

## EFFECTIVE TREATMENT FOR MIXED URINARY INCONTINENCE WITH A PUBOVAGINAL SLING

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### ABSTRACT

**Purpose:** We assessed the results of autologous fascia pubovaginal sling (PVS) in women with mixed incontinence using a validated outcome score and identified risk factors for failure.

**Materials and Methods:** A total of 131 women who received a PVS for sphincteric incontinence (SUI) confirmed by history, physical examination and/or videourodynamic study (VUDS) were identified from a database during the accrual dates 1995 to 2001. Patients with a urethral diverticulum, neoplasm or urinary fistula were excluded. Patients with SUI who also complained of urinary urge incontinence (UUI) and/or had detrusor instability that reproduced incontinence symptoms during VUDS were diagnosed with mixed incontinence (MUI). Patients completed a urological questionnaire, 24-hour voiding diary, pad test, VUDS and cystoscopy preoperatively. The diagnosis of SUI and UUI was further confirmed by physician interview. In patients with MUI detrusor overactivity was classified according to urodynamic criteria. At least 1 year postoperatively the validated Urinary Incontinence Outcome Score (UIOS) was calculated from a 24-hour diary, pad test and questionnaire, and outcomes in patients with SUI and those with MUI were compared. The study was powered a priori to detect a 20% difference in outcome score. Cured patients (UIOS 0) were compared with those who were not cured (UIOS 1 or greater) and univariate analysis was applied to identify the correlates of failed PVS.

**Results:** Of the 131 patients evaluated 33 with a diverticulum or fistula were excluded and 98 underwent PVS. Patient age was 45 to 84 years (median 66). Followup was 1 to 7 years (median 3). A total of 46 patients (48.5%) had simple SUI and 52 (51.5%) had MUI. Two patients were lost to followup (2%) and the procedure was presumed to have failed. There were no differences in age, hormone status, previous surgery or pelvic organ prolapse between patients with SUI and MUI. The cure/improved rate was 97% in 44 SUI cases and 93% in 47 MUI cases, which was a nonsignificant difference ( $p = 0.33$ ). Analysis of the MUI group showed that patients who were cured and not cured had similar age, parity, urethral angle, bladder capacity, leak point pressure and pad tests. Patients with MUI who were cured had a higher number of voids in 24 hours on preoperative voiding diary (12 vs 8,  $p = 0.01$ ), while those who were improved or in whom treatment failed had a greater number of urgency (5.6 vs 4.1,  $p < 0.05$ ) and UUI (5.1 vs 3.0,  $p < 0.01$ ) episodes. Univariate analysis of MUI cases showed that an increasing number of preoperative urgency and urge incontinence episodes correlated directly with PVS failure ( $r = 0.33$ ,  $p = 0.038$  and  $r = 0.35$ ,  $p = 0.048$ , respectively). In contrast, an increasing number of voids correlated with successful PVS ( $r = 0.4$ ,  $p = 0.01$ ).

**Conclusions:** Women with SUI and concurrent urge incontinence or detrusor instability have a successful PVS outcome at a rate comparable to that in women with simple SUI, in contrast to our previous findings. Increasing episodes of urgency and urge incontinence on the preoperative voiding diary correlated directly with surgical failure, while voiding frequently was associated with cure.

**KEY WORDS:** urinary incontinence; transplantation, autologous; bladder; outcome assessment (health care); questionnaires

While surgical correction of sphincteric or stress urinary incontinence is associated with long-term success rates above 80%,<sup>1</sup> urinary urgency and urge incontinence remain difficult to treat as independent entities and as co-factors in patients with stress incontinence. Because postoperative in-

continence of any kind undermines the success rate perceived by the patient and physician, it is essential to understand the impact of urinary urgency and urge incontinence on patients who undergo surgical correction of stress urinary incontinence. We present the results of surgical correction of mixed urinary incontinence by an autologous fascia pubovaginal sling (PVS), as assessed by a validated urinary incontinence outcome score based on strict objective and subjective criteria for outcome analysis. We compared these data with those on a concurrent group of patients who underwent the same surgery for simple sphincteric incontinence (SUI).

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MATERIALS AND METHODS

A total of 131 women who received a PVS for SUI confirmed by history, physical examination and/or videourodynamic study (VUDS) were identified from a database during the accrual dates 1995 to 2001. Patients with a urethral diverticulum, neoplasm or urinary fistula were excluded. Patients with SUI who also complained of urinary urge incontinence (UII) and/or had detrusor instability (DI) that reproduced incontinence symptoms during VUDS were diagnosed with mixed incontinence (MUI). Patients completed a urological questionnaire, 24-hour voiding diary, pad test, VUDS and cystoscopy preoperatively.

A positive response to the question, "Do you lose control and wet yourself when you cough, sneeze, laugh, strain, change position, or exercise?" was considered indicative of SUI. A positive response to the question, "Do you lose control and wet yourself because you get a sudden urge to urinate and can't get to the bathroom in time?" was considered indicative of a history of urge incontinence. Discrepancies between the questionnaire and history were clarified during the patient interview by one of us. All MUI cases were classified according to overactive bladder type using the urodynamic criteria of Flisser et al.<sup>2</sup> DI was defined as involuntary detrusor contractions of any magnitude during the VUDS filling phase and SUI was defined as urethral leakage of urine in the absence of a change in detrusor pressure.

Patients underwent surgical treatment with an autologous rectus fascia PVS performed by a single surgeon, as described previously.<sup>3</sup> Postoperative assessment included 24-hour diary, pad test and a 1-item questionnaire as well as examination with a full bladder. At least 1 year postoperatively the validated Urinary Incontinence Outcome Score (UIOS)<sup>4-6</sup> was calculated and outcomes in SUI and MUI cases were compared. The study was powered a priori to detect a 20% difference in outcome score. Patients who described themselves as cured and had a pad test with less than 8 gm loss and a diary showing no SUI/UII episodes in 24 hours (UIOS 0) were compared with those who were not cured (UIOS 1 or greater). Univariate analysis of preoperative voiding diaries was applied to identify the correlates of a failed PVS.

RESULTS

Of the 131 patients evaluated 33 with a diverticulum or fistula were excluded from study and 98 received a PVS. Patient age was 45 to 84 years (median 66). Followup was 1 to 7 years (median 3). A total of 46 patients had simple SUI (48.5%) and 52 had MUI (51.5%). Two patients with MUI (2%) were lost to followup and the procedure was presumed to have failed. There were no differences in age, hormone status, previous surgery or pelvic organ prolapse between patients with SUI and those with MUI.

Data were collected at the last followup and analyzed using commercially available software. The cure/improved rate was

97% in 44 SUI cases and 93% in 47 in MUI cases, which was a nonsignificant difference (p = 0.33). Analysis of the MUI group showed that cured and not cured patients had similar age, parity, urethral angle, bladder capacity, leak point pressure and pad tests (see table). Patients with MUI who were cured had a higher number of voids in 24 hours on preoperative voiding diary (12 vs 8, p = 0.01), while those who were merely improved or who had failure had a greater number of urgency (5.6 vs 4.1, p <0.05) and UII (5.1 vs 3.0, p <0.01) episodes. Univariate analysis of MUI cases showed that the higher the number of urgency or UII episodes preoperatively, the more likely it was that the PVS would fail (r = 0.33, p = 0.038 and r = 0.35, p = 0.048, respectively). In contrast, an increasing number of preoperative voids in 24 hours correlated with a successful PVS (r = 0.40, p = 0.01). Two of the 4 patients with MUI in whom treatment failed had troublesome UII postoperatively, including 1 with recurrent SUI and 1 in prolonged urinary retention caused by urethral obstruction, which was treated by surgical revision of the sling. Two patients in the SUI group had a poor response due to de novo UII.

DISCUSSION

Despite many advances in our understanding of the pathophysiology of urinary incontinence the problem of urge incontinence remains difficult to treat successfully. In contrast to treatments available for stress incontinence, of which several have a long-term cure rate of above 80%,<sup>7</sup> medical and surgical treatments for urge incontinence currently achieve long-term cure in a far smaller proportion of patients.<sup>8-10</sup> Previously we have reported in a group of 165 patients with preoperative urge incontinence that urge incontinence preoperatively was a risk factor for a relatively poor outcome with persistent urge incontinence in 41% at 10 years of followup after receiving an autologous fascia PVS.<sup>7</sup>

In contrast to our experience, in a retrospective review in 1989 of 52 patients with MUI treated surgically with Burch urethropexy or medical therapy with oxybutynin, imipramine and estrogen Karram and Bhatia found no significant difference in the cure rate between the 2 groups.<sup>11</sup> They concluded that patients should first be treated medically to decrease the incidence of failed surgical intervention. Notably they observed that all failures in the surgical group were due to persistent DI.

Serels et al treated 36 patients with urodynamically diagnosed DI using different types of PVSs, including an in situ vaginal wall sling, free swing vaginal wall, rectus fascia, cadaveric fascia and synthetics, achieving a cure rate of 92% at a followup of 6 months to 4 years.<sup>12</sup> They observed that UII resolved in 75% of patients. Nguyen and Bhatia reported on 38 women with uterovaginal prolapse and motor urge incontinence who underwent surgical repair of prolapse and reported that UII resolved in 63%.<sup>13</sup> Nguyen and Bhatia

Cured vs improved/failed rater in patients with MUI after PVS

	Cured	Not Cured	p Value (t test)
No. pts (%)	34 (66)	17 (33)	
Mean age ± SD	62 ± 13	60 ± 12	Not significant
Mean bladder capacity ± SD (ml)	316 ± 146	346 ± 182	Not significant
Mean vesical leak point pressure ± SD (cm H <sub>2</sub> O)	82 ± 24	81 ± 37	Not significant
Mean pad test ± SD (gm)	101 ± 153	200 ± 230	Not significant
Mean urgency episodes ± SD	4.1 ± 2	5.6 ± 1.8	<0.05
Mean urge incontinence episodes ± SD	3.0 ± 1.7	5.1 ± 2.4	<0.01
Mean voids/24 hrs ± SD	12 ± 4.0	8 ± 3.5	<0.01
No. menopausal, no hormone therapy	11	7	Not significant
No. previous pelvic surgery	19	10	Not significant
No. overactive bladder type:			
I	26	10	Not significant
II	6	5	Not significant
III	1	1	Not significant

Cured—UIOS 0 and not cured—UIOS 1 or greater.

found that postoperative UUI resolution was independently predicted by preoperative low amplitude DI on urodynamic study and bladder trabeculations. In 1987 Jorgensen et al also reported this relationship between low amplitude DI and cure in a series of 16 patients,<sup>14</sup> as did Schrepferman et al in 2000.<sup>15</sup> Other investigators, including Karram and Bhatia,<sup>11</sup> and McGuire and Savastano,<sup>16</sup> did not observe this relationship.

In our series patients with MUI had an overall cure rate comparable to that in patients with simple SUI, while DI in 26% of those with MUI did not predict a poor outcome. This statistically significant finding contradicts our previous observations.<sup>7</sup> A possible explanation is the relative uncertainty of the diagnosis of MUI, which could result in the inclusion of patients in the mixed group who truly have simple SUI. The diagnosis of SUI is relatively objective and it is made by physical examination or a stress test during urodynamic studies. The category of MUI is less clear. Some patients cannot differentiate among the symptoms associated with urinary leakage. When patients admit to sudden loss of urine associated with urgency, it is possible that this condition truly represents SUI combined with waiting too long to void, rather than true UUI. It could confound the resulting analysis. The fact that the incidence of DI in this sample of patients with MUI was lower than the prevalence of DI that we have typically detected in patients with urge incontinence (48% to 64%)<sup>17</sup> supports this hypothesis.

We also found that that an increasing number of urgency and UUI episodes correlated with failure to cure MUI, supporting our suspicion that, in contrast to urgency related to the fear of wetting, true severe UUI is a real risk factor for PVS failure. Patients who voided frequently were more likely to be dry after surgery and it is possible that they adopted frequent voiding as a strategy to control incontinence. That is, patients in whom urgency and resulting frequency were related to the behavioral effects of SUI would be cured at a higher rate than those with DI. Because almost all patients were examined postoperatively with a full bladder, we were able to assess the study population for this finding and observed that virtually none of the cured or improved patients showed postoperative SUI with a full bladder. Therefore, while many patients with SUI have altered voiding frequency to prevent incontinence, in these patients urgency did not appear to be associated with defensive voiding.

It is also possible that our technique of patient selection has changed since our previous findings suggested that UUI is a risk factor for a failed PVS. While this study suggests that UUI did not affect the treatment success rate, it seems clinically clear that a patient with severe, persistent UUI who voids every 30 minutes would be unlikely to have a successful outcome and unlikely to be considered a candidate for a PVS. Therefore, selection bias may have influenced the results of this study. Notably the average number of voids per 24 hours  $\pm$  SD in the MUI group was  $11 \pm 4$ , well below what many patients with severe UUI may experience. We strongly caution clinicians against indiscriminate application of a PVS in all patients with MUI because it may not be appropriate for the subset noted. It should also be apparent that a priori powering of this study to detect a 20% difference in outcome leaves open the possibility that a PVS is less effective for MUI than for SUI but within this 20% margin of difference. Additional analysis in a larger patient sample would resolve this question.

Anticholinergic medications were not systematically administered in the MUI group. Clinically the patients experienced primarily the effects of SUI. All patients were counseled that the PVS was not designed as a primary treatment to ameliorate or cure UUI or urgency and these postoperative

symptoms were likely to remain the same or worsen. To our knowledge it is not yet known whether the response of UUI or DI to anticholinergic medications in this population may predict a similar response after surgery.

We further recommend that all patients with urinary urgency should undergo appropriate evaluation to rule out remediable causes of urgency and UUI, such as tumor or a foreign body. We perform cystoscopy preoperatively to investigate this possibility. In cases of idiopathic urgency or UUI anticholinergic medications, behavior modification therapy and neuromodulation are potential treatments to consider. However, in this group of women with bothersome incontinence associated with low leak point pressure and SUI our primary therapeutic goal was SUI correction with the expectation of a high cure/improved rate based on our preceding published results. It remains to be seen what specific urgency related parameters predict success and failure, although we are optimistic that urodynamic testing may hold some of the answers.

#### CONCLUSIONS

In women with SUI and concurrent urge incontinence or urgency a PVS is equally effective compared with PVS outcomes in women with simple SUI. Increasing numbers of urgency and urge incontinence episodes on the preoperative voiding diary directly correlated with the likelihood of surgical failure.

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