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# Outcomes Following Lumbar And Cervical Spinal Surgery In The Obese: An Acs-Nsqip Database Study

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Outcomes Following Lumbar and Cervical Spinal Surgery in the Obese:

An ACS-NSQIP Database Study

A Thesis Submitted to the

Yale University School of Medicine

in Partial Fulfillment of the Requirements for the

Degree of Doctor of Medicine

By

Rafael A. Buerba

MD/MHS Candidate 2014

## ABSTRACT

OUTCOMES FOLLOWING LUMBAR AND CERVICAL SPINAL SURGERY IN THE OBESE: AN ACS-NSQIP DATABASE STUDY. Rafael A. Buerba (Sponsored by Jonathan N. Grauer). Section of Spine Surgery, Department of Orthopaedics and Rehabilitation, Yale University School of Medicine, New Haven, CT.

Prior studies on the impact of obesity on spine surgery outcomes have focused mostly on lumbar fusions, do not examine lumbar discectomies or decompressions, and have shown mixed results regarding complications. There is also a paucity of literature regarding the effect of obesity on cervical spinal fusion outcomes. The purpose of this thesis was therefore to analyze whether obesity as measured by BMI influences the complication rates, operation times, and lengths of stay in patients undergoing lumbar or cervical spine surgery.

To this end, we conducted a retrospective cohort analysis of prospectively collected data on lumbar and cervical surgeries using the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database from 2005-2010. Patients undergoing lumbar surgery (anterior fusion, posterior fusion, TLIF/PLIF, discectomy, or decompression) and anterior cervical fusion were categorized into 4 BMI groups: non-obese (18.5-29.9 kg/m<sup>2</sup>), obese I (30-34.9 kg/m<sup>2</sup>), obese II (35-39.9 kg/m<sup>2</sup>), obese III ( $\geq 40$  kg/m<sup>2</sup>). Posterior cervical patients were categorized into 2 groups based on BMI: non-obese (18.5-29.9 kg/m<sup>2</sup>) and obese ( $\geq 30$  kg/m<sup>2</sup>) due to the smaller sample size. Patients in the obese categories were compared to patients in the non-obese categories using  $\chi^2$ , Fisher's exact test, student's *t*-test, and/or ANOVA. Multivariate linear/logistic regression models were used to adjust for preoperative comorbidities.

Data were available for 10,387 patients undergoing lumbar surgery. Among all lumbar surgery patients, 25.6% were obese I, 11.5% obese II, and 6.9% obese III. On multivariate analysis, obese I and III had a significantly increased risk of urinary complications and obese II and III patients had a significantly increased risk of wound complications. Only obese III patients, however, had a statistically increased risk of having increased time spent in the operating room, an extended length of stay, pulmonary complications and of having  $\geq 1$  complication (all  $P < 0.05$ ). Regarding cervical fusions, data were available for 3,671 and 400 patients who underwent anterior or posterior cervical fusion, respectively. On multivariate analyses for both anterior and posterior cervical fusions, there were no differences for overall and system-specific complication rates, lengths of hospital stay, re-operation rates, and mortality among the obesity groups when compared to the non-obese groups.

In conclusion, obese patients appear to have higher complication rates than patients who are non-obese after lumbar surgery but not after cervical surgery. After lumbar surgery, the complication rates seem to increase substantially for obese III patients. These patients have longer times spent in the operating room, extended hospital stays and an increased risk for wound, urinary, pulmonary complications and for having at least one or more complication overall. Surgeons should be aware of the increased risk of multiple complications, longer lengths of stay, and longer surgeries for patients with BMI  $\geq 40$  kg/m<sup>2</sup> after lumbar surgery.

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## INTRODUCTION

Obesity is a growing problem that has reached epidemic levels in the US. According to the Centers for Disease Control and Prevention, 78 million of US adults are currently obese (Body Mass Index (BMI)  $\geq 30$  kg/m<sup>2</sup>) (1). Obese patients are at risk for comorbid medical conditions such as heart disease, hypertension, stroke, diabetes, and certain cancers—subsequently raising medical costs (1, 2). Not only is obesity associated with more expensive medical care, but also with more expensive surgical care, given its associations with longer hospitalizations and higher rate of complications (3, 4).

Aside from increased costs, the prevalence of obesity in the population is driving a growing interest for understanding the predictors of surgical outcomes in these patients—particularly after spine surgery. The high prevalence of obesity has led to an increase in obesity-related complications, including back pain and degeneration of the lumbar spine (5-7). As a result, more patients with high BMI are presenting to spine surgeons, and there has thus been a growing interest in understanding the complication risks after spine surgery in this patient population.

Several related single-institution and population-based studies have been conducted, but most studies on the impact of obesity on spine surgery outcomes have focused on lumbar surgery, rather than cervical, and some have noted an association between high BMI and an increased risk of complications after lumbar spine surgery (3, 8-15). However, other results have been mixed, particularly in the nature of the complications. Some studies

have shown no increased risk after lumbar surgery in obese patients (16-18), particularly after minimally invasive surgery (MIS) (19-21), while most have noted an association between high BMI and an increased risk of complications (3, 8-11). Specifically, a few studies have found the obese population to have a higher rate of wound complications (3, 8, 10, 12, 13), DVTs (3, 9), re-operation (14), intra-operative blood loss (11-13, 15), extended hospital stays, and longer operative times (15).

Possible explanations for the inconsistency in the literature may lie in sample size differences and the fact that different BMI thresholds were used to define the obese and comparison cohorts. Most related studies defined obesity as  $BMI \geq 30$ , but some compared the obese group to a non-obese group ( $BMI < 30$ ) (12, 15), others to a normal weight group ( $BMI 18.5-24.9$ ) (22), and others to both a normal group and an overweight group ( $BMI 25-29.9$ ) (17). One large-scale, multi-institutional study compared a morbidly obese group ( $BMI \geq 40$ ) to a normal weight group (defined in their study by absence of ICD-9 codes for obesity, overweight, or underweight) (3), while another compared obese ( $BMI 30-39.9$ ) and morbidly obese ( $BMI \geq 40$ ) patients to a normal or overweight group (defined in their study by absence of ICD-9 codes for obesity and morbid obesity) (13). There was one study that used a non-standard definition for obese ( $BMI \geq 35$ ) and non-obese ( $BMI < 35$ ) (14). Other smaller studies also differed in their definitions of obesity (5, 6, 8, 10, 11, 21, 23, 24).

Given the different BMI thresholds used for defining obesity and the mixed results of the lumbar studies, the question arises as to what degree of obesity is actually associated with

which adverse outcomes in the lumbar spine. The World Health Organization's (WHO) has a graded scale for obesity: obese I (30-34.9 kg/m<sup>2</sup>), obese II (35-39.9 kg/m<sup>2</sup>), obese III ( $\geq 40$  kg/m<sup>2</sup>). Nonetheless, only one of the smaller studies has used this graded scale of obesity in the analysis of spinal fusion complications (10). To the author's knowledge, no large lumbar surgery study has used this graded definition of obesity for this purpose. Furthermore, the majority of studies have mostly focused on lumbar fusions, and there is limited data comparing complications for different types of lumbar surgery.

Regarding the cervical spine, as stated previously—despite the existing literature on lumbar surgical outcomes—there is a paucity of literature on outcomes after anterior and posterior cervical fusions in patients with high BMI. One single institution study found that the thickness of subcutaneous fat was a significant risk factor for surgical-site infections after posterior cervical fusion, whereas obesity (BMI  $\geq 30$  kg/m<sup>2</sup>) was not (25). Aside from this study, one large multi-institutional study has characterized the in-hospital outcomes of patients after cervical anterior and posterior fusions in morbidly obese patients (BMI  $\geq 40$  kg/m<sup>2</sup>) (3). Although this study from California showed an increased risk for in-hospital complications after anterior cervical fusions and no increased risk after posterior cervical fusions, it could not provide information on post-discharge complications and did not provide information on obese patients with a BMI between 30-39.9 kg/m<sup>2</sup>. One other recent study that included patients undergoing cervical, thoracic, and lumbar fusions using a prospectively collected database noted an increase in 30-day complications with increasing BMI, but did not separate its results by procedure nor



stratify patients into obesity categories, making unclear the contribution of high BMI to adverse outcomes in the cervical or lumbar spine (26).

The current thesis is a large-scale, multi-institutional database study using the American College of Surgeons National Surgery Quality Improvement Program (ACS-NSQIP) database. National databases are increasingly being used to address clinical questions with degrees of randomization, speed and power previously not possible. Each database measures different variables and has its specific advantages and limitations to answer clinical questions, particularly for short-term post-operative outcomes.

## **STATEMENT OF PURPOSE**

The specific hypotheses and aims for this thesis presented to the faculty of the Yale School of Medicine are the following:

### ***Specific hypotheses:***

- With increasing BMI, there will be an increased risk of post-operative complications after both, lumbar and cervical surgery.
- Patients with the highest BMI will have the highest risk for adverse outcomes after both, lumbar and cervical surgery.
- Patients with high BMIs will have longer surgeries and longer hospitalizations, indicating that their medical care is more expensive overall.

### ***Specific aims:***

- To analyze whether different degrees of obesity influence the 30-day post-operative complication rates, surgical times, and lengths of stay in patients undergoing lumbar spine surgery.
- To determine the effect of obesity on the 30-day post-operative complication rates, operation times, and lengths of stay following anterior or posterior cervical fusions.
- To compare this thesis's results to the currently available literature.

## MATERIALS AND METHODS

### *Data source/study population.*

The ACS-NSQIP is a publically available, prospectively collected, risk-adjusted, multi-institutional outcomes program whose details of data collection strategies, inclusion criteria, sampling procedures, and outcomes measured have been reported (27-30). ACS-NSQIP collects data on more than 135 variables compliant with the *Health Insurance Portability and Accountability Act*, including preoperative comorbidities, intraoperative variables, and 30-day postoperative morbidity and mortality outcomes for patients undergoing major surgical procedures in both the inpatient and outpatient settings.

The ACS-NSQIP participant-use data files from 2005 to 2010 were used for this study. Together, they contain information on 1,334,886 patients from 258 hospitals in the US. Using Current Procedural Terminology (CPT) codes, we identified all patients who underwent lumbar anterior fusion (CPT 22558), lumbar posterior fusion (CPT 22612), application of lumbar device to interspace from posterior approach which will be referred to from now on as transforaminal lumbar interbody fusion/ posterior lumbar interbody fusion (TLIF/PLIF) (CPT 22612 + CPT 22851), lumbar discectomy (CPT 63030), lumbar decompression (CPT 63047, 63042), anterior cervical fusion (CPT 22551, 22554) or posterior cervical fusion (CPT 22600) in any of the 21 CPT fields available in NSQIP.

Since CPT coding for anterior cervical fusion and discectomy changed in 2011 (31), cases with CPT code 22551 were rare in NSQIP 2005-2010. To optimize capture of patients undergoing anterior fusion, we included those with CPT code 63075 (anterior discectomy) in this study's anterior cervical fusion cohort. Careful review of CPT codes in NSQIP showed that many cases with CPT 63075 had additional codes suggestive of fusion (bone graft, instrumentation, etc.) indicating that the discectomy occurred with fusion despite the absence of fusion codes (22551, 22554). There were some cases in which only CPT 63075 was listed but because NSQIP requires at least a primary code field per case, it is possible that associated codes were not always included. Given that cervical discectomy rarely occurs without fusion, we thus included those cases with primary CPT code of 63075 in this study's anterior cervical fusion cohort.

To focus on the typical adult patient undergoing lumbar or cervical spine surgery, we excluded from the analysis patients who underwent combined anterior and posterior approaches and patients who underwent spinal deformity surgery (additional CPTs: 22800, 22802, 22804, 22808, 22810). We also excluded patients who were pregnant, ventilator-dependent, under 18 years of age, underweight (BMI <18.5 kg/m<sup>2</sup>), and patients who had pre-operative systemic sepsis, emergency operation, a length of stay >365 days, CNS tumor, disseminated cancer, chemotherapy for malignancy ≤ 30 days prior to operation, radiotherapy for malignancy ≤ 90 days prior to operation, acute renal failure, an unrelated procedure under the same anesthetic (e.g. appendectomy), or those with missing data.

This primary independent variable of interest was BMI. For all the lumbar surgery patients and the anterior cervical fusion patients, we used the World Health Organization guidelines (32) to group patients into 3 obesity categories: obese I (30-34.9 kg/m<sup>2</sup>), obese II (35-39.9 kg/m<sup>2</sup>), obese III ( $\geq 40$  kg/m<sup>2</sup>). These 3 groups were compared to the non-obese group of patients (BMI 18.5-29.9 kg/m<sup>2</sup>). Given the smaller sample size for patients with posterior cervical fusion, this cohort was categorized into two groups based on BMI: non-obese (18.5-29.9 kg/m<sup>2</sup>) and obese ( $\geq 30$  kg/m<sup>2</sup>). Other independent demographic and clinical variables included patient gender, race, age, and functional status prior to surgery.

Independent process-of-care variables included American Society of Anesthesiologists (ASA) classification, type of lumbar surgical procedure, single-level vs. multiple level surgery (inclusion of any of the following secondary CPT codes: 22216, 22585, 22612, 22614, 22632, 22800, 22802, 22804, 22808, 22810, 63015, 63035, 63043, 63044, 63048, 63076, 63082, 63091) whether the surgery was classified as an inpatient or outpatient procedure, anesthetic method used, and whether an attending surgeon operated with or without a resident. Independent clinical characteristics of patients included a medical history describing system-specific and general comorbidities.

***Outcome variables.***

Primary clinical outcomes of interest were as follows: 30-day postoperative complications, return to the operating room (OR), and death. Economic considerations

were estimated via hospital length of stay (LOS) and total duration of time the patient spent in the operating room. Complication variables were grouped into the following categories: wound, septic, and system specific (cardiac, respiratory, urinary, and central nervous system). Other complication variables included pulmonary embolism (PE), DVT/thrombophlebitis, graft/prosthesis/flap failure, and receiving a blood transfusion either intra-operatively or post-operatively. An overall complication variable was created to indicate the occurrence of any complication (includes death and one or more complication in any of the complication categories described above; excludes blood transfusions and return to the OR).

Based on clinical experience and given the large standard deviation for the mean LOS for the lumbar surgery population, LOS was dichotomized into regular and extended. We defined extended LOS as exceeding the 70<sup>th</sup> percentile of the LOS in the lumbar spine surgery population for each procedure as follows: anterior fusion  $\geq 6$  days; posterior fusion  $\geq 5$  days; TLIF/PLIF  $\geq 5$  days; discectomy  $\geq 2$  days; decompression  $\geq 4$  days.

Since the standard deviation for the mean LOS in the cervical surgery population was more narrow and since only two procedures were analyzed with a smaller patient sample, extended LOS was defined as exceeding the 80<sup>th</sup> percentile of the LOS in the study population for each cervical procedure as follows: anterior cervical fusion  $\geq 3$  days; posterior cervical fusion  $\geq 8$  days.

***Statistical analysis.***

For descriptive purposes, a univariate analysis of the independent variables by this study's outcomes of interest was performed by  $\chi^2$  test or Fisher's exact test (when applicable) for categorical variables. For continuous variables, analysis of variance (ANOVA) or student's *t*-tests were performed, as appropriate. For non-significant univariate associations, sample size calculations were conducted to verify whether the non-significant result was due to no relation in the sample or due to lack of statistical power as suggested by Olbritch & Wang (33). To better understand the relationships between variables showing significant associations in univariate analyses, multivariable analyses were used to adjust for other outcome variables. In particular, multivariate logistic regression models were used to adjust for preoperative factors for the following outcomes of interest: extended LOS, return to the OR within 30 days, death, PE, DVT/thrombophlebitis, blood transfusions and for overall, wound, septic, and system-specific complications. Multivariable linear regression models were used to adjust for significant independent variables for the mean total OR time. The non-obese patients (BMI 18.5-29.9 kg/m<sup>2</sup>) in each procedure were used as the reference group for the multivariate analyses.

The preoperative predictor variables used in the multivariable analysis included patient demographics, clinical characteristics, and preoperative risk factors. The preoperative variables that were included into the regression models had a  $P < 0.20$  on univariate associations. BMI was always included in the models regardless of its  $P$ -value. A backward stepwise approach was used for the multivariable analysis, using probabilities

of  $\leq 0.05$  for entry and  $\geq 0.10$  for removal from models. Odds ratios with 95% confidence intervals (CI) were calculated. Data analysis and management were performed using SPSS version 19.0 (Chicago, IL). All tests were two-sided, with statistical significance set at a probability value of  $\leq 0.05$ .

This study was deemed exempt from Institutional Review Board approval at our institution because ACS-NSQIP is a public database with no personal identifying information.

***Note about execution of the methods:***

The ACS-NSQIP database is available upon request for any Yale School of Medicine faculty member, as Yale-New Haven Hospital participates in the NSQIP collection program. Dr. Jonathan Grauer requested permission to download the ACS-NSQIP Participant-Use-Files (PUF) from 2005-2010 for research use. The data that is entered into the database is collected by a dedicated NSQIP nurse at each of the participating institutions. Based on ACS-NSQIP guidelines, patients are selected randomly in an alternating cycle. The data recorded is de-identified and submitted to the American College of Surgeons who then creates the PUFs (27-30). The requested PUFs files were then given to the thesis author, Rafael A. Buerba, who then combined the different data sets into one large dataset. From there he selected the procedures by the stated CPT codes using SPSS and prepared the data for analysis by applying the stated exclusion/inclusion criteria and creating new variables from old ones (i.e. use height and weight to create a



BMI variable, use specific complication variables to aggregate them and then create organ-specific complication variables, create dummy variables for multivariate analyses, etc.). All data analyses (sample size and power calculations,  $\chi^2$  tests, Fisher's exact tests, ANOVAs, student's *t*-tests, and multivariate linear/logistic regressions) were performed by the thesis author, Rafael A. Buerba, using SPSS. The methods and statistical analyses were verified step-by-step during the office hours that the statistics department offers for Yale medical students. The methods were then double checked by the co-authors of the manuscripts, which have been already accepted for publication in The Spine Journal (cervical data (Spine J. 2013 Oct 24. pii: S1529-9430(13)01596-9): Fu MC, Grauer JN; lumbar data (Spine J. 2013 Dec 5. pii: S1529-9430(13)01962-1): Fu MC, Gruskay JA, Long III WD, Grauer JN).

## RESULTS

### Patient population

#### *Lumbar Surgery*

From the NSQIP database, we identified 10,387 patients who underwent lumbar spine surgery with the following distribution of procedures: 472 (4.5%) anterior fusions; 1,861 (17.9%) posterior fusions; 650 (6.3%) TLIF/PLIFs; 4,231 (40.7%) discectomies; 3,173 (30.5%) decompressions. Based on BMI, 5,813 (56%) patients were non-obese, 2,660 (25.6%) obese class I, 1,198 (11.5%) obese class II, and 716 (6.9%) obese class III.

Differences in patient demographic and clinical characteristics by BMI are shown in the top half of **Table 1**. Compared with the non-obese group, the obese I, II, III groups had—in general—the following trends with increasing BMI: a greater percentage of women, younger patients (ages 18-64), and Black patients (all  $P < 0.05$ ). There were no differences in the functional status of patients among the BMI groups.

Regarding process-of-care variables (bottom half of **Table 1**), ASA class increased with BMI, as well as the percentage of patients, who underwent multi-level procedures. The percentage of attending physicians operating without residents and the proportion of patients undergoing inpatient procedures were higher in all obesity classes compared to the non-obese group (all  $P < 0.05$ ). There were no differences in the type of anesthesia

used among the BMI groups as most patients underwent lumbar surgery under general anesthesia.

<b>Table 1. Demographic and clinical characteristics of patients undergoing lumbar surgery by Body Mass Index (BMI*) groups (N= 10,387) †</b>					
	<i>BMI</i>				<i>P value</i>
	<i>Non-obese (18.5-29.9 kg/m<sup>2</sup>) n=5,813</i>	<i>Obese I (30-34.9 kg/m<sup>2</sup>) n=2,660</i>	<i>Obese II (35-39.9 kg/m<sup>2</sup>) n=1,198</i>	<i>Obese III (≥ 40 kg/m<sup>2</sup>) n=716</i>	
<b>Demographic &amp; Clinical Characteristics (%)</b>					
<b>Gender</b>					<b>&lt;0.001</b>
Women	45.1%	44.3%	55.2%	64.3%	
Men	54.9%	55.7%	44.8%	35.7%	
<b>Race</b>					<b>&lt;0.001</b>
White	79.3%	77.7%	76.8%	77.8%	
Black	4.9%	6.0%	7.8%	9.9%	
Hispanic	5.1%	5.6%	5.6%	3.6%	
Other <sup>o</sup>	2.0%	1.6%	1.3%	1.7%	
Unknown	8.8%	9.1%	8.5%	7.0%	
<b>Age group</b>					<b>&lt;0.001</b>
18-39 years	64.5%	66.1%	70.5%	78.2%	
40-64 years	27.9%	28.9%	27.1%	20.1%	
65-79 years	7.6%	5.0%	2.4%	1.7%	
≥ 80 years					
Functional status prior to surgery					0.980
Independent in ADL	96.3%	96.3%	96.6%	96.4%	
Partially/totally dependent in ADL	3.7%	3.7%	3.4%	3.6%	
<b>Process-of-care variables (%)</b>					
<b>ASA classification</b>					<b>&lt;0.001</b>
1-2	70.1%	61.5%	48.9%	35.4%	
3-4	29.9%	38.5%	51.1%	64.6%	
<b>Lumbar procedure</b>					<b>0.003</b>
Anterior Arthrodesis (n=472)	5.0%	4.1%	4.6%	2.9%	
Posterior Arthrodesis (n=1,861)	17.0%	19.1%	19.9%	17.6%	
TLIF/PLIF (n=650)	6.2%	6.1%	6.5%	6.7%	
Discectomy (n=4,231)	42.2%	38.9%	36.9%	41.9%	
Decompression (n=3,173)	29.6%	31.8%	32.1%	30.9%	
<b>Vertebral levels</b>					<b>0.023</b>
Single level procedure (n=8,790)	85.4%	94.3%	83.6%	81.4%	
Multi-level procedure** (n=1,597)	14.6%	15.7%	16.4%	18.6%	
<b>Procedure classification</b>					<b>0.000</b>
Outpatient (n=2,161)	22.4%	19.1%	18.0%	19.1%	
Inpatient (n=8,226)	77.6%	80.9%	82.0%	80.9%	
<b>Anesthesia type</b>					0.366
General	98.2%	98.1%	98.8%	98.6%	
Local/MAC/Regional/Spinal	1.8%	1.9%	1.2%	1.4%	
<b>Surgery team</b>					<b>0.033</b>
Attending alone	73.4%	75.3%	77.6%	75.4%	
Attending with resident	26.6%	24.7%	22.4%	24.6%	

\*Body Mass Index (BMI) = bodyweight [kg]/height<sup>2</sup> [m]<sup>2</sup>; <sup>o</sup> included but was not limited to American Indians, Alaska Natives, Asians, or Pacific Islanders; \*\* Multi-level procedure : ≥ 2 levels. ADL (activities of daily living); ASA (American Society of Anesthesiologists); MAC (monitored anesthetic care); † Percentages have been rounded and may not add to 100. Bolded items indicate significance (P value < 0.05)

Differences in patient comorbidities by BMI are shown in **Table 2**. The incidence of having hypertension requiring medication, dyspnea, diabetes and a higher Mallampati scale (scale used to predict ease of intubation) increased with increasing BMI (all  $P < 0.01$ ). Compared with the non-obese patients, obese I, II, III were less likely to be alcohol users ( $>2$  drinks/day) or smokers (all  $P < 0.01$ ). Obese I patients were more likely

<b>Table 2. Comorbidities of patients undergoing lumbar surgery by Body Mass Index (BMI*) groups (N= 10,387) †</b>					
<i>Comorbidities (%)</i>	<i>BMI</i>				<i>P value</i>
	<i>Non-obese (18.5-29.9 kg/m<sup>2</sup>) n=5,813</i>	<i>Obese I (30-34.9 kg/m<sup>2</sup>) n=2,660</i>	<i>Obese II (35-39.9 kg/m<sup>2</sup>) n=1,198</i>	<i>Obese III (≥ 40 kg/m<sup>2</sup>) n=716</i>	
<b>Cardiovascular</b>					
Congestive heart failure	0.1%	0.2%	0.2%	0.2%	0.794
Myocardial infarction	0.2%	0.2%	0.1%	0.1%	0.765
Previous PCI	5.5%	7.0%	6.3%	5.9%	0.058
Previous cardiac surgery	4.2%	4.5%	3.8%	3.4%	0.498
Angina	0.3%	0.5%	0.3%	0.1%	0.490
<b>HTN requiring medication</b>	<b>42.4%</b>	<b>56.4%</b>	<b>60.7%</b>	<b>64.4%</b>	<b>&lt;0.001</b>
<b>Peripheral vascular disease</b>	<b>0.9%</b>	<b>1.2%</b>	<b>0.3%</b>	<b>0.3%</b>	<b>0.047</b>
Rest pain/gangrene	0.2%	0.3%	0.3%	0.7%	0.119
<b>Pulmonary</b>					
<b>Current smoker</b>	<b>26.8%</b>	<b>23.2%</b>	<b>21.6%</b>	<b>20.7%</b>	<b>&lt;0.001</b>
<b>Dyspnea</b>	<b>4.5%</b>	<b>6.8%</b>	<b>9.0%</b>	<b>13.3%</b>	<b>&lt;0.001</b>
COPD	3.0%	3.6%	3.0%	4.6%	0.096
Current pneumonia	0.0%	0.0%	0.1%	0.0%	0.358
<b>Renal</b>					
Currently on dialysis	0.2%	0.2%	0.2%	0.0%	0.609
<b>Cerebrovascular</b>					
Stroke w/ neurological deficits	0.9%	1.1%	1.0%	1.4%	0.716
Stroke w/ no neurological deficits	1.2%	1.6%	0.7%	0.8%	0.056
Transient ischemic attacks	2.1%	2.7%	1.4%	1.7%	0.060
<b>Other</b>					
Weight loss	0.6%	0.2%	0.4%	0.3%	0.148
<b>Diabetes</b>	<b>9.9%</b>	<b>17.6%</b>	<b>23.7%</b>	<b>30.2%</b>	<b>&lt;0.001</b>
<b>Alcohol use</b>	<b>3.9%</b>	<b>2.6%</b>	<b>2.5%</b>	<b>1.0%</b>	<b>&lt;0.001</b>
Open wound/wound infection	0.3%	0.7%	0.3%	0.7%	0.060
Chronic corticosteroid use	2.9%	2.7%	3.0%	4.2%	0.201
Bleeding disorder	1.5%	1.4%	2.0%	0.7%	0.143
Esophageal varices	0.0%	0.0%	0.1%	0.1%	0.150
Impaired sensorium	0.1%	0.1%	0.2%	0.1%	0.864
Pre-op blood transfusion	0.2%	0.2%	0.3%	0.1%	0.937
Recent surgery (w/in 30 days)	1.1%	0.8%	1.5%	1.1%	0.197
<b>Mallampati scale ≥ 3</b>	<b>10.2%</b>	<b>15.4%</b>	<b>20.2%</b>	<b>25.4%</b>	<b>&lt;0.001</b>

\*Body Mass Index (BMI) = bodyweight [kg]/height<sup>2</sup> [m]<sup>2</sup>; PCI (percutaneous coronary intervention); COPD (chronic obstructive pulmonary disease); † Percentages have been rounded and may not add to 100; NS= not significant. Bolded items indicate significance (P value ≤ 0.05)

to have peripheral vascular disease than non-obese patients, while obese II and III

patients were less likely to have peripheral vascular disease than all other BMI groups.

There were no differences among BMI groups in the remaining cardiovascular, respiratory, renal, cerebrovascular and other comorbidity categories.

### *Anterior cervical fusions*

We identified 3,671 patients who underwent anterior cervical fusions. Based on BMI, 2,072 (56.4%) patients were non-obese, 915 (24.9%) obese class I, 419 (11.4%) obese class II, and 265 (7.2%) obese class III. Differences in patient demographic and clinical characteristics by BMI are shown in the top half of **Table 3**. Compared with the non-obese group, the obese groups tended to have—in general—a higher percentage of females and younger patients (both  $P < 0.05$ ). There were no differences among BMI groups regarding their racial compositions and functional status prior to surgery.

Regarding process-of-care variables (**Table 3**, bottom half), ASA class increased with BMI, as well as the percentage of patients who underwent surgery performed by attending physicians operating without residents (both  $P < 0.05$ ). There were no differences among the four BMI groups in the percentage of patients who underwent outpatient vs. inpatient surgery and in the percentage of patients who underwent a multi-level surgery. All patients underwent anterior cervical fusion under general anesthesia.

Differences in patient comorbidities by BMI groups for anterior fusions are shown in **Table 4**. The incidence of having hypertension requiring medication, dyspnea, diabetes and a higher Mallampati scale (scale used to predict ease of intubation) increased with

<b>Table 3.</b> Demographic, clinical characteristics and process-of-care of care variables for anterior cervical fusion patients by Body Mass Index (BMI*) groups (N=3,671) <sup>†</sup>					
	<i>BMI</i>				<i>P value</i>
	<b>Non-obese</b> (18.5-29.9 kg/m <sup>2</sup> ) <i>n</i> =2,072	<b>Obese I</b> (30-34.9 kg/m <sup>2</sup> ) <i>n</i> =915	<b>Obese II</b> (35-39.9 kg/m <sup>2</sup> ) <i>n</i> =419	<b>Obese III</b> (≥ 40 kg/m <sup>2</sup> ) <i>n</i> =265	
<b>Demographic &amp; Clinical Characteristics (%)</b>					
<b>Gender</b>					<b>&lt;0.001</b>
<b>Women</b>	<b>49.5%</b>	<b>44.5%</b>	<b>57.0%</b>	<b>63.3%</b>	
<b>Men</b>	<b>50.5%</b>	<b>55.5%</b>	<b>43.0%</b>	<b>36.7%</b>	
<b>Race</b>					0.054
White	75.7%	74.0%	76.6%	75.5%	
Black	8.4%	11.6%	7.9%	11.7%	
Hispanic	4.3%	5.9%	5.3%	4.5%	
Other <sup>o</sup>	2.5%	2.0%	2.6%	1.1%	
Unknown	9.0%	6.6%	7.6%	7.2%	
<b>Age group</b>					<b>0.023</b>
<b>18-39 years</b>	<b>12.7%</b>	<b>11.5%</b>	<b>13.4%</b>	<b>16.6%</b>	
<b>40-64 years</b>	<b>70.8%</b>	<b>73.8%</b>	<b>76.4%</b>	<b>71.7%</b>	
<b>65-79 years</b>	<b>14.8%</b>	<b>13.4%</b>	<b>10.0%</b>	<b>10.6%</b>	
<b>≥ 80 years</b>	<b>1.6%</b>	<b>1.3%</b>	<b>0.2%</b>	<b>1.1%</b>	
<b>Functional status prior to surgery</b>					0.164
Independent in ADL	96.9%	97.2%	98.1%	95.1%	
Partially/totally dependent in ADL	3.1%	2.8%	1.9%	4.9%	
<b>Process-of-care variables (%)</b>					
<b>ASA classification</b>					<b>&lt;0.001</b>
<b>1-2</b>	<b>69.8%</b>	<b>63.8%</b>	<b>55.7%</b>	<b>35.6%</b>	
<b>3-4</b>	<b>30.2%</b>	<b>36.2%</b>	<b>44.3%</b>	<b>64.4%</b>	
<b>Vertebral levels</b>					0.651
Single level procedure (n=2,855)	77.0%	79.0%	78.5%	78.1%	
Multi-level procedure** (n=816)	23.0%	21.0%	21.5%	21.9%	
<b>Procedure classification</b>					0.714
Outpatient (n=632)	17.0%	17.8%	18.1%	15.1%	
Inpatient (n=3,039)	83.0%	82.2%	81.9%	84.9%	
<b>Anesthesia type</b>					NA
General	100.0%	100.0%	100.0%	100.0%	
Local/MAC/Regional/Spinal	-	-	-	-	
<b>Surgery team</b>					<b>0.012</b>
<b>Attending alone</b>	<b>70.4%</b>	<b>74.4%</b>	<b>75.12%</b>	<b>77.4%</b>	
<b>Attending with resident</b>	<b>29.6%</b>	<b>25.6%</b>	<b>24.9%</b>	<b>22.6%</b>	

\*Body Mass Index (BMI) = bodyweight [kg]/height<sup>2</sup> [m]<sup>2</sup>; <sup>o</sup> included but was not limited to American Indians, Alaska Natives, Asians, or Pacific Islanders; \*\*Multi-level procedure: ≥ 2 levels. ADL (activities of daily living); ASA (American Society of Anesthesiologists). <sup>†</sup> Percentages have been rounded and may not add to 100. NA= not applicable. Bolded items indicate significance (P value ≤ 0.05).

increasing BMI (all  $P < 0.01$ ). Compared with the non-obese patients, obese I, II, III patients were less likely to be alcohol users (>2 drinks/day) or smokers (all  $P < 0.01$ ). There were no differences among BMI groups in the remaining cardiovascular, respiratory, renal, cerebrovascular and other comorbidity categories.

**Table 4.** Comorbidities of patients undergoing anterior cervical fusion by Body Mass Index (BMI\*) groups (N=3,671)<sup>†</sup>

Comorbidities (%)	BMI				P value
	Non-obese (18.5-29.9 kg/m <sup>2</sup> ) n=2,072	Obese I (30-34.9 kg/m <sup>2</sup> ) n=915	Obese II (35-39.9 kg/m <sup>2</sup> ) n=419	Obese III (≥ 40 kg/m <sup>2</sup> ) n=265	
<b>Cardiovascular</b>					
Congestive heart failure	0.1%	0.0%	0.2%	0.0%	0.515
Myocardial infarction	0.1%	0.1%	0.2%	0.0%	0.809
Previous PCI	3.5%	4.3%	4.8%	3.0%	0.445
Previous cardiac surgery	2.7%	2.4%	1.7%	1.5%	0.453
Angina	0.5%	0.5%	1.4%	1.1%	0.115
<b>HTN requiring medication</b>	<b>34.3%</b>	<b>48.7%</b>	<b>55.8%</b>	<b>62.3%</b>	<b>&lt;0.001</b>
Peripheral vascular disease	0.5%	0.8%	0.2%	0.0%	0.352
Rest pain/gangrene	0.0%	0.1%	0.0%	0.0%	0.827
<b>Pulmonary</b>					
<b>Current smoker</b>	<b>37.1%</b>	<b>30.9%</b>	<b>25.8%</b>	<b>20.0%</b>	<b>&lt;0.001</b>
<b>Dyspnea</b>	<b>4.8%</b>	<b>6.9%</b>	<b>11.2%</b>	<b>10.6%</b>	<b>&lt;0.001</b>
COPD	3.0%	3.4%	3.3%	2.3%	0.794
<b>Renal</b>					
Currently on dialysis	0.1%	0.0%	0.0%	0.0%	0.509
<b>Cerebrovascular</b>					
Stroke w/ neurological deficits	1.1%	1.5%	1.2%	1.9%	0.632
Stroke w/ no neurological deficits	1.0%	0.9%	1.2%	0.4%	0.739
Transient ischemic attacks	1.7%	1.3%	2.4%	2.3%	0.478
<b>Other</b>					
Weight loss	0.5%	0.3%	0.2%	0.0%	0.514
<b>Diabetes</b>	<b>7.9%</b>	<b>14.6%</b>	<b>19.6%</b>	<b>28.3%</b>	<b>&lt;0.001</b>
<b>Alcohol use</b>	<b>4.6%</b>	<b>3.6%</b>	<b>1.2%</b>	<b>1.9%</b>	<b>0.003</b>
Open wound/wound infection	0.4%	0.2%	0.2%	0.8%	0.575
Chronic corticosteroid use	2.7%	2.6%	2.9%	1.5%	0.697
Bleeding disorder	0.7%	1.0%	1.4%	1.1%	0.516
Esophageal varices	-	-	-	-	NA
Impaired sensorium	0.1%	0.2%	0.0%	0.0%	0.705
Pre-op blood transfusion	-	-	-	-	NA
Recent surgery (w/in 30 days)	0.7%	0.6%	0.5%	0.8%	0.942
<b>Mallampati scale ≥ 3</b>	<b>10.4%</b>	<b>15.1%</b>	<b>21.3%</b>	<b>23.2%</b>	<b>&lt;0.001</b>

\*Body Mass Index (BMI) = bodyweight [kg]/height<sup>2</sup> [m]<sup>2</sup>; PCI (percutaneous coronary intervention); COPD (chronic obstructive pulmonary disease); HTN (hypertension). <sup>†</sup> Percentages have been rounded and may not add to 100; NA= not applicable. Bolded items indicate significance (P value ≤ 0.05).

### Posterior cervical fusions

We identified 400 patients who underwent posterior cervical fusions. Based on BMI, 247 (61.8%) patients were non-obese and 153 (38.3%) were obese. Differences in patient demographic and clinical characteristics by BMI are shown in the top half of **Table 5**.

There were no significant differences in the composition of the two BMI groups regarding gender, race and age group, or functional status. Regarding process-of-care

variables (**Table 5**, bottom half), the only significant difference between the BMI groups was that obese patients had a greater percentage of patients who were ASA class 3-4 ( $P < 0.05$ ). All posterior cervical fusion patients underwent surgery under general anesthesia.

<b>Table 5. Demographic and clinical characteristics of posterior cervical fusion patients by Body Mass Index (BMI*) groups (N=400)<sup>†</sup></b>			
	<b>BMI</b>		<b>P value</b>
	<b>Non-obese (18.5-29.9 kg/m<sup>2</sup>) n=247</b>	<b>Obese (≥ 30 kg/m<sup>2</sup>) n=153</b>	
<b>Demographic &amp; Clinical Characteristics (%)</b>			
Gender			0.603
Women	41.6%	44.4%	
Men	58.4%	55.6%	
Race			0.495
White	74.1%	71.9%	
Black	13.4%	16.3%	
Hispanic	4.0%	3.3%	
Other <sup>o</sup>	0.4%	2.0%	
Unknown	8.1%	6.5%	
Age group			0.075
Young (18-39 years)	6.5%	5.2%	
Middle Age (40-64 years)	56.7%	68.0%	
Elderly (65-79 years)	26.3%	22.2%	
Super Elderly (≥ 80 years)	10.5%	4.6%	
Functional status prior to surgery			0.195
Independent in ADL	83.4%	88.2%	
Partially/totally dependent in ADL	16.6%	11.8%	
<b>Process-of-care variables (%)</b>			
<b>ASA classification</b>			<b>0.029</b>
<b>1-2</b>	<b>48.2%</b>	<b>36.6%</b>	
<b>3-4</b>	<b>51.8%</b>	<b>63.4%</b>	
Vertebral levels			0.918
Single level procedure (n=193)	48.6%	47.7%	
Multi-level procedure** (n=207)	51.4%	52.3%	
Procedure classification			1.000
Outpatient (n=19)	95.1%	95.4%	
Inpatient (n=381)	4.9%	4.6%	
Anesthesia type			NA
General	100.0%	100.0%	
Local/MAC/Regional/Spinal	-	-	
Surgery team			0.603
Attending alone	58.7%	55.6%	
Attending with resident	41.3%	44.4%	

\*Body Mass Index (BMI) = bodyweight [kg]/height<sup>2</sup> [m]<sup>2</sup>; <sup>o</sup> included but was not limited to American Indians, Alaska Natives, Asians, or Pacific Islanders; \*\*Multi-level procedure: ≥ 2 levels. ADL (activities of daily living); ASA (American Society of Anesthesiologists).

<sup>†</sup>Percentages have been rounded and may not add to 100. NA= not applicable. Bolded items indicate significance ( $P \leq 0.05$ ).



Differences in patient comorbidities by BMI groups for posterior fusions are shown in **Table 6**. When compared to the non-obese group, the percentage of diabetics was higher in the obese group, whereas the percentage of smokers was less (both  $P < 0.05$ ). There were no differences in the remaining comorbidity categories between the two BMI groups.

<b>Table 6. Comorbidities of patients undergoing posterior cervical fusion by Body Mass Index (BMI*) groups (N=400)<sup>†</sup></b>			
<i>Comorbidities (%)</i>	<i>BMI</i>		<i>P value</i>
	<i>Non-obese (18.5-29.9 kg/m<sup>2</sup>) n=247</i>	<i>Obese (≥ 30 kg/m<sup>2</sup>) n=153</i>	
<b>Cardiovascular</b>			
Congestive heart failure	0.4%	0.0%	1.000
Myocardial infarction	0.4%	0.0%	1.000
Previous PCI	6.1%	5.9%	1.000
Previous cardiac surgery	4.0%	2.6%	0.580
Angina	0.4%	0.0%	1.000
HTN requiring medication	54.7%	58.8%	0.468
Peripheral vascular disease	2.0%	2.0%	1.000
Rest pain/gangrene	0.8%	0.7%	1.000
<b>Pulmonary</b>			
<b>Current smoker</b>	<b>30.4%</b>	<b>20.9%</b>	<b>0.048</b>
Dyspnea	6.5%	8.5%	0.552
COPD	8.1%	3.9%	0.143
<b>Renal</b>			
Currently on dialysis	2.4%	0.0%	0.087
<b>Cerebrovascular</b>			
Stroke w/ neurological deficits	3.2%	1.3%	0.329
Stroke w/ no neurological deficits	3.2%	0.7%	0.162
Transient ischemic attacks	3.6%	2.6%	0.774
<b>Other</b>			
Weight loss	1.2%	1.3%	1.000
<b>Diabetes</b>	<b>9.7%</b>	<b>25.5%</b>	<b>&lt;0.001</b>
Alcohol use	8.9%	5.2%	0.241
Open wound/wound infection	2.0%	1.3%	0.713
Chronic corticosteroid use	2.0%	5.9%	0.051
Bleeding disorder	3.2%	2.0%	0.543
Esophageal varices	-	-	NA
Impaired sensorium	2.0%	1.3%	0.713
Pre-op blood transfusion	0.8%	0.0%	0.526
Recent surgery (w/in 30 days)	5.3%	2.6%	0.307
Mallampati scale ≥ 3	16.1%	25.6%	0.321

\*Body Mass Index (BMI) = bodyweight [kg]/height<sup>2</sup> [m]<sup>2</sup>; PCI (percutaneous coronary intervention); COPD (chronic obstructive pulmonary disease); HTN (hypertension). <sup>†</sup>Percentages have been rounded and may not add to 100. NA= not applicable. Bolded items indicate significance ( $P \text{ value} \leq 0.05$ ).

## Unadjusted Outcomes

### *Lumbar Surgery*

On a univariate analysis (**Table 7**), compared with the non-obese group, obese I, II, III patients were more likely to receive a blood transfusion, have extended LOS and have an increased number of wound complications, urinary complications, and at least 1 or more complication(s) overall, but they were less likely to have a CNS complication (all  $P < 0.05$ ). Obese II and III were more likely to have a septic complication, while only obese

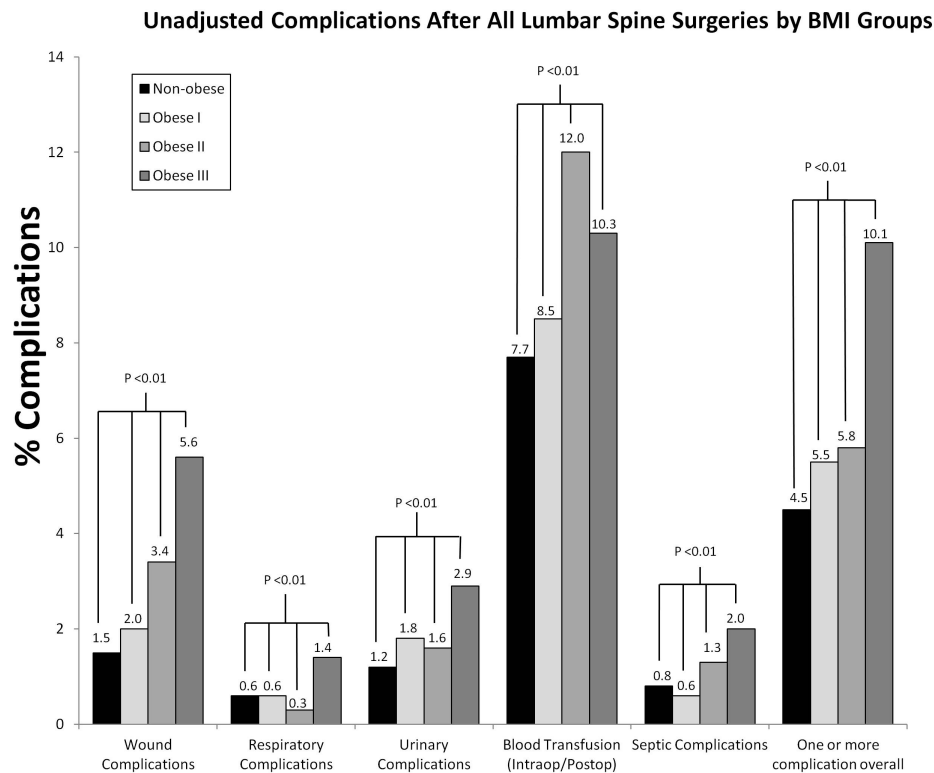
<b>Table 7.</b> Univariate analysis of complications after lumbar surgery by Body Mass Index (BMI) groups (N= 10,387) <sup>†</sup>					
<b>Complications (%)</b>	<b>BMI</b>				<b>P value</b>
	<b>Non-obese (18.5-29.9 kg/m<sup>2</sup>) n=5,813</b>	<b>Obese I (30-34.9 kg/m<sup>2</sup>) n=2,660</b>	<b>Obese II (35-39.9 kg/m<sup>2</sup>) n=1,198</b>	<b>Obese III (≥ 40 kg/m<sup>2</sup>) n=716</b>	
<b>Complications showing significant differences:</b>					
One or more complication(s) overall	4.5%	5.5%	5.8%	10.1%	<0.001
Extended Length of Stay (LOS) <sup>1</sup>	26.4%	28.6%	31.8%	36.3%	<0.001
Wound Complications <sup>2</sup>	1.5%	2.0%	3.4%	5.6%	<0.001
Blood Transfusion (Intraop/Postop)	7.7%	8.5%	12.0%	10.3%	<0.001
Urinary Complications <sup>3</sup>	1.2%	1.8%	1.6%	2.9%	0.001
Septic Complications <sup>4</sup>	0.8%	0.6%	1.3%	2.0%	0.001
Respiratory Complications <sup>5</sup>	0.6%	0.6%	0.3%	1.4%	0.042
CNS Complications <sup>6</sup>	0.4%	0.2%	0.0%	0.1%	0.048
<b>Complications not showing significant differences:</b>					
Cardiac Complications <sup>7</sup>	0.3%	0.2%	0.1%	0.1%	0.325
Death	0.1%	0.1%	0.0%	0.1%	0.644
Pulmonary Embolism	0.3%	0.4%	0.4%	0.6%	0.685
Return to the OR w/in 30 days	3.0%	3.2%	3.6%	3.5%	0.747
DVT/Thrombophlebitis	0.6%	0.7%	0.6%	0.4%	0.780
Graft/Prosthesis/Flap Failure	0.1%	0.0%	0.0%	0.0%	0.802

<sup>1</sup>LOS that exceeds the 70<sup>th</sup> percentile of the LOS in the study population for each procedure as follows: anterior fusion ≥ 6 days; posterior fusion ≥ 5 days; TLIF/PLIF ≥ 5 days; discectomy ≥ 2 days; decompression ≥ 4 days; <sup>2</sup>Includes superficial, deep, organ/space surgical site infection, and wound disruption; <sup>3</sup>Progressive renal insufficiency, acute renal failure, urinary tract infections; <sup>4</sup>Sepsis and septic shock; <sup>5</sup>Pneumonia, unplanned intubation, failure to wean off ventilator; <sup>6</sup>CVA/stroke with neurological deficit, coma >24 hrs., peripheral nerve injury; <sup>7</sup>Cardiac arrest requiring CPR, myocardial infarction; <sup>†</sup>Percentages have been rounded and might not sum to 100. Bolded items indicate significance ( $P \leq 0.05$ ).

III patients were more likely to have a respiratory complication ( $P < 0.05$ ). There were no differences between BMI groups regarding the rates of death, PE, DVT,

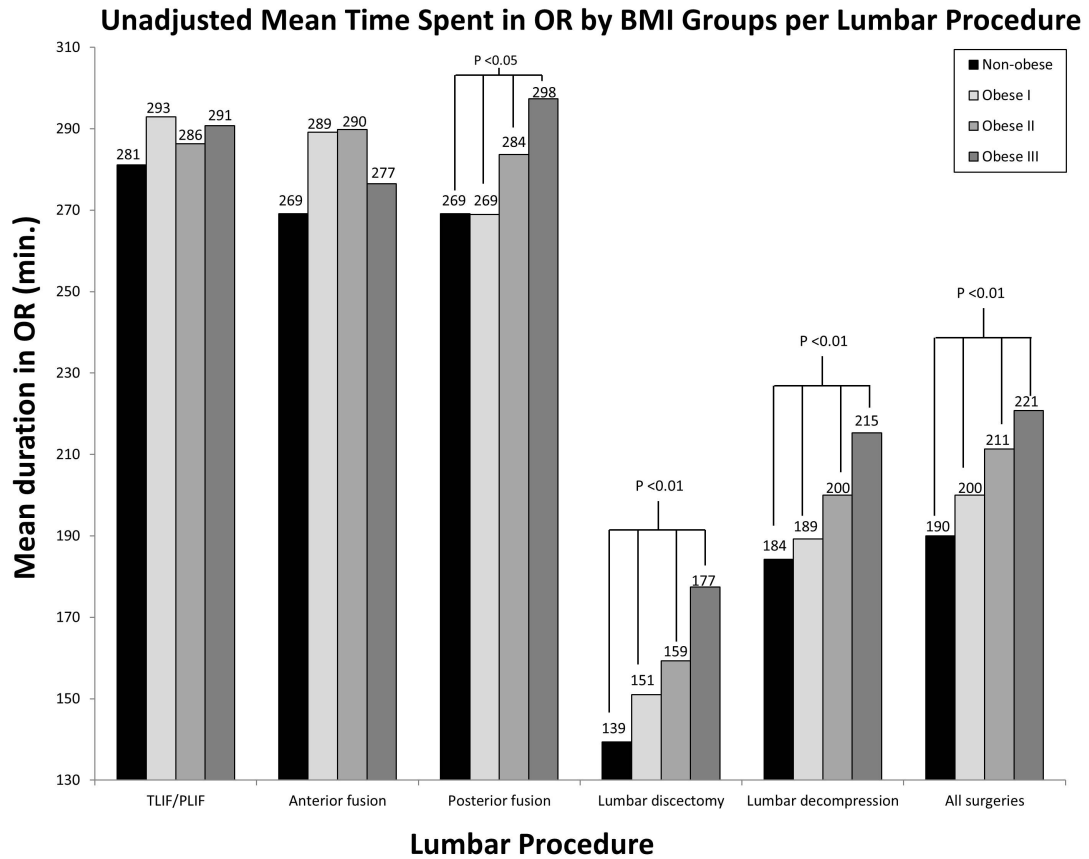
graft/prosthesis/flap failure, return to the operating room or cardiac complications.

**Figure 1** shows a graphic representation of **Table 7** for complications that were significantly associated with high BMI.



**Figure 1.** Unadjusted 30-day clinical outcomes of patients who underwent lumbar spine surgery by BMI group.

**Figure 2** shows the mean duration in the OR for patients by procedure. Compared with normal BMI patients, patients with higher BMIs, in general, spent a significantly greater duration of total time in the operating room for all lumbar surgeries combined. Looking at individual procedures, high BMI was associated with longer times in the OR only for posterior fusions, discectomies, and decompressions, but not for TLIF/PLIF or anterior fusions.



**Figure 2.** Unadjusted mean time spent in the operating room for patients undergoing different lumbar surgery procedures by BMI group.

### *Cervical Surgery*

On univariate analysis for anterior cervical fusions (**Table 8**), obese III patients were more likely to have a DVT when compared to the rest of the BMI groups ( $P < 0.05$ ). For both anterior and posterior cervical fusions, there were no differences among BMI groups regarding the rates of having an extended LOS, death, PE, blood transfusions, re-operation within 30-days, and of having wound, respiratory, urinary, CNS, cardiac, septic, and  $\geq 1$  complication(s) overall.

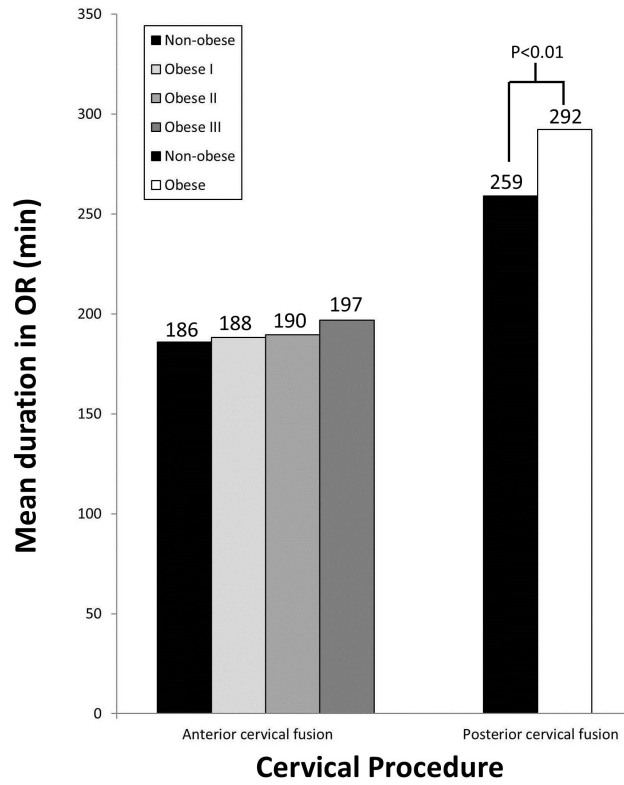
**Table 8.** Univariate analysis of complications and OR times after anterior and posterior cervical fusion by Body Mass Index (BMI)<sup>†</sup>

	<i>Anterior Cervical Fusions</i>					<i>Posterior Cervical Fusions</i>		
	<i>Non-obese</i>	<i>Obese I</i>	<i>Obese II</i>	<i>Obese III</i>	<i>P</i>	<i>Non-obese</i>	<i>Obese</i>	<i>P</i>
	<i>n=2,072</i>	<i>n=915</i>	<i>n=419</i>	<i>n=265</i>	<i>value</i>	<i>n=247</i>	<i>n=153</i>	<i>value</i>
<b>Complications (%)</b>								
Extended Length of Stay <sup>1</sup>	17.7%	15.8%	18.9%	20.0%	0.321	19.8%	18.3%	0.794
Wound Complications <sup>2</sup>	0.8%	0.8%	1.0%	0.8%	0.986	3.6%	3.9%	1.000
Respiratory Complications <sup>3</sup>	1.0%	1.0%	1.0%	1.5%	0.868	2.4%	3.3%	0.755
Death	0.3%	0.0%	0.2%	0.4%	0.423	0.8%	0.0%	0.526
Urinary Complications <sup>4</sup>	0.4%	0.4%	0.5%	0.8%	0.910	2.8%	2.0%	0.748
CNS Complications <sup>5</sup>	0.3%	0.3%	0.0%	0.4%	0.711	0.8%	2.0%	0.375
Cardiac Occurrences <sup>6</sup>	0.2%	0.2%	0.0%	0.0%	0.705	0.8%	0.0%	0.526
Septic Complications <sup>7</sup>	0.1%	0.2%	0.0%	0.0%	0.705	2.0%	0.7%	0.414
Pulmonary Embolism	0.1%	0.0%	0.5%	0.4%	0.102	0.4%	0.7%	1.000
DVT/Thrombophlebitis	<b>0.4%</b>	<b>0.0%</b>	<b>0.0%</b>	<b>1.1%</b>	<b>0.014</b>	0.4%	2.6%	0.073
Blood Transfusion <sup>8</sup>	0.7%	0.4%	0.5%	0.8%	0.845	9.7%	11.1%	0.735
Return to the OR	2.0%	1.5%	2.1%	2.3%	0.769	6.5%	4.6%	0.511
Graft/Prosthesis/Flap Failure	0.0%	0.0%	0.0%	0.0%	NA	0.0%	0.0%	0.0%
≥ 1 complication overall <sup>9</sup>	2.8%	2.4%	3.1%	3.8%	0.656	10.5%	11.1%	0.869

<sup>1</sup>LOS that exceeds the 80<sup>th</sup> percentile of the LOS in the study population: for anterior fusions, extended LOS ≥ 3 days; for posterior fusions extended LOS ≥ 8 days; <sup>2</sup>Includes superficial, deep, organ/space surgical site infection, and wound disruption; <sup>3</sup>Pneumonia, unplanned intubation, failure to wean off ventilator; <sup>4</sup>Progressive renal insufficiency, acute renal failure, urinary tract infections; <sup>5</sup>CVA/stroke with neurological deficit, coma >24 hrs., peripheral nerve injury; <sup>6</sup>Cardiac arrest requiring CPR, myocardial infarction; <sup>7</sup>Sepsis and septic shock; <sup>8</sup>Intra-op/postop blood transfusion. <sup>9</sup>Includes any of the complications listed with the exception of extended LOS, blood transfusion, and return to the OR. <sup>†</sup>Percentages have been rounded and might not sum to 100. NA= not applicable. Bolded items indicate significance (P value ≤ 0.05).

Compared with non-obese patients, obese I, II, III patients did not show significant differences in the total OR. In posterior cervical fusions, however, obese patients had, on average, a longer total OR time and surgical time than non-obese patients (both  $P < 0.05$ ) (Figure 3).

### Unadjusted Mean Time Spent in OR by BMI Groups per Cervical Procedure

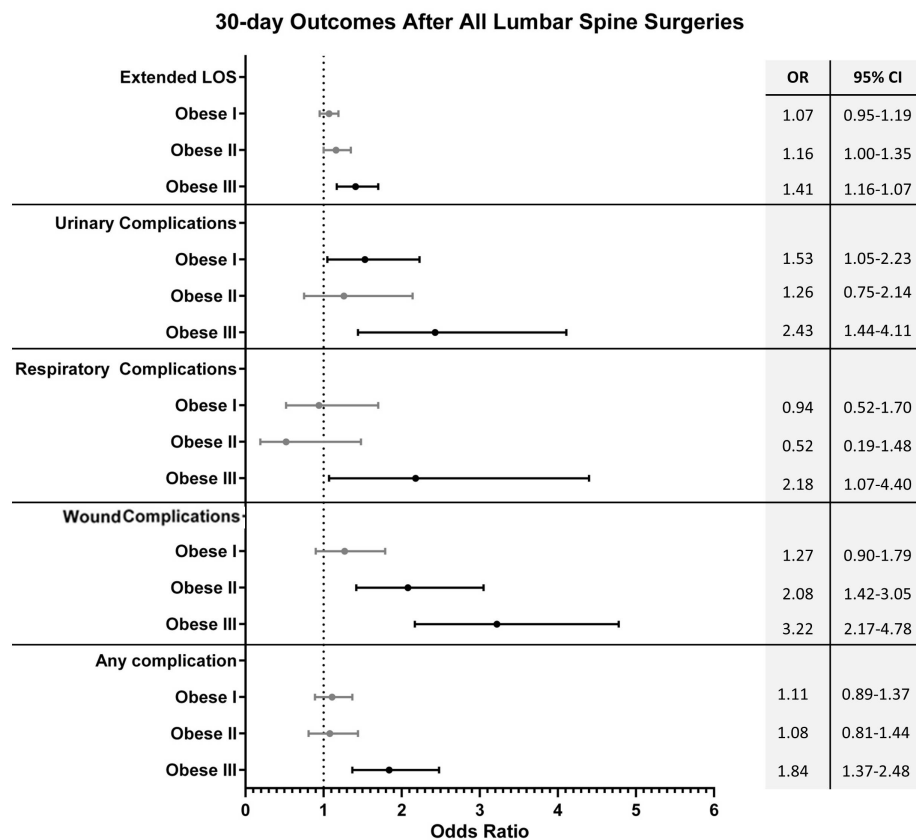


**Figure 3.** Unadjusted mean time spent in the operating room for patients undergoing anterior or posterior cervical fusion surgery by BMI group.

## Adjusted Outcomes

### *Lumbar Surgery*

On a multivariable logistic regression of the entire lumbar surgery population (**Figure 4**), obese II and III patients had an increased risk for having a wound complication. Obese I and III had an increased risk for having a urinary complication. Only obese III patients, however, were at an increased risk for having an extended LOS, a respiratory complication, and of having 1 or more complication(s) overall.



**Figure 4.** Adjusted 30-day postoperative outcomes for patients after all lumbar spine surgeries by BMI group. The non-obese groups of patients (BMI 18.5-29.9 kg/m<sup>2</sup>) were used as the reference group for each procedure and are thus not shown in the figure.

Other predictors for each complication category were as follows (data not shown): wound complications—diabetes, chronic corticosteroid use, multiple-level surgery; urinary complications—inpatient procedure, old age ( $\geq 65$  years), DNR status, esophageal varices, higher ASA class, and multiple-level surgery; extended LOS—female gender, non-white race, old age, dependent functional status, prior surgery in the previous 30 days, general anesthesia, inpatient surgery, higher ASA class; respiratory complications—functional dependent status, chronic corticosteroid use. No differences were observed in risk of death, PE, DVT, graft/prosthesis/flap failure, having a blood transfusion, returning to the operating room or in CNS, cardiac, or septic complications among BMI groups.

Compared with non-obese patients, only obese III patients had greater duration of total operating room times ( $\beta$ -coefficient [minutes] 13.2,  $P < 0.05$ ).

The adjusted outcomes for each lumbar surgery procedure by obesity class are shown on **Table 9**. In anterior fusions, obesity class II showed an increased risk for wound complications. In posterior fusions, obesity class II showed an increased risk for urinary complications and septic complications, whereas obesity class III showed an increased risk for extended LOS, wound complications, respiratory complications, urinary complications, and one or more overall complication(s) overall. In TLIF/PLIFs obese I, II, and III were more likely to have a wound occurrence, while only obese II patients were more likely to receive a blood transfusion. In lumbar discectomy, obese II patients were more likely to have an extended LOS, obese II and III a wound complication, obese



I, II, III a blood transfusion and one or more complication(s) overall. In lumbar decompression, only obese III patients were more likely to have a wound complication.

<b>Table 9.</b> Adjusted outcomes by BMI for each Lumbar Procedure	<b>BMI</b>		
	<b>Obese I (30-34.9 kg/m<sup>2</sup>)</b>	<b>Obese II (35-39.9 kg/m<sup>2</sup>)</b>	<b>Obese III (≥ 40 kg/m<sup>2</sup>)</b>
<b>Lumbar Procedure Complications</b>	<b>OR (95% CI)</b>	<b>OR (95% CI)</b>	<b>OR (95% CI)</b>
<b>ANTERIOR FUSION</b>			
Wound Complications	0.99 (0.19-5.31)	<b>5.6 (1.53-20.46)*</b>	NA
<b>POSTERIOR FUSION</b>			
Extended Length of Stay	0.98 (0.76-1.26)	1.24 (0.89-1.71)	<b>1.86 (1.24-2.79)*</b>
Wound Complications	1.22 (0.62-2.42)	1.70 (0.78-3.70)	<b>2.86 (1.28-6.43)*</b>
Pulmonary Complications	0.76 (0.20-2.89)	0.53 (0.07-4.30)	<b>5.53 (1.75-17.50)*</b>
Urinary Complications	1.84 (0.88-3.84)	<b>2.55 (1.10-5.90)*</b>	<b>5.60 (2.46-12.75)*</b>
Septic Complications	0.69 (0.22-2.24)	<b>3.20 (1.20-8.53)*</b>	2.79 (0.84-9.30)
Any Complication Overall	1.02 (0.67-1.55)	1.09 (0.64-1.84)	<b>2.33 (1.37-3.96)*</b>
<b>TLIF/PLIF</b>			
Wound Complications	<b>5.68 (1.09-29.60)*</b>	<b>7.18 (1.18-43.72)*</b>	<b>11.97 (1.19-73.55)*</b>
Blood Transfusion	0.86 (.50-1.47)	<b>1.96 (1.08-3.55)*</b>	0.61 (0.24-1.55)
<b>DISCECTOMY</b>			
Extended Length of Stay	1.12 (0.92-1.35)	<b>1.32 (1.02-1.73)*</b>	1.28 (0.94-1.76)
Wound Complications	0.95 (0.50-1.82)	<b>2.14 (1.09-4.19)*</b>	<b>3.40 (1.76-6.56)*</b>
Blood Transfusion	<b>2.25 (1.29-3.92)*</b>	<b>2.59 (1.31-5.11)*</b>	<b>2.94 (1.42-6.07)*</b>
Any Complication Overall	<b>2.12 (1.21-3.71)*</b>	<b>2.48 (1.25-4.91)*</b>	<b>2.87 (1.38-5.96)*</b>
<b>DECOMPRESSION</b>			
Wound Complications	1.40 (0.77-2.52)	1.84 (0.91-3.74)	<b>4.10 (2.12-7.95)*</b>

\* P<0.05

### *Cervical Surgery*

Multivariable logistic regression analyses were then performed to address any confounding variables. This was done separately for anterior and posterior cervical cases. **Figure 5** shows selected 30-day adjusted outcomes after both anterior cervical fusions (**top half**) and posterior cervical fusions (**bottom half**) from the multivariate analyses. The non-obese groups of patients (BMI 18.5-29.9 kg/m<sup>2</sup>) were used as the reference group for each procedure and are thus not shown in the figure.

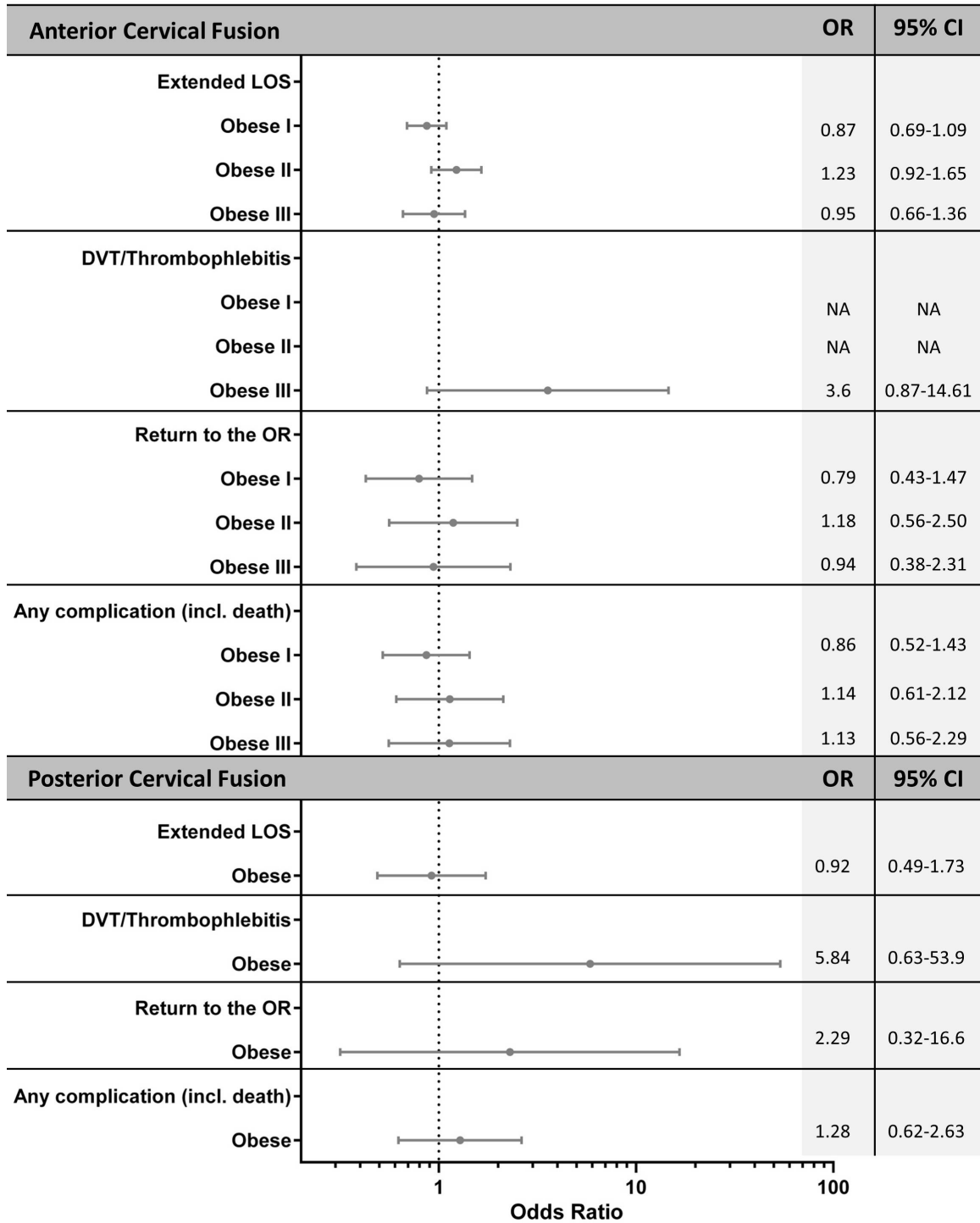
Since there were very few differences seen on univariate analyses for those in the different BMI groups, only variables thought to highlight the most relevant clinical data are shown in the **Figure 5** (extended LOS, DVT/thrombophlebitis, return to the OR, and any complication). DVT/thrombophlebitis is shown as a separate variable since it proved significant for anterior cervical fusions in univariate analysis.

### Anterior Cervical Fusion

As shown in **Figure 5 (top half)**, when compared to the non-obese patient cohort (reference group; not shown in figure), the obese I, II, and III patients did not show an increased risk for having an extended length LOS, a DVT, a re-operation within 30 days, and of having  $\geq 1$  complication overall, including death after anterior fusions. Although not shown in the figure, the patients in the three obesity groups also were not at an increased risk for receiving a blood transfusion, having a PE, and for having wound, respiratory, urinary, CNS, cardiac, and septic complications (data not shown).

Regarding total time spent in the OR by anterior cervical fusion patients, the multivariable linear regression analysis did not show longer total OR times for obese I, II, III patients ( $\beta$ -coefficients [minutes]: 1.84, 3.79, 8.29, respectively, all  $P > 0.05$ ) or longer surgical times ( $\beta$ -coefficients [minutes]: -1.59, 0.35, 5.31, respectively, all  $P > 0.05$ ) when compared to non-obese patients.

### 30-day Outcomes After Cervical Fusion by Obesity Classes



**Figure 5.** Adjusted 30-day postoperative outcomes for patients after anterior and posterior cervical fusion by obesity categorization. The non-obese groups of patients (BMI 18.5-29.9 kg/m<sup>2</sup>) were used as the reference group for each procedure and are thus not shown in the figure.

### Posterior Cervical Fusion

The bottom half of **Figure 5** shows the adjusted 30-day outcomes after posterior cervical fusion in the obese group when compared to the non-obese group (reference group; not shown in figure). Similar to the anterior cervical fusion cohort, the obese were not at an increased risk for having an extended length LOS, a DVT, a re-operation within 30 days, and of having  $\geq 1$  complication overall, including death. There were also no differences in the other complication categories not shown in the figure.

Regarding total time spent in the OR by posterior cervical fusion patients, the multivariable linear regression analysis did not show longer OR times for obese patients ( $\beta$ -coefficient [minutes]: 20.45;  $P=0.083$ ) or longer surgical times ( $\beta$ -coefficient [minutes]: 13.33;  $P=0.175$ ) when compared to non-obese patients—despite showing a significant difference in the univariate.

## **DISCUSSION**

### *Summary of findings*

Obesity is a growing problem in the US and its prevalence has driven research towards understanding surgical outcomes in this population. However, there are mixed results regarding surgical outcomes in the obese after lumbar spine surgery and there is a paucity of literature on short-term outcomes after anterior and posterior cervical fusions in patients with high BMIs. This thesis thus aimed to examine the 30-day clinical outcomes from five common lumbar and two common cervical spine procedures in patients with high BMIs.

Although prior studies have examined the impact of BMI on operative outcomes after spine surgery, this is the first multi-institutional, large scale study to use the WHO obesity classifications to determine the obesity class at which patients are more likely to have a post-operative complication after five common lumbar spine surgeries and anterior cervical fusions. It is also the first study to characterize the 30-day post-surgical outcomes after posterior cervical fusions in the obese ( $\text{BMI} \geq 30 \text{ kg/m}^2$ ) population.

After adjusting for possible confounders, this study showed that complication rates for patients with high BMIs undergoing lumbar surgery were relatively low for obese class I and II patients but had a significant stepped increase for class III obesity patients, particularly for wound complications. It also showed that in lumbar surgery, only obese

class III were more likely to have an extended LOS and longer total OR times when compared to non-obese patients.

Regarding anterior and posterior cervical fusions, this study showed on univariate analyses that obese III patients ( $\text{BMI} \geq 40 \text{ kg/m}^2$ ) had a higher incidence of DVT after anterior fusions and that obese patients ( $\text{BMI} \geq 30 \text{ kg/m}^2$ ) had longer total OR times after posterior fusions when compared to non-obese patients ( $\text{BMI} 18.5\text{-}29.9 \text{ kg/m}^2$ ). However, after adjusting for possible confounders in each procedure, these differences did not retain significance. There were also no significant differences after adjusting for possible confounders in all other complication categories for all three obesity classes after anterior cervical fusions and for obese patients ( $\text{BMI} \geq 30 \text{ kg/m}^2$ ) after posterior cervical fusions. We also showed no differences in the proportion of patients who had extended LOS stay and total OR times among the BMI groups for both procedures after multivariable regression analyses.

### *Lumbar Spine Surgery Results in the Context of Existing Literature*

Prior studies that have looked at the effect of obesity on lumbar surgery outcome have had limitations. The two largest lumbar surgery studies analyzing outcomes in the obese population defined their obese cohort with the use of *ICD-9* coding and focused mostly on lumbar fusions (3, 13). Using *ICD-9* codes for obesity classification has its limitations as this was a voluntarily reported variable that could lead to inaccurate or absent coding; i.e. lack of obesity coding would result in obese patients being included in the normal-

weight category. Highlighting this concern, one study of *ICD-9* codes in spine surgery demonstrated that *ICD-9* codes are prone to greater error regarding surgical complications than prospective methods for assessment of complications (34). Lastly, a limitation of the databases used in these two studies was that the data included only in-hospital events, therefore, post-discharge complications would not have been included in those analyses by definition.

Nevertheless, this thesis confirms expected previous studies' findings that obese patients are at an increased risk of complications after lumbar spine surgery (3, 8-11). In particular, this thesis confirms that obese patients are more likely to have wound (3, 8, 10, 12, 13), respiratory (3), and urinary (3) complications as well as an extended LOS and longer operative times (15) after lumbar surgery. This thesis adds to the literature in that wound complications were most common in class III obesity patients after all types of lumbar surgery and in that obese class III patients, overall, are particularly likely to have at least one or more complication(s) after all lumbar surgeries, especially after posterior fusions or lumbar discectomies.

The finding of greater incidence of wound complications among obese II and III patients after lumbar surgery merits further discussion as several studies have noted increased rates of wound complications/infections in obese patients (3, 8, 10, 12, 13). This thesis suggests that having a BMI  $\geq 35$  places patients at a higher likelihood for developing a wound complication is after lumbar surgery. In general, the higher the BMI of a patient is, the more adipose tissue the patient is likely to have in the back. This is of particular

clinical relevance, as a recent study published by Mehta et al. (24) demonstrated that horizontal distance from the lamina to the skin surface and thickness of the subcutaneous fat are significant risk factors for surgical site infections after lumbar spinal fusion. In their study, Mehta et al. noted that BMI and diabetes were not significantly associated with infections but that having multiple-level surgery was. This thesis's lumbar surgery results are similar to Mehta et al.'s study in that multiple level surgery was found to be a significant predictor for having a wound complication (odds ratio [95% CI]: 1.71 [1.25-2.35]), but differ in that diabetes was also found to be a significant independent predictor for wound complications (odds ratio [95% CI]: 1.78 [1.31-2.42]). Notably on the multivariate analysis, neither having multiple-level surgery nor having diabetes was as strong of a predictor for wound complications as being obese class II or III (odds ratios [95% CI]: 2.08 [1.42-3.05], 3.22 [2.17-4.78], respectively). It should be noted that diabetes is a known risk factor for poor wound healing after spine surgery (35-37) and that the possible mechanisms for delayed wound healing in diabetics have been explored (38-41). In the lumbar patient population of this study, diabetes had a prevalence of 23.7% and 30.2% in the obese II and III cohorts, respectively, and it certainly was a significant predictor for wound complications but not as strong as being either obese class II or III as noted above.

In addition to Mehta et al.'s study, it is important to remember that other studies have cited a greater rate of blood transfusions and of intraoperative blood loss in the obese patient population after lumbar surgery (11-13, 15) as well as longer operative times (15). In the lumbar surgery patient population this study found longer durations in the operating room in the obese class III patients, and an increased rate of blood transfusions



in univariate associations after all lumbar surgery procedures in the obese cohorts. In multivariate logistic regression there was an increased rate for blood transfusions after lumbar discectomies in the obese I-II-III, and after TLIF/PLIFs in the obese II. These study results are of clinical relevance as they point to a potential mechanism for the pathophysiology behind the increased rate of wound complications in obese patients after lumbar surgeries: the combination of longer incisions, longer operation times, greater intraoperative blood loss, greater transfusion rates, greater diabetes prevalence, and greater quantity of soft/adipose tissue that is manipulated during the surgeries is the ideal set-up for tissue necrosis secondary to hypo-perfusion. Thus, it is of no surprise that MIS approaches have been shown to have no increased risk for wound infections in the obese (19-21). The incisions are smaller, there is less blood loss, and there is less soft tissue manipulation.

#### *Cervical Spine Surgery Results in the Context of Existing Literature*

Regarding cervical fusions, this thesis's results differ from the only other large-scale study that has characterized in-hospital complications and costs for morbidly obese/obese class III ( $\text{BMI} \geq 40\text{kg/m}^2$ ) patients after anterior and posterior cervical fusions (3). Unlike this thesis, the referenced study showed an increased risk of in-hospital complications after anterior cervical fusion in obese class III patients when compared to normal weight patients (defined as absence of obesity in *ICD-9* coding). Similar to this thesis, this referenced study did not show an increased risk for complication in the obese class III after posterior cervical fusions when compared to normal weight patients.

This thesis's results also differ in economic considerations. Although this thesis did not measure direct hospitalization costs, it used LOS and duration of time spent in the OR as proxies for hospitalization costs. This thesis did not show differences in multivariable analysis regarding the proportion of patients who had extended LOS and duration of time spent in the OR among the BMI groups. The Kalanithi study showed increased mean total charges and longer lengths of stay for obese class III patients when compared to normal weight patients. Although there were no differences in this thesis, it should be acknowledged that the Kalanithi study provides a more direct and quantifiable economic analysis given that we estimated hospital costs via OR time and LOS.

The differences in cervical fusion results between this thesis and the Kalanithi study could be attributed to several factors. Despite the difference in sample sizes, there were differences in the study design and outcomes between this thesis and the Kalanithi study. This thesis is a retrospective cohort analysis of prospectively collected data comparing the 30-day post-operative outcomes in obese patients after anterior and posterior cervical fusions. The Kalanithi study was a retrospective cross-sectional study comparing in-hospital outcomes in the morbidly obese vs. non-obese patients after anterior and posterior cervical fusion (their study also included anterior and posterior lumbar fusion and has already been referenced in the lumbar surgery discussion of this thesis). The Kalanithi study is also limited in that it only analyzed in-hospital complications, in that it did not analyze obese patients with a BMI between 30-39.9 kg/m<sup>2</sup> as only patients with BMI  $\geq$  40 kg/m<sup>2</sup> were compared to normal weight patients, and in that it did not list the

number of patients who were morbidly obese in each procedure analyzed—making its results difficult to compare to this study. Furthermore, the Kalanithi study used ICD-9 codes to define its patient population and its morbidly obese cohort. Using *ICD-9* codes for obesity classification has its limitations as discussed previously in the lumbar surgery discussion section of this study.

It should be noted that a recent study published by Schoenfeld et al. (26) using the ACS-NSQIP noted an increase in complication rates with increasing BMI. However, this study looked at cervical, thoracic, and lumbar fusions and did not make a distinction regarding the relative contribution of BMI to adverse outcomes in each procedure. Furthermore, the study did not stratify patients into obesity groups, making the cervical and lumbar results of this thesis difficult to compare to theirs.

A notable finding of this thesis is that obesity was not associated with greater complications after both, anterior and posterior cervical spine fusions despite obesity being a clear risk factor for complications after lumbar spine surgery—particularly for wound complications/infections as demonstrated by this thesis and previous studies (3, 8, 10, 12, 13). There are several possible explanations for this difference. First, anterior cervical approaches likely present less opportunity for infection than the posterior lumbar approaches given the distribution of the subcutaneous tissue in these areas of the body. Although obese patients tend to generally have thicker necks than the non-obese, the amount of adipose tissue that needs to be dissected, retracted, and manipulated in the anterior approach to the cervical spine is significantly less than that of the lumbar spine.

This is of relevance as Mehta et al.'s study has shown that the thickness of subcutaneous fat is an independent risk factor for surgical site infections following lumbar spine fusion (24) as discussed previously in the lumbar surgery section of this discussion. This relationship between increased subcutaneous fat and increased risk for wound infection has also been noted after general surgery procedures (42, 43). To reiterate, in the lumbar spine, in addition to larger amounts of adipose tissue being manipulated, it is likely that the incision is much longer and that operative time is increased in these patients. Longer surgeries subject patients to longer duration of time under anesthesia, prolonged retraction and decreased blood flow, likely increasing tissue necrosis at the operative site (11, 24). In this thesis, there were no differences in the operating room/surgical times among the BMI groups in the anterior cervical fusion cohort—a possible explanation for the lack of relationship between high BMI and wound complications.

Regarding posterior cervical fusions, this thesis did not show an increased risk of wound complications in the obese group despite their longer operating room/surgical times in univariate analyses. Unlike lumbar spinal fusions, it is likely that the infection rate was not higher in the obese since these operation/surgical time differences did not retain significance in the multivariate analysis. Furthermore, BMI on its own may not be a significant predictor for wound complications in the posterior cervical spine. A different study by Mehta et al. showed that a BMI  $\geq 30$  kg/m<sup>2</sup> was not a significant risk factor for surgical site infections after posterior cervical surgery; rather, it showed—in line with other studies—that the thickness of subcutaneous fat was a significant risk factor for infection in this population (25). Subcutaneous fat thickness is not measured in the ACS-

NSQIP, thus we could not assess this relationship in this study; however, one would expect posterior cervical subcutaneous fat to generally increase with increasing BMI. Given that the relative small sample size in this thesis of the posterior cervical fusion cohort did not allow for stratification of BMI groups, it is likely that differences—if any—in wound complication rates among increasing obesity classes were unable to delineated in this study population.

### *Limitations*

This study has several limitations. The ACS-NSQIP database does not report on surgeon volume, academic status of hospitals, insurance type of patients, income group of patients, total in-hospital costs, hospital readmissions or outcomes after 30-days. The ACS-NSQIP also does not capture disease/operation-specific variables; therefore, we could not evaluate such spine-specific complications as bowel/bladder incontinence, neurologic deficit, and implant characteristics. The dataset also does not keep records on preoperative antibiotic use or dosage of any medications given. Since it has been shown that the obese tend to have higher wound infection/complication rates (3, 8, 10, 12, 13), it is possible that some obese patients undergoing anterior or posterior cervical fusions may have received stronger or longer doses of antibiotics for infection prophylaxis, consequently lowering their wound infection rate. Another limitation is that the ACS-NSQIP database does not report on whether patients had obstructive sleep apnea as a comorbid condition. Studies have shown that sleep apnea is endemic in the morbidly obese population (44, 45) and that it is a significant risk factor for postoperative

complications (46). Additionally we were also unable to distinguish MIS from open procedures as these cannot be separated by CPT codes, nor could we account for in-hospital glucose or insulin levels as these were not reported in the database.

Another possible limitation to this study has to do with the relatively low complication rates and small difference in complication rates seen after anterior and posterior cervical fusions between the obese and non-obese. Given that the difference in complication rates between the non-obese and the obese were so low (complication percentage differences ranging from 0.0-2.3%), it is possible that these differences could have been statistically significant had we had a much larger sample size. Indeed, sample size calculations showed that for the complication rates cited in this study to reach adequate power (i.e. > 80%) and show statistically significant differences, much larger sample sizes would have been needed. Sample size calculations for the 30-day complications after anterior and posterior cervical fusions are shown in the Appendix. As can be seen in Table A.1, for anterior cervical fusions, only the obese III group was compared to the non-obese for simplification of the sample size calculations. This was deemed appropriate as  $BMI \geq 40$   $kg/m^2$  was the only obesity group that was compared to normal weight patients in the Kalanithi et al. (3) study. Furthermore, if indeed complication rates increase with increasing BMI in the cervical spine, then this would be the obesity class that would be expected to have the highest complication rates. Similarly, Table A.2 demonstrates the sample size calculations needed to achieve adequate power for the 30-day complications after posterior cervical fusions for the non-obese vs. the obese.

As can be seen in the tables, none of the complications achieved an adequate sample size for the percentages shown to achieve statistically significant differences. Although it may seem that our study is underpowered (e.g. a sample of 66,176 would be needed for the variable “ $\geq 1$  complication overall” to show significance between the obese vs. the non-obese after posterior cervical fusions), it is important to make the distinction between statistically significant results and clinically significant results. Defining clinical significance vs. statistical significance has been a topic of debate in the medical literature (47, 48) and many definitions have been proposed for the term “clinical significance” (49-53). Although individual practices vary, according to Brignardello-Petersen et al.’s paper:

*“[M]ost authors agree that a clinically significant result must fulfill the following criteria:*

- *A change in an outcome or a difference in outcome between groups occurs that is of interest to someone; patients, physicians or other parties interested in patient care conclude that the effect of one treatment compared with another makes a difference.*
- *The change or difference between groups must occur in an important outcome. It can be any outcome that may alter a clinician’s decisions regarding treatment of a patient, such as a reduction in symptoms, improvement in quality of life, treatment effect duration, adverse effects, cost effectiveness or implementation.*
- *The change or difference must be statistically significant. The difference must be greater than what may be explained by a chance occurrence”*

Based on the citation above, “clinical significance” is a relatively subjective term that is dependent upon the viewpoints of several parties (i.e. patients and physicians), thus it is difficult to provide a precise definition for this term in our methods. As clinicians, our

research group believes a *significant* statistical difference greater than 2% between two groups to be of clinical relevance. The complication rates in both the anterior and posterior cervical fusion cohorts are indeed very low for the obese and non-obese groups. As can be seen in the Appendix tables, for anterior cervical fusions, the difference in complication rates between the non-obese and the obese III range from 0.0-2.30%, with only extended LOS having a complication difference > 2% for the obese III vs. the non-obese. Similarly, for posterior cervical fusions, the difference in complication rates between the non-obese and the obese range from 0.30%-2.20%, with only DVT having a complication difference > 2%. As indicated by our sample size analysis, a much larger sample would have been needed to delineate whether there are true differences among these variables. Most importantly however, when looking at the overall picture, the “> 1 complication variable” only showed a 1.00% and 0.60% difference between the BMI groups for anterior cervical fusions and posterior cervical fusions, respectively. These small differences in complication rates suggest that the percentage differences between the BMI groups in the cervical data would not have been clinically relevant to most clinicians even if statistical significance had been reached with a larger sample size. An example of this can be seen in the Kalanithi et al.(3) study as their large sample size showed statistical significance for a few complications (DVT/PE, neurological, and renal complications) that may not have been clinically significant as the complication percentage difference between the obese and morbidly obese was < 1% for each of these complication variables.



Although an adequate power of > 80% was not achieved in the cervical spine analysis, we thus believe that the study's sample of 3,671 anterior cervical fusions and 400 posterior cervical fusions was adequate enough to show that from a clinical standpoint, there does not appear to be an increased risk for obese patients after anterior or posterior cervical fusions based on the percentages presented in this thesis. Nevertheless, we were unable to show *statistical* equivalence between the obese vs. non-obese for the cervical spine group and thus this study should be taken together with the existing literature on outcomes after cervical surgery in the obese population in order to guide clinical management.

A specific limitation to this study has to do with the patient selection for anterior cervical fusions. ACS-NSQIP requires at least one primary CPT code field, thus it is possible that associated codes were not always included. For example, there were cases in which only the cervical discectomy CPT code was listed (CPT 63075) without additional CPT codes. However, given that cervical discectomy rarely occurs without fusion, we assumed that patients with only a primary CPT code of 63075 underwent anterior cervical fusion. Although it is possible that patients could have undergone isolated cervical discectomy, we find this to be unlikely as many cases with a primary CPT code of 63075 had additional codes indicative of fusion (bone graft, instrumentation, etc.) without explicitly listing a fusion code (CPT 22551, 22554). Another limitation of this thesis was that the relatively small sample size for posterior cervical fusions did not allow for direct comparison of this study's posterior cervical results with the Kalanithi study for obese III patients.

Despite these limitations, it should be acknowledged that the advantages of ACS-NSQIP is that it provides detailed clinical information on many patients and that it encompasses academic and private hospitals, thus allowing for analysis of a broad cross-section of the population

### *Conclusions*

In conclusion, this thesis is a multi-institutional study that examined clinical outcomes of patients with different BMIs undergoing five of the most common lumbar surgery procedures, anterior cervical fusions and posterior cervical fusions. This study showed an increase in lengths of stay, operation times and risks of complications after lumbar spine surgery in the obese class III population whereas it did not show differences in the overall and system-specific complication rates, lengths of hospital stay, duration of time spent in the OR, re-operation rates, and death in obese patients after either anterior or posterior cervical fusion surgery when controlling for confounding variables.

Despite demonstrating increased risk of complications for obese class III patients after lumbar surgery, particularly for wound complications, obesity class does not seem to represent an absolute contraindication to surgical intervention. Indeed, the 30-day mortality was less than 1% in obesity class III patients, and the overall 30-day complication rate for these patients was 10.1%. It appears that increased adipose tissue, longer operation times, longer incisions, and increased bleeding/transfusion rates, place

these patients at a higher risk for wound complications after lumbar spine surgery.

Reducing surgical risk to these patients remains an important goal; certainly, additional studies will be needed to assess the outcomes of measures taken to minimize complications in these patients. This data should be helpful to physicians when counseling patients of varying BMI who will undergo lumbar spine surgery or cervical fusion surgery.

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## APPENDIX

Table A.1: Sample size calculation needed to achieve 80% power for each 30-day complication after Anterior Cervical Fusions

	<i>Anterior Cervical Fusions</i>			<i>P</i> <i>value</i>	<i>Sample size per group needed</i> <i>to achieve 80% Power</i>
	<i>Non-obese</i>	<i>Obese III</i>	<i>% diff</i>		
	<i>n=2,072</i>	<i>n=265</i>			
<b><i>Complications (%)</i></b>					
Extended Length of Stay	17.7%	20.0%	2.30%	.351	3,575
Wound Complications	0.8%	0.8%	0.00%	1.00	NA
Respiratory Complications	1.0%	1.5%	0.50%	.341	6,105
Death	0.3%	0.4%	0.10%	.570	43,126
Urinary Complications	0.4%	0.8%	0.40%	.360	4,609
CNS Complications	0.3%	0.4%	0.10%	.570	43,126
Cardiac Occurrences	0.2%	0.0%	0.20%	1.00	3,088
Septic Complications	0.1%	0.0%	0.10%	1.00	6,179
Pulmonary Embolism	0.1%	0.4%	0.30%	.303	3,426
DVT/Thrombophlebitis	0.4%	1.1%	0.70%	.120	7,514
Blood Transfusion	0.7%	0.8%	0.10%	.701	92,042
Return to the OR	2.0%	2.3%	0.30%	.817	28,903
≥ 1 complication overall	2.8%	3.8%	1.00%	.329	273

Table A.2: Sample size calculation needed to achieve 80% power for each 30-day complication after Posterior Cervical Fusions

	<i>Posterior Cervical Fusions</i>			<i>P</i> <i>value</i>	<i>Sample size per group needed</i> <i>to achieve 80% Power</i>
	<i>Non-obese</i>	<i>Obese</i>	<i>%diff</i>		
	<i>n=247</i>	<i>n=153</i>			
<b><i>Complications (%)</i></b>					
Extended Length of Stay	19.8%	18.3%	1.50%	0.794	8,474
Wound Complications	3.6%	3.9%	0.30%	1.000	49,589
Respiratory Complications	2.4%	3.3%	0.90%	0.755	4,226
Death	0.8%	0.0%	0.80%	0.526	769
Urinary Complications	2.8%	2.0%	0.80%	0.748	4,525
CNS Complications	0.8%	2.0%	1.20%	0.375	1,185
Cardiac Occurrences	0.8%	0.0%	0.80%	0.526	769
Septic Complications	2.0%	0.7%	1.30%	0.414	974
Pulmonary Embolism	0.4%	0.7%	0.30%	1.000	7,514
DVT/Thrombophlebitis	0.4%	2.6%	2.20%	0.073	377
Blood Transfusion	9.7%	11.1%	1.40%	0.735	5,878
Return to the OR	6.5%	4.6%	1.90%	0.511	1,795
≥ 1 complication overall	10.5%	11.1%	0.60%	0.869	33,088