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, and surgeon experience with the procedure. 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 as a bladder volume 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.

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stress and urge incontinence. Overall a woman was consid-
ered dry only if she was not incontinent under any circum-
stances. 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 ahr the peri-
operative period as stated by the patient, less than 2 gm. 
change in pad weight, and no notations of incontinence on the 
voiding 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 subjec-
tive assessment, patient assessment was used as the final 
arbiter. Postoperatively women were asked about urge incon-
tinence and divided into the 4 groups of cured—urge in-
continence present preoperatively but not postoperatively, 
improved—urge incontinence occurred less than 50% of the 
time compared to preoperatively, persistent—no improve-
ment by at least 50% compared to preoperatively and de 
ovo—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 modificati-
tions. 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 trans-
verse incision is made over the vesical neck. The dissection 
continues laterally just beneath the vaginal epithelium with 
a Metzenbaum scissors pointed toward the ipsilateral shoul-
der of the patient. The endopelvic fascia is perforated at its 
innominate insertion into the ischiopubic ramus. The retro-
pubic 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 inci-
sion is made and the surface of the rectus fascia is dissected 
free of parietal peritoneum. Two parallel horizontal incisions 
4 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 perioso-
tium and directed toward the index finger, which palpates 
the periosseum 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 one 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 
atached 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 (usu-
ally postoperative day 2 to 4), the suprapubic tube is left in 
place for gravity drainage or preferably she is taught inter-
mittent 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 sur-
ger 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 90). Figures 1 and 2 show the 5 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 recur-
rences 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 
incontinence. We found 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 (question-
naire), 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 
ocurred during the passage of the DeBakey clamp from 
above, and both were realized immediately. They were man-
gered 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
PUBOVAGINAL FASCIAL SLING FOR STRESS URINARY INCONTINENCE

1314

FIG. 2. Types of complex incontinence

100%
80%
60%
40%
20%
0%

Cured 73%  Improved 19%  Failed 8%

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

TABLE 1. Pubovaginal sling results for stress incontinence only

<table>
<thead>
<tr>
<th>No. (%)</th>
<th>Simple</th>
<th>Complex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pts.</td>
<td>63</td>
<td>188</td>
</tr>
<tr>
<td>Type 1</td>
<td>14 (22)</td>
<td>19 (10%)</td>
</tr>
<tr>
<td>Type 2</td>
<td>18 (29)</td>
<td>30 (16%)</td>
</tr>
<tr>
<td>Type 3</td>
<td>31 (49)</td>
<td>159 (77)</td>
</tr>
<tr>
<td>Previous surgery (range)</td>
<td>0.78 (0-3)</td>
<td>3.1 (0-19)</td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cure</td>
<td>62 (98)</td>
<td>175 (93)</td>
</tr>
<tr>
<td>Improved</td>
<td>0</td>
<td>9 (5)</td>
</tr>
<tr>
<td>Failure</td>
<td>0</td>
<td>4 (2)</td>
</tr>
</tbody>
</table>

* One death.

TABLE 2. Followup by years and success

<table>
<thead>
<tr>
<th></th>
<th>1 Yr.</th>
<th>3 Yrs.</th>
<th>5 Yrs.</th>
<th>More Than 10 Yrs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pts.</td>
<td>250</td>
<td>103</td>
<td>47</td>
<td>20</td>
</tr>
<tr>
<td>% Stress urinary incontinence (cure)</td>
<td>94</td>
<td>94</td>
<td>96</td>
<td>95</td>
</tr>
<tr>
<td>% De novo urinary incontinence</td>
<td>3</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>% Persistent urinary incontinence</td>
<td>23</td>
<td>26</td>
<td>31</td>
<td>41</td>
</tr>
</tbody>
</table>

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. 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. 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.

Since the introduction of the sling operation in 1910, the procedure has been associated with a high incidence of permanent urinary retention, de novo detrusor instability and, when synthetic slings are used, urethral erosion. 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. 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. 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.

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. In a subsequent series of McGuire et al the success rate was 82% also with minimal morbidity. 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, and McGuire and Lytton, Carr et al reported on 96 women who underwent pubovaginal sling for intrinsic sphincter deficiency. 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. Zaragoza reported a continence rate of 95% using the pubovaginal sling in 60 women with types 2 and 3 stress incontinence. In addition, there were no patients with permanent urinary retention and de novo detrusor instability developed in only 3 (5%).

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

<table>
<thead>
<tr>
<th></th>
<th>Pt.</th>
<th>Physician</th>
<th>Pad Test</th>
<th>Diary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cure</td>
<td>56 (67)</td>
<td>39 (46)</td>
<td>62 (74)</td>
<td>48 (72)</td>
</tr>
<tr>
<td>Cure/improved</td>
<td>78 (93)</td>
<td>80 (85)</td>
<td>79 (94)</td>
<td>53 (79)</td>
</tr>
<tr>
<td>Improved</td>
<td>22 (26)</td>
<td>41 (49)</td>
<td>17 (20)</td>
<td>5 (7)</td>
</tr>
<tr>
<td>Failure</td>
<td>6 (7)</td>
<td>4 (5)</td>
<td>5 (6)</td>
<td>14 (21)</td>
</tr>
</tbody>
</table>

TABLE 4. Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>No Incidence/Total No. Pts. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unexpected permanent urinary retention</td>
<td>4/251 (2)</td>
</tr>
<tr>
<td>De novo urge incontinence</td>
<td>7/251 (3)</td>
</tr>
<tr>
<td>Persistent urge incontinence</td>
<td>38/165 (23)</td>
</tr>
<tr>
<td>Bladder injury during surgery</td>
<td>2/251 (0.8)</td>
</tr>
<tr>
<td>Urethral injury</td>
<td>0/251</td>
</tr>
<tr>
<td>Prolonged pain</td>
<td>1/251 (0.3)</td>
</tr>
<tr>
<td>Death</td>
<td>1/251 (0.3)</td>
</tr>
</tbody>
</table>
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. 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. 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.