

Urological Oncology

Clinical Experience with Limited Lymph Node Dissection for Prostate Cancer in Korea: Single Center Comparison of 247 Open and 354 Robot-Assisted Laparoscopic Radical Prostatectomy Series

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Purpose: There are limited data on the role of limited pelvic lymph node dissection (PLND) in patients with prostate cancer in Korea. The objective of this study was to demonstrate our clinical experience with limited PLND and the difference in its yield between open retropubic radical prostatectomy (RRP) and robot-assisted laparoscopic radical prostatectomy (RALP) for prostate cancer patients in Korea.

Materials and Methods: We retrospectively analyzed 601 consecutive patients undergoing radical prostatectomy and bilateral limited PLND by either RRP (n=247) or RALP (n=354) in Asan Medical Center. All patients were divided into three groups according to the D'Amico's risk stratification method. Clinicopathologic data, including the yield of lymph nodes, were thoroughly reviewed and compared among the three risk groups or between the RRP and RALP subjects.

Results: The mean patient age was 64.9 years and the mean preoperative prostate-specific antigen was 9.8 ng/ml. The median number of removed lymph nodes per patient was 5 (range, 0 to 20). The numbers of patients of each risk group were 167, 199, and 238, and the numbers of patients with tumor-positive lymph nodes were 1 (0.6%), 4 (2.0%), and 17 (7.1%) in the low-, intermediate-, and high-risk groups, respectively. In the high-risk group, the lymph node-positive ratio was higher in RRP (14.9%) than in RALP subjects (2.4%).

Conclusions: We speculate that limited PLND may help in prostate cancer staging in intermediate- and high-risk prostate cancer groups. RRP is a more effective surgical modality for PLND than is RALP, especially in high-risk prostate cancer groups.

Key Words: Lymph node excision; Prostatectomy; Prostatic neoplasms

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INTRODUCTION

In Korea, prostate cancer is the fifth most common malignancy in men [1]. With the introduction of prostate-specific antigen (PSA)-based screening, the clinical stage of newly diagnosed prostate cancer has been migrating downward in the United States [2]. In Korea, however, more than half of newly diagnosed prostate cancer cases are still at an advanced stage [3]. In addition, prostate cancer in Korean patients exhibits poor differentiation and is adversely related

to prognosis after radical prostatectomy [4].

For efficient management of prostate cancer, pelvic lymph node dissection (PLND) is a well accepted staging modality. According to the current guidelines of the European Association of Urology (EAU), for men undergoing radical prostatectomy with intermediate and high risk of prostate cancer, extended PLND is strongly recommended [5]. However, the clinical indications for PLND in low-risk patients and its therapeutic benefits in such patients are controversial [6]. It was reported that limited

PLND is associated with lower complication rates and a shorter hospital stay than is extended PLND [7].

Advanced prostate cancer is common in Korea and is usually found to be poorly differentiated. Before the introduction of robot-assisted laparoscopic radical prostatectomy (RALP), retropubic radical prostatectomy (RRP) was the standard operation method in Korea for a long time. However, even though RALP has increased during the past several years, few studies have investigated the validity of PLND in RRP and RALP. Furthermore, there have been no clinical results, to our knowledge, about the effectiveness of limited PLND in radical prostatectomy. Therefore, the purpose of the present study was to assess the value and effectiveness of limited PLND by reviewing patients with clinically localized prostate cancer undergoing radical prostatectomy and PLND in Korea.

MATERIALS AND METHODS

We analyzed the clinical data of patients with prostate cancer who were treated by radical prostatectomy. From August 2007 to December 2011, a total of 605 patients underwent RRP or RALP with bilateral limited PLND at our hospital. Four patients who were missing complete information on preoperative PSA, clinical stage, and biopsy Gleason sum were excluded from the analysis.

RRPs (n=247) were performed through a lower midline incision by using a technique proposed by Walsh and Donker [8]. RALPs (n=354) were performed as described previously [9]. Limited PLNDs consisted of removing the fibrofatty tissue medial to the external iliac vein, with the distal limit being the circumflex iliac vein. The proximal limit was the bifurcation of the common iliac artery. We completely excised the fibrofatty tissue within the obturator fossa. All lymph node specimens were sent *en bloc* for permanent section pathological analysis.

Variables collected included age, preoperative PSA, biopsy Gleason score, clinical stage, pathologic Gleason score, pathologic stage, and number of total and tumor-positive lymph nodes. Patients were stratified according to the D'Amico classification [10]. Prostate specimens were staged by using the 2010 American Joint Committee on Cancer tumor-node-metastasis staging system [11]. Biochemical recurrence (BCR)-free survival was evaluated by using a single serum PSA measurement of 0.04 ng/ml or greater. Cause of death was attributed to prostate cancer if prostate cancer was recorded as the underlying cause of death or if a patient with hormone-refractory metastatic prostate cancer died. Overall, mortality was defined as death from all causes. Mortality status and cause of death were obtained from the patient's medical record. The Student's t-test and one-way analysis of variance were used for continuous variables, and the chi-square test was used for categorical variables. The association between each predictive factor for node-positive disease and the presence of lymph node metastases were assessed by univariate and multivariate logistic regression analysis. p-values (2-sided)

< 0.05 were considered statistically significant. BCR was estimated via the Kaplan-Meier method. All statistical data were analyzed by PASW ver. 18.0 (IBM Co., Armonk, NY, USA).

RESULTS

The mean age of the 601 patients in the study was 65.0 years (range, 41 to 78 years). Of the total patients, 41% (n=247) were treated with RRP and 59% (n=354) were treated with RALP (Table 1). Mean serum PSA at diagnosis was 9.84 ng/ml (range, 0.04 to 96.61 ng/ml). The clinical stage was T2a or lower in 84.4%, T2b in 4.8%, and T2c or more in 10.8% of the patients. The preoperative Gleason scores obtained by transrectal biopsy of the prostate were 6, 7, and 8 or more in 36.9%, 34.3%, and 28.8% of patients, respectively.

Table 1 shows the descriptive statistics of all patients according to the method of prostatectomy. Compared with that in the patients who underwent RALP, the ratio of tumor-positive lymph nodes to the total number of removed lymph nodes was higher in RRP patients (1.9% vs. 5.8%, p=0.038). In the D'Amico low-risk patient group, however, there was no significant difference in the ratio of tumor-positive lymph nodes to total lymph nodes removed between the RRP and the RALP groups (p=0.373). The preoperative Gleason score and clinical stage were not significantly different between RALP and RRP patients.

The median number of removed lymph nodes per patient was 5 (range, 0 to 20). Lymph node metastases were identified in 21 patients (3.6%), whereas no lymph node involvement was identified in 579 patients (96.4%) undergoing RRP or RALP. Out of 22 patients, 17 (77.3%) had only one tumor-positive lymph node, whereas 2 (9.1%) and 3 pa-

TABLE 1. Patient characteristics and perioperative data

Characteristic	RALP	RRP	p-value
No. of patients	354	247	
Median age (yr)	64.03±7.47	66.38±5.86	< 0.001 ^a
Preoperative PSA (ng/ml)	8.41±8.38	11.88±13.32	< 0.001 ^a
Preoperative Gleason score	6.98±0.98	7.09±1.05	0.208 ^a
Clinical stage			0.853 ^b
≤ cT2a	301	206	
cT2b	16	13	
≥ cT2c	37	28	
Pathologic stage			0.009 ^b
≤ T2c	229	141	
T3	95	65	
≥ T3b	30	41	
Lymph node yield	5.83±3.28	4.59±2.95	0.031 ^a
Positive lymph node	7 (1.9)	14 (5.7)	0.038 ^b

Values are presented as mean±SD or number (%).

RALP, robotic-assisted laparoscopic prostatectomy; RRP, retropubic radical prostatectomy; PSA, prostate-specific antigen.

^a:Student's t-test, ^b:Chi-square test.

TABLE 2. Patient demographics according to D'Amico's low-, intermediate-, and high-risk groups

Variable	Low-risk group	Intermediate-risk group	High-risk group	p-value
Patients	167	198	237	
Age (yr)	63.80±6.95	64.79±7.11	66.00±6.69	0.006 ^a
Method				0.191 ^a
RRP	104 (62.7)	121 (61.1)	129 (54.4)	
RALP	62 (37.3)	77 (38.9)	108 (45.6)	
No. of nodes yielded				0.558 ^b
1-5	102 (61.4)	115 (58.1)	151 (63.7)	
6-10	52 (31.3)	67 (33.8)	69 (29.1)	
11-20	12 (7.2)	16 (8.1)	17 (7.2)	
No. of patients with positive nodes (%)	1 (0.5)	4 (2.0)	17 (7.2)	0.001 ^b

Values are presented as mean±SD or number (%).

RRP, retropubic radical prostatectomy; RALP, robotic-assisted laparoscopic prostatectomy.

^a:One-way analysis of variance, ^b:Chi-square test.

TABLE 3. Comparison of lymph node-positive ratio between RRP and RALP in the D'Amico risk groups

Group & method	Positive lymph node	Negative lymph node	p-value
Low-risk group			0.373 ^a
RALP	0 (0)	104 (100)	
RRP	1 (1.6)	61 (98.4)	
Intermediate-risk group			0.159 ^a
RALP	4 (3.3)	117 (96.7)	
RRP	0 (0)	77 (100)	
High-risk group			0.004 ^a
RALP	3 (2.4)	126 (97.6)	
RRP	14 (13.1)	94 (87.9)	

Values are presented as number (%).

RALP, robotic-assisted laparoscopic prostatectomy; RRP, retropubic radical prostatectomy.

^a:Fisher's exact test.

tients (13.6%) had two and three tumor-positive lymph nodes, respectively.

According to the D'Amico classification, the number of low-, intermediate-, and high-risk patients was 167, 198, and 237, respectively. The mean age in each group was 63.80±6.95, 64.79±7.11, and 66.00±6.69 years in the low-, intermediate-, and high-risk patients, respectively ($p=0.006$; range, 44 to 78) (Table 2). The median lymph node yield for all D'Amico risk groups was 5 (range, 0 to 16, 0 to 20, and 1 to 17 in the low-, intermediate-, and high-risk patients, respectively). There was no significant difference between mean lymph node yields for the low-, intermediate-, and high-risk groups ($p=0.558$). The number of patients with positive lymph nodes in the low-, intermediate-, and high-risk groups was 1 (0.5%), 4 (2.0%), and 17 (7.2%), respectively, which was statistically significant ($p=0.001$).

Compared with that in the patients who underwent RALP, the presence of tumor-positive lymph nodes was

more commonly identified in RRP patients among high-risk patients ($p=0.002$) (Table 3). RRP had a higher lymph node yield than did RALP in the high-risk group (5.54±3.21 vs. 4.84±3.44, $p=0.004$). Therefore, RRP was more effective for PLND than was RALP in the high-risk group.

The mean follow-up period after the operation was 13.9 months (range, 0 to 54) in our study. BCR was identified in 145 patients, and only 1 patient (0.1%) died of the disease. According to the univariate analysis, preoperative PSA, biopsy Gleason score, D'Amico risk group, presence of extracapsular extension, seminal vesicle invasion, and positive lymph node status were significantly associated with BCR (each $p<0.05$) (Table 4). In the multivariate analysis, only preoperative PSA, extracapsular extension, seminal vesicle invasion, and lymph node-positive status were independent predictors of BCR. Figs. 1, 2 show the Kaplan-Meier recurrence-free probability, stratified by lymph node status and operation method, respectively. We observed a shorter BCR in the lymph node-positive groups ($p<0.001$), but no significant difference between the RRP and RALP groups ($p=0.151$).

DISCUSSION

In prostate cancer management, the incidence of lymph node metastasis in clinically localized prostate cancer is reported to range from 2 to 57% [12-14]. However, very few studies have evaluated lymph node metastasis of prostate cancer in Korea. In addition, the difference in the effectiveness of PLND, RRP, and RALP has not been reported. Our data show that lymph node metastases were identified in 3.6% patients with limited PLND and that most patients (86.4%) undergoing radical prostatectomy with lymph node metastasis had only one or two positive lymph nodes. Furthermore, there was only one patient with a tumor-positive lymph node in the low-risk group. Thus, we speculate that PLND may not be worthwhile in low-risk patients in Korea, which agrees with the practice in Western coun-

TABLE 4. Univariate and multivariate Cox regression of BCR predictors in prostate cancer

Predictor	Univariate			Multivariate		
	HR	95% CI	p-value	HR	95% CI	p-value
Operative method (RRP vs. RALP)	1.289	0.915-1.817	0.147	0.895	0.615-1.302	0.561
PSA			<0.001			0.032
10 or less	1	-	-	1	-	-
10-20	1.856	1.237-2.786	0.030	1.561	0.982-2.481	0.060
20 or greater	2.977	1.920-4.616	<0.001	1.889	1.099-3.249	0.021
Biopsy Gleason score			<0.001			0.186
6 or less	1	-	-	1	-	-
7	1.847	1.171-2.913	0.008	1.654	0.817-3.351	0.162
8 or greater	3.228	2.136-4.876	<0.001	2.216	0.939-5.232	0.069
D'Amico risk group			<0.001			0.835
Low	1	-	-	1	-	-
Intermediate	1.503	0.903-2.500	0.117	0.781	0.347-1.757	0.550
High	3.235	2.066-5.065	<0.001	0.803	0.303-2.126	0.659
Extracapsular extension (yes vs. no)	2.398	1.638-3.510	<0.001	1.765	1.180-2.640	0.006
Seminal vesicle invasion (yes vs. no)	4.243	2.747-6.553	<0.001	2.580	1.568-4.247	<0.001
Lymph node status (yes vs. no)	4.844	2.699-8.694	<0.001	2.087	1.085-3.972	0.025

BCR, biochemical recurrence; HR, hazard ratio; CI, confidence interval; RRP, retropubic radical prostatectomy; RALP, robotic-assisted laparoscopic prostatectomy; PSA, prostate-specific antigen.

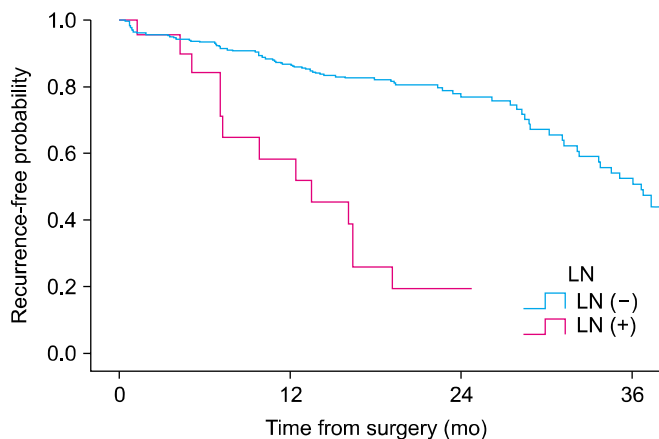


FIG. 1. Kaplan-Meier estimated biochemical recurrence-free survival in prostate cancer patients stratified by lymph node (LN) status.

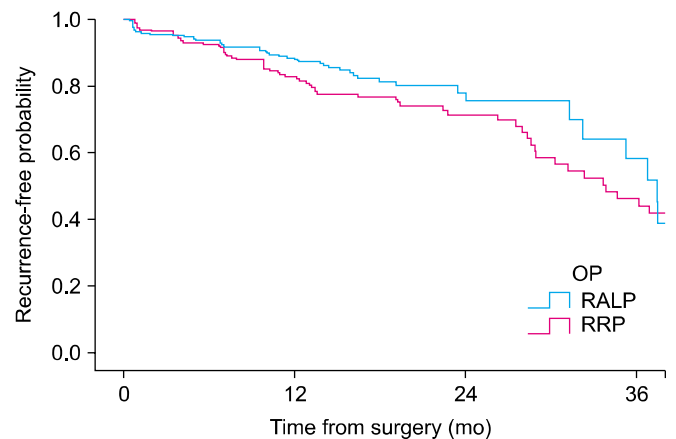


FIG. 2. Kaplan-Meier estimated biochemical recurrence-free survival in prostate cancer patients stratified by operation method. RALP, robotic-assisted laparoscopic prostatectomy; RRP, retropubic radical prostatectomy.

tries, where it is considered unnecessary [5]. On the contrary, tumor-positive lymph nodes were not negligible in the intermediate-risk (2.0%) and high-risk (7.2%) groups. In addition, this is the first study to report that lymph node yields differed according to the surgical methods used; RRP was more effective than RALP in lymph node yield for high-risk patients.

Metastatic spread of prostate cancer most commonly occurs in the pelvic lymph nodes and bones [15]. Therefore, it is very important to detect lymph node metastasis for prostate cancer management. However, the need for and extent of PLND are still controversial [5]. The risk of lymph node involvement is low in men with low-risk prostate cancer and <50% positive biopsy cores [16]. Recent studies have demonstrated that limited PLND has no positive im-

act on BCR in men undergoing radical prostatectomy for low-risk prostate cancer [17]. Cagiannos et al. [18] reported that it is appropriate to omit PLND when the nomogram predicts a probability of 1.5 to 3% or less. According to a National Comprehensive Cancer Network guideline, PLND can be excluded in patients with a <2% probability of nodal metastases predicted by nomogram [19].

In the present study, patients were stratified into low-, intermediate-, and high-risk groups according to the D'Amico classification. Low-risk patients had a PSA of 10 ng/ml or less, a biological Gleason score of 6 or less, and a T1 to T2a pathologic stage. Intermediate-risk patients had a PSA between 10 and 20 ng/ml or a biological Gleason score of 7 or a T2c pathologic stage. High-risk patients had a PSA

of greater than 20 ng/ml, a Gleason score higher than 8, or a T3 or T4 pathologic stage. The preoperative PSA level, pathologic stage, and Gleason score have been demonstrated to be the most predictive prognostic factors in patients with prostate cancer who undergo radical prostatectomy [20].

In the present study, 1 of the 167 patients (0.5%) classified as low risk had a tumor-positive lymph node. In the intermediate-risk group, four patients (2.0%) showed tumor-positive lymph nodes. Weckermann et al. [21] reported a frequency of 5.4% and 11.3% in men with low-risk prostate cancer and cT2a/b and cT2c disease, respectively. They identified positive lymph nodes in 5.4% of patients with low-risk prostate cancer and positive biopsies in only one lobe. If the biopsy Gleason score was ≤ 6 , only 2.8% of the patients were found to have positive lymph nodes.

Schumacher et al. [22] described positive lymph nodes in 11% of 231 patients with a preoperative serum PSA < 10 ng/ml, irrespective of clinical stage and biopsy Gleason score. However, the frequency of positive lymph nodes in men with organ-confined disease and a prostatectomy specimen Gleason score ≤ 6 was only 3.4%, whereas the incidence increased significantly with increasing pathologic T-stage and Gleason score. Despite the low frequency of positive lymph nodes, it would still be helpful to identify predictive variables for the presence of lymph node metastases because established nodal disease will change the clinical management of prostate cancer [6].

A nomogram, which provides highly accurate predictions of the probability of lymph node involvement during radical prostatectomy, seems to be a useful tool for the identification of patients for whom PLND can be safely avoided. However, there is no exact answer to the question of what is a safe level at which PLND can be avoided.

The complications of PLND are well known and include lymph edema; lymphocele; vascular, neural, or ureteral injury; bleeding; and hematoma [15]. Occurrence of these complications in PLND is generally low, but numerous controversies exist regarding the occurrence of complications in extended PLND. Stone et al. [23] reported a greater incidence of complications after the laparoscopic approach when they compared extended PLND with limited PLND (35.9 vs. 2%, $p < 0.001$).

We performed limited PLND to evaluate its diagnostic value. However, because we did not perform extended PLND, we could not compare the results of limited versus extended PLND. Briganti et al. [6] recommended extended PLND except in the case of low-risk prostate cancer, in which PLND is not indicated. Thus, clinical trials including extended PLND should be performed to clarify the results of this study.

A limitation of our study is that the median number of biopsy cores was only five in all cases. However, other studies that evaluated the predictive accuracy of the percentage of positive biopsies also reported a mean number of 7 to 8 biopsies [24-26]. In this study, the mean follow-up period was 13 months. This was too short to evaluate the effective-

ness of limited PLND on biochemical, disease-specific, and overall survival. Therefore, a longer follow-up time is warranted. In addition, the study lacked a prospective, multicenter validation, which is under way in an initial prospective randomized clinical phase III trial.

CONCLUSIONS

Although long-term disease control should be further evaluated, limited PLND may help in staging in intermediate- and high-risk prostate cancer groups. To clarify the results of this study, a clinical trial including extended PLND should be performed. In the D'Amico low-risk group, limited PLND might be less valuable. RRP is more effective than RALP for PLND in high-risk prostate cancer groups in Korea.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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