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Original Article

New diagnostic support tool for patients with leg symptoms caused by lumbar spinal stenosis and lumbar intervertebral disc herniation: A self-administered, self-reported history questionnaire

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ABSTRACT

Background: There are no diagnostic support tools composed of a simple, single-sheet, self-administered, self-reported history questionnaire (SSHQ) for patients with leg symptoms caused by either lumbar spinal stenosis (LSS) or lumbar disc herniation (LDH), at the same time, can discriminate the two diseases.

Methods: We conducted retrospective and prospective derivation studies and a prospective validation study. Based on data from 137 patients with LSS and 206 with LDH, we identified key prediction factors to establish the diagnosis of LSS and LDH, which became the basis of a temporary SSHQ. Next, we performed a prospective derivation study in which 296 patients with LSS or LDH completed preoperatively this temporary SSHQ. After univariate and multivariate analyses of each question, questions on both diseases in addition to age factor were selected, providing the final version of the SSHQ. A validation study was subsequently performed with 342 consecutive patients with leg symptoms. The sensitivity, specificity and likelihood ratio of this SSHQ were calculated to determine the cut-off points for LSS and LDH.

Results: A SSHQ with 15 questions was developed from retrospective and prospective derivation studies. The score of each question was weighted based on the multivariate analysis and then, it was approximated to integer value. According to assessment of the discriminatory performance of the clinical prediction rule of the SSHQ, the cut-off point for LSS was $\geq$13 and that for LDH was $\geq$11. The sensitivity, specificity, and positive and negative likelihood ratios of this SSHQ at those cut-off points were, respectively, 92.7%, 84.7%, 6.07, and 0.09 for LSS, and 91.0%, 85.2%, 6.15, and 0.11 for LDH.

Conclusions: This is the first report of a diagnostic support tool for patients with LSS- or LDH-induced leg symptoms combined in a single SSHQ that could help establish diagnosis of the two diseases in the daily clinical practice.

1. Introduction

Lumbar spinal stenosis (LSS) and lumbar intervertebral disc herniation (LDH) are the two most common causes of back and leg symptoms. LSS and LDH each produce characteristic symptoms. For

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example, most patients with LSS complain of intermittent claudication, but they usually have no other symptoms or only minor ones that can be relieved by sitting or lying down [1]. In contrast, patients with LDH often have difficulty in lumbar flexion, such as when putting on socks or lifting a heavy object. Their symptoms may also be induced when they cough, sneeze or urinate [2]. If all patients with LSS or LDH complained of the disease-specific typical symptoms, it might be easier to make a correct diagnosis. The clinical symptoms of patients with these two diseases, however, occasionally overlap. In addition, other diseases, such as arteriosclerosis obliterans (ASO), may cause similar symptoms. The greatest problem with making a correct diagnosis is that there are no gold standard criteria for LSS and LDH. Imaging studies such as computed tomography (CT) and magnetic resonance image (MRI), which show compression of neural tissues, are insufficient because false-positive and false-negative results are well documented [3–6]. The correct diagnosis of LSS and LDH are thus occasionally difficult not only for primary care physicians, but even for spine surgeons.

Although diagnostic support tools for LSS, composed of a simple questionnaire or a questionnaire plus short clinical examinations, have recently been developed [6–8], there are no such tools for LDH or for discriminating LSS from LDH. We hypothesized that a simple, single-sheet, self-administered, self-reported history questionnaire (SSHQ) that could clearly diagnose whether leg symptoms were caused by LSS or LDH would be useful for daily clinical practice of primary care physicians and orthopedic surgeons, particularly non-spine specialists. Patients would then benefit from an appropriate therapeutic approach without delay. We therefore attempted to develop a single-sheet SSHQ as a diagnostic support tool for LSS and LDH.

2. Methods

The study was approved by the Ethics Committee of Tohoku University School of Medicine and by the institutional review board of each study institution, as necessary. Written informed consent was obtained from each patient. Experienced spinal surgeons diagnosed LSS and LDH after comprehensive evaluations based on the patients' clinical symptoms and physical and radiological examinations. Other experienced physicians diagnosed ASO and diabetes mellitus (DM), when present. Patients with cervical and thoracic myelopathy, previous lumbar surgery, inflammatory lumbar disorders, and/or degenerative scoliosis defined as a Cobb angle of $\geq 10^{\circ}$ were excluded from the study.

2.1. Retrospective derivation study

A series of 137 patients with LSS and 206 patients with LDH whose symptoms were alleviated postoperatively in the Department of Orthopaedic Surgery, Fukushima Medical University and the Department of Orthopaedic Surgery, Sendai-Nishitaga National Hospital were included in this study. The male/female ratio was 63/74 for LSS and 133/73 for LDH. The averaged age was 68 ± 9 years (range, 51–83 years) for LSS and 41 ± 17 years (range, 16–80 years) for LDH.

The patient's symptoms, physical examination, and MRI findings were evaluated in the same way as in our previous study [6]. Patients' age, location, frequency, and severity of pain, symptoms including numbness/tingling sensations, and provocation factors of the symptoms, such as lumbar flexion and extension, were recorded. The physical examination included (1) a gait-load test to confirm neurogenic intermittent claudication and (2) neurological examination [6]. MRI scans were also evaluated. Based on these data, we identified key prediction factors for diagnosing LSS and LDH and then developed a temporary SSHQ as a diagnostic support tool for the two diseases, according to our previous study [6].

2.2. Prospective derivation study

This study was performed at six university hospitals and 66 affiliated hospitals and clinics. A series of 296 patients with LSS, LDH, and other diseases that could cause leg symptoms gave informed consent to participate in the study. There were 99 patients with LSS (male/female = 58/41, age = 70 ± 9 (46–88) years), 97 with LDH (64/33, 45 ± 16 (18–81) years), 34 with ASO (28/6, 72 ± 8 (50–84) years), 27 with DM (15/12, 61 ± 9 (40–78) years), 34 with lumbar spondylosis (16/18, 67 ± 16 (44–88) years), and 5 with other miscellaneous diseases (2/3, 61 ± 13 (47–74) years).

We asked all of the patients to complete the temporary SSHQ. The sensitivity of each question was calculated for patients with LSS or LDH and compared with that of patients without LSS or LDH using univariate and multivariate analyses. Regarding age, we compared the β value of LSS patients whose age were $\geq$60 vs. <60 years and $\geq$70 vs. <70 years. We also compared that value of LDH patients of ages $\leq$30 vs. >30 years, $\leq$40 vs. >40 years, $\leq$50 vs. >50 years, $\leq$60 vs. >60 years, and $\leq$70 vs. >70 years in a univariate analysis, thereby addressing whether age was a predicting factor. Based on these analyses, the final version of the SSHQ was completed in which each question was weighted depending on the LSS and LDH results.

2.3. Prospective validation study

We prospectively evaluated the validity of the final version of the SSHQ. This study was performed at six university hospitals and 107 affiliated hospitals and clinics. The subjects of this study were patients with leg symptoms, including those with LSS, LDH, ASO, DM, and miscellaneous other diseases.

We enrolled 342 consecutive patients: 180 with LSS (male/female 100/80, 69 ± 10 (38–89) years), 109 with LDH (74/35, 44 ± 16 (18–82) years), and 53 with diseases other than LSS and LDH: 29 with ASO (25/4, 73 ± 7 (55–83) years), 22 with DM (14/8, 65 ± 12 (43–78) years), and 2 with other diseases (2/0, 59 (55 and 63) years). We asked all of the patients to complete the SSHQ, after which the scores for each question of each patient were summed to create a total score. The total score of the patients with or without LSS/LDH was statistically compared to determine the cut-off point of each disease in this SSHQ.

2.4. Statistical analysis

In the prospective derivation study, the relationships between LSS/LDH and each question were evaluated by univariate logistic regression analysis. All questions with a value of $p < 0.05$ and the results of stratified age groups depends on each disease were entered into a multivariate logistic regression analysis. A score-based prediction rule for the final version of the LSS/LDH SSHQ was developed according to the results of the multivariate logistic regression analysis. The score of each question of the SSHQ was defined based on the β-value to generate a simple integer value.

In the prospective validation study, after the overall score for each patient was calculated by summing up the score of each question, the sensitivity, specificity and likelihood ratios of the SSHQ were calculated. According to these results, the area under the receiver operating characteristic (ROC) curve (AUC) was estimated. Then, the final cut-off point for the presence of LSS/LDH was determined, which was defined as the point with the highest sum of the sensitivity and specificity. All statistical analyses were performed using SAS software (SAS Institute, Cary, NC, USA).