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Utilization of Pelvic Lymph Node Dissection for Patients with Low-Risk Prostate Cancer Treated with Robotic Assisted Radical Prostatectomy

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Abstract

Introduction—Pelvic lymph node dissection (PLND) is not recommended for low-risk prostate cancer (PCa) patients. However, the rate of PLND in this population is unknown.

Methods—We queried the National Cancer Database for PCa patients who underwent RARP from 2010 to 2013 and stratified them by D′Amico risk classification. We identified the frequency of PLND in low-risk patients and identified factors associated with receipt of PLND. Further, we determined the number of lymph nodes evaluated (quality) and proportion of patients with detected nodal metastatic disease (utility) in each risk group.

Results—Of 51,971 patients with low-risk PCa who underwent RARP, 19,059 (36.7%) received PLND. Predictors of PLND in low-risk patients included rural residence (OR 1.157, 95%CI 1.009-1.327), treatment at an academic center (OR 1.492, 95%CI 1.188-1.874), and high-volume facility (OR 1.327, 95%CI 1.078-1.633). The mean number of lymph nodes obtained in low-risk patients was lower than in intermediate/high-risk patients (4.74 vs 5.86, P<0.0001). Lymph node positivity was identified in 0.4% of low-risk patients and 4.6% of intermediate/high-risk patients.

Conclusions—While PLND is not recommended for low-risk PCa by clinical practice guidelines, it was performed frequently (36.7%) in a large hospital-based data set. PLND in this population was of lower quality (nodal yield) and had less utility of detecting nodal metastatic disease than PLND in intermediate and high-risk PCa. Treatment at a high-volume or academic center was associated with increased use of PLND. Reasons for the variation in practice patterns should be investigated to improve the value of PCa care.

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Keywords

Prostate cancer; Lymph Node Dissection; Low-risk; National Cancer Database; Guidelines

INTRODUCTION

Overtreatment of low-risk prostate cancer (PCa) in the United States has had a negative impact on the costs of care and patient quality of life[1]. The cost of PCa care is projected to reach up to $19 billion in 2020[2]. The high costs of PCa treatment can be attributed to multiple factors including the use of the robotic surgical platform[3, 4], high cost of pharmaceuticals for advanced disease[5], readmissions and post-acute care[6]. These factors, while adding cost to PCa care, may also add value. The use of unindicated treatment, on the other hand, is unlikely to contribute to improved outcomes. This overtreatment occurs most often in patients with very-low and low-risk PCa. While increased utilization of active surveillance may limit excess costs and harms of therapy in this cohort, the use of radical prostatectomy has also increased in low-risk PCa patients[7].

Pelvic lymph node dissection (PLND) at the time of radical prostatectomy for low-risk PCa is not recommended by clinical practice guidelines[8–10]. However, some data suggest that a significant proportion of low-risk PCa patients are inappropriately treated with PLND at the time of radical prostatectomy (RP)[11]. This overuse of PLND in patients unlikely to benefit from the procedure contributes to the cost and morbidity of care without adding value.

We sought to characterize the frequency, quality, and utility of PLND in a contemporary cohort of low-risk PCa patients undergoing robotic-assisted radical prostatectomy (RARP) in the U.S. Furthermore, we aimed to identify hospital and patient characteristics that are associated with the use of PLND in a low-risk population. We hypothesized that PLND was performed frequently at non-academic and low-volume centers. We expected these unindicated PLND procedures to be of low quality with fewer lymph nodes retrieved and to have poor utility with a small chance of detecting lymph node metastases, particularly when compared to a cohort of patients with intermediate or high-risk disease.

METHODS

Study population

The National Cancer Database (NCDB) was queried for patients aged 40-80 who underwent RARP for PCa from 2010 to 2013 (N = 425,811). Patients with low-risk PCa were identified by D'Amico risk criteria based on PSA < 10ng/ml, Gleason score ≤ 6 and clinical stage ≤ T2a (N = 147,694). Intermediate and high risk PCa patients were similarly identified in accordance with standard D'Amico criteria. Patients who underwent RP without robotic assistance or those with unknown or conflicted PLND status or nodal yield were excluded (N = 54,886). Further, patients with missing clinical or socioeconomic parameters were also removed, which left 51,971 patients for analysis.

Outcome and Covariates

The primary outcome of this study was the receipt of PLND. Secondary outcomes included the number of nodes retrieved as a proxy for surgical quality and the detection of nodal metastatic PCa as a proxy for the utility of PLND in this cohort.

Covariates included: age at diagnosis (40-50, 50-59, 60-69, and 70-80), race (white, black, others, and unknown), 2000 census tract annual median income (<$30,000; $30,000-$35,999; $36,000-$45,999; and $46,000+), insurance status (none, private, government, and unknown), geographic region of treating facility (northeast, south, midwest, and west), patient location (metro, urban, or rural), Charlson-Deyo comorbidity score (0, 1, or 2+), hospital academic status (academic or community), and hospital volume (high or low).

Hospital volume was calculated, based on each facility's number of RARP procedures submitted from 2010-2013. Hospitals at which ≥229 RARPs were performed (75^{th} percentile) were considered high volume centers, while those with <229 RARP over the study period were considered low volume centers.

Statistical analyses

Patients' baseline clinical and socioeconomic characteristics categorized in multiple levels were summarized in contingency tables with counts and percentages for PLND vs. no PLND. Hospital information was compiled in the same way. To account for correlation within facilities, the generalized estimation equation (GEE) approach was adopted to analyze the association of receipt of PLND with covariates of interest, in both univariate and multivariate models. For each of the models, the logit link function was employed to relate receipt of PLND with covariate(s), and exchangeable correlation structure within hospital was assumed. Unadjusted and adjusted odds ratio (OR) of receipt of PLND were reported for each covariate in the models along with 95% confidence intervals. With the number of lymph nodes retrieved as an outcome, univariate and multivariate negative binomial regression models with GEE approach equipped with log link and exchangeable correlation were fit. Estimated rate ratios (RR) along with 95% confidence intervals were calculated. All statistical tests were conducted in two-sided format with a significance level of $p \leq 0.05$. Statistical analyses were implemented using SAS 9.4 (Cary, NC).

RESULTS

A total of 51,971 patients with low-risk PCa underwent RARP from 2010-2013 in this cohort. Of these, 19,059 (36.7%) underwent PLND. A majority of patients were white, had private insurance, and resided in a metro area (Table 1). Most patients were treated at a community medical center (55.9%) and treated at a high-volume facility (82.2%).

Significant predictors of receipt of PLND for low-risk PCa in a multivariate setting included: treatment at a high-volume hospital (OR 1.327 [1.078-1.633], p=0.008), treatment at an academic facility (OR 1.492 [1.188-1.874], p=0.0006), and rural residence (OR 1.157 [1.009-1.327], p=0.038). Patients aged 50-59 were significantly less likely to receive PLND than those 40-50 years of age (OR 0.934 [0.88-0.99], p=0.022) (Table 2).

Patients with low-risk PCa had significantly fewer lymph nodes retrieved, on average, during PLND than patients with intermediate- or high-risk PCa (4.7 vs 5.9, p<0.0001). Among all patients undergoing PLND, predictors of higher nodal yield included intermediate- or high-risk PCa (RR 1.226 [1.184-1.27], p<0.0001), treatment at an academic facility (RR 1.364 [1.259-1.479], p<0.0001), treatment at a high volume hospital (RR 1.094 [1.022-1.169], p=0.008), rural residence (RR 1.053 [1.006-1.103], p=0.029), and treatment at a facility in the west region (RR 1.159 [1.032-1.301], p=0.013). Black (vs white) race was associated with fewer lymph nodes retrieved (RR 0.93 [0.91-0.952], p<0.0001)(Table 3).

Finally, nodal metastatic disease was found in 0.4% of low-risk patients who underwent PLND as opposed to 4.6% of intermediate/high risk patients. Additional exploratory analysis was conducted to evaluate the rate of PLND in low-risk PCa patients each year during the study duration (Figure 1).

DISCUSSION

We used a large hospital-based dataset to evaluate the frequency, quality (based on nodal yield), and utility (based on detection of nodal metastatic disease) of PLND for patients with low-risk PCa undergoing RARP. We found that, despite clinical practice guidelines, about one-third of patients with low-risk PCa undergoing RARP received PLND. These PLNDs resulted in lower lymph node yields than those performed for intermediate/high-risk PCa and were very unlikely to result in the detection of nodal metastases (0.4% of cases). Furthermore, contrary to our hypothesis, treatment at academic and high volume medical centers was associated with significantly higher odds of PLND.

Clinical practice guidelines have varied recommendations regarding which patients should receive concurrent PLND with radical prostatectomy. American Urological Association guidelines suggest that PLND is “generally reserved for patients with higher risk of nodal involvement”[9]. The National Comprehensive Cancer Network recommends PLND for patients with risk of lymph node invasion ≥2%[8], while the European Association of Urology recommends extended PLND for patients with a ≥5% probability of lymph node metastasis[10]. Despite the differences in these recommendations, however, PLND is not recommended for low-risk PCa by any guideline.

Schiffmann and colleagues evaluated the use of PLND in PCa patients undergoing RARP and open RP in SEER-Medicare data from 2008-2009[11]. They reported that when PLND was not recommended by National Comprehensive Cancer Network (NCCN) and American Urological Association (AUA) guidelines, it was still performed in 30% (NCCN) and 46.9% (AUA) of cases. Interestingly they also noted that surgical approach and surgeon volume were significant predictors of PLND performance. High-volume surgeons and the use of open RP approach predicted the use of PLND both when it was recommended by guidelines and when it wasn’t. Wenger and colleagues evaluated the likelihood of LN involvement at RP for patients with Gleason score ≤6 PCa from 2004-2011 using both SEER and NCDB databases[12]. They found that the use of PLND for these patients decreased over the study period and was performed in 37% (SEER) and 45% (NCDB) of patients undergoing RP in 2011. A recent analysis of the NCDB by Chalfin et al examined the use of PLND in low-risk

patients undergoing open or robotic RP from 2004 to 2013[13]. Their analysis found that robotic surgery was associated with a lower likelihood of PLND while treatment at an academic center increased the odds of PLND. In contrast to the present study, Chalfin et al did not find any association of rural residence or hospital volume with the use of PLND.

Our study, which included a contemporary cohort of patients undergoing RARP, confirmed many of the findings from other data sources and patient populations. One-third of RARP patients with low-risk PCa underwent PLND and, while individual surgeon volume was not available, treatment at a high-volume or academic center was associated with increased use of PLND for low-risk PCa patients. The motivation for using PLND in this patient population is not obvious from our data or the existing literature. We hypothesize that although financial motivation can be a potential factor in non-academic centers, plausible factors include: disagreement with the current national guidelines, varied surgical training of residents and fellows, and collection of nodal tissue for research purposes in the context of clinical trials.

While the number of lymph nodes retrieved during PLND for PCa is a controversial surrogate endpoint for the quality of RARP[14, 15], we used it to investigate differences in the performance of PLND. Our finding that significantly fewer lymph nodes were harvested in PLND performed for low-risk PCa may be the result of a poorer quality lymphadenectomy. However, an alternate explanation is that a more limited lymphadenectomy was planned for low-risk patients, perhaps reflecting the understanding that the procedure contributes to possible complications without significant benefit. While the use of a more limited lymphadenectomy may limit the risks of complications[16], it is not recommended by guidelines and would still contribute to the costs of surgery. High-volume and academic centers were associated with higher numbers of nodes harvested, which is consistent with other reports in non-low-risk PCa[17].

Our study confirmed, in this contemporary cohort, the low utility of PLND in low-risk PCa patients. Only 0.4% of patients who underwent PLND for low-risk disease were noted to have lymph node metastasis, while patients with intermediate- or high-risk were 10-fold more likely to be found to have positive lymph nodes. This is consistent with previous findings from large databases and institutional cohorts and confirms that PLND can safely be avoided in low-risk PCa patients[12]. Finally, we noted that the number of low-risk PCa patients undergoing RARP over the study period decreased, as would be expected given the increasing understanding of the biology of low-risk PCa and the increased use of active surveillance in the United States. However, the proportion of low-risk PCa patients who underwent PLND during RARP remained stable over this same time period. This suggests that, among urologists performing RARP for low-risk PCa, PLND is thought to be beneficial for low-risk patients despite guidelines or factors other than patient oncologic benefit are driving this practice.

Our results confirm that PLND is unlikely to add value to the care of low-risk PCa patients. However, the use of a limited PLND may not cause harm to patients, though we were not able to evaluate this with the available data. Nevertheless, unindicated PLNDs certainly contribute to the costs of care for these patients. In 2017, the Medicare physician fee

schedule assigns 26.8 relative value units (RVUs) to RARP (CPT 55866) and 12 RVUs to laparoscopic PLND (CPT 38571)[18]. When billed together with RARP as the primary procedure, the reimbursement for PLND is generally reduced by 50%. While the actual reimbursement will differ based on the payor and physician region, the additional physician fee for PLND performed concurrently with RARP from Medicare is approximately $347, while the reimbursement for RARP alone is estimated at $1498[18]. Adding PLND to RARP, therefore, increases reimbursement by approximately 23%. Using this calculation to generalize across the over 19,000 PLND included in this study yields a total of over $6.6 million in additional payments to surgeons for PLND at the time of RARP in low-risk PCa patients alone. While this is not a major source of RARP costs worldwide, it is not insignificant.

The strengths of this study are the use of a large hospital-based database of contemporary patients. Previous studies of the use of PLND included an earlier era of the adoption of robotic technology for RARP, which may have had an impact on the use of PLND. Additionally, previous work has demonstrated the trend over time toward minimizing the use of PLND for low-risk patients, perhaps as a result of increasing concern for overtreatment of low-risk PCa. This study also differs from others as the included population is homogenous with respect to robotic surgical approach and low-risk features. Open and laparoscopic RP were excluded as these procedures are performed in a small minority of contemporary RP procedures in the US. Open RP has been associated with significant differences in PLND use and lymph node yields when compared to RARP[11]. Furthermore, it is likely that open and laparoscopic RP are primarily performed by a different subset of urologists than RARP and the inclusion of these surgical approaches could add a confounding factor to the analyses.

Several limitations to this analysis warrant discussion. First, the use of the NCDB allowed for the collection of large, national, hospital-based data with several patient and hospital covariates. However, the limitations of the database preclude the inclusion of several potentially significant surgeon factors, including advanced training and surgeon operative volume. Additionally, the lack of long-term clinical data limits our analysis of the downstream benefits or harms of PLND in a low-risk PCa population. Furthermore, it is well known that the specific methods of pathological analysis of lymph node tissue can impact the number of lymph nodes detected and investigated[19, 20]. With this data, we are unable to account for differential processing and pathological analysis of lymph node tissue. Finally, clinical factors that can influence the decision to perform lymphadenectomy, such as an intraoperative finding of a suspicious lymph node, were not captured in this analysis.

This study demonstrates that, despite increased awareness of the overtreatment of low-risk PCa, the use of PLND in a non-guideline adherent fashion continues to occur in a significant proportion of RARP cases for low-risk PCa. These PLND procedures have a lower nodal yield than those performed for intermediate- or high- risk PCa and rarely lead to improved surgical staging for the patient. Surprisingly, treatment at academic and high volume centers is associated with the use of PLND in low-risk patients. Future efforts should evaluate both financial costs and patient complications related to these procedures. Additionally, surgeon

decision-making factors impacting the utilization of PLND, and strategies to improve guideline development and guideline adherence, should be investigated.

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Abbreviations

PLND	pelvic lymph node dissection
PCa	prostate cancer
RP	radical prostatectomy
RARP	robotic-assisted radical prostatectomy
NCDB	National Cancer Database
OR	odds ratio
RR	rate ratio

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Clinical Practice Points

Pelvic lymph node dissection is not recommended for patients with low-risk prostate cancer. Despite guidelines recommending against its use, PLND is used in a significant proportion of patients undergoing RALP for low-risk PCa. Academic and high volume centers appear to be more likely to perform PLND for low-risk patients. When PLND is performed in low-risk patients, metastatic PCa is discovered in an exceedingly small proportion (0.4%) of patients. These findings should be of interest to policy makers and urologists. Further research should be performed to identify reasons for this overuse and potentially implement policy to improve guideline concordant treatment.

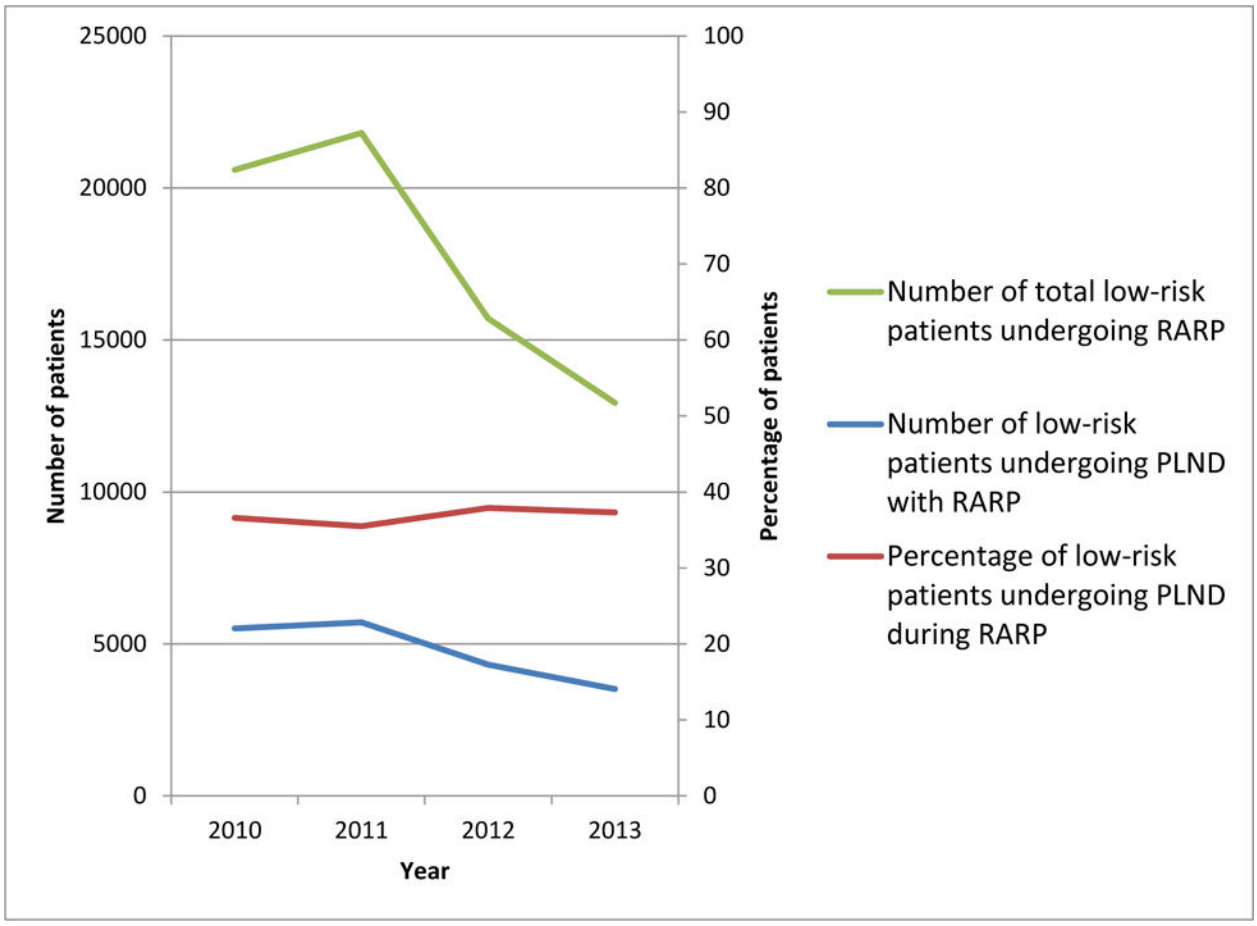

Figure 1.
Change in number and proportion of low-risk PCa patients undergoing RARP and PLND over the study period.

Table 1

Baseline characteristics of patients with low-risk prostate cancer who underwent RARP from 2010-2013.

	Group	PLND (N = 19,059)	NO PLND (N = 32,912)	p-value	Total
Age (years)	<50	1,484 (7.8)	2,329 (7.1)	0.008	3,813 (7.3)
	50 – 59	7,641 (40.1)	13,504 (41)		21,145 (40.7)
	60 – 69	8,594 (45.1)	14,708 (44.7)		23,302 (44.8)
	70 – 80	1,340 (7)	2,371 (7.2)		3,711 (7.1)
Race	White	15,950 (83.7)	27,821 (84.5)	<0.0001	43,771 (84.2)
	Black	2,178 (11.4)	3,786 (11.5)		5,964 (11.5)
	Others	596 (3.1)	823 (2.5)		1,419 (2.7)
	Unknown	335 (1.8)	482 (1.5)		817 (1.6)
Insurance	None	212 (1.1)	355 (1.1)	0.001	567 (1.1)
	Private	13,595 (71.3)	22,952 (69.7)		36,547 (70.3)
	Government	5,111 (26.8)	9,315 (28.3)		14,426 (27.8)
	Unknown	141 (0.8)	290 (0.9)		431 (0.8)
Median Income, $	< 30,000	1,741 (9.1)	3,249 (9.9)	<0.0001	4,990 (9.6)
	30,000 – 35,999	2,616 (13.7)	5,095 (15.5)		7,711 (14.8)
	36,000 – 45,999	4,607 (24.2)	8,726 (26.5)		13,333 (25.7)
	≥ 46,000	10,095 (53)	15,842 (48.1)		25,937 (49.9)
Charlson-Deyo Score	0	16,155 (84.8)	27,827 (84.5)	0.607	43,982 (84.6)
	1	2,618 (13.7)	4,557 (13.9)		7,175 (13.8)
	2+	286 (1.5)	528 (1.6)		814 (1.6)
Residence	Metro	16,079 (84.4)	27,150 (82.5)	<0.0001	43,229 (83.2)
	Urban	2,616 (13.7)	4,948 (15)		7,564 (14.5)
	Rural	364 (1.9)	814 (2.5)		1,178 (2.3)
Facility type	Academic	10,611 (55.7)	12,319 (37.4)	<0.0001	22,930 (44.1)
	Community	8,448 (44.3)	20,593 (62.6)		29,041 (55.9)
Facility location	Northeast	5,122 (26.9)	5,897 (17.9)	<0.0001	13,952 (26.8)
	Midwest	5,624 (29.5)	8,328 (25.3)		11,019 (21.2)

	Group	PLND (N = 19,059)	NO PLND (N = 32,912)	p-value	Total
	South	5,820 (30.5)	12,987 (39.5)		18,807 (36.2)
	West	2,493 (13.1)	5,700 (17.3)		8,193 (15.8)
Hospital Volume	High	16,762 (88)	25,981 (78.9)	<0.0001	42,743 (82.2)
	Low	2,297 (12)	6,931 (21.1)		9,228 (17.8)

Table 2

Multivariate analysis of predictors of PLND receipt for low-risk prostate cancer.

	Group	OR (95% C.I.)	p-value
Age (years)	<50	reference	
	50 – 59	0.934 [0.88, 0.99]	0.022
	60 – 69	0.964 [0.914, 1.017]	0.181
	70 – 80	0.956 [0.875, 1.044]	0.318
Race	White	reference	
	Black	1.013 [0.933, 1.101]	0.757
	Others	1.018 [0.928, 1.116]	0.707
	Unknown	1.039 [0.914, 1.181]	0.556
Insurance	Private	reference	
	None	1.101 [0.951, 1.274]	0.198
	Government	0.985 [0.937, 1.035]	0.548
	Unknown	0.961 [0.814, 1.134]	0.634
Median Income, $	< 30,000	reference	
	30,000 – 35,999	1.008 [0.93, 1.092]	0.847
	36,000 – 45,999	0.975 [0.91, 1.045]	0.479
	≥ 46,000	1.029 [0.953, 1.11]	0.468
Charlson-Deyo Score	0	reference	
	1	1.006 [0.963, 1.051]	0.801
	2+	0.989 [0.876, 1.116]	0.853
Residence	Metro	reference	
	Urban	1.088 [0.992, 1.216]	0.072
	Rural	1.157 [1.009, 1.327]	0.038
Facility type	Community	reference	
	Academic	1.492 [1.188, 1.874]	0.0006
Facility location	Northeast	reference	
	Midwest	0.996 [0.735, 1.349]	0.977
	South	0.793 [0.595, 1.056]	0.112
	West	0.793 [0.568, 1.107]	0.173
Hospital volume	Low	reference	
	High	1.327 [1.078, 1.633]	0.008

Table 3

Multivariate analysis of predictors of higher nodal yield in PCa patients undergoing PLND and RARP.

	Group	RR (95% C.I.)	p-value
Risk	Low	reference	
	Intermediate/high	1.226 [1.184, 1.27]	<0.0001
Age (years)	<50	reference	
	50 – 59	0.985 [0.962, 1.009]	0.206
	60 – 69	0.985 [0.959, 1.011]	0.249
	70 – 80	1.016 [0.986, 1.047]	0.302
Race	White	reference	
	Black	0.93 [0.91, 0.952]	<0.0001
	Others	0.984 [0.954, 1.014]	0.295
	Unknown	0.958 [0.909, 1.011]	0.116
Insurance	Private	reference	
	None	1.057 [0.997, 1.121]	0.063
	Government	0.992 [0.978, 1.006]	0.241
	Unknown	1.054 [0.994, 1.117]	0.08
Median Income, $	< 30,000	reference	
	30,000 – 35,999	1.013 [0.992, 1.035]	0.213
	36,000 – 45,999	1.002 [0.979, 1.026]	0.855
	≥ 46,000	1.011 [0.986, 1.037]	0.406
Carlson-Deyo Score	0	reference	
	1	1.006 [0.99, 1.022]	0.486
	2+	1.015 [0.968, 1.066]	0.537
Residence	Metro	reference	
	Urban	1.018 [0.991, 1.047]	0.19
	Rural	1.053 [1.006, 1.103]	0.029
Facility type	Community	reference	
	Academic	1.364 [1.259, 1.479]	<0.0001
Facility location	Northeast	reference	
	Midwest	1.107 [0.997, 1.229]	0.056
	South	1.015 [0.922, 1.117]	0.766
	West	1.159 [1.032, 1.301]	0.013
Hospital volume	Low	reference	
	High	1.094 [1.022, 1.169]	0.008