Effects of New 1-Step Posterior Reconstruction Method on Recovery of Continence after Robot-Assisted Laparoscopic Prostatectomy: Results of a Prospective, Single-Blind, Parallel Group, Randomized, Controlled Trial

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Purpose: We devised a 1-step posterior reconstruction technique that opposes the median dorsal raphe only to the posterior counterpart of the detrusor apron rather than to Denonvilliers' fascia. In a retrospective study we previously found that during robot-assisted laparoscopic prostatectomy this new technique could significantly shorten continence recovery time. We designed a prospective clinical trial to confirm this.

Materials and Methods: We designed a single-blind, parallel group, randomized, controlled trial. A total of 100 men who underwent robot-assisted laparoscopic prostatectomy performed by a single surgeon at a referral center were randomly allocated to the intervention group (50) or the control group (50) from October 2012 through August 2013. The intervention group underwent posterior reconstruction with this new technique before vesicourethral anastomosis. All patients in each group were treated with anterior reconstruction. The study primary end point was time to continence recovery, defined as no pad use. Secondary outcomes were time to recovery of social continence, defined as 0 or 1 pad used per day.

Results: One control was excluded from analysis due to open conversion and 4 patients were excluded since they withdrew from participation. Median time to complete continence recovery did not differ significantly between the intervention and control groups (106 and 119 days, respectively, $p = 0.890$). However, time to social continence recovery was significantly shorter in the intervention group than in controls (median 18 vs 30 days, $p = 0.024$).

Conclusions: One-step posterior reconstruction did not significantly shorten time to complete continence recovery. However, it seemed to have a marginal benefit on early recovery of social continence.

Key Words: prostatic neoplasms, prostatectomy, robotics, urinary incontinence, treatment outcome

Abbreviations and Acronyms

DF = Denonvilliers' fascia

EPIC = Expanded Prostate Cancer Index Composite

MDFR = median dorsal fibrous raphe

PDA = posterior counterpart of detrusor apron

PR = posterior reconstruction

RALP = robot-assisted laparoscopic prostatectomy

RCT = randomized, controlled trial

RP = radical prostatectomy

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Study received Seoul National University Bundang Hospital institutional review board approval

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INCONTINENCE is one of the most common complications after RP and it significantly decreases quality of life.[1] Since Rocco et al reported the PR surgical technique to reduce the risk of this problem,[2] it has been adopted by many urologists for open, laparoscopic and robotic RP.[3] Many

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retrospective studies showed promising results using the original or a modified technique[2,4–11] but the results of prospective trials were not consistent.[12–16] Despite this controversy a survey by ERUS (European Association of Urology Robotic Urology Section) revealed that 51.7% of robotic surgeons always performed PR and 19.8% of robotic surgeons sometimes perform this reconstructive step.[17]

Many researchers believe that DF is a key anatomical structure to restore.[2,5,9–11] In contrast, we proposed the concept of the PDA as a key structure on the proximal side.[18] The PDA includes the vesicoprostatic muscle and its extension to the bladder.[19,20] It is identical in structure to the additionally fixed posterior bladder wall 1 to 2 cm from the new bladder neck described by Rocco et al in their original technique.[2,11] However, it is more specifically described as the posterior lip of the bladder neck (full thickness) and the vesicoprostatic muscle in the protocol of the phase III trial of the original Rocco et al reconstruction procedure (ClinicalTrials.gov NCT01809522).

While the DF is connective tissue, the PDA is a thick, smooth muscle and fibrous tissue connected to the outer longitudinal detrusor muscle and adventitia.[18] The DF could provide good traction and the PDA is a relatively thicker and stronger structure than the DF.[21] Thus, the PDA is theoretically a more appropriate structure for PR.

We devised a 1-step PR technique that opposes the MDFR only to the PDA without including the DF. Our retrospective analysis revealed that using this new PR method during RALP significantly shortened time to continence recovery.[18] Therefore, we performed this prospective RCT to confirm our result.

MATERIALS AND METHODS

Ethics Statement

This study was approved by the Seoul National University Bundang Hospital institutional review board. We obtained written informed consent from all participants before trial screening. The study is registered at ClinicalTrials.gov (NCT01714219).

Trial Design and Participants

We designed a prospective, single-blind, parallel group RCT comparing continence recovery in men treated with RALP by a single surgeon (SEL) at a tertiary referral center in the Republic of Korea. The surgeon had experience with more than 700 open RPs and 660 RALPs before the current trial. We strictly followed the 2010 CONSORT statement[22,23] to design and report this trial. The clinical trial is registered in ClinicalTrials.gov (NCT01714219). No change was made in the protocol after trial commencement. Patients were randomly assigned to an intervention group or a control group at a 1:1 ratio. Study inclusion criteria were pathologically proven prostate cancer (cT3a or less) and the intent to undergo RALP. Exclusion criteria were prior hormone therapy, prior radiation treatment to the prostate or pelvis, preoperative urinary incontinence and refusal to participate.

Interventions and Surgical Technique

Conventional 6-port transperitoneal RALP was performed with the minor modification that we previously described.[18] As indicated the neurovascular bundles were spared after counseling the patient. The usual dissection plan for the posterior side of the prostate was between the prostatic capsule with the DF or inside the DF. Pelvic lymph node dissection was done in men with high risk cancer.

In the intervention group our 1-step PR technique was performed before the vesicourethral anastomosis as previously described.[18] Reconstruction was done between the posterior part of the rhabdosphincter, including the MDFR only to the PDA without including the DF (fig. 1). To achieve this we made 4 or 5 stitches of continuous running suture with 18 cm 3-zero Monocryl® using a vas pledget starting at the right posterior side of the urethral sphincter (fig. 2). During this procedure the stitches should be full thickness at each side and the operator must be cautious not to incorporate the lissosphincter. Our previous report includes a video that should help in understanding our technique.[18] In the control group this PR procedure was omitted. A van Velthoven vesicourethral anastomosis was created and anterior reconstruction was performed in each group as we previously described.[18]

Outcomes

We measured continence status using the validated Korean version of the EPIC questionnaire[24] at screening,

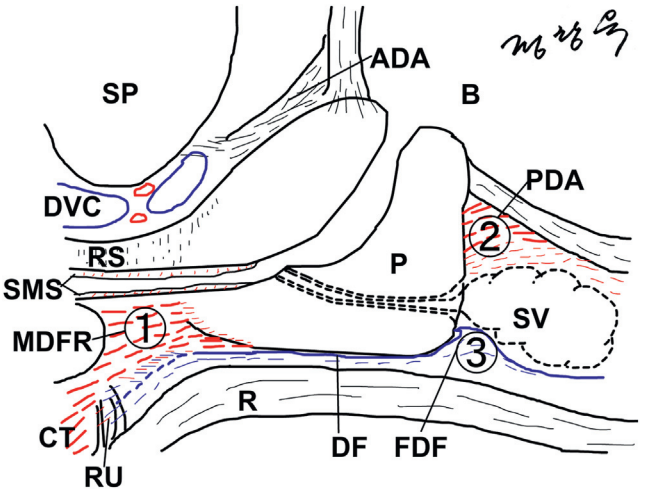

Figure 1. Anatomy of midline sagittal section of prostate (*P*). *ADA*, anterior detrusor apron. *B*, bladder. *CT*, central tendon. *DVC*, dorsal vascular complex. *FDF*, DF folding. *R*, rectum. *RS*, rhabdosphincter. *RU*, rectourethralis muscle. *SMS*, smooth muscle sphincter. *SP*, symphysis pubis. *SV*, seminal vesicle.