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Clinical Study

Clinical classification criteria for radicular pain caused by lumbar disc herniation: the radicular pain caused by disc herniation (RAPIDH) criteria

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Abstract

BACKGROUND CONTEXT: Classification criteria are recommended for diseases that lack specific biomarkers to improve homogeneity in clinical research studies. Because imaging evidence of lumbar disc herniations (LDHs) may not be associated with symptoms, clinical classification criteria based on patient symptoms and physical examination findings are required.

PURPOSE: This study aimed to produce clinical classification criteria to identify patients with radicular pain caused by LDH.

STUDY DESIGN: The study design was a two-stage process. Phase 1 included a Delphi process and Phase 2 included a cohort study.

PATIENT SAMPLE: The patient sample included outpatients recruited from spine clinics in five countries.

OUTCOME MEASURES: The outcome measures were items from history and physical examination.

MATERIALS AND METHODS: In Phase 1, 17 spine experts participated in a Delphi process to select symptoms and signs suggesting radicular pain caused by LDH. In Phase 2, 19 different clinical experts identified patients they confidently classified as presenting with (1) radicular pain caused by LDH, (2) neurogenic claudication (NC) caused by lumbar spinal stenosis, or (3) non-specific low back pain (NSLBP) with referred leg pain. Patients completed survey items and specialists documented examination signs. A score to predict radicular pain caused by LDH was developed based on the coefficients of the multivariate model. An unrestricted grant of less than US$15,000 was received from MSD: It was used to support the conception of the Delphi, data management, and statistical analysis. No fees were allocated to participating spine specialists.

FDA device/drug status: Not applicable.

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RESULTS: Phase 1 generated a final list of 74 potential symptoms and signs. In Phase 2, 209 patients with pain caused by LDH (89), NC (63), or NSLBP (57) were included. Items predicting radicular pain caused by LDH ($p<.05$) were monoradicular leg pain distribution, patient-reported unilateral leg pain, positive straight leg raise test <60° (or femoral stretch test), unilateral motor weakness, and asymmetric ankle reflex. The score had an AUC of 0.91. An easy-to-use weighted set of criteria with similar psychometric characteristics is proposed (specificity 90.4%, sensitivity 70.6%).
CONCLUSIONS: Classification criteria for identifying patients with radicular pain caused by LDH are proposed. Their use could improve the homogeneity of patients enrolled in clinical research studies.

Keywords: Back pain; Classification criteria; Disc herniation; Diagnosis; Lumbar radicular pain; Lumbar radiculopathy; Sciatica

Introduction

Low back pain (LBP) is a common symptom leading patients to visit primary care and musculoskeletal specialty providers [1]. Many individuals with LBP also report an associated leg pain that may indicate nerve root involvement. Lumbar disc herniation (LDH) is the most frequently identified cause of radicular pain [2]. However, disc herniations may be found on imaging tests of asymptomatic individuals [3]. Guideline recommendations to decrease the use of spinal imaging in patients with acute LBP, including radicular leg pain without signs suggesting serious etiologies, emphasize the role of history and physical examination findings as key to guiding initial management [4–6]. Therefore, the diagnosis of radicular pain is predominately clinically based.

In musculoskeletal diseases, the need for classification criteria was recognized 30 years ago as an important step to identify and distinguish patients with a specific disease from those without disease to create homogenous groups of patients for clinical or population studies [7]. In the field of LBP, the Quebec Task Force recognized the necessity to differentiate LBP patients with leg pain and neurologic signs from other categories of LBP patients [8]. Although clinicians are trained to identify patients with radicular pain caused by LDH, no consensus has emerged to produce classification criteria for these patients [9]. As a consequence, researchers use a wide range of eligibility criteria leading to a considerable heterogeneity among patients enrolled in these studies [10]. Classification criteria are useful in clinical research to ensure that study participants have the disease in question and that different centers are studying patients with the same clinical condition [11]. When classification criteria are accepted internationally, they can encourage the use of uniform disease definitions and ensure that studies from divergent locations evaluate the same disease entity [12]. For several musculoskeletal diseases (eg, rheumatoid arthritis and spondyloarthropathy), widespread adoption of classification criteria has been a key factor leading to improved patient selection and treatment [13]. The absence of such classification criteria for several low back-related conditions has been identified as a limitation in terms of understanding the physiopathology and evaluating new treatments [9,10].

In view of the large economic burden related to LBP syndromes [14], there is an urgent need to develop classification criteria for LBP-related syndromes [10]. During a workshop at the 11th Forum for Primary Care Research on Low Back Pain in Boston, MA, a multidisciplinary, international group proposed the development of classification criteria for LBP-related neurologic leg symptoms.

Materials and methods

The present study was designed according to rules defined by Fries for constructing classification criteria [15] and focused on radicular pain caused by LDH and neurogenic claudication (NC) caused by lumbar spinal stenosis. Here, we report on the development and validation of clinical classification criteria for radicular pain caused by LDH.

Selection of potential items

A convenience sample of 17 spine specialists (see Supplementary Appendix A) participated in the item selection phase (Phase 1) of the study. The spine specialists were selected according to their background in the field of spine care and research, and a range of individuals in terms of country of origin and specialties were recruited to increase generalizability. A list of patient-reported symptoms and clinical signs considered useful in diagnosing radicular pain caused by LDH or NC caused by spinal stenosis was generated from a structured literature review with additional items suggested by the participants.

Delphi process

A Delphi consensus process consisting of rounds of expert review [16,17] was then conducted using a computer-based survey program to reduce the list of items to those deemed potentially important for the diagnosis of each syndrome. When relevant, a precise definition of the test was provided in a separate booklet. For each round, the spine specialists rated the usefulness of each criterion "to differentiate patients with radicular pain caused by LDH from all others" on a 7-point Likert-type scale ranging from 1 (useless) to 7 (very useful). No other framing was provided for the other numbers available.

For Round 1, items were excluded if they had a mean score of <3 or had a rating of 1 by more than 25% of the participants, or if more than 50% of the reviewers answered "don't