Does indigo carmine prevent early artificial urinary sphincter cuff erosion?

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PETROU SP, THIEL DD, ELLIOT DS, BRODERICK GA, WEHLE MJ, YOUNG PR. Does indigo carmine prevent early artificial urinary sphincter cuff erosion? The Canadian Journal of Urology. 2006;13(4):3195-3198.

Introduction: *Urethral erosion following artificial urinary sphincter (AUS) placement is hypothesized to be secondary to unrecognized intra-operative urethral injury. Intra-urethral indigo carmine solution (ICS), a blue dye, following urethral mobilization should identify intra-operative urethrotomy and prevent early post-operative cuff erosion.*

Methods: *Retrospective review was completed of all men undergoing AUS (AMS 800 device) insertion between January 2000 and January 2005 for post prostatectomy stress incontinence at one institution. Operative reports were examined for use of intra-operative injection of ICS as well as documentation of urethral injury. Post-operative course was reviewed for evidence of early cuff erosion. All patients were followed a minimum of 6 months post-operatively.*

Results: *Seventy-eight men underwent AUS placement during the investigative period. Forty-one men received intra-operative ICS injection following urethral mobilization and 37 men did not. ICS identified one intra-operative urethral injury. No urethral injuries were noted in the non-injection group. The ICS group suffered 3 (7.3%) early urethral erosions; the control group had one early urethral erosion (2.7%).*

Conclusion: *Intra-operative ICS use is easy, safe, and able to identify urethral injury. However, its use did not preclude the incidence of early cuff erosion. This may postulate the existence of early urethral cuff erosion as a separate entity not dependent on intra-operative urethrotomy.*

Key Words: urinary incontinence, prosthesis, artificial, urinary sphincter, prostatectomy

Introduction

Since its introduction in 1983, the AMS 800 artificial urinary sphincter (AUS) has been the gold standard for managing post-prostatectomy incontinence in men.[1,2] Meta-analysis reveals 73% continence rates with a 10-year device survival of 66%.[3]

Accepted for publication April 2006

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Urethral erosion necessitating device removal is a devastating complication occurring in 5%-14% of patients with a calculated global rate of 12%.[3,4] Early cuff erosion occurring the first weeks to months after implantation is thought to be secondary to unrecognized intra-operative urethral injury.[5,6]

Indigo carmine solution (sodium indigotindisulfonate), a blue dye, has been used by surgeons for over 8 decades to evaluate urothelial integrity intra-operatively.[7] Its popularity has expanded with increased use in anti-incontinence surgery to detect intra-operative ureteral injury.[8] Intra-operative urethral ICS injection should identify iatrogenic urethral violation and thereby prevent

consequent early urethral erosion.[9] We report on the efficacy of ICS injection to identify intra-operative urethral injury and thus eliminate early post-operative urethral erosion.

Methods

With institutional review board approval, patient operative reports and medical records were reviewed. Seventy-eight men (mean age 73.4 years) between the years 2000-2005 were identified who underwent placement of an AUS with a bulbourethral cuff for post-prostatectomy incontinence at one institution. Patient operative notes were retrospectively reviewed for use of intra-operative ICS, evidence of intra-operative peri-urethral blue extravasation, and urethral injury.

Early cuff erosion was defined as that occurring within 6 months of device implantation. All patients were followed for a minimum of 6 months postoperatively with urinalysis and physical exams. All patients had a 6 week interval between AUS implantation and activation. All patients were discharged home on first generation cephalosporin or quinolone antibiotics for 2 weeks following device implantation.

The post-operative course was reviewed specifically for evidence of early urethral cuff erosion. Patients underwent cystourethroscopy if they had signs of infection or erosion including new onset perineal pain, erythema or warmth, as well as new onset gross hematuria or incontinence following device activation. Eroded cuffs were treated with complete AUS removal.

Operative technique

Techniques of AUS implantation to the bulbar urethra have been previously described.[10] We place a 16 French urethral catheter prior to circumferential dissection of the bulbar urethra. After circumferential isolation of the proximal bulbar urethra, the foley catheter is removed. White unfurled surgical sponges are placed circumferentially around the bulbar urethra. A 14 French foley catheter or Toomie syringe is then placed in the fossa navicularis and 60 mL of Indigo Carmine Solution (200 cc normal saline: 1 ampule indigo carmine) is injected into the urethra, Figure 1. Visual inspection is performed looking for blue staining of the sponges or leakage from the urethra with injection. If no extravasation or evidence of urethral injury is noticed, placement of the AUS urethral cuff proceeds in the standard fashion.

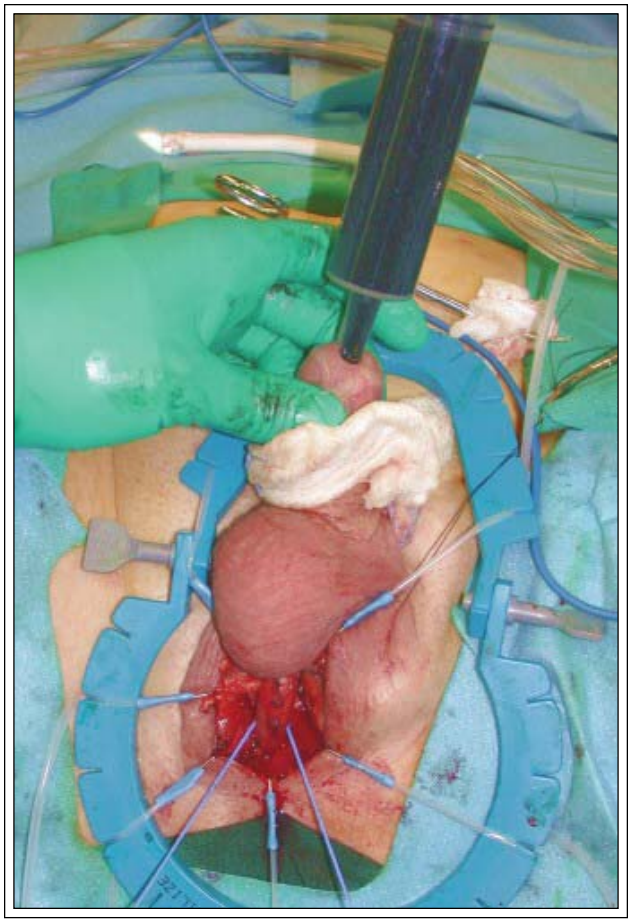

Figure 1. Injection of indigo carmine solution intra-operatively. The bulbous urethra has been mobilized using standard technique (see text). The indigo carmine solution is then injected per urethra and observation for potential blue extravasation is completed.

Results

Seventy-eight men were identified that had AUS implantation between January 2000 and January 2005 with a bulbourethral cuff for post-prostatectomy incontinence. All patients had a single cuff placed. Table 1 lists patient characteristics, cuff sizes, reservoir pressures and radiation history of both groups. Forty-one men (mean age 73.3 years) underwent intra-operative ICS injection following urethral mobilization. Thirty-seven men (mean age 76.6 years) did not receive post-dissection ICS injection.

ICS identified one intra-operative urethral injury in the injection group (n = 41) and that case was terminated. There were no complications or side effects noted from ICS injection.

Four out of 78 patients (5.1%) had cuff erosion

TABLE 1. **Characteristics of ICS group and control group**

	ICS group	Control group
Number of patients	41	37
Mean age	73.2	76.6
Previous radiation	13	7
Cuff sizes		
4.0 cm	16	10
4.5 cm	23	26
5.0 cm	2	1
Reservoir pressure		
61-70 cm H_2O	33	34
51-60 cm H_2O	8	3

within 6 months of AUS implantation. Table 2 lists characteristics of patients with cuff erosion. The ICS group suffered three early urethral erosions. One of three patients had a positive post-operative urine culture at the time of explantation. One patient had previous external beam radiotherapy following a radical prostatectomy.

The group that did not receive intra-operative ICS injection (n = 37) had one early urethral erosion. This patient had prior radiotherapy following prostatectomy and a negative urine culture at the time of device erosion. There were no detected intra-operative urethral injuries in this group.

No other patients have eroded or had clinical signs of erosion within the 6 month follow-up period.

Discussion

The artificial urinary sphincter (AUS) has been established as the gold standard of therapy for post-prostatectomy urinary incontinence due to intrinsic sphincter deficiency.[1,2] AUS cuff erosion is the most common cause of non-mechanical device failure and its overall incidence is noted to be around 6.5%.[1] AUS cuff erosion is a serious complication requiring cuff removal that often leads to a return of incontinence and patient dissatisfaction.[11]

Most urethral erosions after an artificial urinary sphincter placement have been noted to occur within the first 4 to s6 months.[12,13] These early erosions are hypothesized to be secondary to unrecognized iatrogenic urethral injury.[11,14,15] The use of a bladder neck cuff for post-prostatectomy incontinence is exceedingly rare with placement of the AUS cuff almost always being around the bulbous urethra.[9] During mobilization of the bulbous urethra, the most difficult area of dissection with the greatest potential for intraoperative injury is at the 12 o'clock position.[12] Options noted to diminish potential injury at this site have included use of a cutter clamp with synchronous cystourethroscopy as well as post dissection urethral injection of a saline methylene blue solution.[14]

Indigo carmine solution (sodium indigotindisulfonate), a blue dye, has been used by surgeons for over 8 decades to evaluate urothelial integrity intra-operatively.[7] The use of intraoperative intraurethral injection of indigo carmine solution is an extremely simple step, but one of great value in detecting intraoperative urethral injury. Injection detected one intra-operative injury at the 12 o'clock position of the bulbous urethra that was not otherwise noticed. The injection proved to be safe with no reactions noted at the time of intra-operative administration. No patients on their postoperative visit had any urinary tract infections noted.

Intra-operative blue dye extravasation following urethral dissection should logically identify an iatrogenic urethrotomy. Three patients (7.3%) in the ICS injection group had evidence of early cuff erosion with only one of the patients having noted intraoperative blue extravasation raising the possibility that intraoperative urethrotomy is not the sole cause of early AUS cuff erosion.

Possible etiologies of early cuff erosion other than intraoperative urethrotomy include infection, urethral devascularization, and traumatic post-operative urethral catheterization.[13,16] Urethral injury secondary to intra-operative cautery has been noted as a cause of metachronous AUS cuff erosion.[12] It is felt that early erosions are usually associated with infection though it is unclear whether the erosion occurred first with a secondary infection or an infection precipitated the

TABLE 2. **Characteristics of eroded patients**

	Age	ICS injection	Radiation	Cuff	Reservoir	Interval to erosion	Urine culture
1	78	No leak	Yes	4.5	51-60	58 days	Negative
2	83	No leak	No	4.5	61-70	10 days	Negative
3	72	No leak	No	4.0	61-70	140 days	Negative
4	75	Not done	Yes	4.5	61-70	8 days	*C. Freundii*

cuff erosion.[16] It is noteworthy that only one of the four erosions in our series had a positive urine culture.

Primary deactivation with secondary activation has diminished the rate of early urethral erosion associated with urethral mobilization and devasularization.[13] All of the patients had an interval to activation of at least 6 weeks. Martins and Boyd declared the risk for infection-erosion was significantly increased in the presence of two factors: radiation exposure and improper post-operative urethral manipulation.[16] Two of the four erosions in the series had radiation exposure prior to device implantation. One of the two patients had a positive urine culture with *Citrobacter Freundii*.

ICS solution helped identify one intra-operative urethrotomy that was not noticed otherwise. The defect was repaired and the procedure terminated. We do not routinely recommend synchronous placement of a urethral cuff following urethrotomy.

Our working hypothesis was that early AUS cuff erosion was secondary to unrecognized intra-operative urethrotomy and that intra-operative indigo carmine solution injection would identify such injuries thereby preventing early cuff erosion entirely. This was not the case. Potential explanations include: ICS injection does not have 100% sensitivity in detecting small intra-operative urethrotomies; or early erosion itself is a separate entity not related to urethrotomy but rather a combination of all the factors discussed above.

Conclusion

Intraoperative indigo carmine solution at the time of artificial urinary sphincter placement is a simple and a non-time consuming step. It has inherent value in aiding the detection of intraoperative urethral injury as well as establishing urethral integrity at the time of cuff placement. However, absence of indigo carmine extravasation following urethral mobilization intra-operatively cannot guarantee freedom from early urethral cuff erosion. □

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