Insertion of Artificial Urinary Sphincter with Preservation of Bulbospongiosus Muscle in Patients at Risk for Sphincter Erosion: an Assessment of Patient Satisfaction

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ABSTRACT

Purpose: To evaluate the safety and patient satisfaction following artificial urinary sphincter (AUS) placement with preservation of the bulbospongiosus muscle in patients at risk for erosion.

Materials and Methods: The records of 67 patients who underwent AUS placement between the dates of 1997-2004 were reviewed. Patients were identified as being at risk for erosion if they had radiation therapy or previous erosion of an artificial sphincter. These patients underwent sphincter implantation emphasizing preservation of the bulbospongiosus muscle complex. Patients completed a phone interview and also returned an anonymous questionnaire containing the UDI-6, IIQ-7, PGI-I and a 10 point Likert scale to assess satisfaction.

Results: 21 men were identified as high risk for erosion. Average daily pad usage preoperatively was 6.4. No urethral injuries or intraoperative complications occurred. Cuff size ranged from 4.0 to 5.0. Three revisions were necessary to downsize the cuff. At a mean follow-up of 35.8 months, 15/21 participated in the surveys. Two-thirds considered themselves "cured" or "greatly improved" following sphincter placement. The average daily pad usage decreased to 3.1. On a scale of 1-10, the average self-grading of satisfaction was 8. None of the patients felt the surgery was difficult to undergo, and all but 3 would repeat the procedure again. No patients developed erosion or infection of the device.

Conclusion: AUS placement can be safely done in patients at high risk for erosion by preserving the bulbospongiosus muscle complex. Long-term results are favorable with two-thirds of this difficult population highly satisfied with the result.

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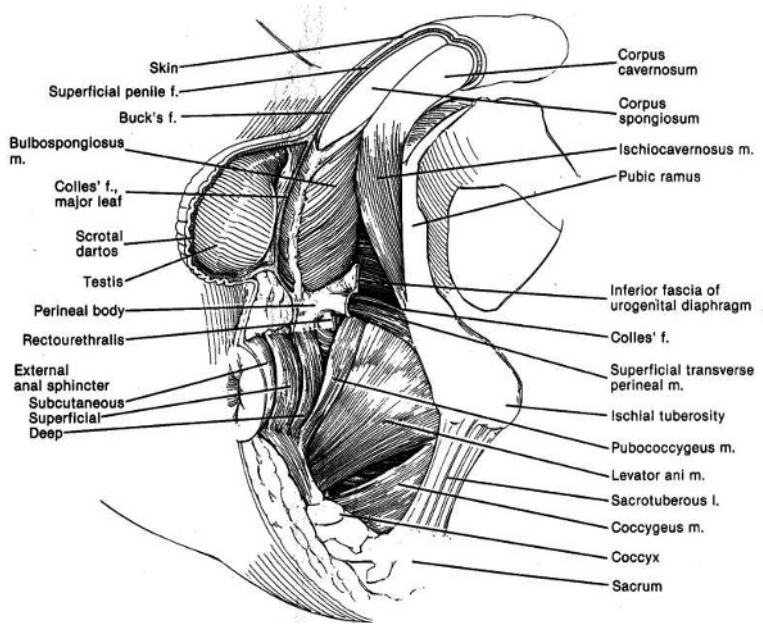
INTRODUCTION

Urinary incontinence rates in males range from 1.6% to 24% (1). The incidence of incontinence following radical prostatectomy has been reported to range from 2.5 (2) to 87% (3). This wide discrepancy is a result of several factors. The definition of incontinence varies widely among series, ranging from any degree of wetting to total incontinence. The method of data acquisition also has a significant effect on reported rates of incontinence. Studies that involve patient questionnaires and/or direct patient input generally have higher rates of incontinence than data obtained by chart review or physician interview. In a sample of Medicare patients undergoing radical prostatectomy, 47% had leakage of urine daily, and 6% needed surgical intervention (4). Incontinence after prostatectomy has a significant negative impact on a patient's quality of life. Herr discovered in a questionnaire-based study that in 26% of patients surveyed, incontinence seriously affected the overall quality of life, and that 53% of patients 5 years after surgery would not undergo surgery again (5). In a survey of quality of life issues in men treated for localized prostate cancer compared to a normal age-matched control, patients following radical prostatectomy scored significantly worse on a scale evaluating urinary function (6) with one quarter to one half of incontinent males noting significant limitations in quality of life (7).

Intrinsic sphincter deficiency (ISD) is the predominant cause of post-prostatectomy incontinence. Excellent results have been achieved utilizing an artificial urinary sphincter in the surgical correction of ISD in men following prostatectomy. The first artificial urinary sphincters (AUS) were introduced in the 1970s and today's devices still bear resemblance to their predecessors (8). The advent of kink-free tubing and narrow backed cuffs has led to currently acceptable mechanical failure rates of less than 8% and projected 5-year product survival of 75% (9). Perhaps the most feared complications of AUS placement are the occurrence

Figure 1. Male Perineum,© Saunders Publishing



of infection and urethral erosion of the device. Patients considered at high risk for these complications include those with urethral stricture disease, previous radiation therapy, and erosion of a previous sphincter device. With special consideration for these disease processes, many men have been successfully implanted with positive outcomes (10).

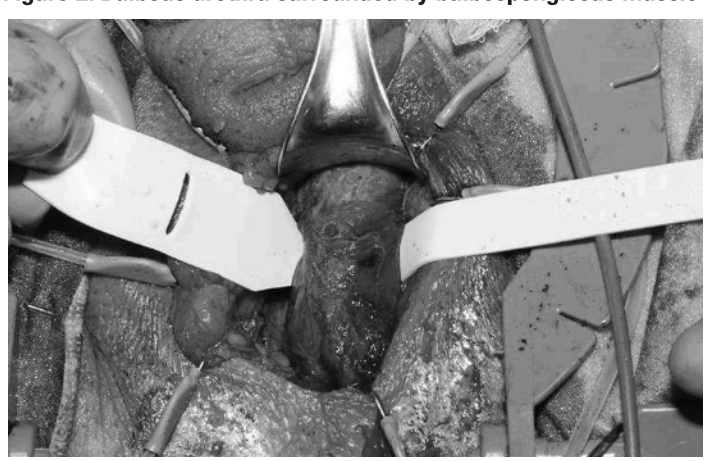
Many descriptions of AUS placement call for division of the bulbospongiosus muscle, which overlies the bulbous urethra and corpus spongiosum (Figure 1), for cuff approximation to the corpus spongiosum. We have been utilizing a technique which emphasizes preservation of the muscle complex, placing the cuff around the bulbospongiosus muscle. Other aspects of the procedure include use of a low pressure regulating balloon (51-60cm) and deactivation for 3 months. We sought to determine the feasibility of this muscle sparing technique and patient satisfaction in subjects at risk to develop complications after artificial sphincter placement.

PATIENTS AND METHODS

The records of 67 patients who underwent AUS placement for post-prostatectomy incontinence from 1996 to 2004 were reviewed. Patients were identified as being at risk for erosion if they had prior radiation therapy or previous erosion of an artificial sphincter. We identified 21 men ranging in age from 54 to 84 (mean 73.1) as being at high risk for sphincter complications. Thirteen patients had undergone previous radiation, ten experienced cuff erosion, and two suffered with both adverse conditions. A careful review of the patients' histories was conducted with attention to note preoperative pad usage, urodynamic findings, and cystoscopic findings. The records were also evaluated for any early or late surgical complications.

One surgeon (JCW) performed all operations with strict adherence to the technique of sphincter implantation emphasizing preservation of the bulbospongiosus muscle complex, use of a low-pressure regulating balloon, and deactivation for 3 months. The technique follows: patients are placed in the dorsal lithotomy position. A 16 French Foley catheter is inserted. A midline incision over the perineum is created, exposing the bulbospongiosus muscle. The dissection is carried laterally around the muscle complex, and the corpora cavernosa are usually identified laterally. The bulbous urethra with the preserved overlying muscle complex may be grasped gently with a Babcock clamp. The anterior extension of the muscle surrounding the urethra is easily identified and serves as a landmark to gain access around the anterior urethra without injuring the urethra. One should be able to develop this space without the need to puncture through this tissue. Once this space is developed, blunt dissection with a right angle clamp and passage of the measuring tape and cuff can be done without difficulty (Figure 2). Repeat cystoscopy is performed to assess the urethral integrity prior to seating the cuff. A low-pressure regulating balloon (51-60 cm H_2O) is placed in the preperitoneal space in the lower aspect of the abdomen. Patients are hospitalized overnight for observation and given a voiding trial on postoperative day one. All sphincters are deactivated for 3 months.

Figure 2. Bulbous urethra surrounded by bulbospongiosus muscle



Patient satisfaction was assessed by a phone interview by an independent researcher and a mailed questionnaire for each patient. Multiple validated questionnaires were used as part of the survey. These include the Urogenital Distress Inventory (UDI-6), the International Incontinence Questionnaire (IIQ-7), and the Incontinence Quality of Life questionnaire (I-QOL). In addition, the patients also completed a self-assessment of improvement (Patient Global Impression of Improvement, PGI-I) and a linear analog scale assessing satisfaction.

RESULTS

The mean follow-up is 35.8 (6-82) months. Daily pad usage preoperatively was an average of 6.4 per patient and 5 patients wore penile clamps. There were no urethral injuries. Cuff size ranged from 5.0 cm (8 cases), 4.5 cm (8 cases), to 4.0 cm (5 cases). One patient developed postoperative urinary retention that was managed with short term intermittent catheterization. There were no cases of sphincter infection. Following AUS placement the average pad usage was 3.1 per patient per day. Three patients (14%) were dissatisfied with their initial results and were managed with cuff downsizing. To date no implant has been removed for infection or erosion.

Fifteen of the 21 eligible patients participated in the follow-up survey. Three patients had expired and an additional 3 were lost to follow-up. On the self-impression of improvement questionnaire (11), 10 of 15 (66.7%) considered themselves "cured" or "greatly improved" following AUS placement. The average scores on the incontinence questionnaires were: UDI-6 (7.0), IIQ-7 (5.3), and I-QOL (45.1). On the linear analog scale of 1-10 the average self-grade for satisfaction was 8 (5-10). None of the patients stated the surgery was difficult to undergo, and all except three would undergo the surgery again if needed.

DISCUSSION

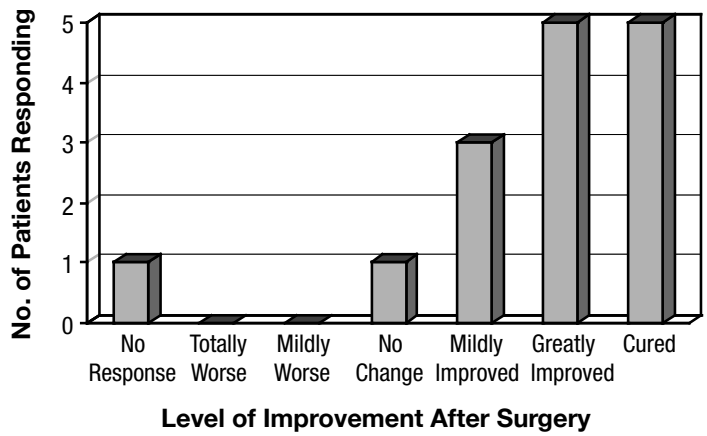
As increased public awareness encourages more men to seek incontinence treatment, increasingly complex cases of post-prostatectomy incontinence will be encountered. More men will present after radiation therapy or after having a previously eroded sphincter device. Despite these potential problems, both sets of patients have been demonstrated to be amenable to AUS placement. Irradiated patients have been found to achieve a social continence rate of 87% with a 12.5% risk for erosion or infection (12). De novo reimplantation for erosion or infection has been determined to offer continence rates of 95.8% with 8.7% of the patients experiencing repeat erosion (13).

Over the last decade various techniques have been developed to address AUS placement in high risk patients. A technique that involves placement of two cuffs in tandem has been demonstrated to offer a successful alternative to patients experiencing non-mechanical failure with one cuff (14). Although an excellent alternative for patients with severe ISD and incontinence following a 4.0 cm cuff, this procedure may possibly increase the risk of erosion as a result of having two cuffs placed in the setting of irradiated or fibrotic tissue. The tandem cuff sphincter placement is not considered a "salvage" procedure, and should be utilized primarily in the setting of bulbous urethral tissues following failure of a 4.0 cuff. This procedure may also be useful when the physical bulk of the bulbous urethral tissues is inadequate for reimplantation of a single cuff. A more recent innovation includes placement of a single cuff in a more distal location with the incorporation of tunica albuginea of the corpora cavernosa (15). This is an excellent procedure facilitating a more distal location of the urethral cuff while theoretically protecting from erosion. More tissue becomes available for cuff compression, facilitating cuff placement in a more distal location. Early results indicate good patient satisfaction though erosions can occur up to 15% of the time (10). This procedure should be cautiously considered in men with a penile prosthesis or who are sexually active.

The technique we have utilized is similar to one that is commonly used by many urologists (11). An obvious risk of the muscle sparing procedure is urethral atrophy causing recurrent incontinence. For this reason, some surgeons advocate placement of the urethral cuff directly on the corpus spongiosum to prevent thinning and atrophy of the muscle (12). In cases where erosion is a risk, some authors advocate minimal dissection around the urethra and yet others skeletonize the corpus spongiosum (7, 13). We feel that in patients who are high risk for poorly vascularized or fibrotic tissue, minimal dissection of the urethra offers safer cuff placement. This study confirms our assumption as we encountered no urethral injury or subsequent erosion. The salient points of the above procedure (muscle sparing, low-pressure balloon, and deactivation for 3 months) are all steps taken to ensure maximal tissue viability at the time of cuff activation.

If reasonable expectations are set, 90% of patients will have a positive outcome following AUS placement even if faced with some residual incontinence (14). We sought to ascertain patient satisfaction following AUS

Figure 3. Self-Impression of Improvement



placement in a group of patients who were determined to be high risk for complications. As mentioned above, the average score for the incontinence questionnaires UDI-6 and IIQ-7 were 7.0 and 5.3, respectively. Subjectively, 66.7% of these patients were satisfied and considered themselves "cured" or "greatly improved" (Figure 3). While not meant to be taken as objective data, these findings point toward patient satisfaction.

During this intermediate term follow-up, 3 patients required revision. Two of these 3 patients had had previous erosion. In each instance they were downsized to a 4.0 cm cuff. If unacceptable incontinence continues, these patients must be considered potential candidates for tandem cuff or transcorporal cuff placement.

This study is limited by the lack of preoperative assessment via the same questionnaires and more objective pad testing data. A comparison to preoperative data would be invaluable in gauging improvement, and more objective pad testing would more optimally quantify urine leakage. Despite these limitations, we feel that the data as presented demonstrate that AUS placement preserving the bulbospongiosus muscle is a procedure that achieves a high degree of patient satisfaction in these patients at risk for complications.

CONCLUSIONS

Artificial urinary sphincter placement has proven effective in many patient populations including those previously irradiated and those with prior cuff erosion. We demonstrate that an approach which conserves the bulbospongiosus muscle overlying the bulbous urethra is safe in these patients. In this difficult group of patients, two thirds of the patients were highly satisfied with the level of continence achieved. Artificial urinary sphincters should be considered in patients with ISD even in cases of previous irradiation or erosion.

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