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Catheter-less robotic radical prostatectomy using a custom-made synchronous anastomotic splint and vesical urinary diversion device: report of the initial series and perioperative outcomes

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Level of Evidence 3b

OBJECTIVE

To study the feasibility of avoiding a urethral catheter after robotic radical prostatectomy by using suprapubic diversion with a urethral splint, as urethral catheterization is often a source of major discomfort and pain to the patient, and can cause more concern to the patient than the procedure; we present the outcomes of a pilot study.

PATIENTS AND METHODS

This pilot study involved 30 patients; in group 1 (the study group of 10 patients) we used a custom-made suprapubic catheter which provided a small anastomotic splint, multiple holes for drainage and the ability to retract the splint to give a voiding trial before removing the drainage device. Group 2 was a control group of 20 patients who had standard urethral catheterization with an 18 F Silastic Foley catheter. Demographic, intraoperative and outcome data were measured and analysed. Urethral symptoms were recorded using a specially developed questionnaire.

RESULTS

The two groups were comparable in terms of age, serum prostate specific antigen level, body mass index, Gleason scores, tumour stage, operative duration, amount of bleeding, console times, anastomotic leakage and postoperative retention rates. The study group had significantly less penile shaft or tip pain and discomfort during walking or sleeping. No patient in either group had haematuria or clot retention requiring irrigation.

CONCLUSION

Urethral catheter-less robotic radical prostatectomy is feasible. The advantages are decreased penile shaft and tip pain, and decreased patient discomfort and an earlier return of continence.

KEYWORDS

catheter, suprapubic, urethral, robotic prostatectomy

INTRODUCTION

Robotic radical prostatectomy (RP) has emerged as a common surgical procedure in the management of clinically localized prostate cancer. Patients choosing this procedure are usually driven by its cosmetic benefits, earlier continence, shorter recovery time and minimal blood loss [1–3]. Despite the smaller incisions, early ambulation and shorter hospital stay, a few patients, especially younger ones, continue to complain about the urethral Foley catheter. They experience urethral discomfort, penile tip pain, and meatal encrustation and irritation due to the indwelling catheter. Recovery is essentially uneventful and smooth, leading patients to focus on the catheter and complain that they wish that there was no need for a urethral catheter. With this background we explored the idea of avoiding a urethral catheter without compromising the time-tested principle of splinting the anastomosis in the initial few days after robotic RP. This quest was guided both by patient demand and the potential for complications which can occur after urethral catheterization, e.g. urethral stricture, meatal stenosis, urethritis and ascending urethral bacterial colonization.

The catheter after RP splints the anastomosis and prevents the formation of cross synechia, and drains the bladder. We sought alternatives for achieving these two goals while obviating the need for a tube exiting through the penis. One such alternative was a urinary drainage tube using the suprapubic route. However, this would not splint the anastomosis, thus increasing the risk of bladder neck contracture. Therefore we sought a custom-made tube which would not only drain the bladder but also splint the anastomosis. After experimentation with a few initial prototypes, we settled on a custom-made catheter which provided a small anastomotic splint, two balloons to prevent either upward or downward migration, multiple holes for drainage and the ability to retract the splint to give a voiding trial before removing the drainage device.

The aims of our study were: (i) to develop a technique of urethral catheter-less robotic RP

FIG. 1. The custom-designed suprapubic device with a retention mechanism, drainage holes for diverting urine from bladder and a distal splinting tip to keep the anastomosis patent.

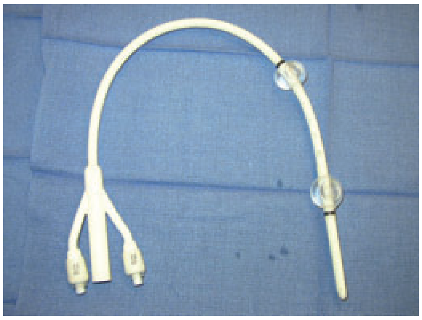
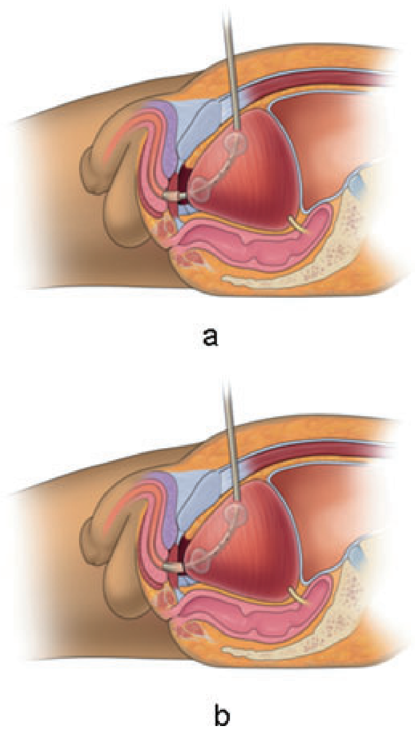


FIG. 2. The device inserted suprapubically with the proximal balloon snug to the anterior bladder wall, the distal splint in the urethra and drainage holes in between, before and after the anastomosis.



using this modification; (ii) to compare the immediate outcome of the catheter-less approach with our standard technique of robotic RP, in terms of discomfort, pain, penile tip irritation, need for urethral catheterization and clot retention; (iii) to evaluate early urinary continence between groups; and (iv) measure the incidence at 6 months of bladder neck contracture. We present the findings of a pilot study involving 30 patients (10 study patients and 20 controls) who completed 6 months of follow-up.

PATIENTS AND METHODS

This was a prospective, non-randomized pilot study to evaluate the feasibility of the urethral catheter-less technique in patients undergoing robotic RP. We now have institutional review board approval for randomized study. Between February and April 2007, the feasibility of the approach was tested in 10 patients who specifically requested this modification and provided signed informed consent. These data were compared with those from 20 contemporary patients who were not treated with this modification, but were matched for age, tumour stage, and prostate volume and who had conventional urethral catheterization technique.

Eligible patients were those with early prostate cancer who were scheduled to undergo robotic RP; those with large prostates (>75 mL), median lobe, a high body mass index (BMI) (>30 kg/m^2), high-risk cancers (Gleason 8–10, clinical stage ≥T3) and those with relatively abnormal coagulation parameters were excluded from the pilot study. Data were collected prospectively before, during and after RP; the duration of the catheterization was 7 days in all 30 patients.

The proposed device for the study was intended to serve two purposes, i.e. to splint the anastomosis and to divert urine. As it was our intention to avoid the urethral route, we tried several custom-made prototypes in human cadaveric experiments, which entered the bladder anteriorly and had a distal elongated splint to bridge the anastomosis. The final prototype had a suprapubic drainage tube with a retention mechanism, drainage holes for diverting urine from the bladder, and a distal splinting tip to keep the anastomosis patent. This tube was easy to deploy during surgery and to remove after 7 days. Since then we have found a patented (for RP) custom-designed device which could be used for this purpose (Fig. 1) having a suprapubic drainage tube, two retention balloons, drainage holes for diverting urine from the bladder and a distal splinting tip to keep the anastomosis open beyond the second balloon [4]. The first balloon is positioned just inside the anterior bladder wall (to avoid dislodgement) and the second one a several centimetres distal, so as to sit snugly on the bladder side of vesico-urethral junction (Fig. 2). The distal splint is long enough to avoid formation of synechia across the anastomosis. The urinary drainage holes are between the balloons. The tube is stiff and with multiple holes to avoid blockage by blood clots. This patented device is currently being evaluated through an Institutional Review Board for feasibility, safety and patient satisfaction outcomes.

Demographic, laboratory, oncological, intraoperative and outcome data were measured and entered in an Institutional Review Board-approved database. At the time of catheter removal 7 days after surgery, urethral symptoms were recorded using a specifically developed questionnaire, comprising 12 questions pertaining to: (a) pain at the suprapubic site, in the penile shaft and penile tip, testicular pain and use of pain medications; (b) discomfort while walking and sleeping (c) fever; (d) erosion/encrustation at tip of penis; (e) bladder spasms.

Additional third-party telephone interviews were conducted at 10, 14, 21 and 30 days after RP to determine the early continence status. Patients were considered continent if they were either using no pad or one security liner during stressful activities. The IPSS was obtained before and at 1, 3 and 6 months after RP.

All patients were treated with the athermal trizonal nerve-sparing technique of robotic RP [5], with total reconstruction of the continence mechanism [3]. Our continence preservation technique involves seven key elements: (i) Preservation of the puboprostatic ligaments and arcus tendineus; (ii) creation of a muscular flap behind the bladder neck (which is later sutured to the distal end of Denonvilliers' fascia behind the sphincter); (iii) control of the dorsal venous complex using a puboprostatic ligament-sparing suture which also provides anterior suspension; (iv) preparation of a thick and long urethral stump during apical dissection; (v) the 'Pagano principle', reinforcing the flap behind the bladder neck; (vi) the 'Rocco principle', suturing of the retrotrigonal flap to the distal end of Denonvilliers' fascia, close to the urethral stump, to prevent caudal retraction of the central tendon, thus providing posterior support; and (vii) re-attachment of the arcus tendineus and puboprostatic plate to the bladder neck after anastomosis is completed.

The urethrovesical anastomosis was made in several layers using two 3-0 poliglecaprone 25 sutures on a RB needle [6]. Once the two posterior layers of anastomosis were completed, (Rocco suture followed by a posterior bladder suture) we introduced the device through a suprapubic puncture made under direct vision and entered the bladder 5–8 cm proximal to the bladder neck and advanced the distal attached tip of the device through the anastomosis. It took 2–3 min to complete this phase of the surgery and the anterior anastomosis was completed in two layers (bladder, followed by reconstruction of the puboprostatic-arcus tendineus complex) [2]. At 7 days after surgery the suprapubic device was removed, following a cystogram (Fig. 3). The degree of pain, discomfort and bother were assessed by the self-administered questionnaire.

The chi-square test and Student's *t*-test were used to compare the group characteristics and the incidence of complications between the groups, with critical values and statistical significance at $P < 0.05$.

RESULTS

This study was completed in early 2007 and the series is now sufficiently mature to provide data on the early outcomes and long-term complications, e.g. bladder neck contractures. Group 1 was the study group of 10 patients who had a robotic RP using a catheter-less approach; group 2 comprised 20 patients matched for age, tumour stage and prostate volume who had the conventional urethral catheterization technique in the same period (February to April 2007). The two groups were also comparable in terms of console times, amount of bleeding, or volume of blood transfusion (none), anastomotic leakage (none) and retention rates after RP (none) ($P > 0.05$); these values are shown in Table 1.

As shown in Table 1, most patients achieved continence in 6–12 weeks; group 1 had a greater percentage who became continent almost immediately, but this was not statistically significant (five of 10 vs four of 20, $P = 0.09$).

Table 1 also summarizes data on pain, discomfort and early ambulation; no patient in group 1 had pain in the penile shaft or tip, vs 18 in group 2 ($P < 0.05$). Two patients in group 1 complained of minimal pain at the suprapubic puncture site; two in group 1 also had discomfort walking and sleeping, vs 14 in group 2 ($P < 0.05$) and three in group 1 had bladder spasms, vs eight in group 2. No patient in either group had haematuria or clot retention requiring irrigation, or symptoms suggestive of a bladder neck contracture at the 6-month follow-up. One patient underwent bowel surgery unrelated to the suprapubic procedure.

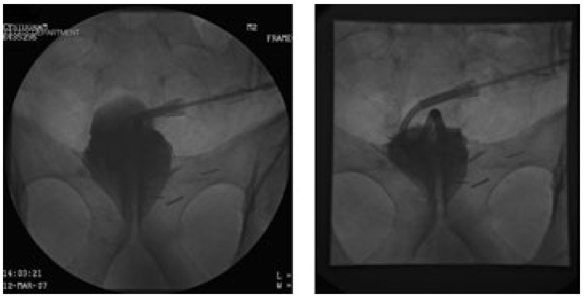


FIG. 3.
A cystogram taken 7 days after RP in a study patient, showing no evidence of leak.

DISCUSSION

RP is the most common oncological procedure performed by urologists, and leaving an indwelling urethral catheter is considered mandatory after open or laparoscopic RP, to allow anastomotic healing. The duration of catheterization is 5–7 days in most minimally invasive series [1,7–10]. Urinary catheterization is a source of infection, discomfort, anxiety and embarrassment to the patient undergoing RP. Definitive morbidity, e.g. discomfort, bacteriuria and urethral stricture, is directly associated with the duration of catheterization [11].

There have been no published clinical trials with suprapubic catheterization for RP. In gynaecological and vascular procedures, suprapubic catheters are better than urethral catheters [12–14]. In a review of five randomized control trials comparing suprapubic and urethral catheterization in colorectal surgery, patients with a suprapubic catheter had less pain and discomfort than the urethral group, and a suprapubic catheter was preferred by those patients who had experience with both. In addition, the ability to attempt normal voiding is enhanced [15]. Evidence from the Cochrane review suggested that suprapubic catheters were better than indwelling urethral catheters in term of bacteriuria, need for re-catheterization and discomfort [16]. The risk of developing bacteriuria from a catheter increases by 3–6% per day with the urethral catheter; this would mean that by 7–10 days the risk would increase to 50%.

Suprapubic catheterization is a standard procedure used routinely in urological practice for other indications. The anticipated adverse events include a blocked catheter, slippage or displacement of the catheter, and visceral injury. Displacement is a rare event and can be remedied simply by placing a urethral catheter, with no consequences to the final result. The chances of visceral injury are minimal when the suprapubic puncture is made under direct vision. In the present pilot study, the catheter-less group had minimal pain or discomfort and had no problems in walking or sleeping. This might be one of the most important benefits of our novel approach. The patients had an earlier return to normal function and to normal activity.

Other problems associated with indwelling urethral catheters include encrustation of the catheter, bladder spasms resulting in urinary leakage, haematuria and urethritis. A suprapubic tube is more 'patient-friendly', with no risk of urethral damage, bladder spasms occur less often, and suprapubic tubes are more sanitary. They cause fewer UTIs than standard urethral catheters. Thus the benefits of the suprapubic route are reduced infection, control and monitoring of return of normal voiding, reduced need to re-catheterize, avoidance of the risk of urethral stricture, and improved patient satisfaction.

This was a pilot study of the feasibility of the technique and hence only 10 patients were enrolled. A randomized study with more patients is required to confirm these findings.

In conclusion, urethral catheter-less robotic RP is feasible, with the advantages of

TABLE 1 The characteristics before, during and after RP in the two groups

Variable	Group 1	Group 2	P
Mean (range):			
Age, years	60.8 (52.8–67.3)	60.0 (55.8–66.3)	NS
BMI, kg/m^2	26.1 (22.9–33.2)	27.3 (23.1–34.2)	NS
Serum PSA, ng/mL	4.2 (2.0–6.8)	5.5 (3.2–12.1)	NS
IPSS	10 (2–26)	10.66 (0–24)	NS
Prostate volume, mL	35 (20–50)	32 (20–60)	NS
Biopsy Gleason score, *n*			NS
2–6	8	14	
7 (3 + 4)	2	6	
7 (4 + 3)	–	–	
8–10	–	–	
Clinical stage			NS
T1b	–	–	
T1c	9	17	
T2a	1	3	
T2b	–	–	
T3	–	–	
During RP			
Estimated blood loss, mL	170	155	NS
Console time, min	80 (52–108)	78 (46–110)	NS
Extra time for procedure, min	3 (2–5)		NS
Blood transfusion	Nil	Nil	
After RP			NS
Pathological stage			NS
T2a	1	2	
T2b	1	–	
T2c	7	8	
T3a	1	–	
Duration of catheterization or device removal, days	7	7	NS
Clinical urinary leak	Nil	–	NS
Post operative retention	Nil	Nil	NS
Bladder neck contracture	Nil	Nil	NS
Continence (no pads), *n* or *n* (%), within:			
1 week	5	4 (20)	NS
6 weeks	10	16 (80)	NS
Continence within 12 weeks	10	18 (98)	NS
Pain and discomfort			
Pain in penile shaft or suprapubic puncture site	2	18	<0.05
Erosion at penile tip	0	5	NS
Discomfort walking/sleeping	2	14	<0.05
Bladder spasms	3	8	NS

NS, not significant.

decreased penile shaft and tip pain, and decreased patient discomfort and an earlier return of continence. In this pilot study there was no late-term complication such as bladder neck contracture.

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CONFLICT OF INTEREST

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Abbreviations: **RP**, radical prostatectomy; **BMI**, body mass index.