

## Female Urology

### RESULTS OF PUBOVAGINAL SLING FOR STRESS INCONTINENCE: A PROSPECTIVE COMPARISON OF 4 INSTRUMENTS FOR OUTCOME ANALYSIS

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#### ABSTRACT

**Purpose:** Presently to our knowledge there are no standardized techniques to assess outcomes after surgery for stress incontinence. We performed a prospective blinded study to assess the correlation among physician and patient assessments, and a validated 24-hour pad test and voiding diary.

**Materials and Methods:** A total of 84 women were evaluated before and after pubovaginal sling for stress incontinence with a voiding diary, pad test and symptom questionnaire (patient assessment) administered by a blinded third party. The operating surgeon evaluated the patient using history, physical examination, pad test and voiding diary but was blinded to results of the outcome questionnaire. Preoperative focused neurourological examination and video urodynamics confirmed stress incontinence. Patients were assessed at least 1 year postoperatively. We compared patient assessment (cured, improved, failure) to the outcome of the pad test, voiding diary and physician assessment. The physician and questioner were blinded to each other. We considered patients with a pad test of 0 to 2 ml. as cured, 50% or more volume reduction as improved and less than 50% volume reduction as failure. Postoperative assessment did not differentiate between stress and urge incontinence. The kappa coefficient was used for statistical comparison.

**Results:** Average patient age was 58 years and average followup for the entire group was 4 years. Agreement among the 4 instruments to assess outcome was excellent ( $k > 0.9$ ) with respect to cured/improved versus failure but only good for cured versus improved versus failure ( $k > 0.5$ ).

**Conclusions:** Outcomes following incontinence surgery may vary depending on how the analysis was performed, patient selection, definition of success and so forth. Our results indicate that a pad test and voiding diary are reliable and should be part of the normal followup after pubovaginal sling for sphincteric incontinence. When these tests are used in conjunction with defined parameters of success, there is excellent agreement with patient feelings in regard to success or failure of surgery. Nevertheless, these instruments and methods are imperfect at best.

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

There are many different surgical techniques for treating stress incontinence but to our knowledge no consensus regarding efficacy and no standardized techniques are available to assess outcomes following surgery. Recently several reports have documented a significant disparity in outcomes when patient questionnaires were compared to retrospective chart reviews. These studies demonstrated a high rate of persistent incontinence when outcomes were assessed using a validated patient questionnaire (46%) compared to retrospective chart review (70 to 100%).<sup>1,2</sup> We compare outcomes after pubovaginal sling using a validated patient questionnaire, validated voiding diary, validated 24-hour pad test and retrospective chart review by a physician.

#### MATERIALS AND METHODS

We performed a prospective blinded analysis of 84 consecutive patients with simple and complex sphincteric incontinence who underwent a pubovaginal sling procedure by a single surgeon. Sphincteric incontinence was defined as visible leakage from the urethra during increases in abdominal pressure in the absence of a detrusor contraction. Complex stress incontinence was defined as sphincteric incontinence accompanied by urge incontinence, "pipe stem urethra," urethral or vesicovaginal fistula, urethral diverticulum, grade 3 or 4 cystocele and/or neurogenic bladder. Pipe stem urethra, that is a fixed, scarred urethra, was defined subjectively based on physical examination, cystoscopic appearance and urodynamic findings. Urodynamic findings that supported the diagnosis of pipe stem urethra included sphincteric incontinence demonstrable without but not with the urodynamic catheter in place and a much lower uroflow compared to without the urodynamic catheter in place. Both findings

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suggest a low compliant urethra. Since there are no reported normal values for these urodynamic parameters, the diagnosis was made clinically and no numeric cutoffs were used. Simple stress incontinence was defined as that which did not meet the criteria for complex incontinence, and this group included women with detrusor instability (if they did not have urge incontinence) and those with failed prior surgery for incontinence.

The 84 women who underwent neurourological history, physical examination and video urodynamics preoperatively represent a subset of 251 previously reported on for pubovaginal sling.<sup>3</sup> The women completed a validated 24-hour pad test and voiding diary preoperatively and at least 1 year postoperatively. Video urodynamics studies were performed as previously described using a urodynamic unit, 7F double lumen catheter and medium fill cystometrogram with radiopaque contrast material. While performing urodynamics we followed all recommendations of the International Continence Society, except that during cystometry the patient was instructed to neither try to void nor try to inhibit voiding but simply to report sensations to the examiner. Since 1992 a Valsalva leak point pressure determination was performed. With a bladder volume of 150 ml. the patient was asked to cough and strain, and the lowest vesical pressure that caused visible leakage from the urethra was considered the Valsalva leak point pressure. If no leakage occurred with the urethral catheter in place, it was removed and the lowest abdominal pressure recorded during cough and Valsalva's maneuvers that produced urine leakage was called the abdominal leak point pressure.

Postoperatively the patient was scheduled to be evaluated at 1 month, 6 months, 1 year and yearly thereafter. 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 the woman in the lithotomy position and asked her to strain to check for recurrent incontinence as well as any signs of genital prolapse (cystocele, rectocele and enterocele). All available patients were contacted in person (at the followup visit) or by telephone, and asked to complete a validated postoperative voiding questionnaire administered by a blinded third party (see Appendix). We compared the questionnaire with the pad test, voiding diary and surgeon assessment (retrospective chart review) of the outcome of surgery. The 24-hour pad test and voiding diary were completed on the same day, that is before the followup visit.

Results of surgery were classified according to physician assessment, pad test, voiding diary and patient questionnaire. Physician assessment was a retrospective chart review, including the diary and pad test, performed by the operating surgeon who was blinded to the questionnaire. Patients were assessed as dry—never incontinent under any circumstances, improved—50% or more reduction and failure—less than 50% reduction in incontinence. For the pad test patients were assessed as cured—less than 2 gm. change, improved—50% decrease and failure—not improved by more than 50%. For the voiding diary patients were classified as cured—no notations of incontinence at all, improved—50% or greater decrease in incontinence notations compared to preoperatively and failure—less than 50% improvement in incontinence notations. On the questionnaire patients assessed themselves as cured—considers herself

cured by the operation and satisfied, improved—feels improved by the operation and would recommend it to a friend, and failure—considers the operation to have failed. For this analysis no distinction was made between postoperative stress and urge incontinence. The kappa coefficient was used for statistical analysis comparing the questionnaire to the pad test, voiding diary and surgeon assessment of outcome.<sup>4</sup>

RESULTS

Average patient age was 56 years (range 19 to 80). Mean followup for surgery was 3.8 years (range 1 to 15). Table 1 shows the patient questionnaire outcomes (stress and urge) for the simple and complex incontinence groups. Agreement was excellent ( $k > 0.9$ ) among the 4 instruments for outcome assessment with respect to cured/improved versus failure rate (table 2) but only good for cured versus improved versus failure ( $k > 0.5$ ).

DISCUSSION

Most outcome studies of stress urinary incontinence surgery based on retrospective chart reviews demonstrate success rates from 70 to 100%.<sup>3-12</sup> In contrast Haab et al reported a 73% cure rate for stress incontinence and 46% overall cure rate (stress and urge) for pubovaginal sling for intrinsic sphincter using a patient based questionnaire.<sup>1</sup> Sirls et al compared retrospective chart reviews following modified Pereyra bladder neck suspensions with patient questionnaires.<sup>2</sup> These investigators also found disparate success rates between these 2 methods of outcome assessment. They reported a 47% cure rate and 64% improvement rate using patient questionnaires, and a 72% cure rate and 89% improvement rate using retrospective chart reviews. Recently we reported a 92% success rate following pubovaginal sling for all types of stress incontinence using a retrospective chart analysis.<sup>5</sup>

We assessed the correlation among validated outcome instruments (pad test and voiding diary), retrospective chart review by the surgeon and patient questionnaire. The objective measurements we used included a 24-hour voiding diary and pad test. Recently we evaluated these instruments prospectively for reproducibility. Incontinence episodes tabulated in a voiding diary were reproducible when evaluated on 3 separate days. Additionally, pad tests completed on the same days as the voiding diary were also reproducible ( $k > 0.8$ ).<sup>13</sup>

Surprisingly, agreement among these instruments was excellent ( $k > 0.9$ ) for cured/improved versus failure but only good ( $k > 0.5$ ) for cured versus improved versus failure. The voiding diary showed a much higher failure rate than any of the other instruments. We believe that this difference occurs because the patient records each episode of incontinence, no matter how insignificant, as a single episode. Many of these episodes compared to the pad test done at the same time appear clinically insignificant. Interestingly, the women rated themselves to have done better from the operation compared to the surgeon. We believe that this finding is attributed to the strict criteria used to assess outcome. In addition, when we analyzed stress incontinence alone using

TABLE 1. Results of patient questionnaire for simple versus complex stress plus urge incontinence

	Simple	Complex
Total No. pts.	35	49
No. cured (%)	30 (86)	26 (53)
No. improved (%)	4 (11)	18 (37)
No. failure (%)	1 (3)	5 (10)
% Satisfied	96	77

TABLE 2. Comparison of instruments for stress and urge incontinence

	No. Pts. (%)			
	Pt. Questionnaire	Physician Assessment	Pad Test	Diary (67 pts.)
Cured	56 (67)	39 (46)	62 (74)	48 (72)
Cured/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)

the patient questionnaire we noted an 86% cure rate and 11% improved rate in women with simple incontinence. Women with complex incontinence did not fare as well but still had an acceptable success rate, with 53% describing themselves as cured and 37% as significantly improved from surgery. In the complex group the lower cure rate was due to persistent or de novo urge incontinence. More importantly 96% of the simple group and 77% of the complex group described themselves as satisfied with the outcome of surgery and would recommend this procedure to a friend.

Our results are in contradiction to previous reports that have consistently demonstrated patient based questionnaire results to be worse following surgery compared to retrospective chart review. The diaries and pad test are part of our routine followup of patients treated for incontinence, which affords us a heightened awareness of outcomes in clinical practice. Also, we use stringent criteria to judge success and failure. For example, a woman using 5 pads daily before surgery and just 1 pad daily for safety after surgery might consider herself to be cured but if the pad test showed more than 2 gm. urine loss she would be classified as improved.

#### CONCLUSIONS

Outcomes following incontinence surgery may vary depending on how the analysis was performed, patient selection, definition of success and so forth. Our results indicate that a pad test and voiding diary are reliable and should be part of the normal followup after pubovaginal sling for sphincteric incontinence. When these tests are used in conjunction with defined parameters of success, there is excellent agreement with patient feelings in regard to success or failure of surgery. Nevertheless, these instruments and methods are imperfect at best. They relate to cure, improvement and failure with respect only to incontinence. Cure implies a restoration to normal yet this is usually not the case. Many women note that they void differently after "curative" surgery. Some have to lean forward or squat, many have reduced uroflow compared to preoperative values and some have prolapse. We must choose our words, such as cure, more carefully. Perhaps as others have suggested we should use different words, such as responders and nonresponders, or describe improvement in terms of percent of normal. Although we are pleased with the performance of these instruments, we consider them an intermediate step toward our goal of developing more meaningful outcome instruments.

#### APPENDIX: QUESTIONNAIRE<sup>1</sup>

- How much leakage of urine do you have now?
  - None
  - Mild
  - Moderate
  - Severe
- If you do now leak, how does it occur?
  - Mostly with coughing, sneezing or physical activity
  - Usually not with physical activity, but leakage occurs suddenly with an urge to urinate before it can be controlled
  - Leakage of urine occurs in both of the situations described above
  - Not sure when leakage occurs
- How much improved is your urine leakage compared to before the sling surgery?
  - 100% better
  - 90% better
  - 80% better
  - 70% better
  - 60% better
  - 50% better
  - 40% better

- 30% better
  - 20% better
  - 10% better
  - The same
  - Worse than before the sling surgery
- Do you wear any protective pads for urine leakage?
    - Yes
    - No
  - If you are wearing pads, how many do you use in 24 hours?
    - More than once per hour
    - Every 1 to 2 hours
    - Every 3 to 4 hours
    - Less than once every 4 hours
  - How many times do you wake from sleep to urinate?
  - If your incontinence returned after sling surgery, how long did it take?
  - If your incontinence returned after sling surgery, how did it occur?
    - Gradually over a few months
    - Suddenly over a few days or weeks
  - Do you currently use a catheter to empty the bladder?
    - Yes
    - No
  - Do you get usually the urge to urinate?
    - Yes
    - No
  - Since surgery, do you have problems with pelvic pain?
    - Yes
    - No
  - If you are having intercourse, is it painful?
    - Yes
    - No
  - Overall, how satisfied are you with the results of your sling surgery?
 

0	1	2	3	4	5	6	7	8	9	10
Not Satisfied					Very Satisfied					
  - Knowing what you know now, would you have the sling surgery again?
    - Yes
    - No
  - Would you recommend the sling surgery to a friend?
    - Yes
    - No
    - Not sure

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