THE PROGNOSTIC VALUE OF ELECTRODIAGNOSTIC TESTING IN PATIENTS WITH SUSPECTED LUMBOSACRAL RADICULOPATHY

by

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STATEMENT OF DISSERTATION APPROVAL

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ABSTRACT

Electrodiagnostic testing, consisting of needle electromyography and nerve conduction studies, is the primary method used to objectively measure and document pathological changes or injury to the neuromuscular system, including proximally located spinal nerve roots. Clinicians employ electrodiagnostic testing to evaluate patients with low back pain (LBP). One specific cause of LBP is lumbosacral radicular syndrome (LRS), which is commonly known as *sciatica* or *lumbar radiculopathy*. The presence of radiating leg symptoms is common to all patients with LRS but radiculopathy is distinguished by the presence of measurable nerve root injury. Little is known about prognostic factors in these patients; however, recent evidence suggests the presence of radiculopathy found on needle electromyography may predict better functional outcomes. The primary purpose of this dissertation work was to investigate the prognostic value of electrodiagnostic testing in patients with LRS receiving physical therapy.

Electrodiagnostic testing was performed on 38 patients with LRS participating in a randomized trial comparing different physical therapy treatment programs. Patients were grouped and analyzed according to the presence or absence of radiculopathy. The primary outcome measure was changes in LBP-related disability assessed using the Roland and Morris disability questionnaire (RMDQ). Patients with radiculopathy (n=19) had statistically significant and

clinically meaningful improvements in RMDQ scores at every posttreatment follow-up occasion regardless of physical therapy treatment received. The final multilevel growth model revealed improvements in RMDQ scores in patients with radiculopathy at the 6-week (-8.1, 95% CI, -12.6 to -2.6; *P*=.006) and 6-month (-4.1, 95% CI, -7.4 to -0.7; *P*=.020) follow-up occasions compared to patients without radiculopathy. Physical therapy treatment group was not a significant predictive factor at any follow-up occasion. An interaction between electrodiagnostic status and time revealed faster weekly improvements in RMDQ scores in patients with radiculopathy at the 6-week (-0.72, 95% CI, -1.4 to -0.04; *P*=.040) through the 16-week (-0.30, 95% CI, -0.57 to -0.04; *P*=.028) follow-up occasions compared to patients without radiculopathy.

The presence of lumbosacral radiculopathy identified with electrodiagnostic testing is a favorable prognostic factor for recovery in LBP-related disability regardless of physical therapy treatment received.

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LIST OF ABBREVIATIONS

ANOVA……..analysis of variance

BMI……..body mass index

CI……..confidence interval

CNS……..central nervous system

EDX…….electrodiagnostic

EMG……..electromyography

EOTA……extension-oriented treatment approach

ESI……..epidural steroid injection

gmc…….grand mean centered

ICC……...intra-class correlation coefficient

LBP……low back pain

LR-……...negative likelihood ratio

LR+……positive likelihood ratio

LRS……...lumbosacral radicular syndrome

MCID……...minimal clinically important difference

MGM…….multilevel growth modeling

MMT……manual muscle test

MRI…….magnetic resonance imaging

NPRS……numeric pain rating scale

OR……...odds ratio

OSW……Oswestry disability questionnaire

RMDQ…….Roland and Morris disability questionnaire

SLR……..straight leg raise

Sn…….sensitivity

Sp…….specificity

WNL…….within normal limits

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seemingly impossible schedule of work, school, church, coaching, and occasional fun over the past four years without complaint. I dedicate this work to my family.

CHAPTER 1

INTRODUCTION

This dissertation is broadly concerned with the topic of clinical neurophysiology and lower back pain (LBP). More specifically, the role and potential clinical value of neurophysiologic findings in patients with LBP and leg pain was investigated. For the purposes of this work, electrodiagnostic (EDX) testing, which consists of needle electromyography (EMG) and nerve conduction studies, was the clinical tool used to obtain neurophysiologic information. In order to evaluate the clinical utility of EDX testing in patients with LBP and leg pain, the following research questions were formulated in order to guide study design and analyses: Is EDX testing a reliable clinical tool? Are the results of EDX testing clinically meaningful with regard to patient outcomes? If the results of EDX testing are clinically meaningful, are they unique or can they be obtained by other means such as patient history or physical examination findings? The manuscripts borne out of the research conducted for this dissertation work, and which form the primary substance of this document, are organized to address each of those questions in turn.

Background

Electrodiagnostic testing evaluates the integrity of the neuromuscular system, including upper and lower motor neurons, the neuromuscular junction, and skeletal muscle.[1-5] Conducted as an extension of the clinical examination, EDX testing is the primary method used to objectively measure and document pathological changes or injury to the neuromuscular system, including proximally located spinal nerve roots.[1-5] Clinicians employ EDX testing to evaluate patients with LBP – which is among the most prevalent and costly conditions to treat.[6]

The majority of LBP is considered nonspecific, or having no clear pathoanatomic cause;[7] however, one specific cause of LBP is lumbosacral radicular syndrome (LRS).[8] Known commonly as *sciatica* or *lumbar radiculopathy*, this syndrome has some unique defining characteristics.[9,10] Most commonly the result of a herniated disc, patients with LRS typically complain of LBP and radiating leg symptoms which are often described as sharp, piercing, throbbing, aching, or burning, along with dermatomal paresthesia.[2,10] When describing LRS, the terms *sciatica* and *radiculopathy* are often used interchangeably but are not synonymous. The presence of radiating leg symptoms is common to all patients with LRS, but radiculopathy is distinguished by the presence of objectively measurable nerve root injury, which is difficult to determine from the clinical examination alone.[4,5,10] Despite only 10% to 25% of episodes of LBP being classified as LRS,[8,10] these patients have a heightened risk of persistent symptoms[8] and eventual progression to costly[11] and invasive treatments, including surgery.[12,13]

Research has demonstrated the utility of EDX testing in evaluating patients with LRS. Cho et al. (2010),[14] in an evidence-based review of EDX testing in patients with LRS, found that limb and lumbar paraspinal muscle needle EMG likely aid in the diagnosis of radiculopathy, along with H-reflex testing for S1 lesions. Coster et al. (2010),[15] investigating patients with LRS referred from primary care, examined the diagnostic value of history, physical examination, and needle EMG for predicting nerve root compression on MRI. The results revealed that ongoing denervation found on needle EMG was superior (Odds Ratio=4.5) to straight leg raise testing (OR=3.0), more pain on coughing, sneezing, or straining (OR=2.1), and dermatomal radiation (OR = 2.1). Additionally, 7% of patients in this study with a normal MRI had abnormal needle EMG findings. Dillingham et al. (2000),[16] examining patients with LRS, identified an optimal needle EMG screen by demonstrating that 98-100% of radiculopathies could be identified by sampling 5 limb muscles along with the lumbar paraspinal muscles.

Reliability of Electrodiagnostic Testing

Clinicians employ EDX testing to evaluate patients with LRS,[4,5] one of the most common conditions referred for EDX testing.[3] Although research has demonstrated the utility of EDX testing – needle EMG in particular – for evaluating patients with LRS,[14-16] the lack of examiner masking to the patient's history and physical examination in studies utilizing needle EMG has been identified as a potential source of bias, which may weaken the evidence that EDX

testing is a valid diagnostic tool.[17] Recent studies have demonstrated that masking in EDX research can be successfully employed in patients with lumbar spinal stenosis[18,19] as well as lumbosacral radiculopathy[20] in order to validate the results of the needle EMG examination. Given the routine use of EDX testing to evaluate patients with suspected nerve root injuries, it is surprising that so few studies have investigated the reliability of needle EMG as a diagnostic test.[20,21] Furthermore, no published studies have investigated the reliability of needle EMG among Physical Therapist electromyographers or among patients referred for physical therapy. Research demonstrating the reliability of needle EMG as a diagnostic tool in a variety of settings is essential in order to establish the validity of needle EMG testing in patients with suspected lumbosacral radiculopathy. Part of the focus of this dissertation work was to investigate the reliability of needle EMG among experienced Physical Therapist electromyographers in patients with LRS referred for physical therapy.

Prognostic Value of Electrodiagnostic Testing

Although a recent study found that in patients with LRS, female gender, smoking, and adverse neural tension signs were factors predictive of slower recovery and worse long-term outcomes,[22] little is known about prognostic factors in these patients, particularly related to clinical examination or diagnostic test findings. While several studies have provided examples of the diagnostic utility of EDX testing in patients with LRS[1,14-16,23] few studies have examined the prognostic value of EDX testing in this patient population, particularly related to

conservative treatment interventions.[24-27] Generally speaking, prognostic factors identify patients who will have better outcomes or recover more rapidly and would therefore be useful as a clinical screening tool.[28] For example, Derr et al. (2009),[29] investigating the prognostic value of EDX testing in patients with fibular neuropathy at the knee, found that 94% of patients with motor nerve conduction responses in the extensor digitorum brevis and tibialis anterior muscles had a "good" outcome, which the authors defined as at least a 4/5 manual muscle grade for ankle dorsiflexion. In contrast, only 46% of patients in which these motor nerve conduction responses were absent achieved a good outcome.

Identification of a prognostic factor or factors, which can be reliably measured, could fundamentally change the approach to treating patients with LRS by providing evidence-based recommendations for guiding their medical management. Such a finding would have the potential to advance the knowledgebase within the field of rehabilitation science pertaining to the diagnosis and treatment of LBP while at the same time strengthening clinical outcomes research in the field of physical therapy.

Although EDX testing is routinely used to evaluate patients with LRS,[4,5] very few studies have investigated the prognostic value of EDX testing in these patients.[25,27] Only a few studies have investigated the prognostic value of EDX testing in patients with LRS, but they are methodologically weak (e.g., retrospective design), are invasive or surgical trials, or include nonrepresentative patient populations (e.g., older subjects, unusually high disability ratings).[24-27] Additionally, no published studies have examined the prognostic value of EDX

testing in patients with LRS receiving physical therapy. The primary focus of this dissertation work was to investigate the prognostic value of EDX testing in patients with LRS referred to physical therapy, employing the scientific rigor of a longitudinal cohort trial design.

Validity of Electrodiagnostic Testing

Research has demonstrated the relationship between some patient history and physical examination findings in patients with LRS and the presence of disc herniation or nerve root impingement on diagnostic imaging.[15,23,30-33] However, few studies have investigated the relationship between patient history and physical examination findings and the results of EDX testing.[32,34] Although EDX testing is routinely used to evaluate patients with suspected nerve root injuries, testing can be uncomfortable and expensive. However, recent studies have suggested that the presence of radiculopathy found on needle EMG may be a favorable prognostic factor for recovery.[24,26] The final component of this dissertation work, therefore, was to examine the value of select history and physical examination variables in patients with LRS for predicting the outcome of EDX testing. In other words, can individual or combined patient history and/or physical examination findings accurately predict the presence of radiculopathy as found on EDX testing? Given the relative discomfort and expense associated with EDX testing, the ability to determine EDX status (i.e., presence or absence of radiculopathy) with some degree of confidence from conventional patient history and physical examination findings would be an asset to clinicians and to

patients, particularly if a patient's EDX status is determined to be clinically meaningful, as some recent studies have suggested.[24,26]

CHAPTER 2

INTERRATER RELIABILITY OF NEEDLE ELECTROMYOGRAPHY IN PATIENTS WITH SUSPECTED LUMBOSACRAL RADICULOPATHY

Nathan J. Savage, Julie M. Fritz, Richard P. Nielsen, and Jeffrey Fraser

Abstract

Objective

This study investigated the reliability of needle electromyography among experienced Physical Therapist electromyographers.

Design

Needle electromyographic recordings from 24 patients with suspected lumbosacral radiculopathy were analyzed. An examiner unmasked to the patient's history and physical examination recorded insertional and resting electromyographic activity which was stored as de-identified digital audio-video files. Two masked examiners reviewed the recordings and provided ratings for individual muscles sampled on all patients. All examiners provided an overall electrodiagnostic impression. Reliability was assessed using Cohen's kappa (κ) statistics.

Results

Reliability of insertional and resting electromyographic activity for all muscles combined was substantial (κ ≥0.68, 95% CI: 0.50 to 0.89; P≤.001), ranging from fair (κ=0.33, 95% CI: -0.25 to 1.0; P>.05) to perfect (κ=1.0, 95% CI: 1.0 to 1.0; P≤.001) for individual muscles examined. Pairwise examiner comparisons revealed moderate (κ=0.43, 95% CI: 0.11 to 0.76; P=.01) to substantial (κ=0.75, 95% CI: 0.48 to 1.0; P<.0001) agreement for the final electrodiagnostic impression and fair (κ_w=0.31, 95% CI: 0.12 to 0.50; P=0.004) to

substantial (κ_w=0.62, 95% CI: 0.37 to 0.87; P<.0001) agreement for the overall electrodiagnostic impression.

Conclusions

The results of needle electromyography in patients with suspected lumbosacral radiculopathy can be reliably assessed by experienced Physical Therapist electromyographers.

Introduction

Electrodiagnostic (EDX) testing, consisting of needle electromyography (EMG) and nerve conduction studies, is used to evaluate the integrity of the neuromuscular system, including upper and lower motor neurons, the neuromuscular junction, and skeletal muscle.[1-5] Conducted as an extension of the clinical examination, EDX testing is the primary method used to objectively measure and document pathological changes or injury to the neuromuscular system, including proximally located spinal nerve roots.[1-5] Clinicians employ EDX testing to evaluate patients with suspected lumbosacral radiculopathy,[4,5] one of the most common conditions referred for EDX testing.[3]

Although research has demonstrated the utility of needle EMG for evaluating patients with suspected lumbosacral radiculopathy,[14-16] the lack of examiner masking to the results of a patient's history and physical examination in studies utilizing needle EMG has been identified as a potential source of bias, which may weaken the evidence that needle EMG is a valid diagnostic tool.[17] Recent studies have demonstrated that masking in EDX research can be

successfully employed in patients with lumbar spinal stenosis[18,19] as well as lumbosacral radiculopathy[20] in order to validate the results of needle EMG. Chouteau et al. (2010),[20] investigating interrater reliability between a single unmasked examiner and 2 masked examiners in patients with suspected lumbosacral radiculopathy, found near perfect agreement for the dichotomized final EDX impression (i.e., evidence of radiculopathy or no evidence of radiculopathy) with Cohen's kappa (κ) values exceeding 0.90. Additionally, the authors found substantial agreement (κ>0.60) for insertional and resting EMG activity of most individual muscles examined. Examiners were Board-Certified by the American Board of Electrodiagnostic Medicine and practiced together in the same facility where all study-related patients underwent EDX testing. In a related investigation, Kendall and Werner (2006)[21] compared the interrater reliability among 66 masked examiners, consisting of both faculty and resident examiners, in patients with suspected lumbosacral radiculopathy. Examiners analyzed insertional, resting, and volitional EMG activity from 6 recorded cases. The authors found a composite agreement of 47% for the diagnostic impression, consisting of 61% agreement among faculty examiners and 29% agreement among resident examiners. However, these values were not corrected for chance agreement using a Cohen's κ or related statistic.[35]

Given the routine use of EDX testing to evaluate patients with suspected nerve root injuries, it is surprising that so few studies have investigated the reliability of needle EMG as a diagnostic test.[20,21] Furthermore, no published studies have investigated the reliability of EDX testing among Physical Therapist

electromyographers or among patients referred for physical therapy. Research demonstrating the reliability of EDX testing as a diagnostic tool in a variety of settings is essential in order to establish the validity of EDX testing in patients with suspected lumbosacral radiculopathy. The purpose of this investigation was to determine the reliability of EDX testing among experienced Physical Therapist electromyographers in patients with suspected lumbosacral radiculopathy referred for physical therapy.

Methods

Patients

Patients in this study were drawn from a larger clinical trial examining physical therapy treatment options for patients with lumbosacral radicular syndrome[36] within which a subset of participants underwent EDX testing at baseline for the purposes of investigating its prognostic value. Digital needle EMG recordings were assessed on 24 patients participating in the larger prognostic study. Patient demographics and clinical characteristics are found in Table 2.1. Institutional Review Board approvals were obtained from the University of Utah and Intermountain Healthcare (Salt Lake City, Utah) for this study.

Electrodiagnostic Testing

All EDX testing was performed by a single independent examiner unmasked to the patient's medical history, clinical examination findings, and

results of the complete EDX testing, including assessment of peripheral nerve conduction and volitional EMG. The unmasked examiner is a licensed Physical Therapist and experienced electromyographer approved by the American Board of Physical Therapy Specialties to sit for the Board-Certification examination in Clinical Electrophysiology with over 2,000 hours of clinical experience performing EDX testing.

The Cadwell Sierra Wave (Cadwell Laboratories, Kennewick, WA) was used to perform, record, and analyze all EDX tests. Standardized peripheral sensory and motor nerve conduction studies including F waves were performed on the symptomatic limb of all patients.[4,5] Sensory and motor nerve distal latencies, conduction velocities, and amplitudes were recorded and analyzed. Needle EMG testing was performed on a standardized set of 5 limb muscles and the lumbar paraspinals with a disposable 50-millimeter monopolar needle electrode. The muscles selected for examination have been demonstrated to identify 98-100% of EMG-confirmable radiculopathies and include the lumbar paraspinals, anterior tibialis, medial gastrocnemius, posterior tibialis, vastus medialis, and biceps femoris short-head.[16] Additional muscles were tested as needed in order to clarify the overall EDX impression (Table 2.2). Limb muscles were analyzed at rest and during volitional contraction. The lumbar paraspinal muscles were analyzed at rest only.

Insertional and resting EMG activity was assessed with a gain of 100-200 microvolts per division and a sweep speed of 10 milliseconds per division. The needle EMG examination was digitally recorded and stored using the Cadwell

Sierra Wave “Reel Time” EMG software application as audio-video files. The exported needle EMG recordings had a video rate of 30 frames per second and an audio rate of 512 kilobits per second. These settings enabled the masked examiners to visualize the needle EMG recordings with essentially the same audio and video resolution as the live waveforms observed by the unmasked examiner.

Consistent with published reports[1,21] the definition in this investigation for the presence of radiculopathy found with needle EMG was abnormal insertional and resting EMG activity or neuropathic motor unit potentials found in at least 2 muscles sharing a common nerve root but from different peripheral nerves. Patients with abnormalities isolated to the lumbar paraspinal muscles were also classified as having radiculopathy.[16] Additionally, adjacent nerve roots above and below the affected level must have been normal.[3-5]

Masked Review and Validation

All recordings were independently reviewed by 2 masked examiners Board-Certified in Clinical Electrophysiology by the American Board of Physical Therapy Specialties. Their assessment of the insertional and resting EMG activity for the individual muscles tested as well as their overall EDX impression were recorded on a standardized examiner form (Figure 2.1).

The needle EMG recordings were de-identified, removing all patient-specific information, with only the gain and sweep speed settings visible along with the name of the individual muscle examined. The de-identified needle EMG

recordings were edited in *Windows Movie Maker* software in order to generate case-specific files and label the individual muscles examined. Each masked examiner was provided an electronic copy of the 24 needle EMG recordings for viewing and analyzing at their convenience.

The masked examiners were instructed to complete the standardized examiner form by analyzing the insertional and resting EMG activity for the individual muscles examined in each of the 24 needle EMG recordings provided. They were informed that the individual muscles on the digital recording and on the standardized examiner form appeared in the same order. Each masked examiner was provided with the definition for the presence of radiculopathy mentioned earlier (see *Electrodiagnostic Testing* section).[16] No specific instructions or guidance was provided to the masked examiners for the interpretation of insertional or resting EMG activity. The procedures used in this investigation did not follow any specific needle EMG testing protocol or evaluation technique such as lumbar paraspinal mapping.[17-19]

On the standardized examiner form, insertional EMG activity was rated as decreased, increased, or normal if left blank. Resting EMG activity, which included evaluating for the presence of fibrillation potentials, positive waves, complex repetitive discharges, or other neuropathic findings, was rated as present or normal if left blank. The author chose a dichotomous scale for rating resting EMG activity as opposed to the commonly used graduated, semiquantitative scale (i.e., rating the relative number of fibrillation potentials and/or positive waves recorded as 0, +1, +2, +3, +4) to define the presence of

resting EMG activity because the *amount* of abnormal EMG activity was not of primary concern, rather the existence and location of abnormal resting EMG activity in order to identify the presence of nerve root injury.[37]

The following system was used for scoring the insertional and resting EMG activity of individual muscles examined: normal insertional and resting EMG activity=0; normal or increased insertional EMG activity with the presence of sustained abnormal resting EMG activity=1. Space was provided on the standardized examiner form for comments by the masked examiners.

Examiners provided an overall EDX impression for each patient, including the involved nerve root(s) when a radiculopathy was deemed present. Patients were classified as having evidence of radiculopathy, possible evidence of radiculopathy, or no evidence of radiculopathy on the standardized examiner form. Consistent with the larger prognostic study, all patients were ultimately given a final EDX impression by dichotomizing them into those with evidence of radiculopathy and those without. This was accomplished by combining patients with evidence of radiculopathy and possible evidence of radiculopathy into one group and comparing them to patients with no evidence of radiculopathy.

Since the masked examiners only had access to the insertional and resting EMG activity portions of the needle EMG examination, they were unable to comment on other EDX possibilities such as mononeuropathy, polyneuropathy, plexopathy, or myopathy.

Statistical Analysis

PASW Statistics for Windows, Version 18.0 (SPSS Inc., Chicago, IL) was used to compute interrater reliability statistics by comparing examiners in a pairwise fashion (X:Y, X:Z, and Y:Z). Cohen's κ statistic was calculated for the insertional and resting EMG activity of individual muscles examined as well as the final EDX impression. For the overall EDX impression, because the categories are ordered, a linear weighted kappa (κ_w) statistic was calculated (http://www.vassarstats.net/kappa.html).[38] This was done because patients categorized as having possible evidence of radiculopathy are more closely related to patients categorized as having clear evidence or no evidence of radiculopathy than either of those categories relate to one another.[35,38] Strength of agreement was based on the following scale of κ values: $\leq$0=Poor agreement; 0.01-0.20=Slight agreement; 0.21-0.40=Fair agreement; 0.41-0.60=Moderate agreement; 0.61-0.80=Substantial agreement; 0.81-1.00=Almost perfect agreement.[35]

Electrodiagnostic sensitivity and specificity values were calculated comparing all examiners (X:Y:Z) as well as the unmasked and masked examiners in a pairwise fashion (X:Y, X:Z). The unmasked examiner's final EDX impression – which included knowledge of the patient's history, physical examination, and complete EDX test results – served as the gold standard for all calculations.

A secondary analysis was performed in which the overall and final EDX impressions were determined based on the raw assessment of insertional and

resting EMG activity provided by the masked examiners on the standardized examiner form. The secondary analysis compares the overall EDX impression provided by the masked examiners to a forced classification of patients based strictly on the ratings of insertional and resting EMG activity provided by the masked examiners. The purpose of the secondary analysis was to determine if the definition of radiculopathy provided to the masked examiners prior to the study was consistently followed.

Preliminary power analysis revealed that 24 needle EMG recordings would provide 90% power to detect substantial agreement ($\kappa>0.60$) between examiners using a one-tailed test of statistical significance at an alpha level of 0.05 assuming the null is $\kappa=0$.[35]

Results

Analysis of Insertional and Resting EMG Activity

Reliability of insertional and resting EMG activity for all muscles combined showed substantial ($\kappa \geq 0.68$, 95% CI: 0.50 to 0.89; $P \leq .001$) agreement across all pairwise examiner comparisons. The level of agreement for individual muscles examined ranged from fair ($\kappa=0.33$, 95% CI: -0.25 to 1.0; $P>.05$) to perfect ($\kappa=1.0$, 95% CI: 1.0 to 1.0; $P \leq .001$) across all pairwise examiner comparisons with the biceps femoris short-head and medial gastrocneumius muscles having the lowest levels of agreement and the vastus medialis muscle having the highest level of agreement (Table 2.3). A summary of each examiners raw EMG

assessment of insertional and resting EMG activity and the overall EDX impression are found in Table 2.4.

Analysis of the Final and Overall Electrodiagnostic Impressions

The level of agreement among the electromyographers for the final EDX impression ranged from moderate to substantial. Agreement between the unmasked examiner and masked examiner A was substantial with a κ value of 0.75 (95% CI: 0.48 to 1.0; P<0.0001). The level of agreement between the unmasked examiner and masked examiner B was moderate with a κ value of 0.53 (95% CI: 0.24 to 0.81; P=0.002). The level of agreement between the masked examiners was moderate with a κ value of 0.43 (95% CI: 0.11 to 0.76; P=0.010) (Table 2.5).

The raw level of agreement among the electromyographers for the overall EDX impression ranged from fair to substantial. Agreement between the unmasked examiner and masked examiner A was substantial with a κ_w value of 0.62 (95% CI: 0.37 to 0.87; P<0.0001). The level of agreement between the unmasked examiner and masked examiner B was fair with a κ_w value of 0.31 (95% CI: 0.12 to 0.50; P=0.004). The level of agreement between the masked examiners was fair with a κ_w value of 0.32 (95% CI: 0.09 to 0.55; P<.05) (Table 2.6).

The sensitivity and specificity values for the final EDX impression combining all examiners was 0.50 (95% CI: 0.24 to 0.76) and 0.90 (95% CI: 0.54 to 0.99), respectively. Comparing the unmasked examiner and masked examiner

A, the sensitivity and specificity values were 0.86 (95% CI: 0.56 to 0.97) and 0.90 (95% CI: 0.54 to 0.99), respectively. Comparing the unmasked examiner and masked examiner B, the sensitivity and specificity values were 0.57 (95% CI: 0.30 to 0.81) and 1.0 (95% CI: 0.66 to 1.0), respectively.

A secondary analysis was performed in which the overall and final EDX impressions for each patient were categorized based on the raw assessment of insertional and resting EMG activity provided by the masked examiners. This was performed in order to classify patients strictly based upon the definition of radiculopathy provided to each masked examiner prior to beginning the study. The secondary analysis resulted in the level of agreement for the final EDX impression ranging from substantial to almost perfect across all pairwise examiner comparisons. The level of agreement between the unmasked examiner and masked examiner A improved from substantial to almost perfect with a κ value of 0.83 (95% CI: 0.60 to 1.0). The level of agreement between the unmasked examiner and masked examiner B as well as the level of agreement between the masked examiners improved from moderate to substantial in both instances with each having κ values of 0.60 (95% CI: 0.29 to 0.91).

Additionally, the secondary analysis resulted in the level of agreement for the overall EDX impression being substantial for all pairwise examiner comparisons. Agreement between the unmasked examiner and masked examiner A remained substantial, but the κ_w value improved to 0.70 (95% CI: 0.48 to 0.92). The level of agreement between the unmasked examiner and masked examiner B as well as the level of agreement between the masked

examiners improved from fair to substantial in both instances with κ_w values of 0.63 (95% CI: 0.35 to 0.91) and 0.66 (95% CI: 0.44 to 0.88), respectively.

Discussion

The results of this investigation demonstrate the reliability of needle EMG among experienced Physical Therapist electromyographers in patients with suspected lumbosacral radiculopoathy referred for physical therapy. Interrater reliability for the assessment of insertional and resting EMG activity was substantial for individual muscles examined, indicating that needle EMG can be used reliably to assess the presence of nerve damage in patients with suspected lumbosacral radiculopathy. The level of agreement among examiners for the final EDX impression ranged from moderate to substantial – improving to substantial to almost perfect when findings at rest were strictly classified – supporting the reliability of needle EMG as a diagnostic test.

Overall, the assessment of insertional and resting EMG activity for individual muscles examined was substantial; however, patterns emerged among examiners which may be indicative of individual clinical preferences for analyzing and recording the results of needle EMG. First, the unmasked examiner consistently rated increased insertional EMG activity in conjunction with the presence of abnormal resting EMG activity and rated very few muscles as having decreased insertional EMG activity. Second, masked examiner A rated several muscles as having decreased insertional EMG activity, including rating some muscles with fibrillation potentials and/or positive waves as having both

increased and decreased insertional EMG activity. Finally, masked examiner B rated all muscles as having normal insertional EMG activity. These findings clearly indicate that individual examiners not only differ in their assessment of insertional and resting EMG activity but may also place varying degrees of emphasis on the importance of insertional and resting EMG activity in formulating their overall EDX impression.

In this study, an unmasked electromyographer was in moderate to substantial agreement with 2 masked electromyographers on the final EDX impression in patients with suspected lumbosacral radiculopathy. The level of agreement found in this investigation was not as high as that reached by the examiners in the study by Chouteau et al. (2010)[20] employing a similar study design. This may be explained by the fact that the examiners in this investigation were geographically separate from one another and having never practiced together are more likely to conduct and analyze needle EMG examinations in distinctly different ways. While this may limit the internal validity of this study, it makes this investigation more pragmatic and may make the findings more generalizable to clinical electromyographers.

Although the levels of agreement in this study did not reach those of Chouteau et al.,[20] it is worth noting that the majority of disagreement occurred across a subset of 5 patients that were judged to have radiculopathy in 4/5 cases by the unmasked examiner, judged to have radiculopathy in 5/5 cases by masked examiner A, and judged to have radiculopathy in 0/5 cases by masked examiner B. Outside of that subset of patients, disagreement on the final EDX

impression among examiners was found in only 3 other cases. The level of agreement on the final EDX impression between the unmasked examiner and examiner A was found to be substantial with a κ value of 0.75. A less robust level of agreement was found between the unmasked examiner and masked examiner B, as well as between the masked examiners, with moderate κ values of 0.53 and 0.43, respectively. These values are likely clinically meaningful given the percentages of agreement between the unmasked examiner and masked examiner A was 88% (21/24 cases), 75% (18/24 cases) between the unmasked examiner and masked examiner B, and 71% (17/24 cases) between the masked examiners.[39] These values are higher than those observed in the study by Kendall and Werner (2006),[21] which employed a slightly different research design and data analytic approach than that used in this investigation.

A secondary analysis was performed which classified patients based strictly upon the analysis of insertional and resting EMG activity as recorded by the masked examiners and following the definition of radiculopathy provided to each masked examiner prior to beginning the study. The secondary analysis resulted in significant improvements in the level of agreement among examiners in both the final and overall EDX impressions. This may be explained by the fact that both masked examiners are clinicians who routinely consider a patient's history, clinical examination, and complete EDX test results in practice when determining if an abnormality such as lumbosacral radiculopathy is present. In this investigation, nearly all instances of disagreement on the overall EDX impression involved the masked examiners categorizing the observed insertional

and resting EMG abnormalities as indicative of a *possible* radiculopathy, as opposed to presenting clear evidence of radiculopathy. In other words, the level of confidence the masked examiners had for declaring the presence of radiculopathy appeared to be insufficient based upon their assessment of the insertional and resting EMG activity alone; this despite the fact that the observed abnormalities fit the strict definition for the presence of radiculopathy.

The sensitivity and specificity values calculated for this study are consistent with published reports which demonstrate that needle EMG tends to be more specific than sensitive.[23] Specificity was measured to be ≥90% across all pairwise examiner comparisons, ranging from 90% to 100%. Clinically, this makes needle EMG a more reliable EDX test for ruling-in a radiculopathy in the presence of abnormal findings than for ruling-out a radiculopathy in the absence of findings. This is significant in terms of the larger prognostic study because it improves the likelihood that patients were properly classified based on the results of their needle EMG examination. In the larger prognostic study, 19 of 38 (50.0%) patients were classified as having evidence of radiculopathy, a percentage that is consistent with previous research;[20,24,26,34] therefore, the likelihood that patients were misclassified based on incidental, false-positive EMG findings is unlikely given the demonstrated diagnostic specificity in this study.

The case can be made that the findings in this investigation are both pragmatic and generalizable to the clinical setting for a few reasons. First, while all examiners are practicing electromyographers, they are geographically separate and have never practiced together. Second, patients included in this

study underwent EDX testing in one of eight different physical therapy clinics with diverse environmental factors impacting the fidelity of the EMG recordings in several instances, a fact which was noted by the masked examiners. Despite efforts by the unmasked examiner to correct or minimize the impact of these environmental factors, at times it was difficult to obtain a clean electrical baseline for analyzing insertional, resting, and volitional EMG activity. Obtaining good electrical fidelity for the performance and interpretation of EDX testing is a challenge routinely encountered by electromyographers in clinical practice. The presence of such factors in this investigation strengthens the generalizability of the results. Third, because nearly all EDX testing was performed either prior to or immediately following a scheduled physical therapy treatment session, the constraints of time (as in clinical practice) may have impacted the quality of EMG recordings produced. Comments from the masked examiners noted the rapid nature of needle insertions at times impacted their ability to properly analyze insertional and resting EMG activity. Despite these challenges, none of which are foreign to clinical practice, an acceptable level of interrater reliability was found for needle EMG in patients with suspected lumbosacral radiculopathy.

Conclusions

The results of needle EMG in patients with suspected lumbosacral radiculopathy referred for physical therapy can be reliably assessed by experienced Physical Therapist electromyographers. This was a more pragmatic study than previously published investigations and the findings can be

generalized to electromyographers in clinical practice. The results of this investigation support the use of masking in EDX research to validate the use of needle EMG as a diagnostic test.

Table 2.1 Patient demographic and clinical characteristics

Patient characteristics (n=24)	
Age (years)	39.75±13.05
Gender	
women (%)	10 (41.66%)
men (%)	14 (58.33%)
BMI (kg/m^2)	27.95±5.48
Smoker (%)	2 (8.33%)
Average LBP baseline	4.75±2.08
Average leg pain baseline	4.67±2.51
Oswestry score baseline	40.63±14.55
RMDQ score baseline	11.75±5.39
Duration current episode (weeks)	27.47±67.94

BMI: body mass index; LBP: low back pain; RMDQ: Roland and Morris disability questionnaire

For each muscle, place an "x" or "?" for any abnormalities *observed* or *possibly* observed during insertional and resting activity. Space is provided for "Other findings" and "Comments" as needed.
Place an "x" in the appropriate box addressing the evidence of radiculopathy. If "Yes" or "Possible" is chosen, please indicate what level or levels are involved. **Save file after each patient!**

Patient ID:	Muscle	Nerve	Root	Ins Act Inc	Ins Act Decr	Fib/Pws Pres	CRD Pres	Other findings?
	Lumbar paraspinals	PPR	L2-L5					
	Anterior tibialis	Deep fibular	L4,L5					
	Medial gastrocnemius	Tibial	S1,S2					
	Posterior tibialis	Tibial	L5,S1					
	Vastus medialis	Femoral	L2-L4					
	Biceps femoris short head	Common fibular	L5-S2					

Evidence of radiculopathy? Yes	Possible	No

If "Yes" or "Possible", what level(s)?

L2	
L3	
L4	
L5	
S1	

Comments:

Ins Act = insertional activity
Inc = increased
Decr = decreased

Fib/Pws = fibrillation potentials/positive waves
Pres = present

CRD = complex repetitive discharges
Pres = present

Figure 2.1 Standardized examiner form

Table 2.2 Individual muscles sampled with needle EMG

Muscle	Number of patients (%)
Lumbar paraspinals	23 (96%)
Anterior tibialis	24 (100%)
Medial gastrocnemius	24 (100%)
Lateral gastrocnemius	4 (17%)
Posterior tibialis	24 (100%)
Extensor hallucis longus	7 (29%)
Vastus medialis	24 (100%)
Biceps femoris short-head	24 (100%)

Table 2.3 Cohen's kappa values (95% CI) for insertional and resting EMG activity of individual muscles tested

Muscle	Unmasked examiner *vs* Masked examiner A	Unmasked examiner *vs* Masked examiner B	Masked examiner A *vs* Masked examiner B
Paraspinals	0.62*** (0.16,1.0)	0.62*** (0.16,1.0)	1.0*** (1.0,1.0)
Anterior tibialis	0.65*** (0.02,1.0)	1.0*** (1.0,1.0)	0.65*** (0.02,1.0)
Medial gastrocnemius	0.78*** (0.50,1.0)	0.78*** (0.50,1.0)	0.50* (0.07,0.93)
Posterior tibialis	0.75*** (0.43,1.0)	0.60*** (0.21,0.99)	0.83*** (0.51,1.0)
Vastus medialis	1.0*** (1.0,1.0)	1.0*** (1.0,1.0)	1.0*** (1.0,1.0)
Biceps femoris short-head	0.51* (0.06,0.95)	0.70*** (0.32,1.0)	0.33 (-0.25,0.91)
All muscles combined[§]	0.72*** (0.57,0.87)	0.74*** (0.59,0.89)	0.68*** (0.50,0.86)

*P<0.05; **P≤0.01; ***P≤0.001

[§]Includes lateral gastrocnemius and extensor hallucis longus which had too few cases to analyze individually.

CI: confidence interval

Table 2.4 Raw findings for insertional and resting EMG activity and overall EDX impression

Muscle	Unmasked examiner	Unmasked examiner A	Masked examiner B
Lumbar paraspinals	0=19, 1=4	0=21, 1=2	0=21, 1=2
Anterior tibialis	0=22, 1=2	0=23, 1=1	0=22, 1=2
Medial gastrocnemius	0=17, 1=7	0=19, 1=5	0=19, 1=5
Lateral gastrocnemius	0=3, 1=1	0=3, 1=1	0=3, 1=1
Posterior tibialis	0=18, 1=6	0=20, 1=4	0=21, 1=3
Extensor hallucis longus	0=2, 1=5	0=2, 1=5	0=4, 1=3
Vastus medialis	0=24, 1=0	0=24, 1=0	0=24, 1=0
Biceps femoris short-head	0=19, 1=5	0=22, 1=2	0=21, 1=3
No evidence of radiculopathy	10	11	16
Possible evidence of radiculopathy	2	5	7
Evidence of radiculopathy	12	8	1

Frequency of insertional and resting EMG activity and overall EDX impression for each examiner.

0, normal insertional and resting EMG activity; 1, and normal or increased insertional EMG activity with the presence of sustained abnormal resting EMG activity

EDX: electrodiagnostic

Table 2.5 Interrater reliability of the final EDX impression

	Unmasked examiner *vs* Masked examiner A	**Unmasked examiner *vs* Masked examiner B**	**Masked examiner A *vs* Masked examiner B**
Cohen's κ (95% CI)	0.75 (0.48,1.0)	0.53 (0.24,0.81)	0.43 (0.11,0.76)
One-sided P value	<.0001	.002	.01

EDX: electrodiagnostic; CI: confidence interval

Table 2.6 Interrater reliability of the overall EDX impression

	Unmasked examiner *vs* Masked examiner A	**Unmasked examiner *vs* Masked examiner B**	**Masked examiner A *vs* Masked examiner B**
Weighted κ_w (95% CI)	0.62 (0.37,0.87)	0.31 (0.12,0.50)	0.32 (0.09,0.55)
One-sided P value	<.0001	.004	<.05

EDX: electrodiagnostic; κ_w = linear weighted kappa value

CHAPTER 3

THE PROGNOSTIC VALUE OF ELECTRODIAGNOSTIC TESTING IN PATIENTS WITH SUSPECTED LUMBOSACRAL RADICULOPATHY RECEIVING PHYSICAL THERAPY

Nathan J. Savage, Julie M. Fritz, John C. Kircher, and Anne Thackeray

Abstract

Study Design

This study used a longitudinal cohort embedded in a randomized clinical trial design.

Objective

This study investigated the prognostic value of electrodiagnostic testing in patients with suspected lumbosacral radiculopathy receiving physical therapy.

Summary of Background Data

Electrodiagnostic testing is routinely used to evaluate patients with suspected lumbosacral radiculopathy. Recent evidence suggests that the presence of radiculopathy found on needle electromyography may predict better functional outcomes in these patients.

Methods

Electrodiagnostic testing was performed on 38 patients with symptoms suggesting lumbosacral radiculopathy participating in a randomized trial comparing different physical therapy treatment programs. Patients were grouped and analyzed according to the presence or absence of radiculopathy based on electrodiagnostic testing. Longitudinal data analysis was conducted using multilevel growth modeling with 10 waves of data collected from baseline through the treatment and posttreatment periods up to 6 months. The primary outcome

measure was changes in low back pain-related disability assessed using the Roland and Morris disability questionnaire (RMDQ).

Results

Patients with radiculopathy (n=19) had statistically significant and clinically meaningful improvements in RMDQ scores at every posttreatment follow-up occasion regardless of physical therapy treatment received. The final multilevel growth model revealed improvements in RMDQ scores in patients with radiculopathy at the 6-week (-8.1, 95% CI, -12.6 to -2.6; *P*=.006) and 6-month (-4.1, 95% CI, -7.4 to -0.7; *P*=.020) follow-up occasions compared to patients without radiculopathy. Physical therapy treatment group was not a significant predictive factor at any follow-up occasion. An interaction between electrodiagnostic status and time revealed faster weekly improvements in RMDQ scores in patients with radiculopathy at the 6-week (-0.72, 95% CI, -1.4 to -0.04; *P*=.040) through the 16-week (-0.30, 95% CI, -0.57 to -0.04; *P*=.028) follow-up occasions compared to patients without radiculopathy.

Conclusions

The presence of lumbosacral radiculopathy identified with electrodiagnostic testing is a favorable prognostic factor for recovery in low back pain-related disability regardless of physical therapy treatment received.

Introduction

Electrodiagnostic (EDX) testing, consisting of needle electromyography (EMG) and nerve conduction studies, is used to evaluate the integrity of the neuromuscular system, including upper and lower motor neurons, the neuromuscular junction, and skeletal muscle.[1-5] Conducted as an extension of the clinical examination, EDX testing is the primary method used to objectively measure and document pathological changes or injury to the neuromuscular system, including proximally located spinal nerve roots.[1-5] Clinicians employ EDX testing to evaluate patients with LBP – which is among the most prevalent and costly conditions to treat.[6]

The majority of LBP is considered nonspecific, or having no clear pathoanatomic cause;[7] however, one specific cause of LBP is lumbosacral radicular syndrome (LRS).[8] Known commonly as *sciatica* or *lumbar radiculopathy*, this syndrome has some unique defining characteristics.[9,10] Most commonly the result of a herniated disc, patients with LRS typically complain of LBP and radiating leg symptoms which are often described as sharp, piercing, throbbing, aching, or burning, along with dermatomal paresthesia.[2,10] When describing LRS, the terms *sciatica* and *radiculopathy* are often used interchangeably but are not synonymous. The presence of radiating leg symptoms is common to all patients with LRS, but radiculopathy is distinguished by the presence of objectively measurable nerve root injury, which is difficult to determine from the clinical examination alone.[4,5,10] Despite only 10% to 25% of episodes of LBP being classified as LRS,[8,10] these patients have a heightened

risk of persistent symptoms[8] and eventual progression to costly[11] and invasive treatments including surgery.[12,13] Furthermore, little is known about prognostic factors in these patients, particularly related to clinical examination or diagnostic test findings.

The primary purpose of this investigation was to examine the prognostic value of EDX testing in patients with LRS receiving physical therapy by measuring short-term and long-term changes in LBP-related disability.

Materials and Methods

Subjects

Patients who were participants in a randomized clinical trial comparing different physical therapy treatments for patients with LRS were recruited to participate in this investigation. These patients met the inclusion criteria for the randomized trial (Table 3.1) and provided additional consent to undergo EDX testing. Institutional Review Board approvals were obtained from the University of Utah and Intermountain Healthcare (Salt Lake City, Utah) for this study.

Study Design and Procedures

The parent randomized trial[36] employed a two-group repeated measures design with patients randomized to receive an extension-oriented treatment approach with or without the addition of mechanical spinal traction provided by licensed physical therapists for up to 12 visits over a 6-week period. Assignment of patients to treatment groups was performed by a blinded research assistant

following baseline data collection. Randomization was stratified according to a clinically-based subgrouping criteria previously identified by Fritz et al. (2007).[40]

Patients consenting to participate in this analysis received additional EDX testing as part of the baseline examination. For the purposes of this investigation, patients were grouped and analyzed according to the presence or absence of radiculopathy determined by EDX testing in order to evaluate the prognostic value of this finding. The primary outcome measure for this analysis was the Roland and Morris disability questionnaire (RMDQ). The reliability, validity, and responsiveness of the RMDQ have been established in patients with LBP and leg pain.[41-44]

Patients were recruited from physician and outpatient physical therapy clinics. Electrodiagnostic testing was conducted by a licensed Physical Therapist who is also an experienced electromyographer with certification in the performance and interpretation of EDX tests.

Self-Report Measures

Follow-up assessments for the parent randomized trial were conducted by a blinded research assistant immediately posttreatment at 6 weeks and again around 6 months after enrollment. Patients completed an Oswestry disability questionnaire[41] (OSW), 0-10 numeric pain rating scales for LBP and leg pain,[45] and a 15-point global rating of change.[46] The RMDQ was collected at baseline and every 2 weeks for 12 weeks and then every 4 weeks until the 6-month follow-up occasion.

Physical Examination Procedures

The physical examination included clinical evaluation for evidence of CNS involvement, including pathological reflexes. Patients were evaluated for clinical signs of lumbosacral nerve root irritation, including neural tension, muscle strength, sensation, and muscle stretch reflexes. Patients performed single or repeated repetition trunk movements while the examiner inquired about changes in their symptom location. Changes in symptom location with trunk movements were defined as peripheralization, centralization, or unchanged.[36] Range of motion was measured using single inclinometer procedures with excellent reliability.[47]

Electrodiagnostic Testing Procedures

All EDX tests were performed using a Cadwell Sierra Wave (Cadwell Laboratories, Kennewick, WA). Patients underwent standardized peripheral sensory and motor nerve conduction studies, including F waves.[4,5] Monopolar needle EMG testing was performed on a standardized set of five limb muscles and the lumbar paraspinals (Table 3.2) with demonstrated reliability in patients with LRS.[1,16,20] Limb muscles were analyzed at rest and during volitional contraction with the lumbar paraspinal muscles being analyzed at rest only. Evidence of radiculopathy was defined by the presence at least one of the following: 1) pathological findings at rest or during volitional contraction indicative of axonal loss in at least two muscles (including the lumbar paraspinals) sharing

a common nerve root but from different peripheral nerves, or 2) findings isolated to the lumbar paraspinals when they could be reliably examined.[1,16]

Patients were classified as having clear, possible, or no evidence of radiculopathy. For analytic purposes, a final EDX impression was given for each patient by dichotomizing patients as having evidence of radiculopathy or not. This was accomplished by combining patients with possible and clear evidence of radiculopathy and comparing them to patients with no evidence of radiculopathy. The insertional and resting needle EMG activity of 24 patients was digitally recorded and saved for masked review by 2 expert examiners Board-Certified in Clinical Electrophysiology by the American Board of Physical Therapy Specialties. Pairwise examiner comparisons for the final EDX impression using Cohen's kappa (κ) statistic revealed substantial agreement (κ=0.75, 95% CI, 0.48 to 1.0; P<.0001) between the unmasked examiner and masked examiner A and moderate agreement between the unmasked examiner and masked examiner B (κ=0.53, 95% CI, 0.24 to 0.81; P=0.002) and between the masked examiners (κ=0.43, 95% CI, 0.11 to 0.76; P=0.010).

Statistical Analysis

PASW Statistics for Windows, Version 18.0 (SPSS Inc., Chicago, IL) was used for all analyses. Data screening insured statistical assumptions for inferential analyses was met. For the longitudinal analysis, RMDQ score was the dependent variable and *EDX status* and *treatment group* were the dichotomous, between-subjects independent predictor variables. The within-subjects predictor

variable was *time* with 10 levels (baseline, 2, 4, 6, 8, 10, 12, 16, 20, and 24 weeks). A 2-level growth model was used to test for between-group differences in growth-curves with repeated measurements nested within patients and patients nested within groups. The level-1 predictor variable time was treated as a random slope with the level-2 predictor variables EDX status and treatment group treated as fixed slopes.[48-52]

The hypothesized multilevel growth model to assess changes in RMDQ scores over time is detailed in Table 3.3. The hypothesized model was fit to investigate linear and quadratic components of change along with EDX status and treatment group as level-2 predictors. Interaction terms were investigated to explore the 2-way interaction between EDX status and time and EDX status and treatment group and the 3-way interaction between EDX status, treatment group, and time. Main effects for EDX status and treatment group were also explored.

Fitting an accurate multilevel growth model which describes and quantifies changes in RMDQ scores over time involves numerous steps, interim models, and model comparisons. The final model includes a level-1 model describing each patient's change over time and a level-2 model describing interpatient differences in change based on the predictor variables EDX status and treatment group. All level-1 and level-2 predictor variables were grand mean centered to improve model interpretation.[53] The use of multilevel growth modeling does not require extrapolation or imputation methods to account for missing data points[53] because patients with at least one data point can be included in the final model.

Intention-to-treat principles were observed analyzing all patients regardless of compliance.

Additional analyses were conducted to examine the clinical impact of EDX status. Changes in numeric ratings (0-10) for average LBP and average leg pain from baseline to the immediate posttreatment 6-week follow-up occasion were examined. A reduction of at least 2 points was considered clinically meaningful.[54] The proportion of patients rating their overall condition at the immediate posttreatment 6-week follow-up occasion as at least "Quite a bit better" on the 15-point global rating of change scale[46] was also examined. Finally, the percentage change in OSW scores was calculated from baseline to the immediate posttreatment 6-week follow-up occasion. An improvement of ≥50% was categorized as a "successful" outcome, while those with <50% improvement was categorized as "unsuccessful".[55,56] Results were examined using the χ^2 test of association.

Sample Size and Power

A priori power analysis was based on detecting the minimal clinically important difference (MCID) in RMDQ scores of 3.5 points at the immediate posttreatment 6-week follow-up occasion.[42] Ordinary sample size calculations assume all data points are independent. With multilevel growth modeling, ordinary sample size estimates are inflated by a design effect, $1+(n-1)p$, where n is the average cluster size and p the estimated intracluster correlation coefficient.[57] The preliminary study by Fritz et al.[55] had an intracluster correlation

coefficient of 0.45. Therefore, based on 4 observations per patient from baseline to the immediate posttreatment 6-week follow-up occasion, a sample size of 18 patients per group would provide 80% power to detect a 3.5 point difference in RMDQ scores.[42]

Results

Forty-seven patients were screened for inclusion in this analysis. Seven patients declined to undergo EDX testing and 2 patients consented but did not complete testing (Figure 3.1). Thirty-eight patients meeting the selection criteria, consenting to participate, and completing EDX testing were analyzed in the final multilevel growth model (Table 3.5). Based on the results of EDX testing, evidence of radiculopathy was clear in 18 patients (47.4%), possible in 3 patients (7.9%), with no evidence of radiculopathy in 17 patients (44.7%). In order to arrive at a final EDX impression, the 3 patients with possible evidence of radiculopathy were dichotomized as having evidence of radiculopathy or not. After considering their medical history, physical examination, and results of the complete EDX testing, 1 patient was classified as having radiculopathy and the remaining 2 as not. This resulted in a total of 19 patients (50.0%) classified as having radiculopathy for further analyses.

The number of patients completing the RMDQ at each follow-up occasion is in Figure 3.1. Actual follow-ups coincided well with scheduled follow-ups, with the exception of the 6-month occasion which occurred on average at 8.01±1.83 months. On average, patients with radiculopathy completed 7.21±2.26 follow-ups

compared to 5.63±2.54 follow-ups for patients without radiculopathy. Overall, 9 patients (23.7%) elected to receive an epidural steroid injection or undergo surgery prior to the 6-month follow-up occasion. Of the 4 patients (10.5%) electing to undergo surgery, 1 occurred during the treatment period and 3 occurred prior to the 6-month follow-up occasion. None of the patients electing to have surgery had evidence of radiculopathy. Five patients (13.2%) received one or more epidural steroid injection, with 3 patients receiving injections during the treatment period and 3 patients receiving injections prior to the 6-month follow-up occasion. Two patients receiving epidural steroid injections had evidence of radiculopathy.

The results of this investigation revealed that patients with radiculopathy found on EDX testing demonstrated statistically significant and clinically meaningful reductions in RMDQ scores compared to patients without radiculopathy at all posttreatment follow-up occasions regardless of physical therapy treatment received (Table 3.5). The results of the final multilevel growth model accounting for all variables included in the model revealed improvements in RMDQ scores for patients with radiculopathy of -8.1 points (95% CI, -12.6 to -2.6; *P*=.006) at the immediate posttreatment 6-week follow-up occasion compared to patients without radiculopathy. This value was -4.1 points (95% CI, -7.4 to -0.7; *P*=.020) at the 6-month follow-up occasion. The variable *treatment group* was not predictive of changes in RMDQ scores at any follow-up occasion. The interaction between EDX status and time revealed faster weekly improvements in RMDQ scores in patients with radiculopathy at the immediate

posttreatment 6-week follow-up occasion (-0.72, 95% CI, -1.4 to -0.04; *P*=.040) through the 16-week (-0.30, 95% CI, -0.57 to -0.04; *P*=.028) follow-up occasion compared to patients without radiculopathy.

Additional analyses revealed that a larger proportion of patients with radiculopathy achieved a clinically meaningful reduction of at least 2 points in average LBP rating (χ^2=3.9, *P*=.049) at the immediate posttreatment 6-week follow-up occasion compared to patients without evidence of radiculopathy. There was no significant difference in the proportion of patients achieving a clinically meaningful improvement in average leg pain rating (χ^2=0.1, *P*=.746). Of the 21 (56.8%) patients rating their overall improvement at the immediate posttreatment 6-week follow-up occasion as at least “Quite a bit better”, 15 of 19 (78.9%) had evidence of radiculopathy compared to 6 of 18 (33.3%) with no evidence of radiculopathy (χ^2=7.8, *P*=.005). Of the 37 patients completing the OSW questionnaire at baseline and at the immediate posttreatment 6-week follow-up occasion, 15 (40.5%) were considered as having a successful outcome, which included 11 of 19 (57.9%) patients with radiculopathy compared to 4 of 18 (22.2%) patients without radiculopathy (χ^2=4.9, *P*=.027).

Discussion

The results of this investigation suggest that in patients with symptoms related to LRS, the presence of radiculopathy identified with EDX testing is a favorable prognostic factor associated with statistically significant and clinically meaningful improvements in LBP-related disability up to about 6 months follow-

up regardless of the type of physical therapy treatment received. Additionally, a greater number of patients with radiculopathy had statistically significant and clinically meaningful reductions in average LBP, rated their overall condition significantly improved, and achieved a successful outcome at the immediate post-treatment 6-week follow-up.

The few studies that have investigated the prognostic value of EDX testing have been methodologically weak employing retrospective designs, were based on interventional or surgical trials, or included nonrepresentative patient populations.[24-27] For example, Annaswamy et al. (2012)[24] prospectively examined the value of EDX testing in patients with LRS receiving epidural steroid injections (ESI) and found that radiculopathy was an independent predictor of pain relief at 6 months but not at 2 months, with no evidence of functional improvement. In contrast, Fish et al. (2008)[26] retrospectively investigated the value of EDX testing in patients with LRS receiving ESI and found no differences in pain relief but significantly greater improvement in disability scores in patients with radiculopathy.[42] Our prospective investigation was the first to examine the prognostic value of EDX testing using patients in a physical therapy setting.

The final multilevel growth model revealed that EDX status was the only factor in our model predictive of short and long-term improvements in RMDQ scores in patients with LRS. These findings are clinically relevant and may help inform the medical management of patients with LRS. If patients with radiculopathy are more likely to recover from their current episode of LBP, then

providers may reconsider or delay further diagnostic testing or aggressive treatment (including surgery) based on abnormal EDX test findings.

Although we found the presence of radiculopathy to indicate a favorable prognosis, it has been suggested that in patients with LBP, providing a specific diagnosis may delay their recovery. Abenhaim et al. (1995)[7] investigated the value of a physician's diagnosis in patients with LBP and found that initial diagnosis was highly associated with chronicity. The authors postulated that chronicity resulted from a *specific* diagnosis (e.g., radiculopathy), leading patients to believe that a *specific* treatment exists to resolve their condition. This labeling effect may result in further testing and treatment directed at a lesion rather than patient-centered functional recovery.[7] This approach could prove problematic in patients with LRS because few effective treatments exist[10,58-61] and failed interventions could prolong recovery or become more invasive or surgical. In this study, patients were not informed of their EDX status and therefore we were not concerned about potential labeling effects. Further research is needed to evaluate the additional prognostic impact of communicating the diagnosis to a patient.

In this investigation, patients with radiculopathy demonstrated improvements over time exceeding the MCID for the RMDQ, which indicates that the observed improvements were on average clinically meaningful.[42-44] Therefore, objective electrophysiologic findings in patients with LRS may help identify patients who are more likely to recover from their current episode of LBP. Whether this improved prognosis is based on receiving physical therapy or is a

more general prognostic effect cannot be determined from our design because of the lack of a no-treatment control group. Our findings are similar to those of Modic et al. (2005)[62] who investigated the role baseline MRI findings in patients with acute LBP or radiculopathy and found that patients diagnosed with disc herniation were 2.7 times more likely to experience ≥50% improvement in RMDQ scores after 6 weeks.

Electrodiagnostic testing may also help identify patients who are less likely to improve from their current episode of LBP. The absence of radiculopathy in patients with LRS may help to identify patients with a poorer prognosis for nonsurgical management, or more specifically for the standard physical therapy treatments used in this study. Additional research is needed to further explore this subgroup of patients with clinical signs of LRS but no evidence of radiculopathy with EDX testing in order to identify the most effective management strategies.

Some limitations of this investigation have been identified. First, the inclusion criteria were clinically-based and therefore specific to the clinical definition and classification of patients with LRS. While this approach is widely accepted and used,[9] definitions of LRS vary across studies; therefore, these results may not be generalizable to patients whose classification of LRS is based on imaging or surgical findings. Second, although every effort was made to complete a patient's EDX testing within 2 weeks of their baseline examination in order to capture findings related to their current episode of LBP, the average time was 2.53±1.83 weeks, ranging from 4 days to 8.57 weeks. Despite some patients

being tested outside of the desired 2-week timeframe, the nature of axonal loss injuries allows for flexibility in the timing of measurement because evidence of nerve damage found on needle EMG testing remains for months and sometimes years after initial insult.[2,3,5]

This study demonstrated that in patients with LRS receiving physical therapy, the presence of radiculopathy found with EDX testing was a favorable prognostic factor for predicting improvements in LBP-related disability up to about 6-months follow-up. These improvements were statistically significant and clinically meaningful. Additionally, a greater number of patients with radiculopathy had statistically significant and clinically meaningful reductions in average LBP, rated their overall condition significantly improved, and achieved a successful outcome at the immediate posttreatment 6-week follow-up. The results of this study are consistent with other published reports investigating the prognostic value of EDX testing in similar patient populations undergoing lumbar epidural steroid injections and surgery.[24-27]

Table 3.1 Patient selection criteria

Inclusion Criteria	Exclusion Criteria
Chief complaint of pain and/or paresthesia in low back with symptoms extending distal to gluteal fold within previous 24 hours.	Known serious spinal pathology or suspicion of serious pathology based on red flags noted in general medical screening.
Modified Oswestry score ≥20%.	Evidence of CNS involvement including presence of pathological reflexes in physical examination.
Age at least 18 and less than 60 years.	Patient report of complete absence of LBP and leg symptoms when seated.
At least one of the following signs of nerve root compression: Positive SLR or crossed SLR test. Sensory deficit in symptomatic limb. Diminished myotomal strength in symptomatic limb. Diminished muscle stretch reflex in symptomatic limb.	Recent surgery (<6 months) to low back including fusion of low back or pelvis. Recent (<2 weeks) epidural steroid injection for LBP and/or leg pain. Current pregnancy. Known inability to comply with the treatment schedule.

SLR, straight leg raise; CNS, central nervous system; LBP, low back pain.

Table 3.2 Standardized needle EMG examination and findings

Muscles sampled*	Peripheral nerve (myotome)	Abnormalities defined
Lumbar paraspinals Anterior tibialis Medial gastrocnemius Posterior tibialis Vastus medialis Biceps femoris short-head	Posterior primary rami (L2-S1) Deep fibular (L4-5) Tibial (S1-2) Tibial (L5-S1) Femoral (L2-4) Common fibular (L5-S2)	*Presence of one or more of the following at rest:* • positive waves • fibrillation potentials • complex repetitive discharges • fasciculation potentials (in conjunction with other findings) *Presence of one or more of the following during volitional contraction:* • large-amplitude motor units (>5 mV) • long-duration motor units (>10 msec) • polyphasic motor units (>5 turns or phases) • reduced recruitment (>12 Hz for initial motor units)

*Additional muscles sampled as needed to clarify exam

mV:millivolts; msec:milliseconds; Hz:hertz

Table 3.3 Hypothesized multilevel growth model

Level 1: within-patients sub-model

$RMDQ_{ij} = B_{0j} + B_{1j}TIME_{gmc} + B_{2j}TIME^2_{gmc} + e_{ij}$

$RMDQ_{ij}$ = RMDQ score repeatedly measured (i) on patients (j)

B_{0j} = Random intercept. Average baseline RMDQ score (0) for patients (j)

B_{1j} = Random slope. Average linear change (1) grand mean centered ($TIME_{gmc}$) in RMDQ scores between patients (j)

B_{2j} = Random slope change. Average quadratic change (2) grand mean centered ($TIME^2_{gmc}$) in RMDQ scores between patients (j)

e_{ij} = Difference between observed and predicted RMDQ scores measured (i) on patients (j)

Level 2: between-patients models

$B_{0j} = V_{00} + V_{01}EDX_{gmc} + V_{02}TG_{gmc} + u_{0j}$

$B_{1j} = V_{10} + V_{11}EDX_{gmc} + V_{12}TG_{gmc} + u_{1j}$

$B_{2j} = V_{20} + V_{21}EDX_{gmc} + V_{22}TG_{gmc} + u_{2j}$

V_{00} = Grand mean value of patient-level intercept B_{0j} at baseline (0) on patients (0)

$V_{01}EDX_{gmc}$ = Average baseline difference in RMDQ scores for *EDX status* grand mean centered (EDX_{gmc})

$V_{02}TG_{gmc}$ = Average baseline difference in RMDQ scores for *Treatment Group* grand mean centered (TG_{gmc})

u_{0j} = Patient-specific variation around these values

V_{10} = Grand mean value of random *linear* slope for repeated measures (1) on patients (0)

$V_{11}EDX_{gmc}$ = Average *linear* difference between EDX_{gmc} slopes

$V_{12}TG_{gmc}$ = Average *linear* difference between TG_{gmc} slopes

u_{1j} = Patient-specific variation around these values

V_{20} = Grand mean value of random *quadratic* slope for repeated measures (1) on patients (0)

$V_{21}EDX_{gmc}$ = Average *quadratic* difference between EDX_{gmc} slopes

$V_{22}TG_{gmc}$ = Average *quadratic* difference between TG_{gmc} slopes

u_{2j} = Patient-specific variation around these values

Full model

$RMDQ_{ij} = V_{00} + V_{01}EDX_{gmc} + V_{02}TG_{gmc} + V_{10}TIME_{gmc} + V_{11}EDX_{gmc}*TIME_{gmc} + V_{20}TIME^2_{gmc} + V_{21}EDX_{gmc}*TIME^2_{gmc} +$

$[V_{01}EDX_{gmc}*V_{02}TG_{gmc} + V_{11}EDX_{gmc}*V_{12}TG_{gmc}*TIME_{gmc}] + (u_{0j} + u_{1j}*TIME_{gmc} + u_{2j}*TIME^2_{gmc} + e_{ij})$;

[interaction terms not implied by model]

RMDQ: Roland and Morris Disability Questionnaire; EDX: electrodiagnostic

Table 3.4 Patient demographic and clinical characteristics

	Final electrodiagnostic impression	
	Evidence of radiculopathy (n=19)	No evidence of radiculopathy (n=19)
Age (years)	38.58±11.76	43.28±12.87
Gender		
women (%)	6 (31.58%)	11 (57.89%)
men (%)	13 (68.42%)	8 (42.11%)
BMI (kg/m^2)	28.62±5.44	29.02±6.59
Smoker (%)	2 (10.53%)	1 (5.26%)
Average LBP baseline	4.89±2.09	4.61±1.96
Average leg pain baseline	5.21±2.68	4.77±2.14
Oswestry score baseline	37.21±11.33	43.37±14.50
Roland and Morris score baseline	11.11±4.92	11.74±5.59
Duration current episode (weeks)	12.07±14.20	68.87±136.25
Randomized to:	10 (52.63%)	10 (52.63%)
EOTA Group (%)	9 (47.37%)	9 (47.37%)
EOTA+Traction Group (%)		

BMI: body mass index; LBP: low back pain; EOTA: extension oriented treatment approach

Table 3.5 Posttreatment multilevel growth modeling results for patients with evidence of radiculopathy corrected for covariates *treatment group*, *time*, and *time*^{2}

Mean follow-up	5.7 Weeks	8.3 weeks	9.9 Weeks	12.3 weeks	16.2 weeks	20.1 weeks	32.0 weeks
Change in RMDQ scores (95% CI)	-8.1 (-13.6,-2.6)	-6.8 (-10.5,-3.0)	-5.0 (-8.8,-1.3)	-5.9 (-9.5,-2.5)	-4.6 (-7.9,-1.1)	-4.3 (-7.6,-0.9)	-4.1 (-7.4,-0.7)
Significance	*P=.006*	*P=.001*	*P=.010*	*P=.002*	*P=.010*	*P=.014*	*P=.020*
EDX status*time interaction (95% CI)	-0.72 (-1.4,-0.04)	-0.56 (-1.0,-0.09)	-0.43 (-0.75,-0.12)	-0.48 (-0.87,-0.09)	-0.30 (-0.57,-0.04)	-0.19 (-0.41,0.04)	-0.09 (-0.24,0.05)
Significance	*P=.040*	*P=.022*	*P=.008*	*P=.016*	*P=.028*	P=.107	P=.179

RMDQ: Roland and Morris Disability Questionnaire; 95% CI: 95% confidence interval; NPRS: numeric pain rating scale

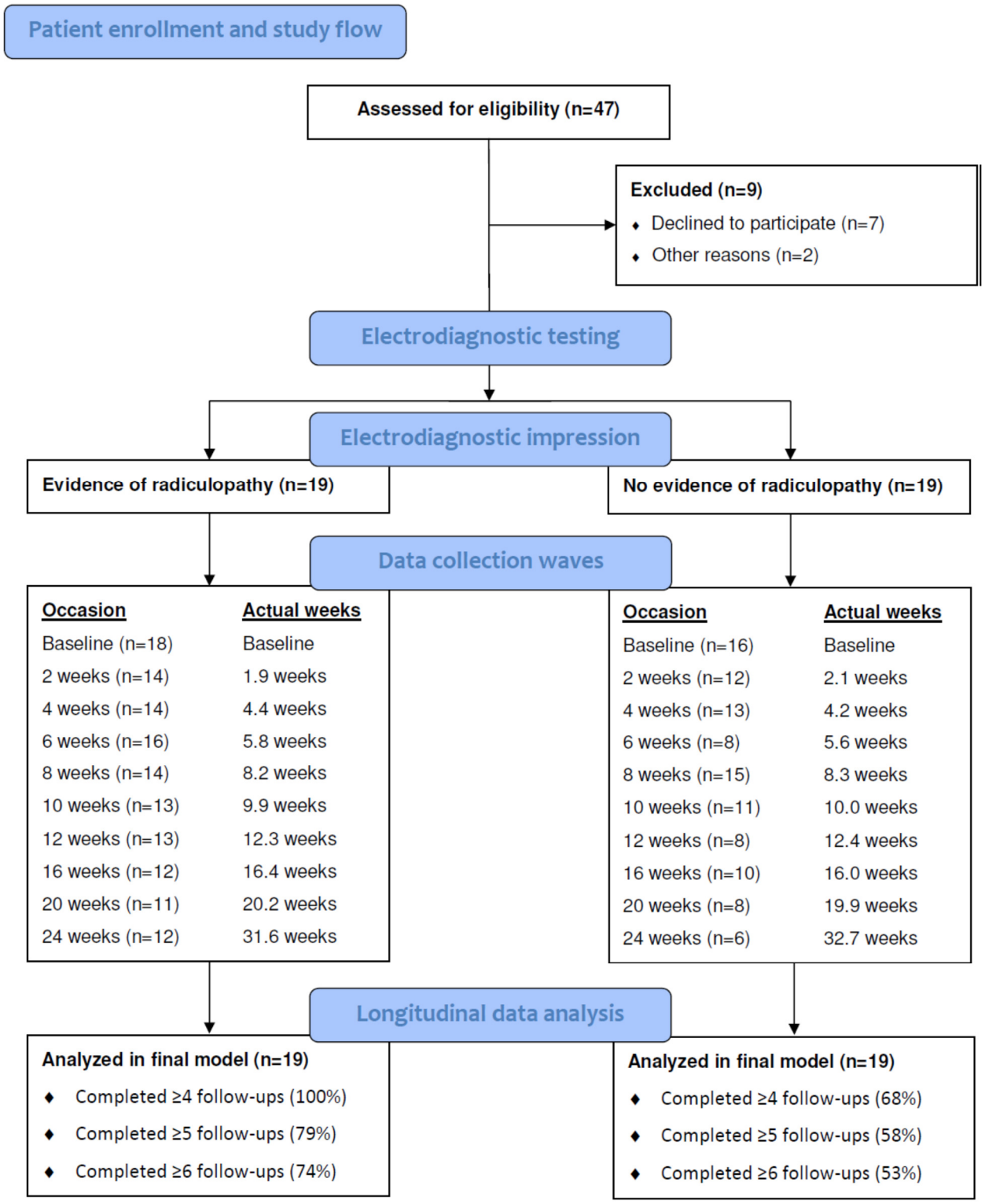

Figure 3.1 Patient enrollment and study flow

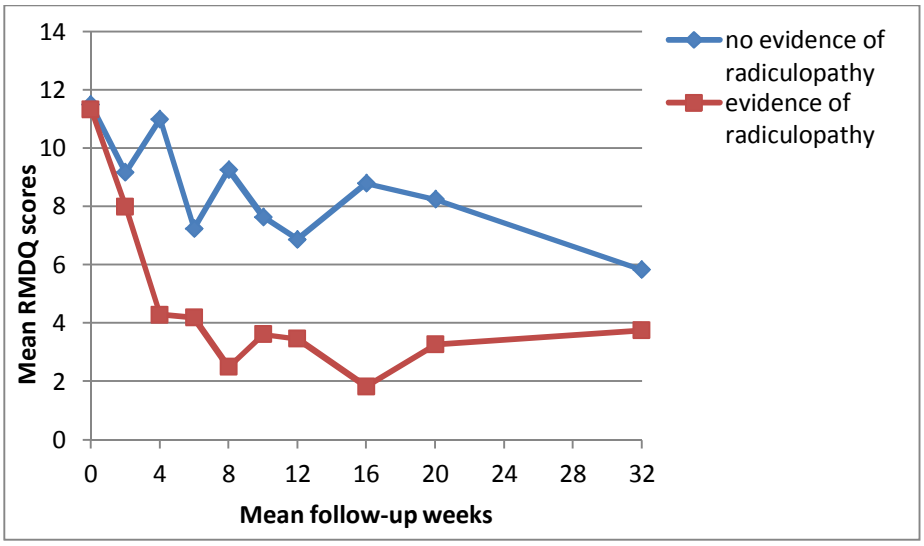

Figure 3.2 Results of multilevel growth modeling

CHAPTER 4

THE VALUE OF HISTORY AND PHYSICAL EXAMINATION FINDINGS FOR PREDICTING THE OUTCOME OF ELECTRODIAGNOSTIC TESTING IN PATIENTS WITH SUSPECTED LUMBOSACRAL RADICULOPATHY

Nathan J. Savage, Julie M. Fritz, and Anne Thackeray

Abstract

Study Design

This investigation used a cross-sectional study design.

Objectives

This study investigated the value of history and physical examination findings for predicting the outcome of electrodiagnostic testing in patients with suspected lumbosacral radiculopathy.

Background

Electrodiagnostic testing is routinely used to evaluate patients with suspected lumbosacral radiculopathy. Recent evidence suggests that the presence of radiculopathy found on electrodiagnostic testing may predict better functional outcomes in these patients. While some patient history and physical examination findings have been shown to predict the presence of disc herniation or neurological insult, little is known about their relationship to the results of electrodiagnostic testing.

Methods

Electrodiagnostic testing was performed on 38 patients with suspected lumbosacral radiculopathy participating in a randomized trial comparing different physical therapy treatment programs. The diagnostic gold standard was the presence or absence of radiculopathy based on the results of the needle

electromyographic examination. Diagnostic sensitivity and specificity values were calculated along with corresponding likelihood ratios for select patient history and physical examination variables.

Results

Patient history and physical examination findings – analyzed individually or in combination – were not strongly predictive of the outcome of electrodiagnostic testing. Diagnostic sensitivity values ranged from 0.026 (95% CI: 0.0,-0.24) to a high of 0.95 (95% CI: 0.72,-0.99) and specificity values ranged from 0.10 (95% CI: 0.018,-0.34) to a high of 0.95 (95% CI: 0.72,-0.99). Positive likelihood ratios ranged from 0.15 (95% CI: 0.0,-2.9) to a high of 2.3 (95% CI: 0.71,-7.7) and negative likelihood ratios ranged from 2.0 (95% CI: 0.35,-11) to a low of 0.50 (95% CI: 0.031,-8.1).

Conclusion

Patient history and physical examination findings were not strongly predictive of the outcome of electrodiagnostic testing in patients with suspected lumbosacral radiculopathy.

Introduction

The evaluation of patients with low back pain (LBP) is concentrated on medical history, a comprehensive physical examination, and specific diagnostic tests when deemed necessary for differential diagnosis.[15,23,34,63] The majority of

LBP is considered nonspecific having no clear pathoanatomic cause;[7] however, one specific cause of LBP is lumbosacral radiculopathy.[8] Known commonly as *sciatica* or *lumbar radiculopathy*, this condition has some unique defining characteristics.[9,10] Most commonly the result of a herniated disc, patients with sciatica typically complain of LBP and radiating leg symptoms which are often described as sharp, piercing, throbbing, aching, or burning, along with dermatomal paresthesia.[2,10] While the presence of radiating leg symptoms is common to all patients with sciatica, lumbosacral radiculopathy is distinguished by the presence of objectively measurable nerve root injury, which is difficult to determine from the clinical examination alone.[4,5,10]

Electrodiagnostic (EDX) testing, consisting of needle electromyography (EMG) and nerve conduction studies, is used to evaluate the integrity of the neuromuscular system, including upper and lower motor neurons, the neuromuscular junction, and skeletal muscle.[1-5] Conducted as an extension of the clinical examination, EDX testing is the primary method used to objectively measure and document pathological changes or injury to the neuromuscular system, including proximally located spinal nerve roots.[1-5] Clinicians employ EDX testing to evaluate patients with suspected lumbosacral radiculopathy,[4,5] with particular emphasis on the results of the needle EMG examination which has high diagnostic specificity in these patients.[3-5,15]

Research has demonstrated the relationship between some patient history and physical examination findings in patients with sciatica and the presence of disc herniation or nerve root impingement on diagnostic imaging.[15,23,30-33]

However, few studies have investigated the relationship between patient history and physical examination findings and the results of EDX testing.[32,34] Although EDX testing is routinely used to evaluate patients with suspected nerve root injuries, testing can be uncomfortable and expensive. However, recent studies have suggested that the presence of radiculopathy found on EDX testing may be a favorable prognostic factor for recovery.[20,24] Therefore, establishing history and/or physical examination findings in patients with suspected lumbosacral radiculopathy which could accurately predict the outcome of EDX testing would benefit patients and clinicians.

The purpose of this study was to investigate the value of select patient history and physical examination findings for predicting the outcome of EDX testing in patients with suspected lumbosacral radiculopathy.

Methods

Subjects

Patients with suspected lumbosacral radiculopathy participating in a randomized clinical trial comparing different physical therapy treatments were recruited for this investigation. These patients met the inclusion criteria for the randomized trial (Table 4.1) and consented to undergo additional EDX testing. Institutional Review Board approvals were obtained from the University of Utah and Intermountain Healthcare (Salt Lake City, Utah) for this study.

Design

This cross-sectional study analyzed the baseline data collected for patients participating in the randomized clinical trial[36] along with the additional EDX testing they consented to undergo. For the purposes of this investigation, patients were grouped and analyzed according to the presence or absence of radiculopathy as determined by the needle EMG examination.

Study Procedures

Patients were recruited from physician and outpatient physical therapy clinics from March 2011 to February 2012. Eligible patients provided a separate written informed consent to undergo EDX testing. Baseline data collection was performed by a research assistant blinded to the patient's EDX testing results. Additional EDX testing was conducted by a licensed Physical Therapist who is also an experienced electromyographer certified in the performance and interpretation of EDX tests. The individual performing the EDX testing (N.J.S.) was blind to the patient's baseline clinical examination findings.

Patient History and Self-Report Measures

Patient history variables thought to be clinically meaningful for the diagnosis of lumbosacral radiculopathy were chosen as variables for this analysis.[15,32,34] At baseline, patients rated how frequently and how bothersome on average their symptoms were during the previous week for the following variables: 1) LBP; 2) leg pain; 3) numbness or tingling in their leg, groin, or foot;

4) weakness in their leg or foot; and 5) LBP or leg pain while sitting. The frequency of these symptoms was rated as follows: 1=not at all; 2=very rarely; 3=a few times; 4=about half the time; 5=usually; and 6=almost always. The level of bothersome for those same symptoms were rated as follows: 1=not at all; 2=slightly; 3=somewhat; 4=moderately; 5=very; and 6=extremely. For analytic purposes, these values were dichotomized so that frequency and bothersome ratings ≥4 were valued at 1 and rating ≤3 were valued at 0. This resulted in identifying patients whose symptoms occurred "about half the time" or more and patients whose symptoms were at least "moderately" bothersome.

Physical Examination Procedures

Physical examination variables thought to be clinically meaningful for the diagnosis of lumbosacral radiculopathy were chosen as variables for this analysis.[15,16,34] Patients were evaluated for signs of lumbosacral nerve root irritation which included postural observation, adverse neural tension signs, diminished sensation, muscle weakness, and diminished muscle stretch reflexes. Patient's spinal posture was evaluated in standing with the clinician recording their observation of alignment as being within normal limits (WNL) or lateral trunk shift being present to the right or left. Straight leg raise and crossed straight leg raise testing was performed with the examiner recording the range of motion. A positive test was reproduction of pain and/or paresthesia in the symptomatic limb at an angle of 70° or less.[36] Sensation to light touch was evaluated in both lower limbs for the L1 (inguinal area), L2 (anterior mid-thigh), L3 (distal anterior thigh),

L4 (medial lower leg/foot), L5 (lateral leg/foot), and S1 (lateral side of foot) dermatomes with findings recorded as WNL, diminished, or absent. Manual muscle testing was performed in both limbs evaluated hip flexion (L2-L3), knee extension (L3-L4), ankle dorsiflexion (L4), hallux extension (L5), and ankle eversion (S1-S2) with findings recorded as WNL or diminished. Quadriceps and ankle muscle stretch reflexes were evaluated in both limbs with findings recorded as WNL or diminished.

Additionally, patients performed single or repeated repetition trunk movements in standing while the examiner inquired about changes in their symptom location. Changes in symptom location with trunk movements were defined as peripheralization, centralization, or unchanged.[36] Range of motion was measured using single inclinometer procedures with excellent reliability.[47]

Electrodiagnostic Testing Procedures

All EDX tests were performed using a Cadwell Sierra Wave (Cadwell Laboratories, Kennewick, WA). Patients underwent standardized peripheral sensory and motor nerve conduction studies, including F waves.[4,5] Monopolar needle EMG was performed on a standardized set of six muscles with demonstrated reliability in patients with suspected lumbosacral radiculopathy[1,16,20] and included the anterior tibialis, medial gastrocnemius, posterior tibialis, vastus medialis, biceps femoris short-head, and the lumbar paraspinal muscles. Limb muscles were analyzed at rest and during volitional contraction. The lumbar paraspinal muscles were analyzed at rest only. Evidence

of radiculopathy was defined by the presence at least one of the following: 1) pathological findings at rest or during volitional contraction indicative of axonal loss in at least two muscles (including the lumbar paraspinal muscles) sharing a common nerve root but from different peripheral nerves, or 2) findings isolated to the lumbar paraspinal muscles when they could be reliably examined.[1,16]

Patients were classified as having clear, possible, or no evidence of radiculopathy. For analytic purposes, a final EDX impression was given for each patient by dichotomizing patients as having evidence of radiculopathy or not. This was accomplished by combining patients with possible and clear evidence of radiculopathy and comparing them to patients with no evidence of radiculopathy. The insertional and resting needle EMG activity of 24 patients was digitally recorded and saved for masked review by two expert examiners Board-Certified in Clinical Electrophysiology by the American Board of Physical Therapy Specialties. Pairwise examiner comparisons for the final EDX impression using Cohen's kappa (κ) statistic revealed substantial agreement (κ=0.75; 95% CI: 0.48,-1.0; P<.0001) between the unmasked examiner and masked examiner A and moderate agreement between the unmasked examiner and masked examiner B (κ=0.53; 95% CI: 0.24,-0.81; P=0.002) and between the masked examiners (κ=0.43; 95% CI: 0.11,-0.76; P=0.010).

Statistical Analysis

PASW Statistics for Windows, Version 18.0 (SPSS Inc., Chicago, IL) was used to organize and summarize all data and generate 2x2 tables for further

analysis. Data screening insured statistical assumptions for inferential analysis was met. Listwise deletion was used for any variables missing for a specific patient. Diagnostic sensitivity and specificity values and the corresponding likelihood ratios were calculated with 95% confidence intervals by inputting the data from the 2x2 tables into an online application (http://www.vassarstats.net/clin1.html)[64] A value of 0.5 was added to any cell containing 0 in order to calculate likelihood ratios.[32]

Consistent with previous studies[32,34] patient history and physical examination variables – whether analyzed individually or in combination – were considered separate diagnostic tests for the presence or absence of lumbosacral radiculopathy. Results of the needle EMG examination and formulation of the final EDX impression served as the diagnostic gold standard for further analysis. The minimum acceptable diagnostic accuracy was a positive likelihood ratio (LR+) of ≥2.0 or a negative likelihood ratio (LR-) of ≤0.50.[32] These values would result in an approximate posttest change in the diagnostic probability for the presence or absence of lumbosacral radiculopathy of at least 15%.[65,66] Meaningful shifts in posttest diagnostic probabilities require a LR+ of ≥10.0 or a LR- of ≤0.1, which would result in at least a 45% change in the diagnostic probability for the presence or absence of lumbosacral radiculopathy.[65,66]

Results

Subjects

Forty-seven patients were screened for inclusion in this analysis. Seven patients declined to undergo EDX testing and 2 patients consented but did not complete testing (Figure 4.1). Thirty-eight patients meeting the selection criteria, consenting to participate, and completing EDX testing were included for analysis (Table 4.2). Based on the results of EDX testing, evidence of radiculopathy was clear in 18 patients (47.4%), possible in 3 patients (7.9%), with no evidence of radiculopathy in 17 patients (44.7%). In order to arrive at a final EDX impression, the 3 patients with possible radiculopathy were dichotomized as having evidence of radiculopathy or not. After considering their medical history, physical examination, and the results of the complete EDX testing, 1 patient was classified as having radiculopathy and the remaining 2 as not. This resulted in a total of 19 patients (50.0%) classified as having radiculopathy for further analyses. Outside of discomfort associated with EDX testing, no adverse events were reported secondary to the physical or electrophysiologic examinations.

Patient History Findings

The diagnostic sensitivity and specificity values along with the corresponding likelihood ratios for select patient history variables are detailed in Table 4.3.

Diagnostic Sensitivity and Specificity

Diagnostic sensitivity values ranged from .026 (95% CI: 0.0,-0.24) in patients reporting having all 5 symptom frequency findings about half the time or more the week prior to baseline examination to a high of 0.37 (95% CI: 0.17,-0.61) in patients reporting leg pain, weakness, LBP or leg pain while sitting, and having at least 3 symptom frequency findings about half the time or more the week prior to baseline examination, respectively. Diagnostic specificity values ranged from 0.33 (95% CI: 0.14,-0.59) in patients reporting LBP or leg pain about half the time or more the week prior to baseline examination to a high of 0.83 (95% CI: 0.58,-0.96) in patients reporting having all 5 symptom frequency and all 5 symptom bothersome findings about half the time or more the week prior to baseline examination, respectively.

Likelihood Ratios

LR+ values ranged from 0.15 (95% CI: 0.0,-2.9) in patients reporting having all 5 symptom frequency findings about half the time or more the week prior to baseline examination to a high of 1.3 (95% CI: 0.51,-3.4) in patients reporting weakness about half the time or more the week prior to baseline examination. None of the LR+ values reached statistical significance at the $P<.05$ level. LR- values ranged from 1.9 (95% CI: 1.1,-3.3) in patients reporting LBP or leg pain while sitting about half the time or more the week prior to baseline examination to a low of 0.87 (95% CI: 0.59,-1.2) in patients reporting weakness

about half the time or more the week prior to baseline examination. None of the LR- values reached statistical significance at the P<.05 level.

Neurological Physical Examination Findings

The diagnostic sensitivity and specificity values along with the corresponding likelihood ratios for select neurological physical examination variables are detailed in Table 4.4.

Diagnostic Sensitivity and Specificity

Diagnostic sensitivity values ranged from 0.026 (95% CI: 0.0,-0.24) in patients with L1 dermatomal deficit to a high of 0.95 (95% CI: 0.72,-0.99) in patients with combined sensory, motor, and reflex deficits. Diagnostic specificity values ranged from 0.10 (95% CI: 0.018,-0.34) in patients with motor and reflex deficits and combined sensory, motor, and reflex deficits, respectively, to a high of 0.95 (95% CI: 0.72,-0.99) in patients with L1 dermatomal deficit.

Likelihood Ratios

LR+ values ranged from 0.20 (95% CI: 0.026,-1.5) in patients with L2 dermatomal deficit to a high of 2.3 (95% CI: 0.71,-7.7) in patients with S1 dermatomal deficit. None of the LR+ values reached statistical significance at the P<.05 level. LR- values ranged from 1.8 (95% CI: 0.48,-6.4) in patients with positive SLR to a low of 0.50 (95% CI: 0.031,-8.1) in patients with combined

sensory, motor, and reflex deficits. None of the LR- values reached statistical significance at the P<.05 level.

Observational and Movement-Based Physical Examination Findings

The diagnostic sensitivity and specificity values along with the corresponding likelihood ratios for select observational and movement-based physical examination variables are detailed in Table 4.5.

Diagnostic Sensitivity and Specificity

Diagnostic sensitivity values ranged from 0.16 (95% CI: 0.042,-0.40) in patients with a lateral trunk shift observed in standing to a high of 0.79 (95% CI: 0.54,-0.93) in patients whose symptoms peripheralize with trunk flexion in standing. Diagnostic specificity values ranged from 0.11 (95% CI: 0.018,-0.35) in patients whose symptoms peripheralize with trunk flexion in standing to a high of 0.79 (95% CI: 0.54,-0.93) in patients whose symptoms centralize with trunk extension in standing.

Likelihood Ratios

LR+ values ranged from 0.33 (95% CI: 0.11,-1.0) in patients with a lateral trunk shift observed in standing to a high of 1.0 (95% CI: 0.58,-1.7) in patients whose symptoms peripheralize with trunk extension in standing. LR- values ranged from 2.0 (95% CI: 0.35,-11) in patients whose symptoms peripheralize

with trunk flexion in standing to a low of 1.0 (95% CI: 0.77,-1.3) for patients whose symptoms centralize with trunk extension in standing.

Discussion

This study investigated the value of select patient history and physical examination findings for predicting the outcome of EDX testing in patients with suspected lumbosacral radiculopathy. Overall, the results of this investigation revealed generally moderate to poor diagnostic sensitivity and specificity values for all patient history and physical examination variables, whether they were examined individually or in combination. This is further evidenced by the fact that only two LR+ values and one LR- values reached even marginally acceptable levels (i.e., ≥2.0 and ≤0.5, respectively) and none of the variables examined individually or in combination reached values considered clinically meaningful (i.e., ≥10.0 and ≤0.1, respectively).[32,65,66]

The diagnostic sensitivity and specificity values in this investigation are generally comparable to those measured in the study by Lauder[34] which also revealed high sensitivity values for sensory, motor, reflex, and neural tension variables, particularly when examined in combination. The most notable difference was found in SLR testing. In this investigation, the diagnostic sensitivity and specificity values for SLR testing was 72% and 16%, respectively. In the study by Lauder, these values were 19% and 84%, respectively. The reason(s) for these differences is unclear. The values in this investigation more closely match those of previous investigations which suggest that SLR testing is

more sensitive than specific in patients with suspected lumbosacral radiculopathy.[15,23,30,31] The values for diagnostic sensitivity and specificity for crossed SLR testing in this investigation were 10% and 84%, respectively, values also consistent with published reports.[15,23,30,31] While both studies included patients with suspected lumbosacral radiculopathy, the study by Lauder consisted of consecutive patients referred for EDX testing while the patients in this investigation were referred for physical therapy and consented to undergo EDX testing as part of their participation in a randomized clinical trial. Whether this resulted in meaningful differences between study populations is unclear, but the author of the aforementioned study expressed concern of selection bias in discussing her results.[34]

The only two variables to generate a LR+ value reaching a marginally acceptable level of ≥2.0 were patients with an S1 dermatomal deficit and patients with a diminished ankle reflex, with LR+ values of 2.3 (95% CI: 0.71,-7.7) and 2.0 (95% CI: 0.72,-5.5), respectively. Assuming a pretest probability of having lumbosacral radiculopathy of 10%,[8,10] then a patient with an S1 dermatomal deficit would result in a posttest probability of having radiculopathy of approximately 20%.[65] The only variable to generate a LR- value reaching a marginally acceptable level (≤0.50) was patients with combined sensory, motor, and reflex deficits with LR- value of 0.50 (95% CI: 0.031,-8.1), a negative test resulting in a posttest probability of having radiculopathy of approximately 5%. These values do not generate particularly meaningful changes in probability for the diagnosis of lumbosacral radiculopathy.

Overall, this investigation revealed that select patient history and physical examination findings – considered individually or in combination – were not strongly predictive of the outcome of EDX testing in patients with suspected lumbosacral radiculopathy. In the end, 17 of 38 (44.7%) patients in this investigation with combined sensory, motor, and reflex deficits had normal needle EMG examinations. Furthermore, 1 (2.6%) patient without a single sensory, motor, or reflex deficit had measurable nerve damage on needle EMG suggestive of lumbosacral radiculopathy. In the study by Lauder,[34] 15% of patients with normal physical examination findings had abnormal needle EMG findings suggestive of radiculopathy. Therefore, based on the results of this investigation, EDX testing provides unique and valuable information in patients with suspected lumbosacral radiculopathy.

Some limitations have been identified for this investigation. Although every effort was made to complete a patient's EDX testing within the first 2 weeks of the intervention period in order to capture findings related to their current episode of LBP, the average time to complete testing from baseline was 2.53±1.83 weeks, ranging from 4 days to 8.57 weeks. Despite some patients being tested outside of the desired 2-week timeframe, within which patients received study related physical therapy treatment, the nature of axonal loss injuries allows for flexibility in the timing of measurement because the evidence of nerve damage on needle EMG has been found to remain months and even years after initial insult.[2,3,5]

Another potential limitation of this investigation is that baseline history and physical examinations were performed by multiple examiners in multiple clinical locations as part of randomized clinical trial from which these data came. Although the principle investigator (N.J.S.) obtained patient history and conducted a physical examination prior to performing EDX testing, these findings were not recorded and procedures standardized like those used for baseline data collection. All examiners were licensed physical therapists trained to follow specific study protocols for data collection and performance of the baseline examinations, including postural observation, neurologic, and physical examinations.[36] This strengthens the generalizability of the findings of this investigation but may weaken the internal validity.

Another potential limitation to this investigation is misclassification of the final EDX impression. The sensitivity and specificity values recorded in the reliability analysis of these data were consistent with published reports, indicating that needle EMG tends to be a more specific than sensitive diagnostic test.[23] Specificity values were measured to be ≥90% across all pairwise examiner comparisons, ranging from 90% to 100%. Clinically, this makes needle EMG more reliable for ruling-in a radiculopathy in the presence of abnormal findings than for ruling-out a radiculopathy in the absence of findings. This is significant in terms of this investigation because it improves the likelihood that patients were properly classified based on the results of their EDX testing. In this investigation, 19 of 38 (50.0%) patients were classified as having evidence of radiculopathy, a percentage that is consistent with previous research;[20,24,26,34] therefore, the

likelihood that patients were misclassified based on incidental, false-positive EMG findings is unlikely given the demonstrated specificity in the reliability analysis.

The results of this investigation are likely clinically meaningful because they suggest that select patient history and physical examination findings are of limited usefulness for predicting the outcome of EDX testing. Obtaining patient history and conducting their physical examination are noninvasive and relatively pain-free processes which can help ascertain whether a patient with LBP or sciatica requires further diagnostic testing. Although EDX testing can be expensive and uncomfortable for patients, the findings of this investigation suggest that such testing may be necessary in order to identify the presence of lumbosacral radiculopathy. This is particularly important if the presence of nerve damage found on EDX testing in patients with suspected lumbosacral radiculopathy is found to be a favorable prognostic factor for recovery, as some recent studies have suggested.[20,24]

Conclusion

Select patient history and physical examination findings were not strongly predictive of the outcome of EDX testing in patients with suspected lumbosacral radiculopathy referred for physical therapy.

Patients with normal physical examinations had abnormal EDX test findings suggestive of lumbosacral radiculopathy. Additionally, a large percentage of patients in this investigation with abnormal history and physical

examination findings had normal EDX test results. These findings suggest that EDX testing is essential in order to identify the subgroup of patients with sciatica that have measurable nerve damage consistent with radiculopathy, which may be an important prognostic factor for recovery.

Table 4.1 Patient selection criteria

Inclusion Criteria	Exclusion Criteria
Chief complaint of pain and/or paresthesia in low back with symptoms extending distal to gluteal fold within previous 24 hours.	Known serious spinal pathology or suspicion of serious pathology based on red flags noted in general medical screening.
Modified Oswestry score ≥20%.	Evidence of CNS involvement including presence of pathological reflexes in physical examination.
Age at least 18 and less than 60 years.	Patient report of complete absence of LBP and leg symptoms when seated.
At least one of the following signs of nerve root compression: Positive SLR or crossed SLR test. Sensory deficit in symptomatic limb. Diminished myotomal strength in symptomatic limb. Diminished muscle stretch reflex in symptomatic limb.	Recent surgery (<6 months) to low back including fusion of low back or pelvis. Recent (<2 weeks) epidural steroid injection for LBP and/or leg pain. Current pregnancy. Known inability to comply with the treatment schedule.

Abbreviations: SLR, straight leg raise; CNS, central nervous system; LBP, low back pain.

Table 4.2 Patient demographic and clinical characteristics

	Final electrodiagnostic impression	
	Evidence of radiculopathy (n=19)	No evidence of radiculopathy (n=19)
Age (years)	38.58±11.76	43.28±12.87
Gender		
women (%)	6 (31.58%)	11 (57.89%)
men (%)	13 (68.42%)	8 (42.11%)
BMI (kg/m^2)	28.62±5.44	29.02±6.59
Smoker (%)	2 (10.53%)	1 (5.26%)
Average LBP baseline	4.89±2.09	4.61±1.96
Average leg pain baseline	5.21±2.68	4.77±2.14
Oswestry score baseline	37.21±11.33	43.37±14.50
Roland and Morris score baseline	11.11±4.92	11.74±5.59
Duration current episode (weeks)	12.07±14.20	68.87±136.25

Abbreviations: BMI, body mass index; LBP, low back pain

Table 4.3 Individual and combined patient history variables

Findings	Sn (95 CI)	Sp (95 CI)	LR- (95 CI)	LR+ (95 CI)
Frequency				
LBP	.26 (.10,.51)	.39 (.18,.64)	1.9 (1.2,2.9)	.43 (.19,.99)
Leg pain	.37 (.17,.61)	.39 (.18,.64)	1.6 (.97,2.7)	.60 (.30,1.2)
Numbness/tingling	.32 (.13,.56)	.56 (.31,.78)	1.2 (.83,1.8)	.71 (.31,1.6)
Weakness	.37 (.17,.61)	.72 (.46,.89)	.87 (.59,1.2)	1.3 (.51,3.4)
LBP/leg pain sitting	.37 (.17,.61)	.33 (.14,.59)	1.9 (1.1,3.3)	.55 (.28,1.1)
Frequency combined				
≥3 present	.37 (.17,.61)	.50 (.27,.73)	1.3 (.80,1.9)	.74 (.35,1.6)
≥4 present	.26 (.10,.51)	.67 (.41,.86)	1.1 (.80,1.5)	.79 (.29,2.1)
All 5 present	.026 (0.0,.24)	.83 (.58,.96)	1.2 (1.1,1.3)	.15 (0.0,2.9)
Bothersome				
LBP	.32 (.14,.57)	.56 (.31,.78)	1.2 (.83,1.8)	.71 (.31,1.6)
Leg pain	.26 (.10,.51)	.50 (.27,.73)	1.5 (1.0,2.1)	.53 (.22,1.3)
Numbness/tingling	.21 (.069,.46)	.61 (.36,.82)	1.3 (.96,1.7)	.54 (.19,1.5)
Weakness	.32 (.14,.57)	.67 (.41,.86)	1.0 (.72,1.5)	.95 (.37,2.4)
LBP/leg pain sitting	.32 (.14,.57)	.44 (.22,.69)	1.5 (.99,2.4)	.57 (.26,1.2)
Bothersome combined				
≥3 present	.26 (.10,.51)	.50 (.27,.73)	1.5 (1.0,2.1)	.53 (.22,1.3)
≥4 present	.16 (.042,.40)	.72 (.46,.89)	1.2 (.92,1.5)	.57 (.16,2.0)
All 5 present	.053 (0.0,.28)	.83 (.58,.96)	1.1 (1.0,1.3)	.32 (.036,2.8)

Abbreviations: Sn, sensitivity; Sp, specificity; LR-, negative likelihood ratio; LR+ positive likelihood ratios; 95 CI, 95% confidence interval; LBP, low back pain.

Table 4.4 Individual and combined neurological physical examination variables

Findings	Sn (95 CI)	Sp (95 CI)	LR- (95 CI)	LR+ (95 CI)
L1 dermatome	.026 (0.0,.24)	.95 (.72,.99)	1.0 (.95,1.1)	.49 (.017,14)
L2 dermatome	.053 (0.0,.28)	.74 (.49,.89)	1.3 (1.1,1.5)	.20 (.026,1.5)
L3 dermatome	.11 (.018,.35)	.84 (.59,.96)	1.1 (.89,1.3)	.67 (.12,3.5)
L4 dermatome	.21 (.069,.46)	.68 (.43,.86)	1.1 (.87,1.5)	.67 (.22,1.9)
L5 dermatome	.53 (.29,.75)	.63 (.39,.83)	.75 (.44,1.3)	1.4 (.69,2.9)
S1 dermatome	.37 (.17,.61)	.84 (.59,.96)	.75 (.52,1.1)	**2.3 (.71,7.7)**
Sensory combined	.68 (.43,.86)	.37 (.17,.61)	.86 (.37,1.9)	1.1 (.68,1.7)
MMT hip flexion	.11 (.019,.36)	.89 (.65,.98)	.99 (.83,1.2)	1.1 (.17,6.7)
MMT knee extension	.22 (.074,.48)	.58 (.34,.79)	1.3 (.97,1.8)	.53 (.19,1.4)
MMT ankle dorsiflexion	.39 (.18,.64)	.74 (.49,.89)	.83 (.55,1.2)	1.5 (.57,3.8)
MMT hallux extension	.39 (.18,.64)	.79 (.54,.93)	.77 (.52,1.1)	1.8 (.65,5.3)
MMT ankle eversion	.28 (.11,.54)	.84 (.59,.96)	.86 (.63,1.2)	1.8 (.49,6.3)
Motor combined	.78 (.52,.93)	.32 (.14,.56)	.70 (.24,2.1)	1.1 (.77,1.7)
Knee reflex	.10 (.018,.34)	.89 (.65,.98)	1.0 (.85,1.2)	1.0 (.16,6.4)
Ankle reflex	.42 (.21,.66)	.79 (.54,.93)	.73 (.49,1.1)	**2.0 (.72,5.5)**
Reflex combined	.47 (.25,.70)	.68 (.43,.86)	.77 (.48,1.2)	1.5 (.66,3.4)
SLR	.72 (.46,.89)	.16 (.042,.40)	1.8 (.48,6.4)	.86 (.61,1.2)
Crossed SLR	.10 (.018,.34)	.84 (.59,.96)	1.1 (.89,1.3)	.67 (.12,3.5)
Combined findings				
Sensory and motor	.84 (.59,.96)	.16 (.042,.40)	1.0 (.20,4.9)	1.0 (.76,1.3)
Sensory and reflex	.84 (.59,.96)	.26 (.10,.51)	.60 (.16,2.3)	1.1 (.82,1.6)
Motor and reflex	.89 (.65,.98)	.10 (.018,.34)	1.0 (.11,8.9)	1.0 (.80,1.2)
All 3 findings	.95 (.72,.99)	.10 (.018,.34)	**.50 (.031,8.1)**	1.1 (.88,1.3)

Abbreviations: Sn, sensitivity; Sp, specificity; LR-, negative likelihood ratio; LR+ positive likelihood ratios; 95 CI, 95% confidence interval; MMT, manual muscle test; SLR, straight leg raise.

Table 4.5 Observational and movement-based physical examination variables

Findings	Sn (95 CI)	Sp (95 CI)	LR- (95 CI)	LR+ (95 CI)
Lateral trunk shift present	.16 (.042,.40)	.53 (.29,.75)	1.6 (1.2,2.1)	.33 (.11,1.0)
Peripherilizes with extension*	.58 (.34,.79)	.42 (.21,.66)	1.0 (.51,1.9)	1.0 (.58,1.7)
Peripherilizes with flexion	.79 (.54,.93)	.11 (.018,.35)	2.0 (.35,11)	.88 (.67,1.2)
Centralizes with extension†	.21 (.069,.46)	.79 (.54,.93)	1.0 (.77,1.3)	1.0 (.29,3.4)

Abbreviations: Sn, sensitivity; Sp, specificity; 95 CI, 95% confidence interval; LR-, negative likelihood ratio; LR+ positive likelihood ratio.

*Pain or paresthesia moving distally away from lumbar spine toward periphery, or paresthesia or neurological sign was worsened or produced.

†Pain or paresthesia moving from periphery toward lumbar spine or was abolished, or paresthesia or neurological sign was improved or abolished.

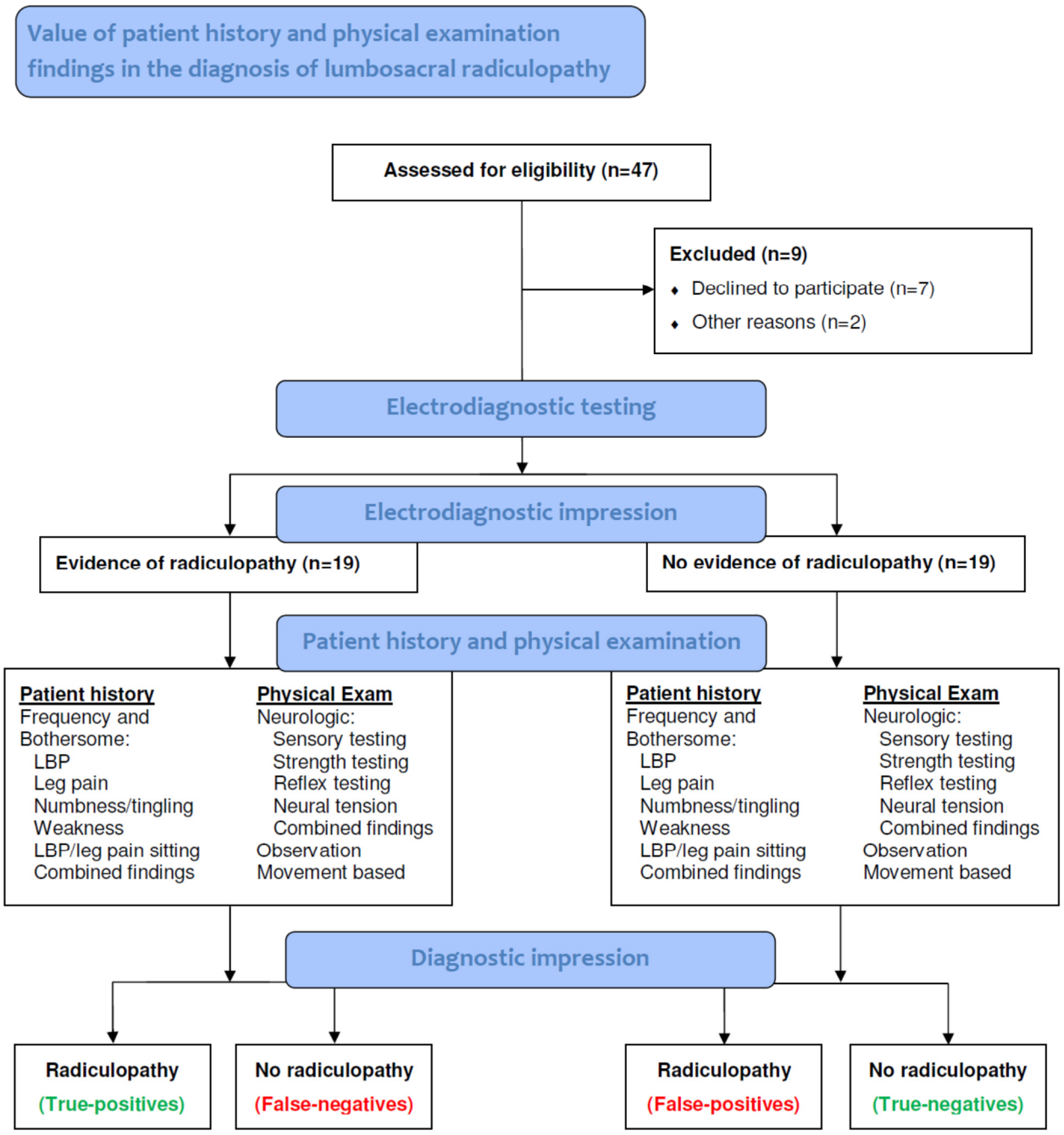

Figure 4.1 Study flow of diagnostic value of patient history and physical examination findings in patients with suspected lumbosacral radiculopathy

CHAPTER 5

CONCLUSION

The research conducted and subsequent manuscripts prepared for this dissertation work focus on the potential clinical value of neurophysiologic findings in patients with lumbosacral radicular syndrome (LRS) using the tool of electrodiagnostic (EDX) testing. In order to evaluate the clinical utility of EDX testing in patients with LRS, the following general research questions were formulated: Is EDX testing a reliable clinical tool? Are the results of EDX testing clinically meaningful with regard to patient outcomes? If the results of EDX testing are clinically meaningful, are they unique or can they be obtained by other means such as patient history or physical examination findings?

Summary of Findings

In general, the results presented in the preceding manuscripts suggest that in patients with LRS referred for physical therapy, the results of EDX testing can be reliably obtained, are clinically meaningful, and provide unique clinical information. More specifically, the findings detailed in the preceding manuscripts can be summarized as follows: in patients with LRS referred for physical therapy, the results of the needle EMG examination can be reliably assessed by

experienced Physical Therapist electromyographers which supports the use of masking in EDX research to validate the use of EDX testing as a diagnostic test; patients with EDX test findings indicative of lumbosacral radiculopathy comprise a specific subgroup of patients with LRS; the presence of lumbosacral radiculopathy identified with EDX testing is a favorable prognostic factor for improvement in LBP-related disability in patients receiving physical therapy; patients with evidence of lumbosacral radiculopathy experienced statistically significant and clinically meaningful improvements in LBP-related disability at both the short-term (6 week) and long-term (around 6 month) follow-up occasions compared to patients with no evidence of radiculopathy; at the immediate posttreatment 6-week follow-up occasion, patients with evidence of lumbosacral radiculopathy experienced statistically significant and clinically meaningful reductions in average LBP, rated their overall condition significantly improved, and were more likely to achieve a successful clinical outcome when compared to patients with no evidence of radiculopathy; and finally, select patient history and physical examination findings are of limited usefulness in predicting the outcome of EDX testing in patients with LRS referred for physical therapy, suggesting that EDX testing is essential in order to identify the subgroup of patients with LRS that have measurable nerve damage indicative of the presence of lumbosacral radiculopathy, which may be an important prognostic factor for recovery.[24,26]

Scientific and Clinical Impact

The findings of this dissertation work generally support previous research which demonstrates the value of EDX testing in patients with LRS.[14-16,24-27] Used as a clinical and diagnostic tool, EDX testing appears to be both reliable and valid (based on the results of EDX testing being highly specific) for detecting the presence of nerve damage in patients with LRS, findings which are supported in this work and in previous studies.[18-20,23] Establishing the reliability and validity of a clinical or diagnostic test is an important step in the process of implementing the use of that tool in clinical practice for the purposes of diagnosing and/or treating patients with LBP.[17]

While a few previous studies have investigated the reliability of EDX testing in patients with LRS,[20,21] this dissertation work was the first to investigate the interrater reliability of needle electromyography (EMG) among Physical Therapist electromyographers and the first to include patients referred for physical therapy. These facts are significant because they help to generalize the reliability of needle EMG across groups of providers and across groups of patients. This is particularly notable when considering that this dissertation work was more pragmatic than previously published reliability studies because the examiners were geographically separate having never practiced together and patient data were collected in eight different physical therapy clinics with diverse environmental factors impacting the fidelity of the EMG recordings in some instances, which is in contrast to previously published reliability studies.[20,21]

In patients with LRS, the presence of nerve damage on needle EMG indicative of radiculopathy has been shown to have high diagnostic specificity.[15,16,23,34] If the validity of a clinical or diagnostic test is understood to mean that a test measures what it intends to measure, or in this case the ability to detect the presence of radiculopathy when radiculopathy is truly present (i.e., high diagnostic specificity), then based on this work and other studies, EDX testing would be considered a valid clinical or diagnostic tool. This notion of validity is particularly meaningful given the unique results provided by EDX testing when compared to patient history and physical examination findings in patients with LRS in this work and other studies.[15,34] Furthermore, the fact that this dissertation work was conducted by Physical Therapists and included patients referred for physical therapy not only helps to substantiate previous studies which investigated the reliability and validity of EDX testing in patients with LRS but supports the generalizability of those findings as well.

With regard to overall impact on patient-centered clinical outcomes, perhaps the most meaningful contribution of this dissertation work is the potential prognostic value of EDX testing in patients with LRS. This finding supports previous studies investigating the prognostic value of EDX testing in patients with LRS but is unique, being the first to investigate patients in a physical therapy setting.

Current research is generally lacking or inconclusive with regard to the existence of favorable prognostic factors in patients LRS.[22] This lack of knowledge is problematic because LRS is a condition in which symptoms are

more difficult to resolve and treatments prescribed for these patients tend to be more costly and invasive including injections and surgery.[8,11-13] Therefore, the identification of a prognostic factor or factors predictive of more favorable patient-centered outcomes which could be reliably assessed with a valid clinical tool could prove rather useful to providers by helping guide the medical management of patients with LRS.

For some patients, learning of the presence of measureable nerve damage found with EDX testing may be alarming and could prompt patients and providers to seek more invasive treatment approaches. However, based on the findings of this work and other studies[24,26,29] the presence of nerve damage on EDX testing may be a favorable prognostic factor; therefore, conservative treatment approaches are likely the most appropriate medical management strategy for the majority of these patients. Although the results of the EDX testing were not revealed to patients participating in the clinical trial from which these data were gathered, patients undergoing testing in clinical practice will likely be made aware of such findings. Notifying a patient of the presence of nerve damage suggests a measurable pathology and indicates a specific diagnosis. This may complicate the medical management of some patients because research has suggested that providing a specific diagnosis to a patient with LBP may delay their recovery. Abenhaim et al. (1995)[7] investigated the value of a physician's diagnosis in patients with LBP and found that initial diagnosis was highly associated with chronicity. The authors postulated that chronicity resulted from a *specific* diagnosis, such as radiculopathy, leading patients to believe that

a *specific* treatment exists to resolve their condition. Although Abenhaim et al. investigated patients injured at work with compensable medical claims the same principle likely influences outcomes in patients with LBP in a variety of clinical settings. Providing patients with the results of their EDX testing, which may reveal the presence of nerve damage, could result in a labeling effect prompting patients and their providers to pursue further testing and/or treatments directed at their nerve lesion rather than patient-centered treatment approaches which emphasize functional recovery.[7] This scenario could prove especially problematic in patients with LRS because so few effective interventions exist[10,58-61] and failed treatments could prolong recovery, increase direct and indirect medical costs, and lead to more invasive treatments including surgery. Therefore, evidence-based recommendations guiding the medical management of patients with LRS, including informing patients and providers that the presence of measureable nerve damage found with EDX testing may be a favorable prognostic factor, has the potential to improve clinical practice, reduce costs associated with diagnosis and treatment, and improve patient-centered functional outcomes.

Limitations

Some limitations to the findings of this dissertation work have been identified. First, the inclusion criteria for study participation were clinically-based and therefore specific to the clinical definition and classification of patients with LRS. While this approach is widely accepted and used,[9] definitions of LRS vary across studies; therefore, these results may not be generalizable to patients

whose classification of LRS is based on imaging or surgical findings. However, the fact that a clinically-based classification approach was used to define the presence of LRS makes these findings more generalizable to providers and patients in a rehabilitation setting where the results of diagnostic imaging or surgical findings may exert less influence on treatment decisions than a treatment-based classification approach.[67-69]

Another potential limitation is misclassification of the final EDX impression. Misclassification, if present, would skew the analysis of the prognostic value of EDX testing because patients were classified as having evidence of radiculopathy or not based on the results of their needle EMG examination, which served as the primary independent variable for all analyses. Additionally, the analysis of the value of select patient history and physical examination findings for predicting the outcome of EDX testing would likewise be skewed because the results of a patient's needle EMG examination served as the gold standard for all analyses.

The sensitivity and specificity values recorded in the reliability analysis of this dissertation work are consistent with published reports which indicate that needle EMG tends to be more specific than sensitive.[23,34] Specificity values were measured to be ≥90% across all pairwise examiner comparisons, ranging from 90% to 100%. Clinically, this makes needle EMG more reliable for ruling-in a radiculopathy in the presence of abnormal findings than for ruling-out a radiculopathy in the absence of findings. This is significant in terms of the findings of this dissertation work because it improves the likelihood that patients

were properly classified based on the results of EDX testing. Of the 38 patients undergoing EDX testing, 19 (50.0%) were classified as having evidence of radiculopathy based on their needle EMG examination, a percentage that is consistent with previous research;[20,24,26,34] therefore, the likelihood that patients were misclassified based on incidental, false-positive EMG findings is unlikely given the demonstrated specificity in the reliability analysis.

Future Research

There is a paucity of EDX-based research involving Physical Therapists, particularly studies utilizing needle EMG as the primary tool of measurement. A cursory PubMed query using the terms “EMG and physical therapist” returned 115 results, 5 of which involved Physical Therapists utilizing EDX testing as an integral tool in their investigation, and none of which utilized EDX testing to investigate patients with LBP.[32,70-72] This lack of Physical Therapist-driven research exists despite the fact that the American Physical Therapy Association administered the first board certification examination in clinical electrophysiology in 1986 and according to the American Board of Physical Therapy Specialties, there are 156 board-certified specialists in clinical electrophysiology as of 2012.[73] Therefore, advancing an agenda which promotes EDX-based research conducted by Physical Therapists is likely to have a significant impact on the knowledge and specialization of those practicing clinical electrophysiology. This impact may be particularly meaningful when research findings are considered within the context of testing patients referred for physical therapy because they

may provide unique information and comparisons when compared to findings from patients undergoing EDX testing in the more traditional physiatry and neurology settings.

An additional benefit to Physical Therapists conducting and publishing high-quality EDX-based research is the opportunity to train future specialists by providing an educational and training infrastructure which promotes an understanding of EDX testing as a clinical tool including instrumentation, test performance, interpretation of findings, and assimilation of the results from the clinical and electrophysiologic examinations with the goal of improving patient-centered outcomes.

The primary focus of this dissertation work was the investigation of the prognostic value of EDX testing in patients with LRS referred for physical therapy. While the results of this work suggest that the presence of radiculopathy found on EDX testing is a favorable prognostic factor in these patients, further research needs to be conducted in order to validate these findings. In order to strengthen the research design, a future investigation could randomize patients based on their EDX status, namely the presence or absence of radiculopathy, as opposed to conducting EDX testing on previously randomized patients, which was the approach used in this dissertation work. A trial which randomized patients based on their EDX status could be structured to investigate various physical therapy treatment approaches, including a no-treatment group. Future studies are also needed to investigate the prognostic value of EDX testing in patients with cervical radicular syndrome, a condition which is related to LRS but

arguably possesses enough unique patient and clinical characteristics that results cannot be generalized across studies.[32]

Another potential line of research related to this dissertation work is to examine the value of real-time neurophysiologic measurements as potential biomarkers of treatment response. Although the results of the larger clinical trial investigating the impact of adding mechanical lumbar traction to an extension-oriented treatment approach[36] – which this dissertation work was a component of – failed to demonstrate an overall benefit of mechanical traction, some patients responded very well to the traction treatments. Of the 38 patients that underwent EDX testing for the prognostic portion of this dissertation work, 18 received mechanical traction, including 9 with evidence of radiculopathy. Of the 9 patients with evidence of radiculopathy that received mechanical traction, 7 (77.8%) were considered as having a "successful" outcome, which was defined as ≥50% reduction in Oswestry disability score at the immediate posttreatment 6-week follow-up occasion; this is compared to only 1 of 9 patients (11.1%) without evidence of radiculopathy achieving a successful outcome (χ^2=8.1, *P*=.004). Comparable results were found for improvements in numeric pain rating for LBP and leg pain at the 6-week follow-up occasion with 8 of 9 patients (88.9%) with evidence of radiculopathy achieving ≥50% reductions in LBP and 6 of 9 patients (66.7%) achieving those reductions in leg pain, respectively. Although based on a small number of patients, these findings suggest that a patient's neurophysiologic status may inform response to traction treatment.

There have been a few studies which suggest that treatment "responders" can be identified based on real-time H-reflex measurements, which is an electrically-induced true reflex involving the S1 nerve root.[4,5] These studies have investigated changes in H-reflex amplitudes during treatment maneuvers in patients with cervical and lumbar dysfunction.[74-76] Therefore, the notion that a neurophysiologic marker such as changes in H-reflex amplitude or latency could be used to identify traction responders is plausible. Furthermore, the existence of a real-time neurophysiologic marker could be used to inform other patient-specific variables such as traction treatment parameters, including patient positioning, force of pull, duration of pull, and treatment frequency.

Conclusions

The results of this dissertation work suggest that in patients with LRS referred to physical therapy EDX testing is a reliable clinical and diagnostic tool, a patient's EDX status is clinically meaningful, and the results of EDX testing provides unique clinical information. Future studies are needed in order to validate the findings of this work, particularly those findings related to the prognostic value of EDX testing in patients with LRS. A lack of EDX-based research conducted by Physical Therapists exists despite a number of highly qualified clinicians providing EDX services and a long-standing professional designation of board-certified specialists. Publication of quality EDX-based studies by Physical Therapists should be promoted in order to strengthen clinical practice and promote specialization in clinical electrophysiology.

APPENDIX

The data analytic approach used in the primary investigation of this dissertation work utilized multililevel growth modeling (MGM) to examine the prognostic value of electrodiagnostic (EDX) testing in patients with lumbosacral radicular syndrome (LRS) referred for physical therapy. The dependent variable in that analysis was LBP-related disability as measured by the Roland and Morris disability questionnaire (RMDQ). The independent variables were EDX status (presence or absence of radiculopathy), treatment group (extension-oriented treatment with and without the addition of mechanical lumbar traction), and time (10 waves of data collection from baseline through the 6-month follow-up occasion).

Because MGM has not been a statistical approach routinely used in longitudinal studies in the rehabilitation sciences, the purpose of this Appendix is to summarize the advantages of MGM for analyzing longitudinal data as well as to detail how this approach was used to analyze the data for this dissertation work.

Advantages of Multilevel Growth Modeling

Multilevel growth modeling explicitly models individual change over time. This approach is more flexible in terms of analyzing data with repeated

measurements because time is treated as a continuous rather than a fixed variable; therefore, it is not necessary to have the same number of observations for each patient or the same spacing between repeated measurements for each patient.[49-53] Also, MGM allows for a more flexible specification of the covariance structure among repeated measurements and analyses can be extended to higher-level models which may include repeated observations nested within patients, patients nested within treatment groups, and treatment groups nested within treatment facilities.[52,53]

Multilevel growth modeling offers a unique data analytic strategy for within-patients designs that is not possible using repeated measures analysis of variance (ANOVA). For example, MGM can be used to model individual-level trends over time, in which polynomial trends can be estimated for each patient rather than simple average trends,[50,53] an approach known as individual growth modeling. In repeated measures ANOVA, individual variation around the group average is treated as unexplained error, but in MGM, regression parameters from all individual growth models, including intercepts, slopes, or both can be treated as random effects for estimation.[51]

The capacity of MGM, which uses likelihood-based estimation, to incorporate all available data in an analysis can be especially useful when following intention to treat principles. An advantage of MGM is that all available data are used in the estimation of model parameters due to the flexible treatment of time as a continuous predictor variable. A patient with only baseline data available can be included in the analysis and contribute to the estimation model

parameters, assuming data are considered missing completely at random or missing at random.[50,53] Furthermore, treating time as a continuous instead of discrete variable increases the statistical power for detecting change.[50,51,53]

In repeated measure ANOVA, the variance-covariance matrix of follow-up occasions over time is assumed to meet the requirement of sphericity, which assumes compound symmetry or that variances at each follow-up occasion are equal and the covariances between all pairs of follow-up occasions are equal.[51] This assumption is unrealistic and is almost certainly violated in most longitudinal studies. In contrast, MGM allows for flexibility in specifying the variance-covariance structure for a given set of data.[50,53] Additionally, because MGM separates the random effects into two parts (between-subject random effects and within-subject random effects), cross-level interaction terms can be examined.[50,52] For example, the interaction between how treatment condition and other between-patient level predictors influence individual growth trajectories (such as within-patient repeated measures over time) can be examined.

Multilevel Growth Model

The process of fitting an appropriate MGM which accurately describes and quantifies change in LBP-related disability over time involves numerous steps, interim models, and model comparisons. Three models will be discussed which reveal the process of modeling and analyzing the data gathered for the principle investigation of this dissertation work, which focused on the potential prognostic value of EDX testing in patients with LRS receiving physical therapy. These

models are: 1) the unconditional means model, 2) the unconditional growth model, and 3) the final MGM for the immediate posttreatment 6-week follow-up occasion.

Unconditional Means Model

The unconditional means model partitions and quantifies variation in RMDQ scores across patients without regard to time. The purpose of this model is to establish whether systematic variation in RMDQ scores is worth exploring and to investigate where that variation resides, within or between patients. Additionally, this analysis provides a baseline from which subsequent models can be compared for goodness of fit.[48,52,53] The unconditional means model is represented as follows:

$$RMDQ_{ij} = B_{0i} + e_{ij}$$

$$B_{0i} = V_{00} + u_{0i}$$

The subscripts represent that an individual patient *i's* observed RMDQ score on follow-up occasion *j* deviates from their patient-specific mean by e_{ij}. The fixed effects of the level-1 unconditional means model estimates the grand mean of RMDQ scores across all occasions and patients.

The unconditional means model allows for the quantification of the within and between-patient variance components by calculating an intraclass correlation coefficient (ICC), which describes the proportion of total variation in RMDQ scores between patients.[48,52,53] Additionally, the ICC summarizes the size of the residual autocorrelation in the composite unconditional means model. In

other words, for each patient, the average correlation between any pair of composite residuals such as between data collection waves 1 and 2, 2 and 3, or 1 and 3. If this value is not zero, it supports the use of MGM as a data analytic strategy for these data because alternative strategies, such as ordinary least squares analysis, assumes zero autocorrelation among residuals.[53]

Unconditional Growth Model

The next step in the process of modeling these data is the formulation of the unconditional growth model, which partitions and quantifies variation in RMDQ scores across patients and over time. The purpose of the unconditional growth model is to establish whether or not systematic variation exists in the observed RMDQ scores, if it is worth exploring, and where that variation exists, within or between patients. Additionally, as with the unconditional means model, this analysis provides a baseline from which subsequent models can be compared for goodness of fit.[48,52,53] The unconditional growth model is represented as follows:

$$RMDQ_{ij} = B_{0i} + B_{1i}TIME_{ij} + e_{ij}$$

$$B_{0i} = V_{00} + u_{0i}$$

$$B_{1i} = V_{10} + u_{1i}$$

The subscripts specify that $RMDQ_{ij}$ scores deviate from their true change trajectory by e_{ij}. Additionally, the second part of the level-2 sub-model depicts interpatient variation in the rates of change (B_{1i}). Because the predictor variables, which were based on a patient's EDX status (presence or absence of

radiculopathy) and treatment group (extension-oriented treatment approach with or without the addition of mechanical lumbar traction), are not included in this model, each part of the level-2 submodel stipulates that a patient's growth parameter (either B_{0i} or B_{1i}) is the sum of an intercept (either V_{00} or V_{10}) and a level-2 residual (u_{0i} or u_{1i}).[53] Time is the only level-1 predictor variable making it the unconditional growth model.

Final Model

Developing the unconditional means model and the unconditional growth model and establishes the need for level-2 predictor variables in order to further explain observed variation in RMDQ scores between patients. The final model fit to these data include a level-1 model describing each patient's change over time and a level-2 model describing interpatient differences in change based upon the predictor variables of a patient's EDX status and treatment group. The composite or final MGM combines the level-1 and level-2 submodels into a single equation. The final model excludes cross-level interaction terms implied by the model that did not help explain variation in the dependent variable.

As a preliminary step to statistical analysis, all level-1 and level-2 predictor variables were centered to improve model interpretation.[48,49,52,53] The level-1 predictor variable time was centered by subtracting the grand mean value for follow-up visits from each individual patient's value. This was labeled with a subscript "gmc" or grand mean centered. Centering time in this way does not impact the rate of change, which is the observed slope, but does impact the

intercept. After centering time, the intercept now represents RMDQ scores for the *average* study patient. The level-2 predictor variables based on a patient's EDX status and treatment group were also centered by subtracting the grand mean value from each individual patient's value. Centering the level-2 predictor variables means that the intercept represents the *average* study patient.

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