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Clinical Studies

Perioperative adverse events after different fusion approaches for single-level lumbar spondylosis ☆

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ABSTRACT

Background: Low back pain from lumbar spondylosis affects a large proportion of the population. In select cases, lumbar fusion may be considered. However, cohort studies have not shown clear differences in long-term outcomes between PSF, TLIF, ALIF, and AP fusion. Thus, differences in perioperative complications might affect choice between these procedures for the given diagnosis. The current study seeks to compare perioperative adverse events for patients with lumbar spondylosis treated with single-level: posterior spinal fusion (PSF), transforaminal lumbar interbody fusion (TLIF), anterior lumbar interbody fusion (ALIF), or combined anterior and posterior lumbar fusion (AP fusion).

Methods: Patients with a diagnosis of lumbar spondylosis who underwent single-level lumbar fusion without decompression were identified in the 2010-2016 National Quality Improvement Program (NSQIP) database. Patients were categorized based on their procedure (PSF, TLIF, ALIF, or AP fusion). Unadjusted Fisher's exact and Pearson's chi-squared tests were used to compare demographics and comorbid factors. Analysis was secondarily done with propensity score matching to address potential differences in patient selection between the study cohorts.

Results: In total, 1816 patients were identified: PSF n=322, TLIF n=800, ALIF n=460, AP fusion n=234. The procedures did not have different thirty-day individual or aggregated (any, serious, minor, or infection) adverse events. Further, propensity score matched analysis also revealed no differences in individual or aggregated thirty-day perioperative events.

Conclusion: The current study demonstrates a lack of difference in thirty-day perioperative adverse events for different fusion procedures performed for lumbar spondylosis, consistent with prior longer-term outcome studies. These findings suggest that patient/surgeon preference and other factors not captured here should be considered to determine the best surgical technique for the select patients with the given diagnosis who are considered for lumbar fusion.

Summary Sentence: Using the NSQIP 2010-2016 databases, this study showed that perioperative adverse events were similar for different surgical approaches of single-level fusion for single-level lumbar spondylosis.

Introduction

Low back pain from lumbar spondylosis affects a large proportion of the population. In the US, the one year prevalence of back pain is greater than 50%, and the lifetime prevalence is up to 80%.[1] While many patients improve on their own or with nonoperative modalities,[2] for those where operative intervention is chosen, one of several surgical intervention may be considered.[3] These include posterolateral spinal fusion (PSF), transforaminal lumbar interbody fusion (TLIF), anterior lumbar interbody fusion (ALIF), and combined anterior-posterior fusion (AP fusion). Multiple papers have shown the complications of a specific individual procedure,[4-14] and a few studies have compared outcomes such as pain, quality of life, disability, or satisfaction between different

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procedures performed for this diagnosis, but without details on complications.[15-20]

Between these four procedures, PSF remains one of the most common techniques,[21] though has limitation in restoring lumbar lordosis due to lack of anterior column support, lesser fusion surface area, and possibly not directly addressing the pain generator of axial back pain.[22] TLIF has the advantage of adding anterior column support, but the restoration of lordosis and fusion surface area may be limited.[23,24] ALIF similarly addresses the anterior column and can well restore lordosis, but has the risks of an anterior approach.[4,25] AP fusion has the theoretical advantage of high initial stability and fusion surface area, though it requires two distinct surgical approaches.[6,7,15,26]

A few studies and meta-analyses have attempted to compare the outcomes of these different approaches in the treatment of degenerative lumbar spine condition. Fritzell et al compared three different fusion techniques and found that all techniques could reduce pain and improve function. No specific fusion technique was found to be superior to the others, with the authors noting small differences in fusion rates and clinical success rates.[15,16,18,21] Cost is another variable that is difficult to factor, as more complex surgeries likely incur higher costs, but this may be affected by many variables.[6,20] Although these patient reported outcomes have been studied, and individual procedure complications have been described, there remains a deficit of knowledge of short-term complications of the procedures in relation to one another. In addition, patient numbers in these studies have been low and often isolated to a single institution.

Considering the risks, benefits, and alternatives for any surgical decision-making is paramount. Without definitive differences in long term surgical outcomes from different surgical approaches for single level lumbar spondylosis,[18] a question arises if there are differences for short-term, peri-operative adverse events. To address this question, the large sample size and high-quality data of the National Surgical Quality Improvement Program (NSQIP) was used to perform a retrospective review of prospectively collected data to compare and contrast these four different surgical management approaches for low back pain.

Materials and methods

Study populations

De-identified data from the NSQIP database from years 2010 to 2016 was utilized. This database collects over 150 variables, including demographic, comorbidities, and thirty day peri-operative outcomes (regardless of discharge status).[27] The data in NSQIP is collected by a certified and trained surgical clinical reviewers, and routine inter-rater reliability audits show less than 5% disagreement rate.[27] The Institutional Review Board at the author's institution granted an exception for studies using this database.

NSQIP provides one primary International Classification of Disease (ICD) code for each case. The current study identified cases of lumbar spondylosis by using ICD, Ninth Edition (ICD-9) code 721.3.

The patients were then identified as having undergone different surgical interventions. Patients who underwent PSF were identified by codes 22612 or 22840. TLIF was organized by codes 22630 or 22633. Cases treated by ALIF only were identified by code 22558, while excluding 22612 and 22840. Patients who underwent AP fusion had code 22558 and included any one of 22612 or 22840.

Cases of trauma, tumor, and infection were excluded. Patients were excluded if they underwent more than one-level surgery, identified by CPT codes for additional levels: 22585, 22614, or 22632. Deformity cases were excluded as well, identified by CPT codes 22800, 22802, 22804, 22808, and 22810. Lastly in order to maintain the population as patients with back pain only, CPT codes for decompression were excluded: 63005, 63012, 63017, 63030, 63047, and 63056.

Patient characteristics and outcomes

The following demographic variables were abstracted directly from NSQIP: patient age, gender, weight, height, American Society of Anesthesiologists (ASA) classification, and comorbid factors of diabetes (use of any pharmacologic agent) and smoking status (smoked in the year prior to surgery). Body mass index (BMI) was calculated based on weight and height. The ASA classification provided a marker for general health status as has been done in prior studies,[28-33] with diabetes[34] and smoking as additional variables to control.

Operative and hospital variables were additionally abstracted. These included operative time, hospital length of stay (LOS), and thirty-day readmissions.

For the first 30 days after surgery, the occurrence of defined adverse outcomes were additionally abstracted. These were tabulated and aggregated into several groups: any adverse events, serious adverse events, minor adverse events, and infections. Serious adverse events were death, cardiac arrest, stroke/cerebrovascular accident, sepsis/septic shock, myocardial infarction, renal failure, pulmonary embolism, peripheral nerve injury, ventilator time > 48 hours, unplanned intubation, or unplanned return to the operating room. Minor adverse events were deep wound infection, superficial wound infection, wound dehiscence, renal insufficiency, deep vein thrombosis/thrombophlebitis, pneumonia, urinary tract infection, or transfusion. The infection group distinctly regrouped several complications: included deep infection, superficial infection, or sepsis.

Statistical analyses

All statistical analyses were performed using STATA version 13 (StataCorp LP, College Station, TX).

Comparisons of the four groups in terms of demographics and comorbid factors were performed using Fisher's exact and Pearson's chi-squared tests. In order to minimize the effects of nonrandom patient selection into each treatment group, propensity score matching was utilized. Propensity matching uses observed covariate data to match patients with similar demographics but from different treatment groups. In this study, each patient treated with AP fusion was utilized as the control and matched with each of the other groups with regard to the following demographic factors: age, gender, BMI, ASA class, diabetes, and smoking status as has been done in prior studies.[35]

After the propensity matched groups were created for each procedure, adverse outcome rates were then compared again using Fisher's exact and Pearson's chi-squared tests.[35] A 2-sided alpha level of 0.05 was set as statistically significant for the analyses, but considering the 17 different adverse events, the alpha level was adjusted to 0.003 according to Bonferroni's correction.[36] Adverse events and binomial outcomes were then aggregated and compared across fusion techniques.

Results

Study population

In total, 1816 patients with single-level lumbar spondylosis were identified. Of these, PSF was performed for 322, TLIF for 800, ALIF for 460, and AP fusion for 234 (Table 1).

Patient characteristics

Table 2 shows the demographic and comorbidities of the patients in the four groups. Patients who underwent PSF tended to have higher BMI (p=0.045), and patients with higher ASA classification (3 or greater) tended to undergo PSF or AP fusion (p=0.027). After propensity score matching, the distributions of BMI and ASA classification in the four groups were not statistically different (p=0.728 and p=0.982, respec-

Table. 1
Case distribution

Procedure	Number of Cases	Percentage
PSF	322	17.73%
TLIF	800	44.05%
ALIF	460	25.33%
AP fusion	234	12.89%

PSF = Posterior spinal fusion, TLIF = Transforaminal lumbar interbody fusion, ALIF = Anterior lumbar interbody fusion, AP fusion = Combined anterior and posterior fusion

tively). Age, gender, diabetes status, and smoking status were not different among the four groups before or after propensity matching.

In terms of hospital and operative variables, no differences were noted in operative times, hospital LOS, and readmissions before or after propensity matching (Table 3).

Outcomes

Table 4 shows the individual adverse events that occurred in the study population. Of all the NSQIP recorded adverse events, 17 occurred at least once in one of the treatment groups. Notably, in PSF, incidence of sepsis/shock (0.62%), deep wound infection (1.24%), and transfusion (10.25%) were elevated relative to the other procedures; further, in TLIF, unplanned return to the OR (3.13%), UTI (1.63%) incidence were elevated. However, after Bonferroni's correction was applied, there were no differences in the rates of the adverse events before or after propensity score matching.

The individual adverse events were also aggregated into several groups: total adverse events, serious adverse events, minor adverse events, and infection. If a patient had any adverse event (serious or minor), this was counted once in total adverse events. Among the four treatment groups, there were no differences in aggregated groupings of adverse events, before or after propensity matching (Table 5).

Discussion

Spondylosis is a major contributor to worldwide morbidity, with an estimated 60-80% of adults experiencing low back pain at some point in their lifetime.[37] While many patients do improve with non-surgical treatment,[2,38-40] surgical management may be chosen for some patients. The most common surgical treatment for lumbar spondylosis is fusion, of which there are multiple surgical approaches, including PSF, TLIF, ALIF, and AP fusion. Numerous studies have demonstrated the effectiveness of a single surgical method in treating patients with lumbar spondylosis, however, there is still controversy surrounding the best practice of care.[4,7,25,41-46]

Comparisons of surgical techniques have been performed, through both randomized and large multicenter retrospective studies.[6,15,16,18-20,47] However, the majority of these studies focus on clinical satisfaction and rates of fusion rather than perioperative complications. To date, there is no clear consensus or evidence on which surgical technique provides the best long-term outcomes with regards to functional status or cost thus raising the question of differences in short-term complications.

Prior studies investigating short-term adverse events have found a general wide array of complications for each of the procedures described. For example, wound infection and hardware failure has been described in PSF,[48] while wound infection, sepsis, and post-operative radiculitis has been shown in TLIF.[9,10] Similar findings have also been found in AP fusion with incidence of infection, wound breakdown and failure of stabilization.[14] In addition, wound breakdown, deep wound infection, postoperative ileus and lacerated vessels have also been reported.[7,10,49] Lastly, studies of ALIF procedures also found infection and wound issues alongside vascular injury, retrograde ejaculation, ileus, lymphocele and post-operative pneumonia.[12,17] None of these studies, however, compared and contrasted the risk for these adverse events to the multiple other procedures.

To our knowledge, no studies have compared and contrasted the perioperative outcomes of the four presented treatment methods. The anal-

Table. 2
Demographics

	PSF (n=322)		TLIF (n=800)		ALIF (n=460)		AP Fusion (n=234)		Fisher's Exact Test	Propensity Score Matched
	Number	Percentage	Number	Percentage	Number	Percentage	Number	Percentage	p-value	p-value
Age									0.065	0.951
≤44	74	22.98%	182	22.75%	120	26.09%	62	26.50%		
45-54	62	19.25%	184	23.00%	126	27.39%	45	19.23%		
55-64	87	27.02%	224	28.00%	104	22.61%	62	26.50%		
65-74	66	20.50%	152	19.00%	85	18.48%	43	18.38%		
≥75	33	10.25%	58	7.25%	25	5.43%	22	9.40%		
Gender									0.206	0.478
Male	157	48.76%	405	50.63%	234	50.87%	101	43.16%		
Female	165	51.24%	395	49.38%	226	49.13%	133	56.84%		
BMI									0.045	0.728
≤24	47	14.60%	144	18.00%	98	21.30%	57	24.36%		
25-29	98	30.43%	266	33.25%	159	34.57%	66	28.21%		
30-34	99	30.75%	222	27.75%	125	27.17%	66	28.21%		
≥35	78	24.22%	168	21.00%	78	16.96%	45	19.23%		
ASA									0.027	0.982
.1	14	4.35%	42	5.26%	11	2.40%	13	5.56%		
.2	162	50.31%	443	55.44%	288	62.75%	116	49.57%		
.3	137	42.55%	300	37.55%	150	32.68%	100	42.74%		
.≥4	9	2.80%	14	1.75%	10	2.18%	5	2.14%		
Diabetes									0.921	0.832
No	270	83.85%	665	83.13%	394	85.65%	196	83.76%		
NIDDM	36	11.18%	91	11.38%	46	10.00%	28	11.97%		
IDDM	16	4.97%	44	5.50%	20	4.35%	10	4.27%		
Moking									0.478	0.799
No	242	75.16%	610	76.25%	341	74.13%	167	71.37%		
Yes	80	24.84%	190	23.75%	119	25.87%	67	28.63%		

Bolding indicates statistical significance at $p < 0.05$. ASA = American Society of Anesthesiologists classification. NIDDM = Noninsulin-dependent diabetes mellitus, IDDM = Insulin-dependent diabetes mellitus

Table. 3
Operative and hospital variables

	PSF (n=322)	TLIF (n=800)	ALIF (n=460)	AP Fusion (n=234)	Fisher's Exact Test	Propensity Score Matched
					p-value	p-value
Operative time (minutes)					0.056	0.365
Mean	185.73	202.31	152.28	194.05		
Standard Deviation	93.59	90.72	94.04	106.45		
Hospital LOS (days)					0.149	0.435
Mean	3.39	3.46	2.93	3.21		
Standard Deviation	2.64	3.18	2.04	1.78		
Readmissions					0.778	0.571
Number	15	34	18	13		
Percentage	3.42	4.25	3.70	4.70		

Bolding indicates statistical significance at $p < 0.05$. LOS = Length of stay

Table. 4
Incidence of adverse events

	PSF (n=322)		TLIF (n=800)		ALIF (n=460)		AP Fusion (n=234)		Fisher's Exact Test	Propensity Score Matched
	Number	Percentage	Number	Percentage	Number	Percentage	Number	Percentage	p-value	p-value
Major Adverse Events										
Death	0	0.00%	1	0.13%	0	0.00%	0	0.00%	1.000	1.000
Cardiac arrest	0	0.00%	1	0.13%	0	0.00%	0	0.00%	1.000	1.000
Stroke/CVA	2	0.62%	0	0.00%	0	0.00%	1	0.43%	0.029	0.624
Sepsis/shock	2	0.62%	1	0.13%	0	0.00%	1	0.43%	0.167	0.624
Myocardial infarction	1	0.31%	3	0.38%	2	0.43%	1	0.43%	0.993	1.000
Pulmonary embolism	1	0.31%	3	0.38%	1	0.22%	0	0.00%	1.000	**
Ventilator > 48 hours	1	0.31%	1	0.13%	0	0.00%	0	0.00%	0.583	1.000
Unplanned reintubation	2	0.62%	2	0.25%	0	0.00%	1	0.43%	0.238	0.624
Unplanned return to OR	10	3.11%	25	3.13%	12	2.61%	7	2.99%	0.964	0.748
Minor Adverse Events										
Deep wound infection	4	1.24%	6	0.75%	1	0.22%	2	0.85%	0.370	0.906
Superficial wound infection	4	1.24%	10	1.25%	4	0.87%	4	1.71%	0.781	0.776
Wound dehiscence	0	0.00%	3	0.38%	2	0.43%	1	0.43%	0.780	1.000
Renal insufficiency	0	0.00%	2	0.25%	0	0.00%	0	0.00%	0.777	**
Deep vein thrombosis	4	1.24%	0	0.00%	3	0.65%	1	0.43%	0.009	0.529
Pneumonia	0	0.00%	4	0.50%	3	0.65%	4	1.71%	0.078	0.228
Urinary tract infection	2	0.62%	13	1.63%	1	0.22%	2	0.85%	0.087	0.617
Transfusion	33	10.25%	49	6.13%	23	5.00%	15	6.41%	0.036	0.868

Level of significance for comparisons of adverse event rates for each of these 17 adverse events was adjusted to $p < 0.003$ according to Bonferroni's correction. ** indicates no occurrences of specific adverse event after propensity matching

Table. 5
Aggregated adverse events and binomial outcomes

	PSF (n=322)		TLIF (n=800)		ALIF (n=460)		AP Fusion (n=234)		Fisher's Exact Test	Propensity Score Matched
	Number	Percentage	Number	Percentage	Number	Percentage	Number	Percentage	p-value	p-value
Any Adverse Event	52	16.15%	101	12.62%	45	9.78%	31	13.25%	0.069	0.448
Serious Adverse Event	15	4.66%	34	4.25%	15	3.26%	9	3.85%	0.759	0.799
Minor Adverse Event	41	12.73%	79	9.88%	33	7.17%	25	10.68%	0.074	0.190
Infection	9	2.80%	16	2.00%	6	1.30%	7	2.99%	0.372	0.635

ysis presented in the current study demonstrated no statistically significant differences in complications such as operative time, hospital length of stay, or readmissions between the different studies. This was mostly consistent with prior studies who had investigated these outcomes, however, some studies had shown longer operative times for AP fusion in comparison to TIF or TLIF.[6,10]

In addition, the current study found no statistically significant differences in the rates of individual adverse events, total adverse events, serious adverse events, or minor adverse events among these surgical approaches evaluated when performed for single level spondylosis. This was done with and without propensity score matching in attempt to account for potential differences in the likelihood that a given patient would be treated by a specific surgical method. No prior study has compared and contrasted these adverse events between the four groups, however, it was thought that this study might find differences in perioperative adverse events between the different surgical approaches, but this was not the case.

As with all database studies, there are inherent limitations. Variations in data collection and inclusion have been reported among the different national datasets.[50,51] There is always the possibility of input errors, information bias, or missing data. Further, it is possible that 30 days of perioperative analysis does not catch all adverse events. Additionally, granularity of data is a limitation due to a lack of collection of factors such as specific patient reported outcomes, orthopaedic/spine specific outcomes, hardware failure, or other procedure specific factors. It does also not capture differences in procedure specifics such as open versus minimally invasive nor the specifics of complications such as presence of cell saver being counted as the adverse complication "transfusion". In addition, the incidence of many of these complications are quite low in these procedures thus making it difficult to detect a difference between populations should one be present. Lastly, the current study does not include lateral approaches which have also been used by a number of surgeons in recent years. Despite these limitations, we feel utilizing these four key procedures with the robust, validated data of NSQIP that tracks patients for thirty days postoperatively provides useful background for surgeons and future studies.[27,51]

Conclusion

Overall, the current study found that TLIF, PSF, AP fusion, and ALIF for single level fusion for lumbar spondylosis have similar adverse outcomes at thirty-day follow-up based on retrospective review of 1816

cases in a prospectively collected national database. These findings suggest that patient/surgeon preference and other factors not captured here should be considered to determine the best surgical technique for the select patients with the given diagnosis who are considered for lumbar fusion.

Declaration of Competing Interest

No conflicts of interest or external sources of funding for this study are reported.

IRB Approval

This study received exemption by our institution's Human. Investigations Committee.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.xnsj.2020.100005.

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