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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The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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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.   © 2015 Elsevier Inc. All rights reserved.

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