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PUBOVAGINAL SLING: 4-YEAR OUTCOME ANALYSIS AND QUALITY OF LIFE ASSESSMENT

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ABSTRACT

Purpose: Stress urinary incontinence is a common disease with a devastating impact on patient quality of life. Needle suspension procedures, which produce disappointing long-term results for type II stress incontinence, are being replaced by pubovaginal slings which previously were reserved solely for the treatment of type III stress incontinence. We report the long-term outcomes of pubovaginal slings for the treatment of types II and III stress urinary incontinence, and assess its quality of life impact.

Materials and Methods: From January 1993 until December 1996, 247 females 10 to 84 years old (mean age 54.5) with type II (54%) or III (46%) stress urinary incontinence diagnosed by fluoroscopic urodynamics received a pubovaginal sling. Concomitant urge incontinence was present in 109 patients (44%). Quality of life was assessed with the Urogenital Distress Inventory short form.

Results: At a mean followup of 51 months (range 22 to 68) the continence rates were 88% overall, 91% for type II and 84% for type III. Preoperative urge incontinence resolved in 81 of 109 patients (74%), while de novo urge incontinence developed in 10 (7%). Intermittent urethral catheterization duration averaged 8.4 days, with 5 women undergoing urethrolysis for a hypersuspended urethra. Secondary procedures were required in 9 patients with type II and 5 with type III incontinence, and included transurethral collagen injections in 6 and repeat pubovaginal slings in 8. There was a 4% complication rate due to pelvic hematoma in 2 cases, incisional hernia in 2, deep venous thrombosis in 1 and pulmonary embolus in 1. Of the 247 patients 235 (95%) completed the quality of life questionnaire with 92% reporting a high degree of satisfaction with low (less than 20 of 100 points) symptom distress scores.

Conclusions: Pubovaginal slings are effective and durable, and significantly improve quality of life in patients with types II and III stress urinary incontinence.

KEY WORDS: urinary incontinence, stress; treatment outcome; quality of life; urethra; vagina

Presently urinary incontinence afflicts an estimated 13 million adults in the United States alone.[1] Due to the prevalence of this condition and dramatic increase in public awareness, urinary incontinence has come to the forefront and is now one of the most common presenting complaints in the urological and gynecological specialties. In fact, in an attempt to understand better the impact of this devastating problem, the World Health Organization concluded that urinary incontinence should be recognized as a disease rather than a symptom or sign.[2] During the last century there have been numerous advances in our understanding of the pathophysiology of urinary incontinence with subsequent improvements in medical and surgical treatment modalities. Unfortunately, there is still a great deal to be learned, particularly in providing accurate, long-term outcomes of the plethora of surgical treatment options for patients with stress urinary incontinence.

The standard classification differentiates stress urinary incontinence due to poor anatomic support mechanisms (types I and II) from incompetence of the bladder neck and proximal urethral closure mechanism (type III). Treatment has consisted of a retropubic or transvaginal suspension procedure for types I and II, while type III stress urinary incontinence has been treated with collagen to restore urethral coapting ability in the absence of hypermobility of the bladder neck or a pubovaginal sling if hypermobility coexists with poor urethral closure. This classical algorithm has recently been questioned as some clinicians have used the pubovaginal sling to treat all types of stress urinary incontinence[3,4] as a result of increasing dissatisfaction with the poor long-term success rates with many of the bladder neck suspension procedures.[5–9]

While the concept of suburethral support was originally introduced in 1907 by Giordano,[10] it was not until its reintroduction in 1978 by McGuire and Lytton that it gained increased clinical use.[11] Unfortunately, the wholesale acceptance of pubovaginal slings by the urological and gynecological communities has been limited by the historically higher incidence of complications with pubovaginal slings, namely, sling erosion, de novo detrusor instability and urinary retention. It appears that sling erosion is directly related to use of allogenic material for the sling, with most contemporary series reporting no erosions with autologous or donor fascia pubovaginal slings.[12–16] A 2% to 12% incidence of urinary retention (greater than 4 weeks) is approximately 80% more common after pubovaginal slings compared with other antiincontinence procedures.[4,15–17] On the other hand, de novo detrusor instability with incidence rates of 3% to 24% is not unique to or more common with pubovaginal slings.[17]

Clearly, to appreciate the clinical value of a treatment

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modality for stress incontinence, one needs to look not only at cure rates and side effects, but also the life impact and patient satisfaction with the treatment. Previously this assessment has been based entirely on medical records from which patient complaints have been extracted and graded by a reviewer. To provide a more accurate assessment of patient satisfaction without any inherent bias, self-administered standardized questionnaires have been developed.[18] We report our experience using rectus fascia pubovaginal slings for the treatment of stress urinary incontinence, and define preoperative factors that could predict long-term outcome regarding continence rates, complications and, most importantly, patient satisfaction.

MATERIALS AND METHODS

Preoperative evaluation. From January 1993 until December 1996, 247 women received a rectus fascia pubovaginal sling. Preoperative evaluation for all patients included a urogynecological history and physical examination, urinalysis and fluorourodynamics. Video urodynamics consisted of simultaneous measurement of the bladder and external sphincter pressures during filling with 20% iodinated contrast material at a rate of 100 ml. per minute. During filling the bladder was assessed for compliance, bladder neck competency, sensation, uninhibited detrusor contractions and vesicoureteral reflux. Urethral function with the bladder filled to 200 to 250 ml. was evaluated by determining the abdominal leak point pressure.[19] Urethral hypermobility was assessed with the patient in an oblique upright position using radiopaque marker movement during a Valsalva maneuver, and was demonstrated when there was greater than 2 cm. mobility of the bladder neck.

Stress urinary incontinence was classified as type II—abdominal leak point pressure greater than 90 cm. water and urethral mobility greater than 2 cm., type III—abdominal leak point pressure less than 60 cm. water, and type II/III—abdominal leak point pressure between 60 and 90 cm. water in combination with urethral hypermobility. For data analysis all cases with abdominal leak point pressure less than 90 cm. water were considered as type III stress urinary incontinence.

Surgical technique. The surgical technique used has been previously described and has had only minor modifications.[11] Briefly, after placement of a Foley catheter a 6 to 8 $\times$ 1 to 1.5 cm. rectus fascia sling is harvested through a Pfannenstiel incision and secured at the ends with a 1-zero polyglactin suture. An inverted U or midline vaginal incision is centered over the proximal urethra, and the endopelvic fascia is sharply perforated lateral and distal to the bladder neck, thus entering into the retropubic position.

The sling sutures are passed from the vaginal incision to the abdominal incision lateral to the rectus muscle using a Sarot or Crawford clamp. The sling is tacked to the periurethral fascia in the midline at the bladder neck with a 3-zero delayed absorbable suture. The vaginal mucosa is closed with a 2-zero chromic suture in an interrupted or running locking fashion. The sling sutures are brought out through the inferior leaf of the rectus fascia and the fascia is closed with 1-zero polyglactin in a running fashion. The sling sutures are tied across the midline over the rectus fascia with the least amount of tension required to prevent urethral motion, which is usually confirmed when 1 to 2 fingers are able to pass between the sling suture knot and the rectus fascia.

The abdominal wound is closed and a povidone-iodine, triple sulfa or estrogen cream impregnated gauze is used to pack the vagina. The Foley catheter is removed on the morning after surgery or as soon as the patient is ambulating. All patients are instructed on intermittent self-catheterization, which is performed until the post-void residual is less than 60 ml.

Postoperative evaluation. Followup included a routine examination 4 weeks and 3 months postoperatively. Information obtained at followup included duration of intermittent self-catheterization, pad usage and urgency. A pelvic examination was performed in patients who underwent a concurrent vaginal procedure. If patients complained of obstructive symptoms or persistent incontinence, or required intermittent self-catheterization at 3 months postoperatively fluoroscopic urodynamics were repeated. Patients were believed to have a hypersuspended proximal urethra when fluoroscopy revealed a concave deformity of the urethra being supported by the pubovaginal sling with no demonstrable mobility. To evaluate long-term outcome and patient satisfaction the Urogenital Distress Inventory short form was mailed to all patients (see Appendix).[18] This instrument is a previously validated tool used to assess symptom distress and quality of life with urinary incontinence, and provides objective measurements to evaluate outcomes of treatment modalities. To test the validity of the questionnaire a telephone retest was conducted on all patients who responded to the questionnaire. A physician not involved with the original procedure (T. M.) performed the chart review, retest and data analysis.

Statistical analysis. Data analysis was performed with commercial statistical software. Univariate analysis (unpaired t test) was used to identify noncontinuous preoperative variables predictive of continuous outcome variables such as continence status. Chi-square cross table analysis was used to investigate relationships between noncontinuous preoperative and outcome variables. Bivariate analysis was used to identify continuous preoperative and postoperative variables predictive of outcome variables. Coefficient correlations of greater than 0.3 were considered important and $p < 0.05$ was considered significant. For the test-retest analysis a paired t test was used for continuous variables and a κ statistic was generated measuring agreement between the 2 tests.

RESULTS

Mean age of our patients was 54.5 years (range 10 to 84), and 54% had type II (133 patients) and 46% had type III (114) stress urinary incontinence (table 1). At a mean followup of 52 months (range 24 to 70) chart review was performed on all 247 patients and the Urogenital Distress Inventory short form was mailed to all patients. Of the 247 patients 235 (95%) responded to the questionnaire and all responders were retested by telephone.

Complete resolution of stress urinary incontinence with no urge incontinence was reported by 88% of the 247 patients, including 91% (121 patients) with type II and 84% (96) with type III stress urinary incontinence. To achieve this level of cure, secondary procedures were performed in 14 patients.

TABLE 1. *Patient demographics*

	Type II	Type III
No. pts.	133	114
Mean age	51.4	54.2
Mean gravity/parity	3.2/2.9	3.6/3.1
Mean pads/day	3.9	4.2
No. concurrent procedures:		
Cystocele	37	49
Rectocele	12	10
Sacrospinalis ligament fixation	4	2
Vaginal hysterectomy	7	9
Abdominal hysterectomy	5	6
Enterocele	11	8
% Preop. urgency	72%	74%
% Preop. urge incontinence	46%	43%
Mean abdominal leak point pressure (cm./H_2O)*	108	42
Mean previous surgery (range)†	0.9 (0–3)	2.4 (0–8)

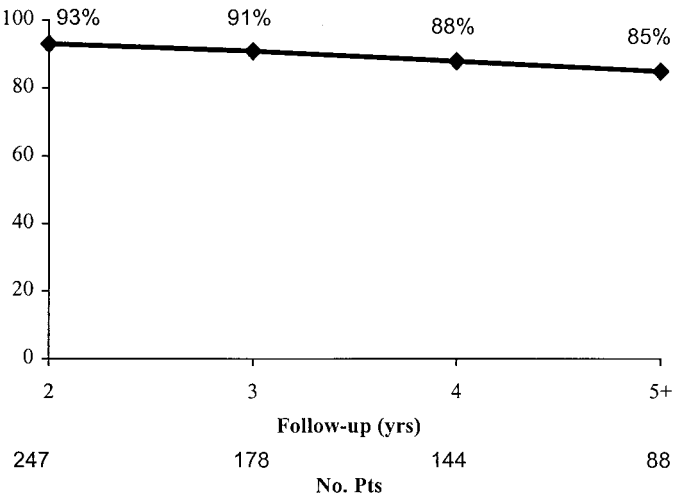
* $p = 0.01$.
† $p < 0.001$.

Transurethral collagen injections were administered postoperatively in 6 patients with type III stress urinary incontinence and all are now continent. Repeat pubovaginal slings procedures were performed in 3 cases originally classified as type II and 5 type III cases. In all 8 cases urodynamics confirmed a low abdominal leak point pressure (less than 60 cm. water pressure) and no evidence of suburethral support. The initial sling failed 45 days postoperatively in 7 cases and 6 months postoperatively in 1. Stress urinary incontinence persisted in 1 case, for a success rate of 87% for repeat pubovaginal sling. No patients had recurrent stress urinary incontinence after 6 months postoperatively and cure rate was 85% in 88 patients now followed for greater than 5 years (see figure).

Of the 109 patients with preoperative concurrent urge related incontinence, defined as involuntary loss of urine precipitated by urge as reported by the patient, 81 (74%) had complete resolution postoperatively. No preoperative variable predicted resolution of urge incontinence postoperatively but concurrent anterior colporrhaphy correlated most closely with resolution of urge incontinence ($p = 0.07$). There was no difference in outcome when patients were evaluated according to the grade of cystocele. Of the 138 patients with pure stress urinary incontinence preoperatively 32 (23%) had de novo urgency, including 10 with associated incontinence, for an overall de novo urge incontinence rate of 7%.

Transient postoperative urinary retention requiring intermittent self-catheterization was the most common side effect of the pubovaginal sling, with 94% of patients requiring catheterization more than 1 day postoperatively. Mean duration of catheterization was 8.4 days, and normal voiding began 1 week, 1 month and 3 months postoperatively in 53%, 92% and 98% of the patients, respectively. There was no statistical difference in time to return to normal voiding with respect to preoperative variables or concurrent procedures performed. In the 5 women with prolonged (greater than 3 months) urinary retention, urethrolysis resolved the urodynamically confirmed hypersuspended proximal urethra with subsequent return to normal voiding in 80%. There were no cases of sling erosion or requirement to remove the sling or suture material. Table 2 summarizes the other complications with the rectus fascia pubovaginal sling.

Of the 235 patients (95%) who responded to the mailed Urogenital Distress Inventory short form all (100%) were retested via telephone with a high correlation of agreement (mean κ 0.91 $\pm$ 0.05, $p < 0.0001$). Patient satisfaction with outcome was inferred when they reported a low distress symptom score. The questions were equally weighted with the answers ranging from "not at all" to "greatly" with a corresponding raw score of 0 to 3, respectively. The sum of the raw scores was made into a 100-point scale, with a net score of less than 20 being defined as experiencing a high rate of satisfaction with outcome. Overall 92% of the group were highly satisfied, with a mean distress score of 16 $\pm$ 3 (range 0 to 48). As expected, patients with persistent urge related incontinence reported the lowest degree of satisfaction ($p < 0.001$). Interestingly, despite experiencing similar outcomes, patients with de novo urge incontinence (mean score 24 $\pm$ 4) did not report the same degree of distress as those with persistent urge incontinence (mean score 44 $\pm$ 5) ($p = 0.01$). Multivariate analysis only weakly correlated preoperative urgency with high distress scores postoperatively ($r = 0.293$, $p = 0.04$).



Durability of cure from stress urinary incontinence after rectus fascia sling.

TABLE 2. *Complications of rectus fascia pubovaginal sling*

Complications	No. Pts. (%)
Sling failure	8 (3.2)
Hypersuspended urethra	5 (2.4)
Pelvic hematoma	2 (0.8)
Incisional hernia	2 (0.8)
Deep venous thrombosis	1 (0.4)
Pulmonary embolus	1 (0.4)
Sling erosion	0

DISCUSSION

It has become increasingly clear to patients and health care providers that to determine more accurately the efficacy of any treatment modality, the impact of the intervention on patient quality of life must be evaluated and reported. This fact particularly applies to the treatment of stress urinary incontinence as the number of surgical techniques dramatically increases. Therefore, the onus remains on the urological community to provide this information to allow our patients the opportunity to make a more informed decision regarding therapy. By using a previously validated quality of life impact questionnaire, we found an overwhelmingly high degree of patient satisfaction with the rectus fascia pubovaginal sling for the treatment of types II and III stress urinary incontinence. While we did not measure the change in quality of life after the pubovaginal sling compared to preoperative assessment, we believe that the low distress scores are attributed directly to the surgical procedure. Preoperative distress is inferred in that all patients originally presented with the complaint of urinary incontinence, rather than the population being derived from a screening program. Furthermore, when asked if they would undergo the procedure again, 92% of the patients responded positively, stating satisfaction with the procedure.

Haab et al found a similarly high degree of patient satisfaction despite a failure rate of 54% in 40 patients with a mean followup of 4 years.[20] We found that life quality directly correlated with outcome, as women with postoperative urge incontinence had the highest distress scores (mean 38, range 18 to 48) with only 1 reporting a willingness to undergo the procedure again ($p < 0.001$). When compared to 217 women with resolution of urinary incontinence 98% reported low (less than 20) distress scores, clearly suggesting that patient satisfaction directly correlated with continence status.

To avoid the inherent overreporting of cure with a retrospective chart review, we determined continence status based on patient survey. With a mean duration since surgery of more than 4 years, 88% of the women reported complete absence of urinary incontinence. Most impressive was the durability of the pubovaginal sling, as of the 88 patients followed longer than 5 years 85% report complete absence of stress urinary incontinence. Our results are similar to those of other long-term followup series, particularly that of Chaikin et al, who reported 95% cure of stress incontinence in 20 patients followed for 10 years.[4] Taken together, these reports demonstrate that when

stress incontinence is resolved for more than 1 year after a pubovaginal sling, the long-term (5 to 10 years) risk of recurrent stress incontinence is low.

Previously a great concern about the pubovaginal sling was that it converted an incompetent bladder neck and proximal urethral closure mechanism into an obstructing system, which in the long term would theoretically create detrusor instability. This concern was suggested by Chaikin et al, when they found a 23% incidence of detrusor instability at 1 year which increased to 41% at 10 years.[4] Unfortunately, they did not discuss whether this increase in incidence was secondary to new cases developing with time or if it resulted from a decrease in the number of evaluable patients with the same absolute number of urge incontinence cases. In our series we have found no evidence to support this concern. In fact, of the 32 patients with de novo urgency 29 (91%) presented within 1 year postoperatively. Furthermore, no variable, not even aging as previously suggested, predicted the development of de novo urgency with or without incontinence.

The opposite extreme of incontinence is urinary retention, with incidence rates ranging from 0% to 12% in contemporary series.[14, 15–17] The trend in these series is clearly a lower retention rate with increasing surgeon experience. The most important aspect of preventing this complication is to avoid placing any tension on the sling, unless permanent intermittent self-catheterization is the desired outcome. When the sling was placed so that it minimized bladder neck hypermobility, normal voiding returned within 30 days postoperatively in 9 of 10 cases.

CONCLUSIONS

The pubovaginal sling is highly effective for types II and III stress urinary incontinence. Secondary to its low morbidity and high rate of cure with proved durability of greater than 5 years, the pubovaginal sling produces a high degree of patient satisfaction. Patients with preoperative urge incontinence and a 26% incidence of failure are at greatest risk for postoperative dissatisfaction and, therefore, they should be carefully counseled preoperatively. However, nearly three-fourths of this high risk group have excellent outcomes with complete resolution of urge and stress incontinence following the sling procedure. With this information and previous reports of equal outcomes in elderly and/or obese women, all patients with type II or III stress urinary incontinence should be considered excellent candidates for a pubovaginal sling.[21, 22]

APPENDIX: UROGENITAL DISTRESS INVENTORY SHORT FORM (UDI-6)

Do you experience, and if so, how much are you bothered by:

1. Frequent urination?
2. Urine leakage related to the feeling of urgency?
3. Urine leakage related to physical activity, coughing, or sneezing?
4. Small amounts of urine leakage (drops)?
5. Difficulty emptying your bladder?
6. Pain or discomfort in the lower abdominal or genital area?

Item response levels are: (0) not at all; (1) slightly; (2) moderately; (3) greatly.

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