CHEST

Comparative Effectiveness of Robotic-Assisted vs Thoracoscopic Lobectomy

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PODCAST

BACKGROUND: Robotic-assisted lobectomy is being offered increasingly to patients. However, little is known about its safety, complication profile, or effectiveness.

METHODS: Patients undergoing lobectomy in in the United States from 2008 to 2011 were identified in the Nationwide Inpatient Sample. In-hospital mortality, complications, length of stay, and cost for patients undergoing robotic-assisted lobectomy were compared with those for patients undergoing thoracoscopic lobectomy.

RESULTS: We identified 2,498 robotic-assisted and 37,595 thoracoscopic lobectomies performed from 2008 to 2011. The unadjusted rate for any complication was higher for those undergoing robotic-assisted lobectomy than for those undergoing thoracoscopic lobectomy (50.1% vs 45.2%, $P < .05$). Specific complications that were higher included cardiovascular complications (23.3% vs 20.0%, $P < .05$) and iatrogenic bleeding complications (5.0% vs 2.0%, $P < .05$). The higher risk of iatrogenic bleeding complications persisted in multivariable analyses (adjusted OR, 2.64; 95% CI, 1.58-4.43). Robotic-assisted lobectomy costs significantly more than thoracoscopic lobectomy ($22,582 vs $17,874, $P < .05$).

CONCLUSIONS: In this early experience with robotic surgery, robotic-assisted lobectomy was associated with a higher rate of intraoperative injury and bleeding than was thoracoscopic lobectomy, at a significantly higher cost.

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ABBREVIATIONS: FDA = US Food and Drug Administration; HCUP = Healthcare Cost and Utilization Project; NIS = Nationwide Inpatient Sample

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Robotic-assisted surgical technologies have been adopted rapidly since US Food and Drug Administration (FDA) approval in 2000. More than 459,000 robotic surgeries were performed worldwide in 2012, with prostatectomy and hysterectomy accounting for the vast majority of procedures.[1,2] The perceived benefits of robotic-assisted surgery are less postoperative pain, fewer complications, and quicker recovery times. Additionally, surgeons can be trained more easily to perform minimally invasive robotic-assisted surgery, which mimics open surgery, in contrast to the current minimally invasive methods, which require significant training. Studies examining the safety and effectiveness of robotic surgery are limited. FDA approval of the technology through the 510(k) premarket approval process did not require clinical evidence of patient benefit. Studies comparing robotic hysterectomy to laparoscopic hysterectomy have found no clinical benefit, but increased costs.[3-6]

The rapid adoption of a new surgical technology without proper safeguards in training brings new risks and could potentially lead to patient harm. Studies comparing the

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safety and effectiveness of robotic-assisted surgical technologies in cardiothoracic surgery are lacking. No large randomized trial has been performed, and any such trial may not be performed because of cost and the significant sample size requirement to detect small differences in outcomes. Observational data are likely to provide the best evidence related to perioperative benefits and harms, including iatrogenic harms.

Robotic-assisted technologies are currently being advocated in general thoracic surgery for lobectomy.[3,7-12] To evaluate the safety and efficacy of robotic-assisted surgery for lobectomies, we performed a population-based analysis using the Nationwide Inpatient Sample (NIS).

Materials and Methods

Data Source

The NIS is maintained by the Agency for Healthcare Research and Quality, as part of the Healthcare Cost and Utilization Project (HCUP). The NIS is the largest all-payer inpatient-care database in the United States and constitutes approximately a 20% stratified sample of all hospital discharges from nongovernment institutions. An extensive description of the NIS (http://www.hcup-us.ahrq.gov/nisoverview.jsp) and the collection and maintenance of data within the database is described elsewhere.[13,14] This study was approved by the institutional review board of Weill Cornell Medical College (Protocol No. EXE-2011-057) and conforms to the data-use agreement for the NIS from the HCUP.

Study Cohort

The study cohort consisted of all patients who visited an HCUP NIS-participating hospital to undergo robotic-assisted lobectomy or thoracoscopic lobectomy. *International Classification of Diseases, Ninth Revision, Clinical Modification* codes were used to identify patients undergoing the previously-mentioned procedures (e-Table 1). To make more meaningful comparisons, we chose to compare robotic-assisted lobectomy with its established minimally invasive counterpart, thoracoscopic lobectomy.[14,15] We included only procedures performed between 2008 and 2011 because the codes for robotic-assisted surgery were introduced in 2007. All patient admissions were elective, and patients were at least 18 years of age at the time of the procedure.

Outcomes

The study outcomes were in-hospital mortality, in-hospital complications, and a composite outcome consisting of in-hospital mortality and/or stroke or myocardial infarction. We identified complications listed as postoperative, known complications of these procedures, and, given that diagnosis and procedure dates were not available in the data, we selected conditions that would make the patient ineligible for such procedures had they presented with them at the time of hospital admission. We identified patients with the following complications (e-Table 1 for *International Classification of Diseases, Ninth Revision, Clinical Modification* diagnostic algorithms): cardiovascular (supraventricular arrhythmia, myocardial infarction, postoperative stroke, or DVT), pulmonary (pneumonia, postoperative acute respiratory insufficiency, postoperative acute pneumothorax, postoperative pulmonary edema, pulmonary collapse, empyema, mechanical ventilation, or concurrent tracheostomy), and infectious (sepsis/shock, urinary tract infection, or postoperative wound infection), as well as iatrogenic complications occurring intraoperatively (accidental puncture or laceration, bleeding).

Variables

We categorized patients according to age (18-55 years, 56-64 years, $\geq$ 65 years), sex (man/woman), race (white/nonwhite), year of procedure (2008, 2009, 2010, or 2011), and insurance status (Medicare, Medicaid, commercial, or other). We identified patients with diagnoses of coronary artery disease, heart failure, hypertension, diabetes, chronic pulmonary disease, peripheral vascular disease, and chronic renal insufficiency during the index hospitalization using validated algorithms (e-Table 1).[16] To summarize a patient's comorbidity burden, we used information gathered during the hospitalization to calculate the Elixhauser comorbidity score.[16,17] We also used the hospital-level information available in the NIS data to categorize hospitals according to location with respect to the census regions (North, West, Midwest, and South), size (small, medium, or large), teaching hospital status, and location (urban/rural).

Given that the NIS data contain all procedures done in a given hospital, but do not necessarily include the same hospitals in any given year's sample, we used the hospital's unique identifier to calculate an average annual procedure volume per facility. Charge data were provided at the discharge level in the NIS database. Cost was estimated using hospital-specific cost to charge ratios, in a preestablished method.[18] When that variable is unavailable, the group-level cost to charge ratio was used, as recommended by the HCUP.[19,20] A Diagnosis Related Group-based scaling factor released by the HCUP in 2009 was then applied to the data.[19,20]

Statistical Analysis

Baseline characteristics for the study population are reported and compared using percentages and χ^2 tests for categorical variables, and medians, interquartile ranges, and Wilcoxon tests for continuous variables. To assess the relationship between exposure to robotic surgery and outcome, we reported crude and adjusted ORs created using univariate and multivariate logistic regression models, respectively. Covariates for