Original Article

Population-Level Comparative Effectiveness of Laparoscopic Versus Open Radical Nephrectomy for Patients With Kidney Cancer

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BACKGROUND: Because there is limited population-based evidence supporting the comparative effectiveness of laparoscopic radical nephrectomy (LRN) after its widespread adoption, we compared trends in hospital-based outcomes among patients with kidney cancer treated with LRN or open radical nephrectomy (ORN). **METHODS:** Using linked SEER-Medicare data, the authors identified patients with kidney cancer who were treated with LRN or ORN from 2000 through 2005. The authors measured 4 primary outcomes: intensive care unit (ICU) admission, prolonged length of stay, 30-day hospital readmission, and in-hospital mortality. The authors then estimated the association between surgical approach and each outcome, adjusting for patient demographics, tumor characteristics, and year of surgery. **RESULTS:** The authors identified 2108 (26%) and 5895 (74%) patients treated with LRN and ORN, respectively. Patients treated with LRN were more likely to be white, female, of higher socioeconomic position, and to have tumor sizes of ≤4 cm (all $P < .05$). The adjusted probability of ICU admission and prolonged length of stay was 41% and 46% lower, respectively, for patients undergoing LRN ($P < .001$). Although uncommon for both groups, the adjusted probability of in-hospital mortality was 51% higher (2.3% vs 1.5%, $P = .04$) for patients treated with a laparoscopic approach. **CONCLUSIONS:** At a population level, patients treated with LRN have a lower likelihood of ICU admission and prolonged length of stay, supporting the convalescence benefits of laparoscopy. In-hospital mortality, however, was higher among patients treated with LRN. The latter finding suggests a potentially unanticipated consequence of this technique and highlights the need for long-term monitoring during and after the widespread adoption of new surgical technologies. *Cancer* **2011;117:4184–93.** *© 2011 American Cancer Society.*

KEYWORDS: kidney neoplasm, patient readmission, length of stay, intensive care, hospital mortality, laparoscopy.

In contrast to pharmaceuticals where novel agents undergo rigorous assessment of safety and efficacy before introduction into clinical practice, the adoption of new surgical techniques and technology is often driven by perceived (rather than proven) clinical benefit, patient and surgeon demand, and economic considerations.[1-3] Accordingly, it is not uncommon for diffusion of surgical innovation to outpace the generation of evidence supporting its safety and effectiveness in diverse clinical settings.[1,4] In some cases, this paradox can expose patients to unanticipated risks associated with widespread implementation of new surgical techniques. Illustrating this point, evaluation of patient outcomes following the widespread adoption of laparoscopic cholecystectomy revealed higher than expected rates of potentially lethal bile duct injuries.[5-7] Likewise, unanticipated adverse outcomes were identified in postdiffusion appraisals of extracranial-intracranial arterial bypass surgeries among patients at risk for ischemic stroke.[8] Given these concerns, there is now growing support for efforts aimed at long-term monitoring of the safety and comparative effectiveness of novel surgical techniques even after their widespread implementation in both academic and community practice.[4]

In urological oncology, laparoscopic radical nephrectomy (LRN) is now widely accepted as the standard of care for many patients requiring complete kidney removal for renal cell carcinoma. When compared with open radical nephrectomy (ORN), the available evidence indicates that LRN provides equivalent cancer control while affording an easier and more rapid convalescence.[9-11] Importantly, however, the actual empirical data supporting this conclusion come mainly

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from case series reported by innovators and early adopters. Moreover, because there is a substantial learning curve associated with this technique,[10,12] it can be argued that LRN represents a quintessential procedure for which additional data are needed to clarify whether the comparative benefits of LRN have been achieved at a population-level and/or whether unintended consequences have occurred during its widespread adoption.

In this context, we used linked Surveillance, Epidemiology, and End Results (SEER)-Medicare data to measure and compare longitudinal trends for the following hospital-based outcomes among patients with renal cell carcinoma treated with LRN versus ORN: 1) intensive care unit (ICU) admission, 2) length of stay (LOS), 3) 30-day hospital readmission, and 4) in-hospital mortality. By evaluating these outcomes during the period of widespread adoption, we can begin to better understand the long-term safety and comparative effectiveness of this now common surgical procedure.

MATERIALS AND METHODS

Data Source

We used linked data from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program and the Centers for Medicare and Medicaid Services (Medicare) to identify patients diagnosed with incident kidney cancer from 2000 through 2005. Based on our prior work, this corresponds with a period of widespread adoption of LRN by the urologic community.[13] SEER is a population-based cancer registry that collects data on incidence, treatment, and mortality. The demographic composition, cancer incidence, and mortality trends in the SEER registries are representative of the entire US population.[14] The Medicare Program provides primary health insurance for 97% of the US population aged $\geq$65 years.[15] Successful linkage with Medicare claims is achieved for over 90% of Medicare patients whose cancer-specific data are tracked by SEER.[15]

Cohort identification and assignment of surgical procedures

After identifying 12,031 patients diagnosed with nonurothelial, nonmetastatic, kidney cancer from 2000 through 2005, we searched inpatient (Medicare Provider Analysis and Review file, based on International Classification of Diseases, 9th revision, Clinical Modification [ICD-9]) and physician claims (Carrier Claims file, based on Current Procedural Terminology [CPT] and ICD-9 codes) to identify kidney cancer-specific diagnosis and procedure codes. We then used a validated, claims-based algorithm to determine the specific surgical procedure for each subject in our cohort.[16] Using this approach, we assigned each patient to 1 of 4 procedures: open radical nephrectomy (ORN), open partial nephrectomy (OPN), laparoscopic radical nephrectomy (LRN), or laparoscopic partial nephrectomy (LPN). We then limited our cohort to patients treated with unilateral LRN or ORN as primary treatment for localized or regional kidney cancer (n = 8003).

Patient-Level Covariates

For each patient in the study cohort, we used SEER data to determine demographic and cancer-specific information, including age, sex, SEER registry, race/ethnicity, marital status, tumor size, and tumor stage. Based on patients' zip codes, we also assigned patients to 1 of 3 socioeconomic strata.[17] We measured pre-existing comorbidity by using a modification of the Charlson index to identify comorbid conditions (including diabetes, renal insufficiency, and cardiovascular disease) from inpatient and physician claims that were submitted during the 12 months before the index admission for kidney cancer surgery.[18]

Primary Outcomes

We assessed the following hospital-based outcomes for patients treated with LRN or ORN: 1) ICU admission, 2) LOS, 3) 30-day hospital readmission, and 4) in-hospital mortality. Our claims-based definitions for the above outcome measures were adapted from the published literature. Briefly, we identified ICU admission through billing codes that indicate time spent in an ICU setting (including intermediate and coronary care units).[19,20] As a secondary step, we verified the use of ICU care based on specific ICU charges and variables indicating ICU day counts greater than 0 during the index hospital admission.[20,21] We defined LOS as the duration between the admission date and final discharge date for the index hospitalization (which included transfers to another acute care hospital). We then used LOS greater than the 90th percentile for all admissions as our definition for prolonged LOS.[22] We defined hospital readmissions based on the presence of a subsequent claim for inpatient care (excluding transfers and claims for skilled nursing facilities or inpatient rehabilitation [DRG 462]) within 30 days of discharge from the index hospitalization.[23] Finally, we defined in-hospital mortality as death during the index hospitalization.

Primary statistical analyses

We used chi-square tests to evaluate the association between surgical approach (LRN vs ORN) and patient-level covariates. We calculated annual rates of ICU admission by dividing the number of events for patients treated with LRN or ORN, respectively, by the total number of patients treated with each technique. We determined the mean and median length of stay by surgical approach for each year. For assessing rates of readmissions, our numerator was the number of readmissions for patients treated with LRN or ORN, and our denominator was the number of patients treated with either LRN or ORN who were discharged alive from the index hospitalization. Annual rates of in-hospital mortality were calculated in the same manner as annual rates of ICU admission. We then assessed for each procedure longitudinal trends in rates of ICU admission, LOS, 30-day hospital readmission, and in-hospital mortality using the Student *t* test or Mantel-Haenszel chi-square test as appropriate.

Next, we fit multivariate logistic regression models to estimate the association between type of surgery and each of our primary outcomes. We treated ICU admission, prolonged LOS, 30-day hospital readmission, and in-hospital mortality as binary (ie, yes/no) variables. We implemented generalized estimating equations to account for clustering of patient outcomes within hospitals, and we adjusted our models for patient characteristics (ie, age, race, sex, marital status, socioeconomic position, and preexisting comorbidity), cancer severity (ie, size, stage), and year of surgery. From our models, we then calculated predicted probabilities of each hospital-based outcome for LRN and ORN, assuming similar patient characteristics, tumor severity, and year of surgery.

Sensitivity Analyses

We then performed several sensitivity analyses to assess the robustness of our primary findings. First, to determine whether geographic variation accounted for our findings, we repeated our analyses after we stratified the study cohort by SEER registry. Second, recognizing the potential implications for postoperative morbidity and mortality, we refit our models after excluding patients with missing data for tumor size ($n = 157$) and comorbidity ($n = 243$). Third, recognizing the lack of granular staging information available through SEER, we also refit our models after applying the following exclusion criteria: 1) patients with regional disease, 2) patients with tumors larger than 7 cm, 3) patients with regional disease and tumors larger than 7 cm, and 4) patients with regional disease and tumors larger than 4 cm. Fourth, to account for differences in hospitals that offer only 1 surgical approach, we also refit our models after limiting the sample to patients treated in hospitals that performed both LRN and ORN from 2000 through 2005. Fifth, we repeated our analyses after excluding patients ($n = 62$) with ICD-9 diagnosis codes indicating a conversion from laparoscopic to open surgery, as these patients were exposed to both surgical approaches. Finally, to assess consistency over time, we repeated our analyses based on a larger sample that also included patients treated with LRN or ORN from 1995 through 1999.

Secondary Statistical Analyses

Next, we performed additional analyses designed to clarify the observed relations between surgical approach and our primary outcomes. First, using methods described previously,[24,25] we determined the annual kidney cancer-specific case-volume for each surgeon and hospital and performed Mantel-Haenszel chi-square tests to examine the relation between case-volume and each primary outcome, stratified by surgical approach. To clarify the observed relation between surgical approach and in-hospital mortality, we then measured and compared the frequency of postoperative complications—both overall and among those patients who experienced in-hospital deaths—for patients treated with LRN versus ORN. Guided by validated methods developed by the Complications Screening Program, we used specific ICD-9 codes to specifically identify complications related to gastrointestinal injury, myocardial infarction, respiratory failure, wound infection, hemorrhage, venothromboembolism, and accidental puncture or laceration, among other diagnoses.[26-28] As a final step, we identified blood transfusions through billing codes and compared the frequency of transfusions by procedure (both overall and among those patients who experienced in-hospital mortality).

All statistical testing was 2-sided, completed using computerized software (SAS version 9.2; SAS Institute, Cary, North Carolina), and carried out at the 5% significance level. This study was deemed exempt by the University of Michigan Medical School Institutional Review Board.

RESULTS

We identified 2108 (26%) patients treated with LRN and 5929 (74%) patients treated with ORN from 2000 through 2005. As presented in Table 1, patients undergoing LRN were more likely to be white, female, and of higher socioeconomic status (all $P < .02$). Patients treated with LRN were also more likely to have a tumor $\leq$4 cm and to have had surgery after 2002 (all $P < .001$).

Table 1. Patient Demographics, Tumor Severity, and Year of Surgery

	LRN	ORN	*P*
No. of Patients	2108	5895	
	%	%	
Age, y			
65-69	25.8	25.5	.014
70-74	25.6	28.5	
75-79	27.9	24.8	
80-84	14.5	15.5	
>84	6.2	5.7	
Race			
Caucasian	84.3	82.0	<.001
African-American	7.4	7.4	
Hispanic	4.0	7.1	
Other	4.3	3.5	
Gender			
Male	55.0	58.0	.018
Female	45.0	42.0	
Married			
Yes	61.3	61.7	.761
No	38.7	38.3	
Socioeconomic status (tertiles)			
High	40.2	31.3	<.001
Intermediate	30.2	32.5	
Low	29.7	36.3	
Charlson comorbidity index			
0	57.6	57.8	.982
1	25.2	25.0	
≥2	17.2	17.2	
Tumor size			
≤4 cm	45.8	36.1	<.001
4-7 cm	39.2	36.4	
>7 cm	15.0	27.5	
Tumor stage			
Local or in situ	80.1	72.5	<.001
Regional	19.9	27.5	
Year of surgery			
2000-2002	25.7	55.3	<.001
2003-2005	74.3	44.7	

Abbreviations: ORN, open radical nephrectomy; LRN, laparoscopic radical nephrectomy.

Figures 1 through 4 present temporal trends for each outcome stratified by surgical approach. Over the entire study interval, patients treated with LRN had a median length of stay of 4 days (range, 1-67 days) whereas patients treated with ORN had a median length of stay of 5 days (range, 3-144 days). Only mean LOS and 30-day hospital readmissions for patients treated with LRN changed significantly (ie, decreased) during the study interval ($P < .05$).

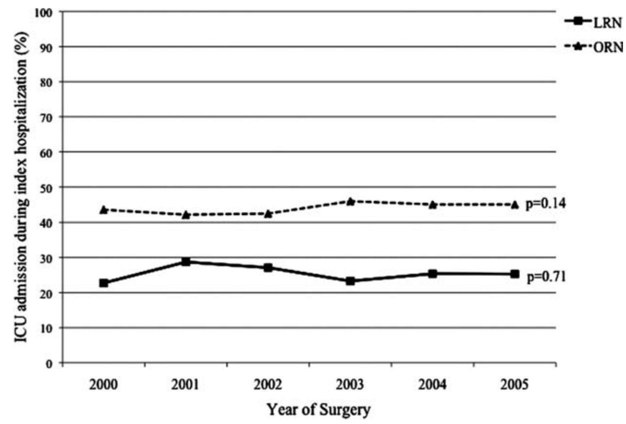

Figure 1. Temporal trends were assessed by Mantel Haenszel chi-square tests of intensive care unit (ICU) admission during index hospitalization by surgical approach from 2000 to 2005. Abbreviations: LRN, laparoscopic radical nephrectomy; ORN, open radical nephrectomy.

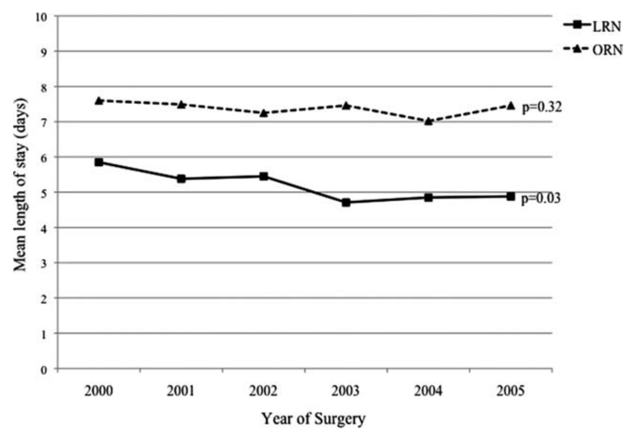

Figure 2. Temporal trends of mean length of stay of index hospitalization by surgical approach from 2000 to 2005 were assessed by linear regression and Student *t* tests. Abbreviations: LRN, laparoscopic radical nephrectomy; ORN, open radical nephrectomy.

After we adjusted for measurable patient and tumor characteristics, as well as year of surgery, patients treated with LRN were significantly less likely to require ICU admission (odds ratio [OR], 0.49; 95% confidence interval [CI], 0.43-0.55) and to have a prolonged LOS (OR, 0.52; 95% CI, 0.42-0.64). The likelihood of readmission did not differ significantly between the treatment groups (OR, 1.05; 95% CI, 0.88-1.26). Conversely, during the entire study interval, patients treated with LRN had a significantly higher risk of in-hospital mortality (OR, 1.54; 95% CI, 1.02-2.32).

Figure 5 depicts these findings further by presenting model-predicted probabilities for each outcome by

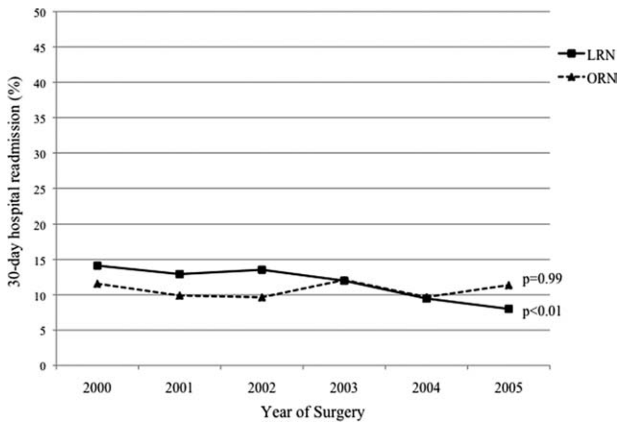

Figure 3. Temporal trends were assessed by Mantel-Haenszel chi-square tests of 30-day hospital readmission by surgical approach from 2000 to 2005. Abbreviations: LRN, laparoscopic radical nephrectomy; ORN, open radical nephrectomy.

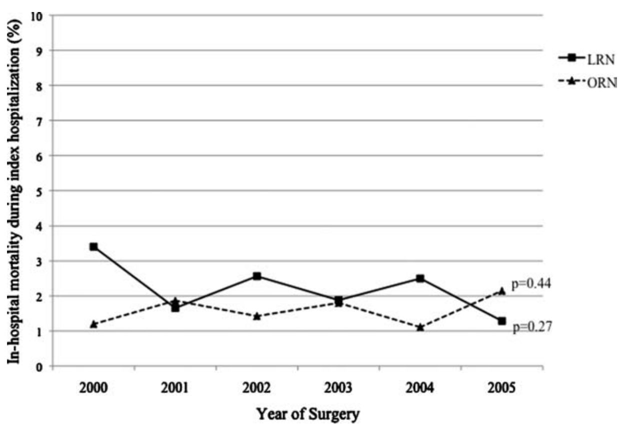

Figure 4. Temporal trends were assessed by Mantel-Haenszel chi-square tests of in-hospital mortality during index hospitalization by surgical approach from 2000 to 2005. Abbreviations: LRN, laparoscopic radical nephrectomy; ORN, open radical nephrectomy.

treatment group. The probability of ICU admission and prolonged LOS was 41% and 46% lower, respectively, for patients undergoing LRN versus ORN. In contrast, although still uncommon, the adjusted probability of in-hospital mortality was 51% higher for patients treated with a laparoscopic versus open approach. These findings did not change substantively when we refit our models after stratifying by SEER registry, excluding patients with missing data or laparoscopic conversions, excluding patients with regional disease and/or larger tumor size, limiting our samples to patients from hospitals where both procedures were performed, or including patients treated from 1995 through 1999.

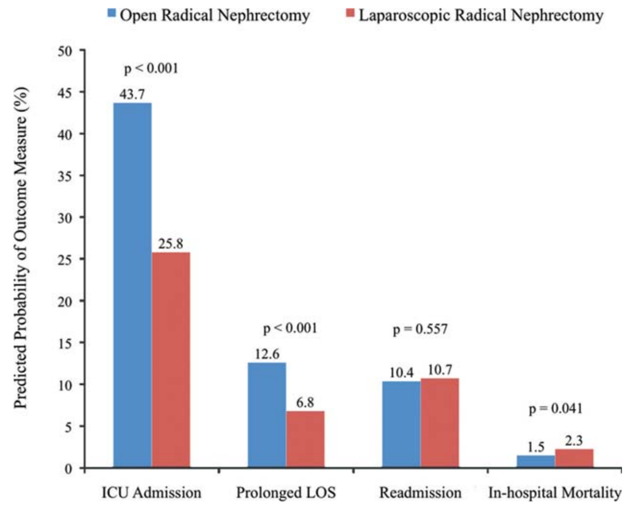

Figure 5. Predicted probabilities of intensive care unit (ICU) admission, prolonged length of stay (LOS), 30-day hospital readmission, and in-hospital mortality are shown according to surgical approach. Prolonged LOS is defined as LOS greater than the 90th percentile. Predicted probabilities are derived from generalized estimating equation models adjusting for patient demographics, Charlson comorbidity index, tumor size and stage, and year of surgery.

Table 2 describes the relation between case-volume (ie, surgeon and hospital) and each hospital-based outcome. Higher-volume surgeons and hospitals had lower rates of ICU admission and prolonged LOS for both surgical approaches, whereas 30-day readmission was associated only with hospital case-volume for patients treated with ORN ($P < .05$). Among patients undergoing LRN, those treated by surgeons in the highest nephrectomy-volume quartile had significantly lower in-hospital mortality than patients whose surgeons were in the lowest volume quartile (1.1% vs 2.8%, $P = .049$). Likewise, patients who underwent LRN at a hospital in the highest kidney cancer case-volume quartile had lower mortality than those treated at hospitals in the lowest quartile (1.3% vs 3.5%, $P = .011$). In contrast to the laparoscopic approach, we observed no variation by volume strata for in-hospital mortality among patients treated with ORN ($P > .20$).

To better understand the observed relation between surgical approach and in-hospital mortality, we also assessed the frequency of postoperative complications and blood transfusions after laparoscopic versus open radical nephrectomy (Fig. 6). Among the entire cohort, patients treated with LRN had fewer postoperative complications and blood transfusions than those treated with ORN (31.7% vs 38.8%, $P < .001$; 1.9% vs 4.2%, $P < .001$, respectively). However, among the subset of patients who

Table 2. Procedure-Specific Outcomes According to Case-Volume Strata

Volume Quartiles	Bottom	Second	Third	Top	*P*
	%	%	%	%	
Hospital case-volume					
ICU admission	53.2	40.9	35.2	25.3	<.001
ORN	56.7	45.2	39.7	30.1	<.001
LRN	35.7	29.4	26.5	16.4	<.001
Prolonged LOS	13.2	12.0	9.3	9.7	<.001
ORN	14.1	13.8	10.7	11.9	.011
LRN	9.1	7.0	5.6	5.5	.026
Readmission	11.3	11.5	10.5	9.3	.030
ORN	11.6	11.6	10.0	9.2	.018
LRN	9.5	11.3	12.2	9.3	.816
In-hospital mortality	2.2	1.9	1.0	1.6	.061
ORN	1.9	1.7	0.9	1.8	.409
LRN	3.5	2.4	1.5	1.3	.011
Surgeon case-volume					
ICU admission	45.0	44.4	38.0	28.1	<.001
ORN	48.3	49.1	41.6	34.5	<.001
LRN	30.0	28.2	27.9	19.3	<.001
Prolonged LOS	12.7	12.7	10.6	8.7	<.001
ORN	13.6	14.4	11.7	11.6	.037
LRN	8.6	6.5	7.5	4.6	.009
Readmission	11.0	10.5	11.3	9.4	.227
ORN	11.0	10.6	11.3	9.3	.350
LRN	11.1	10.1	11.5	9.4	.478
In-hospital mortality	1.8	1.8	1.5	1.4	.224
ORN	1.6	1.9	1.3	1.6	.716
LRN	2.8	1.4	2.2	1.1	.049

Abbreviations: ICU, intensive care unit; LOS, length of stay; ORN, open radical nephrectomy; LRN, laparoscopic radical nephrectomy.

died during the index hospitalization, rates of complications and blood transfusions did not differ by surgical approach (97.6% LRN vs 93.6% ORN, $P = .435$; 14.3% LRN vs 6.5% ORN, $P = .190$).

DISCUSSION

It is widely accepted that for patients with early stage kidney cancer, laparoscopic radical nephrectomy produces equivalent oncologic outcomes with the concurrent benefits of decreased pain and easier overall recovery.[9-11] Accordingly, the recently released American Urological Association (AUA) Guidelines advocate for laparoscopy as the preferred surgical approach for most patients undergoing radical nephrectomy.[29] However, the evidence for this recommendation is based mainly on the experience and outcomes reported by early innovators and adopters with established expertise in this advanced surgical technique. In fact, there are limited data assessing whether or not the dissemination of LRN is translating these benefits to a broader population of patients with renal cell carcinoma.

Among a nationally representative sample of Medicare beneficiaries, we observed that patients treated with laparoscopic versus open radical nephrectomy were significantly less likely to receive postoperative care in an ICU or to have a prolonged LOS during a period of time (2000-2005) that corresponded with escalating adoption of LRN throughout the urological community.[13] Moreover, among patients treated with LRN, average LOS and rates of readmission decreased significantly during the study interval and may now be lower than for patients treated with ORN. Taken together, these comparative trends support the convalescence benefits of LRN at a population level.

Although the translation of these benefits to real-world practice is encouraging, it is worth recognizing that the average LOS and absolute rates of ICU admission among Medicare beneficiaries are substantively higher than those reported in most case series.[9,10,30] In particular, reports from centers with extensive laparoscopic experience suggest that a shorter LOS can be achieved on a national basis for patients treated with LRN.[9,10] As for the

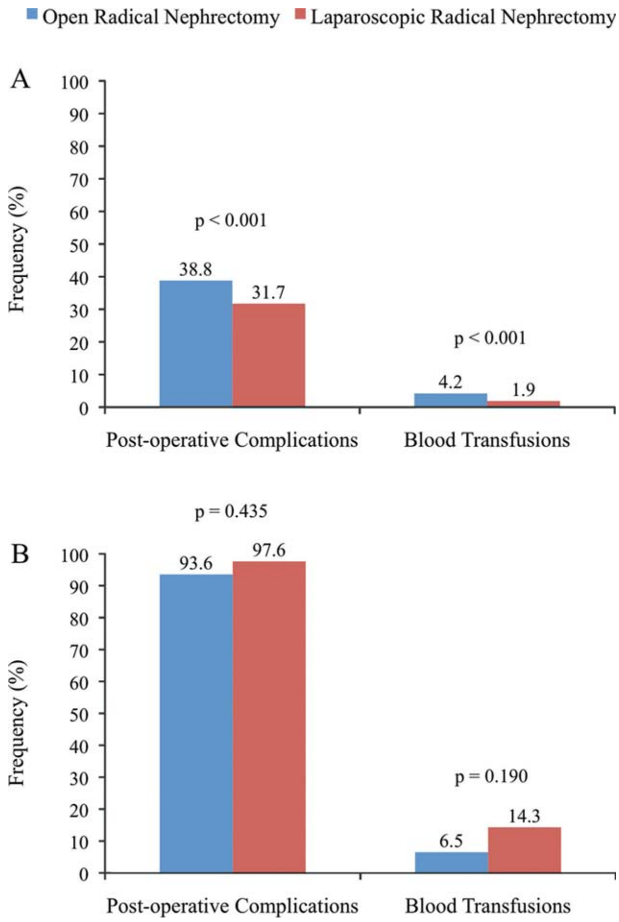

Figure 6. Frequency of postoperative complications and blood transfusion for (A) all patients and (B) those who died during the index hospitalization is stratified by surgical approach. Postoperative complications are based on specific ICD-9 codes as described in the Methods section.

relatively higher rates of intensive care use, 1 explanation is that we include in our definition of ICU utilization patients admitted to intermediate and/or coronary care units. Although these settings may not be ICUs in the most traditional sense, they nonetheless provide higher-intensity and higher-cost care and, therefore, represent clinically important outcomes. Moreover, there is a strong volume-outcome relation with LOS and ICU utilization, and other investigators have noted a similar contrast between case series and population-based data with respect to the frequency of these outcomes.[31] Accordingly, although LRN undoubtedly provides many patients with an easier convalescence, it appears that there is an opportunity for even greater population-level efficiency in the postoperative care of these patients.

Although they generally enjoy a more rapid and less intense recovery, the in-hospital mortality rate among Medicare beneficiaries treated with LRN, although still uncommon, is both substantially higher than that reported in early case series[9-11,30] and 51% greater than that observed for beneficiaries undergoing ORN. This finding is particularly noteworthy given the more favorable tumor characteristics observed for those patients treated with LRN. Although less frequent overall among all patients treated with LRN versus ORN, rates of complications and blood transfusions were actually similar for both treatment groups among the subset of patients who died during the index hospitalization. Taken together, these findings suggest that the relatively higher in-hospital mortality associated with LRN may be a consequence of technical factors and/or failure to recognize and address severe complications in a timely fashion.

This hypothesis is supported, at least indirectly, by our observation that, in contrast to ORN, rates of in-hospital mortality were significantly higher among patients treated with LRN by low-volume surgeons or at low-volume centers. Whereas the general mechanisms underlying the volume-outcome relation have been proposed to include hospital staffing levels, access to health services, processes of care use (eg, preoperative cardiac stress test, critical care consultation, invasive monitoring use), and capacity to manage complications,[32-34] the observation that mortality varies with surgeon and hospital volume for LRN but not ORN points to factors specific to laparoscopy. In this context, and because our study coincided with a period of escalating adoption, the higher in-hospital mortality among patients treated with LRN suggests that significant adverse events may, in fact, be more common during the initial phase (ie, the learning curve) of a surgeon's laparoscopic experience.[10] Although further studies are needed to clarify the cascade of events responsible for this mortality difference, this finding alone highlights the need for long-term monitoring of the safety and comparative effectiveness of novel surgical therapies.

Our findings should be considered in the context of several limitations. First, studies based on observational data are vulnerable to confounding by unmeasured factors that may account for observed differences in outcomes between treatment groups. With respect to mortality, however, patients treated with LRN appeared to be more favorable surgical candidates based on their higher socioeconomic position and less aggressive tumor characteristics. Accordingly, it can be argued that any residual confounding would tend to bias our findings toward the null. Second, given the limitations of claims data, we could not assess more conventional measures of postoperative convalescence including pain and return to work, among others. Nonetheless, the outcomes we did evaluate reflect quite well the overall acute recovery process of patients undergoing surgery for renal cell carcinoma. Third, because SEER data lacks detailed staging information, we were able to adjust our models only for tumor size and local versus regional stage, raising the possibility for residual differences in disease severity between the treatment groups. Nonetheless, it is important to note that our findings did not change substantively when we limited our analyses to patients with only localized disease and/or smaller tumors. Fourth, because our sample is based on Medicare beneficiaries, our findings may not be generalizable to patients aged ≤65 years. Nonetheless, the mortality rates reported herein are consistent with previous population-based analyses that included all adult age groups.[31,35] Fifth, although nationally representative, the geographic footprints of SEER registries do not include many centers with substantial laparoscopic experience and expertise (where mortality rates may be lower than for the general Medicare population). Importantly, however, our specific aim was to evaluate the comparative effectiveness of LRN as it became incorporated widely into clinical practice (and not to simply reassess these outcomes in early adopting centers with established expertise). Finally, although our findings offer valuable insights into the impact of laparoscopy, additional studies using more contemporary data are needed to assess whether these differences dissipate or persist long after the widespread diffusion of LRN.

These limitations notwithstanding, our findings have important implications for surgical oncology practice. In general, these data support laparoscopy as the favored approach for most patients undergoing radical nephrectomy. This minimally invasive technique yields clear benefits at a population level, including shorter stays in the hospital and less frequent use of expensive ICU services. These benefits have been realized, however, at the apparent cost of increased mortality during an era of widespread adoption. The latter finding has direct implications for patient safety during the dissemination of new surgical techniques. In the case of LRN, urologists were (and still are) faced with the challenge of obtaining sufficient formal training in the performance of a technically complex operation with strong external pressures (eg, perceived benefit, competitive necessity, patient preference) to adopt a technique that has clear benefits for patients.[2,3,25,36,37] This tension may have led some urologists to adopt LRN after only limited training, thereby creating an environment where patients were at higher risk for certain rare, but potentially lethal, adverse events.[37] This concern has been recognized by both the urology and surgery communities, and, in recent years, several mentored and simulator-based programs have been developed to facilitate and enhance training in laparoscopy.[38,39] Nonetheless, despite the existence of recommended paradigms for laparoscopic training and credentialing since the early 1990s, training in laparoscopy still relies heavily on preceptorship and self-regulation rather than any formal certification process while credentialing varies by hospitals and generally involves limited regulatory oversight.[40-42]

Similar challenges are now being recognized during the adoption of the robotic platform in surgical oncology.[41] Although industry offers basic training for robotic surgery, the benefits of these programs appear to diminish over time.[43] More vigorous training has been shown to expedite the learning process, transfer technical skill at a higher rate, and lead to higher retention over the long-term.[39,44-46] To promote the advancement of patient care through new surgical technologies while also ensuring patient safety, the American College of Surgeons has established multiple Accredited Education Institutes to facilitate transfer of surgical innovation to practicing surgeons,[47-49] similar programs may be beneficial for urologists and other surgical oncologists who are faced with the challenge of adopting complex new technologies.

As demonstrated by our findings, surgical innovations (including LRN) often yield real and important benefits for patients. However, there may be unanticipated consequences associated with widespread adoption, including potentially avoidable mortality. As such, the experience with LRN provides a valuable lesson on the importance of emphasizing patient safety, long-term comparative effectiveness research, and enhanced systems for postgraduate training and credentialing during and after the introduction of new surgical technologies. Indeed, these issues may be of paramount concern as urological oncologists broaden their use of the robotics platform—especially for more complex procedures such as partial nephrectomy[50]—and pursue newer and more advanced technologies, such as laparoendoscopic single-site surgery (LESS) and natural orifice transluminal endoscopic surgery (NOTES).

Conclusion

In this population-based sample, patients treated with LRN had a lower likelihood of ICU admission and prolonged LOS, findings that support the convalescence benefits of laparoscopy. At the same time, however, the observation that in-hospital mortality was higher among patients treated with LRN suggests a potentially unanticipated consequence of this minimally invasive technique and highlights the need for long-term monitoring during the widespread adoption of new surgical technologies.

CONFLICT OF INTEREST DISCLOSURES

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