Use of Computer Assistance in Lumbar Fusion Surgery: Analysis of 15222 Patients in the ACS-NSQIP Database

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Abstract

Study Design: Retrospective cohort study.

Objective: Several studies have shown that the accuracy of pedicle screw placement significantly improves with use of computerassisted surgery (CAS). Yet few studies have compared the incidence of postoperative complications between CAS and conventional techniques. The objective of this study is to determine the difference in postoperative complication rates between CAS and conventional techniques in spine surgery.

Methods: The American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database was used to identify patients who underwent posterior lumbar fusion from 2011 to 2013. Multivariate analysis was conducted to demonstrate the difference in postoperative complication rates between CAS and conventional techniques in spine surgery.

Results: Out of 15222 patients, 14382 (95.1%) were operated with conventional techniques and 740 (4.90%) were operated with CAS. Multivariate analysis showed that patients in the CAS group had fewer odds to experience adverse events postoperatively (odds ratio [OR] = 0.57, P < .001). Minor adverse events occurred in 2905 (20.2%) patients in the conventional group and in 98 (13.2%) patients in the CAS group (OR = 0.57, P < .001). Blood transfusion was present in 2488 (17.3%) of the patients in the conventional group compared to 81 (11.0%) of the patients in the CAS group (OR = 0.56, P < .001). The mean operative time in the conventional group was 205.2 \pm 106.1 minutes, and it was 227.0 \pm 111.9 minutes in the CAS group. This difference was statistically significant (r = 20.14, P < .001).

Conclusion: This article examined the complications in lumbar spinal surgery with or without the use of CAS. These results suggest that CAS may provide a safer technique for implant placement in lumbar fusion surgeries.

Keywords

spine surgery, conventional, computer-assisted surgery, spine navigation, adverse events, blood transfusion, operation time

Introduction

The challenge of spine surgery is exacerbated by the intricate anatomy of the spine as well as the complexity of surgical interventions for spine pathologies. The impetus has thus been to develop new techniques that can help decrease complication rates.¹ This has been attempted through a variety of approaches ranging from conventional methods to computer-assisted surgeries (CAS).

Spine instrumentation using pedicle implants for numerous pathologies including trauma, degenerative conditions, tumors,

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and deformities is now widely used.² The insertion of spinal implants with the assistance of CAS has led to convincing improvements in clinical and radiological results. CAS provides real-time feedback and anatomical details of the unexposed or partially exposed pedicles, allowing for precise placement of implants and thus more accurate insertion.³ However, despite the valuable success of CAS in terms of clinical and radiological outcome, the adaptation of this technique remains low. Whether CAS significantly decreases complication rates, revision rates, and overall costs remain controversial, and thus the use of CAS in spine surgery continues to be a debatable topic among experts.⁴

The present study aims to characterize and compare the 30day postoperative complications between patients who underwent lumbar spinal fusion with CAS or conventional surgery. Results from this study will provide novel insights regarding the complication rates associated with CAS and may facilitate surgical planning to achieve better patient outcomes.

Material and Methods

This study received an exemption by the institutional review board of the McGill University Health Center.

Data Source

We used the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database, which captures data from more than 400 academic and private participating US and Canadian centers. In the ACS-NSQIP, 300 patient variables are prospectively collected from operative reports, medical records, and patient interviews to assess 30day adjusted surgical outcomes. Patients are identified prospectively and randomly sampled at eligible hospitals. Clinical data is collected for the entire 30-day postoperative period, regardless of discharge status.⁵

Cohort Identification

Patients who underwent anterior and posterior lumbar spine fusions using conventional techniques or CAS from 2011 to 2013 were identified in the ACS-NSQIP database. Posterior lumbar fusion patients were identified using the primary Current Procedural Terminology (CPT) codes 22 612, 22 630, and 22 633. Anterior lumbar fusion patients were identified using CPT code 22 558. Patients who underwent CAS lumbar fusion were identified by the CPT code 61 783. We used the codes 22 585, 22 614, 22 632, 22 845, and 22 842 to identify patients with multilevel spine fusion surgeries. As such, the patient population included those with anterior and posterolateral approaches with or without interbody fusion. Patients with missing preoperative data of interest were excluded.

Among the variables available in the ACS-NSQIP database, demographic characteristic of interest included sex, age, and race. Comorbidities included body mass index (BMI; calculated from each patient's height and weight [kg/m²]), history of diabetes (recorded as history of type 1 or type 2 diabetes), smoking, dyspnea (classified as dyspnea at rest or at moderate excretion), chronic obstructive pulmonary disease, congestive heart failure (CHF), dialysis, hypertension, bleeding disorder, steroid intake for chronic diseases, and American Society of Anesthesiologists (ASA) class. Patients who underwent lumbar fusion were divided into 2 groups, conventional surgery or computer-assisted surgery.

Data on various adverse events in the 30-day postoperative period is explicitly recorded in the ACS-NSQIP on the basis of standard definitions.⁵ This study investigates the relationship between the 2 surgical techniques and the occurrence of any adverse events, serious adverse events, and minor adverse events.⁶⁻⁸ Serious adverse events included death, ventilator support for more than 48 hours, stroke/cerebrovascular accident, deep wound infection, myocardial infarction, sepsis, and pulmonary embolism. Minor adverse events included blood transfusion, urinary tract infection, superficial wound infection, venous thromboembolism, and pneumonia. Intraoperative variables of interest included the number of lumbar levels operated (single vs multi-level), operative time, and length of hospital stay. As unplanned readmission (inpatient hospital stay within 30 days of the primary surgical procedure) and unplanned reoperation (unplanned reoperation related to the primary procedure within the first 30 days) are important clinical variables, we also examined their relationship with CAS and conventional surgeries, although only 2796 and 3057 patients had documented data regarding readmission and reoperation, respectively.

Statistical Analysis

All statistical analyses were conducted using Stata, version 12.0 (StataCorp, LP, College Station, TX). Pearson χ^2 test for categorical variables and Student's *t* test for continuous variable were used to compare patient demographic and preoperative clinical characteristics between patients who underwent lumbar fusion via conventional surgery or CAS. Multivariate logistic regression was conducted to compare the occurrence of complications between patients who had surgery using conventional techniques or CAS. Multivariate linear regression was used to assess the effect of surgical technique on operative time and hospital length of stay. All multivariate analyses controlled for demographic and comorbidity variables are included in Table 1.

Results

Patient Demographics and Clinical Characteristics

A total of 15 222 patients who underwent lumbar spine fusion between 2011 and 2013 were identified in the NSQIP database and met our inclusion criteria. The overall mean age was 42.3 \pm 13.7 years. Patients who underwent lumbar fusion were 44% males and 55% females; the average BMI was 30.3 \pm 6.4. Fifty-three percent of this population had an ASA class of

I able 1. Patients Demographic and Clinical Character	ristics.
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		Lumbar Fusion	l	
	All Patients (N = 15222)	Conventional (N = 14382)	Computer Assisted (N = 740)	P Value
Demographic characteristics				
Age (years)	42.3 ± 13.7	42.3 ± 13.7	42.9 <u>+</u> 13.2	.23
Gender (%)				.46
Woman	55.6	55.7	54.3	
Men	44.4	44.3	45.7	
Race (%)				<.001
White	85.6	85.3	91.4	
Black or African American	5.9	5.9	5.7	
American Indian or Native	0.5	0.5	0	
Native Hawaiian or Pacific Islander	0.3	0.3	0	
Asian	1.5	1.6	0.4	
Unknown	6.2	6.40	2.6	
Comorbidities				
BMI (kg/m ²)	30.3 ± 6.4	30.3 ± 6.4	30.5 ± 6.7	.58
Diabetes (%)				.15
Type I	5.0	5.1	3.7	
Type 2	10.7	10.7	11.9	
Smoking (%)	22.2	22.4	19.1	.03
Dyspnea (%)				
At rest	0.3	0.4	0	<.001
Moderate exertion	6.7	6.8	2.8	
COPD (%)	4.4	4.5	3.9	.43
CHF (%)	0.2	0.2	1.1	<.001
Dialysis (%)	0.2	0.2	0	.22
Hypertension (%)	54.4	54.2	58.1	.04
Bleeding disease (%)	1.6	1.5	2.4	.05
Steroids (%)	3.8	3.7	2.8	.2
ASA class (%)				<.001
I, No disturbance	3.1	3.1	2.4	
2, Mild disturbance	50.7	51.1	42.4	
3. Severe disturbance	44.0	43.5	52.8	
4, Life-threatening disturbance	2.2	2.2	2.3	
Clinical characteristics				
Blood transfusion within 48 hours	0.4	0.4	0	.09
Operation time (minutes)	206.2 + 106.5	205.2 + 106.1	227.0 + 111.9	<.001
Elective surgery (%)	94.8	95.3	96.9	.04
Outpatient (%)	2.1	2.2	0.8	.01
Return to operation room (%)	3.4	3 4	23	.10
Readmission ^a	63	63	65	95
Reoperation ^b	3.6	3.6	2.7	.69

Abbreviations: BMI, body mass index; COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; ASA, American Society of Anesthesiologists. ^aThis variable was reported for only 2796 patients (n = 2719 in the conventional group and n = 77 in the computed-assisted group). ^bThis variable was reported for only 3057 patients (n = 2983 in the conventional group and n = 74 in the computed-assisted group).

1 to 2. Of these patients, 14382 (95.1%) were operated with conventional techniques and only 740 (4.9%) were operated with CAS. Demographics, comorbidities, and clinical characteristics of the patients are summarized in Table 1.

Comparison of patient demographics and comorbidities between the conventional and CAS groups revealed significant differences between the cohorts in race, smoking history, hypertension, bleeding disorder, ASA class, and history of CHF. Patients in the conventional group were more likely to be smokers (P = .03). On the other hand, patients who underwent lumbar fusion with CAS were more likely to be hypertensive (P = .04), had an overall increase in the ASA class (P < .001), and were more likely to have a history of bleeding disorders (P = .05) and CHF (P < .001). Interestingly, a greater percentage of patients who underwent lumbar fusion using the conventional techniques had a history of dyspnea (P < .001). Otherwise, all the other demographics and comorbidities were comparable without any significant difference (Table 1).

With regard to clinical characteristics, patients in the CAS group had a longer operation time by 22 minutes (P < .001).

			Multivariate I	ogistic Regression ^b	
Outcome	Conventional	Computer Assisted	OR	95% CI	P Value
Any adverse event	21.2%	13.9%	0.57	0.46-0.70	<.001
Any severe adverse event	2.6%	1.8%	0.64	0.37-1.13	.122
Death	0.2%	0%	_	_	_
Ventilator >48 hours	0.3%	0.4%	0.61	0.30-1.24	.169
Stroke/CVA	0.2%	0.1%	0.74	0.10-5.51	.771
Deep surgical site infection	0.7%	0.4%	0.54	0.17-1.70	.289
Myocardial infarction	0.3%	0.4%	1.34	0.41-4.36	.60
Sepsis	0.8%	0.8%	0.97	0.42-2.23	.943
Pulmonary embolism	0.6%	0.3%	0.43	0.10-1.78	.249
Any minor adverse event	20.2%	13.2%	0.57	0.46-0.71	<.001
, Blood transfusion	17.3%	11.0%	0.56	0.44-0.70	<.001
Urinary tract infection	1.8%	1.1%	0.60	0.30-1.23	.162
Pneumonia	0.8%	0.3%	0.33	0.08-1.34	.120
Superficial surgical site infection	1.1%	0.8%	0.69	0.30-1.58	.382
DVT/thrombophlebitis	0.8%	0.5%	0.61	0.23-1.67	.341
Return to operation room	3.4%	2.3%	0.64	0.40-1.06	.08
Readmission $(n = 2796)$	6.3%	6.5%	1.03	0.40-2.58	.958
Reoperation $(n = 3075)$	3.6%	2.7%	0.69	0.17-2.89	.614

Table 2. Association of Surgical Technique With Adverse Outcomes^a.

Abbreviations: OR, odds ratio; CI, confidence interval; CVA, cerebrovascular accident; DVT, deep vein thrombosis.

^aValues in boldface indicate statistical significance (P < .05).

^bEach line represent a separate multivariate logistic regression analysis for each variable and adjusted odds ratio and *P* value by controlling for all demographics and comorbidities found in Table 1.

Patients in the conventional group were treated in an outpatient setting in 2.2% of the cases compared with 0.8% in the CAS group (P = .01; Table 1).

Outcomes

The results of the multivariate analyses for adverse outcomes are presented in Table 2. Overall, 3157 (20.9%) of the patients experienced any type of adverse events as mentioned in Table 2, 3054 (21.2%) patients in the conventional group and 103 (13.9%) patients in the CAS group. Multivariate analysis showed that patients in the CAS group had fewer odds to experience any adverse event postoperatively (odds ratio [OR] = 0.57, P < .001). Minor adverse events occurred in 2899 (20.2%) patients in the conventional group and 98 (13.2%) patients in CAS group (OR = 0.57, P < .001; Table 2).

The most common minor adverse event was blood transfusion intra- or postoperatively. A total of 2488 (17.3%) patients in the conventional group, as compared to 81 (11.0%) patients in the CAS group, required a blood transfusion (OR = 0.56, P < .001). To evaluate whether the increased risk of any adverse event and minor adverse events in the conventional group were solely driven by the increased risk of blood transfusion, the same analysis was performed with blood transfusion excluded, and the increased odds remained significant for any adverse events and minor adverse events, respectively (OR = 0.58 for any adverse events, P = .007, and OR = 0.54 for minor adverse events, P = .01). There was no significant relationship between the surgical techniques and any of the severe adverse events (OR = 0.64, P = .1; Table 2). Complication rates for

single-level and the multi-level spinal surgery via conventional surgery or CAS are presented in Table 3.

Apart from blood transfusion, multivariate linear regression showed that the mean operative time in the conventional group was 205.2 \pm 106.1 minutes, and it was 227.0 \pm 111.9 minutes in the CAS group. This difference was statistically significant (coeff = 20.14, P < .001; Table 4). The mean operative time in single-level surgery was 185.1 \pm 93.5 minutes in the conventional group and 196.1 \pm 90.9 minutes in the CAS group (P =.03), while the mean operative time in multi-level surgery was 224.2 \pm 113.5 in the conventional group and 251.6 \pm 120.7 in the CAS group (P = <.001; Table 5). Nevertheless, length of hospital stay in the conventional group (4.05 \pm 4.8 days) and CAS group (4.10 \pm 2.55 days) were not statistically different (coeff = -0.04, P = .82; Table 4).

Discussion

Lumbar fusion is a common and well-established surgical procedure to treat many lumbar spine pathologies.² In recent years, CAS has emerged to take an important part in this procedure in hopes of improving patient outcomes. Evidence-based medicine seeks to base clinical decisions on the best available clinical evidence. Several studies have compared conventional techniques and CAS in terms of pedicle screws insertion accuracy, with results showing better accuracy rates in CAS cases.⁹ Nevertheless, few of them have compared conventional techniques and CAS in terms of clinical outcome postoperatively. To our knowledge, this the first study to compare 30-day

			Multivariate I	ogistic Regression ^b	
Outcome	Conventional	Computer Assisted	OR	95% CI	P Value
Any adverse event					
, Single level	14.0%	7.9%	0.52	0.34-0.78	.002
Multi-level	28.1%	18.7%	0.54	0.41-0.70	<.001
Any minor adverse event					
, Single level	13.0%	7.3%	0.51	0.34-0.79	.002
Multi-level	26.9%	17.9%	0.54	0.42-0.71	<.001

Table 3. Association of Surgical Technique With Adverse Outcomes (Single- and Multi-Level Surgeries)^a.

Abbreviations: OR, odds ratio; CI, confidence interval.

^aValues in boldface indicate statistical significance (P < .05).

^bEach line represent a separate multivariate logistic regression analysis for each variable and adjusted odds ratio and *P* value by controlling for all demographics and comorbidities found in Table 1.

Table 4. Association of Surgical	Technique With Operative	Time and Hospital Length	ı of Stay ^a .
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			Multivariate	Linear Regression ^b	
Outcome	Conventional	Computer Assisted	Coefficient	95% CI	P Value
Operation time (minutes) Hospital length of stay (days)	$\begin{array}{r} 205.2 \pm 106.1 \\ 4.05 \pm 4.8 \end{array}$	$\begin{array}{r} 227.0 \ \pm \ \text{III.9} \\ 4.10 \ \pm \ 2.6 \end{array}$	20.14 -0.04	12.31 to 27.91 -0.37 to 0.30	<.001 .820

Abbreviation: CI, confidence interval.

^aValues in boldface indicate statistical significance (P < .05).

^bEach line represent a separate multivariate logistic regression analysis for each variable and adjusted odds ratio and P value by controlling for all demographics and comorbidities found in Table 1.

Table 3. Association of surgical rechnique with Operative Time (single- and Fund-Level surgene	Table	5. Association of	of Surgical T	echnique	With O	perative Time	(Single- and	Multi-Level Surgerie
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			Multivariate Lir	near Regression ^b	P Value
	Conventional	Computer Assisted	Coefficient	95% CI	r value
Operative time (minutes)					
Single level	185.1 <u>+</u> 93.5	196.1 <u>+</u> 90.9	11.2	0.92-21.5	.033
Multi-level	224.2 \pm 113.5	251.6 ± 120.7	24.1	12.8-35.3	<.001

Abbreviation: CI, confidence interval.

^aValues in boldface indicate statistical significance (P < .05).

^bEach line represent a separate multivariate logistic regression analysis for each variable and adjusted odds ratio and P value by controlling for all demographics and comorbidities found in Table I.

postoperative outcomes between CAS and conventional techniques using the NSQIP database.

In this present study, we used the NSQIP database to further explore the impact of CAS on patients' clinical postoperative outcomes. The NSQIP database has been used frequently in the past in spine surgery research as it offers a distinctive and potent prospect for the assessment of patients' early clinical outcomes.¹⁰ We studied a sample of more than 15 000 patients who underwent lumbar fusion between 2011 and 2013 to determine the impact of CAS on the patients' clinical sequels postoperatively in comparison to conventional techniques. In order to ensure that any significant results are due to the surgical techniques, the groups being compared have to be similar in terms of demographics and clinical characteristics. As shown in Table 1, the demographics were relatively similar in terms of age, gender, and BMI. However, with regard to patients' comorbidities and clinical characteristics, the CAS group was found to have more comorbidities than the conventional group. A greater percentage of patients in the CAS group had a higher ASA class, more frequent history of hypertension, CHF, and bleeding disorder. Yet the multivariate analysis demonstrated that there are significant clinical differences in terms of surgical outcome after accounting for these factors even though patients in the CAS group seemed less healthy. For instance, analysis of the demographics showed that the percentage of patient with bleeding disorder in the CAS group was significantly higher. Despite this fact, patients in the CAS group had significantly less incidence of blood transfusion intra- or postoperatively.

Our analysis showed that the rate of any adverse outcomes associated with lumbar fusion is 20.9%; CAS had less odds of having any adverse events with a rate of 13.9% with reference to 21.2% in the conventional group (OR = 0.57, P < .001). Although no significant decrease in severe adverse events following the use of CAS, a significant decrease in odds of minor adverse events was found in patients who underwent CAS (OR = 0.57, P < .001). According to our analysis, patients undergoing lumbar fusion with CAS were less likely to experience complications following surgery despite having more comorbidity preoperatively. Several studies have reported on postoperative clinical outcome specifically for lumbar spine fusion using conventional methods.^{11,12} Fritzell et al used a sample of 211 patients undergoing lumbar spine fusion.¹² Of these, 52 patients (24.6%) encountered 56 complications. The reported complications included both major complications (46.1%) and minor complications (53.9%). On the other hand, Tsahtsarlis et al studied 100 patients undergoing CAS lumbar interbody fusion; the authors reported a postoperative complication rate of 5%. Of those, venous thromboembolism was 2%, reoperation 2%, and blood transfusion 1%.13 These results were higher than the rates of the overall complications in the conventional group (21.2%) and lower than the rates of overall complications in the CAS group (13.9%). Moreover, few studies compared the operative outcomes between conventional and CAS techniques.¹⁴ Laine et al conducted a randomized study comparing conventional surgery and CAS techniques in terms of pedicle screws placement accuracy and postoperative clinical outcome.¹⁴ Five major complications were reported in the conventional group and one major complication in the CAS group. Despite the relative consistency of the aforementioned results with the results in this report, our sample size was much larger increasing the power of our analysis.

Our findings also showed that the conventional group had greater odds of having blood transfusion intra- or postoperatively when compared to the CAS group (P < .001). Several risk factors for blood transfusion have been identified in the literature.^{15,16} Zheng et al concluded that patient age and number of fused spine levels are the main predictors of blood transfusion in patients undergoing revision following posterior lumbar fusion. Other factors included preoperative hemoglobin and body weight. In a recent study using ACS-NSQIP database, Basques et al stated that patients older than 60 years with ASA class 3 and above, with pulmonary disease or with preoperative anemia, had a higher risk of blood transfusion following lumbar fusion.¹⁷ In our study, the CAS group had a greater percentage of patients with an ASA class higher than 3, bleeding disorders, and a longer operative time. Nonetheless, they required fewer blood transfusions.

In terms of cost-effectiveness, Watkins et al have shown that CAS can be cost-effective in high-volume specialized centers and in complex cases that require longer operative time.¹⁸ This has been illustrated by better pedicle screw placement accuracy, which in turn leads to a decrease in the rate of revisions. Nevertheless, a recent review by Al-Khouja et al concluded that there is no sufficient data in the literature on the cost-effectiveness of CAS; however, their results lean toward cost-effectiveness of CAS.¹⁹ In the present study, the rate of blood transfusion was significantly lower in the CAS group (11.0%) when compared with the conventional techniques (17.3%). For just one of the many complications seen

postoperatively to be greater in the conventional group versus CAS, the cost-effectiveness for decreased need for blood transfusion alone would demonstrated the effect of CAS on surgical cost-effectiveness. The reported cost of a single unit of packed red blood cells in the literature range between US\$522 and US\$1183.²⁰ Taking this into account, the utilization of CAS to guide spinal fusion as opposed to conventional methods can be expected to decrease the number of patients requiring blood transfusions by 913 patients. This estimate was based on the proportional reduction noted in the rate of transfusions between our 2 study groups. Assuming that every patient receives a single unit of packed red blood cells per transfusion setting, the cost of blood transfusion will decrease by a range of US\$476586 to US\$1080079 for all patients involved in the conventional group that required blood transfusions.

The authors recognize and acknowledge some of the limitations of this study, including possible variations in the quality of the data and limitation of the variables available in the ACS-NSQIP database. Additionally, we were not able to assess the effect of important clinical variables such as the number of screws used and the type of CAS system used, but these factors are expected to be similar between the 2 groups. Furthermore, certain confounding factors could not be controlled for, and thus demographics and comorbidities were accounted for in the multivariate analyses. An important confounding factor that might have contributed to these results, specifically the lower incidence of blood transfusion, is the frequent use of minimally invasive approach with CAS surgery, which cannot be adjusted for due to the nature of the database. We also appreciate that the ACS-NSQIP database limits the follow-up time to the first 30 days postsurgery, and thus the occurrence of adverse events occurring after this period remains unclear. Moreover, spine-specific outcomes such as pain and postoperative neurological status were not recorded in the NSQIP database. Consequently, we were unable to make a more detailed assessment of the postoperative status at different points along the spectrum of clinical disease.

In this article, we investigated the impact of 2 different surgical techniques on postoperative outcomes in patients undergoing lumbar fusion. Overall, our analysis showed that CAS had better outcomes in terms of postoperative complications. The significance of these results lies in advocating the consideration of such differences to spine surgeons while making the choice of screw insertion techniques in lumbar fusion surgeries.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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