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Are guidelines important? Results of a prospective Quality Improvement lumbar fusion project.

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Abstract

Background U.S. healthcare is a volume-based inefficient delivery system. Value requires the consideration of quality, which is lacking in most healthcare disciplines.

Objectives: Patients that met specific EBM based criteria pre-operatively for lumbar fusion would achieve higher rates of achieving the minimal clinical important difference (MCID) than those that did not meet the EBM indications.

Methods: All elective lumbar fusion cases, March 2018 - August 2019, were prospectively evaluated and categorized based on evidence-based medicine (EBM) guidelines for surgical indications. The MCID was defined as a reduction of ≥5 points in ODI. Multiple logistic regression identified multivariable-adjusted Odds Ratio of EBM concordance.

Results: 325 lumbar fusion patients were entered with 6-month follow up data available on 309 (95%). The median preoperative ODI score was 24.4 with median 6-month improvement of 7.0 points ($p<0.0001$). Based on ODI scores: 79.6% (246/309) improved, 3.8% (12/309) no change, and 16% (51/309) worsened. 191 patients had ODI-improvement reaching the MCID. 93.2% (288/309) cases were EBM concordant, while 6.7% (21/309) did not.

In multivariate analysis, EBM concordance ($p=0.0338$), lower preoperative ODI ($p<0.001$), lower ASA ($p=0.0056$), and primary surgeries ($p=0.0004$) were significantly associated with improved functional outcome. EBM-concordance conferred a 3.04 (95%CI 1.10–8.40) times greater odds of achieving MCID in ODI at 6 months ($p=0.0322$), adjusting for other factors.

Conclusion: This analysis provides validation of an EBM guideline criteria to establish optimal patient outcomes. The EBM concordant patients had a greater than three times improved outcome compared to those not meeting EBM fusion criteria.

Key Words: Quality Improvement, Lumbar fusion, Evidence-based medicine criteria, Oswestry disability index.

Short title: Quality improvement in Lumbar Fusion Surgery

Introduction

The United States (U.S.) healthcare delivery system is exceedingly costly, with unconstrained spending and expenditures greater than $3.5 trillion in 2017, or 17.9% of the entire gross domestic product (GDP).[1] Spinal care has mirrored this trajectory of increased expenditures, but outcomes in terms of quality improvement are lacking.

Disorders of the lumbar spine are prevalent throughout industrialized nations, with reported rates of disease increasing.[2,3] Instrumentation and fusion, however, are associated with significantly greater expense compared to other options, and U.S. healthcare system is spending over 34 billion dollars annually on spine fusion related healthcare.[3] This increased expenditure has occurred despite the heterogeneity of fusion indications and lack or limited evidence to support their overall implementation.[4]

The lack of medical literature detailing fusion indications has resulted in significant heterogeneity in clinical decision-making regarding optimal patient care. In

In an attempt to provide improved patient care and surgical outcomes through evidence-based medical (EBM) guidance, the North American Spine Society (NASS) published specific diagnoses and qualifying criteria and indications for lumbar fusion procedures (Table 1)[5].

This project was developed as a prospective Quality Improvement (QI) initiative. The primary hypothesis was that patients that met specific EBM based criteria pre-operatively for lumbar fusion (EBM concordant) would achieve higher rates of achieving the minimal clinical important difference (MCID) than those that did not meet the EBM indications (EBM discordant).

Methods

Study Design

A single-center, observational, prospective cohort study to evaluate the clinical competence of EBM guidelines for lumbar fusion through comparison of functional outcomes at 6 months following surgery was conducted. The study protocol was initially considered a Quality Improvement (QI) project and was exempted from patient consent by the Institutional Review

Board (IRB) before the initiation. Prior to submission for publication, the IRB approved its submission. At onset, the project established a process such that all Neurosurgery spine patients would obtain a validated spine PROM and have elective lumbar fusion procedures evaluated for concordance with the NASS EBM guidelines. (Figure 1)

Patient Population & Outcome Measure

Inclusion criteria consisted of all patients greater than 18 years old who underwent elective lumbar fusion surgery from March 2018 until August 2019. All cases were prospectively and pre-operatively evaluated for compliance with EBM guideline criteria by a panel of neurosurgeons, and determined EBM concordant or EBM discordant. This review process did not alter surgical treatment. Patients with acute trauma or emergently treated patients were excluded from the study.

The patient's history, physical examination, and images were detailed from the medical records. Specific NASS fusion criteria, or "indications" were placed into 9 categories: unstable infection, unstable neoplasm, unstable trauma, deformity, stenosis, disc herniations, synovial cyst, discogenic pain, and pseudarthrosis. Those categories were not mutually exclusive, depending on the clinical situation. Individual surgeon and surgical approaches were recorded as either: anterior, posterolateral, or interbody fusion (transforaminal [TLIF], posterior [PLIF], or lateral [LLIF]). Additional clinical variables collected for data analysis were: age, gender, body mass index (BMI), presence of diabetes, osteoporosis, smoking status, previous spine surgery, and American Society of Anesthesiologists (ASA) class (ranging from I to VI with higher classes indicating high burden of systemic illness). Each patient completed an Oswestry-Disability-Index (ODI) questionnaire at each office appointment to evaluate functional outcome. Traditionally these encounters occur prior to surgery and at 2 weeks, 6 weeks, 3 months, 6 months, 12 months, and 24 months post-operatively.

Statistical Analysis

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A power analysis was performed and estimated a total sample size of 247 with 225 EBM concordant and 22 discordant patients. Statistical analysis was conducted using SAS/STAT® software, Version 9.4 for Windows (SAS Institute Inc., Cary, NC, USA). The primary exposure of interest was concordance of surgical indication for fusion with EBM guidelines for lumbar fusion surgery (‘EBM concordant’ vs. ‘EBM discordant’). The primary metric of interest was an improvement in the patient’s ODI at the 6-month-postoperative.[6] Primary analysis defined outcome as a binary variable on the basis of the minimal clinically important difference (MCID) in ODI – an improvement of greater than or equal to five points from preoperative ODI[7-10]. This cut-off for MCID was chosen based on an anchor-based analysis by Monticone et al. that reported a 4.8-point improvement to be an optimal cut-off for this dichotomous outcome (sensitivity 76% and specificity 63%)[10]. All ODI scores are displayed as raw scores (0-50 points) and not as percent disability (0-100). Secondary analyses examined the mean change in ODI (ΔODI) by outcome classification, as well as stratified by specific NASS criteria indication group.

Univariate comparisons by exposure (concordance) and outcome (MCID) group were conducted as chi-square, Fisher Exact tests, student’s T-tests, and Wilcoxon rank-sum tests as appropriate based on frequency table cell counts, and assumptions of normality.

Multivariable logistic regression was employed primarily to produce models adjusting for confounding variables of the relationship between EBM concordance and MCID ODI. Variables were selected *a priori* based on previously observed associations, including significant factors noted in univariate analysis in the present study population. Iterative model selection methods identified the most optimal predictive/best fitting from all possible models, selecting for maximum chi-square score with the most parsimonious model possible to minimize over-fitting. The most ideal model, at minimum, would include all statistically significant covariates at a significance level of p=0.05; variables inducing a greater than 10% change in existing beta-coefficient parameter estimates were included as meaningful confounders regardless of statistical significance in the model. Automated stepwise variable selection methods were then used to generate the most optimal prediction models from higher-order models, including interaction terms[11]; Model goodness of fit was verified through the use of Hosmer-Lemeshow tests.

Results

Descriptive Statistics & Univariate Comparisons

An initial 325 patients were prospectively enrolled, of which 16 were excluded from the final analysis due to: 3 deaths, 6 lost to follow up, and 7 patients with missing follow-up ODI evaluations. The remaining 309 patients (95%) were included for analysis, of which 93.2% (n=288) had EBM concordant indications for fusion, and 21 patients were determined to be discordant with the EBM guidelines. Descriptive statistics and univariate comparisons by outcome classification group are demonstrated in Table 2. Of these, 57% (n=176) were female, and the median age was 65 years (range: 57-72).

There was a total of 191 patients (62%) with improvement in ODI reaching MCID at 6 months follow-up, and 118 who did not. Among those achieving MCID in ODI, 96% (n=183) were EBM concordant, compared to 89% (n=105) of patients who failed to achieve adequate clinical improvement (n=0.0338). (Figure 2, Table 2) Average patient BMI (p=0.8812), smoking prevalence (p=0.1616), attending surgeon (p=0.1309), Age (p=0.2468), and gender distribution (p=0.6370) were not statistically significantly different between outcome groups on univariate comparison (Table 2).

The median preoperative ODI was 24 (IQR 19-31) overall, with a median 6-month improvement of 7.0 (IQR=4-13). The majority of patients demonstrated an improvement at the 6-month follow-up – 246 patients (79.6%) had improvement in ODI scores, 12 remained unchanged from baseline, and 49 reported worsened ODI. (Figure 3A) Among those who improved, 77.6% (191/246) met MCID (≥ 5 points), and 22.3% showed improvement below the minimum threshold (55/246) (0-5 points); 3.8% (12/309) showed no change, and 16.5% (51/309) worsened in their ODI scores. (Figure 3B) Of those who worsened, 68.6% (35/51) had minor worsening (ΔODI ≤ 5), 29.4% (15/51) severe worsening (ΔODI 6-10), and one catastrophic decline (ΔODI >10). (Figure 3C)

EBM discordant mean ODI improvement was only 2.14 points compared to 7.86 in the concordant patients, for a mean difference of 5.71 (95%CI: 2.15 – 9.28; p=0.0018). (Figure 4) The specific clinical indication for fusion for the remaining cases were: 1% (3/309) infection, 1% (4/309) neoplasm, 2% (7/309) trauma, 19% (59/309) deformity, 44% (136/309) stenosis, 6% (18/309) disc herniations, 4% (11/309) synovial cyst, 6% (18/309) discogenic pain, and 10% (32/309) pseudarthrosis. Concordant cases were also meaningfully associated with improved median change in ODI (Figure 5).

Multivariable Logistic Regression

Multivariable logistic regression supported the hypothesis that EBM concordant cases would be associated with improved clinical outcomes, and identified 4 statistically significant covariates of ODI MCID. The most optimal regression model (Wald χ^2 = 39.54, p<0.0001) included only statistically significant variables predicting MCID in ODI, which included EBM concordance (p=0.0322), preoperative ODI (p<0.0001), ASA Class (p=0.0056), and primary surgery (p=0.0004).

EBM concordance conferred a 3.04 (95%CI: 1.10 – 8.40) times greater odds of achieving MCID in ODI at 6 months (p=0.0322), adjusting for other significant covariate factors (Table 3). Preoperative ODI was also positively associated with 6-month ODI, with a 1.58 (95%CI: 1.34 – 1.87) times greater odds of achieving MCID for every 5-point increase in baseline ODI. Patients with a lower ASA class, as a proxy for overall baseline health, demonstrated a 1.98 (95%CI: 1.22 – 3.21) times greater odds for each 1-point decrease in ASA–equivalent to a 7.76 (95%CI: 1.82 – 32.9) times greater odds for an ASA 1 to achieve MCID compared to an ASA 4. Primary/Index surgeries did demonstrably better than revisions in terms of ODI-- Index cases were found to have an adjusted OR of 2.58 (95%CI: 1.53 – 4.37) for MCID, relative to revision cases (p=0.0004).

Primary versus Revision Surgeries – subset of clinical diagnosis group

There were a greater number of primary vs. revision lumbar fusions (57.9%, [179/309] vs. 42.1%, [130/309]) performed, and primary surgeries had better outcomes. (p=0.018) Revision procedures were associated with worse ODI improvement (6.68 points) compared to primary operations (8.03 points, p= 0.018). There was no significant difference in treatment outcomes based on the analysis of the individual surgeons. (p=0.1309) [Table 2]

Discussion

There is significant heterogeneity in surgeons' indications for lumbar spinal fusion surgery, with rates differing by greater than 20-fold[4,12-14]. Spine surgery is a major driver of cost in the U.S. Surgeons are increasingly performing lumbar fusion procedures, which are often incentivized through a volume-to-revenue correlation. Surgical decision making depends on numerous factors, but lumbar instrumented fusions are more invasive procedures and can result in undue complications and worse functional outcomes. Therefore, there is a need to assure that optimal care is obtained as defined by objective measures.

The heterogeneity of lumbar fusion procedures was highlighted by Weinstein in a review of Medicare data that noted variation for these operations is greater than any other surgical procedure.[4] Further, expenditures have increased 500% from 1992-2003.[4] Hence, present patient care algorithms consists of numerous heterogeneous approaches, treatments, and operations. Unfortunately, these algorithms still leave numerous patients without benefits and thus not maximizing healthcare value. The result has been a progressive increase in the volume of lumbar spine fusions over the last several decades without a concurrent increase in quality.[15]

This heterogeneity of operative care and variability of treatments may result from a lack of clinical knowledge and education from the limited EBM guidelines or high-quality literature on lumbar spinal care.[16-20] One recent meta-analysis of lumbar spine fusion surgery reviewed 9,656 articles and noted only 19 random controlled trials or only 0.19 percent were grade I EBM literature.[20]

To better define optimal patient care, the North American Spine Society (NASS) established evidence-based guidelines and published a "Coverage Policy for Lumbar Fusions" after conducting a comprehensive literature review by multidisciplinary experts[5]. These authors' categorized appropriate criteria for lumbar arthrodesis into nine discrete diagnoses based on disease pathology. However, whether compliance with these or any EBM guidelines criteria for lumbar fusions results in improved functional outcomes, has not been previously evaluated either prospectively or retrospectively. It is necessary to demonstrate the efficacy of spine EBM guideline criteria[21,22]. In this current study, our primary hypothesis was that patients that undergo lumbar fusion procedures in agreement with EBM criteria would have improved functional outcomes based on the measurement of baseline to 6-month ODI scores.

The study population consisted of 93.2% (288/309) EBM concordant and 21 patients (6.8%) EBM discordant patients. In univariate analysis, EBM concordance conferred a greater mean ODI improvement compared to the EBM discordance (~2.1 vs. 7.9, 95% CI: 2.15 – 9.28; p=0.0018) (Figure 4). In addition, multivariable logistic regression revealed that EBM concordance (p=0.0322), preoperative ODI (p<0.0001), ASA class (p=0.0056), and primary surgery (p=0.0004) were all significant predictors of achieving a clinically meaningful improvement in ODI (MCID). The most significant finding of our analysis is that patients whose fusion surgery were EBM concordant had 3.04 (95%CI: 1.10 – 8.40) times greater odds of achieving MCID in ODI at 6 months (p=0.0322) (Table 3). These results were irrespective of the individual spine surgeon and the type of fusion method performed. This analysis was performed on a general or heterogeneous cohort of spine fusion patients with diagnoses, including spondylolisthesis patients. These results concur with the SPORT studies spondylolisthesis analysis that illustrated no superiority of a fusion technique, but rather highlighting the importance of the appropriate indication for fusion surgery to achieve MCID[23].

Although the literature supports increased age as a worse prognostic factor, this was not apparent in our population.[24,25] Overall, in this analysis, age as a single variable did not negatively influence these odds as long as the patient's ASA class was not IV-VI. The ability of the elderly patients to meet MCID parameters may justify a more aggressive approach in healthy elderly patients, including octogenarians, but needs further analysis.

This present series had a larger proportion of revision to primary fusion than most series (42.1% vs. 57.9%), which reflects the quaternary referral pattern of the institution. As reported by Waddell et al. in 1979[26] and Djurasovic et al. in 2011[27], revision lumbar surgeries have a lower likelihood of achieving significant clinical improvement. This series showed that primary lumbar fusion resulted in 2.58 higher odds of reaching MCID over revision procedures is consistent with the literature.[26,27] Although further analysis noted that patients that underwent a revision, in accordance with EBM criteria, had a higher probability of achieving MCID (Table 2). This again is a significant addition to the literature as it provides guidance on managing patient expectations and identifying potential patients with an increasingly higher risk for adverse events.

The present management of lumbar spine conditions consists of a significant variability with unrestrained growth in fusion surgery volume without concurrent improvement in quality[28]. This development is a concern since there is a limitation of healthcare resources. The study demonstrates that utilizing EBM criteria may maximize functional outcomes after lumbar fusion procedures while also achieving better stakeholder alignment and improved value.

Limitations

Unfortunately, there are limitations to this study. ODI is one of the most utilized patient-centric, validated objective outcome measures.[7,29,30] However, this metric does not include data on analgesics usage that may influence functional outcome measurements. For example, post-operatively, patients are weaned off all narcotic medications by six months, and this reduction of opiates, though suggestive of functional improvement, may have a negative effect on the ODI.

Furthermore, some patients developed or had pre-existing non-spine related pathology that affected quality of life, and ODI, post-operatively thereby distorting the quality of life impact of their spine surgery. Finally, the proportion of patients undergoing lumbar fusion for each clinical indication was not consistent.

Conclusion

In summary, in a prospective hypothesis-driven analysis, this study has shown that the use of EBM guidelines and algorithms resulted in improved clinical outcomes (ODI). The data presented in this study illustrates that better functional outcomes were achieved when surgeons followed evidence-based lumbar fusion criteria. Further clarification and definition of the best EBM guidelines are needed to improve the quality of spine care.

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Table 1: Summary of NASS coverage criteria with grading of EBM from which these recommendations were made

Spine fusion indications	
1. Infection	"Based on what most practitioners would consider to be accepted practice patterns"
2. Tumor	"Based on what most practitioners would consider to be accepted practice patterns"
3. Trauma	"Based on what most practitioners would consider to be accepted practice patterns" • **Wood et al:** Prospective noted equivalence for operative versus non-operative treatment.
4. Deformity	• **Level III-** Schwab et al 2006 (Improved PCO treating SVA > 5cm, 30 degrees. • **Level III-Glassman et al 2005** (Improved PCO <4cm SVA). • **Level III- Glassman et al 2010** (Worse PCO with non-Operative deformity.
5. Lumbar stenosis	• **Level I - Herkowitz-** (Degenerative Spondylolisthesis). • **Level I** - Weinstein SPORT data (Stenosis and Degenerative Spondylolisthesis). • **Level I –Möller and Hedlund** (Isthmic Spondylolisthesis). • **Level IV – Abumi** (Facet resection).
6. Discectomy	• **Level IV** – McCulloch (L5-S1 facetectomy).
7. Synovial Cyst	• **Level III – Xu** (Cysts and outcomes).
8. Axial Back pain	• **Level I – Fairbank** (Axial LBP). • **Level I – Fritzell** (Axial LBP).
9. Pseudarthrosis	• **Level II- Cassinelli (pseudarthrosis)** •

PCO: posterior column osteotomy; **SVA:** sagittal vertical axis**; SPORT:** Spine Patient Outcomes Research Trial; **LBP:** Lower back Pain

Table 2: Descriptive statistics for the entire cohort and analysis of those patients that met the MCID compared to those that did not:

	Total Population		MCID ODI = Yes		MCID ODI = No		p-value
	n=309		n=191		n=118		
Age; Median (IQR)	65	57-72	65	56-71	65	57-73	0.2468
Pre-Operative ODI; Median (IQR)	48	38-62	52	40-66	42	32-56	<0.0001
BMI; Mean (SD)	30.28	5.87	30.39	6.06	30.1	5.57	0.8812
Smoking; n (%)	48	16%	34	18%	14	12%	0.1616
Revision; n (%)	130	42%	70	37%	60	51%	0.0176
NASS Concordant; n (%)	288	93%	183	96%	105	89%	0.0338
Surgeon; n (%)							
1	30	10%	17	9%	13	11%	0.1309
2	2	1%	1	1%	1	1%	
3	49	16%	23	12%	26	22%	
4	49	16%	30	16%	19	16%	
5	126	41%	87	46%	39	33%	
6	53	17%	33	17%	20	17%	
Indication; n (%)							
Not indicated	21	7%	8	4%	13	11%	0.0305
Infection	3	1%	2	1%	1	1%	
Tumor	4	1%	2	1%	2	2%	
Trauma	7	2%	6	3%	1	1%	
Deformity	59	19%	34	18%	25	21%	
Stenosis	136	44%	89	47%	47	40%	
Disc Herniation	18	6%	11	6%	7	6%	
Synovial Cyst	11	4%	8	4%	3	3%	
Discogenic Pain	18	6%	16	8%	2	2%	
Pseudarthrosis	32	10%	15	8%	17	14%	

Table 3: Odds Ratio estimates:

Odds Ratio Estimates			
Effect	**Point Estimate**	**95% Wald Confidence Limits**	
EBM Concordant +	3.037	1.099	8.397
Pre-Op ODI	1.096	1.060	1.133
ASA Class	0.505	0.312	0.819
Revision Surgery +	0.387	0.229	0.654

Figure 1: Patient flow diagram. Patients enter and assured to have preoperative ODI performed, then at a weekly conference, this is confirmed and office notes and films reviewed, and cases are categorized by EBM indication. If no EBM category is appropriate, the case is labeled EBM discordant or "not indicated." The patients are followed, and if ODI improved greater than five points, the patient achieved the MCID.

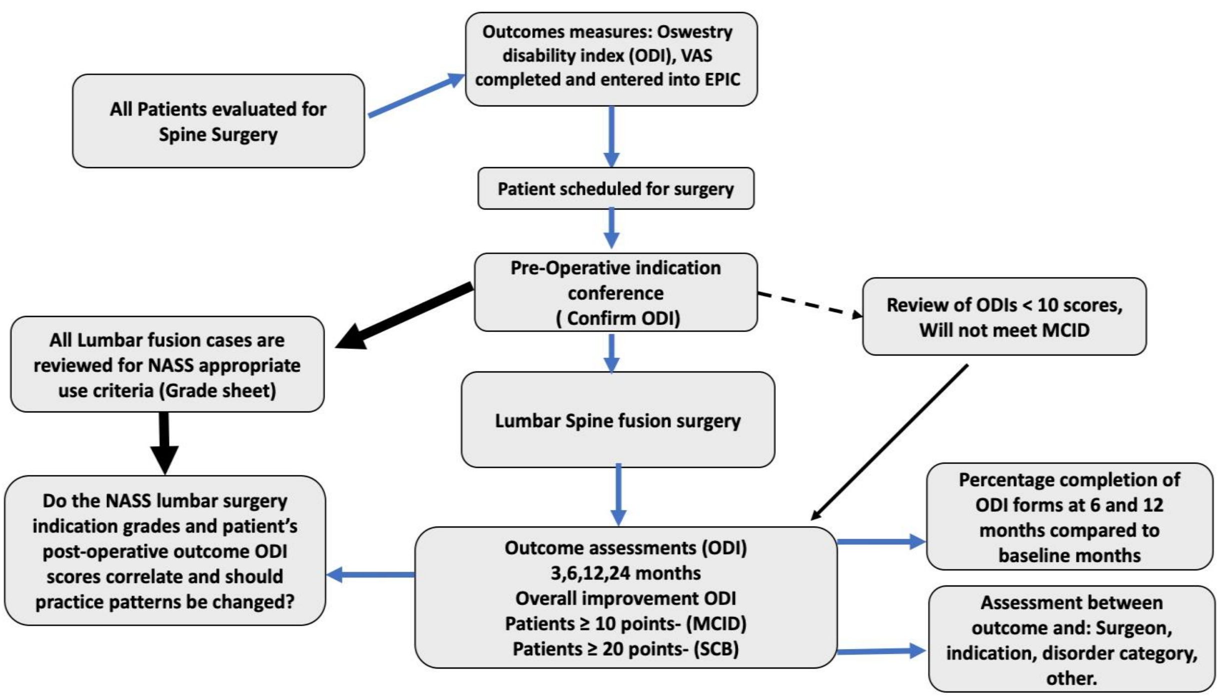


Figure 2: Violin plot and Box/Whisker Plot for the Distribution of Change in ODI at 6 months, stratified by NASS-Concordant indications for lumbar fusion. Width of the violin indicates density of cases at a given Y-axis (delta ODI) value. Circles represent a single case. Box/Whisker Plot box upper/lower bounds are the 25% and 75% limits (Interquartile Range). Dotted box plot lines are the median delta ODI, solid lines are the mean. Y-axis spread of violins and arms of box plots represent range and outliers at either extreme.

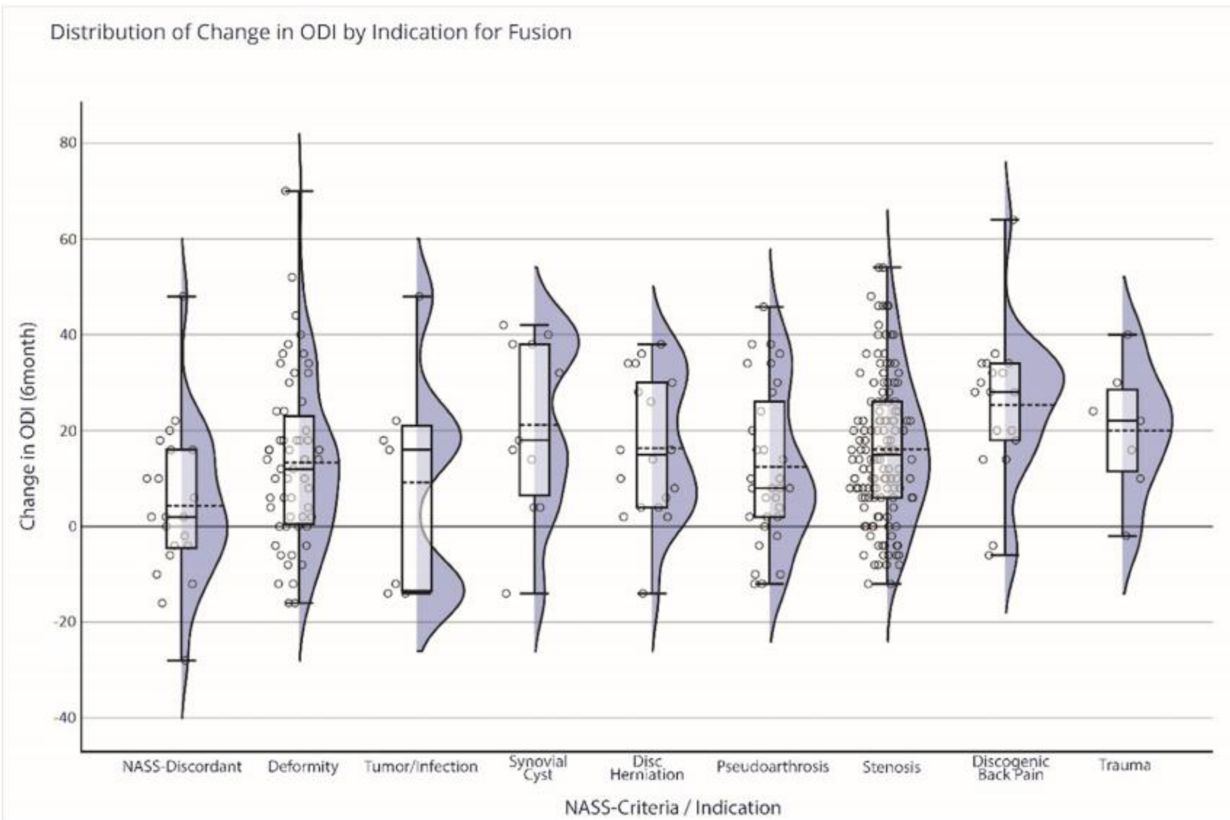
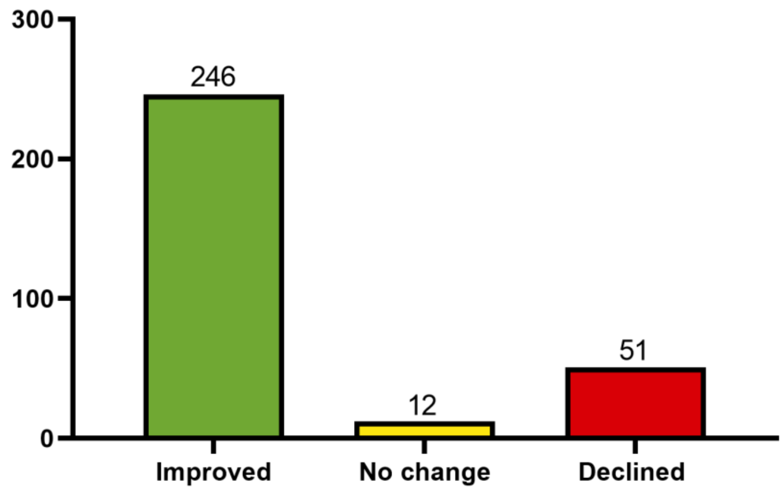


Figure 3: Post lumbar fusion ODI changes from preoperative to 6 months:

- **Figure 3A:** All lumbar fusion patients:



- **Figure 3B:** Subset of patients with improvement in ODI score

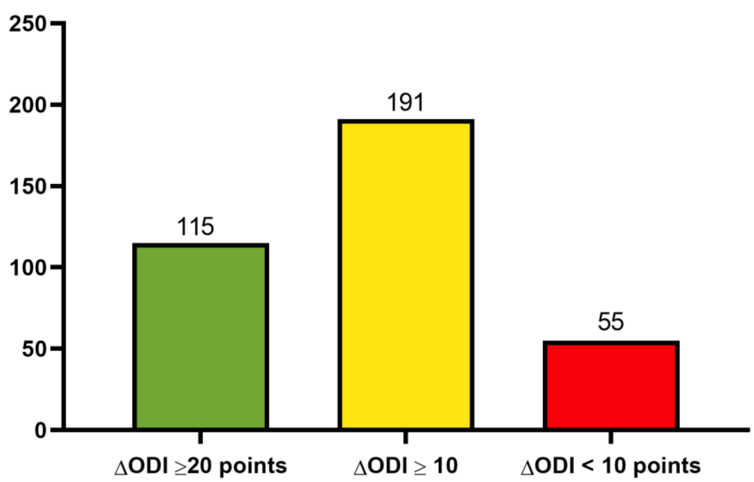


Figure 3C: Subset of patients that worsened in ODI score

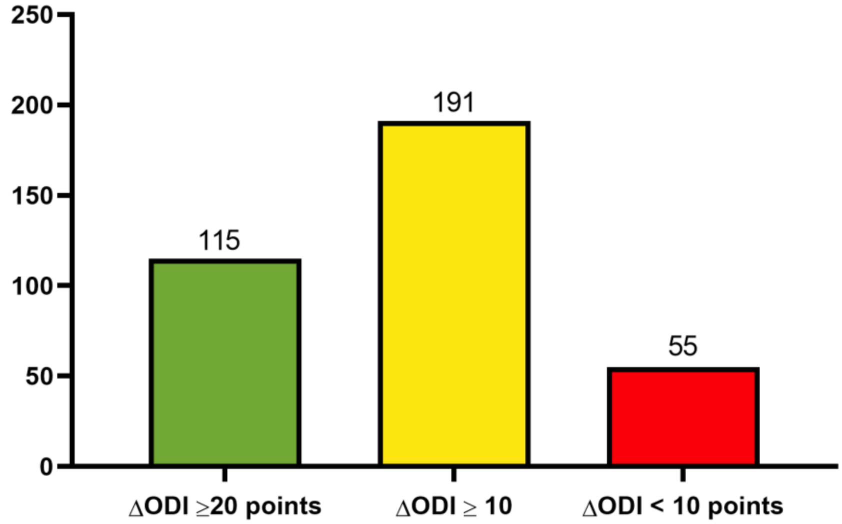


Figure 4: Comparison of improvement from baseline for lumbar fusion patients that met EBM NASS criteria concordant or indicated (Redline) versus EBM NASS discordant or unindicated (Blue line). There is a significantly significant benefit when following the evidence-based medicine guidelines.

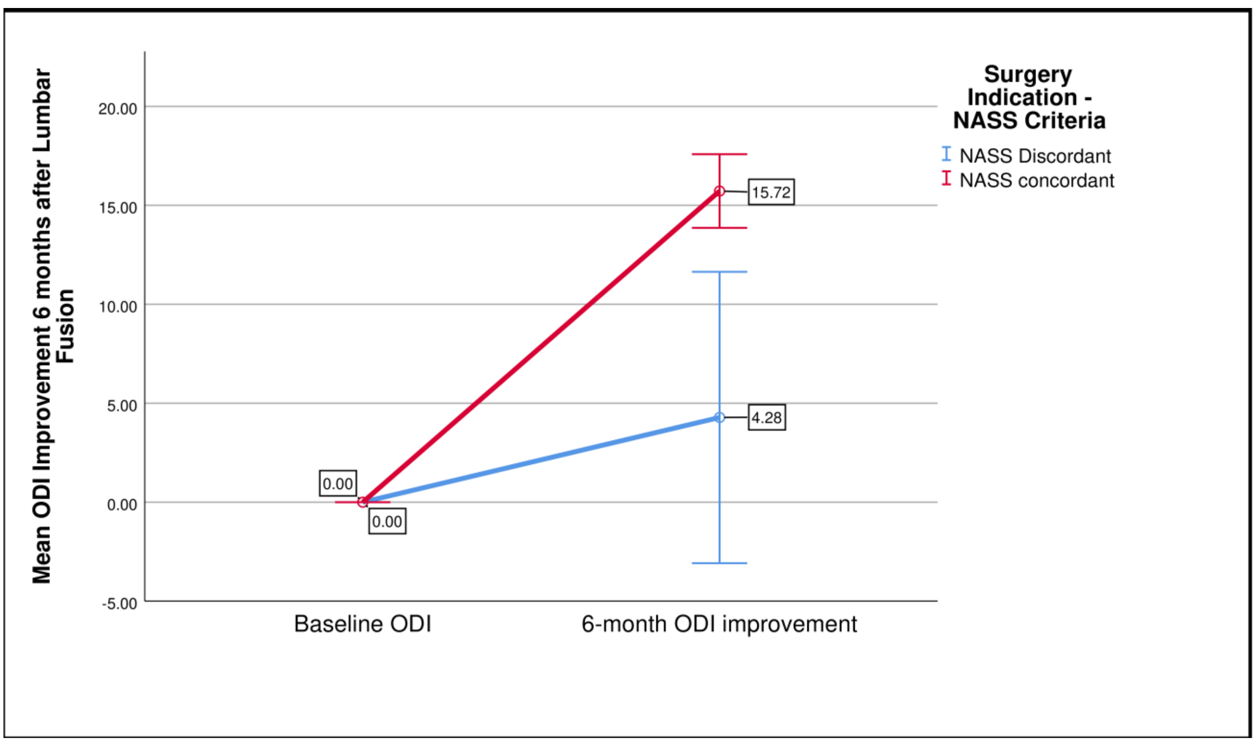


Figure 5: Distribution of EBM concordant cases by clinical diagnosis