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Pelvic lymph node dissection at robot-assisted radical prostatectomy: Assessing utilization and nodal metastases within a statewide quality improvement consortium

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Abstract

Purpose: Several guidelines recommend pelvic lymph node dissection (PLND) at robot-assisted radical prostatectomy (RARP) only when lymph node involvement (LN+) is >2%. Individual surgeon use of PLND is not well-known. We sought to examine variability in PLND performance and detection of LN+ across the Michigan Urological Surgery Improvement Collaborative.

Methods: Data regarding all RARP (3/2012-9/2018) were prospectively collected, including patient and surgeon characteristics. Univariable and multivariable analyses of PLND rate and LN+ rate were performed.

Results: Among 9,751 men undergoing RARP, 79.8% had PLND performed ($n = 7,781$), of which 5.2% were LN+ ($n = 404$). In univariate and multivariable analyses, predictors of PLND included higher Prostate-Specific Antigen (PSA), biopsy Gleason grade (bGG), number of positive cores, and maximum core involvement at $P < 0.05$ for each. Higher PSA, cT stage, bGG, number of positive cores, and maximum core involvement predicted LN+ when PLND was performed ($P < 0.05$ for each). There was significant surgeon variation in the proportion of PLND performed at RARP, yet neither surgeon-annualized RARP volume nor % of PLND performed was associated with LN+ disease ($P > 0.05$). Grade was associated with PLND (60.0%, 77.6%, 91.0%, 97.3%, and 98.5%; $P < 0.001$) and LN+ (0.7%, 2.5%, 5.8%, 8.6%, and 19.9%; $P < 0.001$) for bGG 1,2,3,4,5, respectively. Maximum core involvement also strongly predicted LN+ with rates of 1.5%, 3.8%, and 9.4% for <35%, 35% to 65%, and >65%, respectively ($P < 0.001$).

Conclusions: Nearly 80% of RARP in Michigan Urological Surgery Improvement Collaborative were performed with PLND, including 60% of bGG1 patients (with LN+ in only 0.7%), but significant variability exists between surgeons. Our data indicate limited benefit for favorable-risk CaP patients and support efforts to decrease PLND use going forward.

Keywords: Pelvic lymph node dissection; Prostatectomy

1. Introduction

Pelvic lymph node dissection (PLND) at the time of robot-assisted radical prostatectomy (RARP) is the most effective and accurate method for detecting lymph node metastasis [1].

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PLND provides information about staging benefit, and increased number of nodes removed appears to be associated with improved survival [1,2]. However, PLND increases operative time, surgical morbidity, and can lengthen hospital stays, with risks including lymphocele, deep venous thrombosis, major vascular injury, and obturator nerve injury [1-3]. Guidelines for PLND vary, but are generally based on the patient's preoperative risk of lymphatic metastasis. The American Urological Association recommends PLND for intermediate (Prostate-Specific Antigen (PSA) > 10, Gleason 7 or higher, cT2b or higher) and high-risk patients (PSA > 20, Gleason 8 or higher, cT3 or higher), while the National Comprehensive Cancer Network recommends PLND if the risk of harboring metastatic disease is ≥2%, based upon validated nomograms [4,5]. The European Association of Urology guidelines contain even more stringent criteria, recommending extended PLND when risk of lymph node metastases is ≥5% [5]. Despite these recommendations, recent publications have reported poor adherence to these guidelines and wide variation amongst urologists [6-9]. In practice, individual surgeon use of PLND may vary, and the results of PLND across populations of surgeons are not well-known.

In order to better delineate the use of PLND at time of RARP, we sought to examine surgeon-level variability in PLND performance and the detection of lymph node involvement (LN+) across the Michigan Urological Surgery Improvement Collaborative (MUSIC).

2. Methods

2.1. Patient population

MUSIC was established in 2011 with funding from Blue Cross Blue Shield of Michigan with the goal of improving the quality and cost efficiency of urologic care in the state of Michigan. The collaborative now includes 45 urology practices, including 250 urologists, which represents approximately 90% of the urologists in the state. Practices participating in MUSIC employ trained data abstractors to extract information from the medical record and enter standardized data elements into a web-based clinical registry. For the purposes of this analysis, we identified all men who underwent a RARP for clinically localized prostate cancer (CaP) with or without PLND within the MUSIC registry between March 2012 and September 2018. PLND was performed at the discretion of the surgeon and recorded by data abstractors.

As a general quality assurance step, MUSIC validates the data in the registry via annual on-site quality audits involving the direct review of a random sample of 5% to 10% of cases from each participating practice. The purpose of these visits is to ensure the integrity of the data in the MUSIC registry, as well as, confirm the appropriate identification of cases. In selected instances, MUSIC also uses claims data analyses (i.e., comparing claims data to the information in the registry to ensure concordance) and follow-up phone calls to patients to further substantiate the information in the registry.

2.2. Statistical analyses

The primary outcome of interest was the performance of PLND. We first compared demographic and clinical characteristics for patients in whom PLND was performed and in whom PLND was not performed, and we assessed surgeon-level variation in PLND performance. A multivariable logistic regression model was then fitted to evaluate the association between PLND and preoperative variables of interest. We analyzed age, PSA, clinical T (cT) stage, biopsy grade group (bGG), number of positive cores (#posCores), maximum % (max%) of cancer involvement, and imaging performance and results, as predictors of PLND in this cohort. Abdominopelvic Computerized Tomography (CT) and multiparametric Magnetic Resonance Imaging (MRI) were categorized according to presence or absence of suspicion for Lymph Node metastases. Bone scans were examined surgeon characteristics included annualized RARP volume, proportion of RARP with PLND, and type of practice. The secondary outcome of interest was identification of factors associated with detection of Lymph Node metastases; a second multivariable logistic regression model was fitted to examine the same factors. All statistical testing was performed at the 5% significance level using SAS v9.3 (SAS Institute Inc., Cary, NC, USA).

3. Results

We identified all men within the MUSIC registry who underwent RARP with or without PLND from March 2012 through September 2018. Clinical and demographic characteristics of patients by utilization of PLND are presented in Table 1. Among 9,751 men undergoing RARP, 79.8% had PLND performed ($n = 7{,}781$), of which 5.2% were LN+ ($n = 404$). Thirty-six percent of surgeons performed PLND in >90% of the RARP they performed. Higher clinical T stage, serum PSA, bGG, #posCores, max% of cancer involvement on biopsy, and high surgeon volume were all associated with utilization of PLND in univariate analysis ($P \leq 0.001$ for each) (Table 1). For example, bGG was strongly associated with PLND, with 60.0%, 77.6%, 91.0%, 97.3%, and 98.5% of patients with bGG 1, 2, 3, 4, and 5 undergoing PLND, respectively ($P < 0.001$). Patients undergoing staging with abdominopelvic CT/MRI and bone scan were more likely to undergo PLND, even if the results were negative (Table 1). Consistent with the univariate results, factors independently associated with PLND performance in the multivariable model included increasing PSA, bGG, #posCores, max% of cancer involvement ($P \leq 0.005$ for each, Table 2). A majority of MUSIC surgeons (54.4%) performed PLND for >33% of their low-risk patients undergoing RARP, Although significant variability in the proportion of PLND performed by

Table 1
Characteristics of 9,751 patients undergoing RP without or with PLND

Variable	No PLND	PLND	*P*
No. patients	1,970	7,781	
Age			<0.001
<55	289 (21.2%)	1,074 (78.8%)	
55–65	944 (21.9%)	3,367 (78.1%)	
>65	737 (18.1%)	3,340 (81.9%)	
Race			0.092
White	1,553 (20.7%)	5,934 (79.3%)	
African American	206 (17.8%)	951 (82.2%)	
Other	50 (19.6%)	205 (80.4%)	
Unknown	161 (18.9%)	691 (81.1%)	
Comorbidity			0.857
CCI = 0	1,443 (20.3%)	5,670 (79.7%)	
CCI = 1	327 (19.7%)	1,333 (80.3%)	
CCI ≥ 2	198 (20.4%)	774 (79.6%)	
BMI, median (IQR)	28.3 (25.8–31.3)	28.7 (26.0–31.9)	<0.001
PSA			<0.001
<10	1,774 (22.8%)	5,993 (77.2%)	
10–20	153 (11.0%)	1,232 (89.0%)	
>20	10 (2.3%)	417 (97.7%)	
Clinical T stage			<0.001
T1	1,619 (23.0%)	5,410 (77.0%)	
T2	330 (12.9%)	2,223 (87.1%)	
T3-4	7 (5.8%)	113 (94.2%)	
Biopsy Gleason			<0.001
GG1 (GS 3 + 3)	882 (40.0%)	1,323 (60.0%)	
GG2 (GS 3 + 4)	875 (22.4%)	3,025 (77.6%)	
GG3 (GS 4 + 3)	163 (9.0%)	1,647 (91.0%)	
GG4 (GS 8)	28 (2.7%)	1,024 (97.3%)	
GG5 (GS 9–10)	10 (1.5%)	642 (98.5%)	
Number of positive cores			<0.001
2 or less	859 (32.6%)	1,777 (67.4%)	
3–5	746 (21.0%)	2,809 (79.0%)	
6 or more	349 (10.3%)	3,051 (89.7%)	
Greatest % of cancer involvement			<0.001
<35%	1,114 (30.9%)	2,495 (69.1%)	
35–65%	498 (18.4%)	2,209 (81.6%)	
>65%	342 (10.4%)	2,933 (89.6%)	
D'amico risk group			<0.001
Low	750 (42.5%)	1,014 (57.5%)	
Intermediate	1,084 (19.6%)	4,442 (80.4%)	
High	104 (4.5%)	2,214 (95.5%)	
MRI/CT			<0.001
Not performed	1,679 (28.3%)	4,246 (71.7%)	
Negative	277 (7.8%)	3,297 (92.2%)	
Positive	14 (5.6%)	238 (94.4%)	
Bone scan			<0.001
Not performed	1,837 (26.2%)	5,168 (73.8%)	
Negative	129 (4.8%)	2,544 (95.2%)	
Positive	4 (5.5%)	69 (94.5%)	
Annualized RP volume, median (IQR)			<0.001
0–10	191 (24.7%)	583 (75.3%)	
11–20	270 (24.5%)	833 (75.5%)	
21–40	587 (25.0%)	1,763 (75.0%)	
≥40	747 (14.9%)	4,280 (85.1%)	

PLND = pelvic lymph node dissection.

Table 2
Factors associated with the performance of PLND

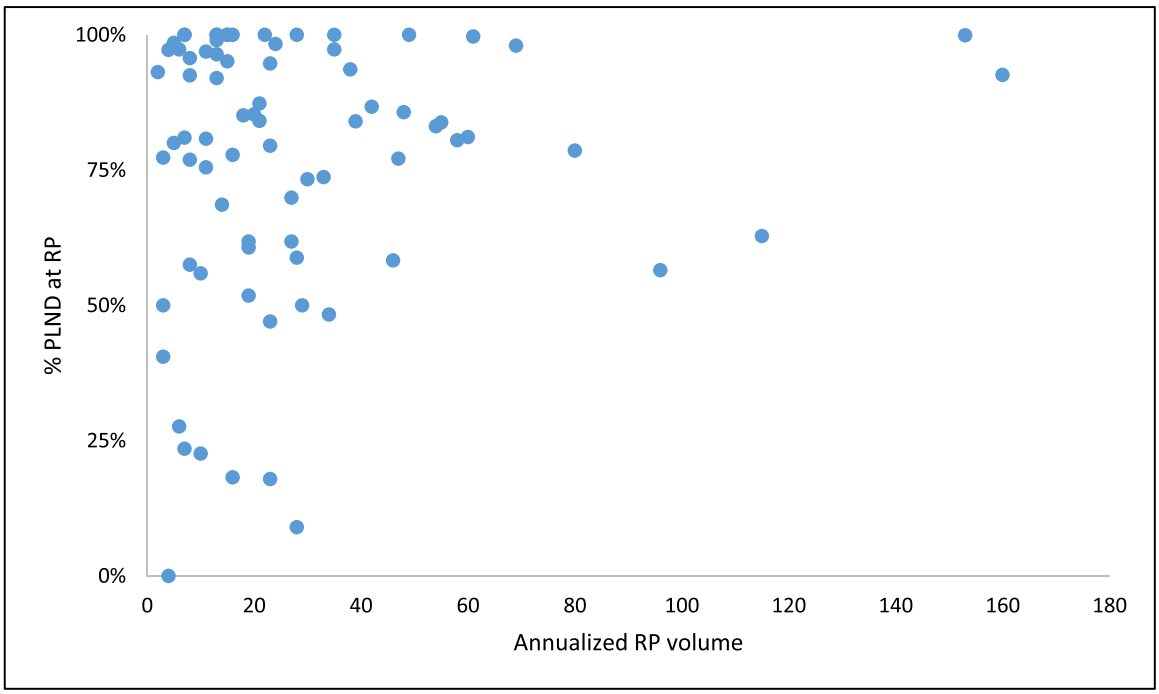
Variable	OR	95% CI	*P*
Age (ref: <55)			
55–65	0.89	(0.70, 1.11)	0.295
>65	0.89	(0.70, 1.13)	0.346
Race (ref: White)			
African American	1.23	(0.95, 1.59)	0.120
Other	0.71	(0.43, 1.17)	0.182
Unknown	0.95	(0.71, 1.29)	0.762
Charlson comorbidity index (ref: 0)			
1	0.97	(0.78, 1.20)	0.755
≥2	0.92	(0.71, 1.19)	0.534
BMI	1.00	(0.98, 1.02)	0.914
PSA (ref: <10)			
10–20	2.64	(2.01, 3.46)	<0.001
>20	15.16	(5.45, 42.20)	<0.001
Clinical T stage (ref: T1)			
T2	1.23	(1.00, 1.51)	0.046
T3–4	0.64	(0.23, 1.82)	0.407
Biopsy Gleason score (ref: GG1 (GS 3 + 3))			
GG2 (GS 3 + 4)	4.40	(3.64, 5.33)	<0.001
GG3 (GS 4 + 3)	20.54	(15.30, 27.58)	<0.001
GG4 (GS 8)	53.85	(30.40, 95.40)	<0.001
GG5 (GS 9–10)	39.18	(16.39, 93.70)	<0.001
No. positive cores (ref: ≤2)			
3–5	1.46	(1.21, 1.75)	<0.001
≥6	2.43	(1.91, 3.09)	<0.001
Greatest percentage of cancer involvement (ref: <35%)			
35%–65%	1.32	(1.09, 1.61)	0.005
>65%	1.67	(1.32, 2.10)	<0.001
CT/MRI (ref: Not performed)			
Neg	2.24	(1.76, 2.84)	<0.001
Pos	2.62	(1.21, 5.67)	0.014
Bone scan (ref: Not performed)			
Neg	1.46	(1.05, 2.03)	0.023
Pos	1.95	(0.36, 10.63)	0.441
Annualized RP volume (ref: <10)			
10–20	2.37	(0.54, 10.44)	0.253
21–40	1.25	(0.30, 5.24)	0.765
≥40	3.32	(0.69, 16.07)	0.135

PLND = pelvic lymph node dissection.
This is a multivariable analysis which is also controlled for surgeon through random effect.

individual surgeons was observed, annualized RARP volume was not a predictor of PLND ($P > 0.05$) (Fig. 1).

In order to identify patient and surgeon characteristics predictive of LN+ disease, we next analyzed patients according to clinical features. In univariate analysis (Table 3), increasing age, PSA, T stage, bGG, #posCores, max% of cancer involvement, African-American race, positive MRI or CT, and positive bone scan were associated with LN+ when PLND was performed ($P < 0.0001$ for each). Biopsy GG was strongly associated with LN+ disease, including 0.7%, 2.5%, 5.8%, 8.6%, and 19.9% of bGG 1, 2, 3, 4, and 5 CaP, respectively ($P < 0.001$). Max% of cancer involvement also predicted LN+ with rates of 1.5%, 3.8%, and 9.4% for max% cancer involvement of

(a)



(b)

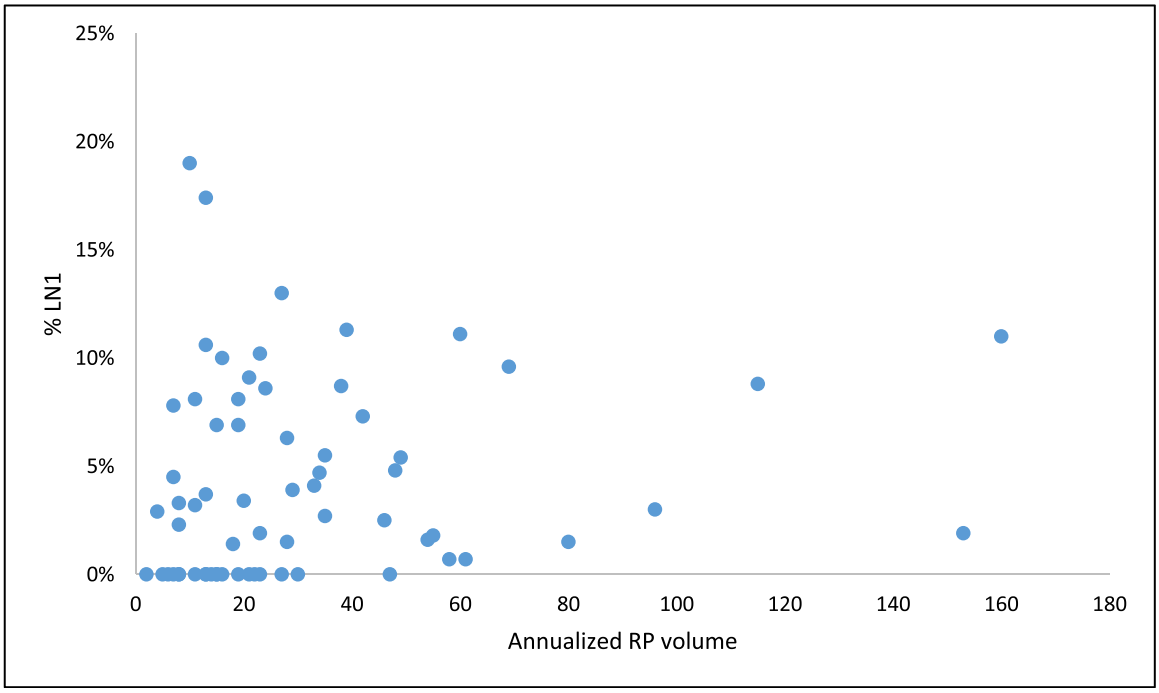


Fig. 1. Proportion of patients (A) undergoing PLND at RP and (B) having LN+ at PLND by individual MUSIC surgeons according to annualized RP volume (each dot represents 1 surgeon). MUSIC = Michigan Urological Surgery Improvement Collaborative; PLND = pelvic lymph node dissection.

<35%, 35% to 65%, and >65%, respectively ($P < 0.001$). Number of cores involved by cancer was also associated with LN+ with rates of 2.0%, 2.8%, and 9.2% for ≤2, 3 to 5, and >6 positive cores ($P < 0.001$).

Similar to the observed amount of variation in the proportion of PLND performed at RARP, there was significant variation in the proportion of LN+ cases per surgeon (range: 0%–19%, Fig. 1B). Annualized RARP volume was not associated with LN+ disease ($P > 0.05$). In multivariable analysis (Table 4), the independent predictors of LN+ disease in patients undergoing PLND were increasing PSA, bGG, clinical T3/4 stage, serum PSA, #posCores, max% of

Table 3
Characteristics of patients by result of PLND

Variable	N0	N1	*P*
No. patients	7,377	404	7,781
Age			
<55	1,030 (95.9%)	44 (4.1%)	0.016
55–65	3,207 (95.2%)	160 (4.8%)	
>65	3,140 (94.0%)	200 (6.0%)	
Race			
White	5,653 (95.3%)	281 (4.7%)	<0.001
African American	878 (92.3%)	73 (7.7%)	
Other	187 (91.2%)	18 (8.8%)	
Known	659 (95.4%)	32 (4.6%)	
Charlson comorbidity index			
0	5,394 (95.1%)	276 (4.9%)	0.095
1	1,250 (93.8%)	83 (6.2%)	
≥2	729 (94.2%)	45 (5.8%)	
BMI, median (IQR)	28.7 (26.0–31.9)	28.9 (25.7–32.5)	0.771
PSA			
<10	5,788 (96.6%)	205 (3.4%)	<0.001
10–20	1124 (91.2%)	108 (8.8%)	
>20	337 (80.8%)	80 (19.2%)	
Clinical T stage			
T1	5,205 (96.2%)	205 (3.8%)	<0.001
T2	2,052 (92.3%)	171 (7.7%)	
T3–4	86 (76.1%)	27 (23.9%)	
Biopsy Gleason			
GG1 (GS 6)	1,314 (99.3%)	9 (0.7%)	<0.001
GG2 (GS 3 + 4)	2,948 (97.5%)	77 (2.5%)	
GG3 (GS 4 + 3)	1,551 (94.2%)	96 (5.8%)	
GG4 (GS 8)	936 (91.4%)	88 (8.6%)	
GG5 (GS 9–10)	514 (80.1%)	128 (19.9%)	
Number of positive cores			
≤2	1,741 (98.0%)	36 (2.0%)	<0.001
3–5	2,730 (97.2%)	79 (2.8%)	
≥6	2,769 (90.8%)	282 (9.2%)	
Greatest cancer involvement			
<35%	2,457 (98.5%)	38 (1.5%)	<0.001
35%–65%	2,125 (96.2%)	84 (3.8%)	
>65%	2,658 (90.6%)	275 (9.4%)	
MRI/CT			
Not performed	4,136 (97.4%)	110 (2.6%)	<0.001
Negative	3,036 (92.1%)	261 (7.9%)	
Positive	205 (86.1%)	33 (13.9%)	
Bone scan			
Not performed	5,031 (97.3%)	137 (2.7%)	<0.001
Negative	2,286 (89.9%)	258 (10.1%)	
Positive	60 (87.0%)	9 (13.0%)	
Annualized RP volume, median (IQR)			
0–10	565 (96.9%)	18 (3.1%)	0.093
11–20	785 (94.2%)	48 (5.8%)	
21–40	1,664 (94.4%)	99 (5.6%)	
≥40	4,054 (94.7%)	226 (5.3%)	

PLND = pelvic lymph node dissection.

Table 4
Factors associated with positive LN at RP/PLND

Variable	OR	95% CI	*P*
Age (ref: <55)			
55–65	1.45	(0.96, 2.18)	0.076
>65	1.74	(1.15, 2.61)	0.008
Race (ref: White)			
African American	1.40	(1.00, 1.95)	0.053
Other	1.47	(0.79, 2.75)	0.228
Unknown	1.06	(0.67, 1.67)	0.813
Charlson comorbidity index (ref: 0)			
1	0.94	(0.69, 1.27)	0.677
≥2	1.01	(0.68, 1.49)	0.967
BMI	1.01	(0.98, 1.03)	0.473
PSA (ref: <10)			
10–20	2.20	(1.66, 2.92)	<0.001
>20	3.63	(2.55, 5.16)	<0.001
Clinical T stage (ref: T1)			
T2	1.29	(1.00, 1.67)	0.054
T3–4	2.26	(1.26, 4.03)	0.006
Biopsy Gleason score (ref: GG1 [GS 3 + 3])			
GG2 (GS 3 + 4)	1.88	(0.88, 4.02)	0.104
GG3 (GS 4 + 3)	3.56	(1.66, 7.63)	0.001
GG4 (GS 8)	4.86	(2.21, 10.72)	<0.001
GG5 (GS 9–10)	9.51	(4.31, 21.03)	<0.001
No. positive cores (ref: ≤2)			
3–5	0.74	(0.47, 1.18)	0.207
≥6	1.67	(1.07, 2.58)	0.023
Greatest percentage of cancer involvement (ref: <35%)			
35%–65%	1.80	(1.14, 2.85)	0.012
>65%	2.82	(1.82, 4.38)	<0.001
CT/MRI (ref: Not performed)			
Neg	1.22	(0.85, 1.75)	0.277
Pos	3.00	(1.68, 5.35)	<.001
Bone scan (ref: Not performed)			
Neg	1.12	(0.77, 1.62)	0.560
Pos	1.58	(0.65, 3.87)	0.314
Annualized RP volume (ref: <10)			
10–20	1.85	(0.68, 5.07)	0.230
21–40	1.71	(0.65, 4.46)	0.276
≥40	1.68	(0.64, 4.43)	0.294
Surgeon level % of PLND at RP	1.30	(0.30, 5.68)	0.729

PLND = pelvic lymph node dissection.
This multivariable analysis is restricted to surgeons with ≥20 included RP/PLND and is also controlled for surgeon through random effect.

involvement with cancer, age over 65, and positive CT/MRI findings (at $P < 0.05$).

4. Discussion

While the incremental morbidity of PLND performed in the context of RARP is small, the staging and therapeutic benefits are statistically marginal, particularly in the low-risk patient population [1,10]. In order to provide a framework for the value of PLND in patients undergoing RARP, we assessed both the variation in performance of PLND and occurrence of LN+ disease in patients who underwent PLND across MUSIC. Our findings are similar to prior studies showing that the current recommendations for the performance of PLND are not consistently being followed [8,9,11–13]. As per the American Urological Association guidelines, all low-risk patients, and per the National Comprehensive Cancer Network guidelines, any patient with a nomogram-predicted chance of lymph node involvement of less than 2%, are generally not recommended to undergo PLND [4,14].

Nearly 80% of RARP in MUSIC were performed with PLND, including 60% of patients with bGG1 CaP. Only 0.7% of bGG1 patients ($n = 9$) were found to be LN+,

indicating the limited benefit of PLND for these patients. This is even more striking, given the relatively high rates of active surveillance for these patients within MUSIC practices, and the proportion of these low-risk patients upgraded to a higher grade group (60.4%) or upstaged to pT3 (14.1%) at final pathology, as has been reported in previous studies [8,15]. We would advocate for active surveillance for all patients with Gleason 6 cancer, as have many other groups and recent guidelines [16,17]. As expected, the rate of PLND in high-risk CaP was high (97.3% for bGG4 and 98.5% for bGG5), with the rates of LN+ disease (8.6% for bGG4 and 19.9% for bGG5) strongly justifying this procedure.

This study is limited by its retrospective nature, although data are substantiated with regular quality audits. Importantly, we do not have data on the quality of PLND, either by number of nodes removed, total and by side, or description of the template of the dissection. Some surgeons certainly performed a more limited PLND, so the rates of LN+ disease in this series could be even higher with greater use of a more extended schema [1,18]. It also stands to reason that the extent of PLND may vary by disease risk, thus influencing pathologic detection of nodal metastases [19]. Despite these limitations, these results show that there is large variation in PLND performance at time of RARP and quality improvement opportunities as a result.

5. Conclusion

Despite current guidelines, utilization of PLND at time of RARP varies widely within the state of Michigan. MUSIC intends to address the variability with quality improvement efforts, including the implementation of appropriateness criteria for PLND at RARP.

Conflicts of Interest

The authors have no conflicts of interest.

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