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## Original aricle

Adherence to pelvic lymph node dissection recommendations according to the National Comprehensive Cancer Network pelvic lymph node dissection guideline and the D'Amico lymph node invasion risk stratification

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#### **Abstract**

**Purpose:** To assess adherence rates to pelvic lymph node dissection (PLND) according to National Comprehensive Cancer Network (NCCN) PLND guideline (2% or higher risk) and D'Amico lymph node invasion (LNI) risk stratification (intermediate/high risk) in contemporary North American patients with prostate cancer treated with radical prostatectomy (RP).

**Material and methods:** We relied on 49,358 patients treated with RP and PLND (2010–2013) in SEER database. Adherence rates were quantified and multivariable (MVA) logistic regression analyses tested for independent predictors.

**Results:** According to NCCN PLND guideline and D'Amico LNI classification, PLND was recommended in 63.3% and 64.9% of patients, respectively. Corresponding adherence rates were 68.8% and 69.1%. Adherence rates improved from 67.3% to 71.6% and from 67.6% to 72.0%, respectively, over time. In MVA, more advanced clinical stage, higher biopsy Gleason score and higher number of positive biopsy cores predicted PLNDs that were performed below NCCN LNI nomogram risk threshold. Conversely, lower clinical stage, lower PSA and lower biopsy Gleason score predicted PLND omission in individuals with risk level above NCCN LNI nomogram risk threshold. MVA results for D'Amico classification were virtually identical.

Conclusions: Adherence to NCCN PLND guideline and D'Amico LNI classification for purpose of PLND is suboptimal in SEER population-based patients treated with RP. However, adherence rates have improved over time. Patients, who did not undergo PLND despite elevated LNI risk, had more favorable PCa characteristics than the average. Conversely, patients, who underwent PLND despite low-risk, had worse PCa characteristics than the average. © 2017 Elsevier Inc. All rights reserved.

Keywords: Lymph node invasion; Nomogram; SEER; Population based; NCCN guideline

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#### 1. Introduction

Despite improved prostate cancer (PCa) imaging, pelvic lymph node dissection (PLND) at radical prostatectomy (RP) still represents the gold-standard to detect lymph node invasion (LNI) and is essential for comprehensive PCa staging [1]. Potential added benefits of PLND include its curative effect in select patients with PCa with oligometastatic LNI [1,2]. However, consideration of PLND omission is also important in select patients with low-risk of LNI, to avoid unnecessary morbidity (lymphoceles, thromboembolic/neurovascular complications) [3,4]. Hence, the decision to perform a PLND should ideally be based on validated PLND guideline or risk stratification scheme [5,6]. The National Comprehensive Cancer Network (NCCN) PCa PLND guideline recommends PLND, when Cagiannos et al. [5] LNI nomogram probability is 2% or higher [7,8]. The latter was developed using predominantly North American patients [5]. Alternatively, in North American clinical practice, PLND recommendations frequently rest on the D'Amico risk stratification scheme and intermediate or high-risk patients represent PLND candidates [4,9–11].

Despite the existence of those 2 North American tools, suboptimal PLND adherence rates (60.8%) were previously reported in North American patients, treated 2006 or earlier [12]. As then, PCa treatment patterns changed, including PLND rates [13–15]. Most change might have occurred in low-risk patients with PCa, who are candidates for alternatives to RP and PLND [15,16]. Additionally, revised Gleason Grading added to differences between historical and contemporary patients, including RP and PLND use [16,17].

To address these changes, we hypothesized that PLND adherence rates to NCCN PLND guideline and to D'Amico risk stratification for PLND have improved. We examined, data from Surveillance, Epidemiology and End Results (SEER) population-based cohort, treated with RP between 2010 and 2013. Sensitivity analyses examined the effect of age and race. Multivariable (MVA) analyses tested predictors of omitted PLND or performed PLND, respectively in discordance with either NCCN PLND guideline or D'Amico risk stratification.

### 2. Material and methods

Patients were diagnosed with adenocarcinoma of the prostate (International Classification of Disease for Oncology [61.9]; histological code: 8140) and underwent RP as primary treatment method between 2010 and 2013. Patient records were retrieved within the SEER database that includes patient demographics, cancer incidence, and survival data from 18 cancer registries, which account for 26% of the US population. Specifically, the SEER data released April 2016 was used for current study, which contains reviewed PSA values for 2010–2013 [18]. Only patients with complete clinical and pathological information were

included. Exclusion criteria consisted of clinical stage T4, metastatic PCa, neoadjuvant therapy, as well as patients, in whom the lymph node procedure was classified as "biopsy" or "aspiration." These selection criteria resulted in a final cohort of 49,358 assessable patients.

#### 2.1. Statistical analyses

Predicted probability of LNI was calculated for every individual using the Cagiannos et al. nomogram, as per NCCN PLND guideline. Patients were categorized according to LNI risk of  $\geq 2\%$ , in whom PLND was recommended vs. LNI risk <2%, in whom PLND was not recommended [9]. The D'Amico risk stratification was used in a similar fashion: intermediate-/high-risk identified patients in whom PLND was recommended vs. low-risk identified patients in whom PLND was not recommended [9]. Subsequently, adherence rates to NCCN guideline and to D'Amico risk stratification PLND recommendations were quantified. Sensitivity analyses focused on age (<60, 60-70, and >70 years) and race (Caucasian, African-American). We also relied on the online version of the Memorial-Sloan Kettering Cancer Center (MSKCC) calculator, which can provide LNI risk estimate with input from PSA, clinical stage, biopsy Gleason grade, number of positive and negative cores, as well as percentage of biopsy samples that were positive for cancer [19]. The annual positive and negative adherence rates to PLND recommendations according to NCCN guideline and D'Amico risk stratification were analyzed in the overall population.

MVA logistic regression analyses tested predictors of "unwarranted PLND," which was not supported by PLND guideline recommendation due to low-LNI risk. We also tested predictors of "unwarranted PLND omission," which was not supported by PLND guideline recommendation due to high-LNI risk.

All tests were 2-sided with a statistical significance set at P < 0.05. Analyses were performed with the R statistical package (the R foundation for Statistical Computing, version 3.2.2).

#### 3. Results

Baseline, clinical and pathological characteristics of 49,358 patients with PCa within 18 SEER registries that underwent RP 2010 to 2013 are presented in Table 1. Most were Caucasian (80.6%), had clinical stage T1c (80.2%) and PSA < 10 ng/ml (83.8%). Biopsy Gleason scores  $\le$ 6, 7 and  $\ge$ 8 were reported in 42.8%, 45.0%, and 12.2% patients, respectively. PLND was performed in 28,601 patients at RP (58.0%).

# 3.1. Adherence rates to NCCN guideline PLND recommendation

PLND was recommended in 63.3% patients based on predicted LNI risk (NCCN PLND guideline) of  $\geq 2\%$ 

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