

Differences in rates of pelvic lymph node dissection in National Comprehensive Cancer Network favorable, unfavorable intermediate- and high-risk prostate cancer across United States SEER registries

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Abstract

Background: The National Comprehensive Cancer Network (NCCN) guidelines recommend pelvic lymph node dissection (PLND) in NCCN high- and intermediate-risk prostate cancer patients. We tested for PLND nonadherence (no-PLND) rates within the Surveillance Epidemiology and End Results (2010–2015).

Materials and methods: We identified all radical prostatectomy patients who fulfilled the NCCN PLND guideline criteria (n = 23,495). Nonadherence rates to PLND were tabulated and further stratified according to NCCN risk subgroups, race/ethnicity, geographic distribution, and year of diagnosis.

Results: Overall, the no-PLND rate was 26%; it was 41%, 25%, and 11% in the NCCN intermediate favorable, intermediate unfavorable, and high-risk prostate cancer patients, respectively ($p < 0.001$). Over time, the no-PLND rates declined in the overall cohort and within each NCCN risk subgroup. Georgia exhibited the highest no-PLND rate (49%), whereas New Jersey exhibited the lowest (15%). Finally, no-PLND race/ethnicity differences were recorded only in the NCCN intermediate unfavorable subgroup, where Asians exhibited the lowest no-PLND rate (20%) versus African Americans (27%) versus Whites (26%) versus Hispanic-Latinos (25%).

Conclusions: The lowest no-PLND rates were recorded in the NCCN high-risk patients followed by NCCN intermediate unfavorable and favorable risk in that order. Our findings suggest that unexpectedly elevated differences in no-PLND rates warrant further examination. In all the NCCN risk subgroups, the no-PLND rates decreased over time.

Keywords: Lymph node excision; Pelvic lymph node dissection; Prostatectomy; Prostatic neoplasms

1. Introduction

Pelvic lymph node dissection (PLND) during radical prostatectomy (RP) for prostate cancer (PCa) is strongly advised because of its accuracy in the detection of lymph node metastasis,^[1] with important implications for establishing patient prognosis and adjuvant treatment after primary surgery. Consequently, the National Com-

prehensive Cancer Network (NCCN) guidelines recommend PLND in all high-risk patients, as well as intermediate favorable and unfavorable risk PCa patients with a lymph node invasion (LNI) probability of $\geq 2\%$.^[2,3] Notably, previous studies have reported PLND rates during RP in the overall cohort of PCa patients without accounting for specific guideline recommendations. However, this approach may fail to adequately estimate the proportion of patients receiving suboptimal treatment. To address this unmet need, we investigated the proportion of patients who did not receive PLND despite being candidates for PLND according to the NCCN guidelines. We hypothesized that virtually perfect adherence to the guidelines would be reported.

2. Materials and methods

2.1. Study population

The Surveillance Epidemiology and End Results (SEER) database samples 26% of the US population and approximates the national geographic and demographic composition, as well as the

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incidence of cancer.^[4] Within the 2010–2015 SEER database, we included nonmetastatic patients, aged between 40 and 75 years, with histologically confirmed adenocarcinoma of the prostate, diagnosed at biopsy (*International Classification of Diseases for Oncology, Third Revision* code 8140 site code C61.9), and treated with RP candidates for PLND according to NCCN guidelines.^[3] The NCCN guidelines recommend PLND in all high-risk NCCN patients, as well as in intermediate favorable and unfavorable risk PCa patients with a nomogram LNI probability $\geq 2\%$.^[2]

Patients with missing vital status, unknown prostate-specific antigen (PSA) or PSA levels >50 ng/mL, unknown clinical T stage/M stage, unknown biopsy Gleason score, biopsy cores <8 or ≥ 24 , or unknown information on lymph node dissection were excluded.

2.2. Statistical analyses

Statistical analyses were based on cross-tabulations, bar plots, and χ^2 tests to address differences in overall nonadherence rates to PLND (no-PLND), followed by specific no-PLND rates according to the NCCN risk classification system (intermediate favorable, unfavorable, high-risk), race/ethnicity (White, African American, Hispanic-Latino, Asian), 4 SEER geographic regions (Northeast, Midwest, West, and South), 16 SEER registries (Appendix 1 [http://links.lww.com/CURRUROL/A26]), and year of diagnosis (2010–2015). Moreover, analyses addressing race/ethnicity, SEER geographic regions, SEER registries, and year of diagnosis were further stratified according to the NCCN risk subgroups. Specifically, the estimated annual percentage change approach was applied to estimate no-PLND rates over time.^[5] For all statistical analyses, R software environment for statistical computing and graphics (version 3.4.3) was used.^[6] All tests were 2-sided with the significance level set at $p < 0.05$.

3. Results

3.1. Study population characteristics

Overall, 23,495 PCa patients treated with RP who fulfilled the NCCN criteria for PLND were identified. Among this cohort, 6039 patients (26%) did not undergo PLND. In general, no-PLND patients exhibited lower PSA, lower International Society of Urological Pathology (ISUP) Gleason grade, and lower median biopsy core positivity rates relative to their counterparts who were treated with RP plus PLND (Table 1). Conversely, no clinically meaningful differences were recorded in age or cT stage according to the PLND status (Table 1).

3.2. No-pelvic lymph node dissection rates according to National Comprehensive Cancer Network risk level

We identified 6949, 10,107, and 6439 NCCN intermediate favorable, unfavorable, and high-risk PCa patients, respectively. The no-PLND rates were as follows: 41% in the NCCN intermediate favorable, 25% in the NCCN intermediate unfavorable, and 11% in the NCCN high-risk subgroup ($p < 0.001$).

3.3. No-pelvic lymph node dissection rates according to race/ethnicity

We identified 16,552, 3399, 1995, and 1284 White, African American, Hispanic-Latino, and Asian patients with PCa, respectively. The no-PLND rates were as follows: 27% in African Americans, 26% in Whites, 26% in Hispanic-Latino, and 23% in Asians (Fig. 1A, $p = 0.09$).

The distribution of no-PLND rates was as follows: Asians (44%) versus Hispanic-Latinos (41%) versus Whites (40%) versus African Americans (39%) within the NCCN intermediate fa-

Table 1

Descriptive characteristics of 23,495 NCCN intermediate favorable, unfavorable, and high-risk prostate cancer patients treated with or without pelvic lymph node dissection (PLND vs. no-PLND).

Characteristics	Overall, n = 23,495*	No-PLND, n = 6039* (26%)	PLND, n = 17,456* (74%)	p†
Age, yr	62 (57–67)	62 (57–66)	62 (57–67)	0.056
Ethnicity				0.032
White	16,552	4266 (26%)	12,286 (74%)	
African American	3399	904 (27%)	2495 (73%)	
Hispanic	1995	520 (26%)	1475 (74%)	
Asian	1284	295 (23%)	989 (77%)	
Unknown/other	265	54 (20%)	211 (80%)	
Year				<0.001
2010	3672	1040 (28%)	2632 (72%)	
2011	3621	1130 (31%)	2491 (69%)	
2012	3748	1046 (28%)	2702 (72%)	
2013	3802	983 (26%)	2819 (74%)	
2014	3966	907 (23%)	3059 (77%)	
2015	4686	933 (20%)	3753 (80%)	
NCCN risk				<0.001
Intermediate favorable	6949	2821 (41%)	4128 (59%)	
Intermediate unfavorable	10,107	2540 (25%)	7567 (75%)	
High risk	6439	678 (11%)	5761 (89%)	
PSA, ng/mL	6.6 (5.0–10.1)	6.0 (4.8–8.7)	6.8 (5.1–10.6)	<0.001
PSA category				<0.001
<10	17,444 (74%)	4875 (81%)	12,569 (72%)	
10–20	4672 (20%)	1010 (17%)	3662 (21%)	
>20	1379 (6%)	154 (2%)	1225 (7%)	
cT stage				<0.001
cT1	17,334 (74%)	4670 (77%)	12,664 (73%)	
cT2	5281 (22%)	1236 (20%)	4045 (23%)	
cT3a	521 (2%)	104 (2%)	417 (2%)	
cT3b	329 (1%)	29 (1%)	300 (2%)	
cT4	30 (<1%)	0 (0%)	30 (<1%)	
ISUP biopsy				<0.001
I	1976 (8%)	915 (15%)	1061 (6%)	
II	11,595 (49%)	3716 (62%)	7879 (45%)	
III	4885 (21%)	978 (16%)	3907 (22%)	
IV	3264 (14%)	325 (5%)	2939 (17%)	
V	1775 (8%)	105 (2%)	1670 (10%)	
% Positive cores	0.40 (0.25–0.58)	0.33 (0.17–0.50)	0.42 (0.25–0.60)	<0.001

ISUP = International Society of Urological Pathology; NCCN = National Comprehensive Cancer Network; PLND = pelvic lymph node dissection; PSA = prostate-specific antigen.

*Median (IQR); n (%).

†Wilcoxon rank sum test; Pearson's Chi-squared test; Fisher's exact test.

vorable risk subgroup (Fig. 1B, $p = 0.6$); African Americans (27%) versus Hispanic-Latinos (26%) versus Whites (25%) versus Asians (20%) within the NCCN intermediate unfavorable risk subgroup (Fig. 1C, $p = 0.016$); and African Americans (12%) versus Hispanic-Latinos (12%) versus Whites (10%) versus Asians (10%) within the NCCN high-risk subgroup (Fig. 1D, $n = 6439$, $p = 0.4$).

3.4. No-pelvic lymph node dissection rates according to Surveillance Epidemiology and End Results geographic regions

Overall, no-PLND rates within SEER geographic regions (Fig. 2) ranged from 36% in the South to 25% in the West, to 25% in the Midwest, and to 17% in the Northeast ($p < 0.001$).

No-PLND rates were as follows (Fig. 2): South (53%) versus West (41%) versus Midwest (39%) versus Northeast (25%) within the NCCN intermediate favorable risk subgroup ($n = 6949$,

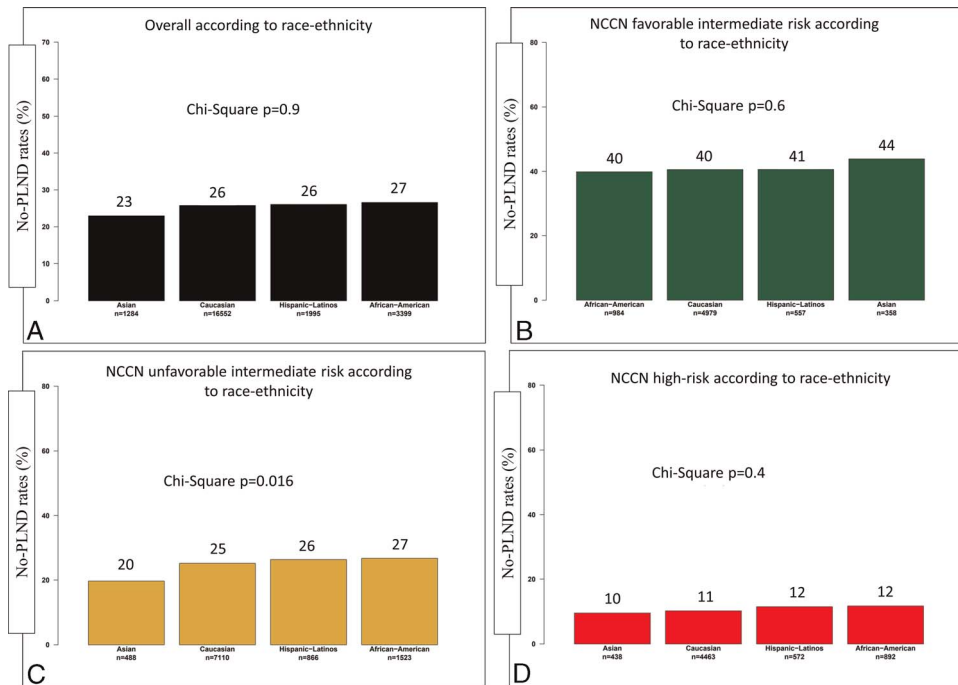


Figure 1. Bar plots depicted no-PLND rates according to 4 different race/ethnicity groups (White, African American, Hispanic-Latino and Asian) in the overall cohort (A) as well as in each NCCN risk subgroup: intermediate favorable (B), intermediate unfavorable (C), high-risk (D). NCCN = National Comprehensive Cancer Network; PLND = pelvic lymph node dissection.

$p < 0.001$); and South (35%) versus West (24%) versus Midwest (23%) versus Northeast (17%) within the NCCN intermediate unfavorable risk subgroup ($n = 10,107$, $p < 0.001$); and South (14%) versus West (11%) versus Northeast (8%) versus Midwest (7%) regions within the NCCN high-risk subgroup ($n = 6439$, $p < 0.001$).

3.5. No-pelvic lymph node dissection rates according to Surveillance Epidemiology and End Results registries

Overall, no-PLND rates across SEER registries ranged from 49% in Georgia to 14% in New Jersey (Supplementary Fig. S1A [http://links.lww.com/CURRUROL/A27], $p < 0.001$). No-PLND rates ranged from 70% in Georgia to 22% in New Jersey within the NCCN intermediate favorable risk subgroup (Supplementary Fig. S1B [http://links.lww.com/CURRUROL/A27], $n = 6,949$, $p < 0.001$), from 49% in Georgia to 13% in Louisiana within the NCCN intermediate favorable risk subgroup (Supplementary Fig. S1C [http://links.lww.com/CURRUROL/A27], $p < 0.001$), and from 20% in Georgia to 6% in San Jose within the NCCN high-risk subgroup (Supplementary Fig. S1D [http://links.lww.com/CURRUROL/A27], $p < 0.001$).

3.6. No-pelvic lymph node dissection rates over time

The distribution of no-PLND rates over time ranged from 28% in the initial year of the study (2010) to 20% in the final year of the study (2015) (Fig. 3A), resulting in an average annual decrease of 7% ($p = 0.02$).

The distribution of no-PLND rates between 2010 and 2015 ranged from 43% to 35%, with an average annual decrease of 4.7% in the NCCN intermediate favorable risk subgroup (Fig. 3B, $p = 0.035$) versus from 27% to 19% with an average annual decrease of 6.6% in the NCCN intermediate unfavorable subgroup (Fig. 3C, $p = 0.044$)

versus from 12% to 8% with an average annual decrease of 6.9% in the NCCN high-risk subgroup (Fig. 3D, $p = 0.048$).

4. Discussion

We hypothesized that extremely low rates of no-PLND would be observed among PLND candidates according to the NCCN PLND guidelines. To test PLND nonadherence in those patients, we relied on the 2010–2015 SEER database. Our study had several noteworthy observations.

First, we identified 23,495 PCa patients treated with RP who fulfilled the NCCN criteria for PLND. These included all high-risk NCCN patients, as well as intermediate favorable and unfavorable NCCN patients with a nomogram-calculated LNI probability $\geq 2\%$. Overall, the rate of no-PLND was 26%. No-PLND patients exhibited lower PSA (PSA < 10 ng/mL: 81% vs. 72%), lower ISUP Gleason grade (I–II: 77% vs. 50%), and lower median biopsy core positivity rate (33% vs. 42%) relative to patients who underwent PLND. Conversely, no clinically meaningful differences in median age and cT-stage were observed. These observations indicate that the urologic community interprets NCCN PLND guideline recommendations and implements less strict criteria for PLND than those based on the actual NCCN PLND guideline definition.^[7,8]

Second, no-PLND rates were highest in the NCCN intermediate favorable subgroup (41%), followed by the NCCN intermediate unfavorable subgroup (25%), and finally the NCCN high-risk subgroup (11%). These observations were particularly noteworthy, especially in the NCCN intermediate favorable and unfavorable risk subgroups, because only patients with nomogram-calculated LNI probability $\geq 2\%$, as stipulated by the NCCN PLND guidelines, were included. Therefore, the greatest efforts aimed at

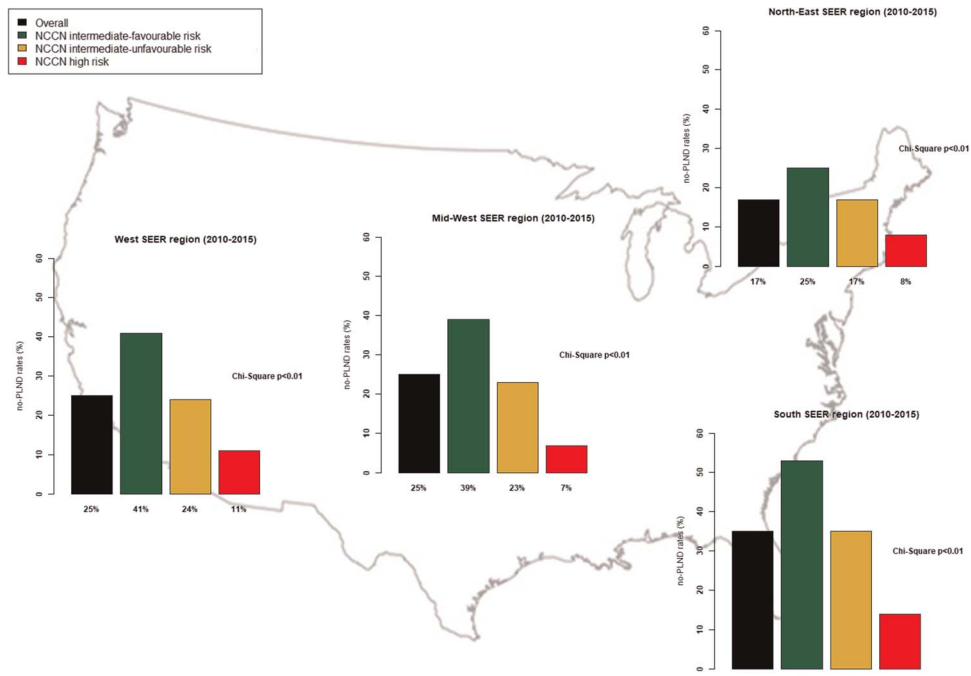


Figure 2. Bar plots depicted no-PLND rates according to 4 different SEER regions (Northeast, Midwest, West, and South). For each SEER region, the overall no-PLND rate and no-PLND rates within each NCCN risk subgroup were recorded: NCCN intermediate favorable, NCCN intermediate unfavorable, NCCN high-risk. NCCN = National Comprehensive Cancer Network; PLND = pelvic lymph node dissection; SEER = Surveillance Epidemiology and End Results.

decreasing no-PLND rates should focus on NCCN intermediate favorable and unfavorable PCa patients,^[9] where noncompliance is the highest.

Third, we examined no-PLND rates according to ethnicity and identified only important differences in the NCCN intermediate unfavorable risk subgroup. Specifically, in the NCCN intermediate

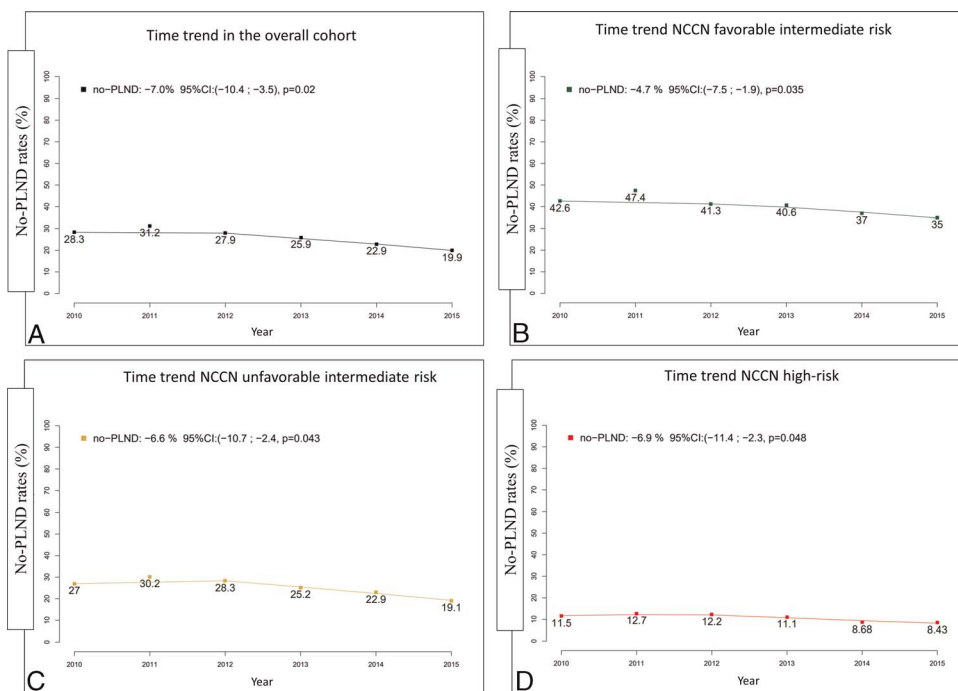


Figure 3. Estimated annual percentage changes in No-PLND rates in the overall cohort (A), as well as for each NCCN risk group: intermediate favorable (B), intermediate unfavorable (C), high-risk (D). NCCN = National Comprehensive Cancer Network; PLND = pelvic lymph node dissection.

unfavorable risk subgroup, Asians exhibited the lowest no-PLND rate (20%) relative to the other 3 race/ethnicity groups. Specifically, higher no-PLND rates were recorded in African Americans (27%), Hispanic-Latinos (26%), and Whites (25%). Consequently, it may be postulated that specific race/ethnicity-based barriers do not apply to PLND access; instead, it seems that broader access is provided to Asian NCCN intermediate unfavorable risk PCa patients than to other race/ethnicity groups. This observation is unexpected because Asian PCa patients usually exhibit a more favorable PCa phenotype and more favorable natural history^[10–12] than other ethnicities.

Fourth, we identified unexpectedly elevated differences in no-PLND rates according to 4 SEER regions: South (36%), West (25%), Midwest (25%), and Northeast (17%). A similar range of differences in no-PLND rates was recorded in the NCCN intermediate favorable (from 53% to 25%) and NCCN intermediate unfavorable (from 35% to 17%) risk subgroups. Conversely, a lower absolute range of differences was recorded in high-risk patients with NCCN (from 14% to 7%). Nonetheless, its magnitude seems highly relevant. Interestingly, the South invariably exhibited the highest no-PLND rates, followed by the West, Midwest, and Northeast regions, respectively. Hence, it seems that specific regions may be identified where the no-PLND rates are the highest. Consequently, most adherence efforts should focus on these regions. Similarly, pronounced differences were identified in the SEER-specific registry-based stratifications. Specifically, no-PLND rates according to the SEER registry ranged from 49% to 15% in the overall cohort, as well as from 70% to 22% in the NCCN intermediate favorable subgroup, from 49% to 13% in the NCCN intermediate unfavorable subgroup, and from 20% to 6% in the NCCN high-risk subgroup. The magnitudes of region-specific no-PLND rate differences and registry-specific no-PLND rate differences are clearly unexpected. These important differences cannot be explained by either clinical PCa characteristics at diagnosis or patient age differences, because stratification according to NCCN risk subgroups accounted for PSA, cT-stage, ISUP Gleason grade group, biopsy core positivity rates, and patient age was restricted from 40 to 75 years. Thus, case-mix differences according to clinical PCa characteristics at diagnosis and/or patient age could not explain the wide range of no-PLND rates across SEER regions and registries. Consequently, the greatest efforts aimed at NCCN PLND guideline adherence should focus on the urologic community within specific SEER regions and specific SEER registries that exhibited the highest no-PLND rates.

Fifth, we tested for differences in no-PLND rates over time (2010–2015). Overall, the no-PLND rate over time decreased from 28% to 20%. This reduction is consistent with improved adherence to the NCCN PLND guidelines. Interestingly, the absolute decrease in no-PLND annual rates was more pronounced in NCCN intermediate favorable ($\Delta = -8\%$; 43%–35%) and NCCN intermediate unfavorable ($\Delta = -8\%$; 27%–19%), followed by NCCN high-risk ($\Delta = -4\%$; 12%–8%), in that order. It is encouraging to observe these trends because they indicate the greatest improvement in NCCN PLND guideline adherence within the NCCN intermediate favorable risk subgroup, in whom no-PLND rates are highest, and in the NCCN intermediate unfavorable risk subgroup, in whom no-PLND rates are intermediate, followed by the NCCN high-risk subgroup, in whom no-PLND rates are lowest.

To our knowledge, several previous studies have addressed no-PLND rates in North America and Europe. Of these, 2 specifically examined the no-PLND rates within the SEER database.^[13,14] Both previous investigators included NCCN low-risk PCa patients, who were no longer considered for surgical management, including PLND. Moreover, neither investigator addressed no-PLND rates according to NCCN risk level and/or nomogram-defined threshold of 2%,

which represents the cornerstone for PLND decision-making in contemporary NCCN intermediate favorable and unfavorable PCa patients. Consequently, previous analyses cannot be interpreted with sufficient detail because NCCN risk subgrouping and/or nomogram risk calculation are clearly required when no-PLND rates are considered. The current analyses addressed these limitations and provided a contemporary assessment according to NCCN risk subgroups. Moreover, unlike previous analyses, we reported important regional and registry differences where doubling of no-PLND rates distinguished between regions and between registries within specific NCCN risk subgroups. Consequently, the current analysis provides several novel observations regarding no-PLND rates. Moreover, we identified specific areas of the United States, where greater emphasis on NCCN PLND guidelines should be placed when adherence to PLND recommendations represents the endpoint.

Our study has some limitations. First, some additional variables that are not included in the SEER database may affect PLND decision-making.^[15,16] Among these are intraoperative findings that may render PLND more complex (ie, previous hernia repair) and reimbursement patterns, in addition to clinician and/or patient preference. Second, the SEER database does not provide information on the extent of PLND and/or specific dissection templates.^[1,17,18] Third, the SEER database does not account for comorbidities, and it may be postulated that PLND may not be performed in patients with a less favorable comorbidity profile, and an adjustment for that variable could not be made in the present study.^[19,20] Finally, we did not have information on the extent to which urologists relied on the NCCN guidelines at the time of deciding upon PLND in the patients enrolled in the current study. However, these data are not available in any retrospective multi-institutional or population-based study analyzing adherence to guideline recommendations for PCa as well as for other diseases. Moreover, it is noteworthy that this bias is characterized by its nondifferential nature and hence (if present) would account for the entire study population equally. Finally, these, as well as all other limitations related to the retrospective, population-based nature of the SEER database, apply to this, as with other similar analyses that were based on the SEER database or other similar large-scale data repositories, such as the National Cancer Database, National Inpatient Sample, and National Surgical Quality Improvement Program.

5. Conclusions

The lowest no-PLND rates were recorded in the NCCN highest-risk patients and vice versa. Based on our findings that indicate unexpectedly elevated differences in no-PLND rates, further investigation is warranted. Correspondingly, in all NCCN risk subgroups, no-PLND rates decreased over time.

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Statement of ethics

Not applicable.

Conflict of interest statement

No conflict of interest has been declared by the author.

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Author contributions

All authors contributed equally to this study.

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