for urge [*UI*] incontinence).
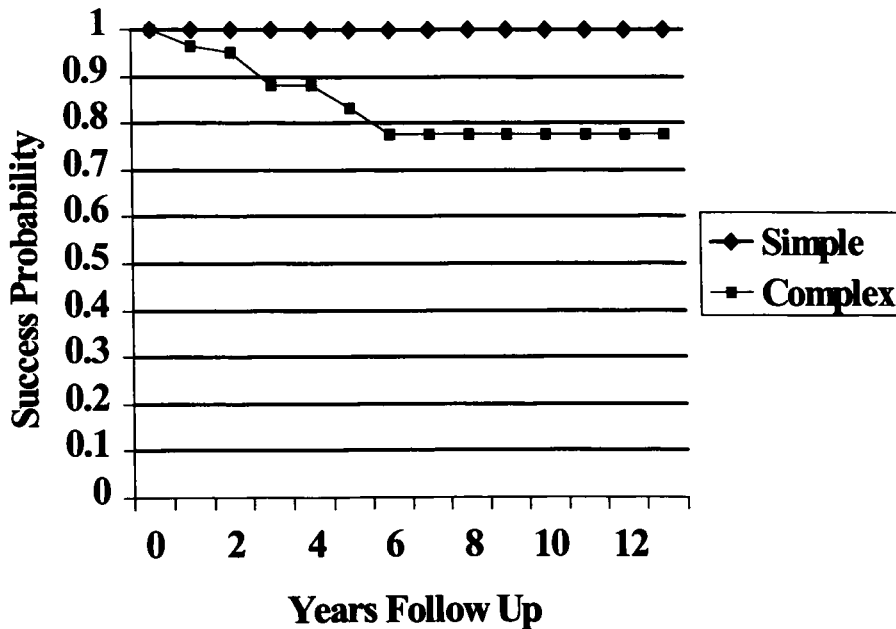

FIG. 5. Kaplan-Meier curve for success rate for stress incontinence following pubovaginal sling (simple versus complex cases)

Our results are in agreement with these reports. Overall in 251 consecutive women with intrinsic sphincter deficiency and/or urethral hypermobility there was a 92% success rate with at least 1-year followup and in 20 a 95% success rate with at least 10-year followup. Once dry no patient had recurrent stress incontinence. We categorized cases as simple or complex because our previous data convinced us that the 3 types of incontinence are not risk factors for failure.[5] We do not believe that leak point pressure or hypermobility has any impact on outcomes after pubovaginal sling. We recognize that these concerns are relevant for other types of incontinence surgery. Therefore, we did not specifically analyze the

outcome based on preoperative Valsalva's leak point pressure or the 3 types of stress incontinence. The simple and complex groups contained women with all 3 types as well as intrinsic sphincter deficiency.

Most failures were due to persistent urge incontinence. De novo urge incontinence developed in only 3% and persistent stress incontinence in only 7% of patients overall (figs. 4 and 5). All cases of failure had a diagnosis of pipe stem urethra preoperatively. Of the 165 patients with preoperative urge incontinence 41% had persistent urge incontinence at long-term followup, which is in agreement with previous reports.[23] There was a trend for an increase in urge incontinence with

time. At 1 year there was a 23% incidence of urge incontinence, which increased to 41% in patients with more than 10 years of followup. Perhaps this trend represents the long-term effects of pubovaginal sling on the bladder with increasing urge incontinence with time, or perhaps it indicates a normal response with aging in these patients. We were not able to analyze if age was a specific risk factor for urge incontinence but intend to do so in a future study. The risk factors for postoperative urge incontinence included preoperative urge incontinence and multiple previous surgeries. Cross et al discussed postoperative urge incontinence and their reported 22% failure rate due to urge incontinence (de novo plus persistent) was similar to ours.[23]

Permanent urinary retention developed following surgery in 4 patients (2%). Of these patients 2 were operated on early in the series and retention was most likely due to excessive sling tension. Since 1985 there have been only 2 more cases of permanent retention, both with concomitant grade 3 to 4 cystocele repairs. We believe that patients with grade 3 to 4 cystocele have a much higher risk of urinary retention than the rest of the population. Since making this observation, if pubovaginal sling is performed at the same time as grade 3/4 cystocele repair, we place the sling through a slightly curved transverse incision over the vesical neck and close it before making a separate vertical incision that does not communicate with it. We believe that this modification decreases scar formation over the sling and that scar tissue leads to decreased elasticity of the sling causing increased compression of the urethra. No cases of permanent retention have occurred since making this modification.

Because of inadvertent potential examiner bias, a blinded third party reevaluated all patients, administered a validated outcome questionnaire and compared the results to the pad test, voiding diary and surgeon assessment. We made these comparisons in 84 consecutive patients and found excellent agreement between the instruments (kappa coefficient greater than 0.9).

CONCLUSIONS

Pubovaginal sling is an effective treatment that lasts for the long term for all types of stress incontinence. We have demonstrated that the procedure can be performed in a reproducible fashion with minimal morbidity. Postoperative urinary retention should be minimal if the sling is not tied with excessive tension. Persistent and de novo urge incontinence remains a vexing problem, about which the patient should be counseled preoperatively.

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