Early Removal of Urethral Catheter with Suprapubic Tube Drainage Versus Urethral Catheter Drainage Alone after Robot-Assisted Laparoscopic Radical Prostatectomy

Sandip M. Prasad,* Michael C. Large, Amit R. Patel, Olufenwa Famakinwa, R. Matthew Galocy, Theodore Karrison, Arieh L. Shalhav and Gregory P. Zagaja

From the Department of Urology, Medical University of South Carolina (SMP), Charleston, South Carolina, and Section of Urology (MCL, OF, RMG, ALS, GPZ) and Department of Health Studies (TK), University of Chicago Hospitals, Chicago and Department of Urology, DuPage Medical Group (ARP), Downers Grove, Illinois

Purpose: Retrospective single institution data suggest that postoperative pain after robot-assisted laparoscopic radical prostatectomy is decreased by early removal of the urethral catheter with suprapubic tube drainage. In a randomized patient population we determined whether suprapubic tube drainage with early urethral catheter removal would improve postoperative pain compared with urethral catheter drainage alone.

Materials and Methods: Men with a body mass index of less than 40 kg/m^2 who had newly diagnosed prostate cancer and elected robot-assisted laparoscopic radical prostatectomy were included in analysis. Block randomization by surgeon was used and randomization assignment was done after completing the urethrovesical anastomosis. In patients assigned to suprapubic tube drainage the urethral catheter was removed on postoperative day 1 and all catheters were removed on postoperative day 7. Visual analog pain scale and satisfaction questionnaires were administered on postoperative days 0, 1 and 7.

Results: A total of 29 patients were randomized to the urethral catheter vs 29 to the suprapubic tube plus early urethral catheter removal at the time of interim futility analysis. Mean visual analog pain scale scores did not differ between the groups at any time point and a similar percent of patients cited the catheter as the greatest bother with nonsignificant differences in treatment related satisfaction. Complications during postoperative week 1 did not vary between the groups. Based on interim results the trial was terminated due to lack of effect.

Conclusions: Patients randomized to suprapubic tube vs urethral catheter drainage for the week after prostatectomy had similar pain, catheter related bother and treatment related satisfaction in the perioperative period. We no longer routinely offer suprapubic tube drainage with early urethral catheter removal at our institution.

Key Words: urethra, prostatectomy, pain, urinary catheterization, cystostomy

Abbreviations and Acronyms

BNC = bladder neck contracture
BPI = Brief Pain Inventory
I-PSS = International Prostate Symptom Score
JP = Jackson-Pratt
POD = postoperative day
PSA = prostate specific antigen
RALP = robot-assisted laparoscopic RP
RCT = randomized clinical trial
RP = radical prostatectomy
SHIM = Sexual Health Inventory for Men
SPT = suprapubic tube
UC = urethral catheter
VAS = visual analog scale

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* Correspondence: Department of Urology, Medical University of South Carolina, 96 Jonathan Lucas St., CSB 644, Charleston, South Carolina 29464 (telephone: 843-792-1666; FAX: 843-792-8523; e-mail: prasads@musc.edu).

In 2014 in the United States alone an estimated 233,000 men will be diagnosed with prostate cancer and 29,480 will die of this disease.[1] As a result of increasing rates of clinically localized disease and adoption of

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minimally invasive surgical techniques, the number of RPs has rapidly increased with almost 80,000 surgeries performed annually in the United States and a 25-fold increase in other countries since the adoption of PSA screening.[2,3] Minimally invasive techniques in RP yield improved cosmesis, shorter inpatient stay, faster return to work and decreased short-term complications.[4–6]

However, for many men who undergo RP the UC required to drain the bladder remains a significant concern preoperatively and a major source of discomfort postoperatively.[7,8] Proponents of RALP argued that direct visual reconstruction of the urethrovesical anastomosis enabled by the robot may allow for shorter time needed for the UC to splint the anastomosis to promote healing and avoid BNC. In addition, prolonged pressure from the UC may compromise the delicate blood flow of the urethrovesical anastomosis in the early healing process.[9]

Given the purported improvement and precision of the urethrovesical anastomosis during RALP we investigated whether early removal of the UC with subsequent suprapubic drainage alone was feasible and safe, and decreased postoperative discomfort. To our knowledge no level I evidence demonstrates the short-term safety and outcomes of early UC removal after RP. We hypothesized that early removal of a UC with suprapubic drainage after RALP would improve postoperative pain compared with traditional UC drainage alone.

MATERIALS AND METHODS

The study population was identified based on referral for RP to 1 of 2 high volume surgeons (ALS and GPZ), who perform approximately 500 RALPs annually. Beginning in August 2011 men with biopsy proven prostate cancer with a body mass index of less than 40 kg/m^2 were offered inclusion into the study. Before this date approximately 200 RALPs with suprapubic drainage and early catheter removal on POD 1 had been performed in the prior 12 months based on patient preference in nonrandomized fashion. Institutional review board approval and study oversight were obtained through the University of Chicago Comprehensive Cancer Center.

Randomization

We performed randomization stratified by surgeon block in a 1:1 ratio of patients assigned to the control group (standard UC drainage) or the intervention group (combined UC and SPT).[10] Treatment assignment was revealed intraoperatively after completion of the urethrovesical anastomosis to minimize any difference in intraoperative factors before randomization.

Surgical Technique

After completing the urethrovesical anastomosis patients randomized to SPT placement had 240 cc normal saline instilled in the bladder to ensure watertight reconstruction along with distension for SPT placement. If a leak was detected, only a UC was left in place and it was noted that the patient did not receive the intervention. At the anterior bladder dome a zero Maxon™ pursestring suture was placed, leaving the 2 tails superior for anterior traction. Two skin incisions were made. The first incision was placed 3 cm above the symphysis pubis for the SPT and the second was located 1 cm above the first incision for suture fixation. A Carter-Thomason device was used to pass the suture outside the body. After the suture was placed on traction a 14Fr Rutner Percutaneous Suprapubic Balloon Catheter (No. G17320, Cook® Medical) was passed through the inferior incision and into the bladder under direct vision. After irrigation fluid return the SPT and UC balloons were filled with 5 and 12 cc sterile water, respectively. The zero Maxon was secured around a button, cinched to approximate the bladder to the anterior abdominal wall and secured to the SPT. A 14Fr JP drain was placed and pneumoperitoneum was released. The SPT was capped overnight and the UC was left to gravity drainage. Our technique is similar to methods in prior studies.[11]

Postoperative Management

All patients were placed on the RALP postoperative pathway, which has been applied to more than 2,500 patients at our institution. Briefly, all patients received a standing regimen of acetaminophen alternating with oral ibuprofen every 3 hours. Intravenous ketorolac was ordered for breakthrough pain while in the hospital. At discharge home patients continued alternating acetaminophen with ibuprofen and tapered until catheter removal. Patients were not sent home with prescriptions for narcotics or anticholinergic medications. Controls had a 20Fr UC until removal on POD 7. The experimental group had a standard 20Fr UC for up to 24 hours postoperatively and a 14Fr SPT until POD 7.

Study End Points

The primary study end point was postoperative pain. We collected information on the breakthrough requirement of inpatient or outpatient narcotics as well as pain assessment using validated pain questionnaires, including VAS, FPS-R (Faces Pain Score-Revised) and BPI. Study participants completed these at baseline (preoperative visit), the evening of POD 0, the morning of POD 1 before catheter and JP drain removal, before discharge home on POD 1 and on the day of catheter or SPT removal (fig. 1). Our primary outcome was VAS and the study was powered to detect a mean difference of 1 point on this 10-point scale. Primary safety end points included emergency room visits, hospital readmission within 30 days of surgery and death. Weekly monitoring was performed continuously throughout the trial. The accrual rate, adverse event patterns and risk level were discussed, and a data safety and monitoring board form was completed to document these factors. Patients were followed a minimum of 1 year to assess for BNC.

Power Analysis and Futility/Efficacy Interim Assessment

Power analysis was based on retrospective data on a series of 202 patients who underwent RALP with combined