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ORIGINAL RESEARCH

Evaluation of Cost, Payments, Healthcare Utilization, and Perioperative and Post-Operative Outcomes of Patients Treated with Posterior Lumbar Spinal Surgery Using Open versus Minimally Invasive Surgical Approaches

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Purpose: Minimally invasive surgery (MIS) of the spine has been associated with favorable outcomes compared to open surgery. This study evaluated matched cohorts treated with MIS versus open posterior lumbar fusion for costs, payments, healthcare utilization and outcomes.
Patients and Methods: This study used the Premier Healthcare and IBM® MarketScan® Commercial and Medicare Databases. Patients with posterior lumbar fusion from 2015 to 2018 were identified and categorized as "Open" or "MIS". Cohorts were matched on patient and provider characteristics. Perioperative complications, hospital costs, healthcare utilization and post-operative outcomes and payments to providers were analyzed. Statistical significance was evaluated using *T*-tests and chi-square tests.
Results: After matching, 2,388 Open and 796 MIS from PHD, and 415 Open and 83 MIS from MarketScan were included. Statistically significant differences between MIS versus Open were found for index hospital costs, $29,181 (SD: $14,363) versus $27,616 (SD: $13,822), p=0.01; length of stay, 2.94 (SD: 2.10) versus 3.15 (SD: 2.03) days, p=0.01; perioperative urinary tract infection, 1.01% and 2.09% (p=0.05); and 30-day risk of hematoma/hemorrhage, 19.28% versus 8.43%, p=0.02. There were observed, but statistically non-significant differences in additional perioperative or post-operative complications, home discharge, 90-day all-cause and spine-related readmission, and 90-day post-operative payments.
Conclusion: Compared to Open, patients that underwent MIS had statistically significant lower length of stay, lower perioperative UTI, greater hospital costs, and higher 30-day risk of hematoma/hemorrhage. The differences observed in post-operative complications and payments and readmissions warrant further investigation in larger matched cohorts.
Keywords: minimally invasive surgical procedures, database, spine, lumbar vertebrae, propensity score, health services research, health care costs

Introduction

As patients age, their risk for developing spinal pathologies, such as degenerative disc disease and deformities increases. As a result, the demand for spinal surgery has also increased, as it is one of the methods for treatment of spinal health issues.[1,2] Despite the growing rate of spinal fusions being performed annually,

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there is still a high risk of complications associated with spinal fusions including substantial blood loss, infection, and pain. These high rates of complication may increase length of stay and reoperation rates, which places a financial burden on hospitals and healthcare systems.[3,4] Technological advancements in spinal surgery have allowed for the development of minimally invasive surgery (MIS) approaches to spine surgery. MIS capitalizes upon small incisions and special instruments to relieve pressure being applied to spinal nerves; thus, reducing muscle and soft tissue trauma to drive quicker recovery. These approaches have since become more popular among spine surgeons because they result in less blood loss and muscle/tissue damage, reduce post-operative pain and risk of infection, and yield better cosmetic results.[5]

Comparative studies of MIS versus Open among lumbar fusion have demonstrated hospital cost savings, lower perioperative healthcare utilization, and lower long-term complications.[6–10] However, less is known about how short-term post-operative payments to hospitals and physicians, post-operative complications and readmissions compare for MIS versus Open surgery. The rationale for understanding short-term post-operative payments and outcomes for MIS is particularly important given the current evidence suggests successful perioperative and long-term post-operative outcomes with these procedures.[7–9,11,12]

The objective of this study was to compare perioperative hospital cost and healthcare utilization, perioperative and 30-day post-operative complications, 90-day post-operative payments and readmissions among patients who underwent MIS or Open posterior lumbar fusion using a matched cohort design.

Methods

Data Sources

This study identified patients that underwent posterior lumbar fusion from October 1, 2015 to March 31, 2018 from the Premier Healthcare Database (PHD) (referred to as the hospital database throughout) and IBM® MarketScan® Commercial Claims and Encounters and Medicare Supplemental databases (referred to as the healthcare claims databases throughout).

The use of PHD and IBM® MarketScan® databases for research was reviewed and considered exempt from Institutional Review Board (IRB) review by the New England IRB. Both data sources contain completely de-identified patient records compliant with the Health Insurance Portability and Accountability Act of 1996.

The PHD is a nationally representative all-payer United States (US) hospital database that houses data on the inpatient and outpatient visits from a diverse sample of hospitals including non-profit or private hospitals, and represents approximately 25% of all US inpatient hospital stays. PHD was used to assess perioperative complications, healthcare utilization and hospital costs.

The IBM® MarketScan® CCAE and MDCR databases contain adjudicated health insurance claims and enrollment data from large employers and health plans who provide private healthcare coverage to employees, their spouses, and dependents. Patient healthcare encounters are captured longitudinally in these databases. MarketScan databases were used to assess post-operative payments and outcomes after discharge.

Study Design

This study was a retrospective database analysis of patients that presented for posterior lumbar fusions.

Study Population

In both the hospital and healthcare claims databases, all adult (>17 years) patients with a posterior lumbar fusion were included. Because of confidentiality reasons, it was not possible to identify the same patients in both data sources.

All patients were selected using ICD-10 procedure codes for posterior lumbar fusion for one-level fusions (ICD-10 code series 0SG0xxx) and a diagnosis-related group (DRG) patient classification equal to 460 (Spinal fusion except cervical without major complication or comorbidity). Two-level fusions were also included in the healthcare claims database with concurrent 0SG0xxx code if patients had add-on CPT-4 codes (22614, 22632, 22634) that indicated two-level surgery, but patients with more than two-level fusion were excluded. All patients had a surgery in the inpatient setting. This surgery was considered the index surgery. In the healthcare claims databases, patients with lumbar or thoracic fusion/revision surgery in the year prior to October 1, 2015 were excluded and included patients were required to have at least 90 days of continuous enrollment post-index surgery to track outcomes and payments.

In the hospital database, admissions were categorized as Open versus MIS based on the ICD-10 code or use of instrumentation specific to MIS or open procedures. In the healthcare claims databases, all admissions were categorized based only on the ICD-10 code.

Variables

Age, sex, and chronic diseases and comorbidities listed in the Elixhauser or Functional Comorbidity Indices (ECI and FCI; listed within Appendix 1) were collected. These chronic diseases and comorbidities were collected if they were present on admission in the hospital database (an indicator they were pre-existing) or occurred 365 days prior to surgery in the healthcare claims databases. The ECI is a set of 31 chronic disease or comorbidity indicators that may impact patients' mortality outcomes and the score is a weighted combination of the 31 comorbidities; obesity is included in the ECI and was used for propensity score matching in addition to the score.[13] The FCI is a set of 18 comorbidity indicators that may impact patients' physical function outcomes and the score is a sum of each comorbidity.[14] FCI was only measured in the healthcare claims databases, because it contains constructs that may not be well captured in a hospital-based database. Because of availability of information in each data source, the collection of additional patient, procedure, and hospital characteristics differed: in the hospital database, race, marital status, payer, hospital geography, bed size, and teaching and urban status were collected. In the healthcare claims databases, patient geography, drug and smoking use, fusion type, allograft or autograft use, cage use, spinal levels fused and neuromonitoring use were collected.

Outcome variables collected in the hospital database were perioperative complications, admission costs for the entire episode of hospital care, length of stay (LOS) and discharge status. The complications collected were localized hematoma/hemorrhage, dysrhythmias, heart failure, urinary tract infection (UTI), nausea/vomiting, acute renal failure, respiratory failure, intestinal obstruction, diaphragmatic hernia, nutrition, dysphagia, anastomosis, device failure, infections (sepsis, pyelonephritis, general), abdominal hernia, myocardial infarction, pleural effusion, surgical injury, thrombosis/deep vein thrombosis (DVT), transient ischemic attack (TIA), pneumothorax, subcutaneous emphysema, allergic reaction, delirium, and unknown complications (includes not specified general complications, and not specified gastrointestinal or respiratory or urinary complications).

The outcome variables assessed in the healthcare claims databases in the 30 days after index fusion were surgical site infection (SSI), localized hematoma/hemorrhage, muscle spasm, durotomy and spinal cord injury; and, in the 90 days after index fusion were all-cause inpatient readmissions and spine-related inpatient readmissions, spine-related inpatient reoperations, total payments for any inpatient or outpatient post-operative care or prescription drugs to hospital or physician providers by healthcare insurers and patients through their health insurance plan, including copays, deductibles, and coordinated benefits.

All variables assessed after the index episode were measured starting day 1 after index fusion to day 30 or 90 post-index fusion. Costs were adjusted for inflation according to the year 2017.

Matching

Cohorts were matched using propensity score (PS) methodology (caliper: 0.2, method: nearest neighbor without replacement, model: logit, ratio: 3:1, Open: MIS). The hospital database cohorts were matched on age, gender, region, married status, race, obesity status, Elixhauser Comorbidity Index (ECI) score, payer status, and hospital bed size, teaching status and urban status.

The healthcare claims cohorts were matched on age, gender, region, pre-index prescription drug use, smoking, substance abuse, ECI and FCI scores, surgical technique, and obesity status.

Data Analysis

All analyses were conducted using R-3.6.0 (R studio Version 1.1.463). Statistical significance was set a-priori at $\alpha \leq 0.05$ (two-sided). Descriptive statistics generated were counts and proportions for categorical variables, and means, medians and standard deviations (SD) for continuous variables. Results are presented by Open versus MIS.

Categorical outcomes were compared using chi-square test and continuous outcomes were compared using two-sample *T*-test.

Results

Hospital Database

The hospital database included 34,335 patients, among which 798 underwent MIS and 33,537 underwent Open. After matching, there were 2,388 and 796 patients, Open and MIS, respectively. Table 1A contains the characteristics of the unmatched and matched cohorts from the hospital database.

Table 1 Descriptive Characteristics of Pre- and Post-Match Open and MIS Patient Cohorts from the Hospital (Table 1A) and Healthcare Claims (Table 1B) Databases, 2015 to 2018

A. Pre- and Post-Match Characteristics of Open and MIS Patient Cohorts, Hospital Database				
	Pre-Match		**Post-Match**	
	Open	**MIS**	**Open**	**MIS**
N	33,537	798	2,388	796
Age (mean, (sd))	62.06 (12.49)	61.76 (13.14)	61.68 (13.02)	61.84 (13.07)
Elixhauser Comorbidity Score (mean (sd))	2.22 (1.77)	2.17 (1.8)	2.17 (1.74)	2.18 (1.80)
Elixhauser Obesity (%)	23.73	19.67	19.89	19.60
Male (%)	43.61	43.99	44.89	43.97
Race (%)				
Black	8.21	12.28	11.81	12.31
Other	6.62	4.26	4.06	4.27
Unavailable	2.61	1.00	1.38	1.01
Caucasian	82.57	82.46	82.75	82.41
Marital Status (%)				
Married	60.71	59.77	59.46	59.92
Single	33.61	36.84	37.40	36.68
Other	5.68	3.38	3.06	3.27
Payer (%)				
Commercial	34.56	32.96	34.46	33.04
Medicaid	6.09	5.01	4.56	4.90
Medicare	50.81	52.38	51.51	52.51
Other	8.54	9.65	9.46	9.55
Region (%)				
Midwest	24.01	18.55	18.84	18.47
Northeast	13.84	11.65	10.59	11.68
South	46.30	63.66	62.44	63.69
West	15.85	6.14	8.12	6.16
Hospital Number of Beds (%)				
000–099	3.63	4.64	4.94	4.65
100–199	11.33	5.26	5.53	5.28
200–299	15.84	9.40	9.17	9.42
300–399	20.02	15.04	14.61	14.95
400–499	12.87	7.02	7.37	7.04
500+	36.31	58.65	58.38	58.67
Teaching status (%)	44.60	59.40	59.09	59.30
Urban hospital (%)	92.45	91.60	92.92	91.58

(*Continued*)

Table 1 (Continued).

B. Pre- and Post-Match Characteristics of Open and MIS Patient Cohorts, Healthcare Claims Databases				
	Pre-Match		**Post-Match**	
	Open	**MIS**	**Open**	**MIS**
N	41,361	83	415	83
Male (%)	43.47	40.96	41.45	40.96
Age (mean (sd))	51.92 (9.37)	53.93 (8.75)	54.02 (8.52)	53.93 (8.75)
Elixhauser Comorbidity Score (mean (sd)	1.81 (1.62)	2.19 (1.57)	2.30 (1.74)	2.19 (1.57)
Elixhauser Obesity (%)	9.83	18.07	20.72	18.07
Functional Comorbidity Score (mean (sd))	3.70 (1.66)	4.34 (1.78)	4.37 (1.76)	4.34 (1.78)
Region (patient level) (%)				
Northeast	9.94	8.43	9.40	8.43
North Central	25.91	34.94	34.94	34.94
South	51.71	48.19	47.23	48.19
West	11.25	6.02	5.54	6.02
Pre-index alcohol use (%)	1.36	–	–	–
Pre-index Substance Abuse (%)	2.45	2.41	2.65	2.41
Pre-index tobacco use (%)	12.64	19.28	16.35	19.28
Surgery Type (%)				
Posterior lumbar fusion only	31.00	7.23	7.71	7.23
Interbody fusion only	11.41	24.10	21.69	24.10
Combined posterior and interbody fusion	57.60	68.67	70.60	68.67
Allograft (%)	29.58	38.55	37.35	38.55
Autograft (%)	48.59	34.94	52.29	34.94
Use of Cages (%)	66.47	90.36	87.23	90.36
Cases with 2 levels (%)	22.04	22.89	22.65	22.89
Cases with Neuromonitoring (%)	35.44	49.40	36.63	49.40
Pre-index Drug Use (%)				
Analgesics	24.84	21.69	22.17	21.69
Anti-convulsant	24.80	31.32	30.12	31.32
Antidepressants	33.77	38.55	37.83	38.55
Benzodiazepines	25.49	32.53	30.60	32.53
CNS drugs	10.82	6.02	7.47	6.02
Muscle relaxants	42.87	43.37	45.06	43.37
NSAIDs	45.90	53.01	55.42	53.01
Opiates	64.34	61.44	61.69	61.44
Moderate strength opiates	63.37	61.44	61.69	61.44
Strong opiates	9.30	3.61	3.13	3.61

Abbreviation: sd, standard deviation.

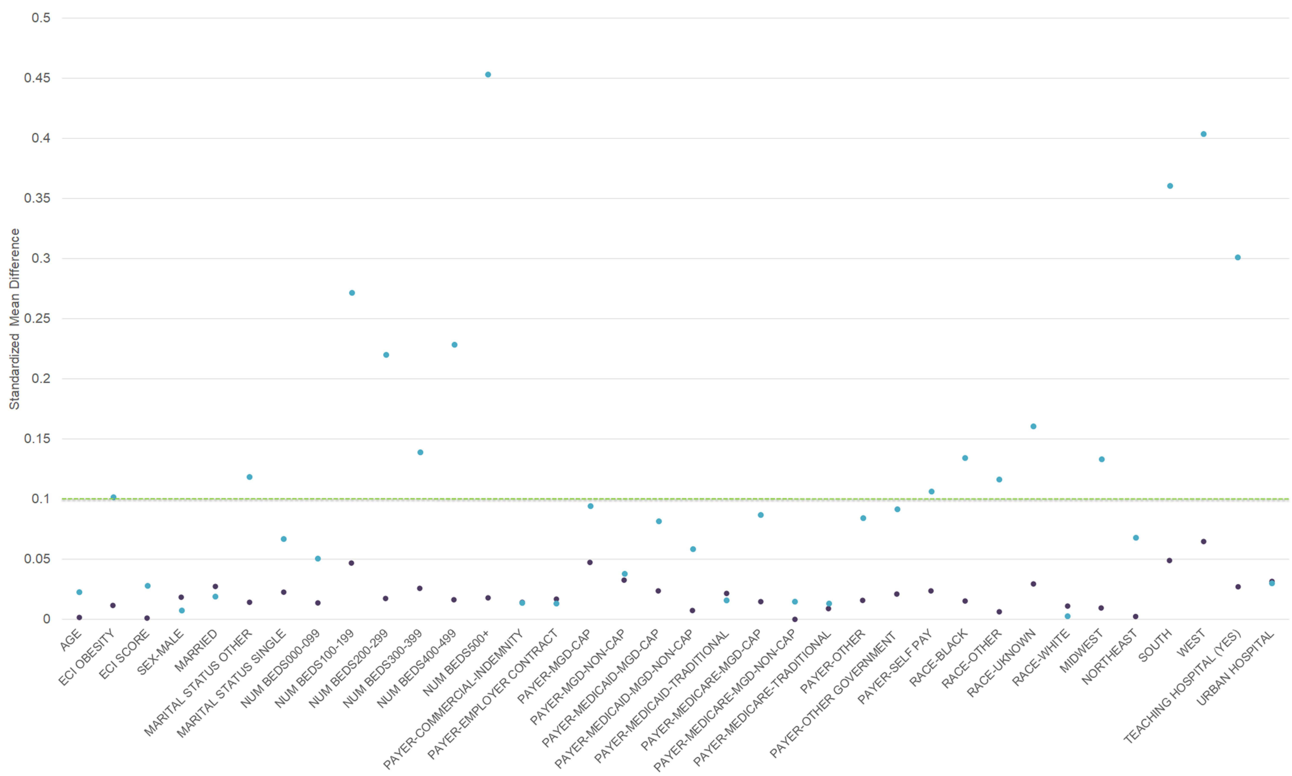

Figure 1 Absolute standardized mean differences (SMD) before and after matching, hospital database. Blue points represent SMDs before and purple points represent SMDs after matching.
Abbreviations: ECI, Elixhauser Comorbidity Index; Num, number; MGD, managed care; Cap, capitated.

The standardized mean differences (SMDs) of cohort characteristics before and after matching are shown in Figure 1. Characteristics with SMDs above 0.10, representing the cut-off for large imbalances between groups, before matching were obesity, other married status, bed sizes between 100 and 500+, self-pay payer, black race, other race, unknown race, Midwest, South, and West regions, and teaching status. After matching, all SMDs were <0.10.

Perioperative complication risk were similar between groups. Table 2 shows the complications with at least >5 cases in one group reported during the index admission. The only statistically significant difference between the groups was UTI, 1.01% and 2.09%, (p=0.05), MIS and Open, respectively. In summary, the Open cohort had statistically non-significant higher risk of perioperative hematoma/hemorrhage, allergic reaction, dysrhythmias, heart failure, nausea/vomiting, acute renal failure, respiratory failure, and

Table 2 Risk of Perioperative Complications (Hospital Database)

Perioperative Complications	Open (n=2,388)	MIS (n=796)	p-value
Localized hematoma or hemorrhage	10.68%	10.05%	0.62
Allergic reaction	4.65%	3.64%	0.23
Dysrhythmias	4.27%	4.02%	0.76
Heart failure	2.18%	1.63%	0.35
Urinary tract infection	2.09%	1.01%	0.05
Nausea vomiting	2.05%	2.01%	0.94
Acute renal failure	1.47%	1.38%	0.86
Respiratory failure	1.13%	0.63%	0.22
Intestinal obstruction	1.05%	0.63%	0.29
Diaphragmatic hernia	1.01%	1.51%	0.25
Unspecified complication	0.67%	0.75%	0.80

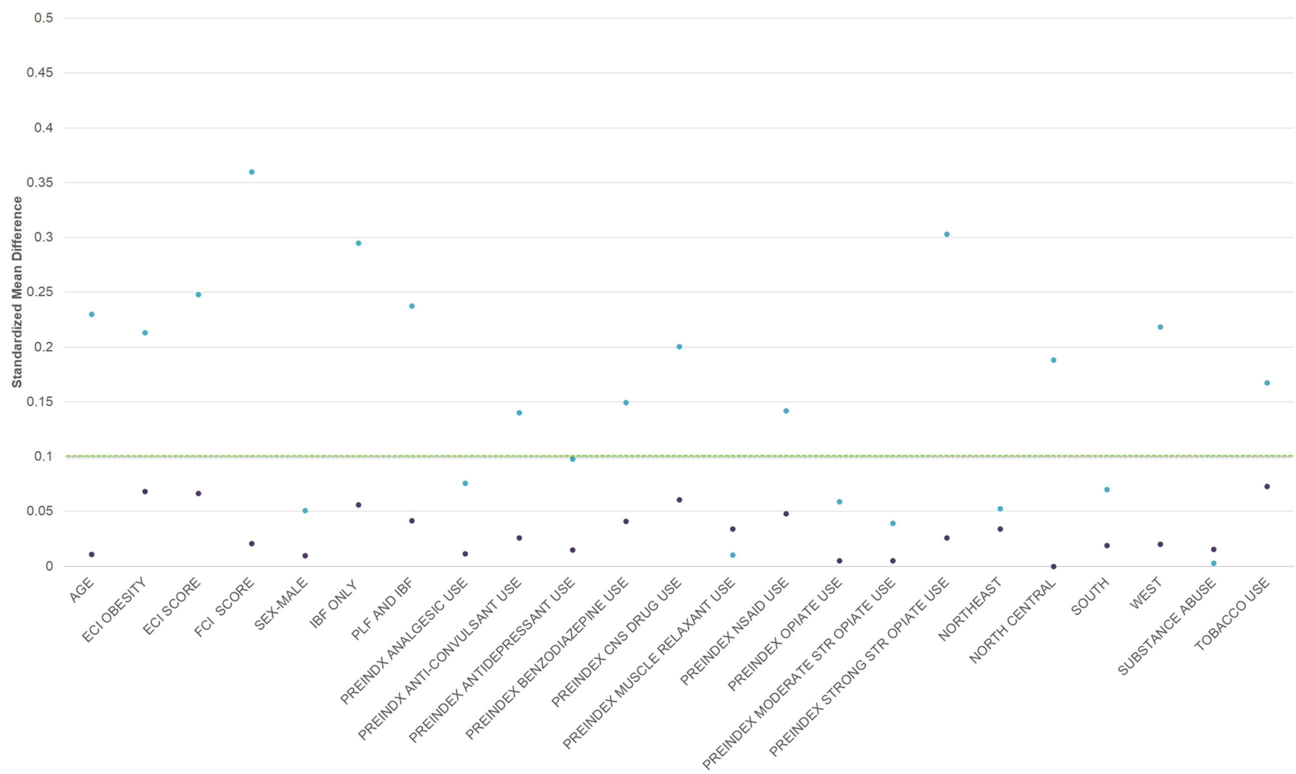

Figure 2 Absolute standardized mean differences (SMD) before and after matching, healthcare claims databases. Blue points represent SMDs before and purple points represent SMDs after matching.
Abbreviations: ECI, Elixhauser Comorbidity Index; FCI, Functional Comorbidity Index; IBF, interbody fusion; PLF, posterior lumbar fusion; STR, strength.

intestinal obstruction; MIS had statistically non-significant higher risk of diaphragmatic hernia and unspecified complications. Complications where ≤5 cases were reported in at least one cohort were anastomosis, delirium, device failure, dysphagia, abdominal hernia, infections (sepsis, pyelonephritis, general), myocardial infarction, nutrition, pleural effusion, pneumothorax, emphysema, surgical injury, thrombosis/DVT, TIA, and unspecified GI/respiratory/urinary (please see Appendix 2, Table 1).

Mean (SD) inpatient costs were greater in the MIS versus the Open cohort, \$29,181 (\$14,363) versus \$27,616 (\$13,822), mean difference, \$1,565, p=0.01). However, LOS was shorter in the MIS versus Open cohort: 2.94 (2.10) days, versus 3.15 (2.03), mean difference, −0.21 days, p=0.01. Greater home discharges were observed in the MIS versus Open cohort; however, this comparison was not statistically significant: 67.96% versus 64.45%, p=0.13.

Healthcare Claims Databases

The healthcare claims databases included 41,444 patients, among which 83 underwent MIS and 41,361 Open surgery. After matching, there were 415 patients in the Open for all 83

Table 3 Risk of 30-Day Complications and 90-Day Readmissions (Healthcare Claims Databases)

	Open (n=415)	MIS (n=83)	p value
30-day Surgical Site Infection	0.96%	1.20%	0.84
30-day Localized Hematoma or Hemorrhage	8.43%	19.28%	0.02
30-day Muscle Spasm	0.72%	0.00%	–
30-day Durotomy	2.65%	0.00%	–
30-day Spinal Injury	0.48%	0.00%	–
90-day All-Cause Inpatient Readmissions	4.10%	1.20%	0.06
90-Day Inpatient Spine-related Readmissions	2.65%	1.20%	0.29

patients in the MIS group. Table 1B contains the characteristics of the unmatched and matched cohorts from the healthcare claims databases.

SMDs of cohort characteristics before and after matching are shown in Figure 2. Characteristics with SMDs above 0.10 before matching were age, ECI score, obesity, FCI score, posterior interbody fusion procedure with or without posterior lumbar fusion, and pre-index use of the following drugs: anticonvulsant, benzodiazepine, central nervous system, NSAIDs, and strong opiates, North Central and West regions, and pre-index tobacco use. After matching, all SMDs were <0.10.

Table 3 presents the 30- and 90-day outcomes. Thirty-day hematoma/hemorrhage events were significantly more common in the MIS (19.28%) versus Open (8.43%) cohort, p=0.02; it was observed in the database that these hematoma/hemorrhage events were not associated with readmissions. The comparison of risk for 30-day SSI, 90-day all-cause inpatient readmission and 90-day spine-related inpatient readmission were not statistically significant. Risk of SSI was 0.96%, Open, versus 1.20%, MIS, p=0.84; risk of all-cause readmissions were 4.10%, Open, versus 1.20%, MIS, p=0.06; risk of spine-related readmissions were 2.65%, Open, versus 1.20%, MIS, p=0.29. No patients in the MIS group experienced 30-day muscle spasm, durotomy, spinal cord injury. Neither group experienced 90-day spine-related inpatient reoperation.

The observed difference in 90-day payments for all inpatient/outpatient post-operative care was not statistically significant, but observed to be higher in the Open cohort: payments averaged $4,677 ($12,403) for Open and $3,807 ($8547) for MIS, mean difference, $-870, p=0.54; and prescription drug payments amounted to $860 ($1,874) for Open versus $640 ($1,005) for MIS cohort, mean difference, $-220, p=0.30.

Discussion

The objective of this study was to evaluate healthcare utilization and economic and clinical outcomes of patients treated with Open versus MIS posterior lumbar fusion using matched cohorts. The patients who underwent Open had statistically significant lower hospital costs, but statistically significant longer LOS when compared to patients who underwent MIS. In regard to perioperative and 30- and 90-day outcomes, the majority of comparisons were not statistically significant with the exception of higher risk of perioperative UTI in the Open cohort and post-operative 30-day hematoma/hemorrhage events in the MIS cohort, that were observed to not require hospitalization.

This current study suggests that the hospital costs of surgery are higher for MIS than Open, mean difference, $1,565, p=0.01. In contrast, Goldstein et al, in a systematic review that focused on hospital cost of MIS versus Open, summarized the hospital costs differences for MIS versus Open transforaminal interbody fusion (TLIF)/posterior interbody fusion (PLIF) cases among five single-center studies and reported costs were 6.1% to 49.3% lower for MIS versus Open.[7] Wang et al also used Premier Hospital Database to estimate hospital costs, as this current study did. Cost differences were higher for Open and did not differ significantly for one-level cases, MIS versus Open, $29,187 versus $29,947, p=0.55, but did among two-level cases, $33,879, MIS, and $35,984, Open, p=0.0023. Wang et al identified a more specific population of patients receiving PLIF by, for example, eliminating patients that had fusion greater than three levels, concurrent anterior surgery, prior fusions, or deformity diagnosis, while our hospital database study did include only one level cases, it did not exclude cases with concurrent anterior surgery or prior fusion or deformity diagnosis from the analysis.[10] Additionally, it is important to consider hospital cost definitions may differ; among the studies included in the Goldstein et al's review, often there was not enough detail to assess what cost items were included to tabulate total hospital cost in each study. Furthermore, in the Goldstein et al review, the studies included were single-center studies and therefore may not be a true representation of cost comparisons on a national level, unlike Wang et al and this study, where a large US-based hospital database was used. It is not unusual to see higher cost for MIS versus Open PLIF; in fact, Twitchell et al found higher hospital cost among MIS versus Open PLIF in a single-center database study, reporting that MIS was 1.14 times more costly than Open; however, this study has the limitation of its single-center design.[15] The contrast in cost differences among studies suggests more research is needed in nationally representative data sources to understand cost differences for the overall population and subpopulations of patients receiving MIS versus Open TLIF/PLIF.

In regard to post-operative payments to providers by health insurers and patients through copay/deductibles/coordinated benefits, the MIS cohort was observed to have lower mean payments of 90-day inpatient/outpatient care and prescription drugs, however these results were not statistically significant. The mean difference in 90-day payments for care was $-870, p=0.54 and for prescription drugs was $-220, p=0.30. The lower payments observed here suggest less healthcare utilization in the post-operative period by patients who underwent MIS.

There is no other study to our knowledge which presents data on 90-day inpatient/outpatient care and drug payment for MIS or Open procedures. However, prior comparative studies and systematic reviews suggest that compared to Open, patients that had TLIF only or TLIF/PLIF MIS procedures have less post-operative healthcare utilization because patients have been reported to have improved quality of life, less post-surgery complication and higher fusion rates, which can equate to less post-operative healthcare utilization and therefore less healthcare payments or costs.[8,11,12] Given these studies of post-operative outcomes only suggest less post-operative payments or costs, more studies are needed to characterize and compare post-operative economic outcomes and healthcare utilization between MIS and Open.

Shorter hospital stays among patients who underwent MIS, as observed in this study, have also been reported in prior studies. The difference in LOS observed in this study was −0.21 days, p=0.01. This difference was not as large as was found in Goldstein et al's systematic review and meta-analysis of perioperative healthcare and post-operative adverse events of TLIF/PLIF cohorts that reported a mean difference of −2.87, 95% confidence interval (−3.82, −1.91) p<0.0001.[8] The larger difference estimated here compared to this current study could be that the Goldstein et al study omitted cases >2 level, but also the majority of studies represented in this review were retrospective or prospective single center, non-randomized studies, which may be biased towards selection of MIS cases that would recover quickly. Wang et al also compared LOS in their study of MIS versus Open PLIF and found a statistically significant difference in LOS for MIS versus Open, 3.35 versus 3.6, p≤0.006, but a larger difference in LOS among 2-level cases, 3.4 days versus 4.03, p≤0.001, MIS and Open, respectively.[10] In this case, the direction of the results using the same data source are similar despite the difference in cohorts between Wang et al and this current study, suggesting patients who underwent MIS are recovering faster regardless of complexity in MIS patient populations.

The higher risk of perioperative UTI in Open compared to MIS was the only statistically significant difference found among perioperative complications evaluated in this study. Similarly, Miller et al found in their systematic review of RCTs no significant differences in perioperative complications among MIS versus Open TLIF. Among these non-significant comparisons that were also evaluated in this study, Miller et al reported a small difference in risk of epidural hematoma in MIS and no occurrence for Open, 0.4% vs 0%, p=0.50, respectively, and of superficial infections in Open versus MIS, 0.4% vs 2.0%, p=0.22, respectively.[9] In this study, although there are differences to Miller et al in the types of infection and hematoma events evaluated, there was also small differences in risk of perioperative (but not post-operative) hematoma/hemorrhage events, 10.68% and 10.05%, Open and MIS, respectively, and a very low risk of general infection and sepsis in the Open group, 0.08%, and 0.04%, respectively, and no cases of infection were found for the MIS group (reported in Appendix 2). This suggests perioperative infection and hematoma differences are potentially minimal among MIS versus Open, but warrants further study in TLIF/PLIF cohorts.

Post discharge from the hospital, more patients who underwent MIS were discharged home than Open; however, this result was statistically non-significant, 67.96% versus 64.45%, p=0.13. The Wang et al study also reported that among the MIS and Open cohorts they evaluated, patients that underwent MIS PLIF had greater home discharge, 90.3%, than patients that that underwent Open PLIF, 87.1%, but did not evaluate if these estimates differed statistically.[10] The proportion of patients discharged for both MIS and Open in this current study are lower than Wang et al's estimates and this may be a reflection of the difference in cohort selection among the studies.

In the post-surgery period, this study found a statistically significant difference of 30-day hematoma/hemorrhage events: 8.43% in Open and 19.28% in MIS group; a potential reason for this higher risk could be the result of detection bias, where the surgeon may be more attentive to hematoma/hemorrhage events for smaller incisions such as those performed for MIS. The other post-operative complications observed in this study were statistically non-significant or did not occur: SSI risk was observed to be lower for Open 0.96% versus MIS 1.20%, p=0.84, and no patients in the MIS group experienced 30-day muscle spasm, durotomy, or spinal cord injury or 90-day spine-related reoperation. In regard to 90-day inpatient readmissions, the risk of all-cause and spine-related readmissions were observed to be higher for Open compared to MIS, but not statistically significant, 4.10% versus 1.20%, p=0.06, and 2.65% versus 1.20%, p=0.29, respectively.

Similarly, in Goldstein's systematic review and meta-analysis of post-operative adverse events among TLIF/PLIF MIS versus Open, the risk ratio for individual complications over a median 24-month follow-up period such as dural tear, infection and overall medical complications were lower for MIS, but only statistically significant for medical complications: 0.39, 95% CI 0.23–0.69, p = 0.001.[8] Although the time frame for the identification of complications was much longer than this current study, this systematic assessment of studies that evaluated complications supports the results seen in the short-term time frame evaluated here. It must be considered, however, the studies included in the Goldstein et al study were mostly retrospective or prospective single center non-randomized studies, and therefore, as mentioned before, may be biased towards selection of MIS cases with certain characteristics such as less comorbidities that would affect the complication outcomes. More studies using matched cohorts, whether through RCTs or propensity score matching, in nationally representative data sources will help to clarify any differences in complication risk of MIS versus Open in both the short and long term.

This study has its strengths and limitations. The databases provided a comprehensive source of patient, procedural and hospital characteristics for patients receiving healthcare within the US. Specifically, the hospital database represents roughly 25% of inpatient hospital discharges in the US per year and contains detailed hospital billing records and clinical coding for patients from most US health insurances. The healthcare claims databases represent an aggregation of US health insurance groups, representing roughly 100 million patients with employer-sponsored insurance with clinical coding and drug use.

Limitations with these databases are the challenge with identifying MIS cases: MIS is a newer technology; thus, there is potential for miscoding the older therapy for the newer therapy and the "Open" cohort in our study may have had contamination of MIS cases; this type of error is not expected to be systematic, but rather random in nature. In future studies using clinical coding, such as used here, validation of the medical coding for MIS procedures would be a prudent step.

Another limitation with the databases used in this study is lack of surgical outcomes such as patient's improvement of neurological symptoms and/or quality of life. In this study, we were unable to compare these measures among MIS and Open patients. Goldstein et al 2016 found in their review of 45 RCT and retrospective/prospective cohort studies of MIS versus Open TLIF/PLIF, published up to 2012, that only 5 publications that reported on quality of life measures.[7] Short form (SF)-12 and SF-36, which include physical and mental component scores, and EQ-5D were the instruments used in these studies.[7] This review qualitatively concluded there were no significant differences in scores among MIS versus Open. The largest difference in scores among these studies was for the SF-12 physical component score where MIS group received 41.2 points versus Open which received 26.9 points (the higher the score means better health status).[7] The lowest difference in scores was 47.0 points versus 46.9 points for SF-36 physical component and 50.1 points versus 50.0 points for SF-12 mental component, both favoring MIS with the higher score.[7] In summary, MIS patients tended to have higher scores than Open patients on these quality of life measures.

Additional limitations included the presence of large group imbalances between smoking and autograft use after matching in the healthcare databases; however, further efforts to match patients were not done to retain all 83 MIS patients for analysis; furthermore, the differences that exist – more smokers and less autograft use – tend toward worse characteristics for the MIS group, and therefore the outcome estimates for the MIS group in the healthcare claims databases represent more conservative estimates. Also, *T*-tests were used to evaluate differences between skewed cost data, but prior work has shown both *T*-tests and Wilcoxon rank sum test applied to the same skewed data can produce similar conclusions and that Wilcoxon does not address unequal variances between groups, which was a characteristic of these data.[16] Finally, findings from the healthcare claims databases are not generalizable to patients with non-private health insurance across the US.

Despite these study limitations, internally the methods to evaluate the study outcomes are rigorous. Propensity score matched cohorts were used to evaluate the study outcomes of interest; this methodology improved the comparability of the baseline characteristics of the two groups to allow direct comparison of the MIS versus Open approach.

Conclusion

This study observed that patients that underwent posterior lumbar fusion with MIS in the hospital setting had statistically significant lower LOS, and Open had statistically significant lower hospital costs. Because of the complicated relationship between LOS and complications and their associated hospital costs, collection and analysis of comprehensive cost and utilization data is an area for future research.

Furthermore, patients treated with MIS had statistically significant lower risk of perioperative UTI and patients treated with Open had a statistically significant lower risk of 30-day hematoma/hemorrhage events that did not require readmissions. Statistically non-significant results including mean post-operative payments and risk of post-operative complications or readmissions among MIS versus Open posterior lumbar fusions warrant further investigation in larger cohorts of matched patients using nationally representative data sources.

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References

1. Bagan B, Patel N, Deutsch H, et al. Perioperative complications of minimally invasive surgery (MIS): comparison of MIS and open interbody fusion techniques. *Surg Technol Int*. 2008;17:281–286.
2. Martin BI, Deyo RA, Mirza SK, et al. Expenditures and health status among adults with back and neck problems. *JAMA*. 2008;299(6):656–664. doi:10.1001/jama.299.6.656
3. Carreon LY, Puno RM, Dimar JR 2nd, Glassman SD, Johnson JR. Perioperative complications of posterior lumbar decompression and arthrodesis in older adults. *J Bone Joint Surg Am*. 2003;85-A(11):2089–2092. doi:10.2106/00004623-200311000-00004
4. Cho KJ, Suk SI, Park SR, et al. Complications in posterior fusion and instrumentation for degenerative lumbar scoliosis. *Spine (Phila Pa 1976)*. 2007;32(20):2232–2237. doi:10.1097/BRS.0b013e31814b2d3c
5. Arts MP, Wolfs JF, Kuijlen JM, de Ruiter GC. Minimally invasive surgery versus open surgery in the treatment of lumbar spondylolisthesis: study protocol of a multicentre, randomised controlled trial (MISOS trial). *BMJ Open*. 2017;7(11):e017882. doi:10.1136/bmjopen-2017-017882
6. Al-Khouja LT, Baron EM, Johnson JP, Kim TT, Drazin D. Cost-effectiveness analysis in minimally invasive spine surgery. *Neurosurg Focus*. 2014;36(6):E4. doi:10.3171/2014.4.FOCUS1449
7. Goldstein CL, Phillips FM, Rampersaud YR. Comparative effectiveness and economic evaluations of open versus minimally invasive posterior or transforaminal lumbar interbody fusion: a systematic review. *Spine (Phila Pa 1976)*. 2016;41(Suppl 8):S74–89. doi:10.1097/BRS.0000000000001462
8. Goldstein CL, Macwan K, Sundararajan K, Rampersaud YR. Perioperative outcomes and adverse events of minimally invasive versus open posterior lumbar fusion: meta-analysis and systematic review. *J Neurosurg Spine*. 2016;24(3):416–427. doi:10.3171/2015.2.SPINE14973
9. Miller LE, Bhattacharyya S, Pracyk J. Minimally invasive versus open transforaminal lumbar interbody fusion for single-level degenerative disease: a systematic review and meta-analysis of randomized controlled trials. *World Neurosurg*. 2020;133:358–365 e354. doi:10.1016/j.wneu.2019.08.162
10. Wang MY, Lerner J, Lesko J, McGirt MJ. Acute hospital costs after minimally invasive versus open lumbar interbody fusion: data from a US national database with 6106 patients. *J Spinal Disord Tech*. 2012;25(6):324–328. doi:10.1097/BSD.0b013e318220be32
11. Adogwa O, Parker SL, Bydon A, Cheng J, McGirt MJ. Comparative effectiveness of minimally invasive versus open transforaminal lumbar interbody fusion: 2-year assessment of narcotic use, return to work, disability, and quality of life. *J Spinal Disord Tech*. 2011;24(8):479–484. doi:10.1097/BSD.0b013e3182055cac
12. Wu RH, Fraser JF, Hartl R. Minimal access versus open transforaminal lumbar interbody fusion: meta-analysis of fusion rates. *Spine (Phila Pa 1976)*. 2010;35(26):2273–2281. doi:10.1097/BRS.0b013e3181cd42cc
13. Elixhauser A, Steiner C, Harris DR, Coffey RM. Comorbidity measures for use with administrative data. *Med Care*. 1998;36(1):8–27. doi:10.1097/00005650-199801000-00004
14. Groll DL, To T, Bombardier C, Wright JG. The development of a comorbidity index with physical function as the outcome. *J Clin Epidemiol*. 2005;58(6):595–602. doi:10.1016/j.jclinepi.2004.10.018
15. Twitchell S, Karsy M, Reese J, et al. Assessment of cost drivers and cost variation for lumbar interbody fusion procedures using the value driven outcomes database. *Neurosurg Focus*. 2018;44(5):E10. doi:10.3171/2018.1.FOCUS17724
16. Zhou XH, Melfi CA, Hui SL. Methods for comparison of cost data. *Ann Intern Med*. 1997;127(8 Pt 2):752–756. doi:10.7326/0003-4819-127-8_Part_2-199710151-00063