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Association of spinal–pelvic parameters with recurrence of lumbar disc herniation after endoscopic surgery: a retrospective case–control study

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Abstract

Purpose This study aimed to investigate the relationship between spinal–pelvic parameters and recurrence of lumbar disc herniation (rLDH) after percutaneous endoscopic lumbar discectomy (PELD) through a retrospective case–control study. **Methods** Patients who underwent PELD for single-segment LDH at our hospital were included in this study. The relationship

between sagittal balance parameters of the spine and recurrence was analysed through correlation analysis, and ROC curves were plotted. The baseline characteristics, sagittal balance parameters of the spine and radiological parameters of the case and control groups were compared, and the relationship between sagittal balance parameters of the spine and recurrence of rLDH after PELD was determined through univariate and multivariate logistic regression analysis.

Results Correlation analysis showed that PI and Δ PI-LL were negatively correlated with grouping (r=-0.090 and -0.120, respectively, P=0.001 and 0.038). ROC curve analysis showed that the area under the curve (ROC-AUC) for predicting rLDH based on PI was 0.65 (CI95%=0.598, 0.720), with a cut-off of 50.26°. The ROC-AUC for predicting rLDH based on Δ PI-LL was 0.56 (CI95%=0.503, 0.634), with a cut-off of 28.21°. Multivariate logistic regression analysis showed that smoking status (OR = 2.667, P=0.008), PI \leq 50.26 (OR = 2.161, P=0.009), Δ PI-LL \leq 28.21 (OR = 3.185, P=0.001) and presence of Modic changes (OR = 4.218, P=0.001) were independent risk factors, while high DH (OR = 0.788, P=0.001) was a protective factor.

Conclusion PI < 50.26 and Δ PI-LL < 28.21 were risk factors for recurrence of lumbar disc herniation after spinal endoscopic surgery and had some predictive value for post-operative recurrence.

Keywords Spinal degenerative disease · Recurrent lumbar disc herniation · Percutaneous transforaminal endoscopic discectomy · Single-centre retrospective case–control study

Introduction

Lumbar disc herniation (LDH) is a common spinal disease characterized by lower back pain and radiating pain in the lower limbs. About two-thirds of adults have experienced back pain, which seriously affects the quality of life and

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work ability of patients [1, 2]. Percutaneous endoscopic lumbar discectomy (PELD) is a minimally invasive surgical method that involves making a small incision in the skin and using an endoscope and special instruments to remove protruding intervertebral disc tissue, thereby relieving pressure on the nerve roots or cauda equina. Spinal endoscopy has the advantages of small trauma, less bleeding, fast recovery and fewer complications [3, 4], and has become one of the main treatment methods for LDH.

However, spinal endoscopy is not foolproof, and one of the most common problems is the recurrence of lumbar disc herniation (rLDH). rLDH refers to the occurrence of intervertebral disc protrusion at the same level after spinal endoscopy, leading to the recurrence or aggravation of the original symptoms. The incidence of rLDH varies

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in different literature [5, 6], generally between 5 and 15%. rLDH not only brings more pain and trouble to patients, but also increases the risk and cost of reoperation, so the prevention and treatment of rLDH has important clinical significance.

At present, the mechanism and influencing factors of rLDH are not fully understood. Some literature suggests that it is related to factors such as age, gender, BMI, smoking history and degree of intervertebral disc degeneration [7–9]. However, few studies have explored the relationship between sagittal balance parameters of the spine and rLDH. Sagittal balance parameters of the spine refer to a set of angular or distance indicators that reflect the alignment and balance state of the spine and pelvis in the sagittal plane, such as pelvic incidence (PI), pelvic tilt (PT), sacral slope (SS), lumbar lordosis angle (LL) and PI-LL difference (Δ PI-LL). Among them, PI is a fixed parameter that reflects the shape and size of the pelvis, while PI-LL is a variable parameter that reflects the role of lumbar curvature in maintaining spinal balance [10]. Some studies have shown that sagittal balance parameters of the spine are related to the occurrence of lumbar disc herniation [11, 12]. This study aims to investigate the relationship between sagittal balance of the spine and recurrence of lumbar disc herniation after endoscopic surgery through a retrospective case-control study.

Methods

Study subjects

From January 2017 to June 2022, patients who were diagnosed with LDH and completed PELD at our hospital were included in this study, and all of these patients had a followup time of more than one year. Patients who underwent initial PELD at another hospital, patients who underwent other surgeries, patients who underwent multisegment PELD and patients with spinal deformities were excluded.

Our study was conducted at our hospital and was reported in accordance with the STROBE standards and in compliance with the Helsinki Declaration [13]. This study was approved by the ethics committee of our hospital. We determined whether patients had developed lumbar and leg pain due to nerve root compression after PELD through outpatient visits and telephone surveys, and we completed MRI for these patients to confirm the diagnosis.

Identification of rLDH

We referred to the definition of rLDH by Shi [14]. In patients who had experienced a pain-free interval after previous surgery, rLDH was defined as intervertebral disc protrusion at the same level, with a minimum of one month as the minimum pain-free interval time after the initial surgery.

Grouping

As shown in Fig. 1, the case group was selected from patients who developed rLDH after PELD at our hospital, and the control group was randomly selected from patients who did not develop rLDH after PELD. Specifically, random sampling was performed according to the random numbers generated by Stata Statistics software (version 17.0, Stata-Corp, Texas, USA).

Detection of indicators

The data were collected from the electronic medical records of our hospital. We extracted the following information: demographic data (age, gender, BMI, surgical level, smoking status), radiographic data (protrusion type for all patients, as well as PI, LL, Δ PI-LL, SS, Modic changes, Pfirrmann classification and intervertebral disc height), the radiographic data were measured by two independent spine surgeons. On the third day after surgery, the patient underwent X-ray and CT examinations. All radiological parameters were measured in this examinations.

The following parameters were obtained on the fulllength standing X-rays of the spine and lumbar MRI of the two groups of patients using CXDI Control Software NE (Canon Medical System, New York, USA). The protrusion types were classified according to the morphology of the disc herniation. A protrusion indicates that the distance between the edges of the disc herniation is less than the distance between the edges of the base. An extrusion is present when the distance between the edges of the disc material is greater than the distance at the base. A sequestration is a subtype of extrusion occurring when the disc material is no longer continuous with the parent disc. PI is defined as the angle between a line perpendicular to the sacral plate at its midpoint and a line connecting this point to the femoral head axis. As growth is completed, the value of PI remains unchanged in a specific individual. LL is measured between the inflection point from lumbar lordosis to thoracic kyphosis and the upper endplate of S1 [10]. This angle is closely related to PI. Schwab proposed the following formula: $PI = LL \pm 9^\circ$. The degree of matching between PI and LL can reflect the sagittal balance of the spine [15]. SS is the angle between the tangent to the upper S1 endplate and the horizontal line. A vertical pelvis means a low sacral slope, while a horizontal pelvis has a high slope. Modic changes are mainly divided into three types [16]. Type I (low T1 and high T2 signal) is related to cartilage endplate fissures and subchondral bone marrow vascular proliferation. Type II (high T1 and T2 signal) reflects bone marrow fat

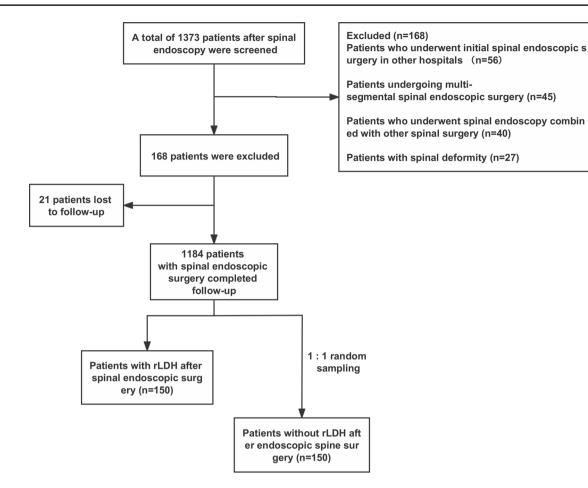


Fig. 1 Study flow chart. Patients with rLDH after spinal endoscopy

degeneration. Type III (low T1 and T2 signal) is considered to be related to subchondral bone sclerosis. Pfirrmann grading is mainly divided into 5 grades based on nucleus structure, boundary between nucleus and annulus fibrosus, signal intensity of nucleus and intervertebral disc height [17]. The disc height (DH) was measured as the average of the anterior and posterior disc heights on the lateral X-ray image. The measurement of the above parameters is shown in the Fig. 2.

Surgical procedure

The surgery was performed by a surgeon with more than 500 cases of spinal endoscopy experience. The surgical methods included percutaneous endoscopic transforaminal discectomy and percutaneous endoscopic interlaminar discectomy, which were determined based on the location and type of lumbar disc herniation and the professional choice of the surgeon. After general anaesthesia, the puncture path was located with a C-arm machine and the puncture point was marked. The lesion segment was located by fluoroscopy after routine disinfection and draping, the safety line was marked, and a suitable puncture point and angle were selected. The puncture needle was inserted into the target segment, an incision was made at the location point, and the working channel was established after stepby-step dilation of the dilator tube. The endoscope was inserted. We performed endoscopic partial discectomy to remove the protruding and degenerated nucleus pulposus until the nerve root was sufficiently decompressed. In some cases we only removed the free nucleus pulposus, while in some cases we tried to remove as much of the degenerated disc tissue and nucleus pulposus as possible, which depends on the size of the annular tear. After confirming that the nerve root decompression was adequate, we withdrew the discoscope and the working channel and sutured the skin.

Of the 150 patients in the case group, 12 chose conservative treatment, 19 chose endoscopy-assisted OLIF revision, and 119 chose posterior fusion after being diagnosed with rLDH. The selection criteria for revision surgery were based on the patient's preference, the surgeon's experience and the anatomical features of rLDH.

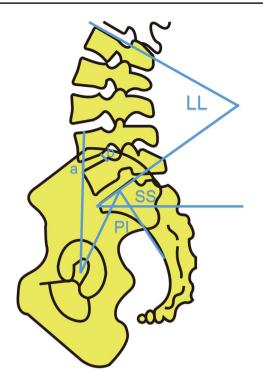


Fig. 2 As shown in the figure, some indicators are measured as follows: PI is defined as the angle between a line perpendicular to the sacral plate at its midpoint and a line connecting this point to the femoral head axis. LL is measured between the inflection point from lumbar lordosis to thoracic kyphosis and the upper endplate of S1. SS is the angle between the tangent to the upper S1 endplate and the horizontal line. DH = (a+b)/2

Statistical Analysis

SPSS 26.0 statistical software (IBM, NY, USA) was used for data analysis. Normally distributed measurement data were expressed as mean ± standard deviation and compared between groups using t-test. Non-normally distributed measurement data were expressed as median (M) and interquartile range (P25, P75) and compared between groups using rank sum test. Spearman correlation analysis was used for correlation analysis. Sensitivity and specificity were calculated using receiver operating characteristic (ROC) curves and area under the curve. According to the cut-off value, the indicators with statistically significant correlation test were classified into two categories, and univariate logistic regression was used to adjust for confounding factors. In univariate logistic regression, variables with a P-value not exceeding 0.05 were included in the multivariate logistic regression model. A *P*-value < 0.05 was considered statistically significant.

Table 1 Spearman correlation analyses

Patients with rLDH after spinal endo-	Correlation analysis		
scopic surgery	r	P value	
PI (deg)	- 0.276	0.001	
LL (deg)	- 0.090	0.119	
$\Delta PI-LL (deg)$	- 0.120	0.038	
SS (deg)	- 0.086	0.135	

rLDH, recurrent lumbar disc herniation; PI, pelvic incidence; LL, lumbar lordosis; ΔPI-LL, PI-LL difference; SS, sacral slope

Results

In this study, a total of 1373 patients who underwent spinal endoscopy at our hospital were included. All of these patients had a follow-up time of more than one year. We lost follow-up with 21 patients for various reasons and excluded them from the study. After telephone or outpatient surveys, 150 patients completed MRI and were finally diagnosed with rLDH based on neurological symptoms and imaging findings. The average time from initial surgery to recurrence was 0.23 to 24 months, and the overall recurrence rate was 10.92% (150/1373).

As shown in Table 1, by performing Spearman correlation analysis between PI, LL, Δ PI-LL, SS and grouping, an inverse relationship exists between the elevation of PI and Δ PI-LL and the recurrence. (r=-0.090 and -0.120, respectively, *P*=0.001 and 0.038). ROC curve analysis showed that the area under the curve (ROC-AUC) for predicting rLDH based on PI was 0.65 (CI95% =0.598, 0.720 Fig. 3A), with a sensitivity of 62% and a specificity of 62.67% when PI was 50.26°. ROC curve analysis showed that the ROC-AUC for predicting rLDH based on Δ PI-LL was 0.56 (CI95% =0.503, 0.634 Fig. 3 B), with a sensitivity of 35.33% and a specificity of 82.67% when PI was 28.21°. The accuracy of predicting recurrence based on whether PI is less than 50.26 was 65%, and the accuracy of predicting recurrence based on whether Δ PI-LL is less than 20.21 was 56%.

In patients who underwent spinal endoscopy and had regular follow-up for more than one year, there were 150 cases in the case group and 150 cases in the control group. As shown in Table 2, there were no statistically significant differences between the case group and the control group in terms of gender (P=0.470), BMI (P=0.645), surgical segment (P=0.274) and protrusion type (P=0.714). However, the age of the case group was significantly higher than that of the control group (P=0.005), and the number of smokers Fig. 3 Receiver operating characteristic area under the curve (ROC-AUC) of rLDH spinal endoscopic surgery was calculated according to the pelvic incidence (PI) and the pelvic incidence -lumbar lordosis (PI-LL) level, A shows AUC = 0.65(CI 95% = 0.5983 to 0.7208), cut-off = 50.26. B shows AUC = 0.56 (CI 95% = 0.5038to 0.6348), cut-off = 28.21

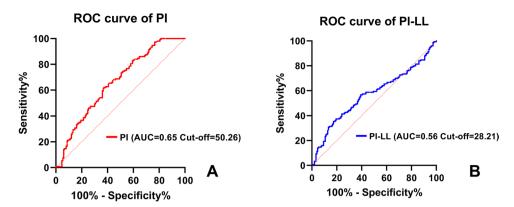


Table 2Clinical characteristicsbetween cases and controls

	Number of cases	Mean±SD	Cases $(n = 150)$	Controls $(n = 150)$	P value
Gender					0.470
Male	150	50%	99(66.00)	51(34.00)	
Female	150	50%	93(62.00)	57(38.00)	
Age (years)		47.94 ± 12.94	50.03 ± 12.96	45.85 ± 12.63	0.005
BMI (kg/m ²)		24.79 ± 10.94	24.50 ± 3.31	25.08 ± 15.14	0.645
Surgical level					0.274
L1/L2	2	0.66%	1(0.66)	1(0.66)	
L3-L4	11	3.66%	6(4.00)	5(3.33)	
L4-L5	127	42.33%	63(42.00)	64(42.66)	
L5-S1	160	53.33%	80(53.33)	80(53.33)	
Smoking status					0.015
Yes	52	17.33%	34(22.66)	18(12.00)	
No	248	82.66%	116(77.33)	132(88.00)	
Type of herniated disc					0.714
Protrusion	153	51.00%	73(48.66)	80(53.33)	
Extrusion	139	46.33%	73(48.66)	66(44.00)	
Sequestration	8	2.66%	4(2.66)	4(2.66)	

BMI, body mass index

in the case group was significantly higher than that of the control group (P = 0.015).

Sagittal balance parameters of the spine and radiological parameters are shown in Table 3. The case group had significantly lower PI (P=0.001), LL (P=0.050) and Δ PI-LL (P=0.043) than the control group. There were statistically significant differences between the case group and the control group in terms of Modic changes (P=0.001) and Pfirrmann grading (P=0.003). The case group had significantly lower DH (P=0.001) than the control group. There was no statistically significant difference between the case group and the constatistically significant difference between the case group and the case group and the control group in terms of SS (P=0.070).

Considering the influence of confounding factors, we performed univariate logistic regression on the indicators with statistically significant differences in Table 2 and 3, and then included indicators with $P \le 0.05$ in univariate logistic regression into multivariate logistic regression. As shown in

Table 4, smoking status (OR = 2.667, P = 0.008), PI \leq 50.26 (OR = 2.161, P = 0.009), Δ PI-LL \leq 28.21 (OR = 3.185, P = 0.001) and presence of Modic changes (OR = 4.218, P = 0.001) were independent risk factors, while high DH (OR = 0.788, P = 0.001) was a protective factor.

Discussion

The recurrence rate of spinal endoscopy reported in the literature is 5-15% [5], and the recurrence rate in this study is 10.92%, which is consistent with the results reported in the literature.

We found that PI and Δ PI-LL were negatively correlated with the recurrence rate, and PI $\leq 50.26^{\circ}$ and Δ PI-LL $\leq 28.21^{\circ}$ were independent risk factors for recurrence. In addition, we also found that smoking status and Modic

	Number of cases	Mean±SD	Cases $(n=150)$	Controls $(n=150)$	P value
PI (deg)		50.85 ± 10.32	48.16 ± 11.06	53.55±8.77	0.001
LL (deg)		34.16 ± 13.76	32.60 ± 13.24	35.72 ± 14.14	0.050
PI-LL (deg)		17.41 ± 15.99	15.55 ± 14.57	19.28 ± 17.14	0.043
SS (deg)		29.12 ± 9.95	28.08 ± 9.39	30.16 ± 10.42	0.070
Modic changes					0.001
No	237	79.00%	101(67.33)	136(90.66)	
Ι	22	7.33%	17(11.33)	9(6.00)	
II	36	12.00%	27(18.00)	5(3.33)	
III	5	1.66%	5(3.33)	0(0.00)	
Pfirrmann Classification					0.003
Ι	12	4.00%	3(2.00)	9(6.00)	
II	52	17.33%	18(12.00)	34(22.66)	
III	133	44.33%	64(42.66)	69(46.00)	
IV	95	31.66%	59(39.33)	36(24.00)	
V	8	2.66%	6(4.00)	2(1.33)	
DH (mm)		8.66 ± 2.40	7.95 ± 2.47	9.37 ± 2.12	0.001

SBP, Sagittal balance parameters; RP, radiological parameters; PI, pelvic incidence; LL, lumbar lordosis; ΔPI-LL, PI-LL difference; SS, sacral slope; DH, disc height

Table 4	SBP factors for patients
after spi	nal endoscopy with
rLDH	

	Univariate analysis OR	Multivariate analysis				
		95%CI	P value	OR	95%CI	P value
Age (years)	1.026	1.007-1.045	0.006	1.015	0.994-1.038	0.164
Smoking status						
Yes	1.000			1.000		
No	2.149	1.152-4.009	0.016	2.667	1.286-5.534	0.008
PI (deg)						
> 50.26				1.000		
< 50.26	2.739	1.717-4.369	0.001	2.161	1.216-3.841	0.009
LL (deg)	0.983	0.967-1.000	0.051			
PI-LL (deg)						
>28.21				1.000		
<28.21	2.606	1.520-4.468	0.001	3.185	1.566-6.478	0.001
SS (deg)	0.979	0.957-1.002	0.071			
Modic changes						
No	1.000			1.000		
Yes	4.713	2.467-9.004	0.001	4.218	1.948-9.134	0.001
Pfirrmann Classification						
Ι	1.000			1.000		
II	1.588	0.382-6.611	0.525	1.462	0.310-6.897	0.631
III	2.783	0.721-10.736	0.137	2.311	0.527-10.129	0.266
IV	4.917	1.248-19.365	0.023	2.982	0.649-13.704	0.160
V	9.000	1.140-71.038	0.037	1.495	0.155-14.384	0.728
DH (mm)	0.766	0.688-0.852	0.001	0.788	0.697-0.890	0.001

SBP, Sagittal balance parameters; PI, pelvic incidence; LL, lumbar lordosis; ΔPI-LL, PI-LL difference; SS, sacral slope; DH, disc height

changes were independent risk factors for recurrence, while high DH was a protective factor.

Our results are consistent with some previous studies, but there are also some differences. PI is an indicator of pelvic tilt angle, which is related to spinal stability and load distribution [18]. Low PI means that the pelvis is tilted backward, leading to a reduction in lumbar lordosis and an increase in intervertebral disc stress. ΔPI -LL is an indicator of the coordination between the lumbar spine and the pelvis, which is related to spinal function and range of motion. There are currently different results regarding the range of Δ PI-LL. Schwab proposed that Δ PI-LL < 10° is an ideal balanced state [15], while Kazuhiro believed that $LL = 32.9 + 0.6^{*}(PI-0.23)^{*}Age$, and the ideal balanced state is related to age [19]. We obtained $PI \le 50.26^{\circ}$ and $\Delta PI-LL \leq 28.21^{\circ}$ as having better predictive value for rLDH after endoscopy through the cut-off value of ROC curve. Therefore, we speculate that low PI and low Δ PI-LL may increase the risk of recurrence of lumbar disc herniation after spinal endoscopy. We admit that lower ΔPI -LL means better match between the pelvis and the spine, but our results show that $\Delta PI-LL < 28.21$ was a risk factor for recurrence after endoscopic surgery. We think there are several reasons for this. First, the PI of the case group was significantly lower than that of the control group, and in some patients in the case group, despite having low PI values, they had large LL, which matched the anterior 3 type proposed by Roussouly. This resulted in a significantly lower ΔPI -LL in the case group than in the control group. Second, in the control group, although they had high PI values, their LL decreased due to disc degeneration, and they compensated by pelvic retroversion, which meant that ΔPI -LL would be higher. Our results suggest that the compensatory mechanism alleviates the intervertebral disc stress, yet the biomechanical implications of the altered disc load distribution in "compensating imbalance" patients remain to be elucidated. These reasons led to the correlation analysis results showing that Δ PI-LL was negatively correlated with recurrence, and the ROC curve and regression analysis revealed that $\Delta PI-LL < 28.21$ was a risk factor for recurrence after endoscopic surgery.

Smoking status is one of the known risk factors for the occurrence and recurrence of lumbar disc herniation [20]. Smoking can directly increase the risk of rLDH [21]. Our results also confirm that smoking is an important risk factor for the recurrence of lumbar disc herniation after spinal endoscopy, suggesting that we should educate and intervene in smoking cessation before and after surgery.

Modic changes refer to abnormal signals in the vertebral bone marrow, which are related to intervertebral disc degeneration, infection, inflammation, etc. [16]. Modic changes can reflect changes in vertebral bone strength and stability, thereby affecting the risk of recurrence of lumbar disc herniation after spinal endoscopy. Our results show that the presence of Modic changes is an important risk factor for recurrence, which is consistent with some literature reports [22, 23].

DH refers to the height of the intervertebral disc, which reflects the degree of intervertebral disc degeneration and functional status. DH can affect spinal stability, load distribution, nerve root compression, etc., thereby affecting the risk of recurrence of lumbar disc herniation after spinal endoscopy. Our results show that high DH is a protective factor for recurrence. Our findings challenge the previous notion that high disc height is associated with increased sagittal mobility, reduced spinal stability and elevated recurrence risk. We propose several explanations for this discrepancy. First, we suggest that lower disc height results in smaller LL and higher disc stress. Patients with high PI values can adjust by increasing pelvic retroversion. Patients with low PI values have limited pelvic retroversion capacity and face a higher recurrence risk. Second, our case group was significantly older than our control group, implying more advanced disc degeneration and lower disc height in the former. These factors reinforce the role of low PI values and disc degeneration as recurrence predictors.

This study has the following advantages: (1) This study is the largest study to date exploring the relationship between sagittal balance of the spine and recurrence of lumbar disc herniation after spinal endoscopy, including 1373 patients with high statistical power. (2) This study used a random sampling control group design, effectively controlling for the influence of confounding factors and improving the credibility of the results. (3) This study used strict diagnostic criteria for recurrence, including neurological symptoms and imaging findings, to avoid misdiagnosis of false positives or false negatives.

This study also has the following limitations: (1) This study is a retrospective observational study and cannot rule out the influence of other unknown or unmeasured confounding factors. (2) This study only included patients who underwent spinal endoscopy at our hospital and may have selection bias and cannot represent all patients with lumbar disc herniation. (3) Another of the limitations of our study is the relatively short follow-up period of one year. We acknowledge that some patients may develop a recurrence at later stages, and that a longer follow-up period would be more accurate and reliable to assess the long-term outcomes of endoscopic surgery for rLDH. However, we chose a oneyear follow-up as a compromise, due to the difficulties in collecting data from patients who had surgery more than two years ago. We suggest that future studies should use a prospective design and a longer follow-up period to confirm our findings and to explore the influence of sagittal alignment on the recurrence of rLDH.

In summary, our results show that PI and Δ PI-LL are negatively correlated with the recurrence rate of lumbar disc herniation after spinal endoscopy, and PI \leq 50.26° and Δ PI-LL \leq 28.21° are independent risk factors for recurrence. In addition, we also found that smoking status and Modic changes were independent risk factors for recurrence, while high DH was a protective factor. These results provide us with some basis and guidance for preventing and treating recurrent lumbar disc herniation. We recommend detailed imaging evaluation of patients before spinal endoscopy to select appropriate surgical indications and methods, as well as smoking cessation education and rehabilitation guidance after surgery.

Conclusions

PI < 50.26 and Δ PI-LL < 28.21 were risk factors for recurrence of lumbar disc herniation after spinal endoscopic surgery and had some predictive value for post-operative recurrence. Clinicians could inform patients with these risk factors about the recurrence risk before surgery and jointly choose the appropriate surgical strategy. Moreover, a more comprehensive rehabilitation programme and a more frequent and longer-term follow-up should be conducted after surgery.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00586-023-08073-w.

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Declarations

Conflict of interest The authors have no relevant financial or non-financial interests to disclose. The authors have no competing interests to declare that are relevant to the content of this article. All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript. The authors have no financial or proprietary interests in any material discussed in this article.

Ethical approval Ethical guidelines were followed by the investigators in performing studies on humans or animals. The approval of the institutional review board of either human or animal ethics is stated in the "Methods" section of the manuscript. Each author has participated sufficiently in the work to take public responsibility for the content of the paper and approves the final version of the manuscript. A statement of author contributions is included in the manuscript. If requested, the authors will provide the data or will cooperate fully in obtaining the data on which the manuscript is based for examination by the editors or their assignees.

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