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PUBOVAGINAL SLING SURGERY FOR SIMPLE STRESS URINARY INCONTINENCE: ANALYSIS BY AN OUTCOME SCORE

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ABSTRACT

Purpose: We assessed the results of pubovaginal sling surgery in women with simple stress urinary incontinence using strict subjective and objective criteria.

Materials and Methods: Simple incontinence was defined as sphincteric incontinence with no concomitant urge incontinence, pipe stem or fixed scarred urethra, urethral or vesicovaginal fistula, urethral diverticulum, grade 3 or 4 cystocele, or neurogenic bladder. A total of 67 consecutive women with a mean age plus or minus standard deviation of 56 ± 11 years who underwent pubovaginal sling surgery for simple sphincteric incontinence were prospectively followed for 12 to 60 months (mean 33.9 ± 22.2). Treatment outcomes were classified according to a new outcome score. Cure was defined as no urinary loss due to urge or stress incontinence, as documented by 24-hour diary and pad test, with the patient considering herself cured. Failure was defined as poor objective results with the patient considering surgery to have failed. Cases that did not fulfill these cure-failure criteria were considered improved and further classified into a good, fair or poor response.

Results: Of the 67 patients 46 (69%) had type II and 21 (31%) had type III incontinence. Preoperative diary and pad tests revealed a mean of 5.9 ± 3.6 stress incontinence episodes and a mean urinary loss of 91.8 ± 81.9 gm. per 24 hours. There were no major intraoperative, perioperative or postoperative complications. Two patients (3%) had persistent minimal stress incontinence and 7 (10%) had new onset urge incontinence within 1 year after surgery. Overall using the strict criteria of our outcome score 67% of the cases were classified as cured and the remaining 33% were classified as improved. The degree of improvement was defined as a good, fair and poor response in 21%, 9% and 3% of patients, respectively.

Conclusions: Mid-term outcome results defined by strict subjective and objective criteria confirm that the pubovaginal sling is highly effective and safe surgery for simple sphincteric incontinence. A followup of more than 5 years is required to establish the long-term durability of this procedure.

KEY WORDS: urethra; bladder; urinary incontinence, stress; outcome assessment (health care)

The reported success rates of anti-incontinence surgery vary considerably according to patient selection, surgical technique and investigator definition of outcome results. Selection of the surgical technique is usually based on the 3 types of stress urinary incontinence, as determined by the relative contributions of urethral hypermobility and intrinsic sphincter deficiency.[1–3] Historically retropubic colposuspension surgery was recommended for patients with type I or II incontinence, while the pubovaginal sling was the treatment of choice for type III or intrinsic sphincter deficiency incontinence.[2,3] Overall the reported failure rates of retropubic suspensions and sling surgery are 12% to 30% and 9% to 15%, respectively.[1–5]

Stress urinary incontinence may be further classified into simple or complex incontinence according to concomitant findings.[4] Complex sphincteric incontinence includes cases associated with concomitant urge incontinence, a pipe stem or fixed scarred urethra, urethral or vesicovaginal fistula, urethral diverticulum, grade 3 or 4 cystocele, or neurogenic bladder. Simple sphincteric incontinence includes cases that do not meet the criteria for complex incontinence, including those of detrusor instability without urge incontinence and those of previous surgical failure. Complex cases often require reconstructive pelvic surgery and/or a pubovaginal sling, while simple cases usually need no more than an anti-incontinence procedure. Most previously published series of the outcome results of sling surgery include complex and simple cases and, therefore, reflect an average outcome of clinically different cases. Data on the outcome results of sling surgery in women with simple sphincteric incontinence are sparse.[4,6]

We have recently introduced a new outcome score that incorporates in user friendly format 3 validated popular instruments, including a 24-hour voiding diary, 24-hour pad test and patient questionnaire.[6,7] Our current study incorporated this new outcome score to assess the efficacy of pubovaginal sling surgery for simple sphincteric incontinence.

MATERIALS AND METHODS

A total of 69 consecutive women with a mean age plus or minus standard deviation of 56 ± 11 years who underwent pubovaginal sling surgery for simple sphincteric incontinence were studied. Two women were lost to followup and, thus, 67 were available for outcome evaluation. All patients were eval-

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uated at least 1 year postoperatively (mean 33.9 ± 22.2 months). Of the women 38 (57%) had undergone surgery for the first time for primary incontinence, while the remaining 29 (43%) had previously undergone 1 to 3 (mean 1.3 ± 0.5) unsuccessful anti-incontinence surgical procedures for recurrent incontinence.

All patients underwent meticulous baseline evaluation, including a complete history and physical examination, standard urinary questionnaire, 24-hour voiding diary, 24-hour pad test, urine culture, noninvasive uroflowmetry, post-void residual urine volume, video urodynamics and urethrocystoscopy. The urethral axis and urethrovesical junction mobility were assessed by a cotton swab test, performed by inserting a well lubricated, sterile, cotton tipped applicator gently through the urethra into the bladder. In the bladder the applicator was withdrawn to the point of resistance at the level of the bladder neck. The resting angle from the horizontal was recorded. The patient was then asked to strain and the degree of rotation was assessed. Hypermobility was defined as a resting or straining angle of greater than 30 degrees from the horizontal.

Multichannel video urodynamics were performed according to the recommendations of the International Continence Society except for cystometry.[8] Contrary to these recommendations, the patient was not instructed to try to inhibit voiding during the filling phase, but rather to report sensations to the examiner. Cystometrography was performed using radiographic contrast medium and a 7Fr double lumen catheter via constant infusion at a medium filling rate with rectal pressure monitoring. Vesical leak point pressure was evaluated at a volume of 150 ml. and defined as the lowest vesical pressure necessary to effect any degree of visible stress incontinence. If the patient had no leakage, vesical leak point pressure was reevaluated at functional bladder capacity, defined as the largest voided volume on 24-hour voiding. If the patient had no leakage with the urethral catheter in place, it was removed and abdominal leak point pressure was defined as the lowest abdominal pressure necessary to effect any degree of visible stress incontinence.

Sphincteric incontinence was defined as visible urinary leakage during increased abdominal pressure with absent detrusor overactivity. Based on the leak point pressure and the degree of urethral mobility cases were categorized as type I—leak point pressure greater than 60 cm. water and cotton swab test less than 30 degrees, type II—greater than 60 cm. water and greater than 30 degrees or type III—less than 60 cm. water regardless of the degree of the urethral mobility. Sphincteric incontinence was further classified as simple or complex according the criteria already presented.

Details of the operative technique of the pubovaginal sling procedure have been reported previously.[4] We prefer to harvest the sling from the rectus abdominus fascia and tie the long sutures attached to the sling ends loosely together over the rectus fascia without any tension. Postoperatively the women were scheduled to be evaluated at 1, 3, 6 and 12 months, and yearly thereafter. At each visit a history, focused examination with a full bladder, 24-hour voiding diary, 24-hour pad test, uroflowmetry and post-void residual urine volume measurement were done. The 24-hour pad test was performed at the same time as the voiding diary before the followup visit. The voiding diary included the time of voiding, voided volume in ml., incontinence episodes and type of incontinence (urge, stress or unaware). For the purpose of analysis no distinction was made between postoperative stress and urge incontinence.

Treatment outcomes were classified according to the new outcome score (Appendix).[6] The outcomes were assessed by an independent third party observer. Briefly, the new outcome score has a possible total of 6 points. Cure (total score 0) is defined by strict criteria, including a 24-hour voiding diary showing no urinary urge or stress incontinence episodes, a 24-hour pad test with a weight gain of 8 gm. or less and a questionnaire in which the patient considers herself cured. Failure (total score 6) is defined as poor objective results with the patient considering treatment as having failed. Cases that do not fulfill these cure-failure criteria are considered improved and further classified as a good (total score 1 or 2), fair (total score 3 or 4) or poor (total score 5) response. Results were analyzed statistically by Student's t and the chi-square tests with $p < 0.05$ considered significant. Data are presented as the mean plus or minus standard deviation, or percent according to the variables.

RESULTS

We evaluated 67 consecutive women with simple sphincteric incontinence, which was confirmed by urodynamics in all. Of the 67 patients 46 (69%) had type II and 21 (31%) had type III incontinence. The mean number of stress urinary incontinence episodes per 24-hour preoperative diary was 5.9 ± 3.6. The mean urinary loss per 24-hour preoperative pad test was 91.8 ± 81.9 gm. Table 1 shows patient characteristics.

All women underwent pubovaginal sling surgery. There were no major intraoperative, perioperative or postoperative complications. All patients resumed spontaneous voiding 2 days to 3 weeks after surgery and 15 (22%) noticed that they voided differently than before surgery with a weak or slow urinary stream, straining or postural changes. None had any clinical evidence of bladder outlet obstruction since postoperatively uroflowmetry and post-void residual urine volume measurements were normal, and none required any intervention, such as catheterization or urethrolysis.

Table 2 shows outcome results according to the new score. Seven patients (10%) had new onset urge incontinence within 1 year after surgery (range 3 to 12 months), while 2 (3%) were much improved postoperatively but still had minimal (drops) persistent stress incontinence occasionally. Overall 67% of cases were classified as cured and 33% were classified as improved by the strict criteria of the new score. Thus, the overall combined cured-improved rate was 100%. The cure

TABLE 1. *Characteristics of patients with simple sphincteric incontinence*

	Primary Stress Incontinence	Recurrent Stress Incontinence
No. pts.	38	29
Mean age ± SD	55 ± 11	58 ± 11
No. previous hysterectomy (%)	5 (13)	11 (38) ($p < 0.05$)
Mean No. previous anti-incontinence surgeries ± SD:		1.3 ± 0.5
Retropubic suspension (%)		8 (28)
Needle suspension (%)		9 (31)
Vaginal wall sling (%)		3 (10)
Pubovaginal sling (%)		3 (10)
Kelly plication (%)		2 (7)
Collagen injection (%)		7 (24)
Other (%)		5 (17)
Mean No. incontinence episodes/24-hr. diary ± SD	4.7 ± 3.7	7.1 ± 3.0 ($p < 0.05$)
Mean wt. gain/24-hr. pad test ± SD (gm.)	80.9 ± 79.9	106.2 ± 82.3
Mean Valsalva leak point pressure ± SD (cm. water)	85.7 ± 35.3	72.5 ± 35.3

TABLE 2. *Outcome results of pubovaginal sling for simple sphincteric incontinence*

Outcome Results	Primary Stress Incontinence	Recurrent Stress Incontinence	Overall
No. pts.	38	29	67
No. total score (%):			
Cure	28 (74)	17 (59) ($p < 0.05$)	45 (67)
Good response	7 (18)	7 (24)	14 (21)
Fair response	2 (5)	4 (14)	6 (9)
Poor response	1 (3)	1 (3)	2 (3)
No. persistent stress incontinence (%)	1 (3)	1 (4)	2 (3)
No. new onset urge incontinence (%)	4 (11)	3 (10)	7 (10)

No failures and 100% overall cured-improved rate.

rate was significantly higher in patients with primary incontinence than in those with recurrent incontinence (74% versus 59%, $p = 0.006$). Of the cases with clinical improvement 14 (21%) were classified as a good, 6 (9%) as a fair and 2 (3%) as a poor response.

DISCUSSION

The results of our study imply that pubovaginal sling is highly effective, safe and durable surgery for women with simple sphincteric incontinence. Using stringent objective and subjective criteria to define the outcome 67% of our cases were classified as cured and the remaining 33% were classified as improved. There were no surgical failures in our cases.

The surgical treatment of stress urinary incontinence has a long and variegated history. In 2 large meta-analysis studies of the surgical treatment of stress incontinence only the colposuspension and sling procedures had a consistent long-term continence rate of more than 80%.[1,2] Retropubic colposuspension surgery is indicated in women with stress incontinence and urethral hypermobility. Although a long-term cured-improved rate of more than 80% and a low complication rate have been reported in the literature, success rates are time dependent with a subsequent decrease for 10 to 12 years, at which time a plateau of 69% is reached.[9] In cases of intrinsic sphincter deficiency or combined urethral hypermobility and intrinsic sphincter deficiency sling procedures are preferred.[1,2,10] Despite a reported cured-improved rate of 86% to 90% until recently pubovaginal sling surgery had never achieved widespread popularity because of the relatively high complication rate, particularly when performed by inexperienced surgeons. 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. We believe that not attaching the sling to the rectus fascia but tying it over the fascia without any tension has had a significant impact on decreasing the poor outcome originally associated with this procedure. We prefer to harvest the sling from the rectus abdominus fascia due to ease of accessibility at surgery but others have recommended fascia lata, cadaveric fascia or synthetic slings.

The reported success rate of anti-incontinence surgery may vary considerably according to the methodology used to define the outcome. Should a patient who is cured of stress incontinence but has new onset urge incontinence be considered cured? We believe that cure should imply the reestablishment of normal voiding patterns. However, in most studies of the surgical treatment of stress urinary incontinence cure means that the patient no longer has stress incontinence. However, she may have persistent or new onset urge incontinence, urinary urgency or difficult voiding. Overall new onset urge incontinence has been reported in up to 20% of patients after retropubic suspension or sling operations.[1,2,4,9,10] Similarly Fulford et al noted that despite the symptomatic control of stress urinary incontinence in 97% of their patients only 80% were satisfied with the surgical results, mainly because of the persistent urge syndrome.[11] Therefore, we believe that no distinction should be made among the various types of urinary incontinence when evaluating the outcome of any anti-incontinence procedure. In patients with persistent incontinence it is important to determine whether it is due to sphincteric or bladder causes, or each cause combined.

Recently we have presented a new outcome score that incorporates a 24-hour diary, 24-hour pad test and patient satisfaction.[6] The relationship of objective evaluation and subjective symptoms is known to be vague. Some patients report that they are cured and yet objective testing shows that they are still wet, while others report that they are still wet in daily life and yet objective testing shows that they are cured. Any assessment must ultimately consider these factors. However, gross classification into cure, improvement and failure may fail accurately to reflect true clinical status. Therefore, strict criteria for cure and failure as well as detailed differentiation among various degrees of improvement, such as a good, fair and poor response, of which all are assessed by the new response score, may provide a more meaningful tool to assess outcome results.

We have previously used this outcome score to evaluate the outcome results of pubovaginal sling surgery and collagen injections in a mixed study population of simple and complex cases.[6,7] Although our overall cured-improved rates were similar to previously published data, the cure rate defined by our strict criteria (no stress or urge incontinence per 24-hour diary, negative 24-hour pad test and patient judgment of cure) were much lower. In our current study we further investigated a specific, relatively homogenous group of patients with simple sphincteric incontinence. They were presumed to have had a better outcome and were considered to be at low risk for postoperative complications. To our knowledge this is the first study to evaluate such patients by strict outcome criteria. There were no surgical failures in our cases. Overall 67% of our cases were classified as cured and the remaining 33% were classified as improved. There were no intraoperative, perioperative or postoperative major complications and all patients resumed spontaneous voiding 2 days to 3 weeks after surgery. Seven patients (10%) had postoperative new onset urge incontinence and none had clinical evidence of bladder outlet obstruction. Although followup was limited to less than 5 years, we believe that these mid-term results indicate that the pubovaginal sling is highly effective and safe for simple sphincteric incontinence.

Recurrent incontinence cases are classified as simple incontinence unless there is an additional significant pathological condition. These cases may be the result of technical failure, such as an inappropriate surgical method or technique, or recurrent hypermobility and/or intrinsic sphincter deficiency. Although using our outcome score the cure rate was higher in cases of primary incontinence, there were no surgical failures in cases of primary or recurrent incontinence. Therefore, we believe that pure recurrent incontinence cases should be classified as simple incontinence.

Clearly as in any clinical classification, some patients do not fit the general framework. We believe that the data in our study as well as in other previously published studies may enable better preoperative consultation with these patients. Furthermore, the most important caveat is that the surgeon should be experienced enough with the chosen surgery to ensure that it is done competently. No matter what the purported benefits of a particular operation, if the surgeon does not possess adequate skills and experience, the outcome is uncertain and serious complications may ensue.

CONCLUSIONS

We used stringent objective and subjective criteria to assess the mid-term (up to 5 years) outcome of pubovaginal sling surgery in a series of 67 consecutive women with simple sphinc-

teric incontinence. There were no surgical failures in these cases. Overall 67%, 21%, 9% and 3% of cases were classified as cured, and as a good, fair and poor response, respectively. Thus, the cured-improved rate in this specific group of patients was 100%. Furthermore, there were no major intraoperative, perioperative or postoperative complications. We believe that these mid-term results indicate that the pubovaginal sling procedure is highly effective and safe for simple sphincteric incontinence. More than 5 years of followup are required to establish the long-term durability of surgery.

APPENDIX: A SIMPLIFIED URINARY INCONTINENCE SCORE FOR THE EVALUATION OF TREATMENT OUTCOMES[6]

Postoperative 24-hour voiding diary
- 0 = No urinary incontinence (urge or stress) episodes.
- 1 = 1–2 incontinence episodes.
- 2 = ≥3 incontinence episodes.

Postoperative 24-hour pad test:
- 0 = Total weight gain of the pads ≤8 g.
- 1 = total weight gain of the pads 9–20 g.
- 2 = total weight gain of the pads >20 g.

Patient questionnaire:
- 0 = The patient considers herself cured.
- 1 = The patient considers herself improved.
- 2 = The patient considers the treatment to have failed.

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