Assessment of Early Continence After Reconstruction of the Periprostatic Tissues in Patients Undergoing Computer Assisted (Robotic) Prostatectomy: Results of a 2 Group Parallel Randomized Controlled Trial

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Purpose: Several case series have shown that reconstruction of the anterior or posterior periprostatic tissues facilitates early return of urinary continence after radical prostatectomy. We conducted a randomized clinical trial comparing early continence rates in patients undergoing urethrovesical anastomosis with or without periprostatic reconstruction.

Materials and Methods: A total of 116 consecutive patients undergoing computer assisted (robotic) prostatectomy performed by 1 of 2 experienced surgeons were randomized to single (without periprostatic reconstruction) or double layer (with periprostatic tissue reconstruction) urethrovesical anastomosis. Urinary loss was measured by pad weight at 1, 2, 7 and 30 days after catheter removal. Patients and data gatherers were blinded to treatment allocation.

Results: There were 57 patients randomized to the single and 59 to the double layer anastomosis group. All patients completed the study and followup. Using the conventional definition of urinary continence (0 to 1 pads daily) 26% and 34%, 49% and 46%, 51% and 54%, and 74% and 80% of patients undergoing single layer or double layer anastomoses were continent at 1, 2, 7 and 30 days, respectively ($p > 0.1$). Of the patients in the 2 groups 7% and 15%, 14% and 14%, 16% and 20%, and 47% and 42% had no urinary leakage (0 gm or 0 pads daily) at these intervals, respectively ($p > 0.1$). In each group 1 patient required prolonged catheterization because of cystographic evidence of anastomotic leakage. There were no other complications.

Conclusions: Early urinary continence rates were high in patients undergoing single or double layer urethrovesical anastomosis. We found no improvement in early continence rates with reconstruction of the periprostatic tissues.

Key Words: randomized controlled trial, robotics, prostatectomy, urinary incontinence

Urinary incontinence is one of the most distressful complications of radical prostatectomy. While 12-month continence rates after radical prostatectomy are excellent in experienced hands (85.5% to 95.2%) few patients are continent in the early postoperative period.[1–5] Observational studies have shown that post-prostatectomy continence rates may be improved with bladder neck preservation[6] or intussusception.[7] More recently several case series have reported technical modifications to urethrovesical anastomosis that have resulted in apparent improvement in urinary continence. However, there are no randomized clinical trials to our knowledge that confirm these outcomes.

Using a modified van Velthoven stitch for urethrovesical anastomosis we achieved a continence rate of 25% within 1 day and 50% within 30 days of catheter removal in more than 2,000 patients undergoing computer assisted (robotic) radical prostatectomy.[8] Rocco et al found that urinary continence rates 30 days after laparoscopic radical prostatectomy improved from 32% to 84% after posterior reconstruction of the rhabdosphincter.[9] Nguyen et al found that continence rates improved from 3% to 34% using a virtually identical technique.[5] Tewari et al reported 1 and 6-week continence rates of 29% and 62%, respectively, after reconstruction of the anterior puboprostatic collar.[10]

We reasoned that if posterior and anterior reconstruction independently improved early continence, the combination might result in an incremental benefit. In a pilot study we found that continence rates after combined reconstruction of the posterior rhabdosphincter and the anterior puboprostatic collar were 69%, 77% and 83% at 1, 7 and 30 days, respectively, with no difference in surgeon specific outcomes. We performed a randomized controlled clinical trial to verify the outcomes detected in the observational studies.

MATERIALS AND METHODS

Study Design

This was a 2 group, parallel, randomized clinical trial comparing early continence results in patients undergoing robotic radical prostatectomy at a single tertiary care institu-

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Study received institutional review board approval from Henry Ford Hospital.

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tion. Surgery was performed by 1 of 2 surgeons with more than 6 years of experience performing robotic radical prostatectomy. Surgeon 1 had performed 2,444 cases and surgeon 2 had performed 811 cases at the start of this trial. The study protocol was approved by the institutional review board at Henry Ford Hospital. Data collection and followup correspondence were done in accordance with the Health Insurance Portability and Accountability Act. Funding was provided by the Vattikuti Urology Institute.

Surgical Technique

We used a previously reported technique of robotic assisted laparoscopic prostatectomy, the VIP technique.[8] We made no special attempt to preserve the bladder neck but did attempt to achieve maximal urethral length. After urethral transection patients were randomized to single or double layer urethrovesical anastomosis.

Single layer anastomosis was performed using a double armed 3-zero monofilament suture.[11] For the 2 layer anastomosis 2, 3-zero double armed monofilament sutures were used (fig. 1). The first suture was passed through the posterior layer of Denonvilliers fascia and then through the posterior rhabdosphincter. After 4 passes from right to left, which created a posterior plate, the suture was tied or locked and held with gentle traction by the second assistant. The urethrovesical anastomosis (inner layer) was then completed as previously described.[8,12] Finally the outer layer was completed by suturing the puboprostatic ligament to the anterior pubovesical collar. Cystograms were done at 7 days after surgery and the catheter was removed if there was no leak or a small contained extravasation.

Measurement of Urinary Leakage

A scale (Fit and Fresh Scale, MEDport, LLC, Providence, Rhode Island) was provided to each patient for pad weighing. Patients recorded the results on a data sheet which was returned to the data gatherers after 1 month.

Sample Size Calculation

The pilot study as well as the observational studies reported in the literature suggested that early urinary continence rates improved by 30% to 50% with periprostatic tissue reconstruction.[5,9,10] Using the Kelsey method for sample calculation for a 30% expected difference a power of 90% and a 1-alpha of 95% with a total sample size of 116 patients were needed.[13] The protocol for the study required a single interim analysis using the Pocock rule.[14] This rule states that we would stop the study at 58 patients if the difference for the primary outcomes reached a significance level of 0.01, which would mean an absolute difference in continence rates of 50% on catheter removal as detected by Rocco et al.[9] An intent to treat analysis was used.

Inclusion and Exclusion Criteria

Consecutive patients undergoing VIP by 1 of 2 surgeons were eligible to participate. All participants signed an institutionally approved consent form. Patients who required bladder neck reconstruction (more than 1 suture placed to narrow the bladder neck) and international patients in whom followup would be difficult were excluded from analysis.

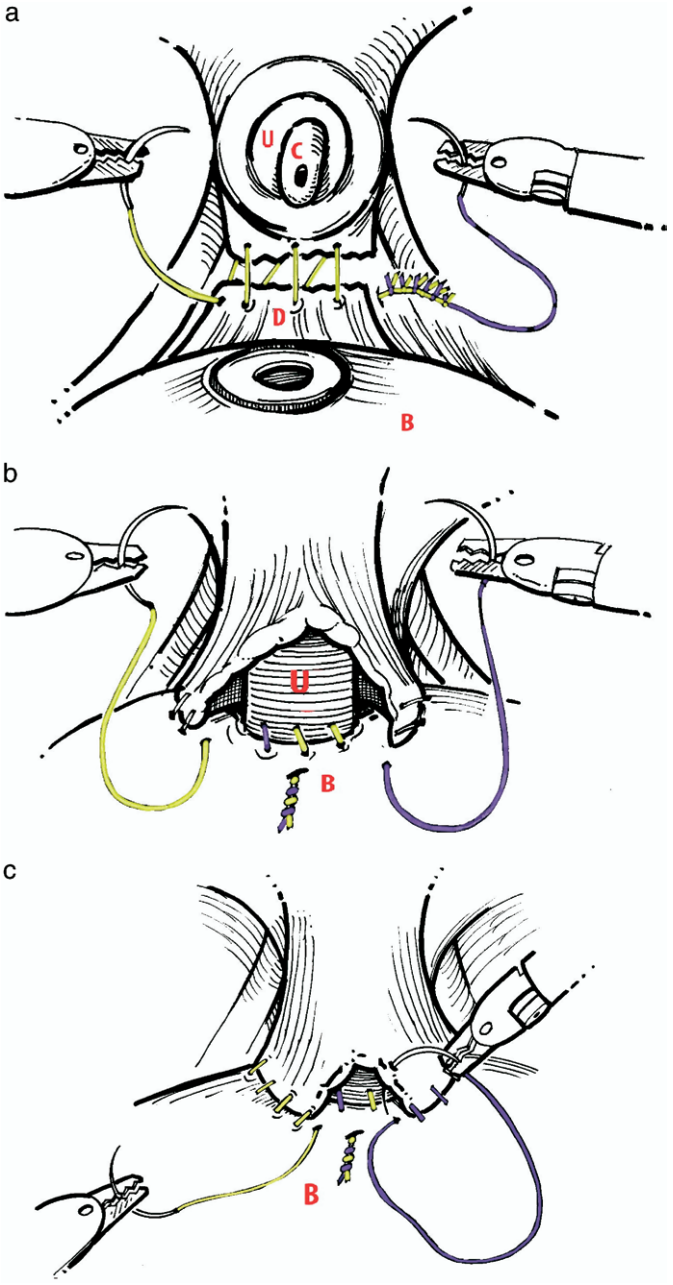

FIG. 1. Surgical technique. *a*, posterior external layer approximating Denonvilliers fascia and posterior rhabdosphincter. Following reconstruction between 5 and 8 o'clock positions formal urethrovesical anastomosis (or internal layer) is begun. *b*, after completion of urethrovesical anastomosis lateral aspects of external layer are completed in stepwise fashion from 8 to 11 o'clock position on left side and from 5 to 1 o'clock position on right side. *c*, anterior pubovesical collar reconstruction is completed approximating puboprostatic ligaments to midline anterior bladder tissue. *B*, bladder. *U*, urethra. *C*, Foley catheter. *D*, Denonvilliers fascia.

Outcomes

The primary outcome of interest was urinary continence, defined as the proportion of patients using 0 to 1 pad (30 gm or less leak) per day, and measured by pad weight at 1, 2, 7 and 30 days after catheter removal. The 3 secondary outcomes measured were 1) urinary continence defined as the percentage of patients with no leakage or 0 pads per day measured by pad weight at the same intervals; 2) median urinary loss (gm per day) recorded in the 2 groups of patients