

Evaluation of Perioperative Clinical Parameters and Quality of Life in Patients Undergoing Radical Perineal or Retropubic Prostatectomy: A Prospective Randomized Study

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Submitted: 2023-12-19

Accepted: 2024-02-23

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Abstract

Objective: The objective of study is to investigate the effects of radical retropubic and perineal prostatectomy methods in addition to the effect of pelvic lymph node dissection on perioperative morbidities, oncological outcomes and 1-year quality of life in patients with clinically local stage prostate cancer.

Material and methods: Patients admitted to our clinic between January 2013 and March 2015 and diagnosed with clinically localized stage prostate cancer were included. A total of 103 patients were randomized into 3 groups in which 38 patients received radical perineal prostatectomy(RPP), 31 had radical retropubic prostatectomy(RRP), and 34 RRP with pelvic lymph node dissection(PLND). Age, comorbidities, preoperative Gleason scores and serum prostate-specific antigen(PSA) data as well as the surgical parameters, clinical and pathological stages, and 1-year follow-up data were recorded for each patient. "Extended prostate cancer index composite (EPIC)" and "SF-12v2" Health Survey (Version 2.0)" questionnaires were used for overall and disease-specific quality of life at month 0, 1, 6 and 12 visits.

Results: No difference was found between the groups with regard to preoperative data such as age, serum PSA levels, clinical stage, biopsy Gleason score and Charlson comorbidity index while intraoperative data for the amount of bleeding and the average amount of transfusion were significantly lower in RPP group(RPP:645cc, RRP:960cc, RRP+PLND:890cc). 1-year recurrence-free survivals for RPP, RRP, and RRP+PLND groups were 9.9 months, 11.2 months and 10.2 months, respectively, with no significant difference. Overall and prostate cancer-specific quality of life was similar for all 3 groups. No additional benefit with nerve-sparing surgery was shown in any of the groups in terms of incontinence and erectile functions.

Conclusion: Perineal dissection is beneficial in terms of the amount of bleeding and blood transfusion while prolonged postoperative drainage and wound infection rates are higher compared to retropubic approach. All 3 groups were similar in urinary, sexual, gastrointestinal and hormonal functions as well as the quality of life.

Keywords: prostatectomy, prostate cancer, perineal, retropubic, quality of life

Cite; Can U, Coskun A. Evaluation of Perioperative Clinical Parameters and Quality of Life in Patients Undergoing Radical Perineal or Retropubic Prostatectomy: A Prospective Randomized Study. New J Urol. 2024;19(1):23-33. doi: [10.33719/nju1406425](https://doi.org/10.33719/nju1406425)

INTRODUCTION

Prostate cancer (PCa) is the 2nd most frequent cancer in men and the 2nd most frequent cause of cancer-related deaths following lung cancer. The risk of developing a prostate cancer during a lifetime in men is 16% and the risk of death from prostate cancer is 2.9%(1). Prostate cancer is denoted as an important health problem particularly among the elderly male population in developed countries(2).

The number of patients with early diagnosed prostate cancer (PCa) has increased due to the widespread use of digital rectal examination(DRE), prostate specific antigen (PSA) and transrectal ultrasound (TRUS)(3,4). Today, the common use of predictive models (Partin tables, Kattan nomograms) allows prediction of pelvic lymph node metastases so that lymph node dissection can safely be excluded(5). Pelvic lymph node dissection (PLND) is recommended when the risk of nodal metastasis is higher than 5% in these nomograms(6). In low-risk PCa, PLND is shown to be unrelated to biochemical recurrence-free survival(7). This led to radical perineal prostatectomy (RPP) draw attention again. This technique has a low rate of mortality and morbidity and also incorporated nerve-sparing surgery in late 1980's(8). Perineal approach may become more popular by description of robot assisted RPP in 2015(9) and performing robotic PLND via perineal approach(10).

Large series have been published that compare the definitive treatments, radical retropubic prostatectomy(RRP) and RPP. Overall oncological outcomes and complication rates are similar, while less blood loss and need for transfusion are observed in RPP group in addition to a shorter hospital stay and less analgesic use(11–15)as a historical open procedure, is modified to incorporate contemporary surgical ideas. There is relatively little in the literature regarding modern adaptations of perineal prostatectomy. This method of anatomic radical perineal prostatectomy has been developed to accomplish a minimally invasive method of achieving goals of disease control and preservation of genito-urinary functions.\n\nMETHODS: Prospective outcome data is accumulated on 508 consecutive radical perineal prostatectomies by a single surgeon. Pathologic stage and PSA detectability are measures of cancer control. Pad use and ability to complete intercourse measure urinary and sexual function. General complications and other outcome measures are evaluated.\n\nRESULTS: Freedom from PSA detectability by pathologic stage is 96.3%, 79.4%, and 69.4% for organ confined, specimen confined and margin positive in the absence of seminal vesical invasion with an average 4 years follow up (3-114 months. In addition, side effects secondary to surgical treatment have a substantial

impact on quality of life (QoL) in clinically local stage PCa group patients with longer life expectancy. Therefore, a choice of primary definitive treatment that can minimize these side effects would be a rational approach(16). Moreover, there is a limited number of studies that investigate the influence of PLND on perioperative morbidities and no study is found in the literature on overall and PCa-specific QoL. We, therefore, aimed to prospectively compare the perioperative morbidities of RPP, RRP, and RRP+PLND techniques that we randomly applied to patients with clinically local stage PCa, and to compare the effects of surgical modalities on overall and PCa-specific QoL during the postoperative period of 1 year.

MATERIAL AND METHODS

Patients admitted to our clinic between January 2013 and March 2015 and diagnosed with clinically localized PCa (pT1-pT2) with a risk of lymph node invasion less than 5% according to Partin table were included in this study. Following the approval of ethics committee, 120 subjects that were planned to be included in the study were randomized into 3 groups. After giving informed consent to participate in the study, 120 subjects of the three groups received RPP, RRP, and RRP+PLND, respectively. 17 subjects who were lost to follow-up due to postoperative social issues or chose to discontinue were excluded from the study. The interventions were performed in our clinic by two experienced surgeons who had completed training on both surgical techniques. Subjects who had unilateral or bilateral nerve-sparing surgery were recorded.

Age, comorbidities, preoperative Gleason scores and serum PSA data as well as the duration of surgery, perioperative amount of bleeding and need for transfusion, postoperative drainage periods, and clinical and pathological stages were recorded. Clinical staging before the surgery was made using total PSA levels, DRE and TRUS-biopsy. Additionally, bone scan and pelvic MRI were performed in subjects with a total PSA level higher than 10 ng/dL. Clavien scoring system was used for perioperative complications and morbidity.

Tumor grade was determined according to Gleason grading system. All biopsy and histologic samples were graded according to 2009 TNM classification and urologic pathology samples were interpreted by an experienced pathologist. Postoperative follow-ups were carried out by clinical evaluation in each visit and by PSA levels at 1, 3, 6 and 12 months. A postoperative PSA value higher than 0.2 ng/dL was considered biochemical progression. None of the subjects with incontinence received additional medical therapy for this condition. Phosphodiesterase-5 inhibitor

was initiated in some of the patients with erectile dysfunction taking into consideration the contraindication issues and patient preferences.

Quality of life was evaluated in two steps. The first one was "The Expanded Prostate Cancer Index Composite (EPIC)" (17), a questionnaire that specific for PCa and the second was "Medical Outcomes Study 12-item Short Form Health Survey (SF-12)"(18) questionnaire that evaluated the overall QoL. Scores from these two questionnaires were recorded individually for each group before surgery (t0) and at postoperative 1 (t1), 6 (t2) and 12 (t3) months. Final scores were between 0-100 and higher scores were considered as better health related QoL. During statistical analysis, t0 score was taken as a basal value and compared to the data at postoperative 1, 6 and 12 months. Then, 3 treatment groups were compared with regard to the changes in scores during postoperative follow-ups.

Patients were asked to evaluate sexual functions using the EPIC form compared to their performance when they were not taking phosphodiesterase-5 inhibitors. The questionnaires were applied by a single doctor verbally by face to face interview with each patient. Patients given preoperative hormone replacement therapy, those with an additional disorder such as arthrosis, ankylosis or coxarthrosis that hamper exaggerated lithotomy position, and those who underwent pelvic or abdominal major surgery were excluded from the study. Post-treatment inquiries were discontinued in patients that were included in the study but were administered postoperative radiotherapy and/or hormone therapy for biochemical recurrence since the QoL scores might influence the outcomes of the study. In patients who underwent additional surgical interventions for postoperative anastomotic strictures, evaluation of the inquiry forms was continued after the second procedure.

The primary endpoint of the study was the comparison of subjects in 3 groups by urinary, sexual, gastrointestinal, hormonal, mental and physical functions and their impact on QoL at preoperative and 1 year of the postoperative period. The secondary endpoint was the comparison of subjects in 3 groups by the average duration of surgery, duration of hospitalization, duration of catheter drainage, amount of bleeding and the need for transfusion, surgical margin positiveness, complications, and 1-year biochemical recurrence.

All participants were informed that their data would be used for clinical research purposes and gave written informed consent to have their clinical data recorded in a private database. This study was approved by Kartal Dr Lütfi

Kırdar Training and Research Hospital Ethic Committee (Registration number and date:514/62/17, 26.03.2015). The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice

Statistical Analysis

Statistical analyses and randomization of the groups were carried out using SPSS (Statistical Package for Social Sciences) 22.0 statistical software package. Suitability of the variables for normal distribution was tested using One sample Kolmogorov-Smirnov. Variables with normal distribution were indicated as the mean and standard deviation. Chi-square, Kruskal-Wallis, Kaplan-Meier, one-way variance analysis (one-way ANOVA) was used for statistical analysis and ANOVA tests were used for repeated measures. Variance homogeneity was tested by Levene test. Paired post-hoc comparisons for groups with meaningful ANOVA results were made using Tukey's HSD test. $P < 0.05$ was considered as statistically significant.

RESULTS

Among 103 patients that were included in the study, 38 received RPP, 31 received RRP and 34 received RRP with PLND. No intraoperative or postoperative mortality was observed. Demographic data and clinical findings before surgery are shown in Table 1. There was no significant difference between groups in terms of mean age ($p > 0.05$). Mean serum PSA levels were similar in all 3 groups ($p > 0.05$). The comorbidity score was higher in RPP group; however, there was no significant difference between 3 groups ($p > 0.05$). There were no significant differences between the groups in terms of clinical stage and Gleason scores from 12-core prostate biopsies ($p > 0.05$).

The mean amount of bleeding during surgery, transfusion given, duration of surgery and the duration of postoperative hospital stay are shown in Table 2. The mean amount of bleeding was significantly lower in RPP group compared to other two groups ($p < 0.05$). Similarly, mean amount of blood transfusions was significantly lower in RPP group compared to RRP+PLND group. The mean duration of the surgical procedure was equal in RRP and RPP groups while it was 28 minutes longer in RRP+PLND group. No statistically significant difference was observed between the groups in terms of hospital stays ($p > 0.05$).

Data regarding prostatectomy pathologies and biochemical recurrence are demonstrated in Table 3. No significant difference was observed when 3 groups were compared for pathological stage and surgical margin positiveness. Among

34 subjects in RRP+PLND group 2 subject had lymph node invasion. Although number of subjects without recurrence was higher in RRP group at the end of the year, no statistically significant difference was found between 3 groups ($p>0.05$).

Similarly, Kaplan-Meier method was used for 1-year average recurrence-free survival and no statistically significant difference was found between 3 groups (Figure 1).

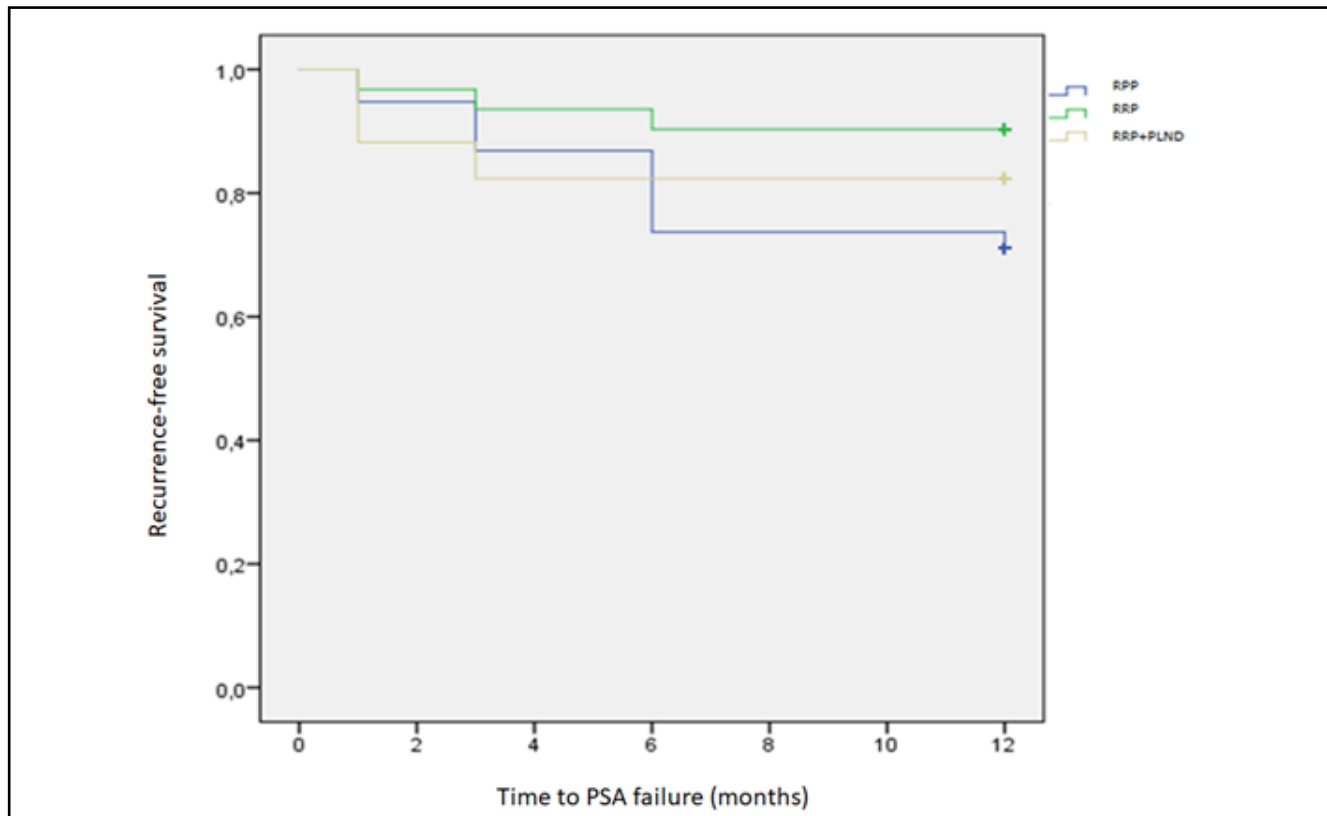


Figure 1. Kaplan-Meier curves for biochemical recurrence-free survival after RRP (blue), RRP (green) and RRP+PLND (gray)

Table 1. Preoperative demographic data and clinical findings by groups

	RRP n=38	RRP n=31	RRP+PLND n=34	p
Age (year)				
Mean(SD)	63.3(6.8)	62.7 (5.1)	63.5 (5.9)	¹ 0.875
PSA (ng/dl)				
Mean(SD)	6.1 (2.3)	6.6 (2.8)	7.5 (3,2)	¹ 0.105
Clinical stage				
T1	24 (63%)	18 (58%)	18 (52%)	² 0.680
T2	14 (37%)	13 (42%)	16 (47%)	
Biopsy gleason score				
6 ≤	31 (82%)	28 (90%)	26 (77%)	² 0.334
7	7 (18%)	3 (10%)	8 (23%)	
Charlson comorbidity score				
Mean(SD)	1.2 (1)	0.6 (0.8)	1(0.9)	³ 0.055

¹One Way Anova $p<0.05$ ²Pearson Chi-square $p<0.05$ ³Kruskal-Wallis $p<0.05$

Table 2. Intraoperative and postoperative data by groups

	RPP n=38	RRP n=31	RRP+PLND n=34	P
Amount of bleeding (cc)				
Mean(SD)	645 (340)	960 (468)	890 (420)	¹ 0.004 ³ (RPP< RRP and RRP+PLND)
Transfusion(units)				
Mean(SD)	0.4 (0.8)	0.8 (1.2)	1.1 (1.1)	² 0.032 ⁴ (RPP< RRP+PLND)
Operative duration (min)				
Mean(SD)	117 (25)	117 (40)	145 (40)	¹ 0.001 ³ (RPP and RRP< RRP+PLND)
Hospital stay (days)				
Mean(SD)	5.2 (3.2)	4.6 (2.1)	4.6(1.9)	² 0.845

¹One Way Anova $p<0.05$ ²Kruskal-Wallis $p<0.05$ ³Tukey HSD ⁴Mann-whitney-U

The complications were classified into 3 groups as intraoperative, postoperative short-term and postoperative long-term and are shown in Table 4 according to Clavien-Dindo system. Approximately one-half of the subjects in RRP+PLND group received blood transfusion which was lower in RPP and RRP groups. The proportion of patients with prolonged drainage was higher in RPP group. Anastomotic stricture, a long-term (first year) postoperative complication, was higher in RRP group. Considering overall complications, no significant difference was observed when 3 groups were compared in terms of presence of at least one complication ($p>0.05$).

Quality of life scores are summarized in Table 5. Comparison of SF-12 scores demonstrated a significant decrease in terms of physical health in all 3 groups at 1 month compared to preoperative assessment. In the comparison made according to EPIC scores, a significant decrease was observed in total urinary score including urinary function, satisfaction, continence and obstructive irritative symptoms in RPP group at 1 month compared to the preoperative assessment, and a significant increase was seen in RPP and RRP+PLND groups at 12 months compared to the preoperative assessment. Total bowel scoring that evaluates bowel functions and satisfaction showed no significant change in the groups at 1 month while a significant increase was observed at 6 and 12 months. Total hormone scores showed no statistically significant change within the first 6 months in all 3 groups while there was a significant increase only in the RRP+PLND group at 12 months compared to the preoperative assessment. Total

sexual score was significantly lower in all 3 groups throughout the visits compared to the preoperative assessment.

There was no significant difference in the visits in terms of SF-12 scores when the groups were compared for the changes in scores. In terms of EPIC scoring, the 3 groups showed no significant difference in the visits by total urinary and incontinence scores in addition to total hormone scores and total sexual scores. When only irritative and obstructive symptoms were compared to preoperative data, the improvement at 12 months was significantly lower in RRP group compared to the other groups.

Eighteen subjects in RPP group, 14 in RRP group and 17 in RRP+PLND group received no nerve-sparing surgery while 15 in RPP group, 12 in RRP and 17 in RRP+PLND had unilateral, and 5 in RPP, 5 in RRP and 10 in RRP+PLND groups had bilateral nerve-sparing surgery. There were no significant differences between the groups with regard to having received nerve-sparing surgery ($p=0.273$).

In Table 6, EPIC incontinence and sexual function scores were given as means at 1 month and 12 months in 3 groups with regard to whether nerve-sparing surgery is performed or not. Thus, no significant difference is found in terms of incontinence scores in 3 groups regarding nerve-sparing surgery ($p>0.05$). Based on the assessment for sexual function scores, 12th-month sexual function scores were higher without statistical significance in patients in all 3 groups undergoing nerve-sparing surgery compared to those who are not ($p>0.05$).

Table 3. Pathological results and biochemical recurrence data

	RPP n=38	RRP n=31	RRP+PLND n=34	P
Pathological stage				¹ 0.353
T2	25 (66%)	25 (81%)	23 (68%)	
T3	13 (34%)	6 (19%)	11 (32%)	
Surgical margin				¹ 0.710
Positive	9 (24%)	8 (26%)	6 (18%)	
Negative	29 (76%)	23 (74%)	28 (82%)	
Localisation of surgical margin				
Apex	4 (11%)	3 (10%)	3 (9%)	
Bladder neck	1 (3%)	2 (7%)	0 (0%)	
Lateral	2 (5%)	1 (3%)	0 (0%)	
More than 1	2 (5%)	2 (7%)	3 (9%)	
Number of patients with biochemical recurrence-free n (%)	27 (71%)	28 (90%)	28 (82.4%)	¹ 0.125
Recurrence free survival mean (months)	9.9	11.2	10.2	² 0.157

¹Pearson Chi-square $p < 0.05$ ²Kaplan-Meier $p < 0.05$

Table 4. Intraoperative and postoperative complications (Clavien-Dindo classification)

	RPP n=38	RRP n=31	RRP+PLND n=34	Müdahale
Clavien grade/Complication				
<i>Intraoperative</i>				
II Bleeding	9 (26%)	10 (29%)	16 (46%)	Blood Transfusion
<i>Postoperative short period</i>				
I Wound infection	4 (11%)	1 (3%)	3 (9%)	Antibioterapy, bedside intervention
Prolonged drainage	7 (18%)	1(3%)	0 (0%)	Long time urethral cateterisation
Id Anastomotic leakage	1 (3%)	0 (0%)	0 (0%)	Long time urethral cateterisation
II Urinary infection	0 (0%)	2 (7%)	1 (3%)	Antibioterapy
Hematuria	1 (3%)	0 (0%)	0 (0%)	Conservative approach+ blood transfusion
<i>Postoperative long period</i>				
IIIa Anastomotic stricture	1 (3%)	5 (16%)	2 (6%)	Endoskopik bladder neck incision
Total (At least 1 complication)	20 (53%)	15 (48%)	18 (53%)	² P=0.919

²Pearson Chi-square $p < 0.05$

Table 5. HRQoL scores by treatment groups (EPIC and SF-12)

	RPP Mean(SD)	RRP Mean(SD)	RRP+PLND Mean(SD)	P value (repeat measures of ANOVA)	
SF-12					
Physical health				0.557	
Preoperative (t0)	53.8 (7)	55 (5.9)	54.5 (5.4)		Not significant
1 st month (t1)	49.1 (6.6)*	45 (6.3)*	43.5 (7.3)*		Not significant
6 th month (t2)	53.5 (4.9)	54.7 (3.4)	53.1 (5)		Not significant
12 th month (t3)	54 (6.4)	54.2 (3.9)	53.7 (5.1)		Not significant
Mental health				0.242	
Preoperative (t0)	52.8 (6.5)	50.3 (6.7)	51.8 (4.2)		Not significant
1 st month (t1)	53.4 (5.8)	50.9 (8.2)	51.9 (6.5)		Not significant
6 th month (t2)	54.4 (5.9)	53.7(3.8) ⁺	55.3(1.9)*		Not significant
12 th month (t3)	54.9 (6)	54.5 (3.2)*	55.3 (2.2)*		Not significant
Total urinary				0.218	
Preoperative (t0)	84.7 (11.8)	81.3 (13.3)	83.9 (14.4)		Not significant
1 st month (t1)	74.6 (13)*	78.4 (13)	79.4 (11.9)		Not significant
6 th month (t2)	90 (10.1)	84.6 (14.7)	89.2 (11.2)		Not significant
12 th month (t3)	94.7 (8.6)*	86.8 (14.2)	92.5 (8.4) ⁺		Not significant
Incontinence				0.811	
Preoperative (t0)	99 (2.9)	99 (3)	99.3 (2)		Not significant
1 st month (t1)	54.2 (25.5)*	69.6 (23.2)*	66.2 (24)*		Not significant
6 th month (t2)	86.9 (17.7)*	83.2 (22.3)*	86.4 (23.6)*		Not significant
12 th month (t3)	95.6 (11.7)	90.2 (14.3)*	92.6 (17.2)		Not significant
Irritative/obstructive symptoms				0.019	
Preoperative (t0)	79 (16.8)	73 (18.5)	75.9 (20.5)		Not significant
1 st month (t1)	89 (8.6)*	85.5 (8.3)*	89.4 (8.7)*		Not significant
6 th month (t2)	92.5 (7.8)*	86.6 (10.8)*	91.7 (5.8)*		Not significant
12 th month (t3)	95 (8)*	86.6 (13.5)*	93.1 (5.6)*		Significant
Total Bowel				0.612	
Preoperative (t0)	93.8 (6.7)	95.4 (3.8)	95.9 (2)		Not significant
1 st month (t1)	93.3 (7.4)	94.2 (5.6)	93.5 (5.8) ⁺		Not significant
6 th month (t2)	97.4 (6)*	97.2 (3.6)*	98.3 (2.8)*		Not significant
12 th month (t3)	97.2 (5.9)*	98 (2.3)*	97.9 (2.7)*		Not significant
Total Hormone				0.644	
Preoperative (t0)	97.6 (3)	96.7 (3.2)	96.7 (3.8)		Not significant
1 st month (t1)	96.8 (2.8)	96.3 (4.3)	95.5 (4)		Not significant
6 th month (t2)	97.6 (2.5)	97.8 (2.9)	96.8 (3.3)		Not significant
12 th month (t3)	97.9 (3.9)	97 (3.7)	99.1 (1.9)*		Not significant
Total sexual				0.529	
Preoperative (t0)	71.6 (11)	72.4 (7.5)	70.4 (11.3)		Not significant
1 st month (t1)	22 (5.8)*	22.5 (6.7)*	21.4 (3.8)*		Not significant
6 th month (t2)	26.4 (15)*	28.6 (16.8)*	25.9 (12.6)*		Not significant
12 th month (t3)	33.3 (20)*	36.5 (19.9)*	30.4 (15.1)*		Not significant

* $p < 0.01$, The difference between before and after treatment is significant+ $p < 0.05$, The difference between before and after treatment is significant

Table 6. Incontinence and sexual function scores at 1 month and 12 months according to whether nerve-sparing surgery is performed or not

Nerve sparing surgery				
		No n (SD)	Yes n (SD)	P (One Way ANOVA)
Incontinence score				
RPP	t0 (n=38)	54 (23.5)	59.1 (28.4)	0.558
	t12 (n=29)	95 (12.1)	96 (11.8)	0.807
RRP	t0 (n=31)	72.4 (23.8)	66 (21.2)	0.437
	t12 (n=27)	89.8 (15.3)	90.7 (13.9)	0.878
RRP+PLND	t0(n=34)	60.5 (19.3)	69.6 (27.8)	0.273
	t12 (n=28)	94.2 (11.1)	90.7 (22.6)	0.605
Sexuel function score				
RPP	t0 (n=38)	6.1 (5.3)	6.4 (6)	0.867
	t12 (n=29)	21 (17.1)	25.7 (27.1)	0.606
RRP	t0 (n=31)	7.7 (6.6)	6.3 (4.9)	0.501
	t12 (n=27)	23.7 (25.3)	26.4 (23)	0.777
RRP+PLND	t0 (n=34)	4.9 (2.1)	6.4 (5.1)	0.261
	t12 (n=28)	16.6 (13.8)	24.3 (24.2)	0.303

DISCUSSION

Factors including the lack of equivalence among patient groups in terms of demographic data, biochemical and oncological parameters demonstrate the need for prospective randomized trials. Differences were found regarding preoperative data (serum PSA, clinical stage, etc.) in some previous non-randomized trials(14,15,19–21) that compare various routes of dissection which led to nonobjective assessments of intraoperative and postoperative data and pathologic results. In a prospective randomized study published by Martis et al. in 2007, 200 subjects were administered RPP and RRP where two groups were similar in terms of both pathological and clinical data which enhanced the reliability and the quality of the study (13). Similarly, in our study, no significant difference was found between 3 groups in terms of preoperative data including age, serum PSA, clinical stage, biopsy Gleason score and Charlson comorbidity index. Despite the benefit seen with perineal dissection in terms of the amount of bleeding and transfusion, no additional benefit was shown with regard to the duration of the procedure (compared to RRP without lymph node dissection), duration of hospital stay, pathological data and biochemical recurrence-free survival. Large trials that compare series of RPP and RRP highlight a shorter hospital stay and a lower amount of bleeding in the perineal group while no difference is observed in terms of oncological and functional outcomes (15,21). In Clavien complication

assessment, perineal dissection has similar benefits in terms of blood transfusion while the duration of postoperative drainage and wound infection is higher compared to other groups. The duration of hospital stay is longer in RPP group in this study compared to other trials. We associate this with increased wound discharge seen in RPP group leading to a prolonged hospital stay. Our study shows similarities with regard to sample pathology, Gleason grading, surgical margin positiveness and biochemical recurrence data when compared to other studies (22,23) perineal, and laparoscopic radical prostatectomy for organ-confined prostate cancer (pT2. In addition to predictive factors that influence the data, we think that surgical experience and good anatomical knowledge are also parameters that affect the outcomes.

Quality of life have been employed in many large series following PCa treatment and were shown to demonstrate no difference with regard to treatment method used (24–26). We observed in our study that physical health has reached preoperative values in the long-term while mental health was better than preoperative values. We think that this demonstrates the positive effect of surgery on overall quality of life. EPIC that we used in this study is an extensive and up-to-date questionnaire that evaluates the functional status of the patients and their satisfaction regarding this condition after PCa treatment (17). Accordingly, there was no statistically significant difference when 3 groups were compared in terms of the change in urinary functions. What draws attention is

that the total urinary score including irritative and obstructive symptoms and patient satisfaction was increased at 12 months in all 3 groups compared to preoperative data. This has shown that the QoL regarding urinary system may be improved in patients with preoperative lower urinary system symptoms provided that appropriate postoperative incontinence rates are achieved. A multicenter study performed by Namiki et al. (14) that compared RRP, RPP, and LRP methods, evaluated the overall QoL (SF-36) and UCLA prostate cancer index (UCLA-PCI) during the 1-year follow-up. Evaluations of physical and mental health show similarities to our study while the urinary function was found to be worse in all 3 groups in all postoperative visits. This may be associated with the absence of questions in UCLA-PCI regarding irritative and obstructive symptoms. In a retrospective study by Mirza et al. in 2011 that included a total of 463 subjects who received RPP, RRP and RALP (robot-assisted laparoscopic prostatectomy), (27) no significant difference was found between the 3 groups in terms of total urinary score and the use of pads in addition to sexual, intestinal and hormonal parameters when EPIC scores in the time window of 12-18 months were evaluated in some of the subjects. The absence of preoperative basal data and retrospective design have been emphasized as the weaknesses of the study. Similarly, no difference was observed between the groups for total sexual scores while postoperative low scores were still being seen at 12 months. In the literature, the rates of postoperative erectile dysfunction have been reported to be 25-90% (28,29). However, potency is shown to be between 31-86% among those who received bilateral nerve-sparing surgery. In this study, erectile function at 12 months was better in subjects who underwent nerve-sparing surgery compared to those who did not in all 3 groups where no additional benefit was shown statistically on continence and erectile functions.

Published complication rates for PLND vary between 4% and 53% led by lymphocele and lower limb edema, DVT, pelvic abscess, ureteral injury, neurovascular injury, and ileus are rare complications. In the study by Daimon et al. (30), no relation was found in low-risk PCa between PLND and biochemical recurrence-free survival, while the shorter duration of surgery and lower mortality rates were underlined in subjects without lymph node dissection. However, the general opinion is that morbidity due to PLND is minimal (31). In this study, lymph node dissection resulted in no additional morbidity in 34 patients that received RRP+PLND and no disadvantages in terms of 1-year overall and PCa-specific QoL. No study in the literature has demonstrated the influence of PLND on QoL. We demonstrated the positive or negative effects of PLND on

both PCa-specific and overall QoL by applying PLND in one of the groups. We found no disadvantage on EPIC score or both physical and mental QoL, or postoperative complications. Furthermore, intraoperative parameters indicated that the duration of surgery was approximately 28 minutes longer and the rate of blood transfusions was higher in PLND group compared to the other two groups. The impact of prolonged surgery on the anesthesiologist might have led to the higher transfusion rates seen in RRP+PLND group despite the lack of significant difference in the average amount of bleeding compared to RRP.

The strengths of the study may be that it has a prospective randomized design, involves homogenized subject groups, and uses follow-up questionnaires specific to PCa. The low number of subjects, the short duration of follow-up for oncological results as well as the scoring being done by face-to-face interviews between the doctor and the patient due to the absence of Turkish validation of the EPIC inquiry form are the weaknesses of this study.

CONCLUSION

Outcomes with higher levels of evidence may be achieved by a prospective randomized study that involves the effects of PLND on QoL, that includes a higher number of homogenized subjects and longer duration of follow-up and that can also compare methods that are specified as minimally invasive.

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