

Success and Failure After Surgery for Degenerative Disease of The Lumbar Spine. an Operational Definition Based on Satisfaction, Pain, and Disability

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Research Article

Keywords: lumbar spine surgery, real world evidence, failure, value-based healthcare, PROMS, patient-reported.

Posted Date: March 18th, 2022

DOI: <https://doi.org/10.21203/rs.3.rs-1446991/v1>

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Abstract

Background: To describe success and failure (S&F) after lumbar spine surgery in terms that are precise and that are equally understandable across the entire health ecosystem.

Methods: Back and leg pain (NPRS scale) and disability (Oswestry Disability Index – ODI) of patients operated were prospectively recorded before and 6 to 12 months after the procedure. Satisfaction was recorded in the postoperative period. Initially, patients were classified as Satisfied or Unsatisfied. Optimal cutoff values for disability and pain were estimated with ROC curves. Satisfied and Unsatisfied groups were subdivided into four categories based on a combination of satisfaction, disability and pain: Success, Incomplete success, Incomplete failure and Failure. These categories were translated into operational definitions with simple verbal terms, according to previously described norms of numeric-to-verbal equivalence.

Results: 486 consecutive patients were recruited from May 2019 to February 2021, with a drop-out rate of 16.4%; Preoperative PROMs mean values were ODI 42.2 (\pm 16.4), NPRS back 6.6 (\pm 2.6) and NPRS leg 6.2 (\pm 2.9) points; 19.3% were classified as Unsatisfied and cutoff values for disability (ODI=28; AUC 0.79) and pain (NPRS=6; AUC 0.79) were defined. Satisfied and Unsatisfied groups were further subdivided based on concordance or non-concordance with the discrimination cutoff values: Success (59.6%) - satisfied with pain and disability levels concordant (NPRS \leq 5, AND ODI \leq 27); Incomplete success (20.4%) - satisfied with pain and disability levels non-concordant (NPRS \geq 6 AND/OR ODI \geq 28); Incomplete failure (7.1%) – unsatisfied with pain and disability levels non-concordant (NPRS \leq 5 AND/OR ODI \leq 27); and Failure (12.4%) - unsatisfied with pain and disability levels concordant (NPRS \geq 6 AND ODI \geq 28). After that, groups were translated to: Success - patients are satisfied and present no or only mild to tolerable pain, and no or borderline disability; Incomplete Success – patients are satisfied despite levels of pain and/or disability worse than the ideal for success; Incomplete Failure – patients are not satisfied despite levels of pain and/or disability better than expected for failure; Failure – patients are unsatisfied and present moderate to severe pain and disability.

Conclusion: It is possible to report S&F after surgery for degenerative disc disease of the lumbar spine with precise and meaningful operational definitions focused on the experience of the patient.

Background

The surgical treatment of Degenerative Disk Disease of the Lumbar Spine (DDL) is characterized by the heterogeneity of indications, techniques and results (1). At the same time, this type of surgery is accompanied by the greatest failure rate among the main surgeries of the locomotor system (2). In the process of shared decision, doctors have the obligation to inform this fact to patients (3), and patients have the right to receive this information. The content of this information should be the clinical pictures of success and failure (S&F) as well as their relative incidences.

The problem in contemporary medicine is that the concept of S&F has never been precisely defined (4)(5) (6). However, an enormous number of decisions are taken every day with the objective of avoiding failure or seeking success. These decisions are taken not only by patients and doctors, but also by payers, hospitals, and industry. In order to improve the interaction between all these stakeholders one requirement is obvious: when one says “failure” or “success”, everybody should understand the same thing.

This scenario offers opportunity for the utilization of an operational definition. Operational definitions may not be perfect, but they allow an honest and predictable interaction among everybody involved in a process. A good operational definition must balance precision (that is, to be based in relevant and well measured data) and communicability (that is, to be expressed in terms that can be understood and make sense to all). The a priori hypothesis of this study is that an operational definition of S&F after lumbar spine surgery that attends to these requirements may be formulated by the combination of satisfaction, pain, and disability measures.

Methods

Population and data collection

This study was performed at Hospital Moinhos de Vento (HMV), a private institution with 485 beds and limited medical staff. HMV has a Clinical Database for many diseases following the ICHOM criteria(7).

Cases of DDL, such as lumbar disk herniation, lumbar stenosis, degenerative spondylolisthesis and back pain due to disk degeneration, treated surgically from May, 2019 to February, 2021 and followed up to 12 months are included in database. Patient reported outcomes measures (PROMs) and data relative to the number of levels and surgical technique were also registered.

Ethics and consent

The study was approved by the Ethics Committee of the Moinhos de Vento Hospital (number 4.543.282 CAAE 41454920.3.0000.5330) and only participants with informed consent form participated. Data from medical records and PROMs were collected after informed consent from the participant. All methods in the study were performed in accordance with relevant institutional and national guidelines.

Patient Reported Outcome Measures (PROMs)

PROMs questionnaires were applied pre and post procedure (telephone and/or electronic forms), and satisfaction was measured with a Likert Scale(8) four levels in the postoperative period. Likert 1 and 2 – very satisfied or satisfied – was used to classify patient as “satisfied” and Likert 3 and 4 – very dissatisfied or dissatisfied – as “unsatisfied”.

Functional disability related to the lumbar spine was reported by the Oswestry Disability Index (ODI)(9). Back and leg pain were measured by the Numerical Pain Rating Scale (0 to 10)(10) and identified as

[NPRS back] [NPRS leg]. Quality of life was analyzed by the Euro Quality of Life 5 Dimension Scale (EQ5D) (11). Unable to work and analgesic use were investigated preoperatively and at 6 and 12 months.

Statistical analysis

Categorical variables were summarized using absolute frequencies and percentages, while continuous variables were analyzed using means, standard deviations, medians and interquartile ranges. To compare proportions, the Chi-square test and Fisher's exact test were used when appropriate, and the Mann-Whitney U test was used to compare continuous variables.

Analyses were stratified into pre- and postoperative periods. Subsequently, the postoperative group was divided into satisfied and unsatisfied and then comparisons between groups were performed. Furthermore, the postoperative group was also divided into success, incomplete success, incomplete failure and failure, and comparisons between group pairs were developed.

The optimal cut-points values of disability and pain were estimated by the Receiver Operating Characteristic (ROC) curve by the method of minimizing the Euclidean distance between the curve and the point (0.1) in the ROC space. The ROC curve of pain was built considering the highest value between NPRS back and NPRS leg. Areas under the curve (AUC) and respective 95% confidence intervals (95% IC) were also estimated. Sensitivity (Sen), specificity (Spe) and correct classification rate were also calculated for both measures. All analyses were carried out using R software, version 4.0.3. Statistically significance was p value < 0.05 .

Results

During the study period 486 patients were operated upon, but 80 (16.4%) did not respond to follow up. After exclusion, clinical cohort included 406 patients (Table 1). Median age was 49.2 years [40.1–60.4], 50.9% were male with a mean body mass index of 27.4 points. The education level was relatively high for the Brazilian population with 56.1% university degree. Main comorbidities were hypertension (50.9%) and depression (10.8%) and 7.9% were smokers. The surgical technique was decompression with fusion in 36.6%, simple decompression in 31.1% and automated percutaneous discectomy in 26.9%. About a quarter (24.4%) of the patients had a history of previous back surgery. All outcomes' measures presented improvement after the surgery.

Table 1
Baseline characteristics for patients

n = 406	n (%) or median [IQR]
DEMOGRAPHICS	
Male	207 (50.9)
Age (y)	49.2 [40.1–60.4]
Caucasian	382 (94.0)
Tertiary education	228 (56.1)
Body mass index (BMI)	27.4 [24.9–30.4]
Smoke	32 (7.9)
COMORBIDITY	
Hypertension	112 (27.5)
Depression	44 (10.8)
Diabetes	25 (6.1)
Heart disease (heart failure, heart attack, angina, atrial fibrillation)	25 (6.1)
Pulmonary disease (emphysema, COPD, asthma)	24 (5.9)
Arthritis	23 (5.6)
Leg pain (poor circulation)	20 (4.9)
Cancer (last 5 y)	11 (2.7)
Liver disease	10 (2.4)
Chronic kidney disease	5 (1.2)
CLINICAL INFORMATION	
Mild systemic disease (ASA II)	271 (67.4)
History of spine surgery	99 (24.4)
Surgery classification	
<i>Decompression and arthrodesis</i>	148 (36.6)
<i>Automated percutaneous</i>	126 (26.9)
<i>Decompression</i>	109 (31.1)
Procedure level	
<i>1 or 2 levels</i>	314 (78.9)

n = 406	n (%) or median [IQR]
≥ 3 levels	84 (21.1)
Length of stay	
	2.0 [1.0–4.0]
	4.4 (15.2)

Global pre and postoperative outcomes are presented in Table 2. Preoperative ODI improved from 42.0 points [32.0–54.0] to 16.0 points [4.4–34.0] in the postoperative. Back pain (NPRS back) and leg pain (NPRS leg) varied from 7.0 [5.2-8.0] e 7.0 [5.0–8.0] points to 3.0 [0.0–6.0] e 3.0 [0.0–6.0], respectively. The same effect was observed in the use of opioids and the incapacity to work due to back problems.

Table 2
Pre- and post-procedure group evaluated for pain, disability and quality of life

	median [IQR] or mean (SD)		
	Pre procedure	Post procedure	p value
Oswestry Disability Index (ODI)			
	42.0 [32.0–54.0]	16.0 [4.4–34.0]	< 0.01
	42.2 (16.4)	21.5 (19.7)	
Numeric Pain Rating Scale (NPRS)			
NPRS low back	7.0 [5.2-8.0]	3.0 [0.0–6.0]	< 0.01
	6.6 (2.6)	3.5 (3.1)	
NPRS leg			
	7.0 [5.0–8.0]	0.0 [0.0–5.0]	< 0.01
	6.2 (2.9)	2.3 (3.1)	
EQ5D-3L			
	0.731 [0.595–0.731]	0.787 [0.640-1.0]	< 0.01
	0.656 (0.10)	0.780 (0.20)	
Prescription opioids	n (%)		
<i>Not or sometimes</i>	243 (60.0)	328 (80.7)	< 0.01
<i>Regularly</i>	162 (40.0)	78 (19.2)	
Over-the-counter analgesics			
<i>Not or sometimes</i>	356 (87.9)	391 (96.3)	< 0.01
<i>Regularly</i>	49 (12.1)	15 (3.6)	
Unable to work due to pain	92 (22.6)	79 (19.4)	0.26
Return to work (< 3 months)		179 (81.7)	

Satisfied and Unsatisfied patients

Outcomes of Satisfied (80.7%) and Unsatisfied (19.3%) patients are presented in Table 3 with clinical profile in postoperative subgroups differed considerably. Satisfied group presented mean values of NPRS back = 2.0 [0.0–5.0], NPRS leg = 0.0 [0.0–4.0] and mean ODI = 12.0 [4.0–26.0] points. Unsatisfied patients presented mean values NPRS back = 7 [0.0–8.0], NPRS leg = 4.0 [0.0–8.0] and mean ODI = 38.0 [24.0–52.0]. Significant improvement between pre procedure and Satisfied patients is observed in practically all

parameters. On the other hand, almost no difference was present between pre procedure and Unsatisfied patients.

Table 3
Satisfied and unsatisfied group evaluated for pain, disability and quality of life

	median [IQR] or mean (SD)			
	Pre procedure (n 406)	Satisfied (n 328)	Unsatisfied (n 78)	p value
Oswestry Disability Index (ODI)				
	42.0 [32.0–54.0]	12.0 [4.0–26.0]	38.0 [24.0–52.0]	< 0.01 ^{ab} 0.06 ^c
	42.2 (16.4)	17.5 (17.4)	38.3 (19.8)	
Numeric Pain Rating Scale (NPRS)				
NPRS low back	7.0 [5.2-8.0]	2.0 [0.0–5.0]	7.0 [0.0–8.0]	< 0.01 ^{ab} 0.13 ^c
	6.6 (2.6)	2.8 (2.8)	6.1 (2.8)	
NPRS leg				
	7.0 [5.0–8.0]	0.0 [0.0–4.0]	4.0 [0.0–7.0]	< 0.01 ^{abc}
	6.2 (2.9)	1.9 (2.8)	4.1 (3.7)	
EQ5D-3L				
	0.731 [0.595–0.731]	0.794 [0.690–1.0]	0.660 [0.520–0.787]	< 0.01 ^{ab} 0.17 ^c
	0.656 (0.10)	0.815 (0.18)	0.636 (0.18)	
Prescription opioids		n (%)		
<i>Regularly</i>	162 (40.0)	48 (14.6)	30 (38.5)	< 0.01 ^{ab} 0.80 ^c
Over-the-counter analgesics				
<i>Regularly</i>	49 (12.1)	9 (2.7)	6 (7.7)	0.03 ^a < 0.01 ^b 0.26 ^c
Unable to work due to pain	92 (22.7)	56 (17.1)	23 (29.5)	0.01 ^a 0.06 ^b 0.20 ^c
Return to work (< 3 months)		156 (87.1)	23 (12.8)	< 0.01 ^a
^acompared satisfied and unsatisfied group ^bcompared pre-operative and satisfied ^ccompared pre-operative and unsatisfied				

Cutoff values of disability and pain according to satisfaction/unsatisfaction

The sensitivity (Sen) and specificity (Spe) of the values for disability and pain used to discriminate between satisfied and unsatisfied patients were studied with ROC curves (Fig. 1), showed a varying narrowly around 75.0% [72.0–77.0]. Both ROC curves [ODI (AUC 0.79) and Pain (AUC 0.79)] presented an “ACCEPTABLE” performance (between 70.0 and 80.0) with values pretty close to “GOOD”(12). The cutoff values for ODI and for back/leg pain were respectively 28 and 6.

Data show that about 75.0% of satisfied patients present pain ≤ 5 and 75.0% of unsatisfied patients pain ≥ 6 points. At the same time, $\sim 75.0\%$ of satisfied patients presented an ODI ≤ 27 and $\sim 75.0\%$ of unsatisfied patients an ODI ≥ 28 points.

Success, Incomplete success, Incomplete failure and Failure

Satisfied and Unsatisfied groups were further subdivided based on concordance or non-concordance with the discrimination cutoff values:

1. Success (59.6%) - satisfied with pain and disability levels concordant (NPRS ≤ 5 , AND ODI ≤ 27);
2. Incomplete success (20.4%) - satisfied with pain and disability levels non-concordant (NPRS ≥ 6 AND/OR ODI ≥ 28);
3. Incomplete failure (7.1%) - unsatisfied with pain and disability levels non-concordant (NPRS ≤ 5 AND/OR ODI ≤ 27);
4. Failure (12.4%) - unsatisfied with pain and disability levels concordant (NPRS ≥ 6 AND ODI ≥ 28).

PROMs values of four categories are presented in Table 4. There is a very significant improvement between preoperative (ODI 42.0 [32.0–54.0], NPRS back 7.0 [5.2–8.0], NPRS leg 7.0 [5.0–8.0]) and Success (ODI 8.0[2.0–16.0], NPRS back 1.0 [0.0–3.0], NPRS leg 0.0 [0.0–1.0]), but almost no difference between preoperative and Failure (ODI 44.4[38.0–54.0], NPRS back 7.0 [6.0–9.0], NPRS leg 7.0 [1.0–9.0]). The mean PROMs values of incomplete success and incomplete failure lie between these two extremes.

Table 4
Failure and Success groups evaluated for pain, disability and quality of life

	median [IQR] or mean (SD)					
	Pre procedure (n 406)	Success (n 242)	Incomplete success (n 86)	Incomplete failure (n 29)	Failure (n 49)	p value
Oswestry Disability Index (ODI)						
	42.0 [32.0–54.0]	8.0 [2.0–16.0]	40.0 [31.1–50.0]	20.0 [10.0–26.0]	44.4 [38.0–54.0]	< 0.001 ^{a,c,d} 0.02 ^b
	42.2 (16.4)	9.2 (8.1)	40.9 (15.3)	22.6 (18.8)	47.7 (13.7)	
Numeric Pain Rating Scale (NPRS)						
NPRS low back	7.0 [5.2-8.0]	1.0 [0.0–3.0]	6.0 [4.0–8.0]	5.0 [2.0–6.0]	7.0 [6.0–9.0]	< 0.001 ^{a,c,d} 0.07 ^b
	6.6 (2.6)	1.9 (2.2)	5.7 (2.7)	4.1 (2.8)	7.3 (2.1)	
NPRS leg						
	7.0 [5.0–8.0]	0.0 [0.0–1.0]	6.0 [3.0-7.8]	0 [0.0–4.0]	7.0 [1.0–9.0]	< 0.001 ^{a,c,d} 0.05 ^b
	6.2 (2.9)	0.9 (1.8)	5.0 (3.1)	2.3 (2.9)	5.3 (3.8)	
EQ5D-3L						
	0.731 [0.595–0.731]	1.0 [0.8-1.0]	0.6 [0.5–0.7]	0.7 [0.6–0.8]	0.5 [0.5–0.7]	< 0.001 ^{a,b,c} 0.04 ^d
	0.7 (0.1)	0.9 (0.1)	0.6 (0.2)	0.7 (0.2)	0.6 (0.2)	
Prescription opioids		n (%)				
<i>Regularly</i>	162 (40.0)	42 (17.4)	60 (69.8)	8 (27.6)	36 (73.5)	< 0.001 ^{a,b,c,d}
Over-the-counter analgesics						

^aPre procedure vs Success, ^bPre procedure vs Failure, ^cSuccess vs Incomplete success, ^dFailure vs Incomplete Failure

		median [IQR] or mean (SD)				
<i>Regularly</i>	49 (12.1)	3 (1.2)	6 (7.0)	0 (0.0)	6 (12.2)	< 0.001 ^{a,c} 0.98 ^b
Unable to work due to pain	92 (22.7)	21 (8.7)	35 (40.7)	6 (20.7)	17 (34.7)	< 0.001 ^{a,c} 0.06 ^b 0.19 ^d
Return to work (< 3 months)		130 (81.2)	26 (86.7)	13 (86.7)	10 (71.4)	0.25 ^c 0.12 ^d
^a Pre procedure vs Success, ^b Pre procedure vs Failure, ^c Success vs Incomplete success, ^d Failure vs Incomplete Failure						

Translation of numerical values into simple and meaningful terms

The translation of numerical values into simple and meaningful terms is the aim of our study. It is not exactly a “result” for it is not originally extracted from our data. A summary of the available literature will be presented in this section to support our rationale.

Satisfaction was linked to back/leg pain ≤ 5 in our cohort, as well as in previous similar studies(13)(14). Pain scales can be numerical, visual or verbal, and the equivalence among these three forms have already been studied (10)(15). For numeric scale, no pain is equal pain 0 to 2; 3 to 4 for mild pain; 6 to 8 for moderate pain and 9 to 10 for severe pain. From the verbal standpoint, pain = 5 is located exactly in the midpoint between mild and moderate pain. But what is the best word to describe pain = 5?

Zelman and coworkers(16) studied the interference of pain in the life of chronic low back patients (sensation of controlled pain, ability to participate in productive activities, decreased irritability, low analgesic intake and willingness to socialize). In this analysis it was demonstrated that a pain = 5 represented the limit between tolerable and intolerable pain. The cutoff value of 5 for back/leg pain was found by us and by other authors. Our data as well as those of the literature support the idea that “tolerable” is an appropriate term to describe a pain = 5. According to this information, patients with pain ≤ 5 can be described as having no, or only mild to tolerable pain.

In Japan(17), the mean ODI value of patients disabled due to spine problems varied from 26 and 28 points at the age of 50 and 70 years, respectively. Other studies, the criteria were stricter and the mean ODI was 21 points for success(18) and 25 points for failure(13). Most studies based on final raw scores found cutoff values for failure between 22 to 30 points(19)(14)(20).

In short terms, the pertinent literature determines the existence of a borderline zone between the ODI values of disabled and non-disabled patients, from 21 to 31 points. Our cohort, an ODI ≤ 27 points was linked to satisfaction and this value lies within this borderline zone. So, patients with an ODI ≤ 27 points can be described as individuals with none disability or borderline disability.

Operational definitions

Our results support the description of four Operational Definitions:

1. **Success**– All patients are satisfied, and all present none or mild to tolerable pain, and no or borderline disability.
2. **Incomplete Success** – All patients are satisfied despite levels of pain and/or disability worse than ideal for success.
3. **Incomplete Failure** – All patients are not satisfied despite levels of pain and/or disability better than expected for failure.
4. **Failure** – All patients are unsatisfied, and all present moderate to severe pain and disability.

Discussion

We measured satisfaction, pain, and disability in a cohort of 406 patients submitted to surgery for DDL. Based on PROMs combination, we created four operational definitions of S&F in the following terms: Success (patients satisfied with no or only mild to tolerable pain, and no or only borderline disability), Incomplete success (patients are satisfied despite levels of pain and/or disability worse than ideal for success), Incomplete failure (patients are not satisfied despite levels of pain and/or disability better than expected for failure) and Failure (patients are unsatisfied with moderate to severe pain and disability).

The clinical profile of Success (ODI 8.0 [2.0–16.0], NPRS back 1.0 [0.0–3.0], NPRS leg 0.0 [0.0–1.0]) is comparable to normal healthy population, that is, pain in the range of “no pain” (10) and ODI in the range of healthy population (9). At the same time, the clinical profile of Failure (ODI 44.4 [38.0–54.0], NPRS back 7.0 [6.0–9.0], NPRS leg 7.0 [1.0–9.0]) demonstrates that these patients remain as sick as before surgery. This model seems well adjusted to the commonsense ideas of Success (suggestive of normal life) and Failure (continuation or worsening of the disease).

These definitions describe the results of surgery in terms that are precise, simple and meaningful. The operational definitions of Incomplete success and Incomplete failure can be considered relatively vague. But they make sense when presented together with respectively S&F. It is intuitive that there is not a sharp limit between S&F. All the pertinent literature relies on satisfaction as the primary anchor of S&F. All success patients are satisfied, and all failures are unsatisfied. Disability and pain quantify the robustness of each subcategory.

Methodological issues

Our S&F model is based on satisfaction, disability, and pain, having satisfaction as the main criterion. The choice of satisfaction as the primary anchor may be debated. Some authors demonstrate that there is a discrepancy between satisfaction and PROMS(21), while others demonstrate that they correlate well (22). It is clear that satisfaction correlates better with the final raw scores than with improvement(17). It

was hypothesized that PROMS may not be the best instruments to evaluate satisfaction (23), for satisfaction depends on a complex and wider array of variables such as physical and mental health, expectations and lifestyle(22,23). Some authors chose satisfaction as the main translation of success(22)and were praised for that(24).Even the concept of minimal clinically important difference (MCID) is based on satisfaction. Satisfaction represents the patient's most comprehensive evaluation of what occurred (25).

We then chose ODI and NPRS (26) as complementary criteria, for they are directly related to the disease. Quality of life is also important in this evaluation, but it is dependent on other social and health factors. EQ5D varies among countries, and is difficult to be explained in simple words. In the same manner, drug use and work status are also important, but were left out of the model because they evaluate the consequences of the disease and not the disease itself.

For the method of this study, we adopted the final raw score of pain and disability as outcomes. Many authors base their studies on pre-to-postoperative variation as well as on MCID (27)(14)(20). Previous studies demonstrated that the analysis S&F based on pre-to-postoperative differences or MCID may have some flaws (6). The results obtained with this strategy are strongly influenced by the severity of preoperative symptoms (18)(28). Final raw scores correlate better with S&F are more simple and objective, and they are not influenced by the intensity of preoperative symptoms (18). Our model describes "how patients will be at the end of treatment" (final raw scores) and avoids referring to an elusive "minimum clinically significant" improvement.

Another peculiarity of our study was to assess pain considering the highest value between back and leg pain. We assume that the patient's suffering is better assessed in this manner. Other authors have previously done the same(4).

The option for an operational definition of S&F

The precise concept (or diagnostic criteria) of S&F after low back surgery has never been, and probably will never be defined(4)(5)(6). Nonetheless, S&F happen and are widely studied. One review at PUBMED with the terms "lumbar spine surgery AND failure" showed 3.268 results. Another one with "lumbar spine surgery AND success", 2.882 results. Concepts or definitions of S&F are based on many PROMs that measure different constructs, so their results are almost never coincident(29). As a result, patients face a myriad of numbers which are difficult to understand. According to some authors, even doctors have difficulty to fully understand the meaning of these numbers(13).

A process of shared decision based on concepts like "33.0% improvement in ODI" or "to reach MCID in leg pain" is almost impossible. This difficulty is more visible in people with low literacy but can happen in more educated people (30). According to Werner et al.(13), patients have more ability to understand percentages of definite types of outcomes than continuous variables. Our method responds to these problems by two ways: a) it divides the possible outcomes into four intuitive types (Success, Incomplete

Success, Incomplete failure and Failure), and b) the myriad of numeric variables was replaced by simple equivalent words.

We emphasized the importance of our operational definitions for the communication among all stakeholders of spine surgery. But there is one specific scenario where this type of definition reaches its most relevant moment: this is the preoperative discussion between patient and doctor concerning the indication of surgery(31). Patients have the right to be informed, and doctors must be in charge of giving the information concerning all possible outcomes, that is, their relative incidences and clinical characteristics. This information must be as precise as possible, and be presented in simple and meaningful terms. This is a prerequisite to assure that patients can exert their freedom of choice (32)(33).

Possible deficiencies of the study

This study was based on a single institution, so our results need to be replicated and tested to obtain better validation. Our cohort includes different diseases (disc herniation, stenosis, etc...), surgical techniques, approaches, and surgeons in one single group. This is in pace with a recent tendency of the surgical literature, the so-called *science of practice*(34,35). With this approach, it was already demonstrated, for example, that return to work (36), improvement of pain, disability and quality of life depend more on the patients' characteristics than on the type of approach, number of levels, the use of fusion, the surgeon experience and other(37).

Another criticism can be made to the relatively short follow-up in patients submitted to fusion. The objective of this study, however, is not to describe the rates of success and failure (which really may depend on time) but to describe a manner (simple and communicable) of reporting the basic endpoints of success and failure. The rates of S&F may change with time, the way they are described may not.

Finally, the problem of reducing all possible outcomes into only 4 categories. The complexity of degenerative disc disease and the heterogeneity of treatments and results deserve a very granular subdivision of possible outcomes. Such a "perfect" definition, on the other hand, would be cumbersome during the process of decision making. It must be recognized that the broader aim of developing a completely truthful and sophisticated definition of S&F has not proven feasible in the context of lumbar spine surgery. The more complex and sophisticated the definition, the more difficult it is to be understood and communicated, and vice-versa. This tradeoff is inevitable. It is the opinion of the authors that the simplicity and communicability of our operational definitions were obtained without compromising precision.

Conclusion

It is possible to report S&F after surgery for DDL with operational definitions based on satisfaction, disability, and pain that are precise, simple, and meaningful to all people involved in the process. Our operational definitions of Success, Incomplete success, Incomplete failure, and Failure may improve the process of shared decision focused on the experience of the patient.

Abbreviations

DDL – Degenerative Disk Disease of the Lumbar Spine

EQ5D - Euro Quality of Life 5 Dimension Scale

MCID - Minimal clinically important difference

NPRS - Numerical Pain Rating Scale

ODI - Oswestry Disability Index

PROMS – Patient reported outcomes measures

Declarations

Ethics approval and consent to participate

The authors declare that the study was approved by the Ethics Committee of the institution Hospital Moinhos de Vento under opinion number 4.543.282. Only participants with informed consent form participated in the study. All methods in the study were performed in accordance with relevant institutional and national guidelines.

Consent for publication

Not applicable.

Availability of data and materials

The data sets generated and/or analyzed during this study are not publicly available because they are patient data the institution does not allow the sharing of raw data, but are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This study is not funded.

Authors' contributions

All authors contributed equally to the work.

Acknowledgements

We thank the VMO team for support in data collection and the patients for collaboration.

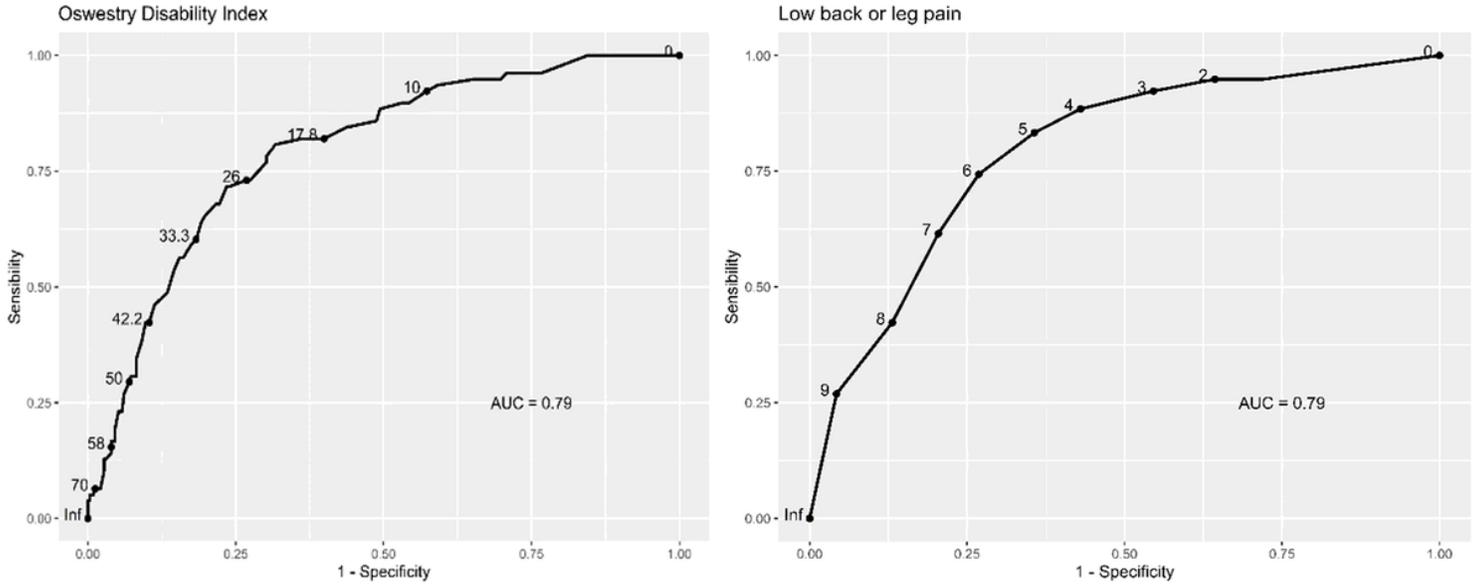
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Figures



Test	Cutoff (points)	Sen/Sp	AUC (95% IC)	Correct classification* (%)
ODI	28	0.72 / 0.77	0.79 (0.74-0.84)	76.0
Pain	6	0.74 / 0.73	0.79 (0.73-0.84)	73.0

Figure 1

Sensibility (Sen) and Specificity (Spe) of ODI and pain values to S&F patients

*Correct classification rate is the sum of the number on the diagonal divided by the sample size in the test data