Detrusorrhaphy and Intrafascial Nerve-Sparing During Robot-Assisted Radical Prostatectomy on Recovery of Continence and Potency: Surgical Feasibility, One-Year Functional and Oncologic Outcomes

Tae Young Shin, Yong Seong Lee*

Purpose: To report the 1-year functional outcomes, oncologic outcomes, and postoperative complications in patients who underwent modified robot-assisted radical prostatectomy (RARP) procedures for achieving early recovery of continence and potency postoperatively.

Materials and Methods: This study included 165 patients who underwent RARP. Overall, 98 patients underwent RARP using our modified detrusorrhaphy and intrafascial nerve-sparing techniques (group 1) and 67 underwent standard RARP (group 2). Continence and potency rates were assessed at 1 week, 1, 3, 6, and 12 months after RARP. Oncologic outcomes comprised positive surgical margins (PSMs) and biochemical recurrence (BCR) rate.

Results: The continence rates were 61.2% and 6.0%, 72.5% and 11.9%, 79.6% and 20.9%, 91.8% and 58.2%, and 97.9% and 74.6% at 1 week, 1, 3, 6, and 12 months in group 1 and 2, respectively. The potency rates were 66.3% and 11.9%, 78.6% and 38.8%, 85.7% and 50.8%, 92.9% and 70.2%, and 95.9% and 79.1% at 1 week, 1, 3, 6, and 12 months in group 1 and 2, respectively. Overall postoperative complication rates (< 10%) were similar between the groups. The PSMs rate was 17.4% and 16.4% in the two groups. The rate of PSMs in the cohort of patients with stage pT2 disease decreased to 13.6% and 12.5% in groups 1 and 2, respectively. BCR rate was 5.1% and 6.0% in groups 1 and 2, respectively.

Conclusion: The use of detrusorrhaphy and intrafascial nerve-sparing techniques is safe and feasible, with our results demonstrating early return to continence and potency. Further studies should be conducted.

Keywords: prostate cancer; robot-assisted radical prostatectomy; continence; nerve-sparing; erectile function

INTRODUCTION

Over the past decades, impaired urinary and sexual function has restricted the quality of life (QoL) of patients after radical prostatectomy.[1] Studies have described numerous surgical adaptations to improve the functional outcomes of radical prostatectomy and the use of advantageous robotic ergonomics and tools during robot-assisted radical prostatectomy (RARP) has allowed the introduction of various surgical techniques.[2–7] Still, the complications are unresolved after RARP, with incidences ranging from 10% to 69% at 1-year follow-up.[8,9] Particularly in increasing number of patients who are younger, postoperative urinary incontinence and erectile dysfunction considerably influence patients' QoL.[10]

In our institution, we have implemented several surgical techniques during RARP in an attempt to achieve early potency and continence. First, to preserve the entire neurovascular bundle (NVB), we focused on the modified clipless intrafascial nerve-sparing approach. Second, we performed a modified detrusorrhaphy technique, which involves reinforcing the posterior detrusor muscles using a zigzag flap during bladder neck reconstruction. The objective of the present study is to describe the detrusorrhaphy and clipless intrafascial nerve-sparing approaches and to evaluate the postoperative 1-year functional and oncologic outcomes after RARP.

MATERIALS AND METHODS

Study population and design

Between March 2015 and August 2018, 280 patients underwent RARP in our institution. All procedures were performed by one surgeon who had experience performing > 800 RARPs. Each patient preoperatively underwent multiparametric magnetic resonance imaging (mpMRI).

This was a retrospective, non-randomized study. Medical records of 280 patients who underwent RARP were retrospectively reviewed. Inclusion and exclusion criteria were: 1) we included 208 patients with 1-year of follow-up and those who had preoperative continence and potency, defined as a Sexual Health Inventory for Men (SHIM) questionnaire score of $\geq$ 17, 2) patients with localized low-risk prostate cancer and Gleason score $\leq$ 7 (cT1–2N0M0) were evaluated, 3) exclusion criteria were any neoadjuvant hormonal treatment, prior radiation therapy, and previous history of urethral stricture and urinary incontinence, 4) we excluded nine patients who presented insufficient data and six patients who

Urology Department, Hallym University Sacred Heart Hospital, Hallym University College of Medicine, Anyang, Korea.
*Correspondence: Urology Department, Hallym University Sacred Heart Hospital, Hallym University College of Medicine, Anyang, Korea.
Tel: +82 31 380 3850. Fax: +82 31 380 3852. E-mail: novavia@hallym.or.kr.
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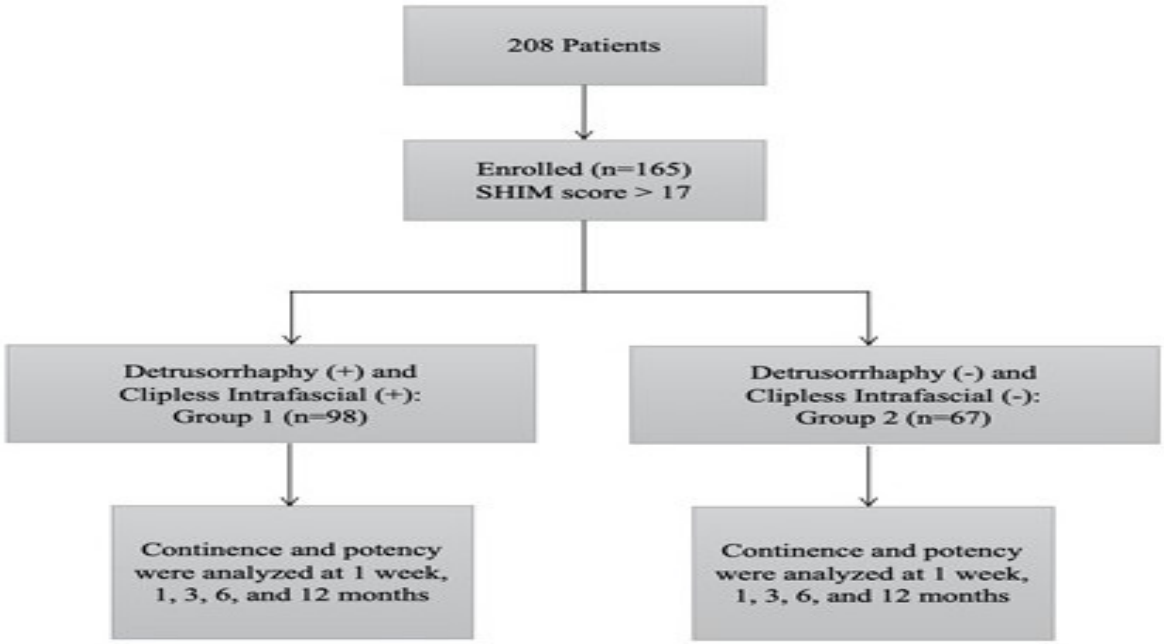

Figure 1. Study flow diagram.

were transferred to our institution after being diagnosed with prostate cancer in other hospitals. Finally, 165 of the 208 patients were included in the study (**Figure 1**): those who underwent the detrusorrhaphy and intrafascial NVB sparing techniques (group 1, 98 patients) between October 2016 and August 2018 and those who underwent standard RARP approach (group 2, 67 patients) between March 2015 and September 2016. The enrolled patients were divided into two subgroups according to a time criterion to compare the learning

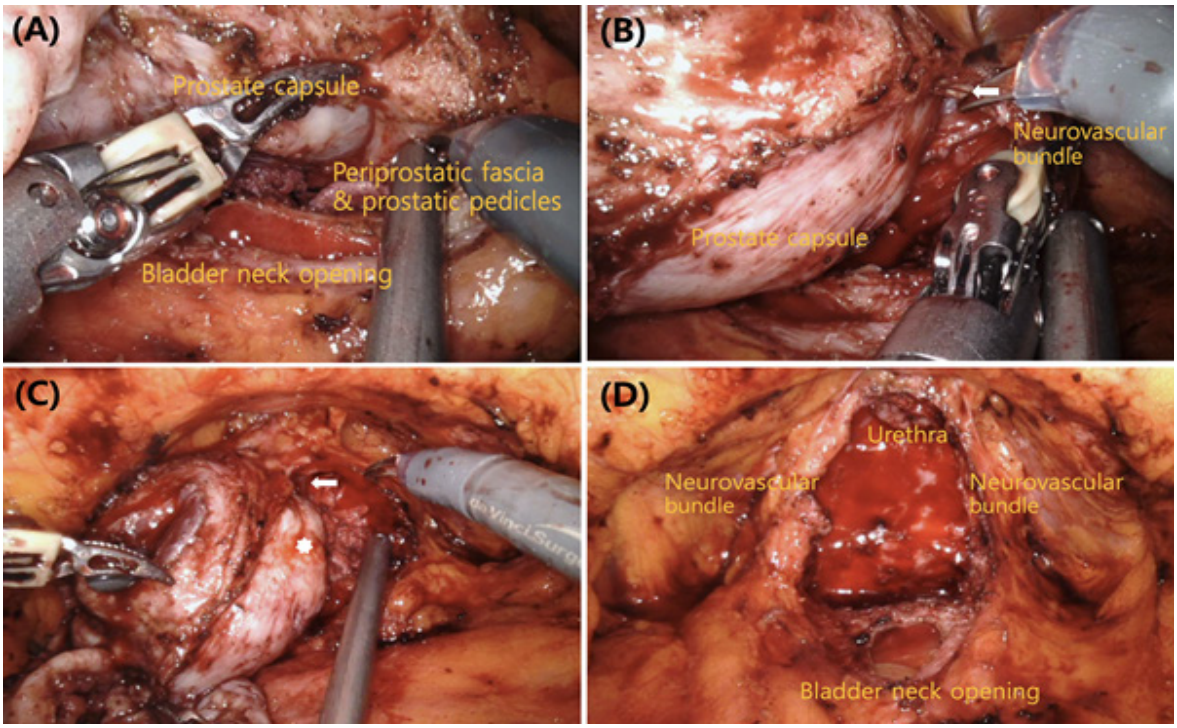

Figure 2. Operative steps. **(A)** Exposure of the prostate capsule by detaching the overlying periprostatic fascia and prostatic pedicles. **(B)** Further mobilization of the prostatic pedicles, including the neurovascular bundles, by using antegrade dissection (distal end of the prostatic pedicles, white arrow). **(C)** Combined blunt and sharp dissection of the neurovascular bundles as far distally to the apex as possible until reaching the urethra (prostate capsule, white star; urethra, white arrow). **(D)** After complete prostate dissection, the preserved neurovascular bundles and prostatic pedicles are clearly visible and become thick.

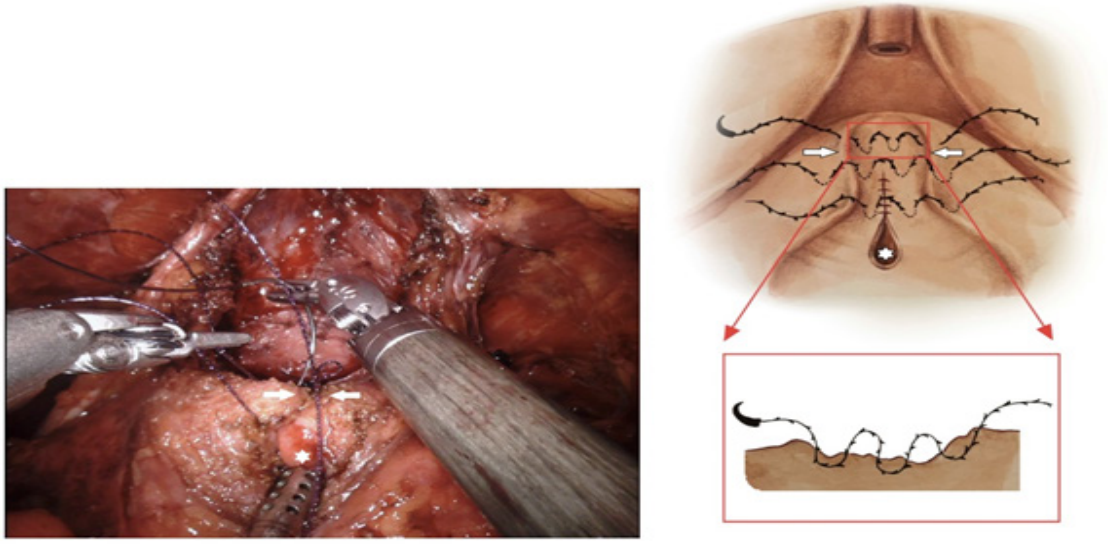

Figure 3. Operative and schematic view of the detrusorrhaphy technique using a flap of dynamic detrusor cuff muscles (detrusor muscles, white arrow; bladder neck opening, white star).

curve. The study protocol was approved by the University Hospital Ethics Committee (No. 2018-05-012).

Surgical techniques

All patients underwent transperitoneal RARP. Patient positioning and port placement were those as described previously.[11] The da Vinci Xi Surgical System was used in all cases.

Intrafascial nerve-sparing technique

The endopelvic fascia was preserved in those with clinical stage ≤ T2c disease. Our intrafascial nerve-sparing technique essentially aims to preserve the surrounding periprostatic structures to the fullest extent. The prostate capsule is carefully exposed after detaching the overlying fat and periprostatic fascia (**Figure 2A**). Arterial pulsations from the cavernous vessels within the NVB are easily recorded with further lateral dissection. These vessels are preserved by gently pushing them posterolaterally toward the rectum. The prostatic pedicles are further mobilized off the prostate capsule in an anterior direction until the most distal ends of the vascular pedicle (**Figure 2B**). The identified vascular pedicles are swept off the prostate, further mobilizing the NVBs, which are then gently eased out of the posterolateral surface of the prostate capsule with a combination of blunt and sharp dissection. We continued antegrade dissection by peeling off the periprostatic fascia, NVBs, and the prostatic pedicle en bloc until reaching the urethra (**Figure 2C**). The use of monopolar electrocautery and clips is vigorously avoided during this dissection. If bleeding occurs from the periprostatic vessels, a brief increase in insufflation pressure can be applied to the bleeding source using hemostatic gauze, while slight venous bleeding is left uncontrolled. In cases of pulsatile arterial bleeding, ligation is performed with 4-0 V-Loc suture. The preserved NVBs are clearly visible after prostate dissection (**Figure 2D**).

Bladder reconstruction and detrusorrhaphy technique

We designed the detrusorrhaphy technique which is designed for thickening and strengthening the detrusor muscles from the posterior bladder neck to the bilateral dissected pedicles area. It was based on the theory that anatomically correct reconstructions would provide functional reinforcement of the detrusor muscles. Our simple modification is different from conventional detrusorrhaphy.[12,13] The difference of the our detrusorrhaphy technique is the use of zigzag suturing, which thickens and strengthens the deteriorated detrusor muscles during posterior dissection of the bladder (**Figure 3**). The conventional reconstruction method focuses on narrowing the bladder neck and suturing both wings of the dissected bladder. The aim of the detrusorrhaphy technique is to reconstruct the detrusor muscles while maintaining a physiologically and anatomically ideal shape. This posterior reinforcement is based on the principles of Parsons and colleagues.[14]

Pelvic lymph node dissection (PLND)

PLND was performed in 88 patients (89.8%) and 61 patients (91.0%) in group 1 and 2, respectively. Extended PLND until common iliac artery area was performed in patients with a risk of lymph node involvement of >5% in the Briganti nomogram.[15] A limited PLND until obturator fossa was performed in patients with an estimated risk of <5%. Hem-o-Lok clips are used instead of cauterization to prevent lymphocele formation.

Data collection and statistical analysis

We assessed following demographic data: age, body mass index (BMI), American Society of Anesthesiologist (ASA) score, prostate volume, PSA level, biopsy Gleason score, and D'Amico risk classification. Baseline sexual function before RARP was assessed with SHIM questionnaire and preoperative continence was evaluated using the International Prostate Symptom Score (IPSS) score. Postoperative complications were recorded and evaluated using the Clavien–Dindo classification.[16]

The primary end point was the postoperative functional and oncologic outcomes. Postoperative functional

Table 1. Demographic, preoperative, perioperative, and histopathologic data for groups 1 and 2

Demographic and preoperative	**Group 1**	**Group 2**	***P*-value**
Patients, number	98	67	
Age, median (IQR), year	60.5 (52.0–69.0)	61.5 (53–70.0)	.685
BMI, median (IQR), kg/m2	25.4 (23.8–28.0)	25.8 (24.4–29.5)	.927
ASA score, median (IQR)	2.0 (1.0–2.0)	2.0 (1.0–2.0)	.875
Prostate volume, median (IQR), cc	39.6 (22.5–70.5)	38.5 (21.0–105)	.435
PSA, median (IQR), ng/ml	6.9 (3.2–11.5)	7.5 (3.5–19.8)	.075
Biopsy Gleason score, median (IQR)			
- 6	21 (21.4%)	16 (23.9%)	.565
- 7	77 (78.6%)	51 (76.1%)	.492
mpMRI site of tumor (%)			
- negative	14 (14.3%)	11 (16.4%)	.459
- apical	21 (21.4%)	14 (20.9%)	.667
- basal	10 (10.2%)	7 (10.4%)	.728
- posterolateral	26 (26.5%)	18 (26.9%)	.814
- anterior	8 (8.2%)	5 (7.5%)	.452
- multiple	19 (19.4%)	12 (17.9%)	.756
IPSS score, median (IQR)	12 (2.0–21.0)	13.5 (3.0–23.0)	.475
SHIM score, median (IQR)	20.0 (17–25)	20.5 (17-25)	.798
D'Amico risk group (%)			
- Low risk	77 (78.6%)	47 (70.2%)	.645
- Intermediate risk	15 (15.3%)	13 (19.4%)	.422
- High risk	7 (7.1%)	7 (10.4%)	.785
Perioperative and histopathologic			
Operative time, median (IQR), min	230 (140–250)	210 (130–300)	.522
Blood loss, median (IQR), ml	200 (80–600)	200 (100–600)	.892
Blood transfusion rate (%)	1 (1.0%)	2 (2.9%)	.535
Nerve sparing (%)			
- Bilateral	90 (91.8%)	59 (88.1%)	.673
- Unilateral	5 (5.1%)	5 (7.5%)	.495
- None	3 (3.1%)	3 (4.5%)	.521
PLND (%)	88 (89.8%)	61 (91.0%)	.348
- Extended PLND	8 (9.1%)	7 (11.5%)	.255
- Limited PLND	80 (91.9%)	54 (88.5%)	.282
Complications (%)			
- Clavien grade 1			
- Clavien grade 2	8 (8.2%)	6 (9.0%)	.592
- Clavien grade 3	0	0	
Pathologic stage (%)			
- pT2	88 (89.8%)	56 (83.6%)	.228
- pT3a	7 (7.1%)	7 (10.4%)	.136
- pT3b	3 (3.1%)	4 (6.0%)	.318
Pathologic Gleason score (%)			
- <6	20 (20.4%)	13 (19.4%)	.785
- 7	73 (74.5%)	47 (70.2%)	.682
- >8	5 (5.1%)	7 (10.4%)	.115
PSMs rate (%)			
- overall	17 (17.4%)	11 (16.4%)	.485
- among pT2 patients	12 (13.6%)	7 (12.5%)	.755
- among pT3 patients	5 (50.0%)	4 (36.4%)	.361
PSMs site (%)			
- apical	9 (52.9%)	5 (45.5%)	.125
- posterolateral	5 (29.4%)	4 (36.3%)	.355
- multifocal	3 (17.7%)	2(18.2%)	.223
Positive PLND (%)	0	0	

IQR, interquartile range; BMI, body mass index; ASA, American Society of Anesthesiologist; PSA, prostate–specific antigen; IPSS, International Prostate Symptoms Score; SHIM, Sexual Health Inventory for Men; PLND, pelvic lymph node dissection.

and oncologic results were analyzed between the two groups. The catheter was removed at 1 week postoperatively. We evaluated the potency rate using a SHIM questionnaire and continence rate using a pad test per day at 1 week and 1, 3, 6, and 12 months after RARP. We considered return to erectile function postoperatively as score of $\geq$ 4 on question 2 of the SHIM or the ability to have successful sexual intercourse. A patient was considered as continent if he applied "0 pad–" per day. Pathologic variables including pathologic stage, Gleason score, and positive surgical margins (PSMs) were evaluated. According to American Urological Association guidelines, biochemical recurrence (BCR) was defined as two consecutive PSA values of $\geq$ 0.2 ng/mL.[17]

Continuous variables were reported as median values and interquartile ranges (IQRs), and categorical variables of frequencies and proportions were reported as percentages. Patient characteristics with continuous variables were analyzed using student's t-test and nonparametric Mann–Whitney test. Independent factors with categorical variables were analyzed using the chi-square test. Chi-square test was used to compare the rate of continence and potency between the groups. We evaluated the rates of PSMs in the two groups. The same analyses were performed in a subgroup of patients with a suspicion of posterolateral tumor at preoperative mpMRI. A *P* value of < .05 was considered to indicate a statistically significant difference. All statistical analyses were conducted using IBM® SPSS® Statistics

Table 2. Continence and potency data at various follow-up points after catheter removal in groups 1 and 2

Time	Patients achieving continence, N (%)		*P*-value	Patients achieving potency, N (%)		*P*-value
	Group 1 (N=98)	Group 2 (N=67)		Group 1	Group 2	
1 week	60 (61.2%)	4 (6.0%)	< .001*	65 (66.3%)	8 (11.9%)	< .001*
1 month	71 (72.5%)	8 (11.9%)	< .001*	77 (78.6%)	26 (38.8%)	< .001*
3 months	78 (79.6%)	14 (20.9%)	< .001*	84 (85.7%)	34 (50.8%)	.036*
6 months	90 (91.8%)	39 (58.2%)	.026*	91 (92.9%)	47 (70.2%)	.208
12 months	96 (97.9%)	50 (74.6%)	.138	94 (95.9%)	53 (79.1%)	.165

* significant at $P < .05$.

for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Demographics

Table 1 summarizes the baseline demographic, clinical, and pathological data for the 165 participants. No significant differences were observed between group 1 and 2 with respect to preoperative demographic and clinical data.

Operative outcomes and complications

Median operative time in groups 1 and 2 was 230 (IQR: 140–250) and 210 (IQR: 130–300) min, respectively. Total operating and console time were comparable between the two groups. The estimated blood loss and overall complication rates (< 10%) were similar between the groups (**Table 1**). No patient experienced any intraoperative complications. Up to 1 year postoperatively, none of the patients had urinary retention, and there were no complications, such as lymphocele, that required further procedures. None of the patients showed the positive pelvic lymphadenopathy findings.

Continence outcomes

Continence rates in groups 1 and 2 were 61.2% and 6.0%, 72.5% and 11.9%, 79.6% and 20.9%, 91.8% and 58.2%, and 97.9% and 74.6% at 1 week, 1, 3, 6, and 12 months of follow-up after RARP, respectively (**Table 2**). Up to 3 months, the continence recovery rate in group 1 was significantly higher than that in group 2 ($P < .001$). On learning curve analysis, a progressive change in the number of continent patients and the difference in operative time between groups at each time point was not recorded. Continence was also assessed using the IPSS score, which revealed no significant between group differences in preoperative IPSS scores (12 and 13.5, respectively). The IPSS scores were comparable between groups at 1, 3, 6, and 12 months of follow-up postoperatively (11.5 and 12.5, 10.5 and 12.5, 6.5 and 8.5, and 6.5 and 8.0, respectively; $P > .05$).

Potency outcomes

Potency rates in groups 1 and 2 were 66.3% and 11.9%, 78.6% and 38.8%, 85.7% and 50.8%, 92.9% and 70.2%, and 95.9% and 79.1% at 1 week, 1, 3, 6, and 12 months of follow-up after RARP, respectively (**Table 2**). Up to 3 months, the potency recovery rate in group 1 was significantly higher than that in group 2 ($P < .05$). Of the 98 patients, 84 were potent at 3 months. The remaining fourteen patients could achieve partial erections, but not sufficient for penetration, with or without the use of oral phosphodiesterase type 5 inhibitors agents. In these patients, in the case of suspected seminal vesicle invasion or encountered adhesion between the NVB and prostate, a slightly wider dissection or unilateral extrafascial nerve-sparing approach was performed to avoid an iatrogenic positive surgical margin.

Pathologic findings and oncologic results

Table 1 shows histopathologic data. The two groups had no differences in their pathologic stage ($P > .05$). The majority of patients (88 patients; 89.8%) in group 1 presented organ-confined disease; seminal vesicle invasion (pT3b) was identified in 3 of the patients (3.1%) and extraprostatic extension (pT3a) was found in 7 patients (7.1%). The postoperative Gleason score 7 corresponded to 73 patients (74.5%) in group 1 (29 Gleason 3 + 4, 39.7%; 44 Gleason 4 + 3, 60.3%).

Overall, 28 of 165 (16.9%) patients in the two groups revealed PSMs at postoperative pathology, without a significant difference between the two groups (groups 1 and 2: 17.4% and 16.4%, respectively; $P > .05$). The rate of PSMs in the cohort of patients with stage pT2 disease decreased to 13.6% (12 of 88 patients with pT2 stage) in group 1and 12.5% (7 of 56 patients with pT2 stage) in group 2, respectively ($P > .05$).

The vast majority of PSMs was found to be apical margin 52.9% (9 patients) and 45.5% (5 patients) and posterolateral margin 29.4% (5 patients) and 36.3% (4 patients) in group 1 and 2, respectively. The PSMs in the posterolateral margin were seen in 9 patients in two groups. A subanalysis of patients with a suspicion of posterolateral tumor in preoperative mpMRI (26 and 18 patients in group 1 and 2) was performed. The posterolateral PSMs were found in 5 (19.2%) of 26 patients in group 1 and 4 (22.2%) of 18 patients in group 2. It shows that there was no significant difference in posterolateral PSMs rate between the two groups.

The patients had a median follow-up period of 27 months (IQR: 17–36). BCR was seen in 5 cases (5.1%) and four cases (6.0%) in group 1 and 2, respectively. Median PSA level at the time of BCR was 0.3 (IQR: 0.2–0.95) ng/mL. Patients with BCR were analyzed with pelvic MRI, bone scintigraphy, and chest and abdominal computed tomography. No metastasis was observed in any case, and patients received adjuvant radiotherapy and/or androgen deprivation therapy.

DISCUSSION

The last decade has seen increased acceptance of RARP as s surgical treatment option for younger and sexually healthier patients with localized prostate cancer.[10] Although RARP is prioritized with consistent oncological outcomes and a lower risk of complications,(18) post-RARP urinary incontinence and erectile dysfunction still have remained the major complications and not shown a satisfactory reduction as expected.

The physiological mechanisms related to post-prostatectomy urinary incontinence have not been fully elucidated. Potential causes of incontinence after RARP are

known to be due to the disruption of normal anatomic contributors to continence.[19] Studies have described numerous surgical adaptations to improve the continence rate of patients.[5–7] We developed the zigzag detrusorrhaphy technique, which is specially designed for thickening and strengthening the detrusor muscles from the posterior bladder neck to the bilateral dissected pedicles area. Performing bladder neck narrowing using zigzag suturing with the detrusorrhaphy technique achieves morphologically and fundamentally different results when compared to using the classic tennis racquet procedure, which simply uses a side by side stitch to narrow the wide-opened bladder neck. When dissecting the base of the prostate, the tissue around the prostate and bladder neck is very tight and the boundaries are unclear. We inevitably deteriorate a large amount of detrusor muscle. Our modified procedure aims to reconstruct the detrusor muscles to maintain a physiologically and anatomically ideal form. The aspect of the detrusorrhaphy technique involves dynamic detrusor cuff detrusorrhaphy, which supports the proximal urethra and bladder neck with contractile detrusor tissue and constricts this outlet.[20] Reconstruction of our detrusorrhaphy technique is thought to prevent hypermobilization of the bladder neck area, thereby reducing stress urinary incontinence, and is considered important for the recovery of continence. Our results revealed early continence rates of 61.2%, 72.5%, 79.6%, 91.8%, and 97.9% at 1 week, 1, 3, 6, and 12 months of follow-up after RARP, respectively. These results are consistent with those of other studies demonstrating the benefits of early recovery of urinary continence, although discrepancies exist in surgical techniques and continence definitions vary. A nonrandomized single-arm study by Porpiglia et al. achieved similar continence rates (71.8%, 77.8%, 89.3%, 94.4%, and 98.0%) at 1 day, 1, 4, 12, and 24 weeks, respectively, after catheter removal.[11]

Recent studies have suggested that the course of NVBs is more involved than that previously described by Walsh.[21] Tewari et al. described a hammock-like nerve distribution on which the prostate rests, revealing that NVB is more a network of multiple finely dispersed nerves than a distinct structure.[22,23] Furthermore, Eichelberg et al. showed that only 46%–66% of all nerves were found in the classical posterolateral location relative to the prostate, while 21%–29% were identified on the anterolateral surface.[24] Nerve-sparing is an important step in radical prostatectomy that determines the functional outcomes of the procedure. We have performed antegrade nerve-sparing, which was similar to the method initially reported by Kursh et al.[25] In developing our athermal clipless intrafascial NVB sparing technique, we focused on two technical principles to spare the NVBs. Our antegrade intrafascial approach included completely eliminating the use of monopolar electrocautery (athermal). Additionally, we dissected the NVBs off the prostate in a medial to lateral direction without ligating the vascular pedicles by Hem-o-Lok clips (clipless). It is possible to eliminate bulk clipping of the pedicles by dividing the pedicle vessels as they enter the prostate. We believe that these factors may result in more viable tissue preservation within the NVBs. Our clipless technique is similar to that described by Chien et al.[26]

The risk of PSMs is highly possible when using the method of following the posterior plane laterally and anteriorly. However, our technique did not seem to affect the oncologic results. The overall PSMs rate (group 1 and 2: 17.4% and 16.4%, respectively) was higher than that noted in a previously reported study.[27] However, the PSMs rate in the cohort of patients with pT2 stage (group 1 and 2: 13.6% and 12.5%, respectively) was similar or lower than that noted in another study.[28] In the subanalysis of posterolateral PSMs, the posterolateral PSMs were found in 5 (19.2%) of 26 patients in group 1 and 4 (22.2%) of 18 patients in group 2. It shows that there was no significant difference in posterolateral PSMs rate between the two groups. Using a validated sexual function questionnaire at 1 week after RARP, we found that the patients returned to 66.3% of their baseline preoperative sexual function scores, which then increased to 78.6%, 85.7%, 92.9%, and 95.9% at 1, 3, 6, and 12 months, respectively. This is a favorable outcome compared with other series of RARP using the same validated questionnaire, in which the percentage of patients reporting a return to baseline sexual function was 53.1%, 69.9%, 82.3%, and 86.7% at 1, 3, 6, and 12 months, respectively.[29]

The limitations of this study are the retrospective nature, the small sample size, and only one surgeon performing the surgeries at a single institution. The design of this study is not a randomized study. Basically, the two groups could not be extracted at the same time, which could result in potential selection bias and running curve bias in patients using the modified surgical methods. However, we believe that these biases can be minimized because the operator has already performed more than 800 RARPs from 2007 to the present and the modified surgical methods are not challenging techniques. Although our data are still maturing, our initial results have shown early recovery of urinary continence and potency. Longer follow-ups on a larger number of patients comparing two concomitant cohorts of patients undergoing our techniques is necessary to evaluate postoperative recovery of urinary continence and potency in a standardized fashion. Furthermore, preexisting comorbidities such as diabetes mellitus and smoking history, prostate weight, BMI, D'Amico risk classification, and nerve-sparing bilaterality, which could potentially affect the continence and potency status,[30] were not recorded. Therefore, we should perform multivariate analysis using various other factors in future studies.

CONCLUSIONS

The use of the detrusorrhaphy and intrafascial nerve-sparing approach during RARP helped to achieve early recovery of continence and potency without compromising oncologic outcomes. The detrusorrhaphy and intrafascial nerve-sparing techniques are safe and feasible. Our findings should be validated to assure reproducibility of the measurement in a prospective comparative study.

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No competing financial interests exist.

CONFLICT OF INTEREST

The authors report no conflict of interest.

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