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Predictors of Long Term Opioid Use following Lumbar Fusion Surgery

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Abstract

Study Design—A population-based retrospective cohort study.

Objective—The aim of this study was to examine risk factors for long-term opioid use following lumbar spinal fusion surgery in a nationally representative cohort of commercially insured adults.

Summary of Background Data—Opioid prescription rates for the management of low back pain have more than doubled in the US over the past decade. Although opioids are commonly used for the management of pain following lumbar spinal fusion surgery, to date, no large-scale nationally representative studies have examined the risk factors for long-term opioid use following such surgical intervention.

Methods—Using one of the nation's largest commercial insurance databases, we conducted a retrospective cohort study of 8,377 adults, aged 21–63 years, who underwent lumbar spinal fusion surgery between January 1, 2009 and December 31, 2012. Long-term opioid use was defined as ≥365 days of filled opioid prescriptions in the 24 months following lumbar fusion. Multivariable logistic regression was used to calculate adjusted odds ratios (ORs) and 95% confidence intervals for the risk of long term opioid use following lumbar fusion.

Results—After adjusting for covariates, the following factors were associated with an increased risk of long term opioid use following surgery: duration of opioid use in the year before lumbar surgery [Referent (0 days); Quartile 1 (1–22 days) OR=2.27, 95% CI=1.48–3.49; Quartile 2(23–72 days): OR=5.94, 95% CI=4.00–8.83; Quartile 3: (73–250 days) OR=25.31, 95% CI=17.26–37.10; Quartile 4 (≥ 250days) OR=219.95, 95% CI=148.53–325.71)], re-fusion surgery (OR=1.32, 95% CI=1.02–1.72), and diagnosis of depression (OR=1.43, 95% CI=1.18–1.74). Receipt of anterior fusion was associated with a modest decrease in the risk of long-term opioid use (OR=0.79, 95% CI=0.63–0.99).

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Conclusions—These findings may provide clinically relevant information to physicians, patients, and their families regarding the risk factors for opioid dependence following lumbar fusion surgery.

Keywords

opioids; lumbar fusion; minimally invasive fusion; low back pain; comorbidity; depression; smoking

Opioid prescription rates for the management of low back pain have more than doubled in the US over the past decade.[1] Opioids are frequently prescribed in patients undergoing lumbar spinal fusion surgery,[2,3,4,5,6] which is used to treat a broad range of conditions associated with low back pain, including degenerative disk disease, disc herniation, spinal stenosis, spondylolisthesis, spondylolysis, scoliosis, and tumor.[7,8,9] Over the past ten years, opioid expenditures for spine-related pain increased by 660%,[1,10] and hospital discharge rates associated with spinal fusion surgeries increased by 137%, with the greatest increase attributable to lumbar and cervical fusion surgeries.[9] In view of these numbers, there is widespread concern about long-term opioid dependence among patients who undergo spinal fusion surgery.[3,11,12] Moreover, the efficacy of long-term opioid use for low back pain following spinal fusion surgery is widely debated.[2,11,13]

A range of studies have examined the risk of long-term opioid use following spine surgery. Collectively, these investigations have shown that a number of factors may adversely affect post-surgical pain and opioid use. [2,11, 14–17] For example, long-term opioid use before spine surgery has been linked with hyperalgesia, opioid tolerance, and opioid use following surgery.[2,11,18] Likewise, type of spine surgery is reported to be associated with a range of post-surgical pain outcomes and opioid dependence.[2,14,15,16,18,19] In addition, behavioral risk factors such as diagnosis of depression and smoking have both been associated with high self-rated pain scores and higher risk of long term opioid use after spine surgery.[2,11,20,21,22] To date, however, risk factors for long term opioid use after lumbar spinal fusion surgery have not been examined in a large-scale nationally representative study. Ours is the first study to focus on this important healthcare issue using one of the nation's largest commercial insurance databases.

MATERIALS AND METHODS

Data source

This study used de-identified administrative health data from Clinformatics Data Mart ™ (CDM, Optum Insight, Eden Prairie, MN), a database of one of the nation's largest commercial health insurance programs. CDM has been used to examine pharmacotherapy and health services in previous studies.[23,24,25,26] Individuals are enrolled in this insurance program under either health maintenance organizations, preferred provider organizations, point of services, or exclusive provider organizations. For each of these plans, providers are required to submit complete claims to receive reimbursement. We used a combination of outpatient, inpatient, and pharmacy claims data. The pharmacy database contains eligibility and claims information for medications from retail pharmacies through a member's

pharmacy benefit. For each medication, the database contains medication name, date of fill, formulation (e.g., oral, transdermal, injectable), dose, quantity, and days of supply. This study was approved by the institutional review board of the University of Texas Medical Branch at Galveston.

Study design

We conducted a retrospective cohort study of 8,377 patients who underwent lumbar fusion between January 1, 2009 and December 31, 2012 for degenerative spine conditions, post-laminectomy or as a re-fusion procedure (Table 1). In order to be included in the study, participants were required to: be between 21 and 63 years of age at the time of surgery, be enrolled in commercial insurance plan through the duration of the study and have complete claims data for 12 months preceding and 24 months following the surgery. Because patients ≥ 65 years of age— in this commercial insurance database— are not representative of the general ≥ 65 year US population (the overwhelming majority of whom receive their health insurance through Medicare). We therefore restricted our analyses to persons ≥ 65 years of age. Because inclusion in the study required a two-year look-back period for the date of surgery, we set the exclusion criterion for this ≥ 65 cohort at 63 years of age. Persons with any of the following diagnoses before surgery were excluded from the study: neoplasm (ICD-9=140–239), fracture (ICD-9=733.1, 733.10, 733.13, 733.95, 733.8, 733.81–733.82, 805–806.9, 839–839.59), infection (ICD-9=324.1, 730–730.99) or inflammation (ICD-9=720.0–720.9) involving the spine; history of a major traumatic accident (ICD-9= E800–E849.9) within 12 months prior to surgery or diagnosis of pregnancy (ICD-9=630–676).

Participants were categorized into one of four groups based on surgical approach to lumbar fusion: posterior (ICD-9-CM=81.05–81.08; CPT=22612, 22614, 22630, 22632, 22840, 22842), anterior (ICD-9-CM=81.04, 81.06; CPT= 22558, 22585), 360° fusion (any anterior or posterior code) and outpatient minimally invasive (OPMI) fusion (identified by an outpatient location for the procedure). For this investigation, we included only persons with complete enrollment data and complete diagnostic and procedure codes. No member of the final study had missing values on any of the study variables. Therefore, no members of the study cohort were excluded from any of the analyses.

Variables

The outcome variable, long term opioid use after lumbar fusion, was defined as ≥365 days of opioid prescriptions dispensed in the two years following surgery, which was measured using pharmacy claims data. Opioids belonged to schedules II, III, IV or IV. (Appendix Table 1: Drug Enforcement Administration (DEA) and therapeutic class codes[27]).

The independent variables included gender, age, geographic region, type of lumbar fusion (posterior, anterior, 360 or OPMI), indication for fusion (degenerative, post-laminectomy or repeat fusion); comorbidities, Elixhauser comorbidty Index[28] excluding depression, obesity and smoking), depression (ICD-9-CM=296.2, 296.3, 300.4, 300.5, 309.0, 309.1 309.28, 309.82, 309.83, 309.89, 311), obesity (ICD-9-CM=278.00, 278.01, 278.02), smoking (305.1) and the total number of days of opioids were dispensed within 365 days prior to the

date of surgery were examined as independent variables. All comorbidities were assessed using a 365 day look-back period from the date of surgery. Opioid use was assessed using pharmacy claims data, while information regarding all other predictor variables was obtained from physician and facility claims data. Opioid use before lumbar fusion use was grouped into quartiles among those with any opioid use (quartile 1=1–22 days; quartile 2=23–72 days; quartile 3=73–250 days; quartile 4>250 days), with 0 days of use serving as the referent.

We used a 2-year window to measure opioid use after surgery. Although this interval is substantially longer than some reported definitions of long term opioid use,[29,30] several studies have reported that a substantial percentage of patients use opioids consistently for up to 2 years following lumbar surgery.[2,31,32–34] We examined long-term opioid use as both a binary (≥365 days) and a continuous outcome. Finally, we examined demographic variables including age and gender.

Statistical analysis

Bivariate analyses including chi-square and one-way analyses of variance (ANOVA) were used to examine differences in the study variables across four fusion types (Table 1). A plot was generated to assess cumulative months of opioid use across the 2-year follow-up period. Multivariable logistic regression models— simultaneously adjusting for all of the aforementioned clinical and demographic covariates— were used to assess the adjusted risk of long term opioid use associated with each of the study variables. All statistical analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC).

RESULTS

A total of 8,377 patients who underwent lumbar fusion surgery were included in the study. The distribution of each of the covariates according to fusion type is presented in Table 1. The mean age of the study population was 49.6 years (SD=8.8). Of the 8,377 participants, 56.13% were females and 86.43% were above 40 years of age. Participants undergoing anterior fusion were younger (mean age=46.8 years), compared to participants undergoing other fusion types. Posterior fusion (65.06%) was the most common surgical approach and degenerative disease (85.25%) was the most common indication for lumbar fusion, regardless of fusion type. Participants who did not have any of the three major indications for lumbar surgery were categorized as “other” (4.25%). Posterior fusion recipients had the highest proportion of ≥2 comorbid conditions (22.86%). Prevalence of depression in the sample was 11.04% overall. Mean duration of opioid use before lumbar fusion was 173 days (SD=204); 15.9% participants did not use opioids before lumbar fusion. Opioid use before fusion did not vary significantly by fusion type. In the 2 year post fusion follow-up period, opioids were dispensed for a mean duration of 385 days (SD=443). Participants undergoing 360° fusion were more likely to experience long term opioid use after surgery (32.76%), compared to other fusion types. Overall, 29.34% participants received long term opioids after surgery.

Figure 1 presents the percentage of patients’ cumulative duration of post-surgery opioid use (1 through 24 months). Approximately 50% of lumbar surgery patients used opioids for a

total of 3 months after surgery; approximately, 40 % used opioids for 6 months; 30% 12 months; and 17% 24 months.

Results from the multivariable logistic regression are presented in Table 2. After adjusting for covariates, opioid use before lumbar fusion was associated with an increased risk of long term opioid use after lumbar fusion. Compared to the referent (0 days), the odds of long term opioid use increased in a monotonic fashion with quartile of pre-surgery opioid use in the year before lumbar surgery [Quartile 1 (1–22 days) OR=2.27, 95% CI=1.48–3.49; Quartile 2(23–72 days): OR=5.94, 95% CI=4.00–8.83; Quartile 3: (73–250 days) OR=25.31, 95% CI=17.26–37.10; Quartile 4 (≥ 250days) OR=219.95, 95% CI=148.53–325.71)], indication for re-fusion (OR=1.32, 95% CI=1.02–1.72), and diagnosis of depression (OR=1.43, 95% CI=1.18–1.74). Receipt of anterior fusion was associated with a modest decrease in the risk of long-term opioid use (OR=0.79, 95% CI=0.63–0.99). Neither Elixhauser comorbidity score nor geographic region were associated with an increased risk of long-term opioid use following surgery.

DISCUSSION

In this nationally representative cohort study of 8,377 adults who underwent lumbar spinal surgery, opioid use before surgery—assessed both as a categorical and continuous variable—was the strongest predictor of long term opioid use following surgery. In addition, diagnosis of depression and having re-fusion surgery were associated with an increased risk of long term opioid use whereas anterior fusion was protective against long-term opioid use.

In general, most of our findings were consistent with previous studies that investigated risk factors for long term opioid use after spine surgery. For example, in a retrospective cohort study of 1002 workers' compensation subjects, Anderson et al reported that long-term opioid use before lumbar fusion was associated with a six-fold higher risk of long-term opioid after lumbar fusion.[2] Likewise, in a prospective cohort study of 583 patients, opioid use before spine surgery was associated with increased incidence of opioid dependence at 12 months after spine surgery.[11] Another prospective cohort study found a positive association between opioid use before spine surgery and increased surgical site pain after surgery.[19] Our findings are also consistent with research showing pre-surgical opioid use as a predictor of various adverse post-surgical outcomes in spine surgery recipients such as poor self-rated pain, disability and overall health.[35] In addition, pre surgery opioid use has been associated with increased hospital length of stay, delay in returning to work, surgical complications and other adverse functional outcomes after surgery.[13,4,36,37] It is possible that some patients with substantial pre-surgery opioid use might have developed addiction disorders prior to surgery. Compared to other risk factors, the considerably higher risk of long term opioid use associated with opioid use before surgery highlights the need for caution in prescribing opioids to individuals planning to undergo lumbar surgery to treat back pain symptoms.

Our findings were not consistent with prior studies that identified comorbidity as an important predictor of poor pain outcomes and high risk of long term opioid use following major orthopedic surgery, including spine surgery.[21,38,39] In addition, the Elixhauser comorbidity index has been linked with increased risk of readmission, various surgical and

post-surgical complications, increased length of stay and mortality following spine or other major surgery.[40,41] It is possible that our focus on just one type of spine surgery (i.e., lumbar fusion) and a single outcome (i.e. risk of long-term opioid use) failed to capture potential adverse post-surgical events associated with baseline comorbidity. Our finding that depression was associated with long term opioid use is also consistent with previous research. Prior studies have reported clinical depression as a risk factor for long term opioid use in spine surgery recipients.[2,21] Preoperative depression has been associated with poor post-surgical pain outcomes, low treatment satisfaction and fewer improvements in symptom severity, disability and walking ability following lumbar surgery.[16,20] Further, clinical depression is reported to be associated with poor return to work status following lumbar fusion surgery.[21]

Our finding that anterior approach to lumbar fusion was associated with a decreased risk of long-term opioid use is in contrast to a recent cohort study of 10,941 participants that reported poorer post-operative outcomes and increased health care utilization following anterior fusion, compared to posterior fusion.[15] However few other studies found no major differences in surgical or functional outcomes between the two approaches or reported slightly better surgical outcomes following anterior fusion.[42,43] We did not find a statistically significant association between OPMI fusion and risk of long-term opioid use. Previous studies reported favorable pain outcomes and shorter duration of opioid use following minimally invasive spinal fusion compared to more invasive open fusion [17,44–47] In general, however our finding is corroborated by the results of a few prior studies that found similar long-term clinical and functional outcomes for the two groups.[48,49]

Our finding of increased risk of long-term opioid use associated with re-fusion surgery is consistent with prior evidence suggesting ongoing post-operative low back pain, and continued narcotic use following repeat lumbar fusion surgery.[50]

Our finding that smoking was not associated with long term opioid use is consistent with several prior studies that reported little or no difference in adverse outcomes following spine surgery.[51–53] Some studies, however, have reported that smoking was associated with an increased risk of perioperative complications, non-healing spinal fusion and higher risk of long term opioid use after spine surgery.[22,54,55] It is important to acknowledge, however, that because smoking is substantially under-reported in administrative claims data, our findings are subject to possible misclassification bias. Further research should examine the impact of nicotine and smoking exposure on pain, with particular emphasis on duration of this outcome.

Our findings should be considered in light of several limitations. First, we used insurance claims data wherein diagnoses and type of surgery were based on billing codes that may not always be accurate or complete. Second, although we used a nationally representative sample, we included only commercially insured patients. Third, pharmacy claims data only captures medications prescribed by physicians in the insurance plan, and some patients may obtain opioids illegally.[56] Fourth, we required 24 month post-fusion insurance enrollment as inclusion criteria, thereby excluding participants who either changed or lost coverage or died during this period. Fifth, our data provide information on the date the prescription was filled

but not on the date it was purchased or picked up by the patient. It is possible, therefore, that some of the drug exposure periods used in this study underestimated the true medication exposure period. It is also possible that some patients who did pick up their prescription did not adhere to the full prescribed regimen.

The Centers for Disease Control and Prevention (CDC) reports one death every 19 minutes from prescription drug overdose; 73% of these deaths result from opioid overdose.[57] Opioids are commonly used agents for post -surgical pain management in patients undergoing lumbar fusion surgery.[2–6] However, evidence regarding risk factors for long term opioid use following lumbar fusion is inconclusive, particularly the potential variation in risk associated with type of surgery, indication for surgery, duration of prior opioid use, or other clinical and behavioral factors.[2,7,11,15,20,22,40] The 2016 CDC guidelines emphasized the role of non-drug alternatives and non-opioid pharmacologic therapy as preferred approaches for chronic pain, in part because little evidence supports effectiveness of long-term opioids in improving pain and function in chronic non-cancer pain.[58]

The strong association between pre-lumbar fusion opioid quartiles and post lumbar fusion opioid use suggests clinicians should closely monitor the use of opioids in the treatment of back pain. In general, opioid use before lumbar surgery has been associated with poor post-surgical outcomes, including poor pain control, longer length of stay, increased risk of infections, and poor wound healing.[4,13,19,33,36,37] While a few prior studies investigated the association between pre-operative and post-operative opioid use in patients undergoing lumbar fusion or spine surgery in general, ours is the first study to assess this association in a nationally representative sample of patients undergoing lumbar fusion surgery. In view of this, our findings are generalizable to commercially insured working adult population in the US. Policies for greater regulation of opioid prescription for back pain and more rigorous screening for risk factors such as substance abuse disorder, prior opioid use, refusion surgery, depression and relevant comorbidities may help improve short term and long term health outcomes in patients undergoing spine surgery.

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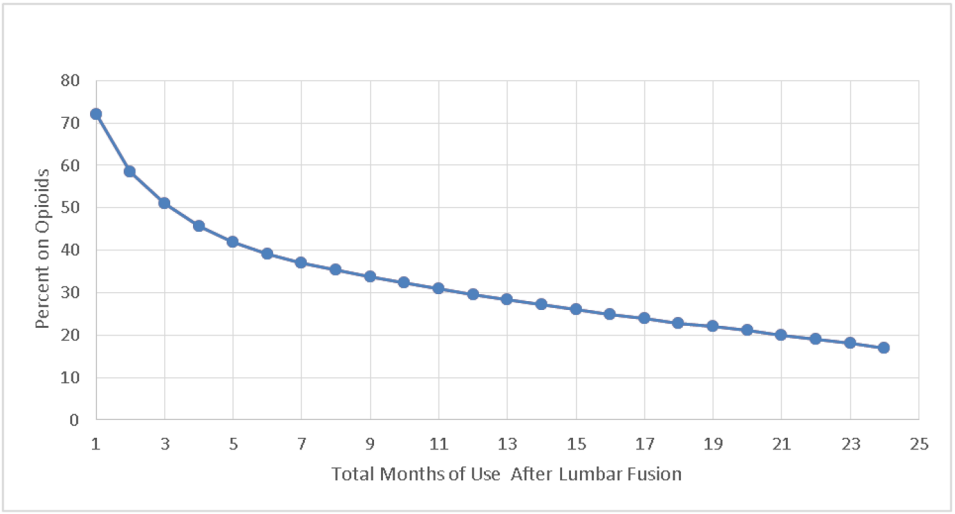

Figure 1.
Cumulative opioid use after surgery

Table 1

Descriptive Statistics of Variables by Fusion Type

	Overall	Posterior (n=5450)	Anterior (n=791)	360 Fusion (n=1230)	OPMI Fusion (n=906)	*p*
Demographic Characteristics	**N (%)**	**N (%)**	**N (%)**	**N (%)**	**N (%)**	
20–29	227 (2.71)	141 (2.59%)	25 (3.16%)	35 (2.85%)	26 (2.87%)	
30–39	910 (10.86)	500 (9.17%)	155 (19.6%)	158 (12.85%)	97 (10.71%)	
40–49	2173 (25.94)	1284 (23.56%)	303 (38.31%)	347 (28.21%)	239 (26.38%)	
50–63	5067 (60.49)	3525 (64.68%)	308 (38.94%)	690 (56.1%)	544 (60.04%)	
Gender						0.47
Male	3675(43.87)	2410 (44.22%)	343 (43.36%)	516 (41.95%)	406 (44.81%)	
Female	4702 (56.13)	3040 (55.78%)	448 (56.64%)	714 (58.05%)	500 (55.19%)	
Region						0.003
Midwest	2306 (27.54)	1530 (28.08)	245 (30.97)	332 (27.06)	199 (21.96)	
Northeast	484 (5.78)	299 (5.49)	41 (5.18)	84 (6.85)	60 (6.62)	
South	4410 (52.68)	2870 (52.68)	389 (49.18)	633 (51.59)	518 (57.17)	
West	1172 (14.00)	749 (13.75)	116 (14.66)	178 (14.51)	129 (14.24)	
Indication						.0001
Degenerative	7141 (85.25)	4722 (86.64%)	629 (79.52%)	1054 (85.69%)	736 (81.24%)	
Post-Laminectomy	391 (4.67)	239 (4.39%)	41 (5.18%)	79 (6.42%)	32 (3.53%)	
Re-Fusion	489 (5.84)	326 (5.98%)	32 (4.05%)	74 (6.02%)	57 (6.29%)	
Other	356 (4.25)	163 (2.99%)	89 (11.25%)	23 (1.87%)	81 (8.94%)	
Comorbidity						
Elixhauser Score						.0001
0	4229 (50.48)	2655 (48.72)	467 (59.04)	625 (50.81)	482 (53.20)	
1	2328 (27.79)	1549 (28.42)	199 (25.16)	347 (28.21)	233 (25.72)	
2+	1820 (21.73)	1246 (22.86)	125 (15.80)	258 (20.98	191 (21.08)	
Depression	925 (11.04)	575 (10.55%)	109 (13.78%)	151 (12.28%)	90 (9.93%)	0.02
Obesity	341 (4.07)	222 (4.07%)	24 (3.03%)	50 (4.07%)	45 (4.97%)	0.26
Smoking	390 (4.66)	251 (4.61%)	39 (4.93%)	56 (4.55%)	44 (4.86%)	0.96
OPR Pre-Fusion						0.15

Spine (Phila Pa 1976). Author manuscript; available in PMC 2018 September 15.

	Overall	Posterior (n=5450)	Anterior (n=791)	360 Fusion (n=1230)	OPMI Fusion (n=906)	*p*
Demographic Characteristics	**N (%)**	**N (%)**	**N (%)**	**N (%)**	**N (%)**	
Q1: 0	1332 (15.90)	896 (16.44%)	112 (14.16)	189 (15.37)	135 (14.90)	
Q2: 1–22 days	1765 (21.07)	1172 (21.50)	146 (18.46)	248 (20.16)	199 (21.96)	
Q3: 23–72 days	1771 (21.14)	1152 (21.14)	174 (22.00)	267 (21.71)	178 (19.65)	
Q4: 73–250 days	1749 (20.88)	1136 (20.84)	178 (22.50)	243 (19.76)	192 (21.19)	
Q5: 250+	1760 (21.01	1094 (20.07)	181 (22.88)	283 (23.01)	202 (22.30)	
OPR Post-Fusion						
Dispensed >=365 days	2458 (29.34)	1557 (28.57%)	235 (29.71%)	403 (32.76%)	263 (29.03%)	0.035

Table 2

Odds Ratio Estimates for Risk of Being Dispensed Opioid Pain Relievers for 365 days or more in 2-year, Post-Fusion Follow-Up Period

Variable	% Dispensed > 365 Days OPR	OR Estimate	95% CI	P-value
Demographics				
Age (n=2459)	49.95 (8.92)	0.99	0.98–0.99	0.0001
Male	1025 (27.89%)	1	Reference	
Female	1433 (30.48%)	1.02	0.89–1.16	0.77
Region				
South	1344 (30.48%)	1	Reference	
Midwest	613 (26.58%)	0.88	0.75–1.03	0.10
Northeast	145 (29.96%)	1.04	0.79–1.38	0.77
West	354 (30.20%)	0.98	0.80–1.19	0.82
Fusion Type				
Posterior Fusion	1557 (28.57%)	1	Reference	
Anterior Fusion	235 (29.71%)	0.79	0.63–0.99	0.04
360 Fusion	403 (32.76%)	1.18	0.98–1.41	0.09
OPMI Fusion	263 (29.03%)	0.87	0.70–1.08	0.20
Indication				
Degenerative	2030 (28.43%)	1	Reference	
Post-Laminectomy	153 (39.13%)	1.14	0.85–1.52	0.38
Re-Fusion	189 (38.65%)	1.32	1.02–1.72	0.04
Other	86 (24.16%)	1.25	0.89–1.75	0.21
Comorbidity				
Elixhauser Score				
0	1036 (24.50%)	1	Reference	
1	723 (31.06%)	1.12	0.96–1.31	0.17
2+	699 (38.41%)	1.15	0.97–1.37	0.11
Depression	458 (49.51%)	1.43	1.18–1.74	<0.001
Obesity	130 (38.12%)	0.91	0.67–1.23	0.53
Smoking	189 (48.46%)	1.12	0.91–1.58	0.21
OPR Use Pre-Fusion				
Quintile 1: 0	29 (2.18%)	1	Reference	
Quintile 2: 1–22 days	86 (4.87%)	2.274	1.48–3.49	<0.001
Quintile 3: 23–72 days	213 (12.03%)	5.939	4.00–8.83	<0.001
Quintile 4: 73–250 days	651 (37.22%)	25.305	17.26–37.10	<0.001
Quintile 5: 250+	1479 (84.03%)	219.946	148.53–325.71	<0.001