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Clinical Study

Predictors of the efficacy of epidural steroid injections for structural lumbar degenerative pathology

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Abstract

BACKGROUND: Lumbar epidural steroid injection (LESI) is a valuable therapeutic option when administered to the appropriate patient, for the appropriate disease process, at the appropriate time. There is considerable variability in patient-reported outcomes (PROs) after LESI, creating uncertainty as to who will benefit from the therapy and who will not.

PURPOSE: We set out to identify patient attributes, which are important predictors for the achievement of a minimum clinically important difference (MCID) in the Oswestry Disability Index (ODI) after LESI.

STUDY DESIGN: A prospective cohort study was carried out.

PATIENT SAMPLE: A total of 239 consecutive patients undergoing LESI for back-related disability, back pain (BP), and leg pain (LP) associated with degenerative pathology comprised the patient sample.

OUTCOME MEASURES: Baseline and 3-month patient self-reported ODI, numeric rating scale-BP and LP, Euro-Qol-5D, and Short Form (SF)-12 scores were recorded.

METHODS: A total of 239 consecutive patients undergoing LESI for degenerative pathology over a period of 2 years who were enrolled into a prospective web-based registry were included in the study. Using the previously reported anchor-based approach, an MCID threshold of 7.1% was established for ODI after LESI. Each enrolled patient was then dichotomized as a "responder" (achieving MCID) or a "non-responder." Multiple logistic regression analysis was then performed, with the achievement of MCID serving as the outcome of interest. Candidate variables included in the regression analyses were age, gender, employment, insurance type, smoking status, preoperative ambulation, preinjection narcotic use, comorbidities, predominant LP or BP symptoms, symptom duration, diagnosis, number of levels, prior surgery, baseline PROs, type of stenosis (central, lateral recesses, or foraminal), injection route (transforaminal, interlaminar, or caudal), and number of injections. Subsequently, we also randomly selected 80% of the patients to serve as the training data for a multiple logistic regression model. Once this predictive model was built, it was validated using the remaining 20% of patients.

RESULTS: There were 124 (62%) patients who achieved MCID for ODI. The existence of central stenosis (p=.006), TF or IL injection route (p=.02) compared with caudal epidural steroid injection,

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higher baseline ODI (p=.00001), and a diagnosis of disc herniation (p=.02) increase the odds of achieving MCID for ODI at 3 months. Symptom duration for over a year (p=.006), prior surgery (p=.08), and preinjection anxiety (p=.001) decrease the odds of achieving MCID. The area under the curve (AUC) for our predictive model's receiver-operator characteristic was 0.81 when using the 80% training data set, and the AUC was 0.72 when using the 20% validation data.

CONCLUSION: We have identified patient attributes that are important predictors for the achievement of MCID in ODI 3 months after LESI. The use of these attributes, in the form of a predictive model for LESI efficacy, has the potential to improve decision making around LESI. Spine care providers can use the information to gain insight into the likelihood that a particular patient will experience a meaningful benefit from LESI.

Keywords: Efficacy; Epidural steroid injection; Lumbar; MCID; ODI; Predictors

Introduction

Lumbar spine disorders affect nearly one-third of the U.S. population, with a lifetime prevalence ranging from 59% to 84%. The direct cost of treating these patients is an estimated $80–$100 billion annually [1–5], and indirect costs from lost work are estimated from $84.1 to $624.8 billion [6]. Notably, more than 80% of spine care expenditures go toward medical interventional modalities [7]. Medicare costs associated with medical interventional spine care have increased markedly over the last decade, as seen in the 629% increase in expenditures for epidural steroid injections from $24 million to over $175 million [6,8–13].

Despite improvements in injection techniques and several randomized controlled trials [6,14–20], important controversies remain regarding the efficacy of lumbar epidural steroid injection (LESI) in degenerative spine diseases. Some degree of short-term improvement in pain and disability is anticipated after LESI, but when this is not the case, patients often undergo repeat procedures or experience delays in surgery. This results in continued and unnecessary use of healthcare resources. Furthermore, LESI is not a completely benign procedure, as it can lead to non-trivial complications such as infection, paralysis, spinal fluid leak, and even death [21,22]. As we move toward value-based care, it is imperative that we attempt to identify those who will truly benefit from LESI.

Currently, we are unable to predict which patients will benefit from LESI and which patients are better suited for surgery. The response to LESI undoubtedly depends on several factors, which include disease pathology and an array of patient attributes. Therefore, it is important to determine how an individual patient's attributes, symptoms, imaging findings, and anticipated method of steroid injection influence the likelihood of meaningful response to LESI. The purpose of our study is to identify those predictive factors for the achievement of a minimum clinically important difference (MCID) in Oswestry Disability Index (ODI) after LESI for structural degenerative lumbar spine pathology.

Methods

Patient selection

Patients presenting to comprehensive spine clinic between 2012 and 2014 were screened for enrollment in a prospective longitudinal web-based spine registry. Six random patients per week with physical examination and imaging findings consistent with primary surgical pathology, but who have chosen a medical management pathway, are screened for study accrual. The inclusion criteria for the study were (1) patients aged 18–70 years; (2) complaints of radiating leg pain (LP); (3) correlative imaging findings of structural degenerative pathology including disc herniation, stenosis (central, foraminal, or lateral recess), and spondylolisthesis. The exclusion criteria were (1) pathologic cause of spinal disease; (2) an active medical or workman's compensation lawsuit; (3) any extra-spinal cause of back pain (BP); (4) non-specific cause of BP; and (5) an unwillingness or inability to participate in follow-up procedures. Of the eligible patients, those who completed 3-months' follow-up were included in this study.

Outcome measures

Patient-reported outcome (PRO) measures for pain, disability, quality of life, and satisfaction are recorded at baseline as well as 3 months after fluoroscopically guided LESI. Validated questionnaires are used to collect PROs: (1) pain—numeric rating scale for BP and LP; (2) disease-specific physical disability—ODI; (3) generic health-related physical and mental quality of life—Short Form-12 physical component score (SF-12 PCS) and mental component score (SF-12 MCS); and (4) preference-based health status—EuroQol-5D (EQ-5D) and (5) North American Spine Society Satisfactory Questionnaire. Based on the previously published values, depression was defined as the Zung depression index>33 and preinjection anxiety was defined as Modified Somatic Perception Questionnaire>12. The outcomes are assessed via a phone interview conducted by an independent investigator not involved with clinical care. Using the previously reported anchor-based approach [23,24], an MCID threshold of 7.1% for ODI was established, allowing patients to be classified as either responders, by virtue of achieving that MCID, or non-responders.

Statistical analysis

Mean, standard deviation, median, quartiles and interquartiles for continuous variables, and frequency for categorical variables were calculated for patient demographics. Multiple logistic regression analysis was used to model the effect of various patient

EVIDENCE & METHODS

Context

The authors sought to develop a model that could help inform capacity to benefit from epidural steroid injections for the treatment of lower extremity radiating pain. They present results from a single center.

Contribution

The authors reported that 52% of their patients reached minimum clinically important difference (MCID) following treatment with epdirual injection. A number of factors, including symptom duration of over one year, prior surgery and preinjection anxiety, increased the odds of failure. Injection route, injections associated with disc herniation and central stenosis, among other factors, were considered favorable characteristics predictive of enhanced capacity to reach MCID.

Implications

The results presented here are valuable in that they can inform decision-making and the preprocedural consent process with respect to expectation management. As a single center study, the results of this work may not be generalizable to patient experience at other centers. Furthermore, given that there were only 124 patients who achieved the outcome of interest, the model may be overfit and some of the statistically significant findings may not be encountered in other settings. More work on the development of predictive modeling for benefit from ESI, as well as the capacity of these models to inform benefit of surgery, is clearly necessary. Given limitations associated with this effort, the results presented here should be considered Level III evidence.

—The Editors

attributes on the likelihood of achieving the MCID for ODI at 3-months' follow-up. The baseline independent variables included in the analysis were patient age, gender, employment status, insurance type (private, Medicaid, Medicare), smoking history, ambulation, opioid use, comorbidities including depression, anxiety and diabetes, pain symptoms classified as predominant LP or BP, symptom duration (less than 12 months and more than 12 months), diagnosis (stenosis vs. disc herniation), prior surgery, baseline PROs, location of stenosis, and route of injection (including transforaminal [TF], interlaminar [IL], or caudal). Eighty percent of patients in our study cohort were also randomly selected, so that their data could be used as the training set for the creation of a predictive regression model. Once the regression model for the achievement of MCID in ODI was built, it was validated using the remaining 20% of enrolled patients. Receiver-operator characteristic (ROC) curve analysis was used to quantify the predictive performance of the regression model. The p-values less than .05 were considered statistically significant. The analysis was performed using the R 3.1.2 (www.R-project.org).

Results

Patient demographics

A total of 239 patients who had completed 3 months' follow-up were available and were included in the study. Of these patients, 46 (19%) had a diagnosis of spondylolisthesis, 141 (58.9%) had stenosis, and 52 (21.8%) had disc herniation. There were 106 male and 133 female patients with a mean age of 60.6±14.2 years. Sixty-three percent of patients experienced duration of symptoms exceeding 12 months and 57% had a history of prior surgery. The mean baseline scores at presentation were 41.01 points for ODI, 0.59 for EQ-5D, 28.71 for SF-12 (PCS), and 6.1 for LP and 6.2 for BP. The mean baseline Zung depression scores and Modified Somatic Perception Questionnaire scores were 33.09 and 5.22, respectively. The route of injection was TF in 174 (72.8%) of patients, IL in 44 (18.4%), and 21 (8.7%) of patients underwent injection by either combined TF and IL routes or a caudal route. The mean number of injections per patient was 2.6. There were 105 (44%) patients who had additional injections following the baseline injection. Table 1 summarizes the preinjection variables.

PRO scores and MCID

A significant improvement in all outcome measures was observed at 3 months' follow-up compared with the baseline: for ODI (42±14.2 vs. 32.2±17.9, p<.001), (0.57±0.23 vs. 0.68±0.24, p<.001) for EQ-5D, (28.6±10.5 vs. 35.1±13.3, p<.001) for SF-12 (PCS), (6.3±2.6 vs. 4.8±2.9, p<.001) for BP, and (6.1±3.1 vs. 4.1±3.4, p<.001) for LP (Table 2). The MCID values were generated using the previously reported anchor-based approach method [25]. The MCID value is 7.1% for ODI, 0.10 for EQ-5D, 2.1 for SF-12 PCS, 1.2 for BP, and

Table 1
Patient preinjection variables

	Total (239)
Age (mean±SD) years	60.6±14.2
Gender: male	106 (44.4%)
Smoker	125 (52.3%)
Primary diagnosis	
Herniated disc	52 (21.8%)
Stenosis	141 (58.9%)
Spondylolisthesis	46 (19.2%)
Motor deficits	33 (13.8%)
Neurogenic claudication	7 (2.9%)
Duration of symptoms (>12 months)	150 (62.8%)
Preinjection bracing	44 (18.4%)
Preinjection physical therapy	171 (71.5%)
History of diabetes	42 (17.6%)
History of congestive heart failure	3 (1.3%)
History of coronary artery disease	18 (7.5%)
History of chronic obstructive pulmonary disease	9 (3.8%)
History of hypertension	129 (54.0%)

SD, standard deviation.

Table 2
Improvement in Oswestry Disability Index (ODI), Short Form-12 physical component score (SF-12 PCS), EuroQol-5D (EQ-5D), numeric rating scale (NRS) for back and leg pain 3 months after injection

	Baseline mean (SD)	3-Month mean (SD)	p-Value
ODI	42.0 (14.2)	32.1 (17.9)	<.0001
EQ-5D	0.57 (0.23)	0.68 (0.24)	<.0001
SF-12	28.6 (10.5)	35.1 (13.3)	<.0001
Back pain	6.3 (2.6)	4.8 (2.9)	<.0001
Leg pain	6.1 (3.1)	4.1 (3.4)	<.0001

1.7 for LP. Of 239 total patients, 124 (52%) patients achieved MCID for ODI. Figure displays scatterplot demonstrating the individual patient variation in achieving or not achieving MCID at 3 months after LESI for structural degenerative spine disease. Each point on the plots represents an individual patient.

Multivariable regression model analysis

The existence of central stenosis (p=.006), TF, or IL injection route (p=.02) compared with caudal epidural steroid injection, higher baseline ODI (p=.00001), and a diagnosis of disc herniation (p=.02) increases the odds of achieving MCID for ODI at 3 months. Symptom duration for over a year (p=.006), prior surgery (p=.08), and preoperative anxiety (p=.001) decrease the odds of achieving MCID. Table 3 demonstrate the coefficient and p-value of the predictive model regression analysis. The area under the curve (AUC) for our model's ROC is 0.81 when using the 83% training data set and 0.72 when using the 20% validation data. Table 4 demonstrates hypothetical patients (A) and patients with differing baseline characteristics (B), demonstrating the predicted odds of achieving MCID for ODI at 3 months.

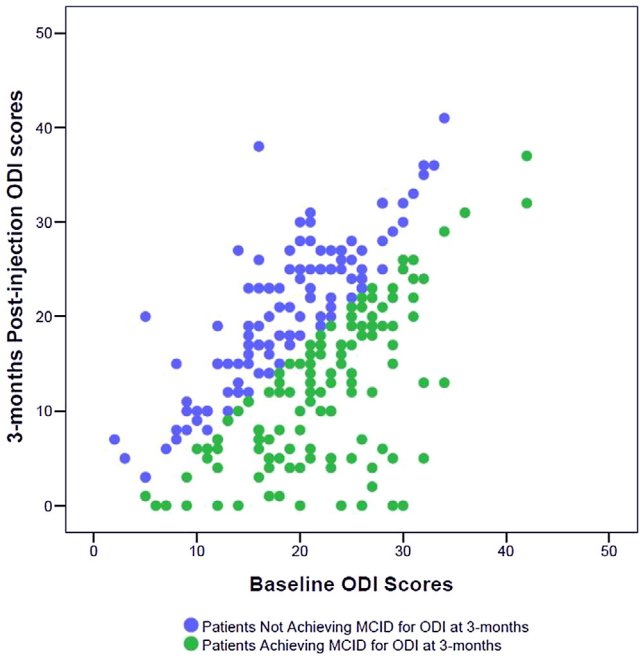

Figure. Scatterplot demonstrates the individual patient variation in achieving or not achieving minimum clinically important difference (MCID) at 3 months after lumbar epidural steroid injection for structural degenerative spine disease. Each point on the plots represents an individual patient. The patients represented in blue failed to achieve MCID for ODI and those represented in green achieved MCID for ODI.

Table 3
Multivariable regression analysis for predicting the minimal clinically important difference in ODI after LESI

Predictor	Odds ratio (95% CI)	p-Value
Central stenosis (mild)	1.4 (0.56–3.53)	.46
Central stenosis (moderate)	2.59 (1.01–6.62)	.05
Central stenosis (severe)	3.56 (1.24–10.26)	.02
Transforaminal/interlaminar route	5.58 (1.36–22.90)	.02
Baseline ODI	1.07 (1.04–1.10)	<.0001
Symptoms>12 months	0.32 (0.12–0.84)	.02
Symptoms 3–12 months	1.34 (0.45–4.01)	.61
Pre-op narcotic use (days)	9.996e-1 (9.99e-1–1.0)	.11
Diagnosis of disc herniation	22.87 (1.56–335.36)	.02
Diagnosis of spondylosis	9.68 (0.76–123.72)	.08
Prior surgery	.55 (0.30–1.04)	.07
Baseline anxiety (MSPQ)	0.87 (0.80–0.94)	.0019

ODI, Oswestry Disability Index; LESI, Lumbar epidural steroid injection; MSPQ, Modified Somatic Perception Questionnaire.

Discussion

We determined the factors that predict the achievement of an MCID in ODI 3 months after LESI. This model can be useful to guide spine care providers in recommending LESI and anticipating the outcome based on patient characteristics. The presence of central stenosis compared with lateral recess or foraminal stenosis, diagnosis of disc herniation, TF or IL injection route compared with caudal ESI and a higher baseline ODI, increases the odds of achieving MCID for ODI at 3 months following LESI procedure.

Studies comparing the benefits of ESI in central versus lateral or foraminal stenosis are sparse [9,26]. Neurogenic claudication, which is often associated with central stenosis, is reported to be less responsive to ESI compared with the patients with stenosis and no complaints of claudication [16,27,28]. In our study, the existence of central stenosis

Table 4
Hypothetical patients (A) and with differing baseline characteristics (B), demonstrating the predicted odds of achieving MCID for ODI at 3 months

	Patient A	Patient B
Central stenosis	2	1
Transforminal/interlaminar	Yes	No
Baseline ODI	30	25
Symptom duration	<3 months	3–12 months
Preoperative narcotic use (days)	30	100
Diagnosis	Disc herniation	Spondylolisthesis
Prior surgery	No	Yes
Baseline MSPQ	4	10
Odds of 3 months MCID for ODI	95.77%	16.94%

MCID, minimum clinically important difference; MSPQ, Modified Somatic Perception Questionnaire; ODI, Oswestry Disability Index.

increased the odds of achieving significant improvement after the LESI compared with lateral recess or foraminal stenosis [27,29]. This may be because of the interaction of location of stenosis with other preinjection characteristics such as baseline ODI. Patients with central stenosis are more disabled at presentation compared with those with foraminal stenosis. In our study, the higher baseline ODI was associated with increased odds of improvement at 3 months. Therefore, the higher baseline ODI scores in these patients can confound the effect of central stenosis on achieving MCID. The patients presenting with the diagnosis of disc herniation were more likely to benefit from LESI. The acute disc herniation leads to mechanical compression and chemical irritation from the immunogenic substances of the nucleus pulposus, resulting in inflammatory radiculopathy [30–32]. In contrast, in spondylotic spinal stenosis, chronic mechanical compression and indirect vascular insufficiency lead to nerve root ischemia and demyelination [33]. Steroids used in LESI are more efficacious in reducing an inflammatory process as occurs in the setting of a disc herniation [34–36], which explains the higher odds of improvement with LESI in patients with disc herniation. Analogous to our findings, several clinical studies, placebo-controlled randomized trials, and systematic reviews have demonstrated better results and higher reduction in absolute ODI points after LESI for disc herniation compared with spondylotic lumbar stenosis [9,37,38].

Another driver of improved outcome after LESI was the route of injection. Previous studies have demonstrated better results with the TF approach compared with the IL and caudal injections because of the proximity of the injection site to the nerve root and better distribution of the drug to the anterior part of the sac [19,39–41]. We found no statistical difference between patients undergoing TF or IL injections; however, both of these routes of administration had statistically superior results compared with caudal injection.

In our study, the symptom duration>12 months was associated with decreased odds of improvement with LESI. Copper et al. [42] reported that the patients with chronic symptoms (>3 months) tend to have worse outcomes than those with acute symptoms. The authors demonstrated that 59.6% of patients had a successful outcome at 1 week post injection, 55.8% at 1 month post injection, 37.2% at 1 year post injection, and 27.3% had a successful outcome at 2 years post injection. The longer duration of symptoms results in more chronic inflammation, which might not respond to the steroid treatment as previously discussed. Similarly, the history of prior surgery was associated with decreased odds of achieving improvement. The history of prior surgery is associated with epidural scarring, which decreases the effectiveness of epidural corticosteroid in controlling the inflammation. Epidural steroids are dependent on flow of the steroid in the epidural space so as to obtain perineural infiltration. Postoperative scarring likely prevents the necessary epidural flow and thereby decreases the effectiveness of injection. Another factor associated with lower odds of achieving benefit from the LESI was the preinjection anxiety symptoms. A number of studies have demonstrated an association between the preoperative psychological distress and poor outcomes following surgery [43–45]. The cognitive intervention during the preinjection period might increase the chances of achievement of MCID for ODI at 3 months.

The effectiveness of LESI in the degenerative spine disease has been challenged by several studies. In a multicenter randomized controlled trial (Spinal Patient Outcomes Research Trial [SPORT]), comparing surgical and medical interventional treatments for degenerative spine pathologies, the authors concluded that there was no difference in avoidance of surgery, complications, or reoperation rates between the patients with ESI undergoing surgery compared with non-ESI patients who had surgery [20,46]. Several studies, however, have demonstrated that LESI has short-term efficacy in selected patients with select disease pathology [7,9,15,16,26,34,47–49]. The limitation in the available literature makes it difficult to provide specific evidence-based recommendations on efficacy of LESI to patients, providers, or policy makers [15,48,49]. Predictive models are cornerstones of defining quality and effectiveness of care for spinal disorders. Therefore, we introduce a predictive model using the patient- and disease-specific effectiveness of LESI in degenerative spine disorders.

Study limitations and strengths

Despite the contributions that this study makes to the literature, there are several limitations. First, the number of patients enrolled in the study is relatively low but adequate to evaluate the variables assessed. Second, the outcome variable of achievement of MCID for ODI is evaluated at 3 months after injection. This is a reasonable follow-up time for the minimally invasive procedure such as LESI; however, we did not analyze the patients that require crossover from injection to surgery. A predictive model analyzing the factors associated with achievement of meaningful improvement in pain and disability at 12 months after injection will define which patients may and which may not achieve long-term benefit from LESI for degenerative spine disease.

Nonetheless, based on the prospectively collected patient-specific attributes, patient-reported outcomes, and injection procedure data with well-defined inclusion and exclusion criteria, we determine factors that predict the odds of achieving benefit from the LESI for degenerative disease. Our analysis was reasonably accurate in predicting the likelihood of achieving MCID for ODI at 3 months, with the AUC for ROC of 0.71. It is important to note that the predictive factors reported in the study only applies to the patients with structural degenerative spine disease with correlative BP and LP, and not to people with non-specific BP. Further validation and development of a robust predictive model is necessary; however, this study provides the framework to begin understanding those who will benefit from an epidural steroid injection. Physicians can assess for the presence or absence of these factors to derive the probability of effectiveness of LESI for an individual patient, thereby promoting value-based care and

increasing the effectiveness of LESI in selected patients with structural degenerative lumbar spine pathology.

Conclusion

We have identified patient attributes that are important predictors for the achievement of MCID in ODI 3 months after LESI. The use of these attributes, in the form of a predictive model for LESI efficacy, has the potential to improve decision making around LESI. Spine care providers can use the information to gain some insight into the likelihood that a particular patient will experience a meaningful benefit from LESI. Taking into account these variables will improve patient selection for LESI and can thereby prevent unnecessary costs and improve the overall value of spine care.

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