Early Medical Complications and Delayed Discharge After Spinopelvic Fusion: A Comparative Analysis of 887 NSQIP Cases from 2006 to 2016

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Abbreviated Title (running head): Complications of Spinopelvic Fusion

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Abstract

Introduction: The effect of pelvic fixation on postoperative medical complications, blood transfusion, length of hospital stay, and discharge disposition is poorly understood. Determining factors that predispose patients to increased complications after spinopelvic fusion will help surgeons to plan these complex procedures and optimize patients preoperatively.

Methods: We conducted a retrospective cohort study using data from the ACS-NSQIP database between 2006 and 2016 of patients who underwent lumbar fusion with and without spinopelvic fixation. Data regarding demographics, complications, hospital stay, and discharge disposition were collected.

Results: A total of 57,417 (98.5%) cases of lumbar fusion without spinopelvic fixation (LF) and 887 (1.5%) cases of lumbar fusion with spinopelvic fixation (SPF) were analyzed. The transfusion rate in the SPF group was 59.3% vs 13% in the LF group \( p < 0.001 \). The mean length of stay (LOS) and discharge to skilled nursing facility (SNF) were significantly different (LOS: SPF 6.5 days vs LF 3.5 days \( p < 0.001 \); SNF: SPF 21.3% vs LF 10.4% \( p < 0.001 \)). After controlling for demographic differences, the overall complication rates were not significantly different between the groups \( (p = 0.531) \). The odds ratio for transfusion in the SPF group was 2.9 \( p < 0.001 \). The odds ratio for increased LOS and increased care discharge disposition were elevated in the SPF group (LOS OR: 1.3, \( p < 0.012 \), Discharge disposition OR: 1.8, \( p < 0.001 \)).

Conclusion: Patients who underwent SPF had increased complications, transfusion rate, LOS, and discharge to SNF or subacute rehab facilities as compared with patients who underwent LF. SPF remains an effective technique for achieving lumbosacral arthrodesis. Surgeons should consider the implications of the associated complication profile for SPF and the value of preoperative optimization in a select cohort of patients.
Introduction

Spinopelvic fixation is an effective technique for achieving lumbosacral arthrodesis. However, achieving solid fixation constructs is often compromised by poor bone quality, complex local anatomy, and significant biomechanical forces in the lumbosacral region. These factors may lead to poor fusions and pseudarthrosis\(^1\). The sacrum is composed predominantly of trabecular bone, which is very porous, and in elderly patients, the sacrum is often osteoporotic\(^2\). Additionally, the cortical shell of the sacrum is generally thin\(^2\). When considering spinopelvic fixation, the surgeon must take into consideration the biomechanical forces acting on the lumbosacral spine. The lumbosacral spine flexes and extends about the L5-S1 annulus fibrosus imparting significant forces on lumbosacral fixation\(^3\). The implementation of spinopelvic fixation increases stiffness and fusion rates from 88% to 94% for lumbosacral fixation\(^4,5\).

The benefits of spinopelvic fixation must be weighed against the potential risks and complications. The effect of pelvic fixation on postoperative medical complications, blood transfusion, and length of hospital stay is poorly understood. Most studies utilize a small patient sample to examine these outcomes. This study aimed to compare the 30-day complications, blood transfusions, length of stay (LOS), and discharge disposition in a large cohort of patients, using a national multicenter database, who underwent lumbar spine fusion with spinopelvic fixation and compare them with patients who underwent lumbar spine fusion without spinopelvic fixation. The objective of this study was to help surgeons better understand the implications of spinopelvic fusion in terms of complication rates, LOS, and discharge disposition.
Materials and Methods

This is a retrospective multicenter study of patients that underwent lumbar fusion using the data from the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database from 2006 to 2016. This research has been approved by the Institutional Review Board of the authors’ affiliated institution. CPT codes were queried to identify patients who underwent thoracolumbar fusion procedures (CPT codes 22610, 22612, 22614, 22630, 22632, 22633, 22634). Patients who underwent pelvic fixation were identified using CPT code 22848. Patients with disseminated cancer, metastatic disease to the spine (ICD 9 198.3, 198.4, 198.5), epidural abscess (ICD 9/10 codes 324.1/G06.1), and ventilator dependence were excluded. Subjects with missing demographic or perioperative data, including age, gender, weight, height, preoperative lab values, functional dependency status, and the like, were excluded from the analysis.

Data collected included age, gender, preoperative functional status (dependent versus independent), body mass index (BMI), American Society of Anesthesiologists (ASA) classification, and medical comorbidities. Comorbidities recorded in the NSQIP database included diabetes, hypertension requiring medication, chronic obstructive pulmonary disease (COPD), congestive heart failure, history of smoking, chronic steroid use, and history of dialysis. Laboratory data reviewed included hematocrit (Hct), albumin, white blood cell count, and anemia. Anemia was defined as hematocrit < 40% in male and < 36% in female. Operative time was collected in addition to complication data. The complication data examined included wound infection, wound dehiscence, pneumonia, reintubation, stroke, renal complications, urinary tract infection (UTI), myocardial infarction (MI), transfusion, deep vein thrombosis (DVT),
pulmonary embolism (PE), sepsis, septic shock, and failure to be weaned from the ventilator for 48 h or longer postoperatively. For the purpose of statistical analysis, complications were divided into two groups. Severe complications included stroke, MI, cardiac arrest, septic shock, PE, reintubation, and failure to be weaned from the ventilator for 48 h or longer postoperatively. The overall complication group included severe complications and wound infection, wound dehiscence, pneumonia, renal complications, UTI, and sepsis. Finally, it was expected that patients who underwent SPF would have longer operative times, which is a specific risk factor for transfusion, DVT, and PE, as such complications were analyzed individually.

Statistical analysis:

Statistical analysis was conducted using STATA (Stata Corp LLC, College Station, TX). Descriptive statistics were used to describe the study population and are presented as a value with standard deviation where appropriate. Univariate analysis was used to analyze differences between the groups in terms of demographic data, preoperative comorbidities, and lab values. Chi-squared test, Fisher’s exact test, or Student’s t-test was utilized as appropriate. Statistical significance was defined as any factor with a \( p \)-value less than 0.05. Significant factors were then analyzed using a multivariate model to analyze the effect of spinopelvic fixation on complication data adjusted for other significant differences between the groups. Post hoc power analysis using dichotomous endpoints with an alpha of 0.05 was performed for complication data, transfusion data and discharge disposition. Post hoc power analysis using continuous endpoints was performed for LOS. These post hoc analyses demonstrated 100% power.
Results

A total of 58,273 patients were available for analysis, which included 57,417 (98.5%) cases in the lumbar fusion without spinopelvic fixation (LF) group and 887 (1.5%) cases in the lumbar fusion with spinopelvic fixation (SPF) group. The mean age in the LF group was 60.2 years, and in the SPF group, 63.4 years ($p < 0.001$). The percentage values of males were 46.3% and 40.6% in the LF and SPF groups, respectively. The percentage of patients who exhibited preoperative anemia was significantly higher (<0.001) in the SPF group (29.1%) than in the LF group (18.1%). The incidence of hypoalbuminemia and the functional dependency status were also significantly higher in the SPF group (SPF 3.3 vs. LF 2 $p = 0.005$ and SPF 4 vs. LF 2.2 $p < 0.001$).

The incidence of preoperative comorbidities was recorded, and the rates of diabetes (diabetes: LF 17.9 vs SPF 15.3% $p = 0.047$) and smoking (smoking: LF 21.3% vs. 13.8% $p < 0.001$) were significantly higher in the LF group than in the SPF group. COPD and ASA class of 3 or greater were significantly more common in the SPF group (COPD: SPF 6.3% vs LF 4.3%, $p = 0.043$, ASA class 3 or greater; SPF 62.6% vs 52.5% $p < 0.001$). No significant differences were observed in the incidences of hypertension, BMI, heart failure, chronic steroid use, or hemodialysis dependence.

Intraoperative data also differed between the groups. The number of levels fused was 2.1 in the SPF group and 1.6 in the LF group ($p < 0.001$), and the operative time was also significantly longer ($p < 0.001$) in the SPF group (6.3 h) than in the LF group (3.5 h). The rate of overall complications within 30 days from surgery in the SPF group was nearly double that of the LF
group (SPF 12.4% vs LF 6.6% $p < 0.001$). The transfusion rate in the SPF was 59.3% as compared with that of the LF group, which was 13% ($p < 0.001$). Finally, in terms of discharge data of patients in the SPF group, the mean LOS was nearly twice that of the LF group (LOS; SPF 6.5 days vs LF 3.5 days $p<0.001$), and discharge disposition to skilled nursing facilities (SNFs) (SNF: SPF 21.3 vs LF 10.4 $p < 0.001$) and subacute rehab facilities was more than double that of the LF group (Table 1).

The factors that were found to be significantly different between the SPF and LF groups via univariate analysis were then assessed using a multivariate analysis model to control for baseline differences between the groups. Once controlling for these differences, the overall medical complication rates were no longer significantly different between the groups (OR 1.1 95% CI 0.9–1.3, $p = 0.531$). The odds ratio for transfusion after SPF was 2.9 as compared with LF (95% CI 2.5–3.5 $p < 0.001$). With regard to LOS and discharge disposition, patients who underwent SPF had increased odds ratios of 1.3 (95% CI 1.1–1.5, $p < 0.012$) for increased LOS and 1.8 (95% CI 1.6–2.0, $p < 0.001$) for discharge to SNF, respectively (Table 2).
Discussion

The principle outcome of this study demonstrated that patients who underwent SPF had significantly increased complications, long hospital stays, and increased rate of discharge to SNF and received more transfusions than those who underwent LF procedures. It was expected that patients who underwent spinopelvic fusion would have an increased transfusion rate given larger surgical exposures, longer operative times, and the additional breach of pelvic bone during instrumentation, which has a rich vascular supply. As such, increased transfusion rates in patients who underwent SPF were an expected outcome and were analyzed separately from the general complication data.

This study demonstrates that patients who underwent SPF were nearly three times more likely to require postoperative transfusions. In a recent study, which examined the association between allogeneic blood transfusion and postoperative infection after major spine surgery, the authors reported a significantly increased infection rate in patients who received transfusions\(^6\). Specifically, patients who required transfusions had a 36% infection rate as compared with a 10% infection rate in those who did not require transfusion \((p = 0.03)\)\(^6\). Other authors have reported that patients who underwent lumbar fusion with blood transfusions had an increased odds ratio of 2.6 (95% CI 1.3–5.3, \(p =.007\)) for infection requiring incision and drainage\(^7\). Conversely, Kothari et al. reported that despite an increased transfusion rate in patients undergoing SPF for deformity, their cohort did not have an increased incidence of wound infection in the first 30 days postoperatively\(^8\). As preoperative anemia was common in patients who underwent SPF in this cohort, measures to address anemia, and optimize patients preoperatively are vital to prevent postoperative transfusions and complications associated with
SPF. The increased risk of transfusion and possibility of postoperative wound infection should be evaluated by surgeons and discussed with patients undergoing SPF.

Data on the examination of medical complications of spinopelvic fusion are limited. Nguyen et al. recently published complication data on a cohort of 260 patients who underwent SPF between 2010 and 2015, with a minimum of 2-year follow-up. The authors focused on hardware-related complications and reported a 4.6% iliac screw fracture rate and a 3.5% iliac screw loosening rate. L5-S1 fusion was not achieved in 8.8% of patients who eventually underwent revision fusion procedures.

There are various techniques and approaches for SPF. Each technique has a different associated fusion rate and complication profile. Studies exist which compare different techniques for SPF, including Jackson intrasacral rods (largely a historical technique), bicortical and tricortical sacral pedicle screw techniques, iliac bolts, and S2AI screws. These techniques have been used with varying degrees of success and are associated with different complication profiles. Iliac screws have been associated with screw prominence, and in a study of 67 patients with spinal deformity, 23 underwent elective removal of hardware postoperatively secondary to prominent hardware. S2-alar-iliac (S2AI) fixation is an alternative to iliac bolts that may be associated with less hardware prominence, as the insertion point of S2AI screws is 15 mm deep to the insertion point used for iliac screws. Still, S2AI screws have been associated with hardware prominence. When comparing S2AI screws and iliac bolts, S2AI screws were found to have fewer unplanned surgeries to address wound complications and decreased rates of hardware failure. S2AI screw may be more advantageous than iliac bolts in terms of overall hardware
complications, including risk for acute infection, implant loosening, revision surgery, pain related to hardware prominence, and wound complications\(^{17}\).

Like Ilyas et al.’s study, the majority of papers which investigate complications related to SPF focus on hardware prominence, hardware failure, revision surgery, wound complications, and the likelihood of achieving arthrodesis\(^{9,14}\). There is little data on the medical complication profile of SPF as compared with LF. As the NSQIP database uses CPT codes, information regarding the specific technique for SPF was not available for analysis. However, the general complication profile associated with SPF as a technique could be studied. Our study demonstrated that patients who underwent SPF had increased complications as compared with the LF group. Extending fixation inferiorly involves larger surgical dissection and the additional instrumentation in sacral bone that has a tendency to bleed. It is expected that patients who underwent SPF have increased general complications as compared with the LF group. However, once the number of levels fused and the patient’s comorbidity profile was controlled for, the general complication profile of SPF procedures did not differ significantly from that of LF procedures. This result is similar to that of Kothari et al. who did not demonstrate an increase in morbidity in their SPF cohort, with the exception of increased rates of intra- or postoperative blood transfusion, and increased LOS\(^{8}\). The authors did not report on their patients’ discharge disposition\(^{8}\).

Ensuring safe and timely home discharge or discharge to an inpatient care facility remains a concern after spinal fusion surgery. Di Capua et al. reported data regarding LOS and discharge disposition from the NSQIP cohort of adult spinal deformity (ASD) cases collected between 2013 and 2014\(^{18}\). In their cohort of only ASD cases, the authors reported that obesity, functional
dependency status, increased operative time, recent weight loss, and ASA class > 3 were all predictive of non-home discharge disposition. The results of the present study are in agreement with those of Di Capua et al. in that SPF was an independent risk factor for non-home discharge disposition among patients who underwent lumbar fusion, including patients with, and without ASD. Di Capua et al. also reported that SPF increased the odds ratio for increased LOS > 5 days in their ASD cohort. The results reported in this paper add to the body of literature addressing the modifiable and non-modifiable risk factors predicting complications, increased LOS, and discharge disposition in patients undergoing SPF for all causes. As the cost per day spent as an inpatient can be over $1000 USD, optimizing preoperative modifiable risk factors and coordinating with rehabilitation centers, insurance providers, and social support systems can provide significant economic and medical benefits to patients.

In addressing the limitations of this study, many limitations inherent to the ACS-NSQIP database must be noted. The ACS-NSQIP database has a disproportionate ratio of large academic medical centers. It has been suggested that these centers take on a caseload comprised of patients with more comorbidities who are at greater risk for complications. As such, the population in the present study may not be representative of the general population. Only 110 patients (12.4%) in the SPF group had sustained medical complications. Although the overall medical complication rate in the SPF group was 12.4%, there remains an uncertainty regarding the completeness in the reporting of 30-day complications. Given the invasive nature of SPF and the medical comorbidities of patients requiring this procedure, it is possible that some general medical complications are underreported. Nonetheless, the utilization of a large multicenter national database was advantageous in analyzing the occurrence of complications during a relatively
uncommon procedure, such as SPF (representing only 1.5% of the entire cohort). Long-term complication data is not available in the NSQIP database and the overall complication rate may therefore be underestimated as a result.

The present study does not report specifically on the implants used for SPF or complications specifically associated with different instrumentation techniques. Rather, the CPT codes for SPF procedures were used. This constitutes a limitation as complications that may be associated with a specific SPF technique, S2AI screws, or iliac bolts, for example, are pooled for a unified analysis. Studying SPF procedures as an aggregate allowed for a larger sample size and enabled an accurate evaluation of significant differences in complications between SPF cases and lumbar fusion cases without SPF.

It was expected that the vast majority of SPF procedures would be at the end of long fusion constructs. However, the mean levels fused in the SPF group were only 2.1. A key finding in this paper is that although spine surgeons associate the term spinopelvic fusion with long construct fusion, the CPT codes that capture this data demonstrate that spinopelvic fusion is also routinely used in shorter constructions and for functional deformity correction. This data demonstrates that even with a mean of 2.1 levels fused in the SPF group, the surgeries were considerably longer. This is likely explained by deeper dissection, difficult pelvic anatomy, increased number in levels fused, and increased complexity in the cases. Other possible reasons for a fewer fusion levels per surgery may be the staged procedures, surgical fixation of failed constructions, or re-operations. It is important to consider the indication for spinopelvic fixation as primary surgical fixation of the pelvis may be fundamentally different from re-operation, staged, or revision.
procedures. The NSQIP database does not provide this data, and further studies addressing the indication for SPF would be helpful. Another limitation inherent to the NSQIP database is that establishing the etiology or reason for surgical intervention is not possible. Because the patients who undergo lumbar fusion or spinopelvic fusion for various etiologies may have different baseline population statistics, some bias into the study may be introduced. Despite this, the large number of cases presented in this study helps surgeons understand the general risk profile of the procedures performed. Furthermore, the statistical analysis took into account the baseline differences between the LF and SPF groups.

The principal outcome of this study demonstrates that patients who undergo SPF have increased transfusion rates, medical complications, LOS, and increased discharge to SNF or subacute rehab facilities as compared with those who undergo LF. SPF remains an effective technique for achieving arthrodesis; however, surgeons should consider the implications of the associated complication profile. To our knowledge, this is the largest study to address complications in SPF patients, accumulated from more than 400 facilities and derived from a cohort of 58,273 lumbar fusion patients over a decade. Further research regarding complications associated with SPF and targeted methods to reduce those complications are warranted.
Table 1: Comparison between the groups

|                              | Total       | Without Pelvic Fix | With Pelvic Fix | P-value |
|------------------------------|-------------|--------------------|-----------------|---------|
| Number of cases              | 58,273      | 57,417 (98.5%)     | 887 (1.5%)      |         |
| Age (years)                  | 60.3        | 60.2               | 63.4            | <0.001* |
| Male (%)                     | 46.2        | 46.3               | 40.6            | 0.001*  |
| Anemia (%)                   | 18.2        | 18.0               | 29.1            | <0.001* |
| Hypoalbuminemia (%)          | 2.0         | 2.0                | 3.3             | 0.005*  |
| Functional dependency status(%) | 2.3         | 2.2                | 4.0             | 0.001*  |
| Comorbidities                |             |                    |                 |         |
| Diabetes (%)                 | 17.9        | 17.9               | 15.3            | 0.047*  |
| Hypertension (%)             | 42.8        | 57.2               | 60.2            | 0.069   |
| COPD (%)                     | 4.9         | 4.8                | 6.3             | 0.043*  |
| Heart failure (%)            | 0.3         | 0.2                | 0.5             | 0.201   |
| Smoking (%)                  | 21.2        | 21.3               | 13.8            | <0.001* |
| Chronic steroid use (%)      | 4.1         | 4.1                | 5.2             | 0.102   |
| Hemodialysis (%)             | 0.2         | 0.2                | 0.2             | 0.987   |
| BMI                          | 30.6        | 30.6               | 30.3            | 0.094   |
| Operative time (mean hours)  | 3.5         | 3.5                | 6.3             | <0.001* |
| ASA category of 3 or higher (%) | 50.7       | 50.5               | 62.6            | <0.001* |
| Average number of levels     | 1.6         | 1.6                | 2.1             | <0.001* |
| Transfusions (%)             | 13.7        | 13.0               | 59.3            | <0.001* |
| Overall complications* (%)   | 6.7         | 6.6                | 12.4            | <0.001* |
| Discharge to SNIF (%)        | 10.4        | 10.2               | 21.3            | <0.001* |
| Length of stay (days)        | 3.7         | 3.7                | 6.5             | <0.001* |

LF – Lumbar Fusion
SPF – Spinopelvic Fusion
BMI – Body Mass Index
COPD – Chronic Obstructive Pulmonary Disease

*Overall complications include wound infection, wound dehiscence, pneumonia, renal complications, urinary tract infection, sepsis, stroke, myocardial infarction, cardiac arrest, septic shock, PE, reintubation, and failure to be weaned from the ventilator for 48 h or longer postoperatively.
Table 2: Multivariate analysis of pelvic fixation effect on complications, transfusions, LOS, and discharge location

|                          | OR   | 95% CI   | P-value |
|--------------------------|------|----------|---------|
| Overall complications*   | 1.1  | 0.9-1.3  | 0.563   |
| Severe complications**   | 1.2  | 0.8-1.6  | 0.346   |
| Transfusions             | 2.9  | 2.5-3.5  | <0.001* |
| DVT                      | 1.1  | 0.6-1.9  | 0.738   |
| PE                       | 0.7  | 0.4-1.5  | 0.437   |
| LOS                      | 1.8  | 1.6-2.0  | <0.001* |
| Discharge to any rehab   | 1.5  | 1.3-1.8  | <0.001* |
| Discharge to subacute rehab | 1.3 | 1.1-1.6 | <0.001* |

SPF – Spinopelvic Fusion
PE – Pulmonary Embolism
DVT – Deep Vein Thrombosis
LOS – Length of Stay

*Overall complications include wound infection, wound dehiscence, pneumonia, renal complications, urinary tract infection, sepsis, stroke, myocardial infarction, cardiac arrest, septic shock, pulmonary embolism, reintubation, and failure to be weaned from the ventilator for 48 h or longer postoperatively.

** Severe complications include stroke, MI, cardiac arrest, septic shock, PE, reintubation, and failure to be weaned from the ventilator for 48 h or longer postoperatively.
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