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Clinical Study

Robotic-assisted pedicle screw placement fails to reduce overall postoperative complications in fusion surgery

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Abstract

BACKGROUND CONTEXT: Surgeons have increasingly adopted robotic-assisted lumbar spinal fusion due to indications that robotic-assisted surgery can reduce pedicle screw misplacement. However, the impact of robotic-assisted spinal fusion on patient outcomes is less clear.

PURPOSE: This study aimed to compare rates of perioperative complications between robotic-assisted and conventional lumbar spinal fusion.

STUDY DESIGN/SETTING: Retrospective cohort study.

PATIENT SAMPLE: A total of 520 patients undergoing lumbar fusion were analyzed. The average ages of patients in the robotic-assisted versus conventional groups were 60.33 and 60.31, respectively (p=.987). Patients with a diagnosis of fracture, traumatic spinal cord injury, spina bifida, neoplasia, or infection were excluded.

OUTCOME MEASURES: This study compared the rates perioperative major and minor complications for elective lumbar fusion between each cohort.

METHODS: This study screened hospital discharges in the United States from 2010 to 2014 using the National Inpatient Sample and the Nationwide Inpatient Sample (NIS). The *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) procedure codes were used to identify 209,073 patients who underwent conventional lumbar fusion (ICD 81.04-8) and 279 patients who underwent robotic-assisted lumbar fusion (ICD 81.04-8 and ICD 17.41, 17.49). Major and minor complications were identified using ICD-9-CM diagnosis codes. The robotic-assisted and conventional fusion groups were statistically matched on age, year, sex, indication, race, hospital type, and comorbidities. Univariate and multivariate logistic regression were used to compare risks of major and minor complications.

RESULTS: We matched 257 (92.11%) robotic-assisted patients with an equal number of patients undergoing conventional lumbar fusion. Minor complications occurred in 16.73% of cases in the conventional group and 31.91% of cases in the robotic-assisted group (p<.001). Major complications occurred in 6.61% of the conventional cases compared to 8.17% of robotic-assisted cases (p=.533). For robotic-assisted fusion, multivariate analysis revealed that there was no difference in the likelihood of major complications (OR=0.834, 95% CI=0.214–3.251) or minor complications (OR = 1.450, 95% CI=0.653–3.220).

CONCLUSIONS: In a statistically matched cohort, patients who underwent robotic-assisted lumbar fusion had similar rates of major and minor complications compared to patients who underwent conventional lumbar fusion.

Keywords: Complication; Cost; Fusion; Inpatient outcomes; Length of stay; Lumbar spine; National Inpatient Sample; Robotic-assisted surgery.

Introduction

Robotic assistance has gained interest in lumbar spine surgery. The most common application of surgical robots in spinal surgery is to assist with pedicle screw placement

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during thoracolumbar fusion [1]. Robotic guidance of pedicle screws has demonstrated increased accuracy of screw placement [2–9], as well as reduced radiation exposure [2–5,7]. Furthermore, robotic assistance enhances surgical management in the presence of anatomical variations, such as atrophic pedicles or complex spinal deformity [10]. Some evidence also suggests that robotic assistance reduces rates of pedicle screw repositioning [2].

Despite repeated demonstration that robotic-assisted lumbar fusion increases accuracy of pedicle screw placement, the impact of this improvement on patient outcomes is less clear. One meta-analysis of 130 studies found a mean pedicle screw misplacement rate of 8.7% without robotic assistance, whereas the rate of misplacement with robotic assistance was recently reported at 2.1% [8,11]. The clinical significance of misplaced screws is uncertain, with the proportion of misplaced screws leading to clinically relevant deficits ranging from 0.2% to 21% in the literature [12,13]. Even still, researchers have noted that robotic assistance may reduce rates of neurological damage in thoracolumbar fusion [3]. Additionally, robotic-assisted thoracolumbar fusion has demonstrated significant reductions in intraoperative complications compared to the conventional technique [2,7]. However, robotic-assisted lumbar fusion has not demonstrated superiority to the conventional technique with regard to postoperative complication rates [2,4,6,7]. A potential reason for this is consistent reporting that robotic assistance prolongs operative time in spine surgery [2,6,7]. Nevertheless, evidence suggests that inpatient length of stay following robotic-assisted spinal fusion is significantly shorter than following fusion by the conventional technique [2,4].

The growing body of literature on robotic-assisted spinal fusion has yet to demonstrate whether this technique offers any clear advantages over the conventional technique with regards to postoperative complications. This study aimed to retrospectively compare short-term inpatient outcomes following robotic-assisted and conventional lumbar fusion over a 5-year period using a robust cohort-matched analysis. As robotic-assisted pedicle screw placement is purported to increase accuracy and facilitate ease of screw placement, the authors suspected that rates of neurologic issues and overall complications may be decreased.

Materials and methods

This study screened over 35 million inpatient hospital discharges in the United States from 2010 to 2014 using the National Inpatient Sample and the Nationwide Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), and Agency for Healthcare Research and Quality. The NIS is a publicly available database comprising a nationally representative sample of twenty percent of all inpatient discharges from community hospitals in the United States (excluding long-term acute care and rehabilitation hospitals) [14]. A major strength of the NIS is that it includes data from all payers and insurance types. The HCUP provides trend weights that are commonly used to extrapolate national estimates from data within the NIS. However, for our cohort-matched study, weighting was not performed.

The *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) procedure codes were used to identify 209,073 patients who underwent conventional lumbar fusion (ICD 81.04-.08) and 279 patients who underwent robotic-assisted lumbar fusion (ICD 81.04.08 and ICD 17.41, 17.49). Patients with an ICD-9-CM code corresponding to a diagnosis of neoplasia, spina bifida, infection, spinal cord injury, or trauma were excluded. Additionally, patients with procedure codes corresponding to revision lumbar fusion were excluded. Details regarding specific diagnosis codes for the exclusion criteria can be found in the appendix. Only elective admissions were included for analysis. After applying the inclusion and exclusion criteria, 279 patients who underwent robotic-assisted lumbar fusion remained available for matching.

Robotic-assisted and conventional lumbar fusion groups were statistically matched based on age (within 5 years), year of procedure (within 1 year), sex, surgical indication, race, hospital type, and comorbidities (Table 1). Notably,

Table 1
Cohort matching characteristics for conventional and robotic-assisted lumbar fusion

	Conventional	Robotic-assisted	p value
Year			<.001
2010–2012	21	76	
2013–2014	236	181	
Age group			.841
<54	63	60	
54–65	74	74	
66–71	58	62	
>71	62	61	
Race			.999
White	211	211	
Non-white	46	46	
Sex			.999
Male	103	103	
Female	154	154	
Teaching status			.999
Nonteaching*	67	67	
Urban teaching	190	190	
Indication			.999
Degenerative disk disease	110	110	
Spinal stenosis	39	39	
Acquired spondylothesis	28	28	
Other	80	80	
Comorbidities			.999
Diabetes	48	48	
Anemia	28	28	
Obesity	39	39	
Hypertension	145	145	
COPD	30	30	

*After matching rural and urban nonteaching categories were collapsed into one variable

operating time and levels fused were not included in our matching criteria. Selected indications for surgery were degenerative disc disease, lumbar spinal stenosis, acquired spondylolisthesis, and "other" (includes congenital and acquired spinal malformations). Prior to matching, race was consolidated into white and non-white categories. The races of individuals in the non-white group included Black, Hispanic, Asian or Pacific Islander, Native American, and other. Case-control matching was performed using the fuzzy extension in Python Essentials, IBM SPSS Statistics for Macintosh, Version 23.0. The average ages prior to matching of the conventional and robotic-assisted groups were 56.70 years and 58.26 years, respectively (p=.108). After matching, the mean patient age in the conventional cohort was 60.36 years compared to 60.44 years in the robotic-assisted cohort (p=.959).

Major and minor perioperative complications were identified using ICD-9-CM diagnosis codes (see the appendix). Major complications included pulmonary embolism, deep vein thrombosis, neurological complications including nerve root injuries and dural tears, pneumonia, acute myocardial infarction, deep surgical site infection (SSI), wound disruption, acute renal failure, mechanical ventilation, prosthetic complication, postoperative shock, and sepsis. Minor complications included blood transfusion, intraoperative hemorrhage, phlebitis and thrombophlebitis, and subcutaneous emphysema. Patient mortality was determined using the Uniform Bill patient disposition.

Inpatient hospital costs were calculated using the hospital specific cost-to-charge ratios provided by the HCUP. Cost was adjusted to the 2016 level of inflation using the consumer price index for medical care from the Bureau of Labor Statistics. Length of stay (LOS) and cost for each cohort were compared using the Mann-Whitney *U* test. Univariate and multivariate logistic regression were used to compare risks of major and minor complications between the cohorts. All calculations were performed using IBM SPSS Statistics for Macintosh, Version 23.0.

Results

We matched 257 (92.11%) robotic-assisted patients with patients who underwent conventional lumbar fusion. Matching characteristics and demographic data are outlined in Table 1. Degenerative disc disease was the most common indication for lumbar fusion in our sample (42.80%). The majority of the patients in the sample were white (81.10%), and 18.68% of patients in each cohort had a diagnosis of diabetes mellitus (DM).

Too few patients in each cohort died to report the mortality rate based on NIS minimum reporting standards. Overall, 93 (36.19%) robotic-assisted patients sustained a complication of any kind compared to 54 (21.01%) patients in the conventional group (p<.001). Patients in the robotic-assisted group experienced minor complications at a significantly higher rate compared to the conventional group (31.91% vs. 16.73%, p<.001) (Table 2). However, after adjusting for cohort characteristics, there was no difference in the likelihood of sustaining a minor complication between patients in the conventional and robotic-assisted cohorts (Table 3). There was no significant difference in the rates of major complications between the robotic-assisted (8.17%) and conventional cohorts (6.61%, p=.500) (Table 2). Multivariate analysis also demonstrated that risk of major complications did not differ between the two procedures (Table 3).

Furthermore, multivariate analysis revealed that DM and race were not associated with an increased risk of

Table 2
Rates of perioperative complications

Complication	Conventional	Robotic-assisted	p value
Minor	43 (16.73%)	82 (31.91%)	<.001
Major	17 (6.61%)	21 (8.17%)	.500
Death	NR*	NR*	

*HCUP prohibits reporting cell sizes of 10 or less in order to protect patient confidentiality

Table 3
Adjusted risks of perioperative complications

	Minor: OR (95% CI)	Major: OR (95% CI)
Procedure		
Robotic-assisted	1.450 (0.653–3.220)	0.834 (0.214–3.251)
Conventional	–	–
Year		
2010–2012	2.044 (1.201–3.479)	2.592 (1.128–5.958)
2013–2014	–	–
Age group		
<54	0.555 (0.292–1.055)	0.405 (0.149–1.097)
54–65	0.536 (0.297–0.967)	0.116 (0.032–0.416)
66–71	0.522 (0.282–0.969)	0.550 (0.233–1.296)
>71	–	–
Race		
White	0.740 (0.426–1.284)	2.567 (0.739–8.914)
Non-white	–	–
Sex		
Male	0.613 (0.383–0.979)	0.943 (0.449–1.980)
Female	–	–
Teaching status		
Nonteaching	1.099 (0.644–1.875)	0.831 (0.316–2.186)
Urban teaching	–	–
Hospital region		
Northeast	0.645 (0.254–1.637)	ID*
Midwest	0.487 (0.219–1.082)	0.262 (0.063–1.082)
South	1.384 (0.716–2.676)	0.689 (0.230–2.064)
West	–	–
Indication		
Stenosis	1.009 (0.507–2.008)	0.687 (0.207–2.284)
Acquired spondylothesis	0.852 (0.383–1.899)	2.012 (0.709–5.711)
Other	2.108 (1.273–3.490)	1.305 (0.567–3.003)
Degenerative disk disease	–	–
Comorbidity		
Diabetes	1.360 (0.760–2.435)	1.555 (0.623–3.879)
No diabetes	–	–

*Insufficient data for analysis.

Table 4
Cost and length of stay for robotic-assisted and conventional lumbar fusion

	Conventional	Robotic-assisted	p (K test)
Hospital cost			<.001
Mean ± SD	$35,430±23,818	$59,149±44,374	
Median	29,139	45,227	
Mean rank	199.91	311.87	
Length of stay			0.029
Mean ± SD	3.89±2.68	4.29±2.58	
Median	3.00	4.00	
Mean rank	243.54	271.46	

experiencing a perioperative complication in our sample. Between the four regions of the United States, there was no difference in the risk of developing any type of perioperative complication. Surgical indication was not associated with any difference in risk for major perioperative complications. However, the indication of "other" was associated with a nearly two-fold greater incidence of minor complications compared to degenerative disc disease (Table 3).

The average length of stay was greater for robotic-assisted fusion ($\bar{x}$=4.29, SD=2.58) compared to conventional fusion ($\bar{x}$=3.89, SD=2.68, p=.029). Additionally, the average inpatient hospital cost of robotic-assisted fusion was $59,149 (SD=44,374) compared to $35,430 (SD=29,139) for the conventional procedure (p<.001) (Table 4).

Discussion

Prior studies have shown that robotic-assisted spinal fusion is superior to the conventional technique with regards to accuracy of implantation [2–8]. Our study examined whether robotic-assisted spinal fusion also demonstrates improved patient outcomes by examining risk of major and minor complications, as well as mortality. The NIS enabled the creation of a large sample, consisting of 257 robotic-assisted lumbar fusion cases rigorously matched with an equal number of conventional fusions. Using a cohort-matched design minimized confounding variables that might arise from patient selection bias when random allocation is not available with a retrospective design. With this design, we were able to demonstrate that the risk of major perioperative complications following robotic-assisted lumbar fusion did not differ from that following the conventional technique. Minor perioperative complications occurred nearly twice as often in the robotic-assisted cohort. However, there was no difference in risk of minor complications between the procedures while controlling for additional variables. The adjusted analysis likely demonstrated no differences in risk of minor complications because it more tightly controlled for patient age, which was not matched precisely, but rather within 5 years, for the cohort matching. Patient mortality was rare in both groups. Though multivariate analysis revealed that DM was not associated with increased risk of perioperative complications, previous literature contradicts this finding. Guzman *et al.* identified significantly increased risk of perioperative morbidity and mortality in this population undergoing degenerative lumbar spine surgery, though when uncontrolled DM and controlled DM were compared, findings were more robust for uncontrolled DM [15].

The results of this research must be compared with caution to previous studies of complications following robotic-assisted fusion. Important factors to consider are differences in study sample, as well as varying definitions of complications. Our research is the first national comparison of robotic-assisted and conventional lumbar fusion. Previous comparisons of patient outcomes consisted of single or multiple institution samples [2–4,6]. Additionally, the complications measured in previous studies are not uniform. For example, Hyun et al. [4] and Kim et al. [6] defined a complication as the need for revision surgery (due to cage dislodgement or screw malposition), whereas Kantelhardt et al. [2] categorized adverse events as aberrant wound healing, infection, intraoperative complication, or cerebrospinal fistula. Furthermore, we dichotomized perioperative complications into major and minor groups, which is a distinction that has not been used in previous studies of patient outcomes following robotic-assisted fusion [2,4,6,7].

Our cohort-matched study adds to the growing body of evidence that there are no differences in short-term perioperative complications between patients who underwent robotic-assisted fusion versus those who underwent conventional fusion. Hyun et al. [4] and Kim et al. [6] found that an equal number of revision surgeries were required in the robotic-assisted and conventional groups. Furthermore, Kantelhardt et al. [2] noted that robotic-assisted fusion significantly reduced the rate of intraoperative adverse events when compared to conventional procedures, but that no difference was observed using their three additional measures of adverse events. In a comparison of robot-assisted pedicle screw placement in patients with pyogenic spondylodiscitis of the lumbar and thoracic spine, Keric et al. [7] demonstrated that no significant differences existed between robotic-assisted and freehand screw placement with regards to intraoperative complications. The same investigators also collected information on postoperative complications, including seroma, wound infection, abnormal wound healing, and revision for misplaced screws. Only revision for misplaced screws demonstrated a significant difference between techniques, with a lower rate following robotic-assisted procedures [7].

There is some additional evidence that suggests robotic-assisted fusion ameliorates risk of perioperative complications. For example, Devito et al. [3] found that only four patients, or 0.7% of their robotic-assisted sample, exhibited signs of neurological deficit following operation. The authors stated that no permanent neurological damage persisted following revision surgery, leading them to conclude

that robotic-assisted fusion reduces risk of permanent nerve injury. However, a weakness of this study is that they did not control with conventional cases.

With regards to LOS, our finding that patients who underwent robotic-assisted fusion had significantly longer inpatient LOS than patients who underwent conventional fusion is not consistent with the literature [2,4]. Kantelhardt et al. [2] and Hyun et al. [4] both report that robotic-assisted fusion significantly decreased inpatient LOS compared to conventional fusion. However, given the fact that these studies were conducted in Germany and Korea, respectively, this difference in findings might be due to variations in health care utilization outside of the United States.

Inpatient hospital costs were significantly higher for the robotic-assisted cohort at almost twice the expense of the conventional procedure. To our knowledge, our study is the first to examine hospital charges for robotic-assisted lumbar fusion despite considerable concern regarding the costs associated with robotic equipment [1,16]. In addition to the initial cost of installing robot systems and the annual cost of technical support, costs exceeding $7,000 have been reported in the literature for the robot-specific materials required for each spinal procedure [16]. Further research is needed to determine whether the significant cost of robotic equipment and associated materials is economically justified in lumbar fusion.

Our findings demonstrate that the adoption of robotic assistance in lumbar fusion is rising (Table 1). As is the case with any new technology in surgery, a prominent concern of many spinal surgeons has been the learning curve for using robotics. Numerous studies have examined the learning curve for pedicle screw placement using robotic guidance by examining execution rate, time per screw placement, accuracy of screw placement, or fluoroscopy time per screw [3–6,17–19]. Overall, evidence suggests that there is indeed a learning curve, which might take as long as 25 surgeries to overcome [19]. Notably absent from studies of the learning curve for robotic-assisted spinal instrumentation is the effect of surgeon experience on patient safety. At the very least, our research might suggest that robotic-assisted lumbar fusion does not increase the risk of perioperative complications despite the increasing adoption of this emerging technology.

The utilization of a statistically matched cohort of patients represents a strength of our study. This research design has been previously used with NIS data to examine perioperative complications following other orthopedic procedures [20]. Although cohort matching cannot entirely eliminate confounding factors, it allows for a strict comparison of procedures that commonly have varying indications and a diverse patient population. Multivariate analysis of the cohorts then allows for a rigorous assessment of the independent effects of each covariate. To our knowledge, this study is the first to adjust for the effects of any covariates while examining perioperative complications following robotic-assisted fusion.

The NIS is commonly employed for orthopedic surgery research, although it has several key limitations. There are many inherent issues with using an ICD-9-CM coded database. Variability in coding practices between different hospitals or physicians, underreporting of complications, and human error are potential confounding factors to consider when working with the NIS. One study that compared lumbar fusion data in the NIS and the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) found that while both databases reported similar patient demographic characteristics, there was significant variation in comorbidities and rates of adverse events between the databases [21]. Additional research has also demonstrated that the indications coded for spinal fusion within administrative databases do not accurately reflect those made by the treating surgeon [22]. Although the external validity of the databases varies, evidence suggests that using national administrative databases to make comparisons between competing procedures, as is the case in our study, is acceptable because the databases remain internally valid [21].

Another limitation to utilizing an ICD-9-CM coded database is the inability to characterize patients on baseline preoperative and intraoperative characteristics specific to spine surgery. Therefore, even though this study rigorously controls for patient demographics and comorbidities, we are unable to determine if the proportion of patients with more severe spinal pathologies varies between the robot-assisted and conventional sample. Furthermore, the NIS does not enable assessment potential relevant covariates such as operative time, as well as of certain complications specific to lumbar fusion such as pedicle screw misplacement. Additionally, the absence of data regarding outpatient complications and mortality, return to the operating room, radiography, functional outcomes, patient-reported outcomes (eg, pain), and readmission rates limits our ability to fully assess postoperative patient outcomes. While there are multiple robotic systems utilized to perform lumbar fusions, ICD-9-CM coding does not allow for differentiation between these systems. Furthermore, there are parameters associated with robotic pedicle screw placement and spine surgery in general that are not contained within the NIS that may have effects on certain postoperative complications. Among others, blood loss, minimally invasive versus open approach, midline versus paramedian approach, past history of thromboembolic event, and history of infection all may play a role in further stratifying complication profiles of these techniques being studied. Despite these limitations, the NIS remains a powerful tool for conducting outcome-based orthopedic research.

Despite using a national database, the sample size of our study remains a limitation. More specifically, we were unable to perform subanalyses on particular complications of interest, such as dural tears or postoperative focal neurological deficits due to NIS minimum reporting standards. Furthermore, a decision was made not to adjust for levels operated

on for either group. This could be viewed as a limitation as one could speculate a correlation between levels involved in surgery and the use of robotic pedicle screw placement.

In conclusion, our study of a nationally representative administrative database found that robotic-assisted lumbar fusion was not beneficial for reducing short-term perioperative complications compared to conventional fusion. Additionally, patients undergoing robotic-assisted procedures had longer LOS and greatly increased hospital costs. Despite the limitations inherent to the database, this study does at least identify a need for further more rigorous study into the efficacy and cost-effectiveness of robotic-assisted surgery techniques and temper immediate surgeon adoption of this newer technology.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.spinee.2018.07.004.

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