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Clinical Study

Can patient characteristics predict benefit from epidural corticosteroid injections for lumbar spinal stenosis symptoms?

Judith A. Turner, PhD[a,b,*], Bryan A. Comstock, MS[c], Christopher J. Standaert, MD[b], Patrick J. Heagerty, PhD[c], Jeffrey G. Jarvik, MD, MPH[d,e,f], Richard A. Deyo, MD, MPH[g,h,i,j], Ajay D. Wasan, MD[k,l], Srdjan S. Nedeljkovic, MD[m], Janna L. Friedly, MD[b]

[a]*Department of Psychiatry & Behavioral Sciences, University of Washington, 1959 NE Pacific St, Seattle, WA 98195, USA*
[b]*Department of Rehabilitation Medicine, University of Washington, 1959 NE Pacific St, Seattle, WA 98195, USA*
[c]*Department of Biostatistics, University of Washington, 1959 NE Pacific St, Seattle, WA 98195, USA*
[d]*Department of Radiology, University of Washington, Box 359728, 325 Ninth Ave, Seattle, WA 98104-2499, USA*
[e]*Department of Health Services, University of Washington, Box 359728, 325 Ninth Ave, Seattle, WA 98104-2499, USA*
[f]*Department of Neurological Surgery, University of Washington, Box 359728, 325 Ninth Ave, Seattle, WA 98104-2499, USA*
[g]*Department of Family Medicine, Oregon Health and Science University, 3181 SW Sam Jackson Park Rd, Portland, OR 97239, USA*
[h]*Department of Medicine, Oregon Health and Science University, 3181 SW Sam Jackson Park Rd, Portland, OR 97239, USA*
[i]*Department of Public Health and Preventive Medicine, Oregon Health and Science University, 3181 SW Sam Jackson Park Rd, Portland, OR 97239, USA*
[j]*Oregon Institute for Occupational Health Sciences, Oregon Health and Science University, 3181 SW Sam Jackson Park Rd., Portland, OR 97239, USA*
[k]*Department of Anesthesiology, University of Pittsburgh, 200 Lothrop St, Pittsburgh, PA 15213, USA*
[l]*Department of Psychiatry, University of Pittsburgh, 3811 O'Hara Street, Pittsburgh, PA 15213, USA*
[m]*Department of Anesthesiology, Perioperative and Pain Medicine, Brigham and Women's Hospital and Spine Unit, Harvard Vanguard Medical Associates, BWH Pain Management Center, 850 Boylston St, Chestnut Hill, MA 02467, USA*

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Abstract

BACKGROUND CONTEXT: Epidural corticosteroid injections are commonly used to treat back and leg pain associated with lumbar spinal stenosis. However, little is known about which patient characteristics may predict favorable responses.

FDA device/drug status: Not approved for this indication (Corticosteroid use as described in the article (different steroids and formulations were used according to practitioner/practice site). No corticosteroid is FDA approved for use in the epidural space, although various corticosteroids are FDA approved for general use).

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

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* Corresponding author. Department of Psychiatry & Behavioral Sciences, University of Washington, 1959 NE Pacific St, Seattle, WA, USA. Tel.: 1-206-543-3997.

E-mail address: jturner@uw.edu (J.A. Turner)

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PURPOSE: The aim was to identify patient characteristics associated with benefits from epidural injections of corticosteroid with lidocaine versus epidural injections of lidocaine only for lumbar spinal stenosis symptoms.
STUDY DESIGN/SETTING: This was a secondary analysis of Lumbar Epidural steroid injections for Spinal Stenosis randomized controlled trial data from 16 US clinical sites.
PATIENT SAMPLE: Patients aged older than or equal to 50 years with moderate-to-severe leg pain and lumbar central spinal stenosis randomized to epidural injections of corticosteroids with lidocaine (n=200) or lidocaine only (n=200) were included.
OUTCOME MEASURES: Primary outcomes were the Roland-Morris Disability Questionnaire (RMDQ) and 0 to 10 leg pain intensity ratings. Secondary outcomes included the Brief Pain Inventory Interference Scale and the Swiss Spinal Stenosis Questionnaire.
METHODS: At baseline, clinicians rated severity of patient spinal stenosis, and patients completed predictor and outcome measures. Patients completed outcome measures again 3 and 6 (primary end point) weeks after randomization/initial injection. Analysis of covariance was used with treatment by covariate interactions to identify baseline predictors of greater benefit from corticosteroid+lidocaine versus lidocaine alone. We also identified nonspecific (independent of treatment) predictors of outcomes.
RESULTS: Among 21 candidate predictors and six outcomes, only one baseline variable predicted greater benefit from corticosteroid+lidocaine versus lidocaine only at 3 or 6 weeks. Compared with patients who rated their health-related quality of life as high on the EQ-5D Index, patients who rated it as poor had greater improvement with corticosteroid than with lidocaine only in leg pain at 6 (but not 3) weeks (interaction coefficient=2.94; 95% confidence interval [CI]=0.11–5.76; p=.04) and in RMDQ disability scores at 3 (but not 6) weeks (interaction coefficient=4.77, 95% CI= −0.04 to 9.59; p = .05). Several baseline patient characteristics predicted outcomes regardless of treatment assignment.
CONCLUSIONS: Among 21 baseline patient characteristics examined, none, including clinician-rated spinal stenosis severity, were consistent predictors of benefit from epidural injections of lidocaine+corticosteroid versus lidocaine only.

Keywords: Lumbar spinal stenosis; Epidural steroid injections; Corticosteroid; Back pain; Leg pain; Predictors; Treatment effect modifiers

Introduction

Lumbar spinal stenosis is one of the most common causes of low back and leg pain and functional limitations among older adults [1–3]. Lumbar epidural steroid injections (ESIs) are performed commonly for patients with this condition, with the goal of improving back or leg pain and function [3]. The rates and costs of lumbar ESIs have increased dramatically in the U.S. Medicare population [4,5] despite the absence of definitive randomized trials establishing efficacy. Medicare expenditures for lumbar ESIs in 2001 were estimated as $450 million, and spinal stenosis diagnoses were associated with 23% of the injections [4].

We recently reported results from the Lumbar Epidural steroid injections for Spinal Stenosis (LESS) randomized controlled trial (RCT), which evaluated epidural injections of corticosteroid+local anesthetic (lidocaine), as compared with epidural injections of lidocaine only, among older adults with neurogenic claudication from lumbar central spinal stenosis [6]. We found little to no benefit associated with the use of corticosteroids versus lidocaine only in these patients at 6 weeks (the primary study end point) for pain-related physical disability or leg pain. Similar proportions of the two treatment groups achieved a clinically meaningful degree of improvement (30% improvement from baseline) in physical disability (Roland-Morris Disability Questionnaire [RMDQ] scores; corticosteroid+lidocaine: 37.3%; lidocaine only: 31.6%) and leg pain intensity ratings (corticosteroid+lidocaine: 49.2%; lidocaine only: 49.7%) at 6 weeks. At 3 weeks, there were small between-group differences in RMDQ scores favoring the corticosteroid group, but these differences were clinically unimportant. In both treatment groups, patients on average improved in pain and function. Nonetheless, it is possible that these average treatment group responses obscure important variability in patient response to treatment, and that there are patient subgroups defined by clinical or demographic characteristics with higher likelihood of a meaningful benefit from corticosteroids.

Currently, however, there is little scientific evidence concerning which, if any, spinal stenosis patient characteristics predict favorable response to ESIs. In a small case series [7], age, gender, body mass index (BMI), and stenosis severity, analyzed individually, were not significantly