Original Article

Osteoporosis is associated with increased minor complications following single level ALIF and PSIF: an analysis of 7,004 patients

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Background: Osteoporosis is a prevalent disease that predisposes patients to fracture and additional post-operative complications, potentially contributing to decreased quality of life. The objective of the current study is to (I) characterize the demographic trends of individuals with osteoporosis undergoing single level posterior spine instrumentation and fusion (PSIF) and anterior lumbar interbody fusion (ALIF); (II) determine the association between osteoporosis and postoperative complications; (III) identify whether the use of bone strengthening medications is associated with improved outcomes.

Methods: A retrospective review of the Mariner Claims Database was conducted on patients undergoing single level ALIF (CPT 22558) and PSIF (CPT 22840) between 2011 and 2017. Diagnosis of osteoporosis (CPT 77080, CPT 77801, CPT 77082) included a bone density scan within two years of surgery. Patients with osteoporosis were 1:1 matched to controls. Patients taking bone enhancing medications prior to surgery were compared to those that did not take medications. Multivariable logistic regression analyses were performed to evaluate post-operative complication risk factors.

Results: 3,502 patients with diagnosed osteoporosis underwent ALIF and PSIF, of which 788 (22.5%) were treated with supplemental medication. Diagnosis of osteoporosis was associated with an increased risk of pulmonary embolism [1.1% *vs.* 0.4%, odds ratio (OR) 2.48, 95% confidence interval (CI): 1.36–4.53, P=0.003] and minor complications (16.7% *vs.* 12.9%, OR 1.15, 95% CI: 1.01–1.30, P=0.039). Revision rates two-years post-operatively were not significantly different between patients with osteoporosis and matched controls (P>0.05). There were no differences in outcomes between osteoporotic patients who received medications and those who did not receive medication (P>0.05).

Conclusions: Osteoporosis is common in a nationally-representative Medicare database cohort. Pre-operative diagnosis of osteoporosis is associated with increased minor complications following ALIF and PSIF. Pre-operative osteoporosis treatment is not associated with a significant difference in post-operative outcomes. The current study can guide pre-operative counseling in this cohort.

Keywords: Spine; lumbar; instrumented fusion; osteoporosis; medications; post-operative complications

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Introduction

In the setting of an aging population, osteoporosis (OP) has been increasingly associated with degenerative and traumatic spine pathology presenting to orthopedic surgeons (1-5). The sequela of osteoporotic fractures can be devastating to patients who may lose their independence, autonomy, and overall quality of life (6-10). OP is associated with an increased fracture risk in addition to perioperative medical and surgical complications (11-13), such as increased hospital length of stay and reoperation rates following various orthopedic procedures (8,14-18). In addition to increased risk of morbidity and mortality, OP is associated with $15–20 billion per year in medical expenses (6,7,11,13,19-21). As peri-operative healthcare outcomes and costs continue to undergo increased scrutiny, it is imperative to identify patient-related factors that may associated with increased complications and resource utilization following surgical intervention.

Osteoporosis is a well-established patient-related risk factor for many orthopedic surgery related complications (11-13), yet little has been reported regarding the association between OP and anterior lumbar interbody fusion (ALIF) and posterior instrumentation and fusion (PSIF). Prior studies have investigated the association between OP and lumbar fusions on poorer outcomes and postoperative complications, but they have been limited to small, single institution analyses (22-30). Furthermore, bone enhancing pharmacotherapeutics such as bisphosphonates and teriparatide have been developed for OP patients and are effective in helping prevent fractures, but there is a paucity of literature investigating the use of pre-operative pharmacotherapeutics on post-operative outcomes following ALIF and PSIF (7,19).

The purpose of the current study is to utilize a national database to investigate the association between pre-operative OP and post-operative complications following PSIF and ALIF. Secondarily, the study evaluates the effect of pre-operative bone enhancing medications on post-operative outcomes. It is hypothesized that patients with OP undergoing PSIF and ALIF will have increased rates of medical and surgical complications, and that patients with OP on pre-operative bone enhancing medication will have improved outcomes compared to those not on enhancing medication.

We present the following article in accordance with the STROBE reporting checklist (available at https://dx.doi.org/10.21037/jss-21-29).

Methods

Data source

A retrospective database review was performed using the commercially available PearlDiver (PearlDiver Inc., Colorado Springs, Colorado, USA; www.pearldiverinc.com) patient records database. The database contains all Mariner private payer, Medicare, and Medicaid patients' records for the years 2010–2018, searchable by International Classification of Diseases (ICD) Ninth and Tenth Edition codes as well as by Current Procedural Terminology (CPT) codes. This study was deemed exempt from institutional review board approval, as all queried data was deidentified and Health Insurance Portability and Accountability Act (HIPAA) compliant. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

Study population

A retrospective review of the Mariner Claims Database was conducted on patients who underwent a single level ALIF (CPT 22558) and PSIF (CPT 22840) between 2011 and 2017. Osteoporosis inclusion criteria was defined by having a previous diagnosis of OP (CPT 77080, CPT 77801, CPT 77082) including a bone density scan within two years prior to surgery. Cases involving same day revision procedures, and patients with a history of spine infection, trauma, or neoplasm were excluded from the study. Patients with diagnosed OP were matched to controls with respect to age, gender, body mass index and comorbidity burden. Using National Drug Code, the following brand and generic anti-osteoporosis formulations were included in the current study: bisphosphonates and teriparatide. Further delineation was made between patients with OP by identifying patients who were prescribed bone enhancing medications within two years prior to surgery versus those that did not take medications.

Outcomes of interest

Osteoporotic patients were compared to those who were not diagnosed with OP with respect to 90-day medical complications, emergency department (ED) visits, readmissions, and one-year reoperation. 90-day major medical complications included pulmonary embolism (PE), pneumonia (PNA), myocardial infarction (MI), cerebrovascular accident (CVA), and sepsis. Other complications assessed deep vein thrombosis (DVT),

Table 1 Patient demographics

Demographics	Osteoporosis, n=3,502 (%)	Matched controls, n=3,502 (%)	P value
Age, years			0.37
<49	93 (2.7)	93 (2.7)	
50–54	240 (6.9)	240 (6.9)	
55–59	448 (12.8)	448 (12.8)	
60–64	585 (16.7)	585 (16.7)	
65–69	756 (21.6)	756 (21.6)	
>70	1,366 (39.0)	1,366 (39.0)	
Gender (female)	3,250 (92.8)	3,250 (92.8)	1.00
Comorbidities			
Obesity (BMI >30 kg/m^2)	595 (17.0)	595 (17.0)	1.00
Depression	977 (27.9)	977 (27.9)	1.00
Chronic kidney disease	238 (6.8)	238 (6.8)	1.00
COPD	259 (7.4)	259 (7.4)	1.00
Diabetes mellitus	874 (25.0)	874 (25.0)	1.00
Congestive heart failure	109 (3.1)	109 (3.1)	1.00
Coronary artery disease	666 (19.0)	666 (19.0)	1.00
Hypertension	2,504 (71.5)	2,504 (71.5)	1.00
Hyperlipidemia	2,452 (70.0)	2,452 (70.0)	1.00
Substance use			
Tobacco	640 (18.3)	640 (18.3)	1.00

BMI, body mass index; COPD, chronic obstructive pulmonary disease.

acute kidney injury (AKI), urinary tract infection (UTI), transfusion, and wound complications and all major medical complications. Information on 90-day surgical site infection was also included in the query. This study also compared OP patients receiving medications to those who did not receive medications to identify any differences in the outcomes of interest.

Statistical analysis

Pearson χ^2 test was used to assess for differences in demographics and preexisting comorbidities. Multivariable logistic regression was used to determine the independent effect of osteoporosis on the postoperative outcomes after adjusting for demographic factors and pertinent comorbidities. Odds ratio (OR) and 95% confidence interval (95% CI) were also reported for all comparisons. R software embedded within the PearlDiver database (R Foundation for Statistical Computing, Vienna, Austria) was used for all statistical analysis. Statistical significance was set at P<0.05.

Results

3,502 patients diagnosed with OP underwent ALIF and PSIF (*Table 1*). Risk of bias was reduced using matching as evidenced by P>0.30. Patients with osteoporosis were more commonly > age 65 (n=2,122, 60.6%) and female gender (n=3,250, 92.8%). The most common comorbidities in the osteoporosis cohort were diagnosis of hypertension (n=2,504, 71.5%) and hyperlipidemia (n=2,452, 70%).

Diagnosis of OP was associated with an increased risk of pulmonary embolism (1.1% *vs.* 0.4%, OR 2.48, 95% CI: 1.36–4.53, P=0.003) (*Table 2*). Two-year revision rates or

Table 2 Postoperative outcomes of patients with osteoporosis (90 days)

Comorbidities and outcomes	Osteoporosis, n=3,502	Matched controls, n=3,502	Osteoporosis *vs.* controls, adjusted OR (95% CI)	P value
MI	25 (0.7)	23 (0.7)	1.09 (0.62–1.92)	0.885
PE	37 (1.1)	15 (0.4)	2.48 (1.36–4.53)	0.003*
PNA	85 (2.4)	95 (2.7)	0.89 (0.67–1.20)	0.497
Sepsis	39 (1.1)	38 (1.1)	1.03 (0.66–1.61)	1.000
AKI	79 (2.3)	81 (2.3)	0.97 (0.71–1.33)	0.936
UTI	301 (8.6)	273 (7.8)	1.11 (0.94–1.32)	0.240
Wound complications	172 (4.9)	161 (4.6)	1.07 (0.86–1.34)	0.575
Transfusion	71 (2.0)	53 (1.5)	1.34 (0.94–1.93)	0.107
DVT	79 (2.3)	67 (1.9)	1.18 (0.85–1.64)	0.358
Major complications	167 (4.8)	153 (4.4)	1.10 (0.88–1.37)	0.457
Minor complications	586 (16.7)	522 (12.9)	1.15 (1.01–1.30)	0.039*
ER visit	514 (14.7)	490 (14.0)	1.06 (0.93–1.21)	0.433
Readmissions	406 (11.6)	365 (10.4)	1.13 (0.97–1.31)	0.127
Infection	143 (4.1)	133 (3.8)	1.08 (0.85–1.37)	0.580
Revision 1 year	192 (5.5)	214 (6.1)	0.89 (0.73–1.09)	0.283
Revision 2 years	258 (7.4)	274 (7.8)	0.94 (0.79–1.12)	0.499

*, indicate significance with P<0.05. PE, pulmonary embolism; PNA, pneumonia; AKI, acute kidney injury; UTI, urinary tract infection; DVT, deep vein thrombosis; MI, myocardial infarction; CVA, cerebrovascular accident.

postoperative medical complications were not significantly increased in patients with OP compared to matched controls (P>0.05).

Of the 3502 patients diagnosed with OP, 788 (22.5%) were prescribed bone enhancing medications prior to surgery (*Table 3*). Patients receiving medication were of similar age with comparable baseline comorbidities compared to those without treatment (P>0.05). Patients receiving medications prior to surgery had no differences in rates of PE within 90 days of surgery compared to those not receiving medications (P>0.05, *Table 4*). There were also no differences in medical complications and two-year revision rates between these two cohorts (P>0.05).

Discussion

The current study demonstrates that osteoporosis (OP) is associated with increased post-operative complications, including pulmonary embolism following PSIF/ALIF. Additionally, bone enhancing medications, such as bisphosphonates and teriparatide, are not associated with a decreased risk of medical or surgical complications. The study represents one of the largest studies to date evaluating the effect of OP on ALIF/PSIF complications in a nationally-representative cohort. The use of a national-database cohort allows for sufficient power to analyze varying levels of osteoporosis severity in this growing patient population.

This study adds to the existing body of literature evaluating the peri-operative burden of OP, efficiency of current therapies, and outcome differences across various surgical procedures (22,24,31-35). Within spine literature, OP has previously been associated with an increased hospital length of stay, likelihood of revision surgery, and post-surgical complications (8,36).

The association of OP and post-operative complications following ALIF/PSIF is consistent with previous literature (16,37). The OP population is largely comprised of older individuals with decreased mobility in the setting of their age and disease complications. OP may be associated with an increased risk of VTE events. Additionally, older patients undergoing spinal surgeries have been found to be

Table 3 Patient demographics

Demographics	Osteoporosis with treatment, n=788 (%)	No treatment, n=2,714 (%)	P value
Age, years			0.036
<49	12 (1.5)	80 (2.9)	
50–54	43 (5.5)	197 (7.3)	
55–59	105 (13.3)	343 (12.6)	
60–64	138 (17.5)	447 (16.5)	
65–69	190 (24.1)	566 (20.9)	
>70	297 (37.7)	1,069 (39.4)	
Gender (female)	747 (94.8)	2,503 (92.2)	0.017
Comorbidities			
Obesity (BMI >30 kg/m^2)	122 (15.5)	473 (17.4)	0.220
Depression	213 (27.0)	764 (28.2)	0.567
Chronic kidney disease	59 (7.5)	179 (6.6)	0.426
COPD	57 (7.2)	202 (7.4)	0.904
Diabetes mellitus	182 (23.1)	692 (25.5)	0.185
Congestive heart failure	30 (3.8)	79 (2.9)	0.247
Coronary artery disease	159 (20.25)	507 (18.7)	0.373
Hypertension	571 (72.5)	1,933 (71.2)	0.527
Hyperlipidemia	568 (72.1)	1,884 (69.4)	0.164
Substance use			
Tobacco	156 (19.8)	484 (17.8)	0.229

BMI, body mass index; COPD, chronic obstructive pulmonary disease.

at an increased risk for PEs (16). While the current study's findings were exclusive to PE, and not in conjunction with DVTs, it is possible that DVTs were underreported as a result of subclinical presentations (37). In contrast, PEs rarely transpire without notice, as they cause more prominent symptoms, and thus are more often recorded.

Indeed, increased research has been dedicated to modifying pre-operative OP with bone enhancing medications, such as bisphosphonates and teriparatide. Atesok *et al.* and others have reported that perioperative treatment with bone enhancing medications, namely teriparatide, can improve bone quality, outcomes, union rates, and post-operative healing in lumbar spinal fusions (24-26,30,34,38,39). In light of this, there is an absence of national database studies evaluating OP in ALIF/PSIF surgeries. As these medications become increasingly common, it is beneficial to evaluate their effects on peri-operative outcomes. The reported nationally-representative cohort does not demonstrate an association between bone-enhancing medications and increased post-operative complications. This finding supports their continued safety in the peri-operative period.

There are several advantages to the current study. First, the use of a large nationally-representative insurance-based database allowed for a well powered sample size with a greater applicability to the patient population of interest. Additionally, utilizing a multivariate logistic regression model to control for extensive patient demographics and comorbidities reduced confounding factors.

The current study has several limitations. Incorrect coding errors are inherent to retrospective querying of a large database (39,40). Additionally, information access was limited on which medication the treated patients were taking and patient medication non-compliance may

Table 4 Postoperative outcomes between osteoporotic patients on medications and no medications

Comorbidities and outcomes	Patients with medication, n=788	Patients without medication, n=2,714	Treatment *vs.* no treatment, adjusted OR (95% CI)	P value
PE	11 (1.4)	26 (1.0)	0.68 (0.34–1.39)	0.390
PNA	22 (2.8)	63 (2.3)	0.83 (0.51–1.35)	0.533
Sepsis	12 (1.5)	27 (1.0)	0.65 (0.33–1.29)	0.294
MI	*	17 (0.6)	0.61 (0.26–1.43)	0.368
CVA	*	*	3.91 (0.70–22.00)	0.103
Minor complications				
AKI	23 (2.9)	56 (2.1)	0.91 (0.76–1.08)	0.296
UTI	82 (10.4)	219 (8.1)		
Wound complication	36 (4.6)	136 (5.0)		
Transfusion	16 (2.0)	56 (2.1)		
DVT	13 (1.6)	66 (2.4)		
Major complications	48 (6.1)	119 (4.4)	1.10 (0.88–1.37)	0.060
Infection	28 (2.6)	115 (4.2)	1.20 (0.79–1.83)	0.452
90-day ER visit	117 (14.8)	397 (12.6)	0.98 (0.79–1.23)	0.923
90-day readmissions	87 (11.0)	314 (11.6)	0.96 (0.44–1.23)	0.778
Revision 1 year	39 (4.9)	153 (5.6)	1.15 (0.80–1.65)	0.510
Revision 2 years	55 (6.9)	203 (7.5)	1.08 (0.79–1.47)	0.692

*, Groups with less than 11 cannot be reported. PE, pulmonary embolism; PNA, pneumonia; AKI, acute kidney injury; UTI, urinary tract infection; DVT, deep vein thrombosis; MI, myocardial infarction; CVA, cerebrovascular accident.

have impacted the treatment group data to an uncertain degree. Another factor rests within this study's OP selection criteria and the lack of information as to the severity of a patient's disease. Patients previously diagnosed with OP within the study's chosen time frame may have improved in their condition by the time of surgery. Despite these limitations, this national study was able to confirm OP as having increased risks for PE and is the first study to forego investigation of negative effects of bone enhancing medications in ALIF/PSIF procedures.

Conclusions

Osteoporosis is associated with an increased risk of PE after ALIF/PSIF. Bone enhancing medication is not associated with a decreased risk of medical or surgical post-operative complications. The current data can be used to counsel patients and guide surgeons identify patient-related risk factors for post-operative complications.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://dx.doi.org/10.21037/jss-21-29

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://dx.doi.org/10.21037/jss-21-29). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related

to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

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