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Preoperative risk factors for nonsatisfaction after lumbar interbody fusion

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ABSTRACT

Introduction: Low back pain (LBP) is a common cause of impaired quality of life and disability and studies regarding surgical management of patients with LBP show a high variation in patient-reported success rate. *Research question:* To find valuable preoperative clinical risk factors and variables associated with a non-satisfactory patient-reported outcome following surgery. *Materials and methods:* The Danish surgical spine database (DaneSpine) was used to collect eight years of pre- and postoperative data on patients undergoing single-level fusions with either posterior- (PLIF) or transforaminal lumbar interbody fusions (TLIF). The primary outcome was patient nonsatisfaction. We collected data on European Quality of Life–5 Dimensions (EQ-5D), visual analogue scale (VAS), Oswestry Disability Index (ODI) score, pain intensity, duration of back pain, previous discectomy, and expectations regarding return to work after

surgery at 2-year follow-up. *Results*: The cohort included 453 patients of which 19% reported treatment nonsatisfaction. The nonsatisfaction group demonstrated higher preoperative VAS scores for back pain (75 \pm 19 vs. 68 \pm 21, p = 0.006) and leg pain (65 \pm 25 vs. 58 \pm 28, p = 0.004). The preoperative EQ-5D score was significantly lower in the nonsatisfaction group (0.203 + 0.262 vs. 0.291 \pm 0.312, p = 0.016). There was no statistical significance between patient nonsatisfaction and preoperative ODI score, age, body mass index, duration of back pain or expectations regarding return to work after surgery.

Discussion and conclusion: Low preoperative EQ-5D scores and high VAS leg and back pain scores were statistically significant with patient nonsatisfaction following surgery and may prove to be valuable tools in the preoperative screening and alignment of patient expectations.

1. Introduction

One of the common causes of impaired health-related quality of life and disability is low back pain (LBP) (Husky et al., 2018). In most cases, LBP is a self-limiting condition categorized as non-specific back pain with no identifiable cause of pain (Chou et al., 2014). In other patients, a chronic condition can develop due to pathological structural changes in the spine based on genetic and ageing processes, such as disc degeneration (DD), spinal stenosis, Modic changes (MC), and facet joint degeneration (Chou et al., 2014), (Udby et al., 2022). These structural changes can impact spinal alignment, neural structures, sagittal balance, and reduce physical function and thereby impair the quality of life (Husky et al., 2018), (Mobbs et al., 2015). Overall, chronic LBP-induced disability represents one of the most important disease entities with a major impact on millions of patient lives (Husky et al., 2018). Surgical management is considered in patients with LBP after failed conservative treatment (Mobbs et al., 2015), (Menendez et al., 2019).

The primary goal of surgical treatment with instrumented interbody fusion is to improve physical function and reduce back-induced pain. Surgically this is obtained by decompression of the neural structures, restoration of lordosis, correction of deformity, and fusion of the functional spine unit (Mobbs et al., 2015). Importantly, this type of surgery should be reserved for patients with specific LBP due to segmental instability, pain causing sagittal malalignment or patients with compression of neurological structures due to disc collapse (Mobbs et al., 2015), (Salimi et al., 2021), (Rousing et al., 2019). Numerous surgical instrumented lumbar fusion options can be utilized to obtain decompression, restoration of alignment and reduced movement of the

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pain-inducing spinal segment (Mobbs et al., 2015), (Rousing et al., 2019).

The specific surgical technique does not appear to affect the longterm patient-reported outcomes (PROs) (Mobbs et al., 2015) but studies on lumbar fusion show a high variation in patient-reported success rate (Menendez et al., 2019), (Krauss et al., 2020). Therefore, there is a need to identify patients at risk of an unsatisfactory outcome following this common surgical procedure.

This study aimed to evaluate preoperative clinical risk factors associated with a non-satisfactory patient-reported outcome after lumbar interbody fusion.

2. Methods

The Danish national surgical spine registry – DaneSpine, collects PROs prospectively using pre- and postoperative questionnaires as well as surgical data collected perioperatively. For this study, DaneSpine data was collected from two institutions, on patients with predominantly LBP \pm leg pain, who underwent surgical treatment with single-level instrumented lumbar fusion surgery, including decompression, if necessary, with the most used lumbar instrumented interbody fusion procedures, respectively the TLIF and PLIF techniques.

The inclusion period was from June 1st, 2010, through May 31st, 2018. Patients were excluded if there were incomplete pre-operative and/or two-year questionnaires as well as patients with spondylolis-thesis and previous spine surgery on the same level besides single-level discectomy.

The preoperative questionnaire included: age, sex, height, weight, smoking, pain medication use, duration of symptoms, comorbidities, and previous surgical treatment. On completing the DaneSpine questionnaires, patients gave written consent for the use of their data in research. All patient data is strictly confidential and is stored according to the Danish Open Administration Act, the Danish Act on Processing of Personal Data, and the Health Act. Institutional review board approval was not required. Approval for data analysis was obtained from the Danish National Center for Ethics (reference number: 2207654).

The study, aimed at identifying preoperative clinical risk factors associated with nonsatisfaction at two-year follow-up. To quantify patient satisfaction, the patients were provided with a survey with three options to choose from regarding how they felt about the result of their back surgery. The options were: "I am satisfied", "I am undecided", and "I am dissatisfied" with only one response allowed. Patients were categorized as either "satisfied/undecided" or "nonsatisfied". For this purpose, the primary outcome measure was patient nonsatisfaction. Secondary outcome measures were visual analogue scale (VAS) scores for back and leg pain, ranging from 0 (no pain) to 100 (worst imaginable pain), the Euro-Qol-5D (EQ-5D) questionnaire (ranging from –0.596 to 1, with higher scores indicating better quality of life) and the Oswestry Disability Index (ODI) questionnaire (ranging from 0 (no disability) to 100 (bedridden)).

Perioperative surgical data collection was recorded by the surgeon after the procedure and included diagnosis, procedure specifications and occurrence of surgical complications such as dural tears and vascular or neural lesions.

For the statistical analysis, patients were stratified based on reported treatment nonsatisfaction at a two-year follow-up. The control group consisted of patients who were satisfied or undecided about the treatment outcome. Statistical Analysis Data analysis was performed in R version 4.2.2. Categorical data are presented by frequencies and related percentages. Continuous data are reported as a mean \pm standard deviation. Continuous data were analyzed using an unpaired *t*-test or Wilcoxon rank sum test and categorical variables were compared using the Pearson x2 test. The significance level was set at 0.05.

3. Results

The cohort included 453 patients of which 84 (19%) reported treatment nonsatisfaction. Preoperative data from the nonsatisfaction group demonstrated higher VAS scores for back pain (75 \pm 19 vs. 68 \pm 21, p = 0.006) and leg pain (65 \pm 25 vs. 58 \pm 28, p = 0.004). Treatment nonsatisfaction was 13% for patients with preoperative VAS scores 0–40, 15% for VAS 41–79 and 25% for VAS 80–100 (see Fig. 1). The



Fig. 1. Preoperative VAS score for back and leg pain. The illustration was created in R version 4.2.2.

Table 1

Baseline characteristics of the entire cohort.

	Not satisfied (n $= 84$)	Satisfied or undecided $(n = 369)$	p- value
Age, yr	50 ± 11	49 ± 11	0.547
Female sex, no. (%)	40 (48)	213 (57)	0.118
Body mass index	27 ± 4	27 ± 4	0.644
Smoker, no. (%)	27 (33)	105 (29)	0.560
Employment status			
Employed, no. (%)	57 (71)	227 (66)	
Unemployed, no. (%)	23 (29)	119 (34)	0.404
Previous spine surgery, no.	54 (64.3)	214 (58)	
(%)			
No previous spine	30 (35.7)	155 (42)	0.349
surgery, no. (%)			
Duration of back pain, no. (%))		
<24 months	27 (32)	114 (31)	
>24 months	57 (68)	255 (69)	0.926
Duration of leg pain, no. (%)			
No leg pain	3 (4)	27 (7)	0.526
<3 months	2 (2)	17 (5)	
3-12 months	17 (20)	89 (24)	
12-24 months	20 (24)	81 (22)	
>24 months	42 (50)	152 (42)	
ODI score ^a , %	50 ± 13	48 ± 16	0.081
EQ5D UK score ^b	0.203 ± 0.262	0.291 ± 0.312	0.016
VAS score for back pain ^c	75 ± 19	69 ± 21	0.012
VAS score for leg pain	65 ± 25	58 + 28	0.037
Self-reported walking distance	e, no. (%)		
<500 m	54 (64)	221 (60)	
>500 m	30 (36)	147 (40)	0.553

Unless otherwise specified data are reported as mean \pm standard deviation.

 $^{\rm a}$ Scores on the Oswestry Disability Index (ODI) range from 0 to 100, with higher scores indicating more severe disability.

^b Scores on the European Quality of Life–5 Dimensions (EQ-5D) range from 0 to 1, with higher scores indicating better quality of life.

^c Scores on the visual-analogue scales (VASs) for back pain and leg pain range from 0 to 100, with higher scores indicating more severe pain.

Table 2

Two-year follow-up for the cohort.

	Not satisfied $(n = 84)$	Satisfied or undecided (n = 369)	p-value
ODI score ^a , %	51 ± 15	30 ± 19	< 0.001
Change in ODI score ^a	0 ± 14	19 ± 18	< 0.001
EQ-5D UK score	0.227 ± 0.303	0.611 ± 0.296	< 0.001
Change in EQ-5D score ^a	0.025 ± 0.295	0.323 ± 0.371	< 0.001
VAS score for back pain	74 ± 20.5	40 ± 29	< 0.001
Change in VAS score ^a	1 ± 23	28 ± 30	< 0.001
VAS score for leg pain	67 ± 26	34 ± 30	< 0.001
Change in VAS score ^a	0 ± 26	24 ± 34	< 0.001
Regular use of pain medicine, no (%)	75 (93)	174 (63)	< 0.001
Use of pain medication sometimes, no (%)	6 (7.4)	101 (37)	
Self-reported back pain			
Worsening	45 (55)	26 (7)	< 0.001
No change	22 (27)	48 (13)	
Moderate improvement	10 (12)	118 (33)	
Significant improvement	5 (6)	140 (39)	
No back pain	0 (0)	31 (9)	
Self-reported leg pain			
Worsening	43 (54)	36 (11)	< 0.001
No change	21 (27)	50 (15)	
Moderate improvement	9 (11)	91 (27)	
Significant improvement	6 (8)	108 (32)	
No leg pain	0 (0)	57 (17)	
Self-reported walking distance	, no. (%)		
<100 m	31 (37)	41 (11)	< 0.001
100–500 m	21 (25)	65 (18)	
500–1000 m	17 (21)	54 (15)	
>1000 m	14 (17)	208 (57)	

Unless otherwise specified data are reported as mean \pm standard deviation. ^a Preoperative score minus score at two-year follow-up. preoperative EQ-5D score was significantly lower in the nonsatisfaction group compared to the satisfaction/undecided group (0.203 + 0.262 vs. 0.291 ± 0.312 , p = 0.016).

No statistically significant difference was found between the groups in regard to preoperative ODI score, age, body mass index, duration of back pain, walking distance or frequency of preoperative sick leave (Table 1). Furthermore, no significant statistical difference was observed concerning the preoperative employment status (see Table 2).

At the two-year follow, nine patients (11%) in the nonsatisfied group showed an improvement in ODI of 30% or more. 17 patients (18%) reported moderate or much improvement in back and leg pain.

A separate sub-group analysis split up the initial "undecided/satisfied" group (n = 369), revealing that treatment satisfaction was 57% (n = 258) and patients who were undecided regarding treatment satisfaction was 25% (n = 111). Additional data from the sub-group analysis can be found in appendices 1 & 2.

4. Discussion

The purpose of this registry-based study was to investigate the association between treatment nonsatisfaction and baseline patient characteristics including PROMs. Firstly, we found pre-operative VAS back and leg scores to be a predictor of postoperative nonsatisfaction. Previous studies including a systematic review on spine surgery and patient satisfaction, found severe preoperative back pain to be associated with higher nonsatisfaction after surgery (Menendez et al., 2019), (Cha et al., 2022), (Lim et al., 2018).

Previous studies on lumbar spine surgery have also demonstrated an association between nonsatisfaction and postoperative walking capacity (Menendez et al., 2019), (Yamashita et al., 2003), (Bouras et al., 2019), indicating that the reduction of leg pain postoperatively can provide increased patient satisfaction due to the improvement in overall physical function compared to the reduction of back pain (Yamashita et al., 2003), (Devin et al., 2020). In our study, the preoperative self-reported walking distance itself did not correlate with postoperative non-satisfaction, which is in line with a retrospective cohort study investigating the self-reported walking distance and postoperative satisfaction levels (Gepstein et al., 2006).

This study also found that lower preoperative EQ-5D scores were significantly associated with postoperative nonsatisfaction. The results of a prospective cohort study undergoing lumbar spine surgery were similar showing that lower preoperative EQ-5D scores were associated with patient nonsatisfaction (Chapin et al., 2017). Another retrospective study found that males tended to have greater baseline EQ-5D scores and greater mean changes in their EQ-5D scores and higher rates of both short- and long-term patient satisfaction (respectively 3 and 12 months postoperatively) (Elsamadicy et al., 2017). Another study found that adolescents had higher postoperative satisfaction and higher baseline/postoperative EQ-5D scores compared to adults (Lagerbäck et al., 2019). The EQ-5D survey examines factors such as mobility, usual activities, washing, and dressing. Our results on the association between EQ-5D scores and nonsatisfaction are supported by the literature and could be a useful tool in preoperative patient selection. The difference between the two groups in our study cannot be attributed to one single cause, but it can be hypothesized that factors derived from the EQ-5D survey, such as poor mobility or low performance of usual activities, may be difficult to correct in patients with severely progressed degenerative diseases of the spine. If these patients do not reach their thresholds of desired activity, they may be dissatisfied.

The preoperative ODI score did not predict with statistical significance the risk of nonsatisfaction. We found, however, that a high postoperative ODI score correlated with patient nonsatisfaction – the more severe the disability, the greater the likelihood of nonsatisfaction. Previous studies have demonstrated similar results with a higher postoperative ODI score being associated with nonsatisfaction (Menendez et al., 2019), (Knutsson et al., 2022), (Yee et al., 2020). It is interesting to note that 11% of patients, in our study, were dissatisfied despite a 30% or more improvement in ODI scores, and thus it is like the EQ-5D score, where there is likely a threshold of disability/inhibition of usual activities before patients become dissatisfied. Although improvements in ODI scores are associated with patient satisfaction (Yee et al., 2020), discrepancies can be found between favourable postoperative ODI scores and patient satisfaction in the literature (Azimi and Benzel, 2017), (Teo et al., 2023).

Several studies concerning postoperative pain and patient satisfaction following spine surgery, knee surgery, or other surgical procedures find that identifying and treating postoperative pain early can be important for achieving long-term patient satisfaction (Menendez et al., 2019), (Knutsson et al., 2022), (Raspopović et al., 2021), (Gan, 2017). Therefore, identification and treatment of postoperative pain following spine surgery should be prioritized to decrease the risk of nonsatisfaction. Results from this study demonstrate an association between higher levels of pain and patient nonsatisfaction both at the preoperative screening and at the postoperative two-year follow-up. One prospective cohort study (Coronado et al., 2015) found that heightened pain sensitivity or pain catastrophizing at a 6-week follow-up after spine surgery could be linked to subsequent persistent pain at a 6-month postoperative follow-up.

It may be theorized that early identification and treatment of postoperative pain may increase patient satisfaction and prevent ongoing long-term pain, as opposed to delayed detection and treatment – as supported in previous studies (Raspopović et al., 2021), (Gan, 2017).

A limitation of our study is the comparison between a nonsatisfaction patient group and a group of patients who were either satisfied or undecided, thus some of the patients belonging to the undecided group might be leaning more towards nonsatisfaction than satisfaction. This approach was chosen to better reflect the clinical reality and increase the external validity. An additional sub-group data analysis of the three groups—satisfied, undecided, and nonsatisfied is presented in Appendices 1 and 2.

This study focuses on pre- and postoperative patient-related outcomes. The study does not account for surgery-related outcomes such as restoration of spinal and sagittal alignment, neural decompression, or successful fusion. Patients' nonsatisfaction may be associated with the failure to achieve specific goals of surgery, such as the above-mentioned surgery-related outcomes, specific postoperative complications, suboptimal pain management, or specific unmet expectations in functional recovery, as the PROMs used in this study might fail to capture the qualitative nuances of patient experiences.

Appendix 1. Baseline characteristics of the entire cohort

The findings of this study also highlight an important consideration in patients with higher preoperative EQ-5D scores and VAS-scores. Such patients might be considered to have an increased need for medical intervention including surgery, but adversely they may face an elevated risk of postoperative non-satisfaction. Thus, patients with severe disability and/or very high pain scores preoperatively should be thoroughly informed on the potential postoperative trajectory including increased risk of non-satisfaction.

Confounders such as age, gender, employment status, smoking habits, BMI, and previous spine surgery were included in the data analysis. Other confounders such as varying types and degrees of comorbidities of the patients, the experience of the surgeons operating, and the preoperative expectations of the patients were not considered and may have influenced the results. It is of importance to note how socioeconomic factors such as ongoing compensation claims, or active retirement plans may influence both preoperative PROMs and postoperative satisfaction (Menendez et al., 2019), (Cheriyan et al., 2015). Ideally, these variables would have been included in the data analysis, but due to the registry-based design of this study, the inclusion of these variables was not possible. Strengths of this study include a registry-based cohort study with extensive pre- and postoperative data collection through validated questionnaires.

Due to the important findings of this study, we recommend further high-quality longitudinal studies with standardized study designs to further investigate preoperative VAS-pain, ODI-score and EQ-5D scores for the prediction of postoperative patient nonsatisfaction.

5. Conclusion

Low preoperative EQ-5D scores and high VAS leg and back pain scores were significantly associated with patient nonsatisfaction following lumbar interbody fusion. Overall, the EQ-5D and VAS leg and back pain may be potentially valuable tools in the preoperative screening and patient expectations should be discussed in cases of high preoperative VAS scores.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

	Not satisfied $(n = 84)$	Undecided ($n = 111$)	Satisfied $(n = 258)$	p-value
Age, yr	50 ± 11	48 ± 10	49 ± 11	0.539
Female sex, no. (%)	40 (48)	62 (56)	151 (59)	0.217
Body mass index	26.9 ± 4	26.3 ± 4	26.8 ± 4	0.540
Smoker, no. (%)	27 (33)	43 (40)	62 (24)	0.009
Employment status				
Not working, no. (%)	42 (58)	58 (59)	120 (51)	0.682
Heavy load, no. (%)	6 (8)	7 (7)	17 (7)	
Light load, no. (%)	17 (23)	18 (18)	58 (25)	
Moderate load, no. (%)	8 (11)	16 (16)	42 (18)	
Previous spine surgery, no. (%)	54 (64.3)	80 (72.1)	134 (51.9)	
No previous spine surgery, no. (%)	30 (36)	31 (28)	124 (48)	< 0.001
Duration of back pain, no. (%)				
<24 months	27 (32)	31 (28)	83 (32)	0.704
>24 months	57 (68)	80 (72)	175 (68)	
Duration of leg pain, no. (%)				
No leg pain	3 (34)	8 (7)	19 (7)	0.379
<3 months	2 (2)	3 (3)	14 (6)	
3–12 months	17 (20)	23 (21)	66 (26)	
12–24 months	20 (24)	22 (20)	59 (23)	
>24 months	42 (50)	54 (49)	98 (38)	

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	Not satisfied $(n = 84)$	Undecided (n = 111)	Satisfied ($n = 258$)	p-value
ODI score*, %	50.3 ± 13	50 ± 13	$\textbf{47.2} \pm \textbf{16}$	0.112
EQ5D UK score **	0.203 ± 0.262	0.261 ± 29	0.304 ± 32	0.024
VAS score for back pain***	75 ± 19	71 ± 19	68 ± 21	0.012
VAS score for leg pain	65 ± 25	56.9 ± 27	59 ± 29	0.119
Self-reported walking distance, no. (%)				
<500 m	54 (64)	69 (62)	152 (59)	0.667
>500 m	30 (36)	42 (38)	105 (41)	

Unless otherwise specified data are reported as mean \pm standard deviation.

*Scores on the Oswestry Disability Index (ODI) range from 0 to 100, with higher scores indicating more severe disability.

**Scores on the European Quality of Life-5 Dimensions (EQ-5D) range from 0 to 1, with higher scores indicating better quality of life.

***Scores on the visual-analogue scales (VASs) for back pain and leg pain range from 0 to 100, with higher scores indicating more severe pain.

Appendix 2. Two-year follow-up for the cohort

	Not satisfied $(n = 84)$	Undecided (n = 111)	Satisfied (n = 258)	p-value
ODI score*, %	51 ± 15	45 ± 15	23 ± 16	< 0.001
Change in ODI score*	-0.4 ± 14	6 ± 14	24 ± 17	< 0.001
EQ-5D UK score	0.227 ± 0.303	0.412 ± 0.297	0.455 ± 0.346	< 0.001
Change in EQ-5D score*	0.025 ± 0.295	$0.151 \pm 0.356)$	0.397 ± 0.352	< 0.001
VAS score for back pain	74 ± 20	63 ± 20	31 ± 26	< 0.001
Change in VAS score*	1 ± 23	9 ± 23	37 ± 29	< 0.001
VAS score for leg pain	67 ± 26	53 ± 28	26 ± 28	< 0.001
Change in VAS score*	0 ± 26	5 ± 29	33 ± 33	< 0.001
Regular use of pain medicine, no (%)	75 (93)	87 (84.5)	87 (50.6)	< 0.001
Use of pain medication sometimes, no (%)	6 (7.4)	16 (15.5	107 (30.1)	
Self-reported back pain				
Worsening	45 (55)	20 (19)	6 (2)	< 0.001
No change	22 (27)	34 (32)	14 (6)	
Moderate improvement	10 (12)	47 (44)	71 (28)	
Significant improvement	5 (6)	5 (5)	135 (52)	
No back pain	0 (0)	1 (1)	30 (12)	
Self-reported leg pain				
Worsening	43 (54)	22 (21)	14 (6)	< 0.001
No change	21 (27)	31 (30)	19 (8)	
Moderate improvement	9 (11)	35 (34)	56 (23)	
Significant improvement	6 (8)	12 (12)	96 (40)	
No leg pain	0 (0)	3 (3)	54 (23)	
Self-reported walking distance, no. (%)				
<100 m	31 (37)	25 (22.7)	16 (6.2)	< 0.001
100–500 m	21 (25)	29 (26.4)	36 (14.0)	
500–1000 m	17 (21)	19 (17.3)	35 (13.6)	
>1000 m	14 (17)	37 (33.6)	171 (66.3)	

Unless otherwise specified data are reported as mean \pm standard deviation.

*Preoperative score minus score at two-year follow-up.

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