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CLINICAL CLASSIFICATION CRITERIA FOR RADICULAR PAIN CAUSED BY LUMBAR DISC HERNIATION: THE RADICULAR PAIN CAUSED BY DISC HERNIATION (RAPIDH) CRITERIA

Stéphane Genevay, MD[a,*], Delphine S. Courvoisier, PhD[a,b], Kika Konstantinou, PhD[c], Francisco M. Kovacs, MD[d], Marc Marty, MD[e], James Rainville, MD[f], Michael Norberg, MD[g], Jean-François Kaux, MD[h], Thomas D. Cha, MD[i], Jeffrey N. Katz, MD[j], Steven J. Atlas, MD[k]

[a]*Division of Rheumatology, University Hospitals of Geneva, Geneva, Switzerland*
[b]*Quality of Care Division, University Hospitals of Geneva, Geneva, Switzerland*
[c]*Arthritis Research UK Primary Care Centre, Research Institute for Primary Care & Health Sciences, Keele University, Newcastle, United Kingdom*
[d]*Spanish Back Pain Research Network, Moncloa University Hospital, Madrid, Spain*
[e]*Department of Rheumatology, Henri-Mondor Hospital, Créteil, France*
[f]*Physical Medicine and Rehabilitation, New England Baptist Hospital, Boston, MA, USA*
[g]*Physical Medicine and Rehabilitation, University Hospital of Lausanne, Lausanne, Switzerland*
[h]*Physical Medicine and Sport Traumatology Department, University and University Hospital of Liège, Belgium*
[i]*Department of Orthopaedic Surgery, Massachusetts General Hospital, Boston, MA, USA*
[j]*Department of Orthopaedic Surgery and Division of Rheumatology, Immunology and Allergy, Brigham and Women's Hospital, Boston, MA, USA*
[k]*Division of General Internal Medicine, Massachusetts General Hospital, Boston, MA, USA*
** Corresponding author. Division of Rheumatology, University Hospitals of Geneva, rue Gabrielle-Perret-Gentil 1205 Geneva, Switzerland. Tel.: +4122 372 36 11; fax: +4122 372 35 30., E-mail address: stephane.genevay@hcuge.ch (S. Genevay)*

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

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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.

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

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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 know." For Round 2, retained items were rescored. Items were selected for the clinical phase if the mean score was ≥4.5 and the difference between the two rounds was ≤1. Additional rounds were planned until all items were either included or excluded.

Clinical study

In Phase 2, 19 spine specialists (surgeons and non-surgeons) who worked in English- or French-speaking countries (see Supplementary Appendix A) and did not participate in the item selection phase screened patients presenting at their clinics with back-related leg pain for study eligibility. Clinical signs were precisely

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defined and, when needed, figures demonstrating the technique were provided to decrease heterogeneity during the testing. The case report form was translated from English into French following the rules defined for cross-cultural adaptation and validation [18].

Patients were included if the spine specialist diagnosed the patient with radicular pain caused by LDH. As a comparison group, patients with NC caused by lumbar spinal stenosis (LSS) or non-specific low back pain (NSLBP) with referred leg pain were also recruited [19]. Exclusion criteria were patients who were younger than 18 years, had LBP without any leg pain, had leg pain not related to a spinal problem, were unable to read or understand the native language of the country, or declined study participation. As recommended for the development of classification criteria [20], spine specialists were asked to enroll similar numbers of patients from each of the three diagnostic groups. Spine specialists were not compensated for their participation in the item selection or clinical phase of the study.

Human subjects' approval was obtained from the ethical committee of the Geneva University Hospitals, Switzerland, with additional approval obtained from each participating institution. Potentially eligible patients consulting participating spine specialists were approached about the study, and informed consent was obtained before enrollment. During the same visit, patients completed a patient survey, and physicians provided information on the presence of symptoms and documented physical examination findings on the provided case report form. Spine specialists also categorized patients into one of the three diagnostic groups using any diagnostic test or procedure felt necessary as part of routine practice and rated their degree of confidence with the diagnosis on a visual analog scale from 0 (not confident at all) to 10 (extremely confident). The participating spine specialists were blinded to the study's planned exclusion of patients diagnosed with a level of confidence below 7.

Sample size calculation

To accurately estimate the coefficients of potential items included in logistic regression models to develop a classification criteria to predict LDH, at least 10 patients per item were needed. Assuming a total of 10 items in the final model, the required sample size was 100 patients. However, because the patients recruited by the same expert were not independent, we multiplied this sample size by a design effect, assuming an intraclass correlation of 0.05 and an average number of patients per physician (cluster size) of 15 [21]. This result led to a final sample size of 170 ($100 \times [1 + (15 - 1) \times 0.05]$). Assuming similar numbers of recruited patients per diagnosis (60 patients with radicular pain caused by LDH, 60 patients with NC related to LSS, and 50 patients with NSLBP), this sample size allowed for the estimation of a 95% confidence interval (CI) around a sensitivity of 80% with a half-interval of 10.1% (ie, 69.9% and 90.1%) and a specificity of 80% with a half-interval of 7.5% (72.5% and 87.5%).

Statistical analysis

We used all items (for both radicular pain caused by LDH and NC caused by LSS) to identify the best criteria set for radicular pain caused by LDH using the experts' clinical diagnosis as the gold standard. We first used univariable generalized estimating equation (GEE) models (logit link) with patients categorized as having radicular pain caused by LDH versus the combined LSS and NSLBP groups as the outcome and each item as the predictor. The GEE model with an exchangeable correlation matrix was used to account for the multicenter study. Items were included in the multivariable models if the univariable p value was <0.1 but were excluded if selected in 10 patients or fewer. We then ran two multivariable GEE models, one with the

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remaining specialist-reported items and the other with the remaining patient-reported items. For items that were very similar and thus highly correlated (eg, different angle limits for the straight leg raise [SLR] test to be considered positive; see Supplementary Appendix B), we introduced each version separately in the multivariable model and chose the model based on the lowest value of the quasi-information criteria. The next step combined all items retained in Step 2 (p value <.1) in a single GEE model (M1, logit link, and exchangeable correlation matrix). Sensitivity analyses were then performed to attempt to simplify the models while retaining good sensitivity and specificity (Models S1–S7). To test the appropriateness of the model selection, we also used the least absolute shrinkage and selection operator (LASSO) method and compared the criteria retained using this statistical model selection with the sequential model selection described earlier. Finally, based on the coefficients of the last GEE model, we assigned a weight to each criterion retained and derived the radicular pain caused by disc herniation (RAPIDH) criteria set. To determine the score cutoff, we used the receiver operating characteristic curve and the area under the curve (AUC). This score cutoff was then used to compute the sensitivity, the specificity, with their respective 95% CIs. All analyses were done using R v3.2.3 (R Foundation for Statistical Computing, Vienna, Austria), with libraries geepack for the GEE analysis, MESS for the quasi-information criterion, and the glmnet for the LASSO model selection.

Results

Delphi process

The literature review and items identified by spine specialists resulted in a list of 236 potential items for spine-related leg pain symptoms and physical examination findings, including 145 associated with radicular pain caused by LDH. The large number of items reflected an inclusive list generation phase with multiple items reflecting small variations among similar concepts (eg, Lasègue sign or SLR test items including five different angles and with three different wordings). In the first round, 23 items were excluded, all based on mean scores of <3, leaving 213 items. In the second round, 118 additional items were excluded. Among the items assessing the same concept, we chose the ones with the highest average score, thus deleting 21 additional items.

Of the 74 remaining items included in the clinical study, 28 were patient-reported symptoms and 46 were physician-reported findings (see Supplementary Appendix B). As all had a stable evaluation (≤1 point difference between rounds on the usefulness scale), the Delphi process ended.

Clinical study

There were 213 patients (average of 10.7 patients enrolled per expert) enrolled in the clinical phase. Four patients were excluded as the spine specialist rated <7 out of 10 their confidence in their diagnosis, leaving 209 patients included the statistical analysis: 89 with radicular pain caused by LDH, 63 with NC caused by LSS, and 57 with NSLBP with referred leg pain (Table 1). Tests used by spine specialists to reach a diagnosis with confidence included magnetic resonance imaging or computed tomography scan for 203 of the 209 patients (86/89 for patients diagnosed as having radicular pain caused by LDH) and electromyography (EMG) for 25 of the 209 patients.

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In univariable analyses, 26 of 74 items were significantly associated with a diagnosis of radicular pain caused by LDH, including 8 patient-reported and 18 specialist-reported items (see Supplementary Appendix B). Overlapping items were combined to create single variables (eg, leg pain increased by either sneezing, coughing, or straining). In addition, items reported by only 10 patients or fewer were dropped from the final analyses.

Table 1
Patients' characteristics—figures are means (standard deviation) unless otherwise specified

	Radicular pain caused by LDH N=89	Other (neurogenic claudication caused by LSS or NSLBP with referred leg pain) N=120	p
Age	46.8 (13.0)	55.8 (18.0)	<.001
Sex (female), n (%)	31 (36.9)	62 (53.0)	.03
Duration of back pain (y)	5.1 (7.6)	7.2 (9.1)	.07
Duration of leg pain (y)	1.8 (4.8)	3.6 (5.5)	.02
Worst pain location, n (%)			.02
Back	14 (16.5)	29 (26.4)	
Leg	48 (56.5)	40 (36.4)	
Both equally	23 (27.1)	41 (37.3)	

LDH, lumbar disc herniation; LSS, lumbar spinal stenosis; NSLBP, nonspecific low back pain.

Multivariable analysis was conducted separately for patient-reported items and specialist-reported items. Items with a p value of <.1 were included in a second multivariable analysis leading to the identification of five items (Table 2). The score derived from this model (M1, Table 3) had an AUC of 0.91 (Fig. 1), and the cutoff to obtain a specificity of ≥90% resulted in a sensitivity of 74%. Simplifying the model by collapsing response categories for retained items (eg, combining bilateral muscle weakness with absence of muscle weakness) resulted in little loss in AUC, sensitivity, and specificity (Table 3). The final model retained patient-reported pain in one leg, and physician-assessed monoradicular leg pain distribution, unilateral motor weakness (vs. no weakness or bilateral weakness), positive SLR test (ie, a typical leg pain is produced between 0° and 60°) or positive femoral stretch test, and asymmetrical ankle reflex (vs. normal reflex or decreased reflex in both legs) (Table 4). The LASSO method resulted in the same five items and confirmed the strength of the results.

Items retained in the final model demonstrated fractional weights that varied twofold (see the respective scores in Table 4). To translate these weights into an easy-to-use scoring method, the score of each item was determined by multiplying by 2 and rounding the results to the nearest integer.

Hence, in the RAPIDH criteria, a weight of 6 was attributed to monoradicular leg pain distribution, 4 to a unilateral decrease in ankle reflex, or a positive SLR test result of <60° or femoral stretch test, and 3 to the other items so that the total score ranged from 0 to 20 (Table 5). Setting the cutoff at 10 provided an AUC of 0.90, with a sensitivity of 70.6% (95% CI: 59.6%–79.7%) and a specificity of 90.4% (95% CI: 83.2%–94.9%) (Model S7, Table 3).

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Table 2
Generalized estimating equation model with logit link and exchangeable correlation matrix to predict radicular pain caused by lumbar disc herniation

	Estimated	OR	p	Score
Intercept	-4.407	0.012	<.001	-
Monoradicular: not monoradicular	1 (reference)	1 (reference)		
Monoradicular: L3 or L4	2.983	19.743	<.001	3.0
Monoradicular: L5 or S1	2.903	18.221	<.001	2.9
Decreased ankle reflex: absence of	1 (reference)	1 (reference)		
Decreased ankle reflex: unilateral	1.623	5.069	.02	1.6
Decreased ankle reflex: bilateral	-0.945	0.389	.15	-0.9
Femoral stretch test or SLR≤60°	1.878	6.540	<.001	1.9
Muscle weakness: absence of	1 (reference)	1 (reference)		
Muscle weakness: unilateral	1.435	4.200	.02	1.4
Muscle weakness: bilateral	-0.767	0.465	.40	-0.8
Patient-reported unilateral leg pain	1.175	3.237	.03	1.2

SLR, straight leg raise; OR, odds ratio.
SLR≤60: SLR is positive if a typical leg pain is produced between 0° and 60°.

Table 3
Se analysis of full and simplified prediction models, with each model's estimation of AUC, Se, and Spe

	AUC	Se	Spe
M1: full model (see Table 2)	0.913	0.74	0.90
S1: combination of "monoradicular L3 or L4" and "monoradicular L5 or S1" (vs. non-radicular)	0.911	0.74	0.90
S2: combination of "bilateral muscle weakness" and "absence of muscle weakness" (vs. unilateral muscle weakness)	0.912	0.75	0.90
S3: " patellar or ankle decrease reflex" instead of "ankle reflex decrease" (vs. normal reflex)	0.905	0.72	0.92
S4: combination of "bilateral ankle decrease reflex" and "absence of decrease ankle reflex" (vs. unilateral ankle reflex decrease)	0.912	0.72	0.90
S5: all S1–S4 modifications	0.902	0.74	0.88
S6: all S1–S4 except S3	0.909	0.71	0.90
S7: S6, simplified weighted model*	0.903	0.71	0.90

AUC, area under curve; M1, full model including all variables; Se, sensitivity; Spe, specificity; S, simplified model; SLR, straight leg raise.
SLR≤60: SLR is positive if typical leg pain is produced between 0° and 60°.
* Simplified weighted model (see Table 4).

Table 4
Results of the final (S6) generalized estimating equation model to predict the diagnosis of radiculopathy caused by lumbar disc herniation

	Estimate	OR	p	Score
Intercept	−4.69	0.01	<.001	—
Monoradicular leg pain distribution	2.88	17.89	<.001	2.9
Unilateral decreased ankle reflex	1.70	5.45	.01	1.7
SLR≤60° (L5 and S1) or positive femoral stretch test (L3 and L4)	1.83	6.26	<.001	1.8
Unilateral muscle weakness (ref. none or bilateral)	1.44	4.24	.02	1.4
Unilateral patient-reported pain in the leg	1.42	4.14	.003	1.4

SLR, straight leg raise; ref., reference; OR, odds ratio.
SLR≤60: SLR is positive if a typical leg pain is produced between 0° and 60°.

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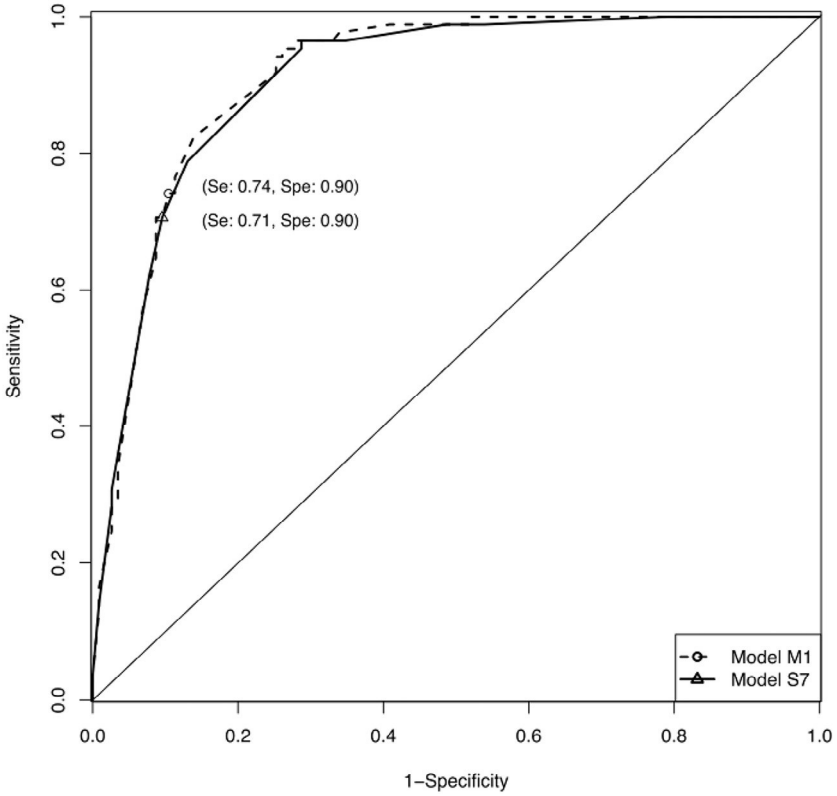

Fig. 1. Receiver operating characteristic curve of the score obtained using the full model (M1) and the RAPIDH score (S7). There is only a minor difference between M1 and the RAPIDH score. RAPIDH, radicular pain caused by disc herniation; Se, sensitivity; Spe, specificity.

Table 5
RAPIDH score (simplified weighted score)

Item	Points
Monoradicular leg pain	6
SLR≤60° or positive femoral stretch test	4
Unilateral ankle reflex decrease	4
Unilateral muscle weakness	3
Unilateral patient-reported pain in legs	3

SLR, straight leg raise; RAPIDH, radicular pain caused by disc herniation.
SLR≤60: SLR is positive if a typical leg pain is produced between 0° and 60°.
The patient is classified as having RAPIDH if the total score is 11 (range 0–20) or more (specificity 90.4%, sensitivity 70.6%).

Discussion

A multidisciplinary, international team developed and validated clinical classification criteria for radicular pain caused by LDH. The proposed criteria contained a majority of items relating to the clinician's examination rather than patient-reported symptoms, and differentiated patients with radicular pain caused by LDH from those with LSS or non-NSLBP with referred leg pain. We propose an easy-to-use weighted score of retained items, the RAPIDH criteria, to identify individuals with radicular pain caused by LDH for use in clinical and population-based research studies.

Despite the large number of items collected at the beginning of the present study, it is notable that the five included in the final classification criteria are classic signs and symptoms of nerve root involvement [22].

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The item with the highest weight was monoradicular leg pain distribution. This pattern of pain distribution has been classically reported as characterizing nerve root pain [23,24], although a study using pain drawing did not confirm this statement [25]. This item might be influenced by the physician's expertise and has a component of subjectivity as reflected by poor reproducibility [26,27]. The other items from physical examination have moderate to good reproducibility with kappa values ranging from 0.5 to 0.7 [28]. Only one item has been derived from patient history (ie, unilateral leg pain) and has not been previously reported for the diagnosis of radicular pain caused by LDH [28–31].

The five items in the classification criteria derived from the statistical analysis had a different impact on the diagnosis of radicular pain caused by LDH precluding a non-weighted set of items. For ease of use, a weighted set of items with rounded figures was derived (RAPIDH score) without significantly altering the performance (AUC 0.903 vs. 0.909). In creating our clinical classification criteria, we sought high specificity to avoid the inclusion of falsely positive cases in the research setting. Thus, the RAPIDH score should not be used as a diagnostic tool because it might misdiagnose individuals with atypical presentations of radicular pain. In clinical practice where sensitivity may be equally important, different clinical criteria may be needed [10].

There have been a few studies focusing on the diagnosis of radicular pain caused by LDH [29,30,32,33], but none of them set the goal of defining classification criteria. All these studies were conducted in single center and none used a specific method to select the items that were clinically tested. One study focused on patients undergoing surgery and used "relief of sciatica at 2 years" as the reference point [33]. Another focused on items from patient-reported symptoms [30], and a third one explored the value of needle EMG [29]. The study most similar to the current one [34] used imaging (magnetic resonance imaging showing nerve root compression by the disc material) as the gold standard, without considering clinical correlation. As nerve root compression on imaging has been reported in asymptomatic individuals [3], its presence does not ascertain that it is the cause of the symptoms.

Strengths

The methods used in the present study complied with published recommendations [9]. In particular, in the absence of valid objective criteria, the diagnosis relied on expert opinion, and two different panels of spine specialists were involved in the item selection process and the clinical evaluation. The items included in the RAPIDH score are frequently reported in clinical research [10] and are in agreement with published guidelines [35], thus supporting face validity. The content validity of this classification criteria is also good as the studied population included patients with radicular pain involving L3–S1 nerve roots. The inclusion of a heterogeneous population of patients with back and associated leg pain at baseline helps ensure that these classification criteria have good construct validity.

Limitations

Although expert opinion was used as the gold standard for the patient's diagnosis in the absence of pathognomonic tests, it represents an intrinsic bias. In the present study, it is likely that the physicians' report of findings was influenced by what they thought was the final diagnosis. Moreover, these results only apply to evaluations performed by spine specialists. In particular, as the item "monoradicular leg pain distribution" has the highest weight in the final classification criteria, the use of the item in a population

assessed by non-specialist physicians less familiar with this concept might decrease the accuracy of the final criteria.

The use of items focused on a specific nerve root deserves specific consideration. The presence of a "unilateral ankle reflex decrease" in the final set increases the diagnostic probability of S1 radiculopathy compared with other levels of lumbar radiculopathy and lowers the sensitivity of the RAPIDH criteria. L5 nerve root reflex has been reported [36] but is rarely acknowledged in the literature [26]. This may explain why it was not selected by the spine specialists during the Delphi process. The "unilateral patellar reflex decrease" (assessing L3 or L4 nerve roots) was more frequently found in patients with radicular pain caused by LDH (see Supplementary Appendix B) but did not remain statistically significantly associated with the diagnosis when integrated in the model (Table3, S3). However, it is important to note that the RAPIDH criteria apply to any radicular pain from L3 to S1.

Conclusions

The present study proposes clinical classification criteria using a set of five items with good specificity and sensitivity for identifying patients with radicular pain caused by LDH. Although this set of items requires validation in different patients and settings, we believe that such criteria represent an important step in the field of spinal pain research and will contribute to improving the quality of future studies and the evaluation of future treatments.

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Supplementary material

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