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RESEARCH ARTICLE

The Effect of Preservation of the Bladder Neck on Incontinence Rates in Patients Who Undergo Robot-Assisted Laparoscopic Radical Prostatectomy

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Abstract

Introduction: We aimed to compare the postoperative continence rates in prostate cancer patients who had robot-assisted radical prostatectomy (RARP) when bladder necks were "unpreserved", "preserved" and "extremely preserved".
Methods: In this study, the data of 184 patients who underwent RARP for localized prostate cancer in our clinic between August 2019 and January 2023 were analyzed. The patients were divided into three groups as the bladder neck was not preserved (Group 1), the bladder neck was preserved (Group 2), and the bladder neck was extremely preserved (Group 3). Incontinence status was evaluated with the 24-hour pad test postoperatively at the 1st, 3rd 6th month and 12th months.
Results: One month after surgery, the rate of fully continent patients was higher in Group 3 (39.1%) than Groups 1 and 2 (27.5% and 32.7%, respectively), however the difference was not statistically significant (p=0.483). At the postoperative 3rd month, the rate of fully continent patients was 56.5% in Group 3, 51.9% in Group 2 and 43.1% in Group 1 (p=0.361). The rate of patients with moderate incontinence was higher in Group 1 compared to other study groups (p=0.019). The rate of fully continent patients was 82.6% in Group 3, 73.1% in Group 2 and 61.5% in Group 1 at 6th postoperative month (p=0.079). At postoperative 6 month a significant difference was observed for moderate incontinence rates (15.6%, 5.8% and 0 for Groups 1, 2 and 3, respectively) (p=0.034). At the postoperative 12th month, the rate of fully continent patients was 91.3% in Group 3, 80.8% in Group 2 and 72.5% in Group 1 (p=0.118).
Conclusion: Our results indicated that the approaches for preserving the bladder neck during RARP did not have a statistically significant effect on the prevalence of incontinence, however reduced the severity of incontinence.

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Introduction

Radical prostatectomy (RP) is the preferred treatment choice in localised prostate cancer. RP approaches are open radical prostatectomy (ORP), laparoscopic radical prostatectomy (LRP) and robot-assisted radical prostatectomy (RARP); LRP and RARP being minimally invasive approaches. Increasing trend for minimally invasive approaches has also affected RP procedures, and there is a global increase in the number of RARP.[1] It has been shown that RARP and ORP are similar for oncological outcomes, however RARP is superior in terms of perioperative results (complication rate, loss of blood and rate of blood transfusion, hospital stay, and duration of urinary catheterization).[2,3] Although various studies reported that RARP is superior to open surgery in terms of post-prostatectomy incontinence (PPI) rates,4 most of the studies indicate that there is no significant difference between two approaches for PPI.[3,5,6] Significant negative effect of PPI on quality of life have prompted clinicians to study on this issue further, and preoperative factors affecting PPI were defined as age, surgeon experience, hospital volume, prostate size and preoperative urinary function and various surgical techniques [prostatic urethra preservation, neurovascular bundle (NVB) preservation, bladder neck preservation, Retzius sparing RP], and the surgical techniques have been employed to reduce postoperative incontinence rates. Those techniques have particularly been established during RARP applications, thanks to its high mobility and magnification features.[7-9] Various studies showed that bladder neck sparing techniques during RARP increased continence rates without compromising oncological principles.[10]

The aim of this study is to compare the incontinence rates of the patients with unpreserved bladder neck, preserved bladder neck and extremely preserved bladder neck after RARP performed for nonmetastatic prostate cancer.

Material and Methods

Ankara Bilkent City Hospital No. 1 Clinical Research Ethics Committee approved the study protocol (date: 26 April 2023, no: E1-23-3483). The study was conducted in accordance with ethical rules and the principles of the Declaration of Helsinki.

In this study, the data of 184 patients who underwent RARP for localized prostate cancer in our clinic between August 2019 and January 2023 were analyzed retrospectively. The patients who had preoperative urinary incontinence were excluded. Demographic data (comorbidities, age, body mass index), preoperative data (PSA level, Gleason score on biopsy, clinical T stage, D'Amico risk groups), perioperative parameters [duration of surgery, estimated blood loss (EBL), nerve preservation status, whether lymph node dissection was performed and bladder neck preservation status], postoperative parameters (hospital stay, drain removal time, urethral catheter removal time, incontinence) and final histopathology results (pathological T stage, Gleason score, surgical margin positivity, extracapsular spread, invasion of seminal vesicle and positive lymph nodes) and complications of the patients included in the study were recorded. Then, the patients were divided into three groups as "bladder neck unpreserved" (Group 1), "bladder neck preserved" (Group 2), and "bladder neck extremely preserved" (Group 3). The collected data were compared among the study groups.

Surgical Technique

All patients underwent transperitoneal RARP using a four-armed DaVinci robotic surgical system (Intuitive Surgical, Inc., Sunnyvale, CA). In our study, "bladder neck preservation" was defined as careful dissection of the bladder neck and the base of the prostate and a vesico-urethral anastomosis without any need for bladder neck reconstruction, and "extreme bladder neck preservation" was defined as the length of the preserved intraprostatic segment of the bladder neck >1 cm, as described by Dal Moro et al.11 The bladder neck was not preserved in presence of median lobe or in patients with a lesion at the base of the prostate on mpMRI, and vesico-urethral anastomosis was performed by applying bladder neck reconstruction after resection.

Evaluation of Incontinence

Incontinence status was evaluated with 24-hour pad test, and the first evaluation for incontinence was done in the postoperative 1st month. Daily urinary incontinence amount was grouped as mild if it was <100 g, moderate if it was 100–400 gr, and severe if it was >400 g.12 After the first evaluation at the first postoperative month, incontinence was re-evaluated with the 24-hour pad test in postoperative 3rd, 6th and 12th months.

Statistical analysis

All statistical analyses were done with SPSS 20.0 (IBM, Chicago, IL, USA) software. Kolmogo-

rov-Smirnov test was used to test the conformity of the quantitative data to the normal distribution. Since the parametric test assumptions were not met and the data did not fit the normal distribution, the quantitative data were analyzed with Mann Whitney-U test among the groups. Chi-square test was employed to test the qualitative data. Significance was set at $p < 0.05$.

Results

A total of 184 patients; 109 patients in Group 1, 52 patients in Group 2, and 23 patients in Group 3, were included in the study. There was no difference among the groups in terms of comorbidities, BMI, prostate volumes, PSA levels, or mean Gleason scores on biopsy. The groups were similar in terms of clinical T stage and D'Amico risk stratification (Table 1).

Table 1: Demographic, laboratory and pre-operative clinical data of the study groups

	Group 1 (n=109)	Group 2 (n=52)	Group 3 (n=23)	p
	n (%)	n (%)	n (%)	value
Age (years) (min-max)	64.37±6.26 (47-78)	64.1±6.27 (52-76)	61.83±7.63 (42-75)	0.33
BMI (kg/m²)(min-max)	27.66±3.3 (20.6-39.2)	27.02±2.68 (22.5-36.1)	27.8±2.77 (24.3-34.9)	0.44
Prostate volume (cc) (min-max)	49.6±25.5 (10-177)	43.4±15.37 (20-80)	41.5±15.36 (20-80)	0.27
Comorbidities; -ASHD	23(21.1%)	7(13.5%)	3(113%)	0.40
-COPD	3(2.8%)	1(1.9%)	0	0.85
-DM	24 (22%)	10(19.7%)	5(21.7%)	0.98
-HT	47(43.1%)	17 (32.7%)	6(26.1%)	0.20
PSA level (ng/dl)	10.05±7.68 (0.5-49)	8.05±5.43 (1.3-30)	10.56±8.4 (3.36-34)	0.26
Gleason score on biopsy	6.52±0.79 (6-9)	6.52±0.8 (6-9)	6.83±0.98 (6-9)	0.29
Clinical T stage; -T1a	1 (0.9%)	0	0	
-T1b	2 (1.8%)	1 (1.9%)	0	
-T1c	58 (53.2%)	22 (42.3%)	11 (47.8%)	0.07
-T2a	41 (37.6%)	19 (36.5%)	6 (26.1%)	
-T2b	3 (2.8%)	0	2 (8.7%)	
-T2c	4 (3.7%)	10 (19.2%)	4 (17.4%)	
D'Amico classification; -Low risk	47 (43.1%)	26 (50%)	6 (26.1%)	
-Medium risk	40 (36.7%)	12 (23.1%)	8 (34.8%)	0.13
-High risk	22 (20.2%)	14 (26.9%)	9 (39.1%)	

BMI Body Mass İndex, ASHD Atherosclerotic Heart Disease, COPD Chronic Obstructive Pulmonary Disease, DM Diabetes Mellitus, HT Hypertension, PSA Prostate Specific Antigen

There was no difference among the groups for duration of surgery or estimated blood loss. Anastomosis time was longer in Group 1 compared to Groups 2 and 3. Considering the number of nerve sparing procedures, unilateral neurovascular bundle preservation was done in 19 patients in Group 1, eight patients in Group 2, and 7 patients in Group 3, and the number of patients who had bilateral neurovascular bundle preservation was 19 in Group 1, 13 in Group 2 and 2 in Group 3, without any difference among the study groups for neurovascular bundle preservation rates (p=0.315). Pelvic lymph node dissection rate was 42.2% in Group 1, 32.7% in Group 2, and 52.2% in Group 3, and there was no difference among the groups. A median lobe was detected in 44 (40.4%) patients in Group 1 and in 3 (5.8%) patients in Group 2, however none of the patients in Group 3 had median lobes. There was no difference among the groups for the length of hospital stay, drain removal time or urethral catheter removal time. Final pathology report mean Gleason scores and pathological T stages were similar among the study groups. There was no difference among the groups for extracapsular spread, seminal vesicle invasion or lymph node positivity. Surgical margin positivity was 30.3% in Group 1, 19.2% in Group 2 and 21.7% in Group 3, without any difference (p=0.296). The surgical margin was positivity rate at the bladder neck level was 8.3% in Group 1, 5.8% in Group 2 and 4.3% in Group 3, and there was no difference among the study groups (p=0.774). The complications were graded as Clavien grade 1 in 11 patients and Clavien grade 2 in 16 patients in Group 1; Clavien grade 1 in 4 patients, Clavien grade 2 in 3 patients and Clavien grade 3 in 1 patient in Group 2; and Clavien grade 1 in 1 patient in group 3, and there was no difference among the groups for complication rates (Table 2).

The rate of fully continent patients at the postoperative 1st month was 39.1% in Group 3, 27.5% in Group 1 and 32.7% in Group 2 (p=0.483). There was no significant difference among the groups for the rates of patients with mild, moderate or severe incontinence. The rate of fully continent patients at the postoperative 3rd month was 56.5% in Group 3, 51.9% in Group 2 and 43.1% in Group 1 (p=0.361). At postoperative third month, there was no significant difference among the groups for the rates of patients with mild and severe incontinence, however the rate of moderate incontinence was higher in Group 1 compared to other study groups (p=0.019).

The rate of fully continent patients was 82.6% in Group 3, 73.1% in Group 2 and 61.5% in Group 1 in postoperative 6th month (p=0.079). There was no difference among the groups for mild incontinence rates, however there was a significant difference for moderate incontinence rates (15.6%, 5.8% and 0 for Groups 1, 2 and 3,

respectively) (p=0.034). Severe incontinence was not observed in Groups 2 and 3 in postoperative 6th month.

Table 2: Peri- and postoperative clinical data of the study groups

	Group 1 (n=109) mean (min-max)	Group 2 (n=52) mean (min-max)	Group 3 (n=23) mean (min-max)	p value
Peri-operative parameters;				
Surgery duration (min)	210.8 ± 47.04 (120-420)	201.4 ± 44.4 (90-310)	197.04 ± 32.5 (135-265)	0.39
Anastomosis duration (min)	28.04 ± 9.28 (15-70)	24.6 ± 6.6 (10-45)	22.3 ± 6.3 (10-35)	**0.011***
Estimated blood loss (mL)	266.2 ± 333.04 (25-2000)	188.9 ± 122.7 (10-700)	210.9 ± 162.3 (50-700)	0.93
Nerve bundle preservation;				
-Unilateral	19 (17.4%)	8 (15.4%)	7 (30.4%)	0.32
-Bilateral	19 (17.4%)	13 (25%)	2 (8.7%)	
Lymph node dissection	46 (42.2%)	17 (32.7%)	12 (52.2%)	0.27
Presence of median lobe	44 (40.4%)	3 (5.8%)	0	**0.000***
Postoperative parameters;				
Hospital stay (days)	5.74 ± 3.2 (2-17)	5 ± 2.9 (2-20)	4.96 ± 2.7 (3-14)	0.28
Drain removal time (days)	4.7 ± 3.3 (1-16)	3.8 ± 2.86 (1-19)	4.4 ± 4.96 (1-23)	0.12
Urethral catheter removal time (days)	14.1 ± 2.88 (10-22)	14.7 ± 5.02 (10-43)	14.1 ± 3.8 (10-26)	0.96
Final pathology results;				
Gleason score	6.7 ± 0.75 (6-9)	6.85 ± 0.64 (6-9)	6.78 ± 0.67 (6-9)	0.29
Pathologic T stage; -T2a	26 (23.9%)	9 (17.3%)	6 (26.1%)	
-T2b	3 (2.8%)	0	0	
-T2c	32 (29.4%)	23 (44.2%)	7 (30.4%)	0.46
-T3a	39 (35.8%)	13 (25%)	7 (30.4%)	
-T3b	9 (8.3%)	7 (13.5%)	3 (13%)	
Surgical margin positivity	33 (30.3%)	10 (19.2%)	5 (21.7%)	0.3
Bladder neck surgical margin positivity	9 (8.3%)	3 (5.8%)	1 (4.3%)	0.77
Extracapsular invasion	46 (42.2%)	20 (38.5%)	10 (43.5%)	0.91
Seminal vesical invasion	9 (8.3%)	7 (13.5%)	3 (13%)	0.56
Lymph node positivity	4 (3.7%)	3 (5.8%)	2 (8.7%)	0.71
Complications;				
Clavien-Dindo Grade 1	11 (10.1%)	4 (7.7%)	1 (4.3%)	
Clavien-Dindo Grade 2	16 (14.7%)	3 (5.8%)	0	0.14
Clavien-Dindo Grade 3	0	1 (1.9%)	0	

*statistically significant

Table 3: The incontinence grade rates of the study groups in postoperative 1st, 3rd, 6th and 12th months

		Full continence n(%)	Mild incontinence n(%)	Moderate incontinence n(%)	Severe incontinence n(%)
Postoperative 1st month	**Group 1 (n=109)**	30 (27.5%)	20 (18.4%)	36 (33%)	23 (21.1%)
	Group 2 (n=52)	17 (32.7%)	14 (26.9%)	13 (25%)	8 (15.4%)
	Group 3 (n=23)	9 (39.1%)	6 (26.1%)	6 (26.1%)	2 (8.7%)
	p	0.483	0.405	0.540	0.312
Postoperative 3rd month	**Group 1 (n=109)**	47 (43.1%)	22 (20.2%)	30 (27.5%)	10 (9.2%)
	Group 2 (n=52)	27 (51.9%)	18 (34.6%)	5 (9.7%)	2 (3.8%)
	Group 3 (n=23)	13 (56.5%)	6 (26.2%)	3 (13%)	1 (4.3%)
	p	0.361	0.145	**0.019***	0.467
Postoperative 6th month	**Group 1 (n=109)**	67 (61.5%)	22 (20.2%)	17 (15.5%)	3 (2.8%)
	Group 2 (n=52)	38 (73.1%)	11 (21.1%)	3 (5.8%)	0
	Group 3 (n=23)	19 (82.6%)	4 (17.4%)	0	0
	p	0.079	0.932	**0.034***	0.700
Postoperative 12th month	**Group 1 (n=109)**	79 (72.5%)	22 (20.2%)	6 (5.5%)	2 (1.8%)
	Group 2 (n=52)	42 (80.8%)	8 (15.4%)	2 (3.8%)	0
	Group 3 (n=23)	21 (91.3%)	2 (8.7%)	0	0
	p	0.118	0.344	0.771	1.000

*statistically significant

In the postoperative 12th month, the rate of fully continent patients was 91.3% in Group 3, 80.8% in Group 2 and 72.5% in Group 1 (p=0.118). There were no patients with severe incontinence in Groups 2 and 3, however severe incontinence was detected in 2 (1.8%) patients in Group 1 (Table 3).

Discussion

Incontinence rate following RP has been decreasing thanks to modified surgical techniques, however PPI remains as the most feared complication for men.[13] Continence status is the most important determinant of quality of life in patients who are undergoing RP, and has a more significant effect than erectile function.14

Urinary continence is achieved by the coordination of the urethral suspension mechanism, which consists of the detrusor muscle, internal sphincter, external sphincter and pubourethral ligaments.[15,16] During RP, these structures are partially damaged or completely removed. Therefore, the etiology of postprostatectomy incontinence is multifactorial (de novo detrusor instability, internal sphincter failure, external sphincter failure due to pudendal nerve damage, decreased length of membranous urethra).[17,18]

PPI rates ranging from 4% to 30% have been reported after RARP.7 It has been supposed that this wide difference is mainly due to the lack of standardization regarding the definition of PPI.[19] In a study in which PPI was evaluated with a questionnaire in the 1st year after RARP, the patients were asked "How much urine leakage do you have?", and the responses "Not at all" and "A little" were defined as continence, and "Moderate" and "Much/Very much" were defined as incontinence, and the PPI rate was reported as 14%.[20] In another study, the patients with <20 g urine leakage in the 24-hour pad test were considered continent and the incontinence rate was reported as 6%.4 A prospective, controlled, nonrandomized study compared RARP and RRP, incontinence at the postoperative 12th month was considered as at least one pad changed per 24 h, and the incontinence rate was reported as 21.3% in the RARP arm and 20.2% in the RRP arm.6 As seen in all those studies, a common language has not been developed for the definition of PPI. In our study, 24-hour pad test was used for the standardization of incontinence, and daily urinary incontinence was defined as mild if it was < 100 g,

moderate if it was 100–400 g, and severe if it was >400 g.12 According to the results of our study, in which continence was defined as "no incontinence", the incontinence rate at the postoperative 12th month was 22.8% (regardless of the subgroup analysis), and our results are in line with the literature data.

The relationship between bladder neck preservation during RRP and continence was first investigated by Walsh et al.[21] Over the next 20 years, the effectiveness of sparing bladder neck in open, laparoscopic, and robotic RP procedures has been evaluated, and conflicting results have been published regarding the influence of bladder neck sparing on functional and oncologic outcomes. Preisser et al. compared the patients who had and who did not have bladder neck preservation during RARP, reported a lower incontinence rate in the ones who had bladder neck preservation only in the 1st week, after urinary catheter removal (60.0% vs. 54.5%), and no difference between the groups at the 3rd and 12th months (80.1% vs. 78.3% at third month and 85.3% vs. 89.6% at first year for bladder neck sparing and bladder neck reconstruction groups, respectively).[22] Freire et al. evaluated the effectiveness of bladder neck sparing in their RARP series, reported that the continence rates 65.6% versus 26.5% ($p<0.001$) at the postoperative 4th month in favor of bladder neck sparing, and the groups were similar in terms of continence at 12th and 24th months.[23] To determine the effective periprostatic structures in the early improvement of urinary continence following RP, Sood et al. evaluated the individual effects of preservation of nerves, bladder neck and Retzius space on early continence by comparing different RARP methods. The authors stated that the methods that preserved the bladder neck (posterior and hybrid method) had the highest continence rates in the 1st week and 1st month after RARP. They concluded that bladder neck preservation was the only significant predictor of early recovery of continence.[24] In our study, although there was no difference among the groups for incontinence rates, it was observed that bladder neck preservation reduced the severity of incontinence.

Li et al. showed that PPI improved gradually within one year after RARP and remained stable after the first year.[25] Ficarra et al. reviewed urinary continence improvement after RARP in a meta-analysis, and reported that PPI gradually decreased in the 1st postoperative year following RARP (PPI rates at 3, 6, and 12 months were 35%, 12%, and 9%, respectively).[7] In our study, incontinence rates decreased gradually in all groups until the postoperative 1st year and reached their lowest levels in the 1st year visits.

The major concern for sparing bladder neck is leaving a positive surgical margin at the level of bladder neck. In a series of 1512 RARP patients, the authors investigated the influence of sparing bladder neck on continence and biochemical recurrence, and found surgical margin positivity as 12.7% in the ones who did not have bladder neck preservation and 9.9% in the ones who had bladder neck preservation ($p=0.3$).22 Dal Moro et al. compared 88 RARP patients who had extreme bladder neck preservation with 88 RARP patients with similar characteristics who did not have bladder neck preservation, and stated that the surgical margin positivity at the bladder neck level was similar in two groups (5.7% in the extreme bladder neck spared group, 6.8% in the bladder neck unspared group). The authors concluded that extreme bladder neck preservation was oncologically safe.[11] In our study, surgical margin positivity rates at the bladder neck level were found as 8.3%, 5.8% and 4.3% in Groups 1, 2 and 3, respectively, and no difference was determined among the study groups in terms of surgical margin positivity.

Retrospective design and limited number of patients included are the major limitations of our study. Prospective randomized studies on a larger patient cohort are needed.

Conclusions

The results of this study showed that the methods that preserve the bladder neck during RARP do not have a significant effects on the continence rates, however they reduce the severity of incontinence. At the same time, bladder neck sparing procedures have been shown to be oncologically safe.

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