Survival benefit and utilization disparities of lymph node dissection in clinically node-negative T2+ penile squamous cell carcinoma: A SEER database analysis

Hangcheng Fu, Abigail George, Uzoma Anele, Mohammed Said, Jamie Messer, Murali K. Ankem
Department of Urology, University of Louisville School of Medicine, Louisville, KY, United States

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Corresponding author: Dr. Murali K. Ankem, Department of Urology, University of Louisville School of Medicine, Louisville, KY, United States; murali.ankem@louisville.edu

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ABSTRACT

Introduction: Penile squamous cell carcinoma (PSCC), although rare, presents significant morbidity. Current guidelines recommend lymph node dissection (LND) or lymph node biopsy on a risk-stratified basis for intermediate- or high-risk patients; however, survival benefits of LND in clinically node-negative patients need further exploration.
Methods: Patients with T2+N0M0 PSCC were identified from the Surveillance, Epidemiology, and End Results (SEER) database (2004–2015). Inclusion required histologically confirmed squamous cell carcinoma localized to the penis. Patients with unavailable staging or unknown followup were excluded. Chi-square tests, Kaplan-Meier survival curves, and multivariable Cox regression analyses assessed disease-specific survival (DSS).
Results: A total of 825 patients were analyzed. The cohort predominantly included non-Hispanic White (65.2%) and Hispanic (22.3%) patients, with a median age of 69 years. Most patients were married (57.2%), while few received radiation (6.6%) or chemotherapy (3.5%). Only 23.5% underwent LND, with no significant variation across T stages. Median followup was 60 months. Chemotherapy usage increased significantly with advancing T stage ($p=0.009$), whereas radiation did not. LND significantly improved DSS overall ($p<0.001$) and specifically in T2 ($p=0.040$) and T3 stages ($p=0.002$). Multivariable analysis identified LND as an independent protective factor (hazard ratio [HR] 0.457, 95% confidence interval [CI] 0.328−0.711, $p<0.001$). Younger patients (<40 years) had higher LND rates (56%) compared to older patients (>70 years; 14.8%).
Conclusions: Despite NCCN guidelines recommending LND for T2N0M0 PSCC, utilization

remains low. Our findings highlight a survival advantage associated with regional LND, underscoring the need for enhanced urologist education to improve adherence and patient outcomes.

INTRODUCTION

Penile cancer is a rare malignancy in North America with an incidence of less than one new case per 100,000 males (1, 2). Though penile malignancies make up less than 1% of cancers in men in the United States, rates are higher, at up to 4.4 out of 100,000 men, in developing countries (1). The most significant prognostic factor is the extent of regional lymph node involvement (2). Inguinal lymph nodes are the first site of metastatic spread in penile carcinoma and thus represent the most significant predictors of survival; the 5-year survival rate of penile cancer patients without inguinal node involvement is up to 85% to 100%, but as low as 15% to 45% in those with inguinal node metastasis (1, 3). Involvement of pelvic lymph nodes represents even more aggressive behavior, such that 5-year survival in those patients drops below 15% and, in these men, delayed surgical intervention adversely affects survival (4, 5). Inguinal lymph node staging is therefore critical when making the diagnosis but is difficult as around 20% to 25% of clinically negative lymph nodes have micro-metastases (1, 3). While local tumor stage and grade are predictive of occult lymph node micro metastasis with high reliability in the low- and high-risk groups, it is less reliable in the intermediate risk group (6). Due to this tendency for early lymphatic metastasis, treatment of regional lymph nodes through surgical dissection is crucial for prognosis, but requires a delicate balance of identifying clinically normal, but involved, nodes without overexposing patients to the complications of lymphadenectomy.

For penile cancer patients without palpable inguinal lymph nodes, The National Comprehensive Cancer Network (NCCN) guidelines recommend surveillance for low risk (Tis, Ta, T1a) disease and imaging and staging with either inguinal lymph node dissection (ILND) or dynamic sentinel lymph node biopsy (DSLNB) in intermediate or high-risk patients (T1b, T2 or higher) (7). In clinically node negative patients, prophylactic ILND has been shown to afford a higher five-year survival rate than in clinically node positive patients (3, 8). Early resection of lymph node metastasis improves disease specific three-year survival of patients with positive lymph nodes from 35% with metastasis to 84% after resection (8, 9). However, prophylactic ILND—while providing optimal survival in clinically node-negative patients—has a more than 80% over-treatment rate and carries its own risks, with a complication rate of up to 25%, including skin necrosis, wound infection, lymphedema, seroma, lymphocele, and deep vein thrombosis (DVT) and is associated with substantial physical and psychological impact on patients (1, 5, 10). However, Bevan-Thomas et al. suggest prophylactic and therapeutic ILND confer an acceptable morbidity risk considering the potential therapeutic benefit and are associated with a lower incidence of complications than palliative ILND (11). Though lymph node dissection (LND) is the cornerstone of staging

and management of penile cancer, only about 19% to 37% of patients with high grade or invasive penile cancer in the United States receive lymphadenectomy (8).

Despite the past study emphasizing the importance of LND in staging penile cancer, no large cohort study focused on the survival benefit of LND in clinical lymph nodes negative patients. In this study, using the Surveillance, Epidemiology, and End Results (SEER) database, we aimed to identify survival benefit and utilization disparities of LND in clinically node-negative T2+ penile squamous cell carcinoma (PSCC).

METHODS

The study received exemption from the Institutional Review Board (IRB Number: 25.0389). Data were obtained from the SEER database 18 registries using SEER*Stat software (version 8.4.2, seer.cancer.gov/seerstat). Patients diagnosed between 2004 and 2015 with penile squamous cell carcinoma (PSCC) were identified. Inclusion criteria were (1) primary penile cancer with codes including prepuce, glans penis, body of penis, overlapping lesion of penis, and penis not otherwise specified (NOS); (2) histologically confirmed squamous cell carcinoma; and (3) pathological stage T2, T3, or T4 with N0 and M0 status. Exclusion criteria included any nodal (N+) or metastatic (M+) disease, T1 tumors, missing Tumor-Node-Metastasis (TNM) stage information, or unknown survival times. From an initial cohort of 5,356 penile cancer cases, 825 patients met inclusion criteria for analysis.

The primary outcome was disease-specific survival (DSS), calculated from the date of diagnosis to death specifically attributed to penile cancer. Additional clinical variables analyzed included age, race/ethnicity, marital status, tumor grade, radiation therapy, chemotherapy, LND status, and T stage.

Differences between groups were assessed using the chi-square test. Kaplan-Meier survival curves were generated and compared using the log-rank test. Univariate and multivariable Cox proportional hazards models were utilized to calculate hazard ratios (HRs) and evaluate the impact of clinicopathologic factors on DSS. Statistical analyses were performed with MedCalc software (version 18.2.1, Mariakerke, Belgium), and statistical significance was set at a two-sided p-value of less than 0.05.

RESULTS

Majority of the T2+N0M0 patients did not undergo lymph node dissection

As previously described, 825 patients were selected from a total of 5,356 penile cancer patients identified in the SEER database from 2004 to 2015The median follow-up for entire cohort was 60 months. Figure 1 illustrates trends over time in LND. There was a modest increase in the proportion of patients undergoing LND (from 17% in 2004 to 31% in 2015). Nevertheless, the majority of patients did not undergo LND or sampling.

Patient characteristics by treatment

Table 1 summarizes the demographics and clinical characteristics of the T2+N0M0 cohort. Among these patients, 539 (65.3%) were non-Hispanic White, 64 (7.8%) were non-Hispanic Black, and 183 (22.2%) were Hispanic. The median age at diagnosis was 69 years. A majority

(57.5%) were married at the time of diagnosis, while 17.7% had never married, and 19.6% were widowed. Tumor grading showed 22.3% as grade 1, 50.2% as grade 2, 21.3% as grade 3, and 0.6% as grade 4. Radiation therapy was administered to 6.3% of patients, while chemotherapy was administered to only 3.5%. Overall, 195 patients (23.5%) underwent LND or biopsy, while the remaining patients did not. By T stage, 503 (61.0%) were T2, 287 (34.8%) were T3, and 35 (4.2%) were T4.

As indicated in Table S1, there were no statistically significant differences in LND rates across T stages (22.7% for T2, 25.4% for T3, and 22.9% for T4). Similarly, radiotherapy rates did not differ significantly across T stages (6.4% for T2, 6.3% for T3, and 5.7% for T4). However, higher T stages correlated with increased chemotherapy use (2.4% for T2, 4.5% for T3, and 11.4% for T4; p=0.009).

Correlation between clinical characteristics and Disease-specific Survival (DSS) in pT2+N0M0 penile cancer

Kaplan-Meier survival analysis (Figure 2) demonstrated significantly improved DSS for patients undergoing LND compared to those who did not (5-year median survival 82.0% vs. 72.2%, p<0.001). Subgroup analysis showed similar survival benefits for patients with T2 (5-year median survival 80.2% vs. 74.3%, p=0.040) and T3 (5-year median survival 85.5% vs. 69.6%, p=0.002) disease but no significant difference in patients with T4 disease.

Multivariate Cox regression analysis as shown Table 2 confirmed that LND (HR: 0.457, 95% CI: 0.310–0.674, p<0.001) and tumor grade significantly impacted DSS. Compared to grade 1 tumors, tumors grade 2 (HR: 2.203, p<0.001), grade 3 (HR: 2.386, p<0.001), and grade 4 (HR: 4.602, p=0.012) were associated with poorer survival.

The disparity of pT2+N0M0 patients who underwent lymph node dissection

Table 3 highlights disparities in the use of LND. Although statistically non-significant, only 21.2% of the Non-Hispanic White patients underwent LND while 31.1% of the Hispanic patients underwent LND (p=0.056). Similarly, only 15% of patients with household incomes less than $35,000 underwent LND compared to 23.8% of higher-income patients. Patients who were separated, widowed, or divorced were less likely to undergo LND (14.3%, 15.1%, and 21.3%, respectively). No non-Hispanic American Indian/Alaska Native patients underwent LND, while 31% of Hispanic patients did. Rural versus urban residence did not influence LND utilization. Age was the strongest predictor of LND: 56% of patients under 40 underwent the procedure compared to only 14.8% of patients older than 70 years (p<0.001).

DISCUSSION

In this study, utilizing a large population dataset, we demonstrated that patients with clinically node-negative T2+ PSCC who underwent LND showed significant DSS benefits compared to those who did not. Older age was associated with a reduced likelihood of receiving LND. Lymph node involvement affects disease prognosis more than primary tumor characteristics and early identification and resection are imperative to patient survival (2, 10, 12). However, despite NCCN guidelines advocating for LND or DSLNB in intermediate or high-risk patients, historical data shows these procedures have been underperformed (8, 13). Correa et

al. reported an increase in the rate of ILND from 23.3% to 33.6% over a decade (2004-2014) in patients for whom ILND was absolutely indicated per NCCN guidelines, with an overall LND rate of 27.2% (13, 14). Consistent with this finding, our analysis of a national dataset from 2004 to 2015 revealed that only 23.5% of patients with T2+N0M0 PSCC underwent LND. Possible explanations for this discrepancy include concerns regarding procedure-related morbidity, limited physician experience, and inadequate guideline awareness. Thus, enhancing patient and community provider education should be a priority.

Previous studies indicate LND significantly predicts improved overall survival in clinically node-positive patients, with evidence from Ma et al. supporting prophylactic LND in clinically node-negative (cN0) patients as beneficial for long-term survival (3, 8). However, few studies have specifically targeted clinical node-negative populations. Our results showed LND to be significantly associated with DSS benefits across the entire cohort ($p<0.001$), specifically within T2 ($p=0.040$) and T3 stages ($p=0.002$), and independently prognostic for improved survival (HR = 0.457, 95% CI 0.328–0.711, $p<0.001$), strongly supporting LND's survival advantages.

The two prevalent ILND approaches include open modified (MILD) and superficial (SILD) techniques, though a minimally invasive approach via robot-assisted video endoscopic inguinal lymphadenectomy is also performed at various centers. In patients with intermediate- and high- risk cN0 penile cancer, Ma et al. suggest MILD is considered the optimal choice for staging given the low prevalence of DSLNB capacity and the complications associated with radical ILND (3). However, SILD has been shown to provide better oncologic clearance with no groin recurrences, but significantly a higher complication rate (15). It has also been suggested that removed lymph node count and density play a role in predicting DSS rate after lymphadenectomy (10). Li et al. found that in patients with pN0 penile cancer, the removal of at least 16 lymph nodes was associated with significantly longer disease specific survival rates (10). Robot-assisted video endoscopic ILND increasingly adopted by various centers, is a feasible technique which yields similar lymph node counts as an open approach as well as reduced hospital stays and lower wound-associated complications (16-19). Sentinel-guided lymphadenectomy is also an alternative to traditional LND, with recent literature describing new marking techniques that do not require nuclear medicine infrastructure such as the combination of indocyanine green (ICG) and superparamagnetic iron oxide nanoparticles (SPION), which thus have more generalized applicability to routine clinical practice. Michalik et al. performed a pilot study the use of ICG and SPIONs injected peritumorally which found a 66% concordance between pre-operative MRI and magnetometerguided sentinel node biopsy and 96% concordance between magnetometer-guided fluorescence imaging and sentinel node biopsy (20). Our study included diverse LND and sampling techniques. However, due to the nature of the SEER database coding, different lymph nodes dissections techniques were not differentiated.

Using SEER database analyses similar to ours, Timothy et al. found survival improvements associated with lymphadenectomy involving ≥8 nodes (14). Due to the nature of the database, the patients included in this study were treated in 17 centers over a 17-year

timeframe, thus ranging various inguinal lymphadenectomy techniques. Therefore, Li et al. performed a standardized study of patients with PSCC treated at a single institution over a 10-year time frame and observed the removal of at least 16 lymph nodes was associated with longer DSS rate in patients with pN0 penile cancer (10). Our findings echoed this, demonstrating survival differences when comparing patients who had ≤5 lymph nodes removed versus those with >5 (p=0.049). However, no incremental survival benefits were observed for patients with >5 nodes removed, highlighting the importance of surgical quality rather than merely node quantity.

Socioeconomic disparities were notable in our findings, with non-Hispanic White patients less likely to receive LND compared to Hispanic patients. Spiess et al. previously noted higher penile cancer incidence among Hispanic and African American populations, with worse survival outcomes for African Americans (21). Our cohort analysis underscored age as the strongest predictor of undergoing LND. Younger age at diagnosis among Hispanic patients possibly explains their higher likelihood of receiving LND compared to non-Hispanic white patients (Table S2). Patients with lower incomes and unmarried status were also less likely to undergo LND, underscoring the need for targeted education and intervention in these high-risk populations to potentially improve survival outcomes.

While the SEER database allows examination that would not be possible outside of a multi-institutional trial, several limitations exist: SEER's geographical coverage does not comprehensively represent the U.S. population, and it lacks critical information such as patient comorbidities or specific risk factors influencing treatment decisions. Additionally, retrospective analysis limitations restrict our ability to clearly differentiate survival benefits due to more accurate staging versus actual micrometastasis removal. Prospective studies remain necessary to validate and expand upon our findings regarding LND’s therapeutic benefits in clinically node-negative PSCC patients.

CONCLUSIONS

In this population-based study, LND was significantly associated with improved DSS in patients with clinically node-negative T2+ penile squamous cell carcinoma. Our findings highlight the urgent need to address disparities in LND utilization and to promote guideline adherence to improve outcomes in this rare but aggressive malignancy.

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FIGURES AND TABLES

Figure 1. Trend in the proportion of clinically node-negative pT2+ penile squamous cell carcinoma patients undergoing lymph node dissection (LND) from 2004−2015.

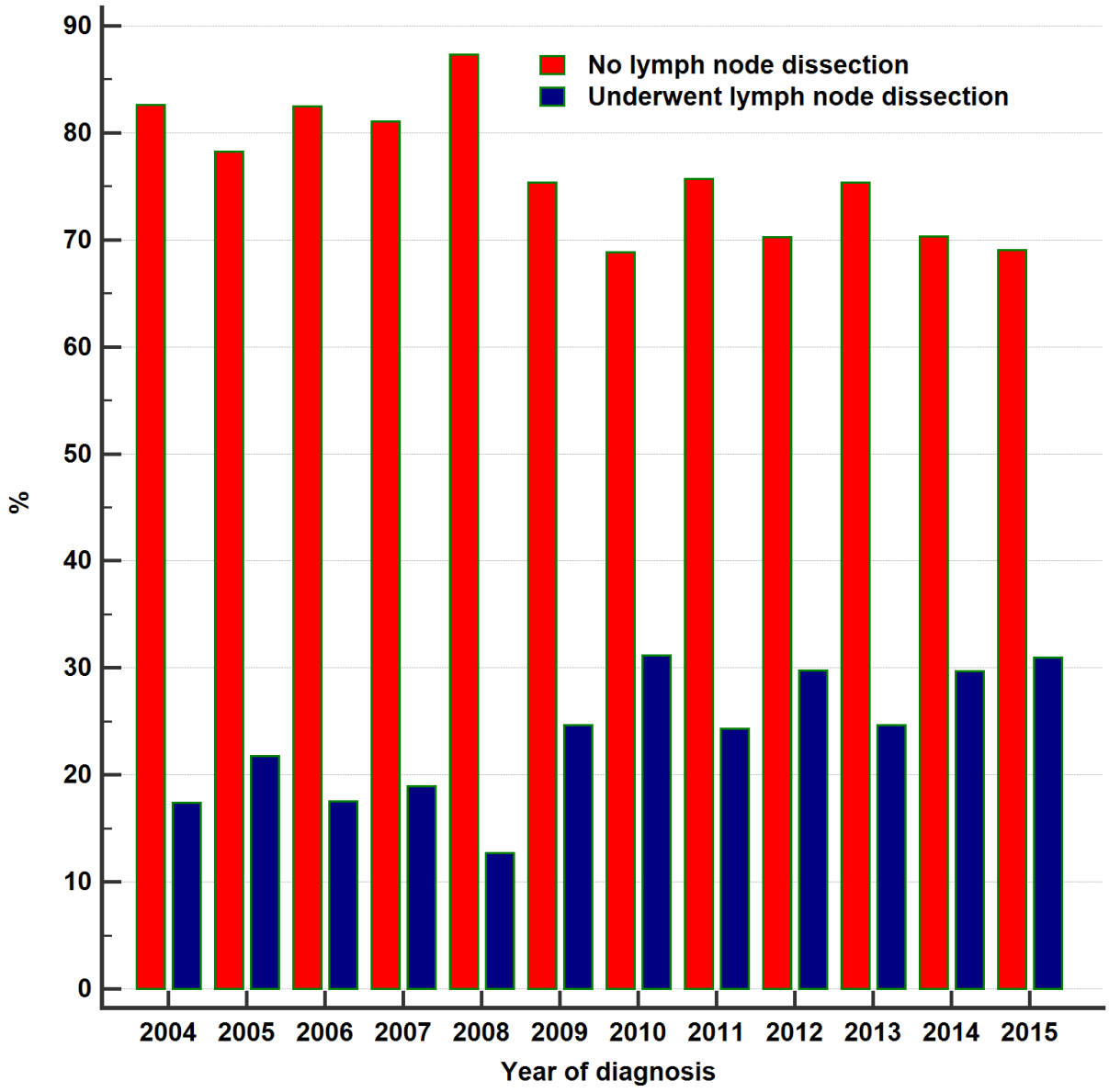

Figure 2. Kaplan-Meier curves comparing disease-specific survival (DSS) between patients with and without lymph node dissection (LND) among clinically node-negative penile squamous cell carcinoma (PSCC) patients**.** (A) All pT2+ patients (median follow-up: 60 months), (B) pT2 patients (median follow-up:61 months), (C) pT3 patients (median follow-up:58 months), and (D) pT4 patients (median follow-up: 65 months).

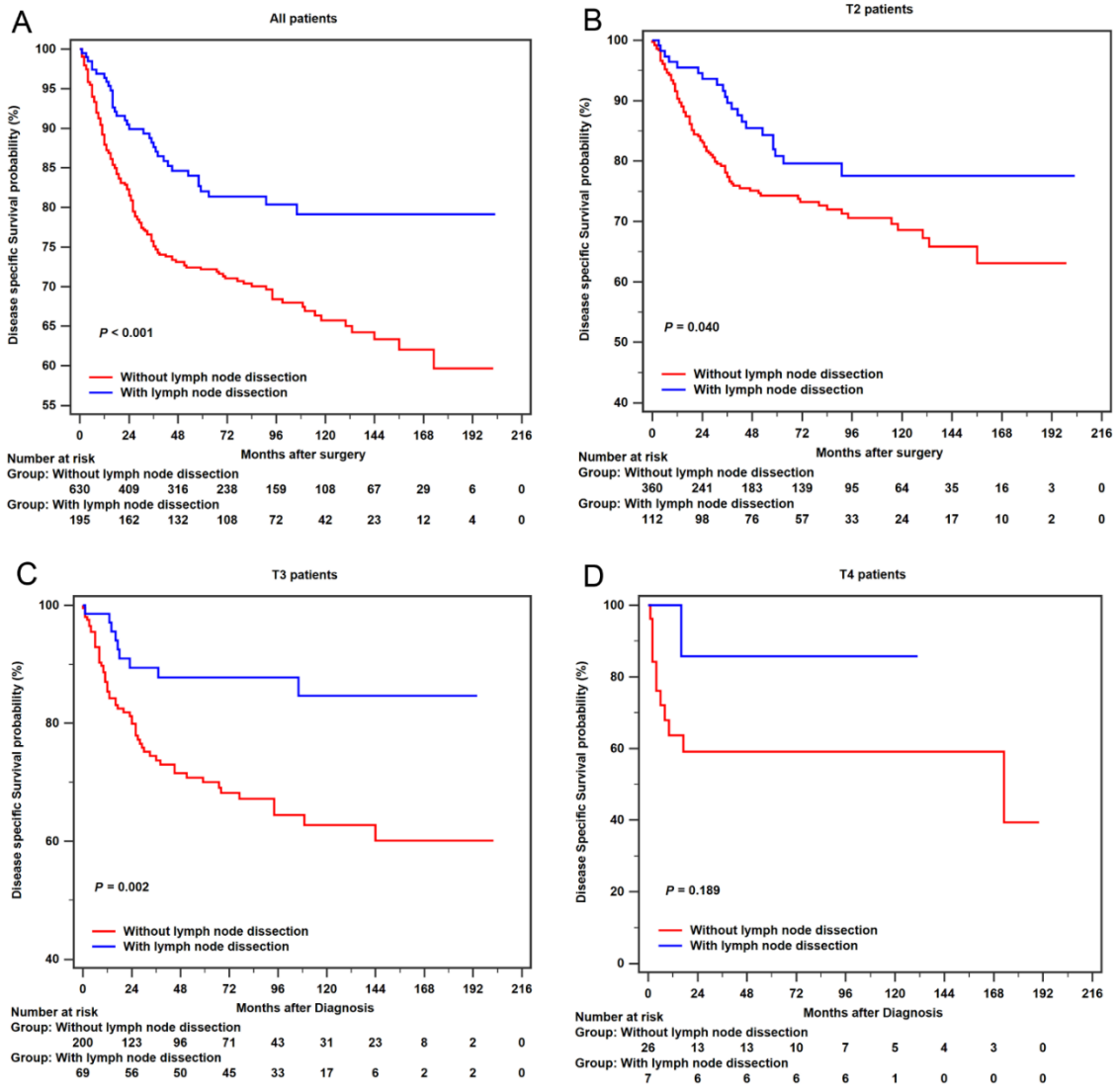

Table 1. Patient demographics and diagnosis of patients with T2+N0M0 penile squamous cell carcinoma	
Variables	**All patients**
All	825
Race	
Non-Hispanic White	539 (65.3%)
Non-Hispanic Black	64 (7.8%)
Hispanic (All Races)	183 (22.2%)
Non-Hispanic Asian or Pacific Islander	34 (4.1%)
Non-Hispanic American Indian/Alaska Native	5(0.6%)
Age at diagnosis[a]	
Mean	67.48±13.2
Median (25−75%)	69 (58−78)
Marital status	
Married	474 (57.5%)
Single (Never married)	145 (17.6%)
Widowed or divorced	161 (19.5%)
Unknown	45 (5.5%)
Grade	
Well differentiated; Grade I	184(22.3%)
Moderately differentiated; Grade II	414 (50.2%)
Poorly differentiated; Grade III	176 (21.3%)
Undifferentiated; anaplastic; Grade IV	5 (0.6%)
Unknown	46 (5.6%)
Radiation	
Without	773 (93.7%)
With	52 (6.3%)
Chemotherapy	
Without	796 (96.5%)
With	29 (3.5%)
Lymph node dissection	
Without	630 (76.5%)
With	195 (23.5%)
T stage	
T2	503 (61.0%)
T3	287 (34.8%)
T4	35 (4.2%)

[a]Calculated as a continuous variable.

Table 2. Multivariable Cox regression analysis of the clinical variables and penile cancer disease-specific survival		
Variables	**HR (95% CI)**	**p**
Chemotherapy (with vs. without[a])	1.808(0.832−3.926)	0.134
Radiation (with vs. without[a])	1.005 (0.013−14.67)	0.958
Lymph node dissection (with vs. without[a])	0.457 (0.310−0.674)	**<0.001**
TNM stage		
T3 vs. T2[a]	1.074 (0.790−1.460)	0.646
T4 vs. T2[a]	1.770 (0.957−3.271)	0.068
Tumor grade		
Grade 2 vs. grade 1[a]	2.203 (1.432−-3.387)	**<0.001**
Grade 3 vs. grade 1[a]	2.386 (1.474−3.863)	**<0.001**
Grade 4 vs. grade 1[a]	4.602 (1.388−15.256)	**0.012**
Unknown vs. grade 1[a]	0.887 (0.364−2.159)	0.792

[a]Reference group. p<0.05 is considered statistically significant. CI: confidence interval; HR, hazard ratio.

Table 3. Association between LND and penile cancer patients social-economic status in T2+N0M0 penile squamous cell carcinoma			
Variables	**No LND**	**LND**	**p**
Rural urban continuum status			0.440
Counties in metropolitan areas >1 million pop	312	112	
Counties in metropolitan areas of 250 000 to 1 million pop	153	37	
Counties in metropolitan areas of <250 000 pop	52	12	
Non-metropolitan counties adjacent to a metropolitan area	63	19	
Non-metropolitan counties not adjacent to a metropolitan area	49	15	
Unknown/missing/no match (Alaska or Hawaii - entire state)	1	0	
Race			0.056
Hispanic (all races)	126	57	
Non-Hispanic American Indian/Alaska Native	5	0	
Non-Hispanic Asian or Pacific Islander	26	8	
Non-Hispanic Black	48	16	
Non-Hispanic White	425	114	
Median household income inflation adjusted to 2021			0.924

$35 000−39 999	19	7	
$40 000−44 999	31	7	
$45 000−49 999	47	14	
$50 000−54 999	40	8	
$55 000−59 999	67	22	
$60 000−64 999	76	24	
$65 000−69 999	94	36	
$70 000−$74 999	64	19	
$75 000+	181	56	
<$35 000	11	2	
Marital status at diagnosis			0.133
Married (including common law)	355	119	
Single (never married)	106	39	
Divorced	59	16	
Widowed	73	13	
Others	37	8	
Age			**<0.001**
<40	11	14	
40−70	281	122	
>70	338	59	

$p<0.05$ is considered statistically significant, χ^2 test for categorical variables. LND: lymph node dissection.