Complications and Failure to Rescue After Laparoscopic Versus Open Radical Nephrectomy

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Abbreviations and Acronyms

ARF = acute renal failure excluding chronic dialysis

FTR = failure to rescue

FTR-M = FTR after major complication

GI = gastrointestinal

GU = genitourinary

LRN = laparoscopic radical nephrectomy

ORN = open radical nephrectomy

PSI = Patient Safety Indicator

RCC = renal cell carcinoma

VTE = postoperative pulmonary embolism or deep vein thrombosis

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Purpose: Since to our knowledge the population level impact of laparoscopy on post-radical nephrectomy morbidity and mortality remains unknown, we compared the rates of postoperative complications and failure to rescue (the fatality rate in patients with a complication) in patients treated with laparoscopic vs open radical nephrectomy.

Materials and Methods: Using linked SEER (Surveillance, Epidemiology and End Results)-Medicare data we identified patients with kidney cancer who were treated with laparoscopic or open radical nephrectomy from 2000 through 2005. After measuring the frequency of postoperative complications and failure to rescue we fit multivariate logistic regression models to estimate the association of these outcomes with surgical approach, adjusting for patient characteristics, cancer severity and surgery year. We also assessed the relationship between case volume, complications and failure to rescue.

Results: We identified 2,108 (26%) and 5,895 patients (74%) treated with laparoscopic and open radical nephrectomy, respectively. The overall rates of complications and failure to rescue were 36.9% and 5.3%, respectively. The predicted probability of any, major, medical and surgical complications was 15%, 12%, 13% and 23% lower, respectively, after laparoscopic than after open radical nephrectomy (each $p < 0.05$). Despite less frequent complications patients treated with laparoscopic radical nephrectomy had a greater probability of failure to rescue (7.6% vs 4.6%, $p = 0.010$). Higher volume surgeons and hospitals had a lower rate of failure to rescue in patients treated with radical nephrectomy (each $p < 0.05$) but not with open radical nephrectomy.

Conclusions: Supporting the decreased morbidity of laparoscopy, patients treated with radical nephrectomy had fewer complications than those who underwent open radical nephrectomy. However, failure to rescue was more common in patients with a complication after radical nephrectomy, suggesting that these events may be more difficult to recognize and manage successfully, especially among less experienced surgeons and hospitals.

Key Words: kidney, nephrectomy, laparoscopy, mortality, complications

Laparoscopic radical nephrectomy is the preferred surgical approach in most patients who require total kidney removal for RCC.[1] Compared with ORN, LRN provides easier, more rapid convalescence while achieving equivalent cancer control.[2,3] Given these patient benefits, LRN has been adopted steadily during the last 2 decades and is now performed by most urologists in the United States.[4]

Although early adopters of LRN reported complication rates equivalent to those of the open technique,[2,3,5] to

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our knowledge it remains unknown whether the widespread dissemination of this groundbreaking procedure changed the frequency and nature of post-radical nephrectomy complications at the population level. Examples show that the dissemination of a complex new technology has yielded intended benefits and unintended consequences. For instance, during its rapid incorporation into general surgery practice laparoscopic cholecystectomy was unexpectedly associated with a higher rate of common bile duct injury.[6] While these injuries were initially accepted as part of the learning curve, they have since been linked to decreased patient survival.[7] Complications similar in severity, eg ligation of the superior mesenteric artery and bowel fistula formation,[8] have been reported early in the LRN experience but additional data are needed to clarify the impact of the widespread adoption of laparoscopy on population level morbidity and mortality in patients who undergo radical nephrectomy for RCC.

In this context we used linked SEER-Medicare data to compare the frequency of complications and the case fatality rate after a complication, so-called FTR, in patients treated with LRN vs ORN. By defining more precisely the prevalence and consequences of complications after LRN vs ORN these data will facilitate efforts to optimize patient safety and better understand the comparative effectiveness of LRN at the population level.

MATERIALS AND METHODS

Data Source, Cohort Identification and Surgery Assignment

We used linked data from the National Cancer Institute SEER Program, and the Centers for Medicare and Medicaid Services to identify 12,031 patients diagnosed with nonurothelial, nonmetastatic kidney cancer from 2000 through 2005, which was a period of widespread urologist adoption of LRN.[4,9] Using a validated algorithm[9] we determined the specific procedure in each patient treated surgically. We then limited our sample to the 8,003 patients treated with unilateral LRN or ORN for localized or regional kidney cancer.

Patient Level Covariates

For each patient we used SEER data to determine demographic and cancer specific information, including age, gender, race/ethnicity, marital status and cancer severity, ie tumor size and stage. We assigned patients to 1 of 3 socioeconomic strata based on patient level Zip Codes[10] and measured preexisting comorbidity using a modification of the Charlson index.[11]

Primary Outcomes

For patients treated with LRN or ORN we assessed 2 outcomes during the index hospitalization or within 30 days of surgery, including 1) postoperative complications and 2) FTR. Guided by the published literature[12–14] we identified specific ICD-9 codes for GI complications, cardiac complications, ARF,[14] GU complications, postoperative hemorrhage, postoperative infection (eg pneumonia or Clostridium difficile), wound complications, pulmonary failure, sepsis, neurological complications and miscellaneous technical complications related to surgery. Each measure was described previously by the Complications Screening Program and validated through chart review.[12,13]

Our catalogue of complications also included PSIs, version 4.2, developed at the Agency for Healthcare Research and Quality, including 1) foreign body left during the procedure, 2) iatrogenic pneumothorax, 3) VTE and 4) accidental puncture or laceration, most often injury to the GI tract, bladder or blood vessel, and referred to in this study as iatrogenic injury.[15,16] We selected these PSIs based on previous validation studies and compatibility with our data set.[15–17]

For analytical purposes we grouped specific complications and PSIs into certain categories, including 1) any complication, 2) major complications (ie pulmonary, cardiac, ARF, VTE, GI, sepsis, wound, iatrogenic injury and hemorrhage), 3) medical complications (ie pulmonary, cardiac, ARF, VTE, GI, sepsis, infection, neurological and infection) and 4) surgical complications (ie iatrogenic injury, wound, GU, hemorrhage, miscellaneous, foreign body left during the procedure and iatrogenic pneumothorax). Finally, we determined procedure specific complication rates by dividing the number of cases in each complication category by the number of patients who underwent LRN or ORN.

FTR is accepted widely as a measure of the timely recognition of and successful management for complications. Measurement of this outcome is now used by various stakeholders, including Agency for Healthcare Research and Quality policy makers, to assess the quality of inpatient care.[15,18] Consistent with the existing literature, we defined FTR as death during the index hospitalization or within 30 days of surgery in a patient who experienced any of the defined complications.[18] In other words, FTR represents the case fatality rate among patients with a postoperative complication. We calculated procedure specific rates of FTR by dividing the number of patients who died after a complication by the total number who experienced a complication. Since minor complications that are unlikely to lead to death may falsely increase the overall FTR rate, we also evaluated and calculated the FTR rate in patients with a major complication, referred to as FTR-M.[19]

Primary Statistical Analysis

We used chi-square tests to evaluate the association between surgical approach (LRN vs ORN) and patient level covariates. We then used the chi-square test or Fisher exact test as appropriate to compare unadjusted rates of complications and FTR in patients treated with LRN vs ORN.

We fit multivariate logistic regression models to estimate the association between surgical approach and our primary outcomes. We specified each outcome (complications and FTR) as a binary (yes/no) variable. We implemented generalized estimating equations to account for patient outcome clustering at hospitals and adjusted our