



National utilization of regional lymph node dissection among patients with kidney cancer and clinical lymphadenopathy undergoing radical nephrectomy



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ARTICLE INFO

Keywords:

Kidney cancer
Clinical lymphadenopathy
Lymph node dissection
Nephrectomy
Renal cell carcinoma

ABSTRACT

Introduction/background: Regional lymph node dissection (LND) may provide oncologic benefit among patients with clinical lymphadenopathy in renal cell carcinoma (RCC) at the time of radical nephrectomy (RN). Yet, little is known about contemporary use of LND for patients with RCC and regional lymphadenopathy. Thus, we assessed national trends in RN and LND among RCC patients with renal masses and clinical lymphadenopathy. **Materials and methods:** From the National Cancer Data Base (NCDB), we identified patients with RCC and clinical lymphadenopathy without distant metastasis (clinical T1-4 N1+ M0) who underwent RN from 2001 to 2011. The primary outcome was concomitant LND at the time of RN. Multivariable logistic regression analysis was used to identify patient and hospital characteristics associated with the primary outcome.

Results: Among 1840 patients with clinical N1+ treated surgically, 78% received LND (n=1444). The proportion of patients who underwent LND increased from 77% in 2001 to 82% in 2011 (p < 0.01 for trend). On multivariable analysis, patients undergoing surgery at academic centers were more likely to undergo LND compared to those treated at community hospitals (OR: 1.59; p < 0.01). In a subset of patients with surgical approach available, robotic or laparoscopic nephrectomy also correlated with lower use of RN and LND compared to open surgery (OR: 0.46; p < 0.01).

Conclusion: Among patients with RCC and clinical lymphadenopathy, ~20% are not receiving LND at the time of RN in the U.S. Academic hospitals and open surgery was associated with receipt of LND. Centralization to tertiary academic hospitals may facilitate greater use of LND.

Introduction

Approximately 60,000 patients are diagnosed with renal cell carcinoma (RCC) in the United States each year [1] While there has been a gradual stage migration to localized renal tumors due to greater use of cross-sectional imaging, it is essential to recognize that approximately 30% of patients present with locally advanced disease, regional lymphadenopathy, or metastatic disease [1,2] Moreover, a significant proportion of patients will go on to develop recurrence [3] Clinical

practice guidelines currently recommend surgical resection as the primary therapy for patients with locally advanced disease and regional lymphadenopathy in the absence of distant metastatic disease [4].

Surgical resection of oncologic disease including lymph nodes may be even more pertinent in light of the recent randomized clinical trial demonstrating a lack of survival benefit for targeted therapy following resection of locally advanced or high-risk RCC [5]. However, several trials are still ongoing and have yet to report the results to better define the optimal management strategies of locally advanced kidney cancer [6].

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<http://dx.doi.org/10.1016/j.ctarc.2017.05.001>

Received 16 January 2017; Received in revised form 24 April 2017; Accepted 15 May 2017

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The role of regional lymph node dissection (LND) in the management of locally advanced RCC remains controversial to some degree. Approximately 40% of patients may harbor regional lymph node metastasis among patients with aggressive pathologic features including tumor size, high Fuhrman grade and central necrosis [7,8]. However, several studies examining the clinical efficacy of LND for nodal metastasis from RCC have been mixed about whether it improves oncologic outcomes. Several observational studies have suggested that LND is beneficial for staging by identifying patients who may benefit from adjuvant therapy and affords a modest improvement in survival [9–11]. However, European Organization for Research and Treatment of Cancer (EORTC) trial 3088 randomly allocated to regional LND or control for localized renal tumors. This study found that regional LND did not confer a survival benefit, though the results were limited due to low overall event rate of lymph node metastases and included patients with mostly localized renal tumors [12]. Consequently, this multi-center trial is largely viewed as limited in answering whether regional LND is beneficial, especially among patients with locally advanced tumors and regional lymph node metastases. At present, there is a key knowledge gap about the national utilization of LND for patients with locally advanced RCC. Addressing this key question is needed and will help elucidate the clinical patterns of patients where complete surgical resection is feasible and which patients will warrant closer surveillance following nephrectomy [13]. In this context, we sought to determine the national rates of RN and LND and identify patient and hospital characteristics associated with its use among patients with RCC renal tumors and clinical lymphadenopathy at presentation.

Methods

Data Source

The National Cancer Data Base (NCDB), a national cancer registry maintained by the American College of Surgeons, Commission on Cancer since 1989, captures an estimated 70% of all newly diagnosed cancer cases from over 1500 cancer programs in the United States and Puerto Rico [14]. Our study was deemed exempt from the Case Western Reserve University institutional review board approval.

Study population

To ascertain the utilization of LND at the time of RN, as recommended by the NCCN guidelines, we identified all patients with clinical regional lymphadenopathy without distant metastases ($T_{any}N1+M0$) prior to surgery or systemic therapy from 2001 to 2011. Regional lymphadenopathy was defined by the clinical TNM staging system and, as a result, the analytic cohort first identified patients with clinical $N1+$. We also limited the cohort to all patients who underwent RN with/without LND as the primary therapy. Those with other known malignancies were excluded. RCC histology was based on the International Classification of Disease for Oncology, 3rd edition and grouped as clear cell (8005, 8310, 8312, 8316), papillary (8050, 8260), chromophobe (8317), or other RCC variants (8318, 8319, 8320, 8323). The aim of the inclusion criteria was to select a patient population who would potentially benefit from regional LND—patients with non-metastatic RCC renal masses and retroperitoneal lymphadenopathy.

Covariates and outcome

Demographic, clinical, and provider covariates were assessed between the two groups, those who underwent LND and those who did not. Demographic factors included gender, age group, race/ethnicity, insurance status (private, Medicare, Medicaid, or uninsured/unknown), and median household income based on year 2000 US census data. Clinical factors included the Charlson-Deyo Comorbidity Index (CCI), tumor histology, and pathologic T-stage. Hospital type was classified as

academic (having a primary affiliation with a medical school, or being a National Cancer Institute-designated comprehensive cancer center) or non-academic (including community cancer programs and comprehensive community programs). The primary outcome of this study was whether or not patients underwent regional LND at the time of RN. A secondary outcome measure for this study was the number of lymph nodes removed among patients undergoing regional LND.

The NCDB provides information about surgical approach (robotic, laparoscopic or open) for only the recent years of our study. To elucidate the possible association of regional LND and surgical approach, we identified a subgroup of patients with clinical $T_{any}N1+M0$ from 2010 and 2011. Similar covariates were used to identify association of patient and hospital characteristics and receipts of regional LND with exception of also adding surgical approach. We dichotomized surgical approach to open versus minimally-invasive surgery (MIS), which was defined as either laparoscopic or robotic surgery.

Statistical analysis

Bivariate associations between the covariates and the two treatment groups were determined using Chi-square. A two sample T-test was used to test for differences in the number of lymph nodes retrieved in the subset of patients treated with RN and LND. Time trend analysis for the percent of cases undergoing LND was performed using a nonparametric Wilcoxon-rank sum test. We also performed a multivariable logistic regression to identify patient and hospital covariates associated with surgical receipt of RN and regional LND. Furthermore, we also performed a similar multivariable analysis for 2010 and 2011 to specifically evaluate the possible impact of surgical approach (open vs. MIS) on the primary outcome measure in a subgroup analysis of years 2010 and 2011. We defined statistical significance with a two-sided p-value < 0.05. Stata MP version 14 MP was used to perform all statistical analyses [15].

Results

During the study interval, we identified 1853 patients diagnosed with non-metastatic RCC with clinical retroperitoneal lymphadenopathy and treated surgically with RN. Table 1 presents clinical and pathologic characteristics of the cohort by performance of regional LND. Overall, 1444 patients underwent a concomitant regional LND at the time of nephrectomy (78%). Patients treated with RN and regional LND tended to be younger and had a lower Charlson comorbidity index score. Approximately half of patients (45%) underwent surgery at academic medical centers which have higher surgical volume. Interestingly, the national use of regional LND increased over time from 77% percent in 2001 to 82% in 2011 (Fig. 1a; $p < 0.001$ for trend).

On multivariable analysis, we identified several covariates associated with performance of regional LND at the time of RN among patients with non-metastatic RCC with regional lymphadenopathy at presentation (Table 2). Although age, gender, and race were not associated with surgical receipt of RN and regional LND, patients with higher comorbidities with Charlson index ≥ 2 had a significantly lower odds of undergoing regional LND compared to healthier patients (adjusted OR: 0.58; 95% CI: 0.37–0.92; $p = 0.02$). Relative to patients who primarily insured with Medicare, patients had higher odds of undergoing RN and regional LND when primarily insured with private insurance (adjusted OR 2.22; 95% CI: 1.46–3.39; $p < 0.01$) or Medicaid (adjusted OR 2.08; 95% CI: 1.11–3.91; $p = 0.02$). Interestingly, patients who underwent surgery at academic hospitals also demonstrated a higher adjusted odds ratio for receipt of RN and regional LND compared to those treated at non-academic/community hospitals (OR 1.59; 95%CI 1.22–2.07, $p < 0.01$). Among the subgroup of patients undergoing concomitant RN and regional LND, academic hospitals also had a higher mean number of lymph nodes harvested than those having surgery at community hospitals

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