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Which regional pain rating best predicts patient-reported improvement in lumbar radiculopathy?

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Abstract

Objective: To determine the best regional pain score cutoff value that corresponds with patient-reported improvement in lumbosacral radiculopathy (LSR).

Design: Retrospective pooled data analysis from three randomized, controlled, multi-center trials using similar outcome assessments. All participants were exposed to interventions (epidural injections).

Setting: Military medical centers (6 US, 1 Germany) and large tertiary care hospitals (4 urban, 1 Veterans Affairs) between 2008 and 2014.

Subjects: 352 active duty military personnel and civilians aged 18 years with LSR.

Methods: Receiver operating characteristics (ROC) with area under the curve (AUC) were calculated for 1-month outcomes for pain (Numeric Rating Scale) using absolute and relative change in regional pain scores (back, leg) to predict clinical improvement (Global Perceived Effect).

Results: Leg pain demonstrated greater predictive ability to identify clinical improvement compared to back pain for both absolute (ROC AUC [95% CI] 0.855 [0.813, 0.896] vs. 0.753 [0.702, 0.805]; $p < 0.001$) and relative (AUC [95% CI]; 0.867 [0.826, 0.909] vs. 0.780 [0.729, 0.831]; $p = 0.002$) reduction in reported pain. Clinical improvement was best identified using leg pain reduction threshold of 1.75 points (absolute) and 23.5% (relative).

Conclusions: Regional-specific pain cutoff ratings predicted clinical improvement for patients with LSR. Cutoff points using newly identified, smaller reductions of 1.75 points and 23.5% more accurately predicted clinical improvement for LSR than conventionally used cutoffs (2 points and

30%). LSR patients report meaningful clinical improvement with smaller reductions in pain compared to other chronic pain diagnoses, suggesting LSR patients may have different expectations.

Introduction

Distinguishing between meaningful improvement and lack thereof in patient populations lies at the heart of effective clinical research. In the field of pain research, measurement of clinical characteristics and subsequent patient outcomes is complicated by the subjective nature of pain.¹ Consequently, approaches to assessing pain commonly employ numeric rating scales (NRS), visual analogue scales (VAS), or other quantifiable instruments.² However, even with such quantitative data, it is challenging to determine what constitutes a meaningful change to patients.³

Guidelines on the clinical importance of treatment outcomes in chronic pain studies indicate that a relative reduction of 30% represents a clinically meaningful difference for patients.⁴ The most robust evidence for this benchmark originates from an analysis of 10 controlled studies of pregabalin in 2,724 patients.⁵ Non-specific chronic low back pain constituted the diagnosis among 2 studies of this cohort, which also included four other pain diagnoses: diabetic peripheral neuropathy, osteoarthritis, fibromyalgia, and postherpetic neuralgia. In this diverse collection of chronic pain conditions, an absolute reduction of 2 points on a 0–10 point scale or a relative reduction of 30% corresponded with a “clinically important difference” in patient response.⁵ Other studies evaluating low back pain include a report by Hagg (2003), which focused on 289 patients with non-specific back pain without clinical or radiological evidence of nerve root compression.⁶ Using a 100 unit VAS, an 18- to 19-point reduction in pain corresponded with a meaningful improvement.⁶ Finally, what constituted meaningful improvement for radicular pain was examined in a subgroup analysis performed in 75 patients who were randomized to receive either epidural steroid or saline injection as part of a clinical trial. The authors found that a 30-point or 50% reduction in overall pain was the ideal cutoff to discriminate those who reported an important improvement in symptoms from those who described their improvement as poor.⁷

Past investigations measured and analyzed changes in global pain scores, which characterize the total level of pain for a patient (elicited by questions such as “what is your overall level of pain?”). As clinical studies have evolved, more detailed pain scores specific to a body region or territory have been increasingly used (i.e., “what is your level of back pain?”). Although some types of back pain may be non-specific, lumbar radiculopathy is consistently characterized by pain in the lower back and one or both legs.⁸ Clinical studies in these patients have begun to record pain scores specific to these two discrete regions of the body. However, regional pain scores may differ from global pain scores in their ability to denote clinically meaningful outcomes for patients given the former’s greater capacity to capture more specific pain information.⁹

Recently, three randomized clinical trials of patients with lumbar radiculopathy measured regional specific pain scores and meaningful improvement.^{10–12} These studies recruited patients with lumbosacral radiculopathy from both military and civilian hospitals. Patients

underwent epidural injections, with most receiving steroid and some receiving sham, saline, or a cytokine inhibitor tumor necrosis factor (TNF)- α injection. All three studies masked assessment of outcome data, which included region-specific average pain scores over the past week for the back and legs. The aim of this study was to address the question of what change in pain score best corresponds with meaningful improvement in patients with chronic pain from lumbar radiculopathy. We hypothesized that reductions in leg pain would better predict a clinically meaningful response than reductions in back pain. Additionally, we posit that changes in pain scores for lumbar radiculopathy would be greater for leg compared to back pain.

Methods

Study design

We retrospectively examined de-identified data from a cohort of all participants enrolled in 3 randomized, controlled, multi-center chronic pain studies that utilized similar study procedures for the assessment of outcomes.^{10–12} Prior to their conduct, all studies secured internal review board permission from every institution participating in patient recruitment, and all participants provided written informed consent. One study examined the impact of magnetic resonance imaging (MRI) on outcomes and decision making in patients referred for epidural steroid injection (ESI). After undergoing MRI, patients were randomized to physician MRI review or no review prior to ESI. MRI showed only a small effect on decision making and made no difference in outcomes.¹¹ The other two studies randomized patients to ESI or non-ESI treatments and favored ESI for modest, short-term pain relief in both cases.^{10,12} Comparison groups included a TNF- α inhibitor etanercept or saline in one¹⁰ and gabapentin in the other.¹² Table 1 presents additional information about eligibility criteria for study participants.

Participants, Settings, and Interventions

Civilian and active duty military personnel aged 18 years or older with a diagnosis of lumbosacral radiculopathy were recruited from pain clinics and primary care settings. Sites included 6 United States military medical centers as well as a military hospital in Germany, a Veteran's Affairs hospital, and 4 large urban tertiary care hospitals. Enrollment for the earliest study began in June 2008 and concluded for the most recent study on 10 June 2014. All participants were exposed to interventions (one or two fluoroscopically guided epidural injections), while patients in one trial¹² were exposed to medications (gabapentin or placebo). A total of 361 patients were randomized in three studies.^{10–12} Among nine patients excluded from this analysis, five received non-study treatments and four were lost to follow up at 1 month.

Main outcome measures

In all 3 studies, outcome data were obtained by research clinicians masked to the treatment group. Patients rated regional specific NRS scores to obtain separate values for back pain and leg pain. NRS scores ranged from 0 (no pain) to 10 (worst pain). NRS scores were assessed at baseline and at 1 month, with each score representing the average pain experienced by the patient in the 1 week preceding assessment. At 1 month, patients rated

clinical improvement using global perceived effect (GPE), defined as a patient's positive response to both questions, "My pain has improved/worsened/stayed the same since my last visit" and "I am satisfied/not satisfied with the treatment I received and would/would not recommend it to others."

Statistical analysis

For each participant, characteristics for regional NRS scores were calculated using both absolute change (1 month value minus baseline value) and relative change (absolute change divided by baseline value). Relative change scores could not be calculated for baseline NRS pain values of 0 (i.e., for patients reporting radicular pain but no back pain), and accordingly those scores were not used in the relative change analysis. To characterize the association between regional NRS scores and meaningful patient improvement, values for sensitivity, specificity, and percent correct classification were derived using receiver operating characteristics (ROC). ROC curves characterize the predictive ability of a measure or scale at a range of cutoff values, with greater area under the curve (AUC) corresponding to enhanced predictive ability. In each analysis, patient improvement served as the dependent variable and either absolute or relative regional NRS change served as the independent variable. Analyses were repeated for both back and leg NRS scores. A direct comparison of NRS ratings tested the equality of AUC for regional pain scores (i.e., change in back vs. leg NRS scores) to predict patient improvement. All analyses were performed using Stata/IC 12.1 (College Station, TX: StataCorp LP). P-values for all tests were set at $p = 0.05$.

Results

Study and Patient Characteristics

The pooled study population for our analysis consisted of 352 patients who had complete data available, including NRS pain ratings (both baseline and 1 month back and leg pain) and clinical improvement (global perceived effect) (Table 2). For the 17 patients with baseline back pain scores of 0, relative change scores were not calculated.

Comparison of Back and Leg Pain Ratings

All three studies reported a reduction in both back and leg pain scores at one month (Table 3). The reduction in leg pain NRS exceeded reductions in back pain scores in all three studies, and this was evident in assessments for both absolute change (Leg mean $\pm$ SD = -2.4 ± 2.8 ; Back = -1.5 ± 2.4) and relative change (Leg = -38.1% ; Back = -25.2%). Meaningful clinical improvement was reported by similar percentages of patients across all three studies and in 62.8% of all patients.

Reductions in leg pain better predicted clinical improvement as measured by global perceived effect than reductions in back pain, as evidenced by a greater area under the curve in ROC analyses (Table 4, Table 5). This relationship remained consistent for both absolute and relative reductions in pain.

Absolute leg pain reduction demonstrated greater predictive ability to identify clinical improvement than did absolute back pain reduction (AUC [95% CI] for leg = 0.855 [0.813,

0.896]; for back = 0.753 [0.702, 0.805]; $p < 0.001$) (Figure 1). Similarly, relative reduction for leg pain demonstrated a higher predictive ability than did relative back pain reduction (AUC [95% CI] for leg = 0.867 [0.826, 0.909]; for back = 0.780 [0.729, 0.831]; $p = 0.002$).

The improvements in leg pain that were best associated with clinical improvement were an absolute value of -1.75 points reduction in NRS pain score and a 23.5% relative reduction in pain score (Figure 2). The back pain reductions that optimally classified clinical improvement were an absolute value of -0.5 points in NRS pain score reduction and a relative reduction of -14.3% .

In subgroup analysis of 227 patients by recorded diagnosis of either herniated nucleus pulposus (HNP) (83%; $n = 189$) or spinal stenosis (17%; $n = 38$), leg pain demonstrated greater predictive ability to identify clinical improvement for both absolute and relative reduction for HNP ($p < 0.001$ for both models), but no difference in clinical improvement prediction was present for spinal stenosis ($p = 0.35$ and $p = 0.24$, respectively).

Discussion

In patients with lumbosacral radicular pain, we found that reductions in average pain scores over the past week for both leg and back pain predicted patient-reported clinical improvement, based on data pooled from three recent randomized controlled trials of epidural steroid injections. Reductions in leg pain scores more accurately predicted patient-reported clinical improvement than reductions in back pain. This association remained consistent regardless of whether absolute or relative changes in pain scores were analyzed. To our knowledge, this is the first time that regional pain ratings have been used in attempt to predict clinical improvement.

These findings highlight two key differences for lumbosacral radiculopathy, but largely concur with previous work done on determining what constitutes a minimal clinically important change for patients in chronic pain.⁵ First, for lumbosacral radiculopathy, a less conservative cutoff for absolute reduction in region-specific leg pain scores of -1.75 provides slightly higher degrees of sensitivity, specificity, and percent correct classification than the cutoff of -2 suggested from non-specific pain score models developed using data from various chronic pain diagnoses. When using region-specific leg pain scores in a clinical context, a change in pain of -2 points provides similar predictive values. Second, a smaller relative reduction in leg pain can result in clinically meaningful patient-reported outcomes for lumbosacral radiculopathy than what has previously been reported. The cutoff for relative reductions in region specific pain scores found in lumbosacral radiculopathy (-23.5%) was lower than values derived from other studies using non-specific pain scores in other chronic pain conditions (-30%). Whereas the measure of clinical improvement, positive global perceived effect, was assessed using a seven-item categorical scale in the studies by Farrar et al, this outcome was recorded as a dichotomous outcome (yes/no) in the three studies included in this analysis. The ability for absolute change in non-specific pain score models to predict clinical improvement from Farrar, et al. (termed “raw change”) aligns well with the absolute leg pain rating model for clinical improvement in this analysis.

⁵ Overall, comparisons of these ROC analyses revealed similar predictive abilities and statistical properties, including correct classification.

While the cutoff values of -1.75 points in region-specific leg pain scores

A probable explanation for differences in these findings regarding lumbosacral radiculopathy versus other chronic pain conditions involves heterogeneity in patient expectations.^{13–15} Past studies have demonstrated that patients pursuing specific treatments may have differing expectations regarding their outcome, such as a chronic limb patients opting for surgical treatment who anticipated complete relief of pain after surgery.¹³ Expectations regarding anticipated outcomes play an important role in the process of response to treatment and the recovery process.^{14,15} These same expectations also likely contribute to the well-known placebo-effect, as observed by Henry Beecher in his 1955 publication “The Powerful Placebo.”¹⁶ Patients with expectations of pain relief may have analgesia from placebo due to various biological mechanisms, including endogenous opioid, dopamine, and cholecystokinin receptors.¹⁷ This may be particularly relevant for interventions such as ESI, as studies have shown that the placebo effect is more powerful for procedures than medications.¹⁸ Regardless of the mechanism, the placebo response plays a prominent role in pain clinical trials with increasing placebo responses over time in clinical trials of some pain conditions in the United States.¹⁹

Epidural steroid injections are most frequently utilized for radicular pain stemming from either a herniated disc(s) or spinal stenosis. Although the presentation of both etiologies may appear similar to non-medical personnel, the two conditions differ by pathophysiology, and the latter may not respond as well to ESI.^{20,21} Radicular pain from a herniated disc typically results from mechanical or chemical nerve root irritation, whereas chronic arterial ischemia and/or venous congestion of the affected nerve roots play a prominent role in neurogenic claudication.²² We found that reduction in leg pain scores predicted clinical improvement in patients with a herniated disc, while the prediction tool fell shy of statistical significance when spinal stenosis patients were analyzed separately. One possible explanation for this is that the two conditions affect quality of life differently, and the elderly, often-retired patients who presented with spinal stenosis may have had different expectations than the younger, more active individuals with herniated discs. However, a second possibility is that the predictive value of leg pain is similar for the two cohorts, but the small number of people with spinal stenosis precluded the chance to achieve statistical significance.

Proper interpretation of these findings should take into account certain limitations of this analysis. These findings may lack generalizability to patient populations beyond adult patients with lumbosacral radiculopathy who consider interventional treatments. A majority of the patients recruited in two of the three studies were male with a military affiliation, reflecting the participating study sites. These patients may be younger, face different physical and psychological stressors, and have a different mindset regarding pain and disability. On the other hand, outcome characteristics demonstrated similar trends across all three studies. Female participants comprised at least one-quarter of participants in each study and more than one-third of the participants in this analysis. Caution should be given to generalizing these findings to outcomes longer than four weeks in duration. It is also

possible that baseline patient characteristics other than those measured across all three studies likely influenced overall clinical improvement. The concordance of findings from this analysis to past studies supports the idea that pain reduction for patients with lumbosacral radiculopathy contributes to clinical improvement in a meaningful way.

In conclusion, an analysis of data from three randomized controlled studies supports the use of regional-specific pain cutoff ratings to predict clinical improvement for patients with lumbosacral radiculopathy. In particular, leg pain ratings provide superior prognostic ability in comparison to back pain ratings regarding patient reported clinical improvement. Prior guidelines based on data from chronic pain populations that did not include lumbosacral radiculopathy suggested pain reductions cutoffs of 2 points or 30%, which may be too conservative to accurately predict clinical improvement for lumbosacral radicular pain. The smaller cutoffs proposed in this analysis, using reductions of -1.75 points and 23.5%, appear to most accurately predict clinical improvement, and should be strongly considered for use when designing clinical trials or interpreting the results of existing studies. Regardless of which cutoffs future studies employ in analysis of pain scores, these findings support the concept that patients with lumbosacral radicular pain may have different expectations given that meaningful clinical improvement occurs with smaller reductions in pain in comparison to other chronic pain diagnoses.

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A. Absolute Reduction in Pain

B. Relative Reduction in Pain

Figure 1. Regional differences in ability of pain score reduction to predict clinical improvement
Comparison of receiver operating characteristics (ROC) area under the curve (AUC) for absolute reduction in pain (figure 1A) and relative reduction in pain (Figure 1B) is * significant to $p < 0.001$ and $p = 0.002$, respectively.

For Figure 1A, absolute reduction in NRS defined as NRS 1 month – NRS baseline. For Figure 1B, relative reduction in NRS defined as absolute reduction in NRS / NRS baseline.

A. Absolute Reduction in Pain

B. Relative Reduction in Pain

Figure 2. Regional differences in ability of pain score reductions to correctly classify clinical improvement

1. For absolute reductions (Figure 2A), the maximum correctly classified improvement for leg and back pain occurred at 1.75 and 0.5 points, respectively. For relative reductions (Figure 2B), the maximum correctly classified improvement for leg and back pain occurred at 23.5% and 14.3%, respectively.

2. Absolute reduction in NRS was defined as NRS 1 month – NRS baseline. Relative reduction in NRS was defined as absolute reduction in NRS / NRS baseline.

Table 1.

Inclusion and exclusion criteria of included studies

Study	Inclusion criteria	Exclusion criteria
Cohen, et al. 2015 ¹²	<ul style="list-style-type: none"> • Age 17 • Lumbosacral radiculopathy symptoms or signs • Symptoms >6 weeks and 4 years • Average leg NRS pain score 4/10 (or 3/10 if leg pain was as bad or worse than back pain) • MRI evidence of herniated disc or spinal stenosis correlating with symptoms 	<ul style="list-style-type: none"> • Previous lumbar spine surgery • Prior ESI within past 3 years • Previous failed trial with pregabalin or gabapentin • Allergy to contrast dye • Cauda equine syndrome • Referral for surgical evaluation • Neuropathic pain > 4 years • Pregnancy • Secondary gain/active litigation • Serious medical or psychiatric condition
Cohen, et al. 2012 ¹¹	<ul style="list-style-type: none"> • Age > 18 years • Lumbosacral radiculopathy symptoms • Leg pain back pain • Agreement to receive ESI regardless of imaging results 	<ul style="list-style-type: none"> • Prior back surgery • Prior ESI within past 2 years • Pain duration > 4 years • Serious neurologic deficit • Serious psychiatric disease
Cohen, et al. 2012 ¹⁰	<ul style="list-style-type: none"> • Age > 18 and <70 years • Lumbosacral radiculopathy symptoms • Symptoms > 4 weeks and < 6 months • Leg pain back pain • Failure of conservative therapy • MRI evidence of disc condition correlating with symptoms 	<ul style="list-style-type: none"> • Previous spinal surgery • Any prior ESI • Allergy to contrast dye • Coagulopathy or systemic infection • Unstable medical or psychiatric condition

Epidural steroid injection (ESI); Magnetic resonance imaging (MRI); Numeric rating scale (NRS)

Table 2.
Baseline characteristics of included randomized controlled trials on lumbosacral radiculopathy

Study	Patients	Age (years)	Female	Opioid Use	Active Duty Status	Baseline NRS Pain	
ID	n	Mean ± SD	%	%	%	Leg	Back
Cohen, et al. 2015 ¹²	143	42.8 ± 13.0	26.6	28.0	54.5	5.4 ± 2.0	4.8 ± 2.5
Cohen, et al. 2012 ¹¹	125	52.2 ± 14.9	57.6	34.4	6.4	6.6 ± 1.9	6.1 ± 2.5
Cohen, et al. 2012 ¹⁰	84	42.3 ± 10.8	29.8	41.7	57.1	6.2 ± 1.9	5.3 ± 2.5
Total	352	46.0 ± 14.0	38.4	33.5	38.0	6.0 ± 2.0	5.4 ± 2.5

Numeric rating scale (NRS); Standard deviation (SD)

Table 3.
Outcome characteristics of included randomized controlled trials on lumbosacral radiculopathy

Study ID	Absolute change in NRS pain		Relative change in NRS pain		Clinical Improvement	
	Leg	Back	Leg	Back		
	Mean $\pm$ SD	Mean $\pm$ SD	%	%	%	%
Cohen, et al. 2015 ¹²	-1.9 $\pm$ 2.5	-1.3 $\pm$ 2.1	-31.7	-23.5		62.9
Cohen, et al. 2012 ¹¹	-2.5 $\pm$ 2.9	-1.7 $\pm$ 2.4	-38.0	-28.7		60.8
Cohen, et al. 2012 ¹⁰	-3.0 $\pm$ 2.9	-1.6 $\pm$ 2.8	-49.3	-23.0		65.6
Total	-2.4 $\pm$ 2.8	-1.5 $\pm$ 2.4	-38.1	-25.2		62.8

Note: Negative changes signify reductions in pain scores. Clinical improvement measured by positive global perceived effect. Standard deviation (SD)

Table 4.
Statistical measures of performance for optimal pain rating cutoff values to predict clinical improvement

Pain (NRS) Rating Model	Area under the curve	Cutoff	Sensitivity %	Specificity %	Positive Likelihood Ratio	Negative Likelihood Ratio	Percent Correct %	P value
Absolute Reduction								
Leg	0.855	-1.75	81.9	83.2	4.9	0.22	82.4	< 0.001
Back	0.753	-0.5	77.8	61.8	2.0	0.35	71.9	
Relative Reduction								
Leg	0.867	-23.5%	85.1	80.9	4.5	0.18	83.5	0.002
Back	0.780	-14.3%	80.0	67.2	2.4	0.30	75.2	

Note: For absolute reduction, n = 352. For relative reduction, n = 335. Area under the curve calculated using receiver operating characteristic analysis. Absolute reduction in NRS was defined as NRS 1 month – NRS baseline. Relative reduction in NRS was defined as absolute reduction in NRS / NRS baseline. Numeric rating scale (NRS).

Table 5.

Statistical measures of performance for select pain rating cutoff values to predict clinical improvement

	Absolute change	Sensitivity	Specificity	Relative change	Sensitivity	Specificity
		%	%		%	%
Leg						
-1		90.1	58.0	-10%	90.1	56.5
-2		81.5	83.2	-20%	86.4	73.3
-3		61.1	90.1	-30%	79.6	84.7
Back						
-1		76.5	62.6	-10%	81.4	60.0
-2		61.5	77.9	-20%	76.7	70.4
-3		41.6	87.8	-30%	64.3	82.4

Note: For absolute reduction, n = 352. For relative reduction, n = 335. Area under the curve calculated using receiver operating characteristic analysis. Absolute reduction in NRS was defined as NRS 1 month – NRS baseline. Relative reduction in NRS was defined as absolute reduction in NRS / NRS baseline. Numeric rating scale (NRS).