THE INFLUENCE OF LEG PAIN ON RECOVERY AFTER ACUTE LOW BACK PAIN AND SUBSEQUENT TREATMENT CHOICES

by

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STATEMENT OF DISSERTATION APPROVAL

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ABSTRACT

Low back (LBP) pain is common and represents a significant societal burden due to costs associated with lost work productivity and medical care. LBP presenting with leg pain, or lumbosacral radicular syndrome (LRS), worsens prognosis and increases disability and cost. Recovery from LBP is highly variable. Improving our understanding of recovery after acute LBP provides an opportunity to change the course of symptoms.

Recent studies have identified distinct recovery patterns among patients with LBP. These are generally represented by recovery, moderate persisting pain, high persisting pain, or recurrence. In a cohort of workers with incident LBP, we examined the presence of these patterns. Using pain scores from monthly follow-up visits over the course of 1 year, we characterized recovery. A growth mixture model identified four distinct trajectories consistent with previous literature with distributions favoring recovery. The four classes were identified as recovered (60%), moderate persisting pain (28%), high persisting pain (8%) and recurrent pain (4%). The presence of leg pain increased pain intensity, slowed recovery, and increased the likelihood of being in the high persisting pain class.

We further characterized these classes by examining the association between baseline covariates and class status using logistic regression. Moderate persisting pain and high persisting pain was more prevalent among Hispanic workers and those reporting more severe prior low back pain. Additionally, high lifting demands and low social

support from coworkers was associated with moderate persisting pain. Workers with LRS were twice as likely to have high persisting pain even after adjusting for race and low back pain history (adjusted OR 2.7 (1.4, 5.4)).

Finally, in a nationally representative cohort from the SPORT population, we examined nonsurgical treatments utilized in managing patients with persisting symptoms of LRS who seek secondary care but do not elect surgical management. The primary nonsurgical interventions used were medication, spinal injections, and physical therapy. Higher baseline disability, the presence of neurologic deficit, and patient preference for physical therapy were all factors associated with receiving physical therapy as an initial management strategy. Patients receiving physical therapy within the first 6 weeks did not demonstrate any significant differences in primary outcomes of pain and disability compared to those who did not receive physical therapy.

Recovery from LBP is highly variable but seems to be described by four distinct patterns of pain. Individuals with low back-related leg pain (LRS) have increased odds of a poor recovery. For patients with persistent LRS, there is significant variation and complexity in nonsurgical management decisions without clear benefit in clinical outcomes. There remains a need to identify optimal management strategies and sequencing of treatment for this population.

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LIST OF ABBREVIATIONS

ANOVA	Analysis of Variance
ANX	Composite Tension-Nervousness Scale
APGAR	Modified Work APGAR (adaptation, partnership, growth, affection, resolve)
BIC	Bayesian Information Criterion
BLRT	Bootstrapped Likelihood Ratio Test
BMI	Body Mass Index
CI	Confidence Interval
CLI	Composite Lifting Index
IDH	Intervertebral Disc Herniation
LBP	Low Back Pain
LBP_Hx	Low Back Pain History
LI	Lifting Index
LMR-LRT	Lo-Mendell-Rubin Likelihood Ratio Test
LRS	Lumbosacral Radicular Syndrome
NPRS	Numeric Pain Rating Scale
OR	Odds Ratio
ZUNG	Modified Zung Depression Index

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CHAPTER 1

INTRODUCTION

Introduction

The aim of this dissertation was to examine recovery in acute low back pain (LBP), the influence of leg pain on recovery, and subsequent management of patients with persisting low back and leg pain. Several specific research questions guided study design and analysis: Can heterogeneity between individuals with incident LBP be explained by different patterns of recovery? How are these patterns identified and are they influenced by the presence of leg pain? What are common management strategies for patients with persisting leg pain? Do those strategies impact clinical outcomes?

Background

Low back pain (LBP) is one of the most common reasons for visiting a Primary Care Provider in the United States and the number of patients seeking spine-related care is on the rise.[26] The estimated economic burden in the United States (U.S.) is equal to that of diabetes, arthritis, and cancer at nearly 86 billion U.S. dollars. Health expenditures for spinal disorders are increasing without demonstrating an associated improvement in perceived physical or mental health.[26] Identifying clinically important subgroups of LBP has the potential to improve management and is identified as a priority in musculoskeletal research.[16]

Lumbar radicular pain (pain going from the back down one or both legs) accompanies approximately 10% of cases of low back pain (LBP).[37] Synonymous terms in the literature include sciatica, lumbar radiculopathy, and lumbar radicular pain. The cost of LBP increases and the prognosis worsens when patients report associated leg pain or lumbar radicular syndrome (LRS).[5, 8, 17, 33] Case definitions can vary from any leg symptoms to objectively measured signs of nerve pathology. This variation results in widely differing estimates for lifetime incidence of sciatica, which is reported to be somewhere between 13-40%.[33, 34]

The course of LRS is often characterized by changes in patient reported disability, pain, and/or work status. The clinical course is favorable with 35-50% of patients with LRS seeking health care reporting some degree of recovery over 4 weeks.[39 24] However, transitions between resolution and recurrence of symptoms are not uncommon. In both clinical and occupational cohorts, a 25% recurrence at 1 year has been reported.[35, 37] Miranda followed the course of LRS in an occupational cohort and noted 53% of participants with severe LRS at baseline exam had persisting severe symptoms 1 year later.[27, 37]

Although the prevalence of LRS is much less than LBP alone, it is a subset of LBP that is responsible for a high percentage of lost workdays and costly procedures such as magnetic resonance imaging (MRI), surgery, and spinal injections. The persisting pain and fluctuating nature of LRS is estimated to increase the prevalence of long-term disability by 10%[33] and triple the likelihood of seeking additional medical care.[6, 8]

Low Back Pain Recovery Trajectories

Predicting the prognosis of acute LBP has proven challenging. Systematic reviews have identified a multitude of factors with associations to prognosis. However, these studies often report inconsistent conclusions regarding important prognostic factors.[18] Furthermore, covariates demonstrating consistent associations with prognosis often demonstrate small effect sizes and wide variation depending on the outcome studies, population, and methodology.

The difficulty in conclusively identifying important prognostic factors in acute LBP may be due in part to unidentified heterogeneity among patients with LBP. There is international consensus on the importance of identifying methods for classifying LBP patients into clinically relevant subgroups.[15] The goal is to improve our ability to target interventions, reduce cost, and improve health outcomes. Identifying subgroups of people with LBP who are likely to benefit from particular treatments has been shown to improve patient outcomes and reduce costs.[9, 20] An important step in this process is to be able to predict recovery. The majority of prognostic studies on LBP are designed to predict an outcome at only a few select data points. Longitudinal studies gathering repeated measures over shorter time periods enable characterization of the course of symptoms and allow for use of statistical modeling to identify more homogenous classes of recovery.

Recent studies of patients with nonspecific LBP have identified distinct recovery patterns or classes based on pain reports, generally defined as rapid recovery, moderate recovery or moderate persisting pain, persisting high pain, and recurring pain.[7, 14, 36] While the trajectories identified across studies were relatively similar, the proportion of patients in each of these recovery patterns was quite varied, as were the characteristics associated with each recovery pattern. Many of these differences are likely attributable to the sample population studied, which included a primary care-based cohort, a population-based chronic LBP cohort, and an occupational LBP cohort off work due to LBP.

Variables consistently related to recovery trajectory included initial pain and poor general health. Inconsistently age, anxiety, and depression influenced classification. Education and salary were both characteristic of recovery class in the occupational cohort. Leg pain was examined in only one study with significant associations to recovery class. A greater proportion of patients with leg pain were classified as high persisting pain both at baseline and at the 1-year follow-up.[14] More work needs to be done to identify the consistency of these recovery classes and characteristics predicting classification.

The Influence of Lumbosacral Radicular Syndrome on Recovery

It is not clear if patients with LRS are a clinically distinct subgroup of LBP. The natural course is favorable for many with LRS and the recovery patterns are generally believed to be similar to LBP without leg pain.[23, 29, 40] Generally, LRS is associated with higher reports of pain but similar rates of change over time.[19] To our knowledge, no one has examined the simultaneous effect of LRS on changes in pain utilizing a longitudinal growth model. This model enables the examination of LRS on both reported pain level and changes in pain, separate constructs in recovery. Nor has this been done in combination with mixture modeling, which allows us to identify and then control for recovery trajectory.

The strength of association between LRS and recovery has been questioned. Recent reports suggest effects sizes are confounded by baseline covariates.[19, 22] The effects of LRS on clinical outcomes are much smaller after controlling for baseline differences. Future examination of the impact of LRS on recovery needs to consider the role of potential confounding if we are to identify the value of LRS as a prognostic indicator. The robust longitudinal nature of the data collection in this study will enhance our understanding of LBP recovery patterns, the relative influence of LRS on those patterns, and characteristics of different recovery patterns.

Management of Persisting Lumbosacral Radicular Syndrome

The lack of understanding on prognosis and recovery in patients with LRS has led to wide variation in management.[25 10] The majority of LRS, particularly in a working population, is attributed to nerve root compression or inflammation due to lumbar disc herniation.[21] Rates of surgery and disability in patients with LRS compared to LBP alone are much higher.[6, 8, 33, 37] While high-cost interventions are common, there is no clear evidence that this improves long-term functional outcomes or reduces disability for these patients.[2, 42]

The most common cause of LRS is nerve root compression due to intervertebral disk herniation (IDH),[30] the presence of which increases the likelihood of surgery in individuals with LBP.[1] Practice guidelines recommend an initial period of nonsurgical management for most patients with LBP and sciatica, with exceptions for cauda equina syndrome and progressive neurologic defecits.[3, 31] Cauda equina syndrome is a result of severe nerve compression within the spinal canal typically noted by a loss of bowel and bladder function. Patients with both cauda equina syndrome and rapidly progressing neurologic deficits such as pronounced strength loss are usually considered urgent surgical candidates to avoid the possibility of permanent damage.

Many guidelines direct patients with LRS toward conservative treatment in the first 6 weeks and consider surgery only if symptoms persist or progressive weakness is present.[12, 28] The most common nonoperative interventions for LRS include advice, medications, physical therapy, and epidural injections.[1, 41 13] While anecdotal reports and case studies suggest good outcomes with various physical therapy interventions,[23, 32] there is a lack of high-quality evidence regarding the efficacy of these treatments.[11, 38] Regardless of intervention, nearly all conservative care LRS study cohorts report a percentage of patients who have persisting pain or progress to surgery.

Estimates on progression to surgery vary from 5% to 39% within the first year of seeking treatment.[24, 29] While there is no treatment that clearly alters the likelihood of progressing to surgery, rates of surgery tend to be lower in studies including physical therapy interventions.[4, 24, 32] Selection bias, timing of intervention, and the intervention itself may all be plausible reasons for these lower rates. Characteristics of patients with persisting LRS symptoms who seek physical therapy have not been well described. Furthermore, it is unclear to what extent physical therapy influences clinical outcomes in this population.

Purpose

The aim of this dissertation was to enhance knowledge regarding the prognosis of low back pain and the role of leg pain or lumbosacral radicular syndrome (LRS) on recovery. The secondary aim was to identify characteristics of patients with persisting LRS who seek physical therapy and the influence of physical therapy on clinical outcomes in this population. This was examined in three papers:

1) The aim of the first paper was to identify latent classes of recovery in an occupational cohort with incident LBP regardless of LRS status. Subsequently, we quantified the extent to which LRS moderated recovery in this same model.
2) In a second paper, we identified prognostic indicators of recovery trajectories in this same cohort. Additionally, we examined the strength of association between LRS and recovery trajectory after controlling for baseline covariates.
3) Finally, we evaluated characteristics of patients with LRS at the secondary care level who received physical therapy and identified factors associated with receiving physical therapy. Additionally, we examined the influence of physical therapy intervention on clinical outcomes over the course of 1 year.

References

1. Atlas SJ, Deyo RA, Keller RB, et al. The Maine Lumbar Spine Study, Part III: 1-year outcomes of surgical and nonsurgical management of lumbar spinal stenosis. *Spine*. 1996;21:1787.

2. Atlas SJ, Keller RB, Wu YA, Deyo RA, Singer DE. Long-term outcomes of surgical and nonsurgical management of sciatica secondary to a lumbar disc herniation: 10 year results from the Maine lumbar spine study. *Spine*. 2005;30:927-934.

3. Atlas SJ, Nardin RA. Evaluation and treatment of low back pain: an evidence-based approach to clinical care. *Muscle Nerve*. 2003;27:265-284.

4. Broetz D, Burkard S, Weller M. A prospective study of mechanical physiotherapy for lumbar disk prolapse: Five year follow-up and final report. *NeuroRehabilitation*. 2010;26:155-158.

5. Carey TS, Evans AT, Hadler NM, et al. Acute severe low back pain: a population-based study of prevalence and care-seeking. *Spine*. 1996;21:339-344.

6. Carey TS, Garrett JM, Jackman A, Hadler N. Recurrence and care seeking after acute back pain: results of a long-term follow-up study. *Medical care*. 1999;37:157-164.

7. Chen C, Hogg-Johnson S, Smith P. The recovery patterns of back pain among workers with compensated occupational back injuries. *Occupational and environmental medicine*. 2007;64:534.

8. Cherkin DC, Deyo RA, Street JH, Barlow W. Predicting poor outcomes for back pain seen in primary care using patients' own criteria. *Spine*. 1996;21:2900-2907.

9. Childs J, Fritz J, Flynn T, et al. A clinical prediction rule to identify patients with low back pain most likely to benefit from spinal manipulation: a validation study. *Annals of internal medicine*. 2004;141:920.

10. Chou R, Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. *Spine*. 2009;34:1078.

11. Chou R, Huffman LH. Nonpharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. *Ann Intern Med*. 2007;147:492-504.

12. Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine*. 2009;34:1066.

13. Cummins J, Lurie JD, Tosteson TD, et al. Descriptive epidemiology and prior healthcare utilization of patients in the Spine Patient Outcomes Research Trial's (SPORT) three observational cohorts: disc herniation, spinal stenosis, and degenerative spondylolisthesis. *Spine*. 2006;31:806-814.

14. Dunn KM, Jordan K, Croft PR. Characterizing the course of low back pain: a latent class analysis. *American journal of epidemiology*. 2006;163:754.

15. Foster ND, Dziedic K, van der Windt DA, Fritz JM, Hay EM. Research priorities for non-pharmacological therapies for common musculoskeletal problems: nationally and internationally agreed recommendations. *BMC Musculoskel Dis*. 2009;10:3.

16. Foster NE, Hill JC, Hay EM. Subgrouping patients with low back pain in primary care: are we getting any better at it? *Man Ther*. 2011;16:3-8.

17. Grotle M, Brox J, Veierod M, Glomsrod B, Lonn J, Vollestad N. Clinical course and prognostic factors in acute low back pain: patients consulting primary care for the first time. *Spine*. 2005;30:976.

18. Hayden JA, Chou R, Hogg-Johnson S, Bombardier C. Systematic reviews of low back pain prognosis had variable methods and results: guidance for future prognosis reviews. *Journal of clinical epidemiology*. 2009;62:781-796 e781.

19. Hill JC, Konstantinou K, Egbewale BE, Dunn KM, Lewis M, van der Windt D. Clinical outcomes among low back pain consulters with referred leg pain in primary care. *Spine (Phila Pa 1976)*. 2011;36:2168-2175.

20. Hill JC, Whitehurst DG, Lewis M, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. *Lancet*. 2011;378:1560-1571.

21. Koes B, Van Tulder M, Peul W. Diagnosis and treatment of sciatica. *BMJ: British Medical Journal*. 2007;334:1313.

22. Kongsted A, Kent P, Jensen TS, Albert H, Manniche C. Prognostic implications of the Quebec Task Force classification of back-related leg pain: an analysis of longitudinal routine clinical data. *BMC Musculoskeletal Disorders*. 2013;14:171.

23. Luijsterburg PA, Verhagen AP, Ostelo RW, et al. Physical therapy plus general practitioners' care versus general practitioners' care alone for sciatica: a randomised clinical trial with a 12-month follow-up. *European Spine Journal*. 2008;17:509-517.

24. Luijsterburg PAJ, Verhagen AP, Ostelo RWJG, et al. Physical therapy plus general practitionersí care versus general practitionersí care alone for sciatica: a randomised clinical trial with a 12-month follow-up. *European Spine Journal*. 2008;17:509-517.

25. Luijsterburg PAJ, Verhagen AP, Ostelo RWJG, Van Os TAG, Peul WC, Koes BW. Effectiveness of conservative treatments for the lumbosacral radicular syndrome: a systematic review. *European Spine Journal*. 2007;16:881-899.

26. Martin BI, Turner JA, Mirza SK, Lee MJ, Comstock BA, Deyo RA. Trends in health care expenditures, utilization, and health status among US adults with spine problems, 1997–2006. *Spine*. 2009;34:2077-2084.

27. Miranda H, Viikari-Juntura E, Martikainen R, Takala EP, Riihim‰ki H. Individual factors, occupational loading, and physical exercise as predictors of sciatic pain. *Spine*. 2002;27:1102.

28. NICE. Referral Advice - a guide to appropriate referral from general to specialist services. Available at: http://www.nice.org.uk. Accessed October 1, 2001.

29. Peul W, Hout W, Brand R, Thomeer R, Koes B. Prolonged conservative care versus early surgery in patients with sciatica caused by lumbar disc herniation: two year results of a randomised controlled trial. *British Medical Journal*. 2008.

30. Porchet F, Wietlisbach F, Burnand B, Daeppen K, J.G. V, Vader JP. Relationship between severity of lumbar disc disease and disability scores in sciatica patients. *Neurosurgery*. 2002;50:1253-1259.

31. Rhee JM, Schaufele M, Abdu WA. Radiculopathy and the herniated lumbar disc. *J Bone Joint Surg*. 2006;88-A:2070-2080.

32. Saal JA, Saal JS. Nonoperative treatment of herniated lumbar intervertebral disc with radiculopathy: An outcome study. *Spine*. 1989;14:431.

33. Smedley J, Inskip H, Cooper C, Coggon D. Natural history of low back pain: a longitudinal study in nurses. *Spine*. 1998;23:2422-2426.

34. Stafford MA, Peng P, Hill DA. Sciatica: a review of history, epidemiology, pathogenesis, and the role of epidural steroid injection in management. *Br J Anaesth*. 2007;99:461-473.

35. Suri P, Rainville J, Hunter DJ, Li L, Katz JN. Recurrence of radicular pain or back pain after nonsurgical treatment of symptomatic lumbar disk herniation. *Arch Phys Med Rehabil*. 2012;93:690-695.

36. Tamcan O, Mannion AF, Eisenring C, Horisberger B, Elfering A, Müller U. The course of chronic and recurrent low back pain in the general population. *Pain*. 2010;150:451-457.

37. Tubach F, Beaute J, Leclerc A. Natural history and prognostic indicators of sciatica. *Journal of clinical epidemiology*. 2004;57:174-179.

38. Vroomen PC, de Krom MC, Slofstra PD, Knottnerus JA. Conservative treatment of sciatica: a systematic review. *Journal of spinal disorders*. 2000;13:463-469.

39. Vroomen PCAJ, De Krom M, Knottnerus J. Predicting the outcome of sciatica at short-term follow-up. *The British Journal of General Practice*. 2002;52:119.

40. Weber H. Lumbar disc herniation: a controlled, prospective study with ten years of observation. *Spine*. 1983;8:131-140.

41. Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical vs nonoperative treatment for lumbar disk herniation: the Spine Patient Outcomes Research Trial (SPORT) observational cohort. *JAMA*. 2006;296:2451-2459.

42. Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical vs nonoperative treatment for lumbar disk herniation: the Spine Patient Outcomes Research Trial (SPORT): a randomized trial. *JAMA*. 2006;296:2441-2450.

CHAPTER 2

THE INFLUENCE OF LEG PAIN ON RECOVERY TRAJECTORIES IN A WORKING COHORT WITH INCIDENT LOW BACK PAIN

Introduction

Low back pain (LBP) is the leading cause of disability from musculoskeletal pain globally.[19] Since 1990, years lost due to ill health or disability from LBP have increased 43%.[20] It is further estimated that 20-40% of LBP can be attributed to occupation.[23] A large amount of heterogeneity is represented by the diagnosis of LBP and efforts to identify the pathoanatomical cause of LBP have proven elusive. Various classification systems of LBP have been presented in an effort to identify more homogenous groups of LBP.[5, 9, 28] More recently, classification based on recovery trajectories has been proposed.[1, 4, 26]

When LBP presents with associated leg pain, often called sciatica or lumbosacral radicular syndrome (LRS), the prognosis for recovery is worse[7] and greater activity and occupational limitations are reported.[14] Approximately 25% of LRS populations noting a resolution of symptoms report a recurrence of symptoms within 1 year.[25, 27] Additionally, working cohorts examining LRS have reported persistent LRS at moderate pain levels for at least 2 years in 50% of cases.[18, 27] A clear understanding of these varied recovery patterns will aid in defining recovery, planning research, and in determining which patients should be considered for additional procedures.

Recent research suggests individuals with nonspecific LBP have distinct recovery patterns that may be determined by baseline demographic and clinical factors.[1, 4] Studies using both latent class analysis and cluster analysis identified four similar patterns of LBP recovery. These are generally represented as groups of 1) high-persisting pain, 2) moderate-persisting pain 3) fluctuating pain, and 4) recovering.[1, 4, 26] Based on posterior probabilities, these trajectories were significantly differentiated by the presence of leg pain.[4] Research thus far has not examined the simultaneous influence of leg pain on pain trajectories. Modeling pain simultaneously may help differentiate if leg pain influences baseline intensity, change over time, or both.

The primary purpose of this research was to identify the influence of LRS on recovery patterns defined by self-reported pain in an occupational cohort reporting incident LBP. Our first aim was to identify latent classes of recovery in workers with LBP regardless of LRS status. We hypothesized distinct recovery patterns or classes identified in previous studies would be reproduced in this population. We further hypothesized the proportion of our sample reporting recovery would be greater than previous studies due to sampling methods.[3] Subsequently, we aimed to identify the extent to which LRS moderated recovery hypothesizing LRS would influence initial pain, change in pain over time, and recovery class.

Methods

This is a secondary analysis from a prospective cohort representing 859 workers from 30 employers across 12 different industries located in Illinois, Texas, Utah, and Wisconsin.[6] Included employers were chosen to represent a variety of physical job exposures. Additionally, employers agreed to allow for monthly follow-up of participants with minimal interruption in workflow. The Institutional Review Boards of the University of Utah, the University of Wisconsin-Milwaukee, and Texas A&M University approved the study.

Study subjects

Participants were 18 years of age, able to provide informed consent, able to speak either English or Spanish, free of major limb deformities or substantial amputations, and had no plans at baseline to retire or leave their employer for 4 years. Subjects included in this analysis had to be considered a LBP or LRS case and have at least four follow-up time points within the year of onset to be included in the analysis.

Baseline data collection

Upon consent, participants completed standardized questionnaires administered by a trained health outcomes assessor. A physical therapist or an occupational medicine physician then administered a structured interview and performed a brief physical examination. Demographic information, medical comorbidities, low back pain history, and psychosocial questions were collected via the questionnaires and structured interview.

Follow-up data collection

Each month, a member of the health outcomes assessment team conducted a brief interview with all participating workers. The interview served to determine LBP or LRS status (present or absent) and pain level. If LBP or LRS was present, pain intensity and location were recorded. Additionally, any treatment, modified duty, or lost work time due to back pain was recorded.

Case definitions

An incident case of LBP was defined as any individual reporting pain between the 12th rib and gluteal fold for a 24-hour period[12] after at least 1 month without LBP.[2] LRS cases were defined as lumbar-related lower extremity pain. If back or leg pain was present, the examiner utilized interview and physical examination information to determine if the pain was musculoskeletal LBP or LRS.

Primary outcome

Self-reported pain intensity on an 11-point numeric pain scale was used as the primary outcome. Participants were asked to give an average pain rating for their LBP and/or leg pain in the past month with 0 representing no pain and 10, the worst possible pain.[13, 16] The highest pain rating reported at each time point was used for all analyses. A secondary outcome of resolved was recorded using a surrogate measure of pain. Resolved required a report of pain as zero within the first 3 months without recurrence during the remainder of the follow-up period.

Data analysis

Analyses were performed using SPSS statistical software (IBM Corp. Version 21) and Mplus Version 6.12 for Mac (Muthen & Muthen, Los Angeles, CA, USA). Descriptive statistics were computed for the sample by cases status and condition. Baseline data and monthly pain outcomes were examined for outliers, missing data, and distribution of variables. A chi-square test was used to compare LBP and LRS participants reporting resolution of pain.

Modeling the data was performed in three steps. First, unconditional growth models were developed to understand change in pain across the sample and establish a base model criterion. Second, growth mixture modeling was performed using the best fitting growth model to identify groups with distinct recovery trajectories or classes (Figure 2.1). The number of classes was determined by examining fit indices Bayesian Information Criterion (BIC), the Lo-Mendell-Rubin likelihood ratio test (LMR-LRT), and the Bootstrapped Likelihood Ratio Test (BLRT) in addition to model stability after each step-wise increase. Finally, using the optimal unconditional mixture model, conditional models were run to identify the influence of LRS status on class and growth factors.

LRS status is expected to influence initially reported pain levels but have less of an impact on change in pain over time.[11] The influence of LRS on recovery class is unknown. However, class membership may explain the relationship between LRS and the growth factors. To examine these differences, we compared three conditional models: classes regressed on leg pain, growth factors regressed on leg pain, and both classes and growth factors regressed on leg pain. A chi-square difference test was used to identify the optimal model.

The results of a Monte Carlo growth mixture model simulation with two classes and a misspecified model suggest a sample size of 125 subjects is needed for power of 0.86 to reject the hypothesis that the model is misspecified. Parameter and standard error estimates at this sample size also appear to have little bias. The addition of a dichotomous covariate to the model is likely to increase the sample size requirement nearly fourfold.[21] In order to identify the extent to which condition (LBP or LRS) moderates recovery class, a sample near 600 is required to have enough power to detect if the influence of condition is significant at a 0.05 level.

Results

Recruitment and follow-up was performed between February 2004 and December 2011 establishing a cohort of 859 workers. Men made up 56.2% of the cohort and the mean age was 37.9 (11.8) years. Within the cohort, 617 workers reported incident LBP with or without leg pain (Figure 2.2). Sixty-six of those individuals did not have at least four follow-up visits recorded and were removed from analysis. We retained 370 incident cases of LBP and 181 incident cases of LRS. Of those with LRS, 87 (50%) reported pain below the knee. Descriptive data for each group are presented in Table 2.1. LRS cases were generally slightly older, more likely female, and reported higher pain at onset.

The follow-up rate varied by month (Figure 2.1). The majority of the sample (87%) reported six or more follow-up visits and were similar by LBP/LRS status. Forty-two percent of LBP participants and 44% of LRS participants had 10 or more follow-up points recorded. Age, sex, and initial pain levels were similar across participants with 10 or more visits and those with 5-9 visits.

Average pain intensity for the LBP cohort steadily decreased from 4.9 (sd 2.1) at baseline to 1.9 (sd 2.7) at 12 months following onset. One hundred thirty-one (24%) participants reported resolution of pain at 3 months and had no reported recurrence during the remainder of the year. Resolution significantly differed by condition with 99 (26%) of LBP and only 32 (18%) of LRS participants reporting resolution. The odds of pain resolution in the LRS group were 0.59 (95% CI 0.37, 0.94).

Unconditional model results

Unconditional growth trajectories were best represented by a curve with intercept, slope, and quadratic parameters (Table 2.2). The greatest variance in pain was at time 1, or baseline. The growth factors predicted only 30% of the variance in pain at baseline, whereas they accounted for over 50% of the variance in pain at all other time points. For additional models, error variances between pain at time point 2 and pain at time point 12 were constrained to be equal, while pain at time point 1 was free to vary. From prior longitudinal analyses, 12 weeks after consultation appears to be a critical point in the natural history of LBP with a clear separation in growth trajectories.[1, 4] Time zero was scaled to represent month 3 for improved interpretation of the growth factor coefficients.

Growth mixture modeling was applied to the quadratic growth model to identify groups with distinctive trajectory patterns of recovery (Figure 2.1). Variance for the quadratic growth factor was fixed to zero to simplify computation and improve model convergence. The mixture model with four classes was better than competing models (model criterion are presented in Table 2.3). The four classes identified trajectories similar to those previously reported with the majority of participants clustered into two groups (Figure 2.3). Growth parameters estimated at month 3 demonstrated many of the differences between the groups (Table 2.4).

The largest trajectory was labeled recovery with 328 (59.5%) of participants. By 3 months, mean pain decreased from 4.7 to 1.65 and continued to decrease with average pain less than one by 6 months and without recurrence. The second largest trajectory described individuals with moderate pain (*n*=155, 28.1%). Pain at baseline was similar to the recovery group at 4.8 with minimal change by 3 months at 4.4. High persisting pain (*n*=44, 8.0%) also demonstrated minimal change in pain reporting 6.0 at baseline and at 3 months. Average change in pain over time was significant in this group, identified by increasing pain. A linear positive trend over time resulted in average pain of 7.2 at 1 year. Recurring pain was the smallest group (*n*=24, 4.4%). Initially these individuals demonstrated a very similar trajectory as those in the recovery group. The primary difference in these individuals, however, was the recurrence of pain. Group classification was defined by a significant quadratic term describing their trajectory demonstrated as a 'U-shape'. Pain appeared to resolve but increase again or recur, resulting in mean pain of 6.4 at 1 year. Across individuals, the average difference in pain at 3 months was 2 points and the average difference in slope, or change in pain, was 1.4.

Conditional growth mixture model

A comparison of growth models suggests LRS predicting class and growth factors was the best fitting model (Table 2.5). At month 3, mean pain for participants with LRS was .62 (95% CI .35, .89) points higher than for those with LBP (Table 2.6). Regression equations by class and condition are presented in Appendix A. Additionally, for those with LRS the odds of being in the high pain class was 2.94 (95% CI 1.47, 5.86) as large as being in the moderate pain class. Only the high pain class was significantly differentiated by LRS.

Discussion

The primary objective of this study was to examine the course of recovery in an occupational cohort with acute LBP and identify underlying homogenous trajectories.

Secondarily, we examined the simultaneous impact of leg pain or LRS on these longitudinal trajectories. Using growth mixture modeling, we identified four distinct patterns of back pain over a 1-year period. Most commonly, participants reported recovery with minimal pain 3-5 months after onset without recurrence. A large portion of workers, however, reported moderate pain that demonstrated very little change over the course the 12 months. Less commonly, participants reported increasing or recurring pain.

Although 2 classes only represented 6% and 8% of the sample, we maintained the 4-class model as it was supported both by step-wise model criterion comparisons and theory. Studies to date suggest trajectory groups similar to those found in our population.[1, 4, 26] Proportions of the samples represented by the trajectory patterns, however, are quite varied. This may be due in part to differing analytical techniques, but is more likely a result of the sample population. In the cohort recruited from a primary care setting, pain trajectories were primarily represented by moderate persisting pain or mild persisting pain.[4] Moderate persisting pain was also a primary trajectory for chronic LBP.[26] Fluctuating pain, although minimal in our cohort, was found to be common in chronic LBP and occupational workers on leave due to LBP.[1, 26] The small distribution of workers from our study in the fluctuating and high pain class is likely secondary to the fact we examined incident low back pain and followed individuals who were primarily continuing to work.

In our population, LRS increased the likelihood a participant would experience the high persisting pain trajectory even after controlling for initial pain levels expected change with time. This is consistent with other occupational cohorts reporting persistent pain in 50% of those reporting LRS.[18] Even after controlling for class status, however, reports of pain were .62 higher in those with LRS than in those with LBP with a slower rate of recovery. While previous studies reported frequent recurrence of symptoms in people with LRS,[25, 27] we did not find LRS significantly predicted a recurring pain trajectory. This may be due in part to the small portion of participants classified as recurrent pain and deserves further examination. Overall, our findings suggest LRS, based on self-reported leg pain, is generally more severe and recalcitrant than LBP even in an acute population.

Strengths of this study include a long follow-up period with monthly in-person assessments and the large sample size. The robust longitudinal nature of the data collection enabled a detailed description of the highly variable course of LBP. Mixture modeling allowed for flexibility in modeling time effects and patterns of variability in an effort to reduce standard errors and identify meaningful subgroups.[8 22] Additionally, modeling LRS concurrently with change in pain enabled the influence of leg pain on class membership.

Several limitations should be considered. The definition of LRS was broad, including all participants with low-back related leg pain below the buttock. Leg pain presenting more distally or with positive neurologic signs has been shown to be associated with a worse prognosis.[15, 17, 24] Separating participants into more distinct leg pain categories may further differentiate the relationship between LRS and recovery class. Nonetheless, self-report of any leg pain in this population still demonstrated a significant relationship with severity and recovery trajectory.

Although we identified four distinct trajectories of recovery for incident LBP and an association between high persisting pain and LRS, this was really only a first step in identifying LRS as a prognostic indicator of recovery trajectory.[10] Workers with LRS were noted to be slightly older, have more co-morbidities, and were more likely to be female. Controlling for these variables may change the association between LRS and recovery.

It is not known if these subgroups are clinically relevant. There is growing literature supporting the four varied trajectories of recovery, but the association between recovery trajectory, increased health care utilization, and lost work productivity has not been established. Optimally, understanding these associations and characterizing pain trajectories will lead to more timely and effective intervention recommendations and contribute to altering the societal burden of LBP.

Conclusion

The majority of workers presenting with acute low back pain are likely to experience resolution or near resolution of pain over the course of 3-5 months. As many as 40%, however, will have persisting pain or recurring pain over the course of 1 year following onset. The presence of leg pain increases overall reports of pain, slows recovery, and increased the likelihood of experiencing high levels of persisting pain. Funding for this study was provided by a grant form the Centers for Disease Control and Prevention (NIOSH), 1U 01 OH08083-01.

References

1. Chen C, Hogg-Johnson S, Smith P. The recovery patterns of back pain among workers with compensated occupational back injuries. *Occupational and environmental medicine*. 2007;64:534-540.

2. de Vet HCW, Heymans MW, Dunn KM, et al. Episodes of low back pain: a proposal for uniform definitions to be used in research. *Spine*. 2002;27:2409-2416.

3. Dunn KM, Croft PR. The importance of symptom duration in determining prognosis. *Pain*. 2006;121:126-132.

4. Dunn KM, Jordan K, Croft PR. Characterizing the course of low back pain: a latent class analysis. *American journal of epidemiology*. 2006;163:754-761.

5. Fritz JM, Cleland JA, Childs JD. Subgrouping patients with low back pain: evolution of a classification approach to physical therapy. *Journal of Orthopaedic and Sports Physical Therapy*. 2007;37:290-302.

6. Garg A, Hegmann KT, Moore JS, et al. Study protocol title: a prospective cohort study of low back pain. *BMC Musculoskelet Disord*. 2013;14:84.

7. Grotle M, Brox J, Veierud M, Glomsrood B, Lunn J, Vullestad N. Clinical course and prognostic factors in acute low back pain: patients consulting primary care for the first time. *Spine*. 2005;30:976.

8. Gueorguieva R, Krystal JH. Move over ANOVA: progress in analyzing repeated-measures data and its reflection in papers published in the Archives of General Psychiatry. *Archives of general psychiatry*. 2004;61:310-317.

9. Haswell K, Gilmour J, Moore B. Clinical decision rules for identification of low back pain patients with neurologic involvement in primary care. *Spine*. 2008;33:68-73.

10. Hayden JA, Cote P, Steenstra IA, Bombardier C. Identifying phases of investigation helps planning, appraising, and applying the results of explanatory prognosis studies. *Journal of clinical epidemiology*. 2008;61:552-560.

11. Hill JC, Konstantinou K, Egbewale BE, Dunn KM, Lewis M, van der Windt D. Clinical outcomes among low back pain consulters with referred leg pain in primary care. *Spine (Phila Pa 1976)*. 2011;36:2168-2175.

12. Hoy D, March L, Brooks P, et al. Measuring the global burden of low back pain. *Best Practice & Research Clinical Rheumatology*. 2010;24:155-165.

13. Jensen MP, Turner JA, Romano JM. What is the maximum number of levels needed in pain intensity measurement? *Pain*. 1994;58:387-392.

14. Kongsted A, Kent P, Albert H, Jensen TS, Manniche C. Patients with low back pain differ from those who also have leg pain or signs of nerve root involvement– a cross-sectional study. *BMC Musculoskeletal Disorders*. 2012;13:236.

15. Kongsted A, Kent P, Jensen TS, Albert H, Manniche C. Prognostic implications of the Quebec Task Force classification of back-related leg pain: an analysis of longitudinal routine clinical data. *BMC Musculoskeletal Disorders*. 2013;14:171.

16. Lauridsen HH, Hartvigsen J, Manniche C, Korsholm L, Grunnet-Nilsson N. Responsiveness and minimal clinically important difference for pain and disability instruments in low back pain patients. *BMC Musculoskelet Disord*. 2006;7:82.

17. Lewis R, Williams N, Matar H, et al. The clinical effectiveness and cost-effectiveness of management strategies for sciatica: systematic review and economic model. *Health Technol Assess.* 2011;15(39)1-578.

18. Miranda H, Viikari-Juntura E, Martikainen R, Takala EP, Riihimki H. Individual factors, occupational loading, and physical exercise as predictors of sciatic pain. *Spine*. 2002;27:1102-1109.

19. Murray CJL, Richards MA, Newton JN, et al. UK health performance: findings of the Global Burden of Disease Study 2010. *The Lancet*. 2013;381:997-1020.

20. Murray CJL, Vos T, Lozano R, et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. *The Lancet*. 2013;380:2197-2223.

21. Muthén LK, Muthén BO. How to use a Monte Carlo study to decide on sample size and determine power. *Structural Equation Modeling*. 2002;9:599-620.

22. Nagin DS, Tremblay RE. What has been learned from group-based trajectory modeling? Examples from physical aggression and other problem behaviors. *The Annals of the American Academy of Political and Social Science*. 2005;602:82-117.

23. Punnett L, Prüss‐Ütün A, Nelson DI, et al. Estimating the global burden of low back pain attributable to combined occupational exposures. *American journal of industrial medicine*. 2005;48:459-469.

24. Selim AJ, Ren XS, Fincke G, et al. The importance of radiating leg pain in assessing health outcomes among patients with low back pain: results from the Veterans Health Study. *Spine*. 1998;23:470-474.

25. Suri P, Rainville J, Hunter DJ, Li L, Katz JN. Recurrence of radicular pain or back pain after nonsurgical treatment of symptomatic lumbar disk herniation. *Arch Phys Med Rehabil*. 2012;93:690-695.

26. Tamcan O, Mannion AF, Eisenring C, Horisberger B, Elfering A, Müller U. The course of chronic and recurrent low back pain in the general population. *Pain*. 2010;150:451-457.

27. Tubach F, Beaute J, Leclerc A. Natural history and prognostic indicators of sciatica. *Journal of clinical epidemiology*. 2004;57:174-179.

28. Werneke MW, Hart DL. Categorizing patients with occupational low back pain by use of the Quebec Task Force Classification system versus pain pattern classification procedures: discriminant and predictive validity. *Physical therapy*. 2004;84:243-254.

Table 2.1. Baseline characteristics of the cohort.

	Means (standard deviation)/ *n* (%)			
	Non cases (*n*=242)	**Low back pain case (*n*=370)**	**Leg pain case (*n*=181)**	**Cases with <4 time points (*n*=66)**
Age (years)	36.3 (11.5)	37.1 (11.4)	42.2 (12.3)	34.7 (11.6)
Sex (male)	148 (61.2)	243 (64.6)	91 (52.0)	35 (53.0)
Body Mass Index (kg/m^2)	29.8 (6.2)	28.8 (5.9)	29.3 (6.0)	27.6 (5.8)
Race				
Caucasian	74 (30.6)	153 (41.2)	71 (39.2)	25 (37.9)
Hispanic	71 (29.3)	97 (26.1)	47 (26.0)	18 (27.3)
African American	36 (14.9)	33 (8.9)	11 (6.1)	6 (9.1)
Asian	8 (3.3)	19 (5.1)	16 (8.8)	1 (1.5)
Other	22 (9.1)	18 (4.8)	9 (5.0)	8 (12.1)
Education (at least some college)	74 (30.6)	126 (34.0)	65 (35.9)	26 (39.4)
Marital status (married)	97 (40.1)	189 (50.9)	99 (54.7)	27 (40.9)
Smoker				
Currently	49 (20.2)	69 (18.6)	29 (16.0)	14 (21.2)
Previously	39 (16.1)	63 (17.0)	32 (17.7)	18 (27.3)
Never	124 (51.2)	188 (50.7)	94 (51.9)	26 (39.4)
Prior low back pain	59 (24.4)	166 (44.7)	97 (53.6)	32 (48.5)
Prior leg pain	11 (4.5)	23 (6.2)	37 (20.4)	6 (9.1)
Highest pain (0-10)	NA	4.5 (2.0)	5.6 (2.2)	5.1 (2.3)

Table 2.2 Goodness of fit statistics for the latent variable growth models.

	Log Likelihood	**Parameters**	**BIC[1]**
Homogenous Error	10842.281	7	21898.286
Freed error	10812.249	17	21732.611
Quadratic*	10678.159	10	21528.482

[1] Bayesian Information Criterion

Table 2.3 Goodness of fit comparisons for the growth mixture models.

	Log Likelihood	Parameters	BIC[1]	LMR LRT[2]	BLRT[3]
1 Class	10738.803	8	21528.482	n/a	n/a
2 Classes	10626.315	12	21328.944	p=.0052	p=.000
3 Classes	10591.871	16	21285.495	p=.0046	p=.000
4 Classes	10540.141	20	21143.982	p=.0003	p=.000
5 Classes	Did not converge				

[1]Bayesian Information Criterion
[2]Lo, Mendell, Rubin Likelihood Ratio Test
[3]Bootsrapped Likelihood Ratio Test

Table 2.4 Description of workers by recovery class.

	High pain (*n*=44)	**Moderate pain (*n*=155)**	**Recovered (*n*=328)**	**Recurring (*n*=24)**
Age, *x* (*sd*)	40.1 (12.6)	37.2 (11.2)	38.8 (12.0)	41.5 (11.5)
Male *n* (%)	24 (54.5)	97 (62.6)	200 (62.0)	13 (54.2)
LRS *n* (%)	23 (52.3)	51 (32.9)	93 (28.3)	8 (33.3)
Treatment during follow-up *n* (%)	42 (93.2)	128 (82.6)	212 (64.4)	21 (87.5)

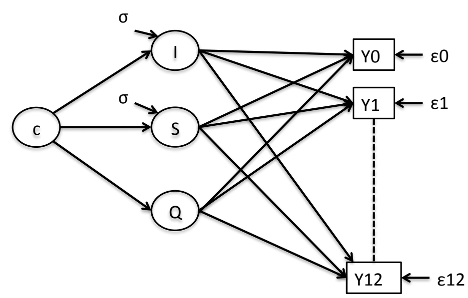
Table 2.5 Comparison of conditional growth mixture models.

Model	**Log Likelihood**	**Change in Parameters**	**Chi-square difference**	**Critical value *p*<.05**
Class and growth factors on LRS	10517.451	(ref)		
Growth factors on LRS	10522.765	1	5.31	3.84
Class on LRS	10533.228	3	15.77	7.81

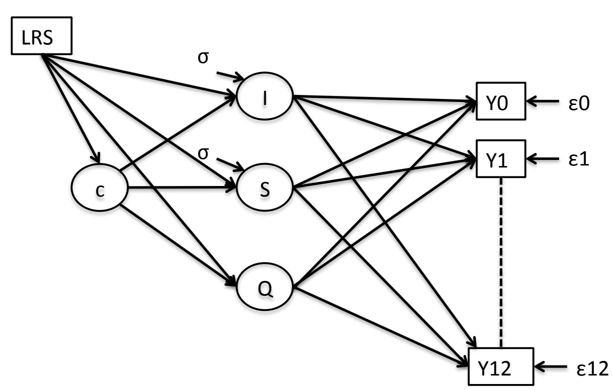
Table 2.6 Growth mixture model parameter estimates.[1]

	High	Moderate	Recovered	Recurring
Unconditional				
Means				
Intercept (I)	6.0**	4.42**	1.65**	1.58**
Slope (S)	.19*	-.07	-.55**	-.67 **
Quadratic (Q)	-.003	-.008	.05**	0.17 **
S with I	-.21**			
Variance				
Intercept	1.56**			
Slope	.03**			
Residual Variances				
Pain Time 1	4.3**			
Pain Time 2-12	2.5**			
Conditional on Lumbosacral Radicular Syndrome (LRS)				
Means				
Intercept (I)	5.69**	4.26**	1.47**	1.34**
Slope (S)	.27**	.018	-.51**	-.61**
Quadratic (Q)	-.008	-.01	.05**	.16**
S with I	-.19**			
I on LRS	.62** (.35, .89)			
S on LRS	-.16** (-.22, -.09)			
Q on LRS	.01 (0, .02)			
Variances				
Intercept	1.44** (1.20, 1.68)			
Slope	.031** (.02, .04)			
Logit probability of class membership				
Class on LRS	1.13**	.05	(ref)	.50
	(ref)	-1.08*	-1.13**	-.628
	.63	-.45	-.50	(ref)
Odds Ratio Class on LRS	2.94 (1.47, 5.86)	(ref)	.95 (.62, 1.46)	1.57 (.65, 3.76)

[1]Time centered at month 3
*p<.05, **p<.01



Model 1: Unconditional



Model 2: Conditional

Figure 2.1 Growth mixture models:(1) unconditional (2) conditional on lumbosacral radicular syndrome (LRS). Latent variables: intercept (I), slope (S), quadratic growth (Q), classes (C). Measurement variables Y= monthly pain measures. Error variances represented by σ and ε.

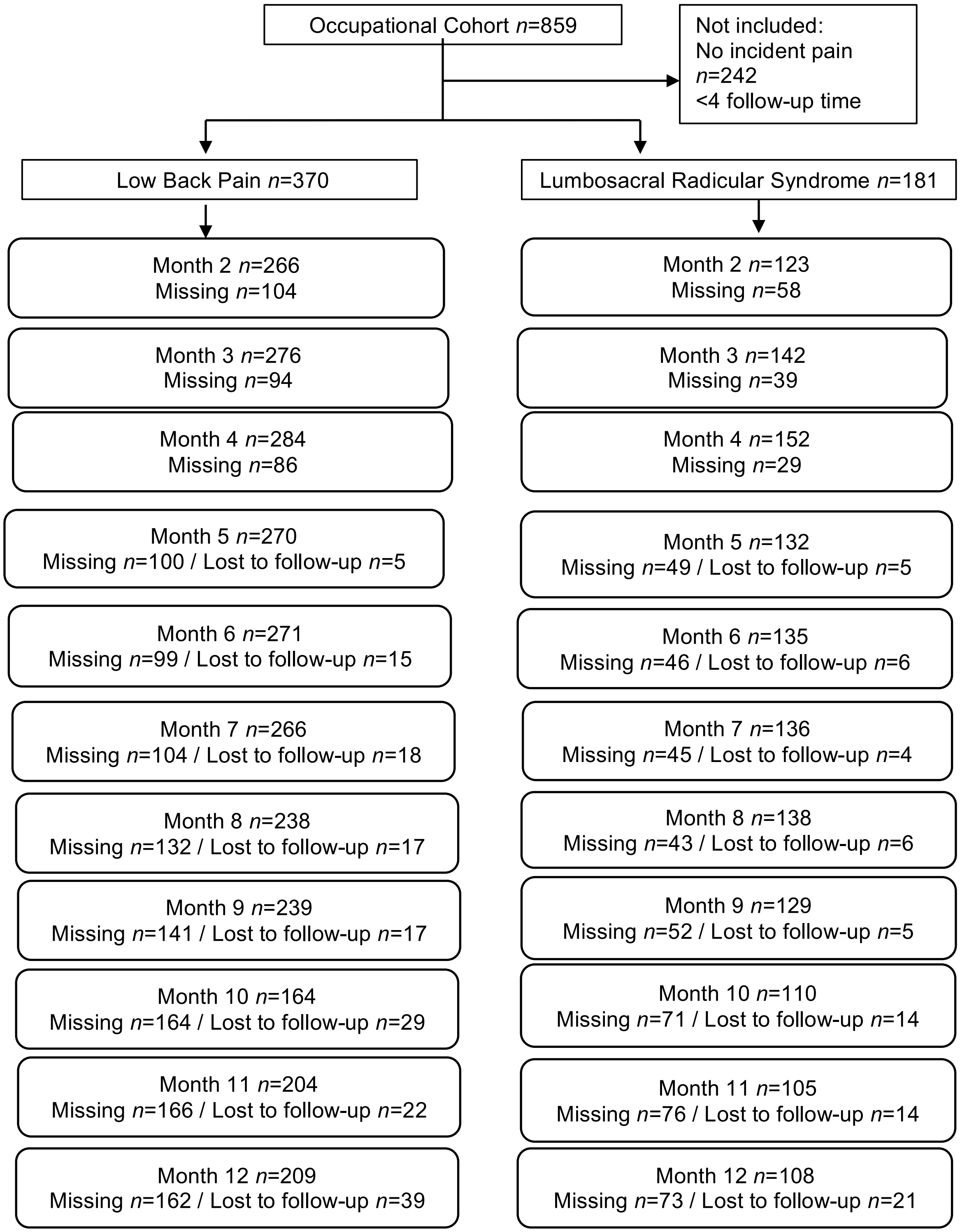


Figure 2.2. Flow of participants in the study

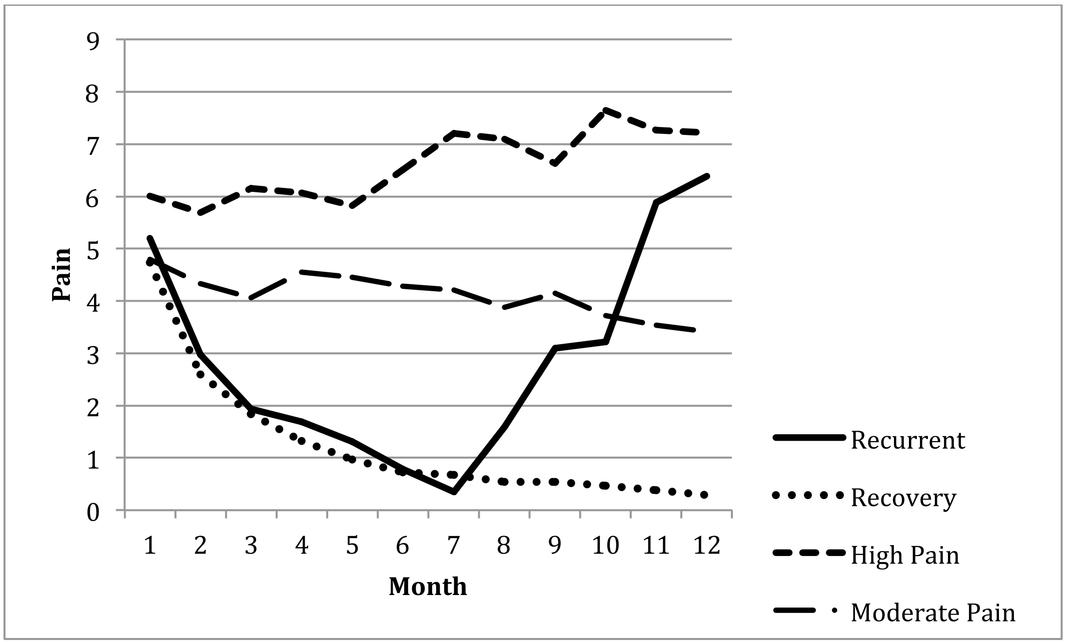


Figure 2.3 Pain trajectories by class.

Appendix: Growth Model Regression Equations

Time is coded (-3, -2, -1, 0, 1, 2, 3, 4, 5, 6, 7, 8, 9)

Unconditional

High Pain = 6.00 + (.11)Time + (-.003)Time^2
Moderate Pain = 4.42 + (.07)Time + (-.008)Time^2
Recovered Pain = 1.65 + (-.55)Time + (.05)Time^2
Recurrent Pain = 1.58 + (-.67)Time + (.17)Time^2

Conditional

LBP (coded 0)
High Pain = 5.69 + (.27)Time + (-.008)Time^2 +.62(0) + (-.16)(0)(Time) + .01(0)(Time)^2

High Pain = 5.69 + (.27)Time + (-.008)Time^2
Moderate Pain = 4.26 + (.018)Time + (-.01)Time^2
Recovered Pain = 1.47 + (-.51)Time + (.05)Time^2
Recurrent Pain = 1.34 + (-.61)Time + (.16)Time^2

LRS (coded 1)
High Pain= 5.69 + (.27)Time + (-.008)Time^2
Moderate Pain = 4.26 + (.018)Time + (-.01)Time^2
Recovered Pain= 1.47 + (-.51)Time + (.05)Time^2
Recurrent Pain= 1.34 + (-.61)Time + (.16)Time^2

+ .62(1) + (-.16)(1)(Time) + .01(1)(Time)^2

CHAPTER 3

CHARACTERISTICS OF RECOVERY TRAJECTORIES AND THE RELATIVE INFLUENCE OF LEG PAIN IN ACUTE OCCUPATIONAL LOW BACK PAIN

Introduction

Billions of dollars are spent on low back (LBP) pain in the United States[26] and it is considered a significant burden worldwide.[28] While the prognosis for acute LBP is favorable, 10-15% of those with acute LBP are reported to have persisting severe pain and another 40% do not report complete resolution of pain.[22] A small percentage of these patients account for a large amount of the costs. Longer duration of disability has been correlated with worse clinical outcomes and higher costs.[15] This correlation has led to an effort by clinicians, researchers, and policy makers to try and identify this small portion early in the course of recovery in order to alter subsequent disability and cost.

Numerous factors have been identified as influencing recovery from LBP. The strength of association for many of these factors is inconsistent,[17] likely due to differences in samples and measurement. Even less is known about prognostic factors affecting recovery in patients with LRS.[1, 16, 36] Classifying LBP patients into homogenous groups based on recovery trajectories has potential to strengthen research on prognosis. Ideally, recovery could be predicted at baseline presentation by a combination of risk factors, which would aid in targeting appropriate interventions and avoiding unnecessary procedures and expenses.

The presence of low back-related leg pain, or lumbosacral radicular syndrome (LRS), is considered a poor prognostic indicator among patients presenting with LBP and is a consistent predictor of poor recovery.[17] Risk stratification tools and classification systems for nonspecific LBP often identify the presence of LRS as a critical piece in identifying risk and appropriate treatment.[2, 7, 19, 29] The prognostic value of LRS after controlling for other baseline factors is unclear, but seems to diminish after adjusting for confounders.[18]

In a prior study, we examined acute LBP in an occupational setting and identified four distinct trajectories of recovery following incident LBP: high persisting pain, moderate persisting pain, recovered, and recurrent pain. We found a significant relationship between pain severity and recovery for individuals with LRS. LRS was associated with higher pain levels, an increased probability of high persisting pain, and a decreased likelihood of complete resolution of pain. This previous analysis controlled for individual variations around recovery but did not control for other potentially important covariates. It remains unclear if the strength of association is due to the unique characteristic of LRS versus other baseline variables that may confound the relationship between LRS and recovery.

The purpose of this secondary analysis was to identify prognostic indicators of recovery trajectories in an occupational cohort with incident LBP. Additionally, we aimed to identify the strength of association between LRS and recovery trajectory after controlling for baseline covariates.

Methods

This is a secondary analysis from a multicenter prospective cohort study of workplace LBP.[12] Worksites were chosen to represent a variety of physical job exposures and required the cooperation of employers to allow for monthly follow-up of participants with minimal interruption in workflow. The Institutional Review Boards of the

University of Utah, the University of Wisconsin-Milwaukee, and Texas A&M University approved the study.

Study participants

Details of worksites involved and inclusion criteria have previously been described.[12] Participants were 18 years of age, able to provide informed consent, and able to speak either English or Spanish. Participants for this analysis had to be considered a case of incident LBP and have at least four follow-up time points within the year of onset. Incident LBP was defined as any report of pain for a 24-hour period[21] after at least 1 month without LBP.[6] Cases were divided into LBP, any individual reporting pain between the 12th rib and gluteal fold, and LRS, lumbar related leg pain distal to the buttock. If a worker reported new onset lumbar or leg pain, a health care examiner utilized interview and physical examination information to determine if the pain was musculoskeletal LBP or LRS.

Baseline data collection

Upon consent, participants completed standardized questionnaires administered by a trained health outcomes assessor. Either a physical therapist or an occupational medicine physician then performed a structured interview and standardized exam. The questionnaire and structured interview were both computerized in an effort to improve data quality and ensure standardized response to questions.

The baseline visit served to collect a number of potentially important covariates. Four constructs appear to summarize prognostic factors for both LBP and LRS:

individual or socio-demographic measures, clinical history, psychosocial status, and occupational factors.[1, 17, 30] A number of items were collected to represent each construct and are outlined as follows.

Individual/Socio-demographic measures

Information was collected on age (years), sex, race, education level (no college/some college), body mass index (BMI), physical activity level, comorbidities, smoking history. Physical activity level was calculated in average minutes per week using a structured questionnaire. Participants were asked to identify the average number of minutes they performed regular exercise and how many times per week. This variable was then collapsed into four categories: none, 1-30 minutes, 31-60 minutes, or >60 minutes. Comorbidities were measured by self-report and patients were asked to only include diagnoses identified by a health care professional. Overall comorbidity scores were calculated as counts for total number of conditions reported by the participant.[5] Smoking history was represented as current, former, or never.[34] Back pain history included dichotomous variables representing prior back pain, prior leg pain, prior treatment for back pain including surgery, and a numeric pain rating for the most severe episode of back pain scaled 0 (no pain) to 10 (worst pain imaginable).

Psychosocial measures

A composite tension-edge-nervous scale (ANX) comprised of eight questions, quantified measures of irritability, tension, and exhaustion. Scores ranged from 0-32 with higher scores representing higher tension. Depression was measured using eight questions form the Zung Depression Index (Zung). Responses were rated on a 4-point scale ranging from never to always with a range of 0-24. Higher scores represented greater feelings of depression. Both scales can be found in Appendix B.

Occupational measures

The Modified Work APGAR scale was used to identify coworker support.[10, 27] It is a 7-item questionnaire with three possible responses (almost always, sometimes, hardly ever) and scores range from 7-21 with higher scores representing greater dissatisfaction with the workplace relations (Appendix B). Job Control was represented by 10 questions used to identify participants' perception of control of their work environment (Appendix B). Responses ranged from 0-34 with higher scores representing less perception of control. An ergonomics evaluation was performed for each job position and a composite lifting index (CLI)[37] was calculated for each job rotation involved in lifting/lowering. The CLI is an index of positioning, forces, environment, weights, frequencies, trunk angles, and job rotation. The final value is a composite number with higher values representing greater mechanical forces on the lumbar spine. From this value, a lifting index (LI) was created to represent low ($CLI \leq 1$), medium ($1 < CLI \leq 2$), or high ($CLI \geq 3$) exposure.[13, 37] The ergonomics team was blinded to the health assessment.

Outcome measures and follow-up data collection

All participants were interviewed monthly to determine the participant's health status. The health assessment team and either an occupational medicine physician or a physical therapist conducted interviews. At this follow-up, the presence or absence of

LBP or LRS was determined along with pain level. Participants were also asked if they had seen a health care professional for treatment and if they had any lost or light duty. The health assessment team was blinded to the ergonomic assessment.

The primary outcome was recovery trajectory class. This was established in a prior study and is a probability of recovery based on monthly pain scores over the course of 1 year from incident pain. Participants were asked to give an average pain rating for their LBP and/or leg pain in the past month with zero representing no pain and 10, the worst possible pain.[23, 25] The highest pain rating reported at each time point was used for all analyses. Longitudinal changes in pain were analyzed for homogeneity using a growth mixture modeling (previously described). We identified four primary classes of recovery: high persisting pain, moderate persisting pain, recovered, and recurrent pain. The outcome for this study was defined as class membership estimated by posterior probabilities of our earlier modeling. While the original analysis identified four classes, one class (recurrent pain) represented only 24 participants and was not used in this analysis.

Statistical analysis

Descriptive data were summarized using mean scores (standard deviation) and frequency counts (percentages) by condition (LBP or LRS) and by class status. Univariate comparisons of covariates across classes were performed using χ^2 tests for categorical variables and ANOVA tests for continuous variables.

We built multivariate models to test whether LRS was associated with class membership (recovery trajectory) after controlling for potential confounders. The smallest group class had only 44 participants. Given the often-recommended case to variable ratio of 10:1, this scenario permits four to five predictor variables. With this in mind, we limited our covariate models to variables that were not collinear, were biologically plausible, and had a univariate *p*-value <.10. Three model blocks were examined before determining the final model: demographic (age, race, LBP history, and physical activity level), psychosocial (Zung, ANX), and occupational (APGAR, Job Control, and LI). "Pain rating for most severe episode of prior LBP" (LBP_Hx) was selected as a covariate to represent history of LBP as it was highly correlated with numerous other characteristics of LBP history. Baseline pain was not included in the model as this value was already used in identification of recovery class. After a final model was established, model parameters were examined with and without LRS.

Patterns of missing data were tested to determine appropriateness for imputation. Multiple imputation with five iterations and pooled estimates for model results are presented. A sensitivity analysis was performed on the best fitting model using listwise deletion to examine the influence of the imputation procedures and stability of estimates. All analyses were performed using SPSS (version 21).

Results

An occupational cohort of 860 workers was recruited from Texas, Utah, and Wisconsin, USA between February 2004 and December 2011. There were 370 incident cases of LBP and 181 incident cases of LRS (total *n*=551). Four recovery classes were identified: high persisting pain (*n*=44), moderate persisting pain (*n*=155), recovered (*n*=328), and recurrent (*n*=24). Only the 3 largest groups were retained for this analysis resulting in a sample of 527 workers.

The mean age was 38.5 (*SD* 11.0) years, with 61% male and mean pain at onset 4.9 (*SD* 2.1). The majority of the sample was comprised of Caucasian (41%) and Hispanic (26%) workers. LRS was present in 167 (32%) cases with 88 (16%) of cases reporting pain below the knee. There were 381 (72%) workers who reported seeking treatment at some point for their LBP, but only 40 (7.6%) reported being on light duty.

Baseline characteristics stratified by recovery class are presented in Table 3.1. Proportions of participants with LRS were significantly different by class. LRS increased the odds of being in the high pain category (unadjusted OR 2.2, 95% CI 1.3, 4.4) over the moderate pain class and the recovered class (unadjusted OR 2.8 95% CI 1.5, 5.2). Moderate persisting pain and recovered classes were not differentiated by LRS (OR 1.2 95% CI .82, 1.9). No significant differences were noted by age or sex. Pain at baseline, however, was about one point higher for the high persisting pain group. There was no difference in reported pain at baseline between moderate persisting pain and recovered. During follow-up, the majority of cases classified as high persistent pain sought medical treatment. This class was also more likely than the recovered class to be assigned light duty OR 3.6 (95% CI 1.5, 8.8).

Sequential logistic regression analyses were performed to assess prediction of recovery trajectory represented by three classes (high persisting pain, moderate persisting pain, recovered). There were 116 (22%) participants with missing data on the lifting index scores, 75 (14%) missing APGAR scores, and 67 (13%) missing race classification. Little's MCAR test was nonsignificant (p = .124) and multiple imputation was used to maximize use of data. The sensitivity analysis removed (24%) of participants. The lowest cell size for categorical variables examined in the sensitivity analysis was 32 (9%).

Comparisons of the models tested are presented in Table 3.2. The logisitic model for demographic variables included age, LBP_hx, race, and physical activity level. Significant predictors of class from this model included race and LBP_hx. Zung and ANX scales represented the psychosocial block of variables without demonstrating significant discrimination between classes. Occupational predictors included the Job Control scale, LI, and modified work APGAR. Both the APGAR and LI significantly influenced model fit. Prior to examining LRS, the final model tested included race, LBP_hx, APGAR, and LI.

Four variables provided good discrimination among groups (good model fit), χ^2 (658.4, n=402) p=1.0 based on the deviance criterion. After the addition of LRS, there was a modest increase in the Nagelkerke R^2 from .12 to .14. The model including LRS demonstrated a statistically significant improvement over models without LRS (Tables 3.3 & 3.4). Overall classification was unimpressive. On the basis of the four variables initially entered, classification for the recovered class was 87%, moderate 13%, and high was 0% for a classification rate of 65%. Adding LRS to the model, classification did not significantly improve classification. Classification was again over-represented by the recovered class. Recovered class was predicted at 86%, moderate at 14%, and high persisting pain 0.4%.

Table 3.5 shows the regression coefficients and odds ratios of each predictor. Hispanic workers were twice as likely as Caucasian workers to be classified into the moderate or high persisting pain trajectories. Low back pain history was also moderately associated with both moderate persisting pain and high persisting pain classifications. Two variables predicted moderate persisting pain, the modified work APGAR and LI. Lower scores on the APGAR and a higher lifting index increase the likelihood of having moderate persisting pain. Consistent with our prior analysis, LRS significantly predicted high persisting pain. Those with LRS were twice as likely to experience high persisting pain even after controlling for demographic and occupational variables. The adjusted odds ratio for the high pain class was not much different than crude odds ratio. Adjusting for baseline covariates diminished the odds ratio between moderate and high pain classes (adjusted OR 1.9 95%CI .96, 4.0).

The sensitivity analysis included only cases with full information on LI and race (n=300). Overall model fit was similar to that of the multiple imputation model with a model chi-square difference of 52.09 (*df* 16), a deviance chi-square of 474.7 (*df* 582) p=1.0, and a Nagelkerke R^2 = .17. Individual items continued to demonstrate a significant impact on model fit. Parameter estimates changed slightly. LBP_Hx no longer significantly predicted moderate persisting pain class (OR 1.1 95% CI 1.0, 1.2) and African American no longer significantly predicted membership in the high persisting pain class (OR 2.5 95%CI .74, 8.5). LBP_Hx demonstrated a very modest impact even in the imputed model and the strength of association remains questionable. Changes in the odds of class membership by race were likely due to the low representation of African Americans in the study and pooled estimates of this variable should be interpreted with caution.

Discussion

The primary aim of this study was to identify characteristics associated with recovery trajectories following incident LBP. Our results indicate both demographic and occupational factors distinguish recovery trajectories in acute, occupational LBP. Initial pain intensity and leg pain further influenced classification of high persisting pain. There also appears to be value in identifying an individual's recovery trajectory as the groups reported differences on health care utilization and light duty.

Initial pain intensity has been reported as predictor of recovery trajectory with patients reporting pain ≤ 7 as having more rapid recovery.[8, 14] In our study, the mean initial pain score for all three trajectories was ≤ 6 and relatively homogenous compared to other longitudinal studies.[8, 35] Initial pain still differed between recovery groups with mean pain significantly higher in those with high persisting pain category. Initial pain did not distinguish between those in recovered and those with moderate persisting pain. Chen et al. reported similar results in an occupational cohort off work for LBP.[3] While the initial pain was generally higher in their study, baseline pain intensity did not predict recovery trajectory.

Additionally, leg pain or LRS plays a unique role in identifying recovery class even after controlling for baseline covariates. LRS increases the likelihood of having high persisting pain without significantly predicting moderate persisting pain. Chou et al. reported that leg pain increased the likelihood of chronic disabling back pain at 1 year but the absence of leg pain was not a strong predictor of signs and symptoms at 1 year.[4] The association with LRS and high persisting pain may represent the specificity of leg pain while the lack of association with LRS and moderate persisting pain may reflect the poor sensitivity of LRS. Further clarification of these trajectories will enhance our understanding of the complex relationships between risk factors and recovery.

The Quebec Task Force (QTF) on spinal pain proposed distinguishing patients by leg pain presentation with four categories thought to represent increasing severity: local LBP, pain above the knee, pain below the knee, and leg pain with neurological signs. Defining lumbar related leg pain by these categories has differentiated recovery.[18, 24, 33] We used a broad definition of LRS, any leg pain below the buttock, and still identified a relationship between recovery class and LRS. The nature of that association would likely change if LRS was distinguished by the task force categories.

Contrary to other research,[8] we did not find recovery trajectories to differ on depression and anxiety. This may reflect the fact data were from a working cohort not necessarily seeking medical treatment for pain.[20] It is also plausible our methodology and/or the constructs collected influenced the relationship. Data regarding depression and anxiety were collected at baseline and, in general, some time prior to the incident pain. While the majority of prognostic studies report a consistent effect for psychosocial variables,[17] this is typically quantified after pain onset and likely influenced by the pain experience. Our model also demonstrated overall fairly poor classification of workers into the medium and high persisting pain categories. There are likely psychosocial constructs influencing this classification that were not measured in our study but may improve overall classification and could be considered in future studies.[9]

Consistent with previous reports, occupational factors significantly influenced recovery.[10, 17] Lifting exposure has been associated with incident LBP and care-seeking for LBP.[11, 13] High lifting demands increased the likelihood of moderate persisting pain but was not a significant predictor of high persisting pain. This finding may again suggest the two persisting pain groups are uniquely identified.

This is the first longitudinal study to identify an association between recovery trajectory and race. This is consistent with prior reports of ethnic differences on pain perception.[32] Portenoy et al. found Hispanic subjects were more likely to report pain and at higher levels than Caucasian subjects. Fewer Hispanic subjects, however, were likely to report an inability to work.[31] The pain experience is complex and appears to differ by culture. Using pain ratings as the marker of recovery may have influenced the relationship between race and recovery trajectory. Future models may consider a multidimensional measure of recovery.

Current evidence provides little consensus on prognostic risk factors for LRS.[1] Previous studies have examined a variety of potential risk factors but fail to examine many risk factors in combination, making it difficult to identify the variables of most influence. This study combines both extensive baseline data and detailed recovery trajectories, advancing our understanding of LRS prognosis and recovery. Questions remain about the utility of identifying recovery class and our ability at baseline to distinctly predict recovery trajectory. Further research is also needed to establish the association between recovery class, cost, and health care utilization.

Limitations in our analysis include the presence of a small subgroup, missing data, and poor classification in our final model. A sample with greater representation in the high pain group would likely improve our classification prediction and permit examination of more variables simultaneously. A fair amount of missing data was noted with nearly a quarter of the sample missing lifting exposure data. While complete data may change the parameters estimated, there was consistency between the strongest predictors and model fit. Poor classification suggests there are unmeasured predictors that can further distinguish between classes. The generalizability of this study outside a working population is limited. Prior studies have reported older age (>65) and work status as predictive of a higher persisting pain.[8, 35] This is population was not represented in our cohort. Additionally, it is possible potentially eligible workers were not enrolled because of absence for LBP. Enrollment was performed on multiple days however, thus capturing many people who may have been absent at initial enrollment.

Conclusion

In acute occupational LBP, moderate persisting pain and high persisting pain is more prevalent among Hispanic workers and those reporting more severe prior low back pain. High lifting demands and low social support from coworkers was also associated with moderate persisting pain. Workers with lumbar related leg pain were twice as likely to high persisting pain even after adjusting for race and low back pain history. Leg pain failed to distinguish moderate pain and high pain recovery classes.

References

1. Ashworth J, Konstantinou K, Dunn K. Prognostic Factors in Non-Surgically Treated Sciatica: A Systematic Review. *BMC Musculoskeletal Disorders*. 2011;12:208.

2. BenDebba M, Torgerson WS, Long DM. A validated, practical classification procedure for many persistent low back pain patients. *Pain*. 2000;87:89-97.

3. Chen C, Hogg-Johnson S, Smith P. The recovery patterns of back pain among workers with compensated occupational back injuries. *Occupational and environmental medicine*. 2007;64:534-540.

4. Chou R, Shekelle P. Will this patient develop persistent disabling low back pain? *JAMA: the journal of the American Medical Association*. 2010;303:1295-1302.

5. de Groot V, Beckerman H, Lankhorst GJ, Bouter LM. How to measure comorbidity: a critical review of available methods. *Journal of clinical epidemiology*. 2003;56:221-229.

6. de Vet HCW, Heymans MW, Dunn KM, et al. Episodes of low back pain: a proposal for uniform definitions to be used in research. *Spine*. 2002;27:2409-2416.

7. Delitto A, George SZ, Van Dillen LR, et al. Low back pain. *J Orthop Sports Phys Ther*. 2012;42:A1-57.

8. Dunn KM, Jordan K, Croft PR. Characterizing the course of low back pain: a latent class analysis. *American journal of epidemiology*. 2006;163:754-761.

9. Foster NE, Thomas E, Bishop A, Dunn KM, Main CJ. Distinctiveness of psychological obstacles to recovery in low back pain patients in primary care. *Pain*. 2010;148:398-406.

10. Fransen M, Woodward M, Norton R, Coggan C, Dawe M, Sheridan N. Risk factors associated with the transition from acute to chronic occupational back pain. *Spine*. 2002;27:92-98.

11. Garg A, Boda S, Hegmann KT, et al. The NIOSH Lifting Equation and Low-Back Pain, Part 1 Association With Low-Back Pain in the Backworks Prospective Cohort Study. *Human Factors: The Journal of the Human Factors and Ergonomics Society*. 2014;56(1):6-28.

12. Garg A, Hegmann KT, Moore JS, et al. Study protocol title: a prospective cohort study of low back pain. *BMC Musculoskelet Disord*. 2013;14:84.

13. Garg A, Kapellusch JM, Hegmann KT, et al. The NIOSH Lifting Equation and Low-Back Pain, Part 2 Association With Seeking Care in the Backworks Prospective Cohort Study. *Human Factors: The Journal of the Human Factors and Ergonomics Society*. 2014;56(1)44-57.

14. Hancock MJ, Maher CG, Latimer J, Herbert RD, McAuley JH. Can rate of recovery be predicted in patients with acute low back pain? Development of a clinical prediction rule. *European Journal of Pain*. 2009;13:51-55.

15. Hashemi L, Webster BS, Clancy EA. Trends in disability duration and cost of workers' compensation low back pain claims (1988-1996). *Journal of Occupational and Environmental Medicine*. 1998;40:1110-1119.

16. Haugen A, Brox J, Grøvle L, et al. Prognostic factors for non-success in patients with sciatica and disc herniation. *BMC Musculoskeletal Disorders*. 2012;13:183.

17. Hayden JA, Chou R, Hogg-Johnson S, Bombardier C. Systematic reviews of low back pain prognosis had variable methods and results: guidance for future prognosis reviews. *Journal of clinical epidemiology*. 2009;62:781-796 e781.

18. Hill JC, Konstantinou K, Egbewale BE, Dunn KM, Lewis M, van der Windt D. Clinical outcomes among low back pain consulters with referred leg pain in primary care. *Spine (Phila Pa 1976)*. 2011;36:2168-2175.

19. Hill JC, Whitehurst DG, Lewis M, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. *Lancet*. 2011;378:1560-1571.

20. Hoving JL, Van der Meer M, Volkova AY, Frings-Dresen MHW. Illness perceptions and work participation: a systematic review. *International archives of occupational and environmental health*. 2010;83:595-605.

21. Hoy D, March L, Brooks P, et al. Measuring the global burden of low back pain. *Best Practice & Research Clinical Rheumatology*. 2010;24:155-165.

22. Itz CJ, Geurts JW, Kleef M, Nelemans P. Clinical course of non‐specific low back pain: A systematic review of prospective cohort studies set in primary care. *European Journal of Pain*. 2013;17:5-15.

23. Jensen MP, Turner JA, Romano JM. What is the maximum number of levels needed in pain intensity measurement? *Pain*. 1994;58:387-392.

24. Kongsted A, Kent P, Jensen TS, Albert H, Manniche C. Prognostic implications of the Quebec Task Force classification of back-related leg pain: an analysis of longitudinal routine clinical data. *BMC Musculoskeletal Disorders*. 2013;14:171.

25. Lauridsen HH, Hartvigsen J, Manniche C, Korsholm L, Grunnet-Nilsson N. Responsiveness and minimal clinically important difference for pain and disability instruments in low back pain patients. *BMC Musculoskelet Disord*. 2006;7:82.

26. Martin BI, Deyo RA, Mirza SK, et al. Expenditures and health status among adults with back and neck problems. *JAMA: the journal of the American Medical Association*. 2008;299:656-664.

27. Mielenz TJ, DeVellis RF, Battie MC, Carey TS. Stop using the modified work APGAR to measure job satisfaction. *Pain research and treatment*. 2011;Epub Dec 7.

28. Murray CJL, Vos T, Lozano R, et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. *The Lancet*. 2013;380:2197-2223.

29. National Guideline C. Low back disorders. Available at: http://www.guideline.gov/content.aspx?id=38438&search=acoem. Accessed 8/5/2013.

30. Pengel LH, Herbert RD, Maher CG, Refshauge KM. Acute low back pain: systematic review of its prognosis. *BMJ*. 2003;327:323.

31. Portenoy RK, Ugarte C, Fuller I, Haas G. Population-based survey of pain in the United States: differences among white, African American, and Hispanic subjects. *The Journal of Pain*. 2004;5:317-328.

32. Rahim-Williams FB, Riley Iii JL, Herrera D, Campbell CM, Hastie BA, Fillingim RB. Ethnic identity predicts experimental pain sensitivity in African Americans and Hispanics. *Pain*. 2007;129:177-184.

33. Selim AJ, Ren XS, Fincke G, et al. The importance of radiating leg pain in assessing health outcomes among patients with low back pain: results from the Veterans Health Study. *Spine*. 1998;23:470-474.

34. Shiri R, Karppinen J, Leino-Arjas P, Solovieva S, Viikari-Juntura E. The association between smoking and low back pain: a meta-analysis. *The American journal of medicine*. 2010;123:87 e87-35.

35. Tamcan O, Mannion AF, Eisenring C, Horisberger B, Elfering A, Müller U. The course of chronic and recurrent low back pain in the general population. *Pain*. 2010;150:451-457.

36. Verwoerd A, Luijsterburg P, Lin CW, Jacobs W, Koes B, Verhagen A. Systematic review of prognostic factors predicting outcome in non - surgically treated patients with sciatica. *European Journal of Pain*. 2013;17(8):1126-37.

37. Waters TR, Putz-Anderson V, Garg A, National Institute for Occupational S, Health. *Applications manual for the revised NIOSH lifting equation*. US Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Division of Biomedical and Behavioral Science; 1994.

Table 3.1 Baseline variables by recovery class.

	Mean (standard deviation)/ *n* (%)			
	High Pain (*n*=44)	**Moderate Pain (*n*=155)**	**Recovered (*n*=328)**	***p*-value**
Age (years)	40.2 (12.6)	37.2 (11.2)	38.8 (12.0)	.281
Sex (male)	24 (54.5)	97 (62.6)	200 (62.0)	.660
Body Mass Index (kg/m^2)	29.0 (5.1)	29.8 (5.7)	28.5 (6.0)	.127
Race				.100
Caucasian	13 (31.8)	55 (35.5)	147 (44.7)	
Hispanic	17 (38.6)	59 (32.3)	71 (21.6)	
African American	6 (13.6)	8 (5.2)	24 (7.3)	
Other	2 (4.5)	8 (5.2)	27 (8.2)	
Education (some college)	11 (25.0)	30 (19.4)	124 (37.7)	.533
Marital status (married)	31 (70.5)	70 (45.2)	170 (51.8)	.147
Smoker				.543
Currently	12 (27.3)	27 (17.4)	56 (17.1)	
Previously	8 (18.2)	21 (13.5)	62 (18.8)	
Never	21 (47.7)	75 (48.4)	171 (52.0)	
Routine Physical Activity				.658
None	12 (27.3)	30 (19.4)	66 (20.1)	
1-30 min/day	14 (31.8)	42 (27.1)	87 (26.5)	
30-60 min/day	9 (20.5)	21 (13.5)	58 (17.7)	
>60 min/day	6 (13.6)	31 (20.0)	80 (24.4)	
LOW BACK PAIN (LBP) HISTORY				
Prior LBP	24 (54.5)	80 (51.6)	142 (43.2)	.127
Prior leg pain	13 (29.5)	20 (12.9)	27 (8.2)	.000
Pain rating for most severe episode (0-10)	7.7 (2.0)	7.3 (2.1)	6.9 (2.4)	.004
Prior treatment	26 (59.1)	77 (49.7)	135 (41.2)	.017
Physical therapy or chiropractic	21 (47.7)	57 (36.8)	94 (28.7)	
Spinal Injection	4 (9.1)	9 (5.8)	12 (3.7)	
Lumbar surgery	2 (4.5)	2 (1.3)	10 (3.0)	
Imaging	18 (40.9)	49 (31.6)	72 (22.0)	
Medication	22 (50.0)	66 (42.6)	105 (32.0)	
Prior worker's compensation for LBP	4 (9.1)	23 (14.8)	19 (5.8)	.003
MEDICAL HISTORY				
Hypertension	8 (18.2)	19 (12.3)	38 (11.6)	.509
Hyperlipidemia	6 (13.6)	30 (19.4)	52 (15.9)	.233
Osteoarthritis	5 (11.4)	14 (9.0)	18 (5.5)	.158
Diabetes mellitus	2 (4.5)	4 (3.2)	12 (3.7)	.973
Comorbidity count (0-14)	.77 (.81)	.69 (.93)	.72 (.93)	.895

Table 3.1 continued

Mean (standard deviation)/ *n* (%)

	High Pain (*n*=44)	**Moderate Pain (*n*=155)**	**Recovered (*n*=328)**	***p*-value**
PSYCHOSOCIAL				
Modified ZUNG Depression (0-24)	7.9 (4.9)	9.1 (4.2)	8.3 (4.7)	.201
Composite tension-edge-nervousness (0-32)	11.1 (5.1)	10.8 (6.2)	9.8 (5.9)	.155
OCCUPATIONAL				
Lifting exposure				.004
Low	11 (25.0)	20 (12.9)	63 (19.1)	
Medium	13 (29.5)	49 (31.6)	125 (38.0)	
High	9 (20.5)	55 (35.5)	66 (20.1)	
Modified APGAR (7-21)	11.7 (4.7)	11.5 (4.1)	10.4 (3.9)	.034
Organizational/Job related control (0-34)	12.7 (8.0)	15.0 (7.8)	13.2 (7.3)	.050
INCIDENT CASE				
Pain at incident episode (0-10)	5.9 (2.3)	4.8 (2.0)	4.7 (2.1)	.003
Pain at 1 year (0-10)	7.3 (2.0)	3.4 (1.8)	.27 (.83)	.000
Lumbosacral radicular syndrome	23 (52.3)	51 (32.9)	93 (28.4)	.000
Pain distal to the knee	17 (38.6)	20 (12.9)	51 (15.5)	.000
Medical care for incident episode (Y/N)	41 (93.2)	128 (82.6)	212 (64.6)	.000
Number of months reporting medical care	5.1 (3.4)	3.4 (2.9)	1.7 (1.9)	.000
Light duty (Y/N)	8 (18.2)	13 (8.4)	19 (5.8)	.018

Table 3.2 Model fit comparisons for logistic models estimating class status as a function of demographic, psychosocial, or occupational variables.

Model block	Log Likelihood		Chi-square	*df*	*p*-value	Nagelkerke R^2
Demographic	Intercept Final	904.783 866.463	38.3	16	.001	.085
		LBP_Hx[1]	16.2	2	.000	
		Race	20.1	6	.000	
Psychosocial	Intercept Final	739.984 735.378	6.0	4	.203	.014
Occupational	Intercept Final	801.966 773.351	28.	8	.000	.064
		APGAR[2]	6.1	2	.05	
		LI[3]	17.9	4	.001	

1. Numeric pain rating for most severe episode of prior low back pain (continuous range 0-10).
2. Modified work APGAR (continuous range 0-10).
3. Lifting index (low, med, high).

Table 3.3 Logistic regression model fit estimates for class status.

Model block	Log Likelihood		Chi-square	*df*	*p*-value	Nagelkerke R^2
Without LRS	Intercept	782.289				
	Final	719.254	53.03	14	.000	.137
	Deviance		620.9	736	.999	
With LRS	Intercept	835.708	72.26	16	.000	.156
	Final	763.251				
	Deviance		701.1	844	1.0	

Table 3.4 Logistic regression analysis of class status.

Variables	χ^2 to remove	*df*	*p*-value
Final model without LRS			
LBP_Hx	13.9	2	.001
APGAR	6.5	2	.039
LI	21.8	4	.000
Race	20.0	6	.003
Final model with LRS			
LBP_Hx[1]	11.1	2	.004
APGAR[2]	6.6	2	.037
LI[3]	20.2	4	.000
Race	21.0	6	.001
LRS	9.1	2	.011

1. Numeric pain rating for most severe episode of prior low back pain (continuous range 0-10).
2. Modified work APGAR (continuous range 0-10).
3. Lifting index (low, med, high).

Table 3.5 Parameter estimates for the final logistic model analysis of class status.

Class	Moderate persisting pain			High persisting pain		
Predictor	*beta*	*se*	OR (95% CI)	*beta*	*se*	OR (95% CI)
LBP_Hx[1]	.071	.029	**1.07 (1.0, 1.2)**	.133	.048	**1.14 (1.0, 1.3)**
APGAR[2]	.069	.029	**1.07 (1.0, 1.1)**	.061	.046	1.1 (.97, 1.2)
LI[3] (ref Low)						
High	1.22	.321	**3.4 (1.8, 6.4)**	-.070	.475	.93 (.34, 2.4)
Mod	.462	.331	1.6 (.82, 3.1)	-.209	.459	.81 (.33, 2.0)
Race (ref Caucasian)						
Hispanic	.838	.258	**2.3 (1.4, 3.8)**	1.15	.415	**3.2 (1.4, 7.1)**
African American	-.187	.523	.83 (.29, 2.4)	1.142	.578	**3.1 (1.0, 9.8)**
Other	-.040	.331	.02 (.02, 1.0)	.059	.603	1.1 (.33, 3.5)
LRS[4]	-.349	.229	1.4 (.91, 2.2)	1.00	.342	**2.7 (1.4, 5.4)**

1.Numeric pain rating for most severe episode of prior low back pain (continuous range 0-10).
2.Modified work APGAR (continuous range 0-10).
3.Lifting index (low, med, high).
4.Lumboradicular Syndrome.

Appendix: Psychosocial and Job Related Scales

Modified Zung Depression Index (8) 0-24

Please indicate for each of the following questions which answer best describes how you have been feeling recently.

	Rarely or none of the time (<1 day per week)	Some or little of the time (1-2 days per week)	A moderate amount of time (3-4 days per week)	Most of the time (5-7 days per week)
I feel downhearted and sad	0	1	2	3
I feel that nobody cares				
I get tired for no reason				
I feel that I am useful and needed				
I am still able to enjoy those things I used to				
I eat as much as I used to				
I am more irritable than usual				
I feel hopeful about the future				

(ANX) Individual questions/composite tension-edge-nervous scale (8) 0-32

	Never (0)	Seldom (1)	Some-times (2)	Often (3)	Always (4)
How often do you have family problems that irritate or bother you?					
How often are you physically exhausted after work?					
How often are you mentally exhausted after work?					
How often during the past month have you felt uneasy?					
How often during the past month have you felt “on the edge”?					
How often during the past month have you felt tense?					
How often during the past month have you felt “down”, blue or depressed?					
How often during the past month have you felt nervous or anxious?					

Modified Work APGAR (7) (7-21)

Please place a checkmark in the box corresponding with how you feel about each of the following statements.

	Almost always	Some of the time	Hardly ever
I am satisfied that I can turn to a fellow worker for help if something is troubling me.	1	2	3
I am satisfied with the way my fellow workers talk things over with me and share problems with me.			
I am satisfied that my fellow workers accept and support my new ideas and thoughts.			
I am satisfied with the way my fellow workers respond to my emotions, such as anger, sorrow, or laughter.			
I am satisfied with the way my fellow workers and I share time together.			
I enjoy the tasks involved in my job.			
I am satisfied with how well I get along with my closest or immediate supervisor.			

Job control (10) 0-34

All in all, how satisfied are you with your job?	Very (0)	Somewhat (1)	A little (2)	Not at all (3)	
My job requires working very hard (physically).	Strongly agree (3)	Agree (2)	Disagree (1)	Strongly disagree (0)	
My job requires working very fast.	Strongly agree (3)	Agree (2)	Disagree (1)	Strongly disagree (0)	
I am NOT asked to do an excessive amount of work.	Strongly agree (0)	Agree (1)	Disagree (2)	Strongly disagree (3)	
I have enough time to get the job done.	Strongly agree (0)	Agree (1)	Disagree (2)	Strongly disagree (3)	
I am free from conflicting demands that others make.	Strongly agree (0)	Agree (1)	Disagree (2)	Strongly disagree (3)	
How much influence or control do you have over the variety of tasks you perform?	Very much (0)	Much (0)	Moderate amount (2)	A little (3)	Very little (4)
How much influence or control do you have over the order in which you perform tasks at work?	Very much (0)	Much (0)	Moderate amount (2)	A little (3)	Very little (4)
How much influence or control do you have over the pace of your work, that is how fast or slow do you work?	Very much (0)	Much (0)	Moderate amount (2)	A little (3)	Very little (4)
How much influence or control do you have over the extent to which you can work ahead and take a short break during work hours?	Very much (0)	Much (0)	Moderate amount (2)	A little (3)	Very little (4)

CHAPTER 4

NONSURGICAL TREATMENT CHOICES BY INDIVIDUALS WITH LUMBAR INTERVERTEBRAL DISC HERNIATION IN THE UNITED STATES: ASSOCIATIONS WITH LONG-TERM OUTCOMES.

Introduction

Low back pain management is costly and expenditures are on the rise.[24] Lumbosacral radicular leg pain, commonly called sciatica, is associated with a poor prognosis and increased care seeking.[4, 5, 14] The immense costs associated with sciatica can be largely attributed to high rates of diagnostic testing, lost workdays, and invasive medical interventions.[20, 30]

Sciatica is most commonly attributed to an intervertebral disk herniation (IDH).[19] In acute cases of symptomatic IDH, 70% of those seeking health care are estimated to significantly improve or resolve over the course of 6 weeks.[33] These estimates decline to between 43 and 60% in patients presenting with longer duration sciatica (generally greater than 6 weeks).[2, 16, 29] Despite marginal success in management of chronic symptoms, persisting or recurring sciatica from IDH is a common reason for seeking additional health care.[4]

A number of nonsurgical treatments are advocated for IDH, including epidural injections, medication, education, chiropractic care, and physical therapy. However, identifying the optimal management strategy is elusive as there is little evidence that any one intervention is superior at influencing clinical outcomes.[15, 17, 21, 22, 32] The heterogeneity of studies examining IDH also makes it difficult to identify conclusive prognostic factors and predict the impact of treatment intervention.[1, 15, 22, 31] Guidelines recommend physical therapy intervention for IDH; however, little is known about which patients participate in physical therapy and how often physical therapy is utilized in this population. Additionally, physical therapy is more commonly recommended on initial presentation to primary care.[26, 27] The utility of physical therapy intervention after a patient has been referred to secondary care is unknown.

The Spine Patient Outcomes Research Trial (SPORT) was a multicenter study that compared the effectiveness of surgery to nonsurgical management for IDH in both an observational and a randomized cohort.[35, 36] Patients in the surgical and nonsurgical arms of the study demonstrated improvement in pain and function across time.[35, 36] In the observational cohort, these improvements were significantly greater for those in the surgical group at each time point.[35] Patients randomized to treatment reported no significant differences between groups for pain and function over time.[36] Given the breadth of data collected, the SPORT trial provides an opportunity to examine the characteristics and outcomes of patients with IDH managed nonsurgically. In both the observational study and the randomized trial, patients in the nonsurgery group received "usual care". While physical therapy was an option for treatment in the conservative care cohort, not all patients received physical therapy, allowing for further analysis of the cohort receiving nonsurgical management.

The purpose of this study was to examine the characteristics of IDH patients treated nonsurgically who participated in physical therapy and those who did not. Furthermore, we sought to examine the subsequent impact of receiving physical therapy on clinical outcomes over the course of 1 year. Specifically, the aims of this study were: 1) evaluate demographic and clinical differences between patients with lumbar IDH at the secondary care level who received physical therapy and those who did not; 2) identify factors associated with receiving physical therapy; 3) examine the influence of physical therapy intervention on clinical outcomes over the course of 1 year.

Methods

Study participants

Participants were recruited from 13 multidisciplinary spine centers throughout the United States between March 2000 and November 2004. Each institution's human subjects committee approved a standardized protocol. Inclusion in SPORT required patients to present with persistent symptoms of lumbar disc herniation (>6 weeks) as identified by lumbar related leg pain extending below the knee or into the anterior thigh and positive neural tensions signs or corresponding neurologic deficit. Confirmatory advanced vertebral imaging (MRI or CT) demonstrating disk herniation corresponding with clinical symptoms was also required. Patients were ineligible if they had a prior history of lumbar surgery, cauda equina syndrome, scoliosis greater than 15°, radiographic evidence of segmental instability, or evidence of vertebral fractures. Additional exclusion criteria included spine conditions of a nonmusculoskeletal origin (infections, tumors), pregnancy, and inability or an unwillingness to have surgery.[35, 36]

Nonsurgical management

While patients in the nonsurgical cohort could receive any nonsurgical interventions deemed appropriate by their provider, the minimum intervention advised was active physical therapy, education/counseling with home exercise instruction, and nonsteroidal anti-inflammatory (NSAID) drugs if tolerated. If this was not effective, participating providers were encouraged to individualize treatment and aggressively pursue other nonsurgical strategies.[3] Treatments received were tracked at each follow-up assessment. For this analysis, patients receiving physical therapy within the first 6 weeks of management were compared to those who did not receive physical therapy.

Outcome measurements

Primary outcome measures included the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) bodily pain and physical function scales[25] and the American Academy of Orthopaedic Surgeons MODEMS version of the Oswestry Disability Index (ODI).[7] The SF-36 is a generic health status measure scaled from 0 to 100 with higher scores indicating better health. The ODI measures patient reported disability scored from 0 to 100 with higher scores indicating greater disability. Cross-over to surgery was also recorded. Primary measures were collected at baseline, 6 weeks, 3 months, 6 months, and 1 year.

Secondary outcome measures included opioid use, patient self-rated overall improvement, and satisfaction with symptoms. Leg symptom severity was measured with the Sciatica Bothersome Index (SBI).[7] The SBI is rated from 0-24, with higher scores indicating worse symptoms.

Data analysis

Baseline characteristics of patients in the nonsurgical cohort were compared between those receiving physical therapy during the 6-week period after enrollment and those who did not. Stepwise logistic regression was used to investigate baseline factors associated with receiving physical therapy during the first 6 weeks. Variables correlated with treatment at a significance level of $p<.10$ were entered into the equation.

Significance of $p<.05$ was required to be retained in the final model. Baseline demographic characteristics, co-morbid health conditions, physical exam findings, treatment preference, and outcome measure scores (Tables 4.1 and 4.2) were considered for entry. The chi-square statistic was used to compare rates of cross-over to surgery between groups at 1 year following enrollment.

A mixed effects model was used to evaluate change from baseline between groups for the primary outcomes using a random individual effect to account for the correlation between repeated measures from the same participant. Statistical significance was defined as $p<.05$ and all hypotheses were considered two-sided. Analyses of outcomes at each time point were performed only on individuals continuing with nonsurgical management. Patients crossing over to surgery were censored from additional analyses occurring after surgery. Analyses were adjusted for age, sex, marital status, smoking status, race, compensation, herniation location, working status, stomach comorbidity, depression, other comorbidities, self-rated health symptom progression, duration of most recent episode, treatment preference, baseline outcome scores (SF-36 and ODI), and treatment center. SAS procedures PROC MIXED was used for continuous data with normal random effects, and PROC GENMOD for binary and non-normal secondary outcomes, software version 9.1 (SAS Institute Inc, Cary,NC).

Results

Of the 1215 patients in the combined cohorts, 256 in the randomized cohort were assigned to receive nonsurgical management and 191 in the observation cohort chose nonsurgical management (Figure 4.1). Of patients assigned or choosing nonsurgical management, 362 (76%) had complete information regarding physical therapy utilization and were included in the analysis. One hundred forty-three patients (40%) received physical therapy intervention within 6 weeks of enrollment. Among those receiving physical therapy, 42 patients (29%) attended 3 or fewer physical therapy visits, another 42 attend 4-6 visits, 32 (29%) patients attended 7-10 visits, and 27 (19%) attended 11 visits or more.

There were few differences at baseline between those receiving physical therapy and those who did not (Table 4.1 and Table 4.2). Patients receiving physical therapy were more likely have symptoms for less than 6 months (p=0.031), reported greater dissatisfaction with their symptoms (p=0.048), and reported a preference for nonsurgical care (p=0.002). Additionally, patients in the physical therapy cohort were less likely to have received an injection at baseline (p=0.042). A variety of interventions were reported during the first 6-weeks of treatment (Table 4.3). Medications and injections were the most commonly used interventions for both groups. Patients receiving physical therapy were noted to have higher use of muscle relaxants (p=0.003) and medical devices in general (p=0.006).

The final logistic regression model indicated baseline ODI, treatment preference, and the presence of neurologic deficit to be associated with having received physical therapy within the first 6 weeks of enrollment. Higher baseline ODI scores and any neurologic deficit increased the odds of having physical therapy (adjusted OR 1.02 95% CI 1.01, 1.03, p=0.005 and adjusted OR=1.82 95% CI 1.11, 2.98, p=0.018, respectively). A preference for nonsurgical treatment also increased the odds of participating in early physical therapy compared to no preference (adjusted OR=1.83 (95% CI 1.04, 3.21

p=0.036), whereas a preference for surgery reduced the odds of physical therapy utilization compared to no preference (adjusted OR=0.36 95% CI 0.15, 0.91, *p*=0.03).

During the first year, 61 (28%) patients not receiving physical therapy and 35 (24%) receiving physical therapy progressed to surgery (OR 1.6, 95% CI 0.99, 2.57 *p*=0.54). Comparisons of patient-centered outcomes for patients who did or did not receive physical therapy within the first 6 weeks after enrollment are presented in Table 4.4 and in Figures 4.2 and 4.3. Changes in pain and disability were generally equivocal across groups. Significant differences were noted with only two comparisons, opioid use at 6 weeks and LBP bothersomeness at 1 year. Within the group receiving physical therapy, a greater percentage of patients reported opioid use within the first 6 weeks (12.5, 95% CI 1.9, 23.1, *p*=0.02). The physical therapy group also reported significantly greater improvement in LBP bothersomeness at 1 year (-0.4, 95% CI-0.8, 0, *p*=0.05).

Discussion

The results of this secondary analysis of the SPORT study provide important information on utilization of physical therapy among patients with lumbar IDH in a nationally representative cohort. Factors associated with receiving physical therapy were consistent with the other reports correlating symptom severity and patient preference with subsequent treatment. [9, 10] We were unable to identify significant differences in progression to surgery or change in patient-centered outcomes for patients with IDH receiving physical therapy intervention within the first 6 weeks of study enrollment compared to those not receiving physical therapy. However, the observational design of this study limits conclusions on the effectiveness of physical therapy in this population.

For patients with lumbar IDH receiving continued conservative care, common interventions included physical therapy (40%), injections (42%), and NSAID, Cox2, or oral steroid medications (44%). The utilization of physical therapy in conservative management of IDH in the SPORT cohort was slightly lower, but similar, to prior studies. Atlas and Österman reported the use of physical therapy in 49% and 54% of patients receiving conservative management of IDH.[2, 28] Bed rest/activity restriction and the use of injections were markedly different from prior reports. The Maine Lumbar Spine Study reported only 19% of the conservative care cohort received injections.[2] In this same study, bed rest was used as a management strategy for 41% of the cohort while only 1% of the SPORT cohort reported using activity restriction. Recommendations to stay active reflect best practice guidelines[6] and represents a large shift from earlier studies utilizing bed rest during the first week of management as part of the treatment protocol for patients with IDH.[34] The increase in lumbosacral injections is consistent with trends across the United States, but may also be explained by the geographical variation represented in the SPORT.[11, 12]

Factors influencing utilization of physical therapy in the secondary care setting are poorly understood. A recent in-depth cross-sectional study using data from a consortium of US spine-care centers examined physician referral to physical therapy.[10] A multitude of factors influenced physical therapy referrals, including both patient presentation and physician related characteristics. This suggests referral to physical therapy is complex and highly variable. Our results indicated higher patient reported disability, neurologic deficit, and treatment preference were associated with utilization of physical therapy. In contrast, Freburger et al. reported patients with higher disability were less likely to be referred to physical therapy.

Freburger also noted patients who had received physical therapy in the past were less likely to be referred again presumably having exhausted the treatment effect. This was not the case in our cohort. At baseline, 72% of patients in the nonsurgical cohort reported having received physical therapy prior to enrollment in the study. Prior physical therapy did not predict the use of physical therapy after enrollment in the study. A few notable differences between the two studies include study inclusion criteria and study protocols. First, the inclusion criteria for our cohort limited much of the variation around diagnosis. Second, participating physicians in the current study were encouraged to recommend active physical therapy. Finally, patients and physicians willing to participate in research are likely different than a usual care cohort.

Both Freburger et al. and SPORT demonstrated treatment preferences play a role in physical therapy utilization. We noted patient preference for surgery and preference for nonsurgical care both independently influence utilization of physical therapy. Examining only the observation cohort from this trial, Lurie et al. reported patients perceiving prior nonsurgical care as ineffective were more likely to have a preference for surgery. However, the expectation of benefit from nonsurgical care was the most powerful single predictor of patient preference.[23] Similarly, Freburger reported patients with a high expectation for improved function were more likely to be referred to physical therapy.[10] Understanding a patient's past experience and perception of conservative treatment is pivotal in examining further utilization and appropriate referral.

We failed to identify significant differences in pain and disability among those receiving physical therapy after enrollment compared with those who did not. It is difficult to judge the value of the physical therapy intervention in the current study as it was unstandardized and specific details were not reported. Joint mobility and active exercise interventions are noted to be superior to passive interventions for improving pain and disability in patients with lumbar IDH receiving physical therapy.[15, 18] More research is needed, however, to outline definitive parameters of the most effective physical therapy intervention for patients with IDH. Without a standardized physical therapy protocol, it is difficult to know if the treatment effect was attenuated due to practice variation or simply ineffective.[13]

For patients assessed in secondary care settings, rates of recovery are reportedly worse than for acute cases of sciatica due to IDH.[2, 29, 33] Many interventions are advocated without clear benefit of any one intervention long term.[15, 22] Research informing treatment selection and treatment sequencing is needed to optimize the effectiveness of nonsurgical management. At present, the equivalency of nonsurgical treatment interventions suggests treatment choice should be considered preference sensitive and involve shared decision making between providers and patients.[8]

Several limitations need to be considered when interpreting the results of this study. Results represent a secondary analysis of patients in a larger trial. As stated previously, subgroups studied were not randomized and the initial study design of the SPORT trial did not identify these subsets *a priori.* As such, there is risk of selection bias and the possibility of unidentified confounders between comparison groups limiting conclusions on the efficacy of physical therapy as a nonsurgical management strategy.

Finally, the variation associated with the nonstandardized approach to conservative management in the SPORT trial obscures the evaluation of a particular treatment strategy.

Conclusion

This secondary analysis of a nationally representative cohort from the SPORT population demonstrates the variety of nonsurgical treatments utilized in managing patients with IDH who seek secondary care but do not elect surgical management. The primary nonsurgical interventions used were medication, spinal injections, and physical therapy. Higher baseline disability, the presence of neurologic deficit, and patient preference for physical therapy were all factors associated with receiving physical therapy as an initial management strategy. Patients receiving physical therapy within the first 6 weeks did not demonstrate any significant differences in primary outcomes of pain and disability compared to those who did not receive physical therapy. These results highlight the variation and complexity in nonsurgical management decisions for patients with IDH. There remains a need to identify optimal management strategies and sequencing of treatment for this population.

Key Points

- This study suggests patients with persisting symptoms from lumbar intervertebral disc herniation seek a variety of conservative care management strategies the most common being medications, epidural steroid injections, and physical therapy.

- Symptom severity and patient preference increase the odds of a patient seeking physical therapy and should be considered when discussing treatment options with a patient.
- The observational design and nonstandardized approach to conservative treatment in this study limits conclusions on the effectiveness of physical therapy in patients at the secondary care level with lumbar intervertebral disc herniation.

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References

1. Ashworth J, Konstantinou K, Dunn K. Prognostic Factors in Non-Surgically Treated Sciatica: A Systematic Review. *BMC Musculoskeletal Disorders*. 2011;12:208.

2. Atlas SJ, Deyo RA, Keller RB, et al. The Maine Lumbar Spine Study, Part III: 1-year outcomes of surgical and nonsurgical management of lumbar spinal stenosis. *Spine*. 1996;21:1787-94.

3. Birkmeyer NJ, Weinstein JN, Tosteson AN, et al. Design of the spine patient outcomes research trial (SPORT). *Spine*. 2002;27:1361-72.

4. Carey TS, Garrett JM, Jackman A, Hadler N. Recurrence and care seeking after acute back pain: results of a long-term follow-up study. *Medical care*. 1999;37:157-164.

5. Cherkin DC, Deyo RA, Street JH, Barlow W. Predicting poor outcomes for back pain seen in primary care using patients' own criteria. *Spine*. 1996;21:2900-2907.

6. Dahm KT, Brurberg KG, Jamtvedt G, Hagen KB. Advice to rest in bed versus advice to stay active for acute low-back pain and sciatica. *The Cochrane database of systematic reviews*. 2010;6.

7. Daltroy L, Cats-Baril W, Katz J, Fossel A, Liang M. The North American Spine Society lumbar spine outcome assessment instrument: reliability and validity tests. *Spine*. 1996;21:741-9.

8. Elwyn G, Edwards A, Kinnersley P, Grol R. Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices. *The British Journal of General Practice*. 2000;50:892-9.

9. Ferreira ML, Machado G, Latimer J, Maher C, Ferreira PH, Smeets RJ. Factors defining care seeking in low back pain:A meta-analysis of population based surveys. *European Journal of Pain*. 2010;14:747. e741-747. e747.

10. Freburger JK, Carey TS, Holmes GM. Physician referrals to physical therapists for the treatment of spine disorders. *The Spine Journal*. 2005;5:530-541.

11. Friedly J, Chan L, Deyo R. Geographic variation in epidural steroid injection use in Medicare patients. *The Journal of Bone & Joint Surgery*. 2008;90:1730-1737.

12. Friedly J, Chan L, Deyo R. Increases in lumbosacral injections in the Medicare population: 1994 to 2001. *Spine*. 2007;32:1754-1760.

13. Fritz JM, Cleland JA, Brennan GP. Does adherence to the guideline recommendation for active treatments improve the quality of care for patients with acute low back pain delivered by physical therapists? *Medical care*. 2007;45:973-980.

14. Grotle M, Brox J, Veierud M, Glomsrood B, Lunn J, Vellestad N. Clinical course and prognostic factors in acute low back pain: patients consulting primary care for the first time. *Spine*. 2005;30:976-82.

15. Hahne AJ, Ford JJ, McMeeken JM. Conservative management of lumbar disc herniation with associated radiculopathy: a systematic review. *Spine*. 2010;35:E488.

16. Haugen A, Brox J, Grøvle L, et al. Prognostic factors for non-success in patients with sciatica and disc herniation. *BMC Musculoskeletal Disorders*. 2012;13:183.

17. Jacobs WC, van Tulder M, Arts M, et al. Surgery versus conservative management of sciatica due to a lumbar herniated disc: a systematic review. *European Spine Journal*. 2011;20:513-522.

18. Jewell DV, Riddle DL. Interventions that increase or decrease the likelihood of a meaningful improvement in physical health in patients with sciatica. *Phys Ther*. 2005;85:1139-1150.

19. Koes B, Van Tulder M, Peul W. Diagnosis and treatment of sciatica. *BMJ: British Medical Journal*. 2007;334:1313-17.

20. Kongsted A, Kent P, Jensen TS, Albert H, Manniche C. Prognostic implications of the Quebec Task Force classification of back-related leg pain: an analysis of longitudinal routine clinical data. *BMC Musculoskeletal Disorders*. 2013;14:171.

21. Lewis R, Williams N, Matar H, et al. The clinical effectiveness and cost-effectiveness of management strategies for sciatica: systematic review and economic model. *Health Technol Assess.* 2011;15(39):1-434.

22. Luijsterburg PAJ, Verhagen AP, Ostelo RWJG, Van Os TAG, Peul WC, Koes BW. Effectiveness of conservative treatments for the lumbosacral radicular syndrome: a systematic review. *European Spine Journal*. 2007;16:881-899.

23. Lurie JD, Berven SH, Gibson-Chambers J, et al. Patient preferences and expectations for care: determinants in patients with lumbar intervertebral disc herniation. *Spine*. 2008;33:2663-68.

24. Martin BI, Turner JA, Mirza SK, Lee MJ, Comstock BA, Deyo RA. Trends in health care expenditures, utilization, and health status among US adults with spine problems, 1997–2006. *Spine*. 2009;34:2077-2084.

25. McHorney CA, Ware Jr JE, Rachel Lu J, Sherbourne CD. The MOS 36-ltem Short-Form Health Survey (SF-36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. *Medical care*. 1994;32:40-66.

26. National Guideline C. Guideline for the evidence-informed primary care management of low back pain. Available at: http://www.guideline.gov/content.aspx?id=37954&search=low+back+pain. Accessed 8/5/2013.

27. National Guideline C. Low back disorders. Available at: http://www.guideline.gov/content.aspx?id=38438&search=acoem. Accessed 8/5/2013.

28. Österman H, Seitsalo S, Karppinen J, Malmivaara A. Effectiveness of microdiscectomy for lumbar disc herniation: a randomized controlled trial with 2 years of follow-up. *Spine*. 2006;31:2409-2414.

29. Peul W, Hout W, Brand R, Thomeer R, Koes B. Prolonged conservative care versus early surgery in patients with sciatica caused by lumbar disc herniation: two year results of a randomised controlled trial. *British Medical Journal*. 2008;336:1355.

30. Selim AJ, Ren XS, Fincke G, et al. The importance of radiating leg pain in assessing health outcomes among patients with low back pain. Results from the Veterans Health Study. *Spine (Phila Pa 1976)*. 1998;23:470-474.

31. Verwoerd A, Luijsterburg P, Lin CW, Jacobs W, Koes B, Verhagen A. Systematic review of prognostic factors predicting outcome in non - surgically treated patients with sciatica. *European Journal of Pain*. 2013;17(8):1126-37.

32. Vroomen PC, de Krom MC, Slofstra PD, Knottnerus JA. Conservative treatment of sciatica: a systematic review. *Journal of spinal disorders*. 2000;13:463-469.

33. Vroomen PCAJ, De Krom M, Knottnerus J. Predicting the outcome of sciatica at short-term follow-up. *The British Journal of General Practice*. 2002;52:119-123.

34. Weber H. Lumbar disc herniation: a controlled, prospective study with ten years of observation. *Spine*. 1983;8:131-140.

35. Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical vs nonoperative treatment for lumbar disk herniation: the Spine Patient Outcomes Research Trial (SPORT) observational cohort. *JAMA*. 2006;296:2451-2459.

36. Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical vs nonoperative treatment for lumbar disk herniation: the Spine Patient Outcomes Research Trial (SPORT): a randomized trial. *JAMA*. 2006;296:2441-2450.

Table 4.1 Baseline demographic characteristics.

	Had Physical Therapy During First 6-Weeks (*n*=143)	**No Physical Therapy During First 6-Weeks** (*n*=219)	*p*-value
Age (years)	43.7 (11.5)	42.9 (11.6)	0.49
Sex (female)	64 (45%)	89 (41%)	0.51
Body Mass Index (kg/m^2)	27.5 (5.5)	28 (5.5)	0.40
Race	118 (83%)	192 (88%)	0.22
Education (at least some college)	116 (81%)	159 (73%)	0.08
Marital status (married)	101 (71%)	151 (69%)	0.82
Work Status			0.29
Full or part-time	91 (64%)	152 (69%)	
Disabled	17 (12%)	16 (7%)	
Other	35 (24%)	51 (23%)	
Receiving compensation	25 (17%)	25 (11%)	0.14
Smoker	33 (23%)	57 (26%)	0.61
Co-morbidities			
Depression	18 (13%)	30 (14%)	0.88
Joint Problem	35 (24%)	48 (22%)	0.66
Other[1]	69 (48%)	113 (52%)	0.61
Treatment prior to enrollment			
Physical therapy	100 (70%)	159 (73%)	0.67
Injection	51 (36%)	103 (47%)	0.04
Symptom duration <6 months	122 (85%)	165 (75%)	0.03
SF-36-Bodily Pain	32.8 (21.4)	34.2 (21.5)	0.51
SF-36-Physical Functioning	44.8 (24.4)	47.7 (27.1)	0.31
SF-36-Mental Component Score	45.7 (12.1)	46.2 (11.0)	0.64
Oswestry Disability Index (0-100)	42.9 (18.8)	39.0 (21.2)	0.08
Sciatica Frequency Index (0-24)	14.1 (5.2)	14.7 (5.5)	0.32
Sciatica Bothersomeness Index (0-24)	14.3 (5.2)	14.0 (5.6)	0.65
Back Pain Bothersomeness (0-6)	3.9 (1.7)	3.7 (1.9)	0.18
Leg Pain Bothersomeness (0-6)	4.4 (1.6)	4.2 (1.7)	0.42
Very dissatisfied with symptoms	104 (73%)	136 (62%)	0.05
Symptom status			0.08
Getting better	42 (29%)	53 (24%)	
Staying the same	57 (40%)	113 (52%)	
Getting worse	44 (31%)	52 (24%)	
Treatment Preference			0.002
Non-Surgical	109 (76%)	133 (61%)	
Surgical	26 (18%)	50 (23%)	
Not Sure	8 (6%)	36 (16%)	

[1]Other comorbidities include problems related to stroke, diabetes, osteoporosis, cancer, fibromyalgia, chronic fatigue syndrome, post traumatic stress disorder, alcohol drug dependence, heart, lung, liver, kidney, blood vessel, nervous system, hypertension, migraine, anxiety, stomach or bowel.

Table 4.2 Baseline examination findings.

	Had Physical Therapy During First 6-Weeks (*n*=143)	**No Physical Therapy During First 6-Weeks** (*n*=219)	*p*-value
Pain Radiation	138 (97%)	213 (97%)	0.92
Straight Leg Raise Ipsilateral	89 (62%)	139 (63%)	0.91
Straight Leg Raise Contralateral/Both	13 (9%)	26 (12%)	0.51
Neurological Deficit	109 (76%)	145 (66%)	0.06
Reflexes - asymmetric depressed	55 (38%)	70 (32%)	0.25
Sensory – asymmetric decreased	77 (54%)	96 (44%)	0.08
Motor – asymmetric weakness	49 (34%)	74 (34%)	0.98
Herniation Level			0.18
L2-3/L3-4	17 (12%)	14 (6%)	
L4-L5	53 (37%)	90 (41%)	
L5-S1	73 (51%)	114 (52%)	
Herniation Type			0.29
Protruding	52 (37%)	66 (30%)	
Extruded	78 (55%)	137 (63%)	
Sequestered	12 (8%)	15 (7%)	
Posterolateral hernation	104 (73%)	170 (78%)	0.35

Table 4.3 Nonsurgical treatments received during the first 6 weeks after enrollment.

	Had Physical Therapy During First 6-Weeks (*n*=143)	**No Physical Therapy During First 6-Weeks** (*n*=219)	*p*-value
Providers/Services/Treatments			
Education/Counseling	13 (9%)	10 (5%)	0.14
Emergency Room Visits	6 (4%)	17 (8%)	0.25
Surgeon	29 (20%)	41 (19%)	0.82
Chiropractor	12 (8%)	14 (6%)	0.61
Internist/Neurologist/etc.	62 (43%)	62 (28%)	0.005
Acupuncturist	4 (3%)	5 (2%)	0.97
Other	29 (20%)	31 (14%)	0.17
Injections	60 (42%)	92 (42%)	0.92
Activity Restriction	7 (5%)	5 (2%)	0.30
Medications			
NSAIDs	62 (43%)	91 (42%)	0.82
Cox inhibitors	40 (28%)	53 (24%)	0.50
Oral Steroids	5 (3%)	8 (4%)	0.83
Narcotics	51 (36%)	57 (26%)	0.07
Muscle relaxants	32 (22%)	23 (11%)	0.003
Other Medications	57 (40%)	77 (35%)	0.43
Devices			
Brace	6 (4%)	6 (3%)	0.65
Corset	3 (2%)	0 (0%)	0.12
Magnets	4 (3%)	2 (1%)	0.34
Orthopedic pillow	16 (11%)	10 (5%)	0.03
Shoe inserts	8 (6%)	4 (2%)	0.10
TENS machine	4 (3%)	3 (1%)	0.57
Other medical devices	5 (3%)	8 (4%)	0.84
None	107 (75%)	189 (87%)	0.006
NSAIDs or Cox2 or Oral Steroids	65 (45%)	96 (44%)	0.85

Table 4.4 Primary and secondary outcomes for patients who received or did not receive physical therapy during the first 6 weeks after enrollment.[1]

Outcome	6-Week				3-Month			
Number of patients	PT 143	No PT 219	Treatment Effect (95% CI)	*p*-value	PT 117	No PT 165	Treatment Effect (95% CI)	*p*-value
SF-36 Bodily Pain	16.1 (1.8)	18.1 (1.5)	-2.0 (-6.7, 2.7)	0.41	22.6 (2.0)	25.2 (1.6)	-2.6 (-7.7, 2.5)	0.31
SF-36 Physical Function	11.9 (1.7)	12.1 (1.4)	-0.2 (-4.6, 4.2)	0.93	16.8 (1.8)	18.1 (1.5)	-1.2 (-6.1, 3.6)	0.61
SF-36 Mental Component Summary	2.8 (0.8)	3.1 (0.7)	-0.3 (-2.3, 1.8)	0.79	3.5 (0.9)	4.8 (0.7)	-1.3 (-3.6, 0.9)	0.24
Oswestry Disability Index (0-100)	-8.7 (1.5)	-10.1 (1.2)	1.4 (-2.5, 5.2)	0.49	-12.8 (1.6)	-15.5 (1.3)	2.6 (-1.5, 6.8)	0.21
Sciatica Bothersomeness Index (0-24)	NA	NA	NA	NA	-6.3 (0.5)	-6.3 (0.4)	0 (-1.3, 0.5)	0.99
Leg Pain Bothersomeness (0-6)	NA	NA	NA	NA	-1.9 (0.2)	-2.0 (0.1)	0.1 (-0.3, 0.5)	0.73
Low Back Pain Bothersomeness (0-6)	NA	NA	NA	NA	-1.2 (0.1)	-1.1 (0.1)	-0.1 (-0.5, 0.3)	0.59
Very/Somewhat Satisfied with Symptoms (%)	23.1	24.7	-1.6 (-11.3, 8.1)	0.74	33.1	35.7	-2.6 (-15.0, 9.8)	0.67
Self-Rate Progress: Major Improvement (%)	37.9	35.2	2.7 (-8.6, 14.1)	0.64	54.2	49.5	4.6 (-8.6, 17.9)	0.48
Opioid Use (%)	**31.6**	**19.1**	**12.5 (1.9, 23.1)**	**0.02**	15.5	14.8	0.7 (-8.0, 9.4)	0.87

Outcome	1-Year			
Number of patients	PT 100	No PT 139	Treatment Effect (95% CI)	*p*-value
SF-36 Bodily Pain	28.9 (2.1)	29.6 (1.7)	-0.7 (-6.1, 4.7)	0.79
SF-36 Physical Function	23.6 (1.9)	22.3 (1.6)	1.3 (-3.7, 6.4)	0.61
SF-36 Mental Component Summary	2.8 (0.9)	4.4 (0.8)	-1.6 (3.9, 0.8)	0.19
Oswestry Disability Index (0-100)	-18.0 (1.6)	-16.2 (1.4)	-1.7 (-6.1, 2.6)	0.43
Sciatica Bothersomeness Index (0-24)	-7.5 (0.5)	-7.0 (0.4)	-0.5 (-1.9, 0.8)	0.43
Leg Pain Bothersomeness (0-6)	-2.6 (0.2)	-2.2 (0.1)	-0.4 (-0.8, 0)	0.07
Low Back Pain Bothersomeness (0-6)	**-1.6 (0.1)**	**-1.2 (0.1)**	**-0.4 (-0.8, 0)**	**0.05**
Very/Somewhat Satisfied with Symptoms (%)	49.6	46.6	3.0 (-11.1, 17.2)	0.68
Self-Rate Progress: Major Improvement (%)	60.7	51.9	8.8 (-5.1, 22.7)	0.23
Opioid Use (%)	6.9	9.7	-2.8 (-9.4, 3.8)	0.40

[1]Values represent mean change from baseline (standard error) or percentages. Values have ben adjusted for center, age, sex, marital status, smoking status, race, compensation, herniation location, working location, working status, stomach comorbidity, depression, other comorbidity, self-rated symptom progression, duration, treatment preference and baselines scores (for SF-36 and ODI). NA indicates data was not assessed.

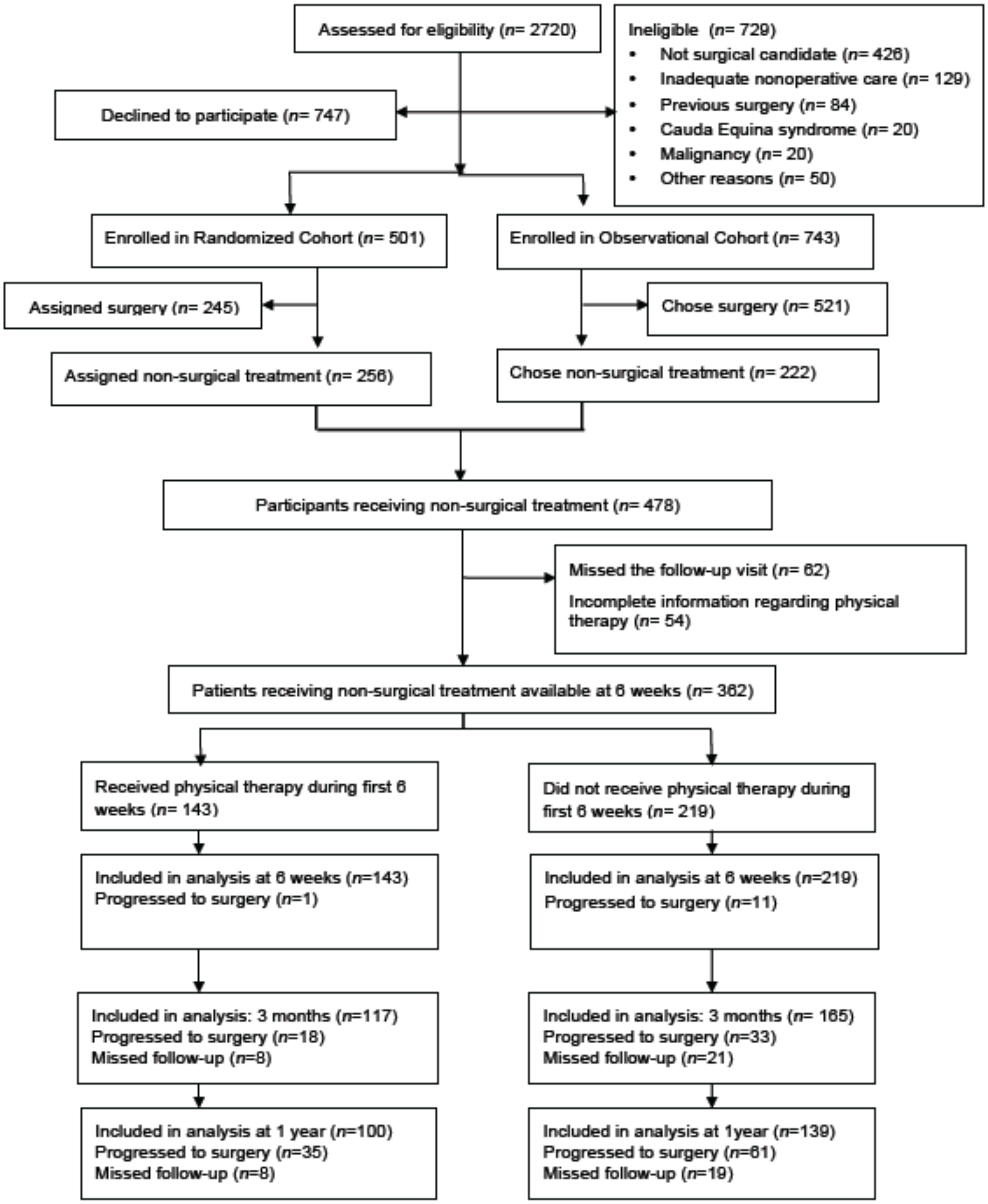

Figure 4.1 Flow of patients through the study.

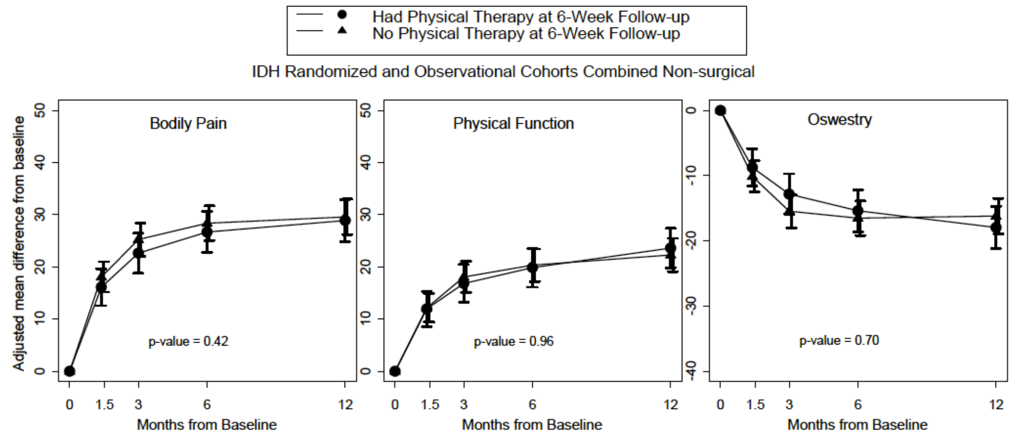

Figure 4.2 Primary outcomes over time.

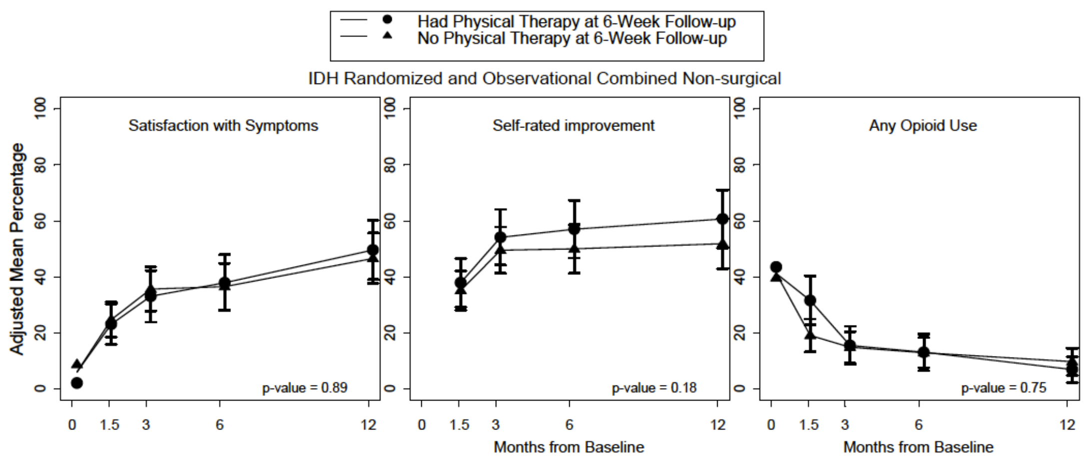

Figure 4.3 Secondary outcomes over time.

CHAPTER 5

CONCLUSION

Summary of Findings

This dissertation began with several specific research questions: Can heterogeneity between individuals with incident low back pain (LBP) be explained by different patterns of recovery? How are these patterns identified and are they influenced by the presence of leg pain? What are common management strategies for patients with persisting leg pain? Do those strategies impact clinical outcomes?

From our research, we conclude that four patterns of recovery exist after an episode of acute occupational LBP. Nearly 60% of those will experience significant reduction in pain over the course of 3-5 months with 26% reporting complete resolution of pain. Baseline odds are in favor of improvement. The remaining 40%, however, risk persisting pain or a recurrence of symptoms. For those not recovering, the majority (28%) will experience some level of persisting moderate pain demonstrating little to no change after onset. Another 8% are likely to have high persisting pain identified by higher baseline pain and a slower rate of recovery. A small portion of workers (4%) will report near resolution of symptoms before a experiencing a recurrence of pain at moderate intensity.

In general, workers presenting with leg pain will have higher pain and slower recovery, regardless of recovery class. Moderate persisting pain and high persisting pain is more likely among Hispanic workers and among those reporting more severe prior low back pain. High lifting demands and low social support from coworkers further increases the likelihood of experiencing moderate persisting pain. Whereas lumbar related leg pain increased the odds of high persisting pain.

Many nonsurgical interventions are available for those experiencing persisting leg pain with common management referral to physical therapy (40%), spinal injections (42%), and/or medications (44%). Higher baseline disability, the presence of neurologic deficit, and patient preference for physical therapy may prompt workers to seek treatment by a physical therapist. The value of this management strategy remains unclear.

Future Research

There are some key questions driving future research. Is there value in identifying classes of recovery? Can the different classes of recovery be reliably predicted at baseline? How soon after onset can we identify one's recovery trajectory?

Prognosis and recovery have been defined by many different end-points, including clinical outcomes, sick leave, absenteeism, and care-seeking. These end-points are influenced by an array of individual and work related factors[1, 4] If we are to utilize recovery trajectories to shift the cost of LBP, future studies should consider how recovery trajectories are related to end-points associated with high cost. A strong association would encourage earlier monitoring and assessment of intervention strategies. Even with a moderate association, aggregating prognostic indicators for both recovery class and cost may help establish a more robust risk profile. With data from the parent study, we can explore these associations further. Examining the relationships between recovery trajectories, care seeking, and work limitations we can begin to understand how recovery trajectories and cost relate.

We can further explore at what point in time these trajectories are defined and how this differs by class. Knowing when to compare differences in change aids providers in treatment planning but can also direct research follow-up.

Furthermore, applying structural equation modeling to these data can help us understand the complex relationships between many covariates and outcomes. Using theoretical constructs to model relationships and pathways between covariates and outcome will help us understand how covariates are related and aid in determining the most parsimonious set of prognostic indicators.[2, 3]

References

1. Ozguler A, Leclerc A, Landre M-F, Pietri-Taleb F, Niedhammer I. Individual and occupational determinants of low back pain according to various definitions of low back pain. *Journal of epidemiology and community health*. 2000;54:215-220.

2. Schmidt SJ, Mueller DR, Roder V. Social cognition as a mediator variable between neurocognition and functional outcome in schizophrenia: empirical review and new results by structural equation modeling. *Schizophrenia bulletin*. 2011;37:S41-S54.

3. Somers TJ, Shelby RA, Keefe FJ, et al. Disease severity and domain ‐ specific arthritis self ‐ efficacy: Relationships to pain and functioning in patients with rheumatoid arthritis. *Arthritis care & research*. 2010;62:848-856.

4. Waddell G, Burton AK. Occupational health guidelines for the management of low back pain at work: evidence review. *Occupational medicine*. 2001;51:124-135.