

Review began 12/04/2023

Review ended 12/07/2023

Published 12/13/2023

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Lateral Lumbar Spinal Stenosis: Associations With the Oswestry Disability Index, Visual Analogue Scale, and Magnetic Resonance Imaging

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Abstract

Introduction

Degenerative lumbar spinal stenosis is a communal problem in the sixth decade of life involving L4/L5 and L5/S1 levels. Lateral spinal stenosis is often underestimated because of no established relationship between the clinical symptoms and MRI findings. We conducted a study to establish an association between the degree of anatomical lateral stenosis, posterior disc height, and disc degeneration from MRI with the daily disability and pain severity for lateral lumbar spinal stenosis.

Methods

This was a cross-sectional study involving 121 patients with distinct clinical symptoms of lateral lumbar spinal stenosis evaluated from February 2018 to December 2019. The clinical data were evaluated using the Oswestry Disability Index (ODI) and Visual Analogue Scale (VAS), while magnetic resonance imaging (MRI) was assessed qualitatively for the anatomical gradation of lateral spinal stenosis, the magnitude of posterior disc height, and the extent of disc degeneration. Statistical analysis for the correlation between posterior disc height and ODI and VAS scores was evaluated using Pearson's correlation test via SPSS version 23.0 (IBM Inc., Armonk, New York), and the association between the extent of lateral stenosis and disc degeneration on MRI with ODI and VAS scores was determined by the Fisher Exact Test via STATA version 14.0 (StataCorp LLC, College Station, Texas). The association was considered statistically significant with a P-value of less than 0.05.

Results

The analysis of 121 patients showed the mean age of the patients was 58.7 ± 7.1 years old. The number of female patients was higher compared to male patients, 52.9% and 47.1%, respectively. 97.5% of the patients were married or cohabiting, and 76.0% had an abnormal body mass index. The mean score of ODI and VAS was $62.2 \pm 10.7\%$ and 79.3 ± 8.6 respectively. 49.6% of the patient presented with a crippling disability with ODI assessment, while 59.5% presented with high pain intensity with VAS assessment. MRI assessment of anatomical grading lateral stenosis of L4/L5 level revealed that 45.5% of the patients had grade 2 lateral recess stenosis, 63.6% had grade 2 foraminal stenosis, and 44.6% had extraforaminal stenosis. L5/S1 level analysis showed that 43.0% had grade 2 lateral recess stenosis, 62.0% had grade 2 foraminal stenosis, and 29.8% had extraforaminal stenosis. 64.5% of patients had grade 4 disc degeneration of L4/L5 with mean posterior disc height of $7.0\text{mm} \pm 1.7\text{mm}$ while 59.5% had grade 4 disc degeneration of L5/S1 with mean posterior disc height of $6.3\text{mm} \pm 1.8\text{mm}$. However, no statistically significant association between clinical symptoms and MRI findings was found.

Conclusions

There was no significant association between the clinical symptoms of pain and disability and the MRI findings for the anatomical gradation of lateral spinal stenosis, the magnitude of posterior disc height, and the extent of disc degeneration. A comprehensive clinical evaluation remains essential for an accurate diagnosis, emphasizing the necessity of appropriately correlating MRI findings with their clinical significance.

Categories: Rheumatology, Radiology, Orthopedics

Keywords: magnetic resonance imaging (mri), clinical features, visual analogue score, oswestry disability index, lateral spinal stenosis

Introduction

Lateral lumbar spinal canal stenosis is a degenerative disease resulting from the cumulative narrowing of the

How to cite this article

Norisyam Y, Salim A A, Bahrin Z, et al. (December 13, 2023) Lateral Lumbar Spinal Stenosis: Associations With the Oswestry Disability Index, Visual Analogue Scale, and Magnetic Resonance Imaging. Cureus 15(12): e50475. DOI 10.7759/cureus.50475

lateral recess and intervertebral foramen of the spinal canal, causing impingement on the nerve root. This narrowing occurs due to the hypertrophy of surrounding osseocartilaginous and ligamentous structures as part of the degenerative process. The anatomical elements of lateral lumbar stenosis can be categorized into lateral recess, foraminal, and extraforaminal stenosis. Degenerative spinal stenosis is a common presentation that can result in significant disability and have a negative impact on the patient's quality of life. Many patients present in their sixth decade of life, where degeneration plays a significant role, and most exhibit lateral canal stenosis affecting both sides of the L4/L5 and L5/S1 levels [1,2].

In clinical practice, magnetic resonance imaging (MRI) is considered the gold standard modality for diagnosing patients with lumbar spinal stenosis [3,4]. Accurate pre-intervention diagnosis is vital to achieving satisfactory treatment outcomes for patients [5].

Previous studies on lumbar stenosis have predominantly focused on patients with central canal stenosis [2], leaving a gap in clinical data and literature concerning the association between clinical symptoms and disability and the severity of lumbar spinal stenosis as determined by MRI. It was anticipated that lateral lumbar spinal stenosis would exhibit more pronounced clinical manifestations due to the limited anatomical space for nerve roots in comparison to central stenosis. However, the diagnosis and assessment of lateral stenosis are often overlooked or underestimated, as there is a lack of a well-defined association between the radiological degree of stenosis and the severity of pain and daily disability.

The primary objective of this study is to assess the connection between clinical symptoms and disability and the anatomical gradation of lateral spinal stenosis, the magnitude of posterior disc height, and the extent of disc degeneration as determined through MRI assessment.

Materials And Methods

This research has been approved by the Human Research Ethics Committee of the authors' affiliated institution with the approval Code USM/JEPeM/17080369, and the patients provided written informed consent.

Patients

This was a cross-sectional study carried out at the University of Sciences, Malaysia, from February 2018 to December 2019. The study subjects involved 121 patients aged 50 years and older who presented at the clinic with clinical presentations suggestive of lateral lumbar spinal stenosis. They underwent magnetic resonance imaging after assessments by orthopedic spine surgeons following established treatment failure over three months of non-operative therapy.

The exclusion criteria for patient selection included those who presented with only back pain, had a primary diagnosis of malignancy, experienced a recent spinal fracture within three months, underwent lumbosacral spinal surgery, had spondylitis, or had congenital spinal anomalies. Patients with cognitive impairment prohibiting completion of the questionnaires were also excluded from the study. By MRI, only patients with moderate central canal stenosis with predominant radiculopathy and claudication clinically were included, excluding patients with severe central canal stenosis.

Assessment of clinical symptoms

The level of disability experienced by the patients was evaluated using the Oswestry Disability Index (ODI) to validate a response to chronic lower back pain, as established by Fritz et al. [6]. It is considered the most effective for the evaluation of persistent severe disability, as concluded by Davies et al. [7]. Most authors use the ODI to evaluate the association and correlation of the disability index with magnetic resonance imaging findings [8-12].

The overall current low back and leg pain severity can be evaluated by a self-administered Visual Analog Scale (VAS) with a range of 0-100mm during outpatient clinic follow-up, as validated by Delgado et al. [13]. Most authors use the VAS to determine the association and correlation of pain intensity with magnetic resonance imaging findings [2,11,12].

Completion of a data collection sheet for demographic data and assessment of clinical symptoms by ODI and VAS questionnaires must be done within three months after the MRI evaluation.

Magnetic resonance imaging

All patients were undergoing the same study protocol for study purposes. MR imaging of the lumbar spine was performed in a supine position with both knees flexed using a 3.0-T MRI system (Achieva 3.0T TX; Philips Healthcare, Best, Netherlands). Fast spin echo (FSE) T1-weighted and T2-weighted images were obtained in the axial and sagittal planes. The protocol comprised sagittal T1 FSE (T1 fast spin echo, TR 400msec, TE 10ms); sagittal T2 FSE (TR 3160msec, TE 120msec); axial T2 FSE (TR 4740msec, TE 120 msec). For all sequences, a 4 mm slice thickness was used. The intersection gap was 0.6-1.3 mm, and the echo train

lengths were 6 and 30 for T1 and T2 weighted imaging, respectively.

Imaging examinations

MRI analysis was conducted with the assistance and guidance of a radiologist, involving the qualitative grading of nerve root compression in the lateral recess, foraminal, and extraforaminal areas. Additionally, it included the quantitative grading of posterior disc heights and the qualitative grading of disc degeneration at the bilateral L4/L5 and L5/S1 levels. The analysis was performed in a blinded manner, without knowledge of the clinical findings and radiological reports.

Weishaupt et al. introduced a grading system for nerve root compression in the lateral recess, utilizing T2-weighted images at the axial inferior endplate. The grades were assigned as follows: 0 for no contact of the nerve root with the disc, 1 for nerve root contact without deviation, 2 for nerve root contact with deviation, and 3 for nerve root compression [14]. An illustrative example of MRI evaluation for lateral recess stenosis is depicted in Figure 1, with a small red arrow indicating grade 1 stenosis (disc in contact with nerve root without deviation) and a large red arrow indicating grade 2 stenosis (evident deviation of the nerve root).

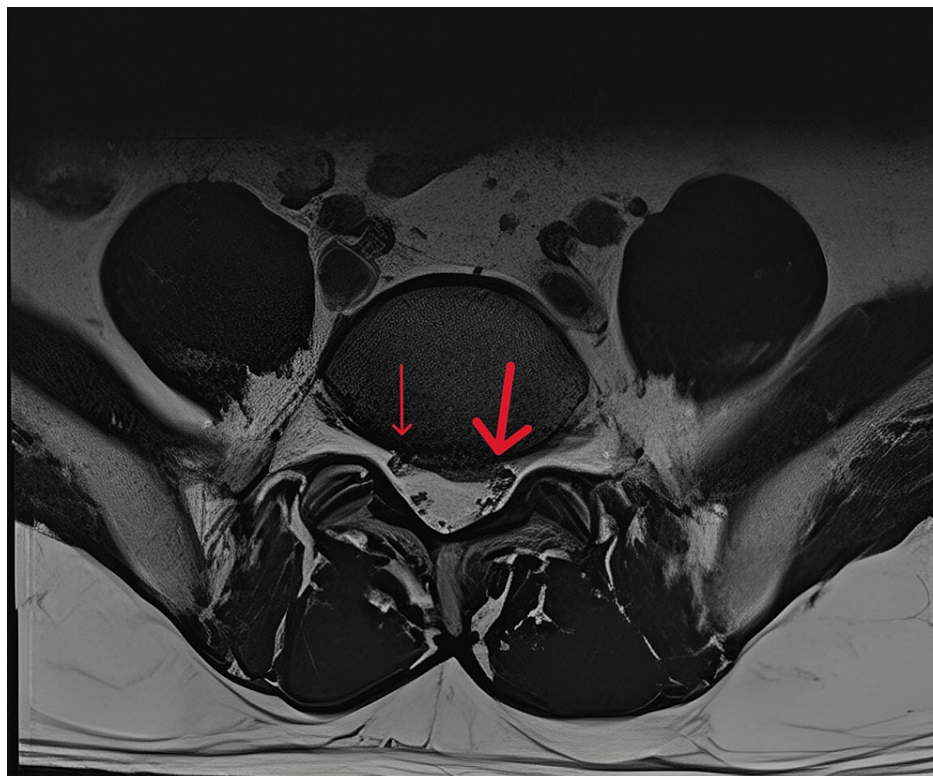


FIGURE 1: Axial view of T2-weighted MRI, with a small red arrow indicating grade 1 stenosis where the disc is in contact with the nerve root without deviation, while a large red arrow shows grade 2 stenosis with evident deviation of the nerve root

The qualitative assessment of foraminal stenosis, based on T1-weighted parasagittal images, was graded as follows: grade 0 for normal foramina, grade 1 for mild foraminal stenosis, grade 2 for moderate foraminal stenosis, and grade 3 for severe stenosis. This grading was determined by Wildermuth et al. [15]. An example of MRI evaluation for foraminal stenosis is shown in Figure 2, with a small red arrow indicating grade 1 stenosis and a large red arrow indicating grade 2 stenosis (epidural fat only partly surrounding the nerve root).

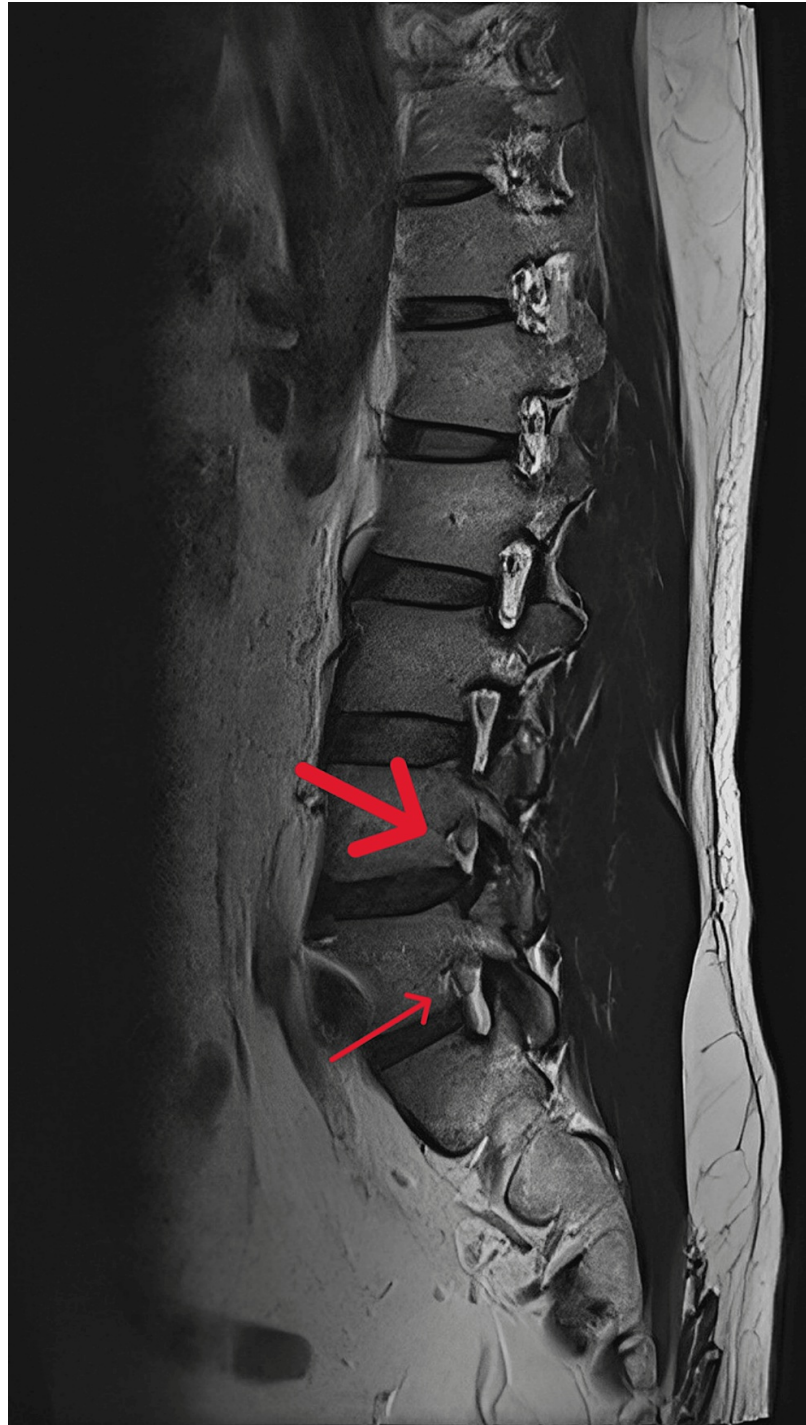


FIGURE 2: Parasagittal view of T1-weighted images of MRI, with a small red arrow indicating grade 1 stenosis, featuring compression of the epidural fat where the remaining fat still completely surrounds the nerve root, and a large red arrow indicating grade 2 stenosis, where the epidural fat only partly surrounds the nerve root

Extraforaminal nerve root entrapment was evaluated from T1-weighted axial images at the center of a disc, with an evident circumferential loss of perineural fat signal, and was graded as either yes or no entrapment [16-18]. The MRI assessment of extraforaminal stenosis is depicted in Figure 3, with a small red arrow indicating no stenosis and a large red arrow indicating extraforaminal stenosis (absence of perineural fat signal).

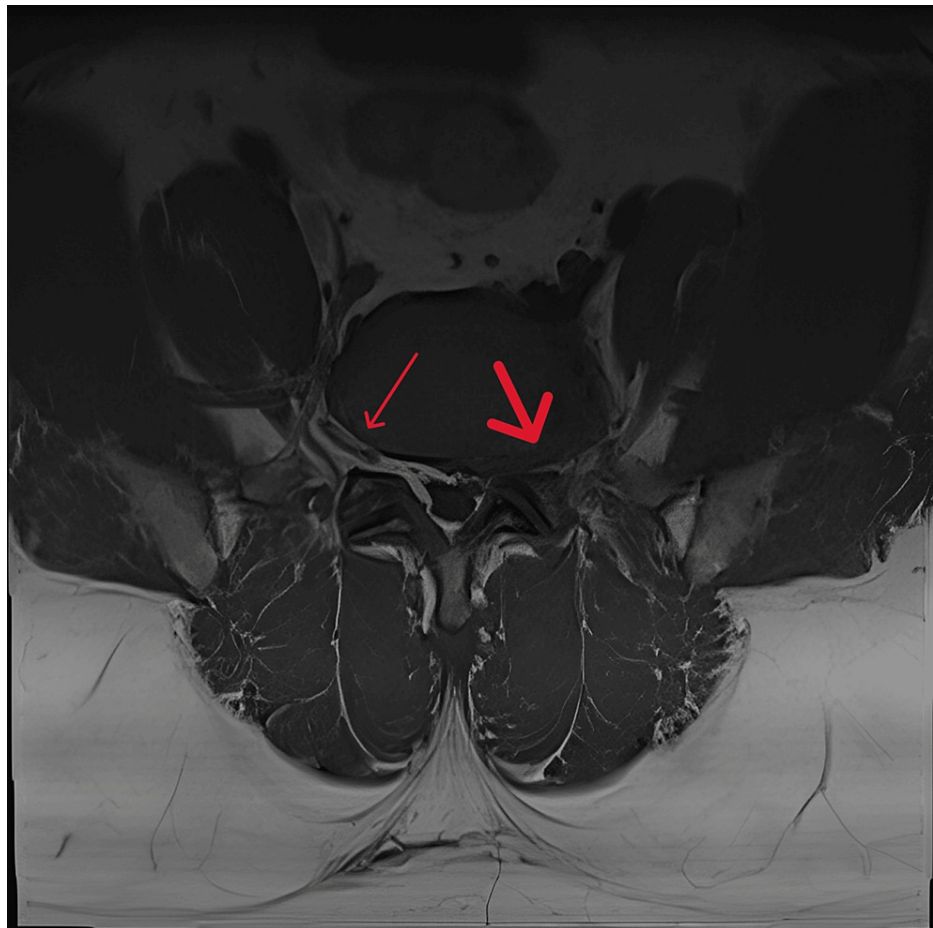


FIGURE 3: Axial view of T1-weighted MRI images, with a small red arrow indicating no stenosis and a large red arrow indicating extraforaminal stenosis with an absence of perineural fat signal

Cinotti et al. proposed a quantitative assessment of posterior disc height, calculated from a T2-weighted mid-sagittal view as the shortest distance between the adjacent superior and inferior endplates [19]. Pfirrmann's Grading System was used to score the degree of lumbar intervertebral disc degeneration from a T2-weighted midsagittal view. The grades were as follows: 1 for a homogeneous bright white disc with a clear distinction of nucleus and annulus structure, 2 for an inhomogeneous bright white disc with a clear distinction of nucleus and annulus structure, 3 for an inhomogeneous grey disc with an unclear distinction of nucleus and annulus structure and a slightly decreased disc height, 4 for an inhomogeneous grey to black disc with a loss of distinction of the nucleus and annulus structure and a moderately decreased disc height, and 5 for an inhomogeneous black disc with a loss of distinction of the nucleus and annulus structure and a collapsed disc space [20,21].

Statistical analysis

Data analysis was conducted using Statistical Packages for Social Science (SPSS) version 23.0 and STATA version 14.0. When patients had multilevel spinal stenosis, the level and side with the worst stenosis were selected for the study's association. The same principle was applied for the assessment of posterior disc height and grade of disc degeneration in L4/L5 and L5/S1, with the worst score chosen for the association analysis.

The correlation between posterior disc height and ODI and VAS scores was evaluated using Pearson's correlation test via SPSS version 23.0 (IBM Inc., Armonk, New York).

The association between the extent of lateral stenosis and disc degeneration on MRI with ODI and VAS scores was determined by the Fisher Exact Test via STATA version 14.0 (StataCorp LLC, College Station, Texas). This test was chosen as a replacement for the Chi-squared test, as it is more accurate for small cell sizes with expected values less than five. The result of the association was considered statistically

significant, with a p-value of less than 0.05.

Results

A total of 121 patients were clinically evaluated for degenerative lateral lumbar spinal stenosis, and patient characteristics are summarized in Table 1. The assessment of ODI scores showed that patient symptoms and disability ranged from a minimal score of 24% to a maximal score of 92%, with a mean value of 62.2% ± 10.7%. Based on the percentage disability score of the ODI, out of the 121 patients, one patient (0.8%) demonstrated moderate disability, 53 patients (43.8%) had a severe disability, 60 patients (49.6%) were crippled, and seven patients (5.8%) were bedridden.

Variables	Results
Age (year)	58.7 (range 50 -77)
Male/female	57/64 (47.1/52.9)
Married	118 (97.5)
Height (cm)	158.2 (12.0)
Weight (kg)	71.9 (11.5)
BMI (kg/m2)	29.1 (6.0)
ODI score	62.2 (10.7)
VAS score	79.3 (8.6)

TABLE 1: Clinical characteristics of the study subjects with lateral spinal stenosis (n=121)

Data are numbers of patients (n), with percentages in parentheses or means, ± standard deviations in parentheses

ODI - Oswestry Disability Index; VAS - Visual Analogue Pain Scale

According to VAS scores, patient pain intensity ranged from a minimal score of 55 to a maximal score of 90, with a mean value of 79.3 ± 8.6. In the overall VAS scores, six patients (5.6%) had severe pain (scores 41-60), 72 (59.5%) had high pain (scores 61-80), and 43 (35.5%) had very high pain (scores 81-100). None of the patients had minimal to moderate pain. Table 2 summarizes the analysis of anatomical lateral stenosis at L4/L5, while Table 3 provides the analysis for L5/S1 based on MRI findings.

L4/L5 level	Grades			
	0	1	2	3
Lateral Recess n (%)	7 (5.8)	18 (14.9)	55 (45.5)	41 (33.9)
Intraforaminal n (%)	0	27 (22.3)	77 (63.6)	17 (14.0)
Extraforaminal n (%)	54 (44.6)			

TABLE 2: Number of grades of lateral lumbar stenosis for lumbar levels L4/L5 (n=121)

Data are numbers of patients (n), with percentages in parentheses

L5/S1 level	Grades			
	0	1	2	3
Lateral Recess n (%)	7 (5.8)	50 (31.4)	52 (43.0)	12 (9.9)
Intraforaminal n (%)	2 (1.7)	25 (20.7)	75 (62.0)	19 (15.7)
Extraforaminal n (%)	36 (29.8)			

TABLE 3: Number of grades of lateral lumbar stenosis for lumbar levels L5/S1 (n=121)

Data are numbers of patients (n), with percentages in parentheses

Through MRI analysis, the posterior disc height at L4/L5 demonstrated a mean of 7.0 mm \pm 1.7 mm, ranging from 2.3 mm to 11.9 mm. Similarly, at the L5/S1 level, the mean posterior disc height was 6.3 mm \pm 1.8 mm, ranging from 1.5 mm to 10.4 mm. The evaluation of intervertebral disc degeneration at L4/L5 and L5/S1 is detailed in Table 4.

Lumbar level	Grades				
	1	2	3	4	5
L4/L5 n (%)	0	0	36 (29.8)	78 (64.5)	7 (5.8)
L5/S1 n (%)	0	1 (0.8)	34 (28.1)	72 (59.5)	14 (11.6)

TABLE 4: Grades of lumbar disc degeneration for lumbar levels L4/5 and L5/S1 (n=121)

Data are numbers of patients (n), with percentages in parentheses

No statistically significant correlation was found between posterior disc height and the distribution of ODI and VAS scores. For the L4/L5 level, the Pearson's correlation coefficient (r) was 0.11 (p=0.22) for ODI and 0.06 (p=0.95) for VAS. At the L5/S1 level, the correlation coefficients were -0.41 (p=0.65) for ODI and 0.74 (p=0.41) for VAS. Figures 4-7 depict scatterplots illustrating the relationship between posterior disc height and the distribution of ODI and VAS scores.

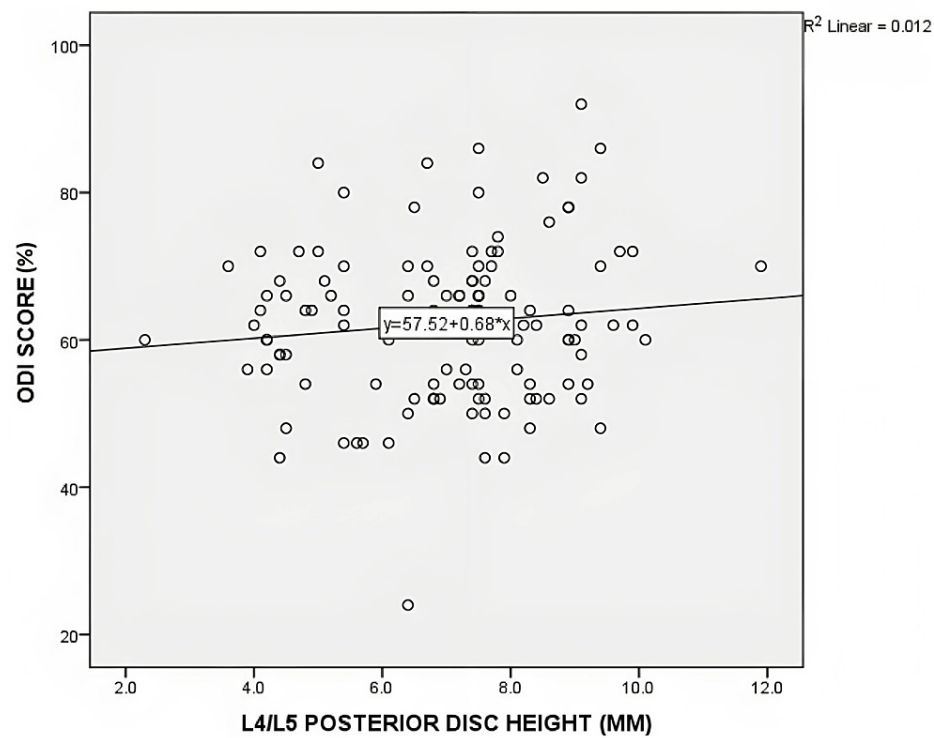


FIGURE 4: Scatterplot graph of correlation between the posterior disc height of L4/L5 on MRI with ODI score (n=121)

MRI - magnetic resonance imaging; ODI - Oswestry Disability Index scale

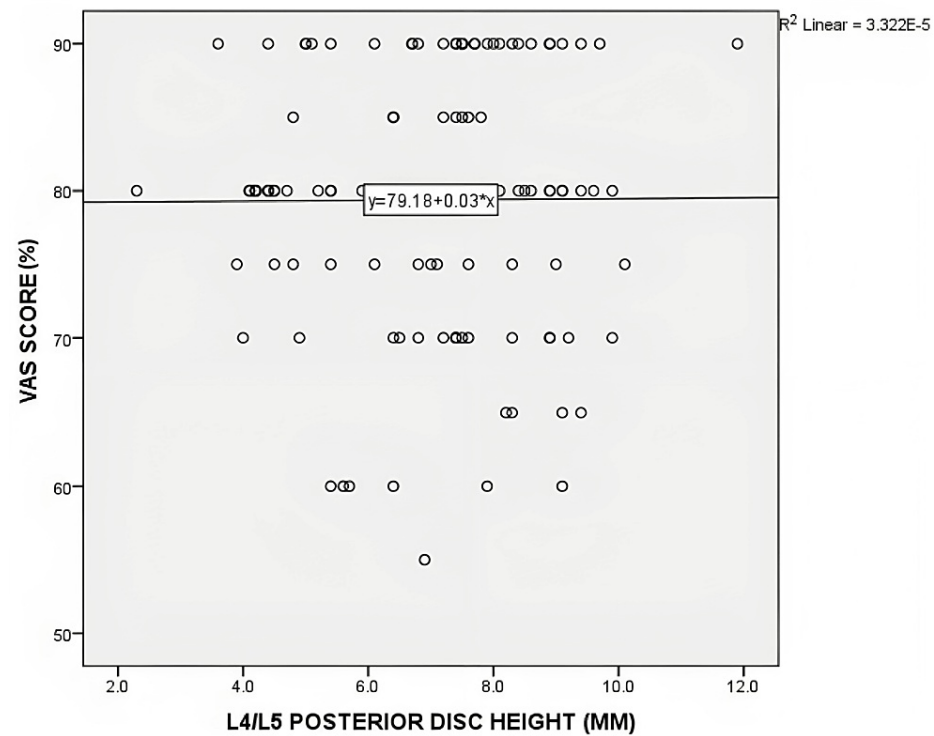


FIGURE 5: Scatterplot graph of correlation between the posterior disc height of L4/L5 on MRI with VAS score (n=121)

MRI - magnetic resonance imaging; ODI - Oswestry Disability Index scale

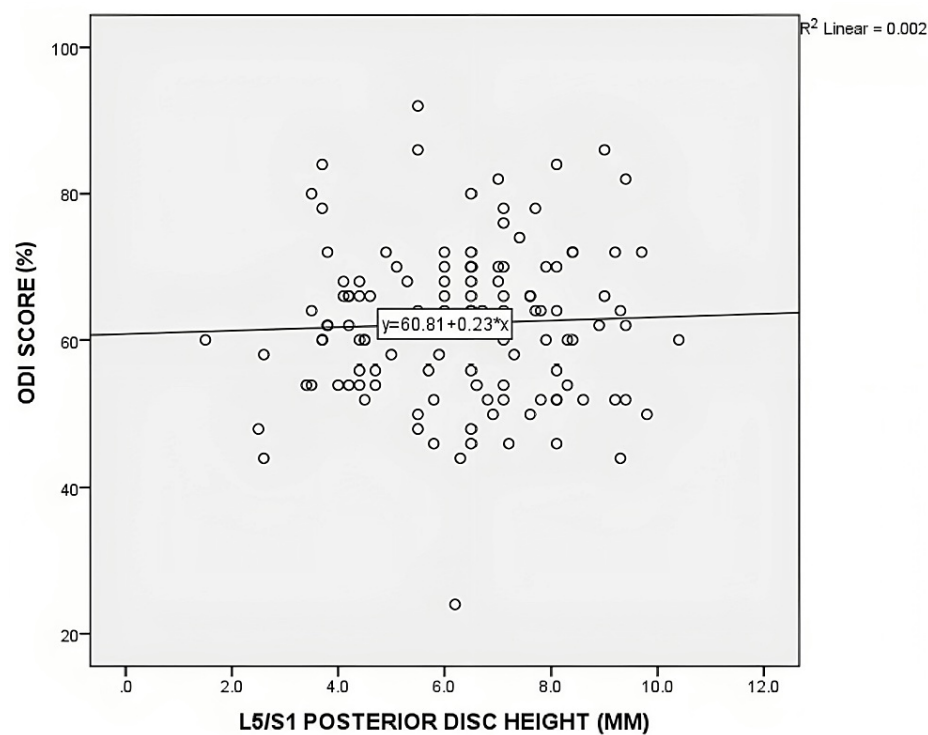


FIGURE 6: Scatterplot graph of correlation between the posterior disc height of L5/S1 on MRI with ODI score (n=121)

MRI - magnetic resonance imaging; ODI - Oswestry Disability Index scale

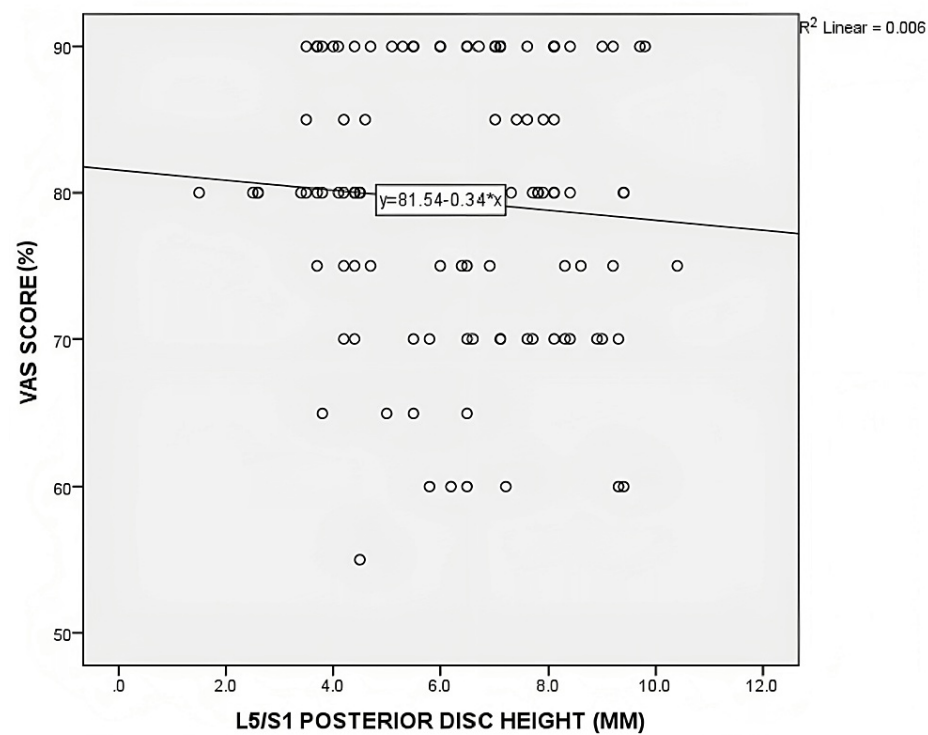


FIGURE 7: Scatterplot graph of correlation between the posterior disc height of L5/S1 on MRI with VAS score (n=121)

MRI - magnetic resonance imaging; ODI - Oswestry Disability Index scale

Further statistical analysis, conducted in line with the study's objectives, revealed no statistically significant association between the distribution of ODI and VAS grading, the anatomical grading of lateral recess stenosis, foraminal stenosis, extraforaminal stenosis, or disc degenerative grading, as detailed in Table 5.

MRI findings	ODI*	VAS*
Grading of lateral recess stenosis	0.824	0.822
Grading of foraminal stenosis	0.622	0.227
Grading of the extraforaminal stenosis	0.442	0.952
Disc degenerative grading	0.562	0.966

TABLE 5: Association between the anatomical grading of lateral recess stenosis, anatomical grading of foraminal stenosis, grading of the extraforaminal stenosis and the disc degenerative grading based on MRI with ODI and VAS grading (n=121)

Data are number of p-value based on the Fisher-Eexact test* All p-values less than 0.05 were considered, as statistically significant.

MRI - magnetic resonance imaging; ODI - Oswestry Disability Index scale

Discussion

Based on our findings, the mean age of the sample participants was 58.7 years. We specifically targeted the sixth decade of life to yield optimal results, as this period significantly contributes to the degenerative process, particularly due to relative estrogen deficiency, resulting in a higher prevalence among females.

The majority of the patients were married or cohabiting, which is important to achieve good results since almost all the patients have similar family environmental and psychosocial contributions. This similarity is reflected fairly in the severity of symptoms, as it was the main determinant for the subjective experience of pain and disability among the patients. Most of the patients had an abnormal body mass index, with 76% of them being overweight or obese. This finding is consistent with the fact that obesity is strongly related to biomechanical changes contributing to degenerative lumbar stenosis. An increased body mass index will result in higher shear forces that overload the joints and torque on the lumbar disc, potentially leading to facets and disc degeneration.

Analysis of lateral lumbar stenosis revealed a notably higher prevalence of lateral recess stenosis at the L4/L5 level, affecting 79.4% of patients with moderate to severe compression, compared to 52.9% at the L5/S1 level. The prevalence of moderate to severe foraminal stenosis was consistent at both levels, affecting 77.7% of the patients. These findings align with previous studies indicating a greater occurrence of severe lateral stenosis at the L4/L5 level and severe foraminal stenosis at the L5/S1 level based on MRI assessments and their association with clinical symptoms in the general population, as concluded by Ishimoto et al. [22]. This observation can be explained by the susceptibility of the lower lumbar region, especially the L4/L5 level, to high mechanical stress, connecting a mobile segment of the lumbar spine to a relatively rigid sacrum and pelvis.

Examining the prevalence of extraforaminal stenosis, the L4/L5 level showed a higher involvement (44.6%) compared to the L5/S1 level (29.8%). This result is consistent with a prior study by Lee et al. that reported a 39.5% occurrence of extraforaminal stenosis [23]. The phenomenon is attributed to the loss of intervertebral disc height due to disc degeneration, leading to the anterosuperior subluxation of the superior articular process of the inferior vertebra, causing stenosis.

The calculated mean posterior disc height in symptomatic patients was 7.0 ± 1.7mm for the L4/L5 level and 6.3±1.8mm for the L5/S1 level, significantly lower than the measurements in normal subjects, which were 10.1±1.0mm and 8.5 ± 1.0mm, respectively [24]. A separate cadaveric dissection study by Cinotti et al. showed an average posterior disc height of 6.55 ± 1.7mm for L4/L5 and 5.29 ± 1.9mm for L5/S1 [19].

The majority of our patients exhibited degenerated lumbar discs, with 64.5% graded as Pfirrmann grade 4 for L4/L5 and 59.5% for L5/S1. Additionally, 5.8% were graded as 5 for L4/L5, and 11.6% for L5/S1. In comparison, a previous study reported lower rates of disc degeneration, with Pfirrmann grade 4 at 34.5% for L4/L5 and 33.7% for L5/S1, while showing similar findings for L5/S1 disc degeneration as published by Middendorp et al. [9]. The observed differences are likely due to degenerative changes within the intervertebral discs, characterized by the loss of water content, diminished nutritional transport, and reduced proteoglycan content. Disc aging leads to changes, particularly in the nucleus, becoming less

gelatinous and more fibrous. These significant changes can manifest as the loss of homogeneous brightness of the disc with a diminished clear distinction between the nucleus and annulus, as well as a decrease and collapse of the disc height as observed on MRI."

Our study suggests challenges in reliably diagnosing lateral lumbar stenosis based solely on imaging findings, as there appears to be an inconsistency between clinical symptoms and imaging results. This inconsistency may be attributed to the limited capability of MRI in identifying nerve root compression adequately.

Static images of canal dimensions might not predict a patient's symptoms without assessing the dynamic nature of the disease process. The degree of compression is dynamic and likely varies based on the patient's condition. The limitations of our study lie in conducting routine clinical MRI with patients in a supine position, which may not reflect symptoms that worsen in an upright position due to alterations in nerve element compression. Therefore, upright MRI imaging, especially under axial loading, becomes crucial for a comprehensive assessment, as it causes displacement of anatomical structures leading to nerve root compression, not observed in the supine position, as suggested by Beattie et al. [25].

The absence of association in our study might also be linked to the fluctuating nature of symptoms over time, potentially following a natural course that could either improve or remain stable, thereby affecting the perceived pain and disability of the patient [26].

Pain and disability experienced by the patient are subjective and influenced by emotional, psychological, and genetic factors. Although we evaluated disability using the ODI score, which is widely accepted and has strong psychometric properties, it remains subjective and may not consistently correlate with the severity of radiological spinal stenosis [27].

A comprehensive history and thorough physical examination are essential for diagnosing degenerative lateral spinal stenosis. While MRI evidence of nerve compression is necessary, it should be clinically assessed before being attributed solely as the cause of back pain. Therapy should be directed towards the patient's most disturbing symptoms rather than solely relying on the severity of radiographic narrowing.

This study aims to establish a robust predictive value concerning the relationship between clinical symptoms, disability, and MRI imaging. The research featured a selectively chosen elderly population aged 50 years and above, specifically targeting those with typical presentations while excluding patients with severe central stenosis. To ensure data quality, symptom recording and disability assessment were carried out solely by the principal investigator, while a detailed visual qualitative MRI analysis was conducted by an experienced radiologist.




Several limitations were identified in this study. It's important to note that this was a cross-sectional study, limiting its ability to provide conclusive evidence for the broader population. Furthermore, the study encompassed a relatively small sample size recruited exclusively from our center. Additionally, MRI evaluations were not conducted at the peak of clinical symptoms and disability but rather within three months of their presentation due to constraints in immediate MRI availability.

Conclusions

In summary, our findings conclude that there is no significant interrelation between clinical symptoms, pain severity, the extent of daily disability, and the observed MRI results for the anatomical gradation of lateral spinal stenosis, the magnitude of posterior disc height, and the extent of disc degeneration. Lumbar spinal stenosis remains a clinical-radiological syndrome, and a comprehensive clinical evaluation remains essential for an accurate diagnosis, emphasizing the necessity of appropriately correlating MRI findings with their clinical significance. On the other hand, MRI is a gold standard diagnostic tool for decision-making in the management and intervention of patients with spinal stenosis.

Appendices

Below are the supplemental materials for the study, including the data collection sheet (Figure 9), the subject information and consent form, which incorporates the participant's material publication consent form (Figure 10), and the Human Research Ethics Committee approval letter (Figure 11).



DATA COLLECTION SHEET

Research Title: Lateral Lumbar Spinal Stenosis: Correlation of Oswestry Disability Index, Visual Analogue Scale and Magnetic Resonance Imaging (MRI)

Researcher's Name : Dr Norisyam Yusoff MMC54312

R/N:	AGE:	SEX: <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE																																				
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FIGURE 8: Data collection sheet.

Participant's Material Publication Consent Form

Signature Page

Research Title: *Visual Analogue Spinal Stenosis: Association of Oswestry Disability Index, Lumbar Analogue Scale and Magnetic Resonance Imaging (MRI)*

Researcher's Name: *Dr Noriyasu Yuzoff (MMC-5412)*

To become a part this study, you or your legal representative must sign this page.

By signing this page, I am confirming the following:

- I understand that my name will not appear on the materials published and there has been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.
- All the published materials will be shared among the medical practitioners, scientists and journal worldwide.
- The materials will also be used in local publications, book publications and accessed by many local and international doctor's worldwide.
- I hereby agree and allow the materials to be used in other publications required by other publications with these conditions:
- The materials will not be used as advertisement purposes nor as packaging materials.
- The materials will not be used out of context - i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.


Participant Name

Participant I C No.	Participant's Signature	Date

Name and Signature of Individual Conducting Consent Discussion	Date

Note: All participants who are involved in this study will not be covered by insurance

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UNIVERSITI SAINS MALAYSIA

30th October 2017
 Dr. Norlilyn Yusoff
 Department of Orthopaedics
 School of Medical Sciences
 Universiti Sains Malaysia
 16150 Kubang Keratan, Kelantan.

JEPeM Code : USM/JEPeM/17083069

Protocol Title : Lateral Lumbar Spinal Stenosis: Association of Oswestry Disability Index, Visual Analogue Scale and Magnetic Resonance Imaging (MRI).

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankaja Etik Penyelidikan Manusia (JEPeM) Universiti Sains Malaysia (USM). Your study has been assigned study protocol code USM/JEPeM/17083069, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from 30th October 2017 until 29th October 2018.

Study Site: Hospital Universiti Sains Malaysia.

The following researchers also involve in this study:

1. Dr. Mohammad Faisan
2. Dr. Joehaimery Johari
3. Dr. Chandrahan Nadarajan

The following documents have been approved for use by the study:

1. Research Proposal


In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:

1. Patient Information Sheet and Consent Form (English version)
2. Patient Information Sheet and Consent Form (Malay version)
3. Oswestry Disability Index (ODI)
4. Visual Analogue Scale (VAS)
5. Data Collection Form

Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.

While the study is in progress, we request you to submit to us the following documents:

1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of JEPeM-USM FORM 3(B) 2017: Continuing Review Application Form. Subsequently this need to be done yearly as long as the research goes on.
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using JEPeM-USM FORM 3(A) 2017: Study Protocol Amendment Submission Form.



CONFIRMED BY:

National Pharmaceutical Regulatory Agency (NPRM)

Focus on Ethical Review Committees in Asia & Western Pacific Region

Jawatankaja Etik
 Penyelidikan Manusia (JEPeM)
 Human Research Ethics Committee (USM HREC)

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3. Revisions in the informed consent form using the JEPeM-USM FORM 3(A) 2017: Study Protocol Amendment Submission Form.
4. Reports of adverse events including from other study sites (national, international) using the JEPeM-USM FORM 3(B) 2017: Adverse Events Report.
5. Notice of early termination of the study and reasons for such using JEPeM-USM FORM 3(C) 2017.
6. Any event which may have ethical significance.
7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of close of completion of the study using JEPeM-USM FORM 3(D) 2017: Final Report Form.

Please note that forms may be downloaded from the JEPeM-USM website: www.jepem.usm.my

Jawatankaja Etik Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Review of Health-related Research and Sampling and Evaluating Ethical Review Practices, CIOMS Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

"ENSURING A SUSTAINABLE TOMORROW"

Very truly yours,

PROF. DR. MOHD SHUKRI OTHMAN
 Deputy Chairperson
 Jawatankaja Etik Penyelidikan (Manusia) JEPeM
 Universiti Sains Malaysia

Approved-On: Norlilyn Yusoff=ECM/USM/17083069

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Concept and design: Zairul Bahrin, Azizul A. Salim, Mohd I. Yusof, Mohammad Paiman

Critical review of the manuscript for important intellectual content: Zairul Bahrin, Azizul A. Salim, Mohd I. Yusof, Mohammad Paiman, Chandran Nadarajan

Supervision: Zairul Bahrin, Mohd I. Yusof, Mohammad Paiman

Disclosures

Human subjects: Consent was obtained or waived by all participants in this study. Human Research Ethics Committee of the University of Science, Malaysia issued approval Code USM/JEPeM/17080369. Jawatankuasa Etika Penyelidikan, JEPeM-USM is hereby granted approval for study protocol code USM/JEPeM/17080369. JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guideline and Good Clinical Practice (GCP) Standards. **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

References

1. Sipola P, Leinonen V, Niemeläinen R, et al.: Visual and quantitative assessment of lateral lumbar spinal canal stenosis with magnetic resonance imaging. *Acta Radiol.* 2011, 52:1024-31. [10.1258/ar.2011.110083](https://doi.org/10.1258/ar.2011.110083)
2. Kuittinen P, Sipola P, Aalto TJ, et al.: Correlation of lateral stenosis in MRI with symptoms, walking capacity and EMG findings in patients with surgically confirmed lateral lumbar spinal canal stenosis. *BMC Musculoskelet Disord.* 2014, 15:247. [10.1186/1471-2474-15-247](https://doi.org/10.1186/1471-2474-15-247)
3. Jönsson B, Annertz M, Sjöberg C, Strömqvist B: A prospective and consecutive study of surgically treated lumbar spinal stenosis. Part I: Clinical features related to radiographic findings. *Spine (Phila Pa 1976).* 1997, 22:2932-7. [10.1097/00007632-199712150-00016](https://doi.org/10.1097/00007632-199712150-00016)
4. Geisser ME, Haig AJ, Tong HC, et al.: Spinal canal size and clinical symptoms among persons diagnosed with lumbar spinal stenosis. *Clin J Pain.* 2007, 23:780-5. [10.1097/AJP.0b013e31815349bf](https://doi.org/10.1097/AJP.0b013e31815349bf)
5. Atlas SJ, Keller RB, Wu YA, Deyo RA, Singer DE: Long-term outcomes of surgical and nonsurgical management of lumbar spinal stenosis: 8 to 10 year results from the maine lumbar spine study. *Spine (Phila Pa 1976).* 2005, 30:936-43. [10.1097/01.brs.0000158953.57966.c0](https://doi.org/10.1097/01.brs.0000158953.57966.c0)
6. Fritz JM, Irrgang JJ: A comparison of a modified Oswestry low back pain disability questionnaire and the Quebec back pain disability scale. *Phys Ther.* 2001, 81:776-88. [10.1093/ptj/81.2.776](https://doi.org/10.1093/ptj/81.2.776)
7. Davies CC, Nitz AJ: Psychometric properties of the Roland-Morris disability questionnaire compared to the Oswestry Disability Index: a systematic review. *Phys Ther Rev.* 2009, 14:399-408. [10.1179/108331909X12540993898134](https://doi.org/10.1179/108331909X12540993898134)
8. Sirvanci M, Bhatia M, Ganiyusufoglu KA, et al.: Degenerative lumbar spinal stenosis: correlation with Oswestry Disability Index and MR imaging. *Eur Spine J.* 2008, 17:679-85. [10.1007/s00586-008-0646-5](https://doi.org/10.1007/s00586-008-0646-5)
9. Middendorp M, Vogl TJ, Kollias K, Kafchitsas K, Khan MF, Maataoui A: Association between intervertebral disc degeneration and the Oswestry Disability Index. *J Back Musculoskelet Rehabil.* 2017, 30:819-23. [10.3233/BMR-150516](https://doi.org/10.3233/BMR-150516)
10. Splettstößer A, Khan MF, Zimmermann B, Vogl TJ, Ackermann H, Middendorp M, Maataoui A: Correlation of lumbar lateral recess stenosis in magnetic resonance imaging and clinical symptoms. *World J Radiol.* 2017, 9:223-9. [10.4329/wjr.v9.i5.223](https://doi.org/10.4329/wjr.v9.i5.223)
11. Salama AA, Alarabawy RA, Dawoud MM, et al.: Functional disability of occupational-related lumbar disc degeneration: evaluation by magnetic resonance imaging with surgical correlation. *Egypt J Radiol Nucl Med.* 2017, 48:189-99. [10.1016/j.ejrm.2016.11.010](https://doi.org/10.1016/j.ejrm.2016.11.010)
12. Yu LP, Qian WW, Yin GY, Ren YX, Hu ZY: MRI assessment of lumbar intervertebral disc degeneration with lumbar degenerative disease using the Pfirrmann grading systems. *PLoS One.* 2012, 7:e48074. [10.1371/journal.pone.0048074](https://doi.org/10.1371/journal.pone.0048074)
13. Delgado DA, Lambert BS, Boutris N, McCulloch PC, Robbins AB, Moreno MR, Harris JD: Validation of digital visual analog scale pain scoring with a traditional paper-based visual analog scale in adults. *J Am Acad Orthop Surg Glob Res Rev.* 2018, 2:e088. [10.5435/JAASGlobal-D-17-00088](https://doi.org/10.5435/JAASGlobal-D-17-00088)
14. Weishaupt D, Schmid MR, Zanetti M, et al.: Positional MR imaging of the lumbar spine: does it demonstrate nerve root compromise not visible at conventional MR imaging?. *Radiology.* 2000, 215:247-53. [10.1148/radiology.215.1.r00ap06247](https://doi.org/10.1148/radiology.215.1.r00ap06247)
15. Wildermuth S, Zanetti M, Duewell S, et al.: Lumbar spine: quantitative and qualitative assessment of positional (upright flexion and extension) MR imaging and myelography. *Radiology.* 1998, 207:391-8. [10.1148/radiology.207.2.9577486](https://doi.org/10.1148/radiology.207.2.9577486)
16. Lee SY, Kim TH, Oh JK, Lee SJ, Park MS: Lumbar stenosis: a recent update by review of literature. *Asian Spine J.* 2015, 9:818-28. [10.4184/asj.2015.9.5.818](https://doi.org/10.4184/asj.2015.9.5.818)
17. Grenier N, Gréselle JF, Douws C, Vital JM, Sénégas J, Broussin J, Caillé JM: MR imaging of foraminal and extraforaminal lumbar disk herniations. *J Comput Assist Tomogr.* 1990, 14:243-9. [10.1097/00004728-199003000-00016](https://doi.org/10.1097/00004728-199003000-00016)
18. Park YK, Kim JH, Chung HS, Suh JK: Microsurgical midline approach for the decompression of extraforaminal stenosis in L5-S1. *J Neurosurg.* 2003, 98:264-70. [10.3171/spi.2003.98.3.0264](https://doi.org/10.3171/spi.2003.98.3.0264)
19. Cinotti G, De Santis P, Nofroni I, Postacchini F: Stenosis of lumbar intervertebral foramen: anatomic study on predisposing factors. *Spine (Phila Pa 1976).* 2002, 27:223-9. [10.1097/00007632-200202010-00002](https://doi.org/10.1097/00007632-200202010-00002)
20. Pfirrmann CW, Metzendorf A, Zanetti M, Hodler J, Boos N: Magnetic resonance classification of lumbar

- intervertebral disc degeneration. *Spine (Phila Pa 1976)*. 2001, 26:1873-8. [10.1097/00007632-200109010-00011](https://doi.org/10.1097/00007632-200109010-00011)
21. Tan TL, Borkowski SL, Sangiorgio SN, Campbell PA, Ebrahimzadeh E: Imaging criteria for the quantification of disc degeneration: a systematic review. *JBJS Rev*. 2015, 3:e2. [10.2106/JBJS.RVW.N.00056](https://doi.org/10.2106/JBJS.RVW.N.00056)
 22. Ishimoto Y, Yoshimura N, Muraki S, et al.: Associations between radiographic lumbar spinal stenosis and clinical symptoms in the general population: the Wakayama Spine Study. *Osteoarthritis Cartilage*. 2013, 21:783-8. [10.1016/j.joca.2013.02.656](https://doi.org/10.1016/j.joca.2013.02.656)
 23. Lee S, Kang JH, Srikantha U, Jang IT, Oh SH: Extraforaminal compression of the L-5 nerve root at the lumbosacral junction: clinical analysis, decompression technique, and outcome. *J Neurosurg Spine*. 2014, 20:371-9. [10.3171/2013.12.SPINE12629](https://doi.org/10.3171/2013.12.SPINE12629)
 24. Niemeläinen R, Videman T, Dhillon SS, Battié MC: Quantitative measurement of intervertebral disc signal using MRI. *Clin Radiol*. 2008, 63:252-5. [10.1016/j.crad.2007.08.012](https://doi.org/10.1016/j.crad.2007.08.012)
 25. Beattie PF, Meyers SP, Stratford P, Millard RW, Hollenberg GM: Associations between patient report of symptoms and anatomic impairment visible on lumbar magnetic resonance imaging. *Spine (Phila Pa 1976)*. 2000, 25:819-28. [10.1097/00007632-200004010-00010](https://doi.org/10.1097/00007632-200004010-00010)
 26. Sengupta DK, Herkowitz HN: Lumbar spinal stenosis. Treatment strategies and indications for surgery . *Orthop Clin North Am*. 2003, 34:281-95. [10.1016/s0030-5898\(02\)00069-x](https://doi.org/10.1016/s0030-5898(02)00069-x)
 27. Smeets R, Köke A, Lin CW, Ferreira M, Demoulin C: Measures of function in low back pain/disorders: Low Back Pain Rating Scale (LBPRS), Oswestry Disability Index (ODI), Progressive Isoinertial Lifting Evaluation (PILE), Quebec Back Pain Disability Scale (QBPDS), and Roland-Morris Disability Questionnaire (RDQ). *Arthritis Care Res (Hoboken)*. 2011, 63:S158-73. [10.1002/acr.20542](https://doi.org/10.1002/acr.20542)