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Analysis of Early Outcome: Burch Procedure versus Pubovaginal Sling

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Abstract: The Burch vesicourethral suspension (BUVS) has long been the procedure of choice for female stress urinary incontinence (SUI) because of its low complication rate and high success rate for all but those patients with type 3 SUI. The pubovaginal sling (PVS) procedure yields a high success rate in those with type 3 SUI but has not gained wide use for all types of SUI, owing to initial reports of a higher complication rate. A retrospective review of early effectiveness and complications associated with BUVS performed on 36 women without type 3 SUI compared to that for PVS performed on 42 women (24 with and 18 without type 3 SUI) at our institution was carried out. To ensure reasonable comparability between groups, homogeneous subsets of 18 women undergoing BUVS and 18 women undergoing PVS were defined. Using conservative criteria for early complications, PVS patients experienced half the complications of BUVS patients with a comparable rate of success.

Keywords: Burch vesicourethral suspension; Pubovaginal sling; Stress urinary incontinence; Valsalva leak-point pressure

Introduction

Urinary incontinence afflicts 10%–25% of women between 15 and 60 years of age, or approximately 9 million women in the United States [1,2]. The cost of products and services to treat urinary incontinence is estimated to be greater than $7 billion annually, or $778 per patient [2]. Stress urinary incontinence (SUI) is the most common cause of involuntary loss of urine in women [3]. It can be treated medically or surgically [4], with surgical treatment generally sought for cases involving substantial discomfort and inconvenience.

Since the Kelly plication [5] was introduced in 1914, various surgical treatments, generally classified as suspension or sling procedures, for SUI have evolved with the intent to improve efficacy and morbidity [6–14]. Comparative analysis of all the surgical procedures for SUI caused by abnormality of urethral descent (type 2) indicate that the BUVS has the best long-term outcome and is associated with a low complication rate [15,16]. Yet suspension procedures in general are reported to have a failure rate of 30%–40% or more when performed on patients with type 3 SUI [4]. Thus there is a subset of patients who will fail the BUVS because of intrinsic sphincter deficiency (type 3) that is not identifiable preoperatively or which occurs de novo postoperatively. Type 3 SUI should be suspected in women who fail prior suspension procedures, present with severe SUI, have a prior history of radiation therapy or pelvic fracture, and in patients with neurological disorders such as spina bifida, although reliable diagnostic procedures to identify type 3 SUI preoperatively are lacking.

The definitive procedure for type 3 SUI is the PVS [7,17]. This has not achieved widespread popularity because it is technically more demanding and has been reported to have a higher complication rate, approaching 31% [7,18]. The two most troublesome complications are permanent urinary retention and/or bladder instability [7]. However, after modifications advanced by Blaivas [7], these complications have become less frequent. The long-term success rate of PVS for all types of SUI has recently been reported to be 86% [19]. With the advent of a lowered complication rate for PVS and its universal applicability to patients with SUI, it would appear to be the procedure of choice. However, such a decision might best be based on a comparative

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analysis of patient outcomes associated with BUVS and PVS procedures. Undertaking such a comparison is complicated by the various use of rectus fascia or fascia lata. A literature search did not reveal any studies directly comparing the PVS using exclusively rectus fascia or fascia lata to the BUVS. As with most comparisons of surgical procedures comparability is potentially confounded by having multiple and different surgeons perform the respective procedures. Although not a formal solution to this limitation, obtaining case series from 'best practice' may provide reasonable comparability in a naturalistic setting.

Materials and Methods

We retrospectively evaluated a consecutive series of medical records from 78 female patients who were operated on for SUI between February 1995 and November 1996 at our institution. Because urologic surgeons exclusively perform the PVS on patients first seen in Urology or referred by Gynecology, whereas gynecologic surgeons exclusively perform the BUVS, the respective surgeons are assumed to represent 'best practice'. A primary reason for an SUI patient to be referred from Gynecology to Urology is because of confirmed type 3 SUI requiring PVS rather than BUVS. As the Departments of Urology and Gynecology collaborate in the management of SUI patients, remaining aspects of preoperative diagnosis and post-operative management are consistent across patients. All patients were followed for a minimum of 3 months postoperatively.

Forty-two patients (24 with and 18 without type 3 SUI) underwent PVS and 36 (without type 3 SUI) underwent the BUVS procedure. Thirty-four patients had rectus fascia utilized for the PVS, and 8 had fascia lata, obtained from either lateral thigh. The BUVS and PVS were performed as described by Kiilholma et al. [20] and Blaivas [7]. Preoperative evaluation consisted of a history and physical examinations, a Q-tip test and multichannel videourodynamics with the Dantec model #UD5000. PVS was offered to patients with all types of SUI where clinically appropriate, irrespective of the degree of urethral mobility or dysfunction. The BUVS was offered only to those patients with hypermobility (based on a Q-tip test greater than 30° or videourodynamics) and a high Valsalva leak-point pressure (VLPP; >90 cmH_2O). A possible unreliable VLPP measurement was avoided by reducing significant bladder prolapse with a pessary as necessary. Patients identified as having type 3 SUI (defined by us as VLPP less than 90°) were offered only the PVS procedure because of the high failure rate of the BUVS in this group. Twenty-two of the 92 PVS patients had VLPP less than 90 cmH_2O. The remaining 20 PVS patients had VLPP greater than 90 cmH_2O.

All patients received an i.v. antibiotic (either Kefzol 1 g, ampicillin 1 g, Unasyn 1.5 g or gentamicin 80 mg) 1 hour preoperatively and postoperatively for only 24 hours. All patients had sequential stockings placed 1 hour preoperatively, which were maintained until the patient was fully ambulatory. All Foley catheters were removed the morning after surgery. If the patient failed a voiding trial she was given the option of learning clean intermittent catheterization, to be done every 6 hours, or having a Foley catheter placed until a 1-week follow-up appointment. At discharge all patients were scheduled to have follow-up appointments at 1 week, 1 month and 3 months, and were instructed to return before a scheduled follow-up appointment if complications occurred.

Telephone calls were used to screen for adverse clinical outcomes, which might not have been identified in the clinic, and informally query patient satisfaction and success. Success was defined as being continent and pad free at the time of phone contact. Patient satisfaction was defined as an affirmative response to each of the following questions: 'Would you recommend this operation to a friend with a similar urinary incontinence problem?' and 'Would you do this operation over again now knowing what you experienced?'

The following complications were recorded: urinary retention (including duration in number of weeks postoperatively), prolonged retention, defined as the inability to void after 4 weeks postoperatively, number of urinary tract infections, operative transfusions, onset of new enteroceles, onset of new urge incontinence necessitating medical treatment, and incidence of wound infection. Data on age, prior number and type of bladder suspensions and collagen therapies, length of follow-up, length of operation in minutes (measured as time under anesthesia), length of hospitalization in days and total operating room, anesthesiology, surgeon and hospital charges were also collected. Total charges were used as a proxy measure of cost, recognizing that these frequently do not reflect absolute cost. However, within a single institution charges are expected to be applied in a consistent manner, compared to widely varying fee schedules and billing practices across multiple institutions. As such, charges here may appropriately measure relative differences in resource utilization.

All patients had a post-void residual recorded in milliliters at the 1-month follow-up appointment. These determinations were performed by the Bladder Scan, Model BVI 2500, Diagnostic Ultrasound Corp, Kirkland WA 98083, USA.

Statistical Analysis

Patient characteristics for those receiving BUVS or the PVS procedures were summarized using medians for the continuous variables age, pads per day prior to surgery, follow-up time and length of time in the operating room. The binary variables, including incidence of prior suspension procedures, prior collagen injection therapy and prior or concomitant gynecologic procedures, were summarized using frequencies. Group differences were tested using the Wilcoxon test for continuous variables and χ^2 or Fisher's exact test (where small frequencies

were encountered) for binary variables. Binary satisfaction and complication outcomes were summarized as frequencies and differences between patients receiving PVS or BUVS procedures tested by χ^2 or Fisher's exact test, as appropriate. Days of hospitalization, postvoid residual at 1 month and total charges were summarized for the two groups by medians and differences evaluated using the Wilcoxon test. All statistical tests were two-sided and $P<0.05$ was used to define significance.

Because this study was observational, it could not be assumed that patients receiving either BUVS or PVS procedures were comparable prior to surgery. Therefore, in addition to comparisons based on the full complement of data, a subset analysis was performed. All hypothesis testing was repeated on a subset of patients, excluding 18 who had the BUVS procedure with concomitant gynecologic procedures (such as hysterectomy) and 24 who had the PVS procedure specifically because of an identifiable type 3 SUI. These exclusions were aimed at making the two patient groups more comparable in terms of complexity of surgical procedures and the extent of SUI.

Results

Comparisons of patient characteristics and outcomes for all 78 who received the BUVS or PVS procedures are given in Table 1. Patients receiving the PVS procedure were somewhat older and used more pads per day prior to surgery, although these differences are not significant. However, BUVS patients were followed significantly longer than PVS patients (15 vs. 9 months, $P<0.001$). BUVS patients also had substantially more prior or concomitant gynecologic procedures than PVS patients (70% vs. 48%, $P = 0.055$). The operating room time for PVS patients was significantly longer, with a median of 140 minutes compared to 115 minutes for BUVS patients, $P = 0.016$. Finally, PVS patients had significantly more prior suspension procedures (29% vs. 3% $P = 0.002$) and prior collagen injection therapies (21% vs. 0%, $P = 0.003$) than BUVS patients.

Despite substantial differences in patient groups, success and satisfaction rates of 90%–95% were comparable. However, the incidence of any complication was markedly higher among BUVS than PVS patients, at 42% and 26%, respectively. This difference is not significant but appears to accrue from higher rates of urinary retention and wound infection among BUVS patients. At 1 month, postvoid residuals for BUVS and PVS patients are significantly different at 50 ml and 30 ml, respectively ($P = 0.020$). Total charges are significantly higher for PVS than BUVS patients, $9,372 and $8,856 respectively ($P = 0.020$), despite significantly shorter hospital stays (median 2 vs. 3 days; $P<0.001$).

Table 1. Summary of characteristics and outcomes for BUVS and PVS patients, n=78

	BUVS n=36	PVS n=42	P
Patient characteristics			
Age in years (median)	47	55	0.119
Pads per day (median)	3	4	0.440
Follow-up in months (median)	15	9	<0.001
OR time in minutes[1] (median)	115	140	0.016
Prior suspension procedures (n, %)	1 (3)	12 (29)	0.002
Prior collagen injection therapy (n, %)	0 (0)	9 (21)	0.003
Prior/concomitant gynecologic procedures (n, %)[2]	25 (70)	20 (48)	0.055
Outcomes			
Success (n, %)	32 (89)	39 (93)	0.697
Would recommend procedure (n, %)	34 (94)	40 (95)	1.000
Would do again (n, %)	33 (92)	40 (95)	0.657
Any complication (n, %)	15 (42)	11 (26)	0.148
Urinary retention (n, %)	4 (11)	1 (2)	0.175
Postoperative urinary tract infection (n, %)	4 (11)	10 (21)	0.223
Wound infection (n, %)	6 (17)	2 (5)	0.134
Intraoperative transfusion (n, %)	2 (6)	0 (0)	–
New-onset enterocele (n, %)	0 (0)	1 (2)	–
New-onset urge incontinence (n, %)	1 (3)	0 (0)	–
Days of hospitalization (median)	3	2	<0.001
Post residual void at 1 month in ml[3] (median)	50	30	0.020
Total charges in US$[4] (median)	8856	9372	0.020

[1]OR time available for only 17 patients receiving BUVS without ancillary gynecologic procedures and for 35 PVS patients.
[2]Data available for only 33 patients receiving BUVS without ancillary gynecologic procedures and 42 patients receiving PVS.
[3]Data available only for 25 patients receiving BUVS and 37 patients receiving PVS.
[4]Data available only for 25 patients receiving BUVS without ancillary gynecologic procedures and 37 patients receiving PVS.
– indicates frequencies too small for meaningful tests of comparison.

A summary of replicated analyses applied to a patient subset selected to provide better comparability of outcomes for BUVS and PVS patients appears in Table 2. Median age was very similar for the two groups, as were the number of pads used per day prior to surgery. The disparity between lengths of follow-up is less in this subset, with a median of 12 months follow-up for BUVS and 9 months for PVS patients ($P = 0.316$). Similarly, the length of time in the operating room remains significantly longer for PVS than BUVS patients. However, there is better comparability with respect to the rate of prior gynecologic procedures. None of the patients in either group received blood transfusions. Overall success and satisfaction rates remain high and comparable between patient groups in the subset analysis. However, the difference in overall complication rates of 56% and 17% for BUVS and PVS is significant, and largely attributable to a 28% rate of wound infections vs. 0% in these two groups, respectively. Despite widely differing complication rates, hospital lengths of stay are comparable in the subset analysis. Post residual void volume differences observed in the full complement remain in the subset analysis, although these are not significant most likely due to the smaller sample size. Total charges remain significantly different for BUVS and PVS patients in the subset analysis (median \$8,763 vs. \$9,266; $P = 0.021$). All 6 patients who failed either the BUVS or PVS were requested to have repeat videourodynamics free of charge. All patients declined.

Discussion and Conclusions

The concept of internal sphincteric deficiency (ISD) was first introduced by McGuire [21] in 1980. With ISD, SUI can occur irrespective of the anatomic position of the proximal urethra. Therefore, in treating SUI with any suspension procedure, correct identification of ISD is critical. Many diagnostic tools, such as static infusion urethral pressure profile (UPP), maximum urethral closure pressure (MUCP), cystoscopy, cystogram, electromyography (EMG) and VLPP, have been used to assess sphincteric function. Unfortunately, each of these techniques has its limitations [21–27]. Currently, the most widely used diagnostic technique to select type 3 SUI incontinence is the determination of VLPP. There is considerable overlap in the VLPP between type 2 and type 3 SUI. Even in patients with VLPP below 60 cmH_2O, 24% had type 2 SUI [22]. About 13% of women who had never had any operations had primary ISD [28]. In this study we chose a VLPP greater than 90 cmH_2O for the BUVS procedure, to minimize the inclusion of the type 3 SUI patients. However, outcome analysis addressing the predictive value of VLPP for failure or

Table 2. Summary of characteristics and outcomes for BUVS patients, excluding those with concomitant gynecologic procedures and PVS patients, excluding those with type 3 SUI, n=36

	BUVS n=18	PVS n=18	P
Patient characteristics			
Age in years (median)	56	54	0.950
Pads per day (median)	3	3	0.698
Follow-up in months (median)	12	9	0.316
OR time in minutes[1] (median)	110	140	0.003
Prior suspension procedures (n, %)	1 (6)	3 (17)	0.603
Prior collagen injection therapy (n, %)	0 (0)	0 (0)	–
Prior/concomitant gynecologic procedures (n, %)[2]	9 (53)	7 (39)	0.404
Outcomes			
Success (n, %)	17 (94)	16 (89)	1.000
Would recommend procedure (n, %)	16 (89)	18 (100)	0.486
Would do again (n, %)	16 (89)	18 (100)	0.486
Any complication (n, %)	10 (56)	3 (17)	0.021
Urinary retention (n, %)	3 (17)	0 (0)	0.229
Postoperative urinary tract infection (n, %)	2 (11)	3 (17)	1.000
Wound infection (n, %)	5 (28)	0 (0)	0.045
Intraoperative transfusion (n, %)	0 (0)	0 (0)	–
New-onset enterocele (n, %)	0 (0)	0 (0)	–
New-onset urge incontinence (n, %)	1 (6)	0 (0)	–
Days of hospitalization (median)	2	2	0.363
Post residual void at 1 month in ml[3] (median)	50	20	0.063
Total charges in US$[4] (median)	8763	9266	0.021

[1]OR time available for only 16 patients receiving BUVS and for 15 PVS patients.
[2]Data available for only 17 patients receiving BUVS without ancillary gynecologic procedures and 18 patients receiving PVS.
[3]Data available only for 14 patients receiving BUVS and 17 patients receiving PVS.
[4]Data available only for 16 patients receiving BUVS without ancillary gynecologic procedures and 14 patients receiving PVS.
– indicates frequencies too small for meaningful tests of comparison.

success of the BUVS procedure has never been performed.

For up to 2 years, the success rates between the BUVS and PVS are similar. We recognize that median follow-up time was longer for BUVS than PVS patients, possibly allowing for the identification of more complications. It should be noted that the difference in complication rates is due primarily to postoperative urinary tract or wound infections, which would be equally identifiable in the immediate postoperative period. That the wound infection rate may appear high is probably due to the very conservative definition of wound infection we used, which included minor infections such as seroma, requiring only minimal incision and drainage not associated with prolonged hospitalization or i.v. antibiotics.

We imposed a strict criteria for defining our success. All of the patients who failed in our study have marked improvement in their urinary incontinence. This correlates well with the high patient satisfaction rates, which were similar in both groups. None of our patients developed permanent postoperative urinary retention.

A significant difference in operating room time between BUVS and PVS patients remained in the subset analysis despite exclusion of BUVS patients having concomitant gynecologic procedures. This substantiates the claim that the PVS procedure is more technically complex. However, claims that the complication rate for PVS are higher than BUVS are not supported by the present study, in which there is a significantly higher complication rate for the BUVS. It might be argued that the longer follow-up for BUVS patients permitted more opportunity to accrue and identify complications. However, the most prevalent complications, including urinary retention, postoperative urinary tract infection and wound infection, are relevant only for the first several months after surgery, for which follow-up was complete for both groups. At the very least this finding suggests that the PVS procedure involves no more risk than the BUVS, and invites reinspection of the complications associated with these surgeries. It is interesting to note that differing complication rates are not reflected in differing success, patient satisfaction, length of hospitalization or total charges.

Although the PVS procedure appears significantly more costly than the BUVS, probably due in part to the longer operating room time, in the short term it is easy to recognize how cost savings to both managed care and to patients might accrue over the long term. For example, if the PVS procedure provides a better initial success rate for patients with all types of SUI, then repeat operations for failures can be avoided. Similarly, if the PVS is widely adopted, preoperative evaluation can be streamlined by the physical presence of SUI and a well recorded voiding diary. Costly videourodynamic studies (charge of $1058 at our institution) can be omitted in most PVS patients except in the most complicated cases of urinary incontinence, such as post-radiation therapy, a history of pelvic fractures or neurologic disorders. Because of the need to demonstrate high VLPP in the BUVS patients, urodynamic studies become necessary to select out those with type 3 SUI.

We did not include in our analysis other potential risk factors, such as morbid obesity, chronic steroid therapy and chronic obstructive pulmonary disease, because the numbers are too small to be meaningful. None of our patients who failed surgery had any of these risk factors.

For the short term the clinical outcome of the PVS for all types of SUI appears to be as good as the BUVS procedure for type 2 urinary incontinence. With the PVS it is possible to spare most patients the discomfort and expense associated with the preoperative urodynamic evaluation. If the long-term outcome remains unchanged, the PVS should be considered the procedure of choice for female SUI because of its applicability for all types of SUI and its potential in cost savings.

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EDITORIAL COMMENT: The authors present short-term results of the Burch procedure performed for GSI with documented urethrovesical junction hypermobility compared to the results of the suburethral sling performed for any type of GSI, regardless of urethral function or bladder neck support. The real decision on surgical procedure is clearly stated to be which surgical department performed the operation. There are therefore more than two different patient populations undergoing different procedures by different surgeons. The short-term results presented by the authors indicate that the sling procedure, although more costly, has fewer complications than the Burch procedure, with equivalent success rates even when applied to patients with varying degrees of GSI. Other centers have consistently over time reported higher incidences of postoperative complications, including postoperative voiding dysfunction, detrusor instability, urinary tract infection and wound healing problems (when using foreign sling material), in association with the sling procedure. Added to the short follow-up time, the lack of objective postoperative evaluation and poor assessment of subjective patient response and change in quality of life, it is premature to conclude that the sling procedure should be performed on all patients with stress loss of urine with no preoperative urodynamic testing.