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The utility of lockout valve reservoirs in preventing autoinflation in penile prostheses

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Abstract. *Introduction*: Autoinflation is a troublesome complication following penile prosthesis placement that may be potentiated by prevesical scarring following radical prostatectomy. We evaluated the frequency of autoinflation and other complications following penile prosthesis placement in radical prostatectomy patients and controls as a surrogate to establishing the utility of lockout reservoirs in preventing autoinflation. *Methods*: 139 prostheses (including 14 with lockout reservoirs) were placed in 132 men (including 35 post-prostatectomy patients) over a $5^1/_2$ year period at our institution. Outcomes assessed include postoperative complications and the need for revision or replacement of the prosthesis. Multivariable regression analysis was used to determine the association of patient, device-specific, and perioperative characteristics with these outcomes. *Results*: There was no difference in the postoperative complication and re-operation rates between post-prostatectomy patients and controls (both $p > 0.77$). The incidence of autoinflation in post-prostatectomy patients and controls was 3% and 5%, respectively ($p > 0.99$). Patients with prior prostheses were 3 times as likely to develop a postoperative complication or require prosthesis revision ($p = 0.02$). *Conclusion*: Penile prostheses are well tolerated in post-prostatectomy patients with comparable outcomes to those men with organic erectile dysfunction. The frequency of autoinflation does not appear to be increased in post-prostatectomy patients. Initial results with the lockout valve reservoir in preventing autoinflation are encouraging though additional study is warranted to justify their routine use.

Key words: Autoinflation, Penile prosthesis, Postoperative complication, Radical prostatectomy

Introduction

Since its introduction in 1973 [1], the inflatable penile prosthesis has taken a prominent role in refractory erectile dysfunction which is reflective of its high (80–91%) patient and partner-reported satisfaction rates [2–4]. However, troublesome prosthetic-related complications (e.g. subacute infection and autoinflation) contribute significantly to patient dissatisfaction [3]. Consequently, manufacturers have attempted to address these nuisances with novel modifications such as antibiotic impregnated components and reservoirs with anti-refluxing (lockout) valves. However, the utility of such adaptations is unknown.

With a high prevalence (up to 80%) [5] of erectile dysfunction following radical prostatectomy for prostate cancer and the marginal response (43%) [6] of these men to oral medications, placement of an inflatable penile prosthesis remains a viable option after pharmacological venues have been exhausted. However, scarring in the prevesical space after radical retropubic prostatectomy may potentiate the risk of autoinflation. Indeed, up to 40% of renal transplant recipients (who would have similar prevesical scarring) implanted with three-piece devices suffer from autoinflation [7].

In this context, we evaluated the utility of the lockout valve reservoir in preventing autoinflation in post-prostatectomy patients and in those implanted for other etiologies of erectile dysfunction. To this end, we assessed the safety and efficacy of all devices implanted in post-prostatectomy patients when compared to those implanted without prior prostatectomy. Secondarily, we sought to elicit associations of demographical and device-specific factors with postoperative complication and re-operation rates.

Materials and methods

Subjects

Eligible subjects for this study consisted of 132 men who had 139 inflatable penile prostheses placed at our institution between January 1, 1995 and August 15, 2001. Of these patients, 35 men had undergone a radical retropubic prostatectomy (n = 33) or radical cystoprostatectomy (n = 2) for prostate cancer. One patient in this group had persistent autoinflation and 1 had a mechanical malfunction that mandated replacement of their prostheses. Thus, the study group is composed of 37 prostheses that were placed in 35 men. Comparisons were made to a control group consisting of 97 men without a prior history of open prostate surgery who had 102 inflatable penile prostheses placed. Of these 97 patients, 5 required a second prosthesis – 2 for infection, 1 for corporal erosion, and 2 for mechanical malfunction. Among these 97 patients, the etiology of erectile dysfunction was thought to be organic in all cases. The prevalence of co-morbidities among patients with organic erectile dysfunction was – diabetes mellitus in 35%, peyronie's disease in 22%, combined androgen blockade for prostate cancer in 6%, coronary artery disease in 12%, and hypertension in 45%.

Technique

Patients were given vancomycin and gentamicin one hour prior to incision. Minor modifications were made to a technique that has been previously described [8–10]. Briefly, a midline penoscrotal or vertical infrapubic incision was typically made. Two to 3 absorbable sutures were pre-placed along either side of the corpora incision site, the corpora was incised and dilated to 14 Fr., measured, and irrigated with a bacitracin and neomycin containing solution. Cylinders were always placed with rear-tip extenders and the corpora were re-approximated with a horizontal mattress closure using the pre-placed sutures. The reservoir (for 3-piece devices) was placed through the transversalis fascia via the external inguinal ring, and the pump placed in a pouch external to the tunica vaginalis adjacent to the testes. Surgery was performed under regional or general anesthesia, and patients remained in the hospital overnight for intravenous antibiotics. The Foley catheter was removed on the morning following surgery, and patients received a 7-day course of a first generation cephalosporin. Prostheses implanted included the 700 Ultrex, 700 CX(M), Ambicor, and Dynaflex devices from American Medical Systems, Inc., and the Mentor Corporation's Alpha-1 prosthesis with and without a lockout reservoir. Per surgeon preference, devices with lockout reservoirs were generally used in post-prostatectomy patients.

Analysis

Outcomes assessed included postoperative complication rates and device longevity in post-prostatectomy and control groups. The frequency of autoinflation in devices with and without a lockout reservoir was compared as an additional endpoint. Comparisons between continuous data were performed using the two-tailed *t*-test and those between nominal variables were made using the chi-square test (or Fisher's exact method where appropriate). Prosthesis survival analysis was assessed using Kaplan-Meier curves and the log rank (Mantel-Cox) test. Multivariable logistic regression was utilized to determine the association of patient, device-specific, and perioperative factors with the occurrence of a postoperative complication or the need for additional surgery related to the implanted device [11]. All analyses were conducted using Statview 5.0 (SAS Institute, Cary, NC) and all $p < 0.05$ were considered significant.

Results

Pre-treatment and follow-up data stratified by whether or not the patient had undergone a radical prostatectomy is shown in Table 1. Post-prostatectomy patients were older (63 vs. 54 years, $p = 0.0001$) and had a shorter duration of follow-up (28 vs. 37 months, $p = 0.04$) than their counterparts with organic erectile dysfunction.

Implant specific and postoperative outcomes are also listed in Table 1. Post-prostatectomy patients were more likely to have a three-piece device with a lockout reservoir (27% vs. 4%) and less likely to have a two-piece (5% vs. 9%) or a one-piece (3% vs. 13%) device placed than those in the control group ($p = 0.0009$). We noted no differences in overall postoperative complication and re-operation rates between the two groups. Five-year revision-free survival for the penile implants was similar between prostatectomy (80%) and control (90%) groups (Mantel-Cox $p = 0.26$). Overall, 14% of post-prostatectomy patients and 12% of controls required prosthesis revision (p

Table 1. Clinical, operative, and postoperative characteristics as a function of previous radical prostatectomy (± standard deviation)

Variable	Post-prostatectomy group (n = 37)	Control group (n = 102)	Entire sample (n = 139)	*p*-value
Age	63 ± 8	54 ± 12	56 ± 12	0.0001
Virgin prosthesis (%)	30 (81)	70 (69)	100 (72)	0.20
Time elapsed since implant (months)	28 ± 23	37 ± 25	35 ± 25	0.04
Etiology (%)				–
Organic	–	102 (100)		
Post-prostatectomy	37 (100)	–		
Device (%)				0.0009
Alpha 1	–	9 (9)	9 (7)	
Alpha 1 with lockout reservoir	10 (27)	4 (4)	14 (10)	
Ambicor	2 (5)	9 (9)	11 (8)	
700 CX	1 (3)	2 (2)	3 (2)	
Ultrex	23 (62)	65 (63)	88 (63)	
Dynaflex	1 (3)	13 (13)	14 (10)	
3-piece prosthesis (%)	34 (92)	80 (78)	114 (82)	0.08
Postoperative complication (%)	7 (19)	18 (18)	25 (18)	>0.99
Need to revise prosthesis (%)	3 (8.1)	5 (4.9)	8 (5.8)	0.43
Need for replacement prosthesis (%)	3 (8.1)	8 (7.8)	11 (7.9)	>0.99
Overall need for re-operation (%)	5 (14)	12 (12)	17 (12)	0.77

= 0.77) at a mean follow-up of 28 and 37 months, respectfully.

Twenty-five patients developed a postoperative complication (Table 2). Of these, 5 patients had 2 complications thereby comprising a total of 30 complications following penile prosthesis surgery. We noted no difference in the frequency of any single postoperative complication in the post-prostatectomy and control groups (all $p > 0.19$). Specifically, only 1 (3%) post-prostatectomy patient and 5 (5%) patients in the control group had persistent autoinflation after prosthesis implantation ($p > 0.99$). Of these patients, only one (a post-prostatectomy patient) opted for replacement of his prosthesis. This patient's device was removed and replaced with the Alpha-1 with lockout reservoir and has been free of autoinflation since. Among 3-piece devices implanted, only 4 (5%) Ultrex and 2 (22%) Alpha-1 autoinflated compared to no Alpha-1 device with a lockout reservoir ($p = 0.10$). Among only post-prostatectomy patients, only 1 patient with an Ultrex implant developed autoinflation compared to no patients with lockout reservoirs ($p > 0.99$).

Multivariate logistic regression analysis was performed to determine associations of pre-treatment, device-specific, and perioperative factors with the development of a postoperative complication or the need for any subsequent operation because of penile prosthesis implantation. Patients with prior prostheses were 3 times as likely to develop a postoperative complication as those who had never had a penile prosthesis (31% vs. 13%, $p = 0.02$). Other factors – including age, surgeon experience, type of device implanted, etiology of erectile dysfunction, and comorbidities – were not associated with postoperative morbidity (each partial correlation R = 0). Similarly, the only factor associated with the need for any additional procedure after prosthesis implantation was having a prior implant (odds ratio 3.4, $p = 0.02$).

Comment

Autoinflation remains a troublesome complication of inflatable penile prosthesis surgery with an incidence of 2 to 4% in 3 piece implants [7, 12]. Correct placement of the reservoir into an adequately dissected prevesical space may minimize the risk of its occurrence [13]. However, autoinflation appears to be more problematic in patients who have had previous extraperitoneal surgery – the standard location for reservoir placement. Cuellar and Sklar [7] noted

Table 2. Postoperative complications in inflatable penile prostheses

Complication	Post-prostatectomy group (n = 37)	Control group (n = 102)	Entire sample (n = 139)	*p*-value
Erosion (%)	1 (3)	3 (3)	4 (3)	>0.99
Infection (%)	1 (3)	4 (4)	5 (4)	>0.99
High-riding pump (%)	3 (8)	3 (3)	6 (4)	0.19
Mechanical malfunction (%)	1 (3)	5 (5)	6 (4)	>0.99
Persistent pain (%)	1 (3)	1 (1)	2 (1)	0.46
Hematoma (%)	1 (3)	–	1 (0.7)	0.27
Autoinflation (%)	1 (3)	5 (5)	6 (4)	>0.99

an overall autoinflation rate of 9% in renal transplant patients compared to only 4% in non-transplant patients. Even more striking was the 40% incidence of autoinflation in transplant recipients implanted with 3 piece devices compared to 4% in the non-transplant population [7]. These findings are suggestive that patients with prior extraperitoneal surgery are predisposed to autoinflation after 3 piece prosthesis placement.

To address the problem of autoinflation, investigators have proposed overfilling the reservoir to enlarge the prevesical space [14] or reducing reservoir volume [15]. To a similar end, the Mentor Corporation has developed an optional reservoir that contains an anti-refluxing or lockout valve that may prevent undesired egress of fluid from the reservoir to the cylinders.

In this study, none of the 14 patients implanted with a lockout valve reservoir have developed autoinflation – including 10 placed in post-prostatectomy patients and 4 placed in patients with organic erectile dysfunction. In contradistinction to the finding of higher autoinflation rates in patients with previous extraperitoneal surgery [7], we found that autoinflation occurred in only 1 (3%) post-prostatectomy patient compared to 5 (5%) patients with no prior extraperitoneal surgery ($p > 0.99$). Despite the theoretical benefits that the lockout reservoir may confer, we noted no improvement in the autoinflation rates in these devices when compared to others with standard reservoirs (0% vs. 4%, $p > 0.99$). However, this may be reflective of the low incidence of autoinflation in our study (overall 4%) and our limited experience with the device given its relative novelty. Nonetheless, the absence of autoinflation in patients with a lockout reservoir is promising, and a statistically significant benefit may be realized as more of these devices are implanted.

A secondary endpoint of this study was to evaluate outcomes of inflatable prostheses after radical prostatectomy when compared to those implanted for other reasons. One prior study has addressed these issues specifically in prostate cancer patients who received external beam radiation therapy. The authors reported a 6% revision rate and concluded that placement of penile prostheses is safe in post-radiotherapy patients with minimal intraoperative and postoperative morbidity [16]. In our contemporary series, we demonstrated similar findings of low morbidity and need for re-operation in post-prostatectomy patients when compared to those with implants for organic erectile dysfunction. Revision-free survival (Mantel-Cox $p = 0.29$) and postoperative complication rates (Table 2) of the post-prostatectomy and control groups were similar. The validity of these findings is augmented by the consistency of the complication rate of our control group with that of a large multi-institutional study [12].

The final objective of this study was to elicit demographic and device-specific characteristics associated with the development of a postoperative complication or need for surgical revision. Our study population, which is enriched with post-prostatectomy patients (27%), provided an excellent setting to assess the association of radical prostatectomy with these outcomes. However, we noted that only patients with prior penile implants were more likely to develop a postoperative complication following prosthesis placement (31% vs. 13%, $p = 0.02$). Multivariate logistic regression analysis confirmed that previous prosthesis placement was independently associated with higher postoperative complication and revision rates.

The principle limitations of this study were its lack of randomization and the small population implanted with a lockout reservoir (albeit a function of the novelty of the device within the marketplace). The problem in assessing the utility of this device is further augmented by the infrequent occurrence of autoinflation thereby making a single institutional trial inefficient. These limitations notwithstanding, this study serves as a basis for a large, multi-institutional trial to effectively establish the value of these reservoirs and other novel modifications to penile prostheses prior to routine use.

Conclusions

Patients undergoing prosthesis replacement surgery are at 3-fold increase risk for postoperative complications and need for surgical revision. Conversely, post-prostatectomy patients do not appear to be at higher risk for autoinflation and other complications of penile prosthesis surgery when compared to controls. Consequently, the lockout valve reservoir should be implanted in the context of clinical trials attempting to establish their utility in a rigorous fashion and justify their expense. This notwithstanding, the initial outcomes with the lockout reservoir are promising with a 0% autoinflation rate. However, larger trials are necessary to adequately assess the implications of this and other prosthetic modifications.

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