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The current management of low back pain (LBP) offers low to moderate improvement in pain and disability. Kjaer et al.<sup>[1]</sup> suggested that Modic changes (MCs) constitute the crucial element in the degenerative process around the disk in relation to LBP and clinical findings. Modic changes in the lumbar spine were first reported by de Roos et al.<sup>[2]</sup> in 1987. Modic et al.<sup>[3]</sup> systematically described the types of signal changes, classification criteria, and pathological changes in 1988. Modic changes are classified into three types: type 1 lesions indicate that the vascularized

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## ABSTRACT

**Objectives:** This study aimed to investigate differences in vertebral fat distribution and bone density between patients with and without Modic changes (MCs) using a magnetic resonance imaging (MRI)-based vertebral bone quality (VBQ) scoring system.

**Patients and methods:** In this retrospective study, 189 patients (95 males, 94 females; mean age: 54±2.2 years; range, 18 to 82 years) with primary single-level disk herniation were reviewed between June 2021 and June 2022. The patients were divided into the MC group (n=99) and the non-MC (NMC) group (n=90). The subcutaneous fat tissue thickness and bone mineral density were determined. The system consisted of two scores: the VBQ score, which reflected the fatty infiltration within the vertebral body, and the endplate bone quality (EBQ) score, which reflected the signal intensity (SI) of the upper and lower endplates. The EBQ score is a novel measurement that we introduced in this study. The VBQ and EBQ were measured and scored using MRI scans. The mean SI of the upper and lower endplates (endplate SI)/the bone marrow SI (marrow SI) was measured.

**Results:** There was a considerable difference in subcutaneous fat tissue thickness between the MC and NMC groups (1.40 vs. 1.16 cm, p=0.01). The EBQ scores of the L4 and L5 vertebrae and endplate SI/marrow SI of all vertebral body levels were significantly higher in the MC group.

**Conclusion:** The occurrence of MCs in the lumbar spine may be associated with abnormal fat distribution. The distribution of vertebral fat in patients with MCs is distributed earlier in the upper and lower endplates of the vertebral body, and this trend is not observed in patients without MC. The thickness of subcutaneous fat tissue is a key factor in the occurrence of MCs.

**Keywords:** Dyslipidemia, endplate bone quality, fat distribution, intervertebral disk degeneration, Modic change, vertebral bone quality.

fibrous tissue in the bone marrow is undergoing an active degenerative process; type 2 lesions reflect fat replacement in the bone marrow and are thought to be stable with chronic fat infiltration and deposition; type 3 lesions are believed to be associated with endplate sclerosis.<sup>[3,4]</sup> Modic changes are strongly associated with disk degeneration and LBP.<sup>[5,6]</sup> However, the etiology and pathological features of MCs are not well understood and cannot explain why they occur in only a small proportion of patients with disk degeneration.

While exploring the etiology and pathogenesis of MCs, the authors found that abnormal fat metabolism may play a role in many aspects. First, abnormal fat metabolism can lead to obesity, a relatively heavy spinal load, disk degeneration, and an increased risk of endplate injury. Özcan-Ekşi et al.<sup>[7]</sup> reported that subcutaneous fat tissue thickness (SFTT) is a good predictor of severe intervertebral disk degeneration (IVDD) and MCs. Second, if the adipose tissue in the bone marrow of the vertebral body increases, it can activate some signaling pathways and inflammatory factors. Additionally, the response of myeloid tissue to inflammatory stimulation may change the structure of the bone marrow or local microenvironment, resulting in MCs in the vertebral body.<sup>[8,9]</sup>

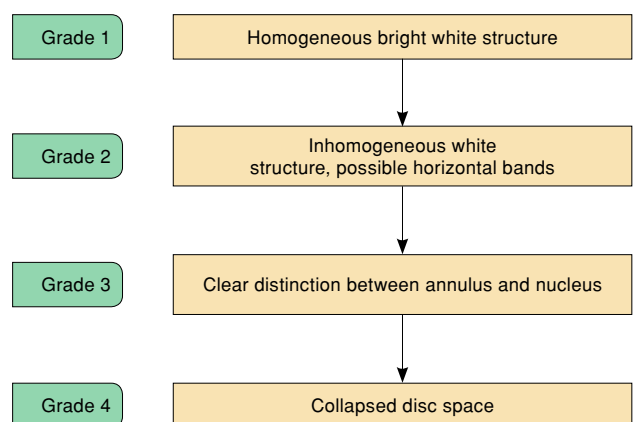
Magnetic resonance imaging (MRI) is often used in the evaluation of patients with LBP.<sup>[10]</sup> Furthermore, MRI has a role in detecting osteoporosis, and the appearance of the bone marrow is determined by the relative amount of fat, protein, water, and bone cells on the MRI sequence. Previous studies have revealed that an additional sequence of MRI could provide additional information on the bone marrow composition.<sup>[11-13]</sup> The vertebral bone quality (VBQ) score is a popular new technique for assessing bone quality by determining fatty infiltration within the vertebral body.<sup>[14]</sup> Modic changes often occur at the vertebral endplate; therefore, the endplate bone quality (EBQ) score was introduced in this study.<sup>[15]</sup>

The signal intensity (SI) of the endplate and the vertebral body on an MRI image can reflect the degree of fat infiltration or inflammation, which may affect the bone quality and the occurrence of MCs. Therefore, the authors developed an MRI-based VBQ scoring system consisting of two scores: the VBQ score, which reflects the fatty infiltration within the vertebral body, and the EBQ score, which reflects the SI of the upper and lower endplates. The EBQ score is a novel measurement that was introduced in this study to evaluate the endplate changes associated with MCs.

This study aimed to investigate the differences in vertebral fat distribution and bone density between patients with and without MCs using the MRI-based VBQ scoring system. We hypothesized that patients with MCs would have more fat infiltration in the endplates and lower bone density than patients without MCs.

## PATIENTS AND METHODS

A total of 189 patients (95 males, 94 females; mean age: 54±2.2 years; range, 18 to 82 years) with primary single-segment disk herniation who were hospitalized in the Third Hospital of Hebei Medical University between June 2021 and June 2022 were retrospectively reviewed. The disk degeneration was assessed according to the Pfirrmann classification (Additional Figure 1). The patients were divided into the MC group (n=99) and the non-MC (NMC) group (n=90). The inclusion criteria for the MC group were the presence of any type (1, 2, or 3) or range (A, B, or C) of MCs on the MRI images, as described by Modic et al.<sup>[3]</sup> The MC range was classified into three categories according to the percentage of the endplate area involved in MCs: category A represented <25%, B represented 25-50%, and C represented >50%. The independent variables of this study were the presence or absence of MCs, the SFTT, and the blood lipid levels. The outcome parameters of this study were the VBQ and EBQ scores, the bone mineral density (BMD), and the mean SI of the upper and lower endplates (endplate SI) divided by the bone marrow SI (marrow SI). Subcutaneous fat tissue thickness, triglycerides, high-density lipoprotein, low-density lipoprotein, and total cholesterol levels were measured in all patients. The MRI images and BMD measurements were retrospectively analyzed. The exclusion criteria



**ADDITIONAL FIGURE 1.** Algorithm used for grading lumbar disk degeneration.

were vertebral fracture, previous lumbar spine surgery, spinal infection, and severe spinal deformity.

The MRI of the lumbar spine was performed with a Magnetom Avanto 1.5T (Siemens Healthineers, Erlangen, Germany) superconducting scanner. The Pfirrmann grade, SFTT, VBQ, and EBQ were obtained from the MRI data. Image evaluation was performed by an experienced radiologist and an orthopedic surgeon who were unaware of the patients' information (T1 sagittal position: repetition time/echo time=546/9.7 msec, section thickness=4 mm; T2 sagittal position: repetition time/echo time=2,850/103 msec, section thickness=4 mm). The evaluation included an MRI scan image showing the classification and location of the MCs.<sup>[16]</sup> In addition, the degree of IVDD was assessed based on the Pfirrmann grade on the MRI T2-weighted images.<sup>[17]</sup>

The lumbar and hip dual-energy X-ray absorptiometry BMD T-scores were recorded. The BMD assessment criteria were as follows: osteopenia (T-score between -1.0 and -2.5 standard deviation [SD]) or osteoporosis (T-score <-2.5 SD) was the lowest T-score residing in the femoral or vertebral region.<sup>[17-19]</sup>

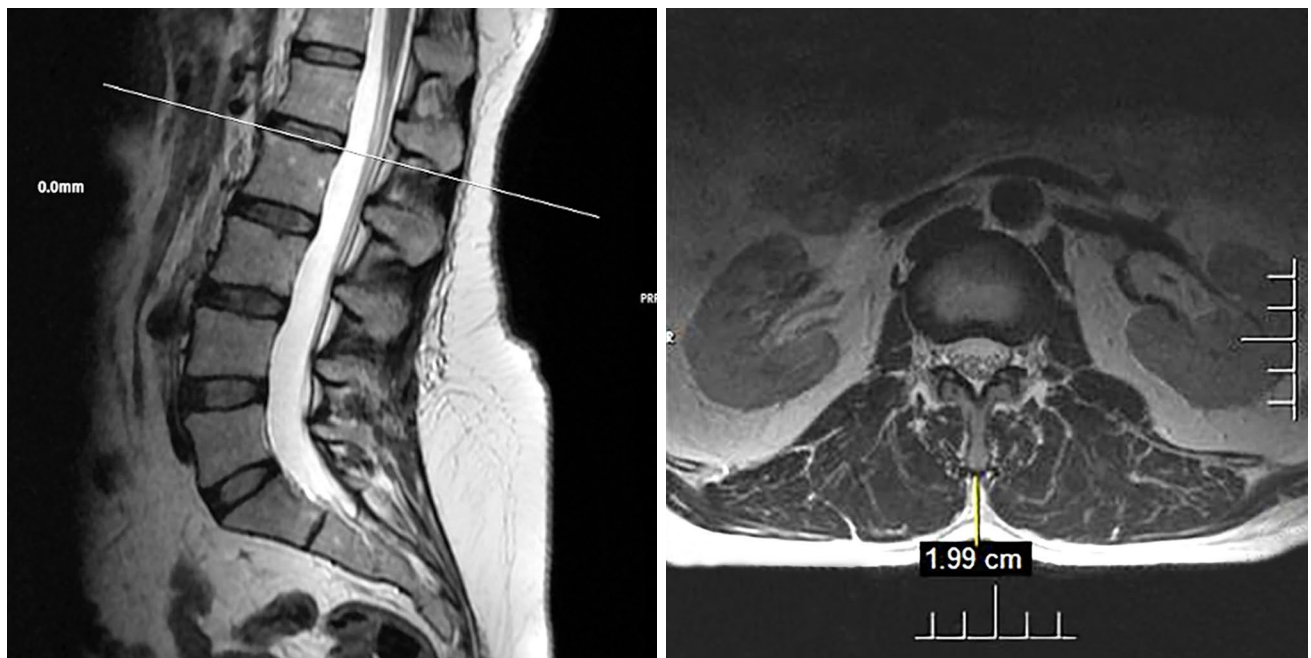
In axial T2-weighted lumbar MRI, the SFTT was measured as the vertical distance from the spinous process tip of the L1 vertebral body to the skin (Figure 1). Two authors defined this method;

this technique was interpreted by the raters in a substantially consistent manner.<sup>[7]</sup>

The VBQ and EBQ scores were assessed with lumbar T1-weighted MRI.<sup>[14,15]</sup> The vertebral body was excluded if the entire vertebral body was abnormal. For example, if the cerebrospinal fluid (CSF) in the L3 space was completely blocked, the region of interest (ROI) of the CSF was placed at the L2 or S1 level. The VBQ score was calculated by dividing the median SI at L1-L4 levels by the SI of the CSF.

The VBQ, EBQ, and SFTT, observed and measured by two independent researchers, were the mean values of the range and location of MCs, as well as the grading and measurement of the IVDD in statistical analysis. To assess the concordance of the various measurements between the raters, 50 patients were randomly selected, observed, and measured independently by two experienced spine surgeons.<sup>[20]</sup> Three weeks later, the same observations and measurements were made by each observer.

The VBQ score was calculated by drawing an ROI around the vertebral body on the sagittal T1-weighted MRI image, excluding the endplates and the posterior elements. Afterward, the median SI of the ROI was measured, which represented the SI of the vertebral body. Next, another ROI was drawn around the CSF on the same image, and the median



**FIGURE 1.** Measurement technique of subcutaneous fat tissue thickness at the L1/L2 level on T2-weighted axial lumbar magnetic resonance imaging

SI of the ROI was measured, which represented the SI of the CSF. Finally, the SI of the vertebral body was divided by the SI of the CSF value to obtain the VBQ score. A higher VBQ score indicated a higher degree of fatty infiltration within the vertebral body (Figure 2).

The EBQ score was calculated by drawing an ROI of 3 mm in width along the upper and lower endplates on the sagittal T1-weighted MRI image, excluding the cortical bone. Afterward, the median SI of the ROI was measured, which represented the SI of the endplate. Next, another ROI was drawn around the center of the vertebral body on the same image, and the median SI of the ROI was measured, which represented the SI of the bone marrow. Finally, the SI of the endplate value was divided by the SI of the bone marrow to obtain the EBQ score. A higher EBQ score indicated a higher SI of the endplate, which could reflect the presence of MCs (Figure 3).

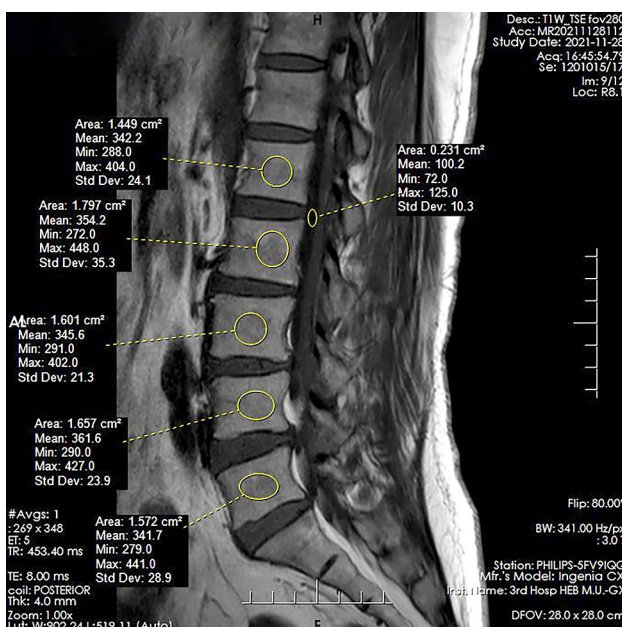
**Statistical analysis**

The sample size for the study was determined based on a power analysis using G\*Power software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). A medium effect size ( $f=0.25$ ), an alpha level of 0.05, and a power of 0.80 were used for the independent sample t-tests. The required sample size was estimated to be 84 patients in each group. However, a total of 189 patients were enrolled to account for possible dropouts and missing data.

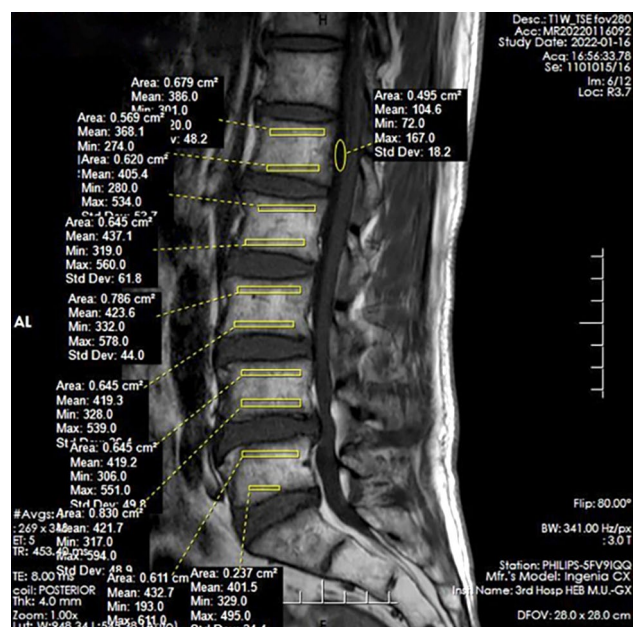
Data were analyzed using IBM SPSS version 26.0 software (IBM Corp., Armonk, NY, USA). The intragroup correlation coefficient was calculated to test the reliability among and within raters. The Shapiro-Wilk test was used to assess the normality of continuous variables. Independent-sample t-tests were used for normally distributed variables and Mann-Whitney U tests for nonnormally distributed data. Normally distributed variables were presented as the mean  $\pm$  standard deviation (SD), and nonnormally distributed variables were presented as median (range) values. The vertebral endplates and bone marrow VBQ scores were generally distributed in each group. The interobserver reliability was assessed using the intragroup correlation coefficient. The differences in VBQ and EBQ scores between the MC and NMC groups were tested by independent sample t-tests. Signal intensity differences between the upper and lower endplates of the target vertebral body and the vertebral center were analyzed by independent sample t-tests. A  $p$ -value  $<0.05$  was considered statistically significant.

**RESULTS**

There was no significant difference in sex, age, triglycerides, cholesterol, high-density lipoprotein, low-density lipoprotein, or VBQ between the two groups ( $p>0.05$ ) (Table I). There was no difference in BMD between the two groups. The SFTT was higher in the MC group than in the NMC group



**FIGURE 2.** Representative image of the region of interests used to calculate the vertebral bone quality score.



**FIGURE 3.** Representative image of the region of interests used to calculate the endplate bone quality score.

**TABLE I**  
Comparison of patient characteristics between the MC group and NMC group

Characteristics	MCs (n=99)			NMCs (n=90)			p
	n	%	Mean±SD	n	%	Mean±SD	
Age (year)			53±2.1			55±2.3	0.261
Sex							0.059
Male	43	43.4		52	57.8		
Female	56	56.6		38	42.2		
Cholesterol (mmol/L)			4.86±0.15			4.70±0.18	0.243
HDL-C (mmol/L)			1.23±0.09			1.32±0.11	0.192
LDL-C (mmol/L)			2.92±0.13			2.79±0.14	0.183
Triglyceride (mmol/L)			1.55±0.07			1.52±0.08	0.838
Lumber T score			-0.93±0.12			-1.21±0.13	0.394
Femoral T score			-1.62±0.14			-1.71±0.15	0.663
SFTT (cm)			1.40±0.12			1.16±0.14	0.012*

MCs: Modic changes; NMCs: Non-modic changes groups; SD: Standard deviation; HDL-C: High-density lipoprotein cholesterol; LDL-C: Low-density lipoprotein cholesterol; SFTT: Subcutaneous fat tissue thickness; \* P<0.05, compared with the non-Modic changes group.

(1.40 vs. 1.16 cm, p=0.01). Similarly, there was a significant difference in EBQ scores for the L4 and L5 vertebrae between the MC and NMC groups (L4 EBQ: 2.98±0.65 vs. 2.73±0.88, p<0.05; L5 EBQ: 3.21±1.53 vs. 2.84±0.90, p<0.05; Table II). The remaining vertebral EBQ scores were not significantly different (L1 EBQ: 2.9176±0.65 vs. 2.7970±0.91; L2 EBQ: 2.9627±0.63 vs. 2.8670±0.91; L3EBQ: 2.94±0.62 vs. 2.7676±0.92). In the MC group, the SI value within 3 mm of the endplate was higher than that at the center of the vertebral body. In contrast, in the NMC group, the SI value within 3 mm of the endplate was smaller than that at the center of the vertebral body. Therefore, the endplate SI/marrow SI of the vertebral body of each lumbar level was significantly different. The SI of the

MC group was higher than that of the NMC group (Table III).

The distribution of Modic types and ranges in the MC group were compared, as shown in Tables IV and V. The majority of the MC group had type 2 MCs (87.9%), followed by type 1 (5.1%), type 3 (3%), and mixed type (4%). The most common Modic range was A (46.5%), followed by B (32.3%) and C (21.2%). The level of disk herniation and the proportion of severe IVDD between the MC and NMC groups were also compared, as shown in Tables IV and V. The most common level of disk herniation was L4/L5 in both groups (70.7% in the MC group and 76.7% in the NMC group), followed

**TABLE II**  
Comparison of VBQ and EBQ between the MC group and NMC group

Characteristics	MCs (n=99)	NMCs (n=90)	p
	Mean±SD	Mean±SD	
VBQ	2.80±0.02	2.82±0.03	0.878
L1EBQ	2.91±0.65	2.79±0.91	0.303
L2EBQ	2.96±0.63	2.86±0.91	0.407
L3EBQ	2.94±0.62	2.76±0.92	0.123
L4EBQ	2.98±0.65	2.73±0.88	0.026*
L5EBQ	3.21±1.53	2.84±0.9	0.046*

VBQ: Vertebral bone quality score; EBQ: Endplate bone quality score; MCs: Modic changes; NMCs: Non-modic changes groups; SD: Standard deviation; \* P<0.05, compared with the non-Modic changes group.

**TABLE III**  
Comparison of the ratio of endplate SI/marrow SI between the MC group and NMC group

Lumbar level	MCs	NMCs	p
	Mean±SD	Mean±SD	
L1	1.07±0.03	1.00±0.06	<0.001*
L2	1.05±0.01	1.00±0.05	<0.001*
L3	1.03±0.05	0.97±0.01	<0.001*
L4	1.07±0.01	0.98±0.02	<0.001*
L5	1.13±0.02	0.99±0.04	0.006*

SI: Signal intensity; MCs: Modic changes; NMCs: Non-modic changes groups; SD: Standard deviation; \* P<0.05, compared with the non-Modic changes group.

TABLE IV

Comparison of disk level between the MC group and NMC group

	MCs (n=99)		NMCs (n=90)	
	n	%	n	%
L1/2	1	1	2	2.22
L2/3	1	1	3	3.33
L3/4	12	12.12	2	2.22
L4/5	70	70.7	69	76.66
L5/S1	15	15.15	14	15.55

MCs: Modic changes; NMCs: Non-modic changes groups.

TABLE V

Comparison of the proportion of severe IVDD between the MC group and NMC group

	MCs (n=99)		NMCs (n=90)	
	n	%	n	%
L1/2	38	38	26	28
L2/3	44	44	38	42
L3/4	57	57	42	57
L4/5	91	91	79	87
L5/S1	80	80	62	68

IVDD: Intervertebral disk degeneration; MCs: Modic changes; NMCs: Non-modic changes groups. IVDD means grades IV and V intervertebral disk degeneration.

by L5/S1 (15.2% in the MC group and 15.6% in the NMC group). The proportion of severe IVDD was higher in the MC group than in the NMC group at all levels, except for L3/L4, where it was equal (57% in both groups).

In the MC group, there were five (5.1%) type 1 cases, 87 (87.9%) type 2 cases, three (3%) type 3 cases, and four (4%) mixed type cases (Figure 4). For the MC range, there were 46 cases of A, 32 cases of B, and 21 cases of C (Figure 5). At the level of disk herniation, the MCs mainly occurred at the L4/L5 level (70.7%) and L5/S1 level (15.15%).

In terms of disk herniation location, within the MC group, the majority of cases occurred at the L4/L5 level, accounting for 70.7% of cases, while the L5/S1 level was the second most common site with 15.15%. Similarly, in the NMC group, disk herniation was predominantly found at the L4/L5 level, representing 76.66% of cases, with the L5/S1 level accounting for 15.55% of cases. This indicates that both groups experienced lumbar disk herniation

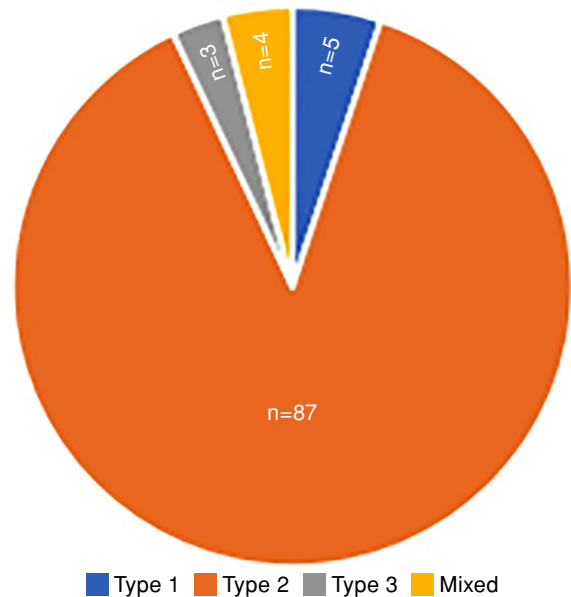


FIGURE 4. The type of modic change.

and disk degeneration primarily in the L4/L5 and L5/S1 regions.

In the NMC group, the level of disk herniation was L4/5 in 79 (87%) patients and L5/S1 in 62 (68%) patients. In the MC group, there were 91 (91%) L4/L5 segments and 80 (80%) L5/S1 segments. As shown in Figure 5, the distribution of MCs was mainly concentrated in the L4/L5 and L5/S1 segments (Figure 6).

For all the above measurements, such as the VBQ score, EBQ score, and SFTT, as well as the grading of Modic change range, location, and Pfirrmann classification, the inter- and intrarater reliability coefficients were above 0.8.

## DISCUSSION

This study is the first to report the VBQ and EBQ scores of patients with MCs.<sup>[21]</sup> The results showed that the difference in EBQ between the two groups may be related to abnormal fat distribution in the vertebral body. The distribution of vertebral fat in patients with MCs is distributed earlier in the upper and lower endplates of the vertebral body, and this trend is not observed in patients without MCs. The EBQ and VBQ scores reflect the SI of the endplate and the vertebral body on MRI images, which may indicate the degree of fat infiltration or inflammation. A higher EBQ score means a higher SI of the endplate, which may suggest the presence

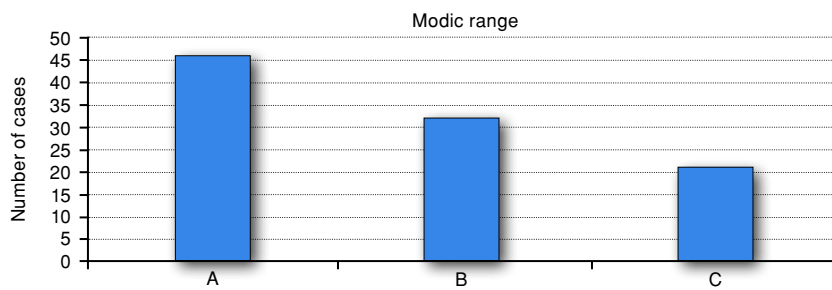


FIGURE 5. The range of modic change.

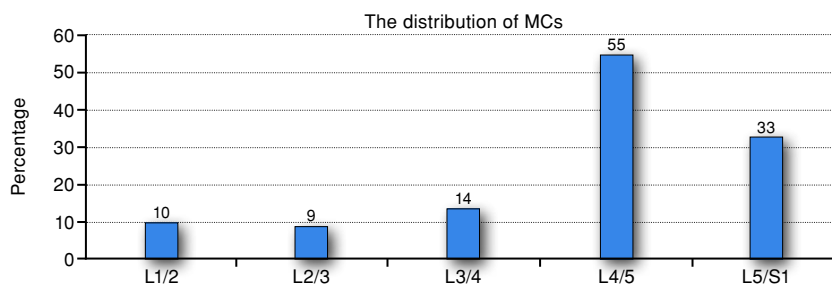


FIGURE 6. The distribution of MCs.

MCs: Modic changes.

of MCs. A lower EBQ score means a lower SI of the endplate, which may indicate a normal or sclerotic endplate. The EBQ score is different from the SI, which is a quantitative measure of the brightness of the image. The EBQ score is a ratio of the SI of the endplate to the SI of the bone marrow, which is a relative measure of the contrast between the endplate and the vertebral body. In this study, the most common level of disk herniation and MC was L4/L5, followed by L5/S1. This is in agreement with previous studies that reported a higher prevalence of MCs in the lower lumbar segments.<sup>[22]</sup> This may be explained by the higher mechanical load and stress that these segments experience, which may lead to more damage and inflammation in the endplates and disks.

Studies<sup>[23]</sup> report that endplate sclerosis occurs in all three Modic subtypes. In addition, mixed MCs were observed. Modic changes were generally more frequent in patients with LBP (43%) than in those without LBP (6%). We did not analyze the differences among Modic subtypes since we considered MCs to be a dynamic variable.

The segments in which MCs most commonly occurred in this retrospective study were

concentrated at L4/L5 and L5/S1, which is consistent with findings reported in the literature.<sup>[24,25]</sup> The incidence of severe IVDD at L4/L5 and L5/S1 was 91% and 80% in the MC group and 87% and 68% in the NMC group, respectively. This is broadly consistent with reports in the literature.<sup>[26]</sup>

Albert et al.<sup>[27]</sup> found that when the lumbar disk degenerates, the stress on the functional unit of the spine redistributes, and the load on the endplate increases, leading to microfracture of the endplate. Recurrent microfractures of the endplate may be the leading cause of MC formation. Abnormal fat metabolism can lead to obesity, which aggravates stress in the functional units of the spine, and we can assess obesity and obesity-related health problems by measuring the SFTT at the upper lumbar level. Özcan-Ekşi et al.<sup>[4]</sup> reported that SFTT is a good predictor of severe IVDD and MCs. According to the literature, SFTT represents body fat content as well as being overweight.<sup>[28]</sup> This is more representative of patient weight than body mass index, with a higher risk of disk degeneration and MCs when SFTT >0.9 cm. The mean values in both groups were >0.9 cm since the inclusion criteria for this study were patients with LBP requiring

surgery and severe disk degeneration. According to the results, as the thickness of subcutaneous fat increases, the occurrence of MCs also increases. In one study, 58% of endplates were ruptured at the time of 17% IVDD, suggesting that endplates are a weaker site in the functional unit of the spine.<sup>[29]</sup> In the same patients with severe IVDD and endplate microfracture, there were also many patients without MCs in the vertebral body; this phenomenon may be related to the response of vertebral bone marrow adipose tissue to inflammatory stimuli released by the intervertebral disk.

According to a previous study, a large number of cytokines, such as tumor necrosis factors, interleukin-6, and interleukin-8, accumulate in disk tissue with MCs.<sup>[8]</sup> These proinflammatory cytokines and injury-related molecules can penetrate from the intervertebral disk to the bone marrow through the endplate injury gap and react with the bone marrow of the vertebral body, resulting in changes in the local microenvironment and structure of the bone marrow of the vertebral body. Currently, fatty tissue is considered to be a highly active metabolic structure that contributes to systemic inflammation and the secretion of large amounts of proinflammatory cytokines.<sup>[30]</sup> In addition, it was reported that an increase in very-low-density lipoprotein diameter promotes the development of MCs.<sup>[31]</sup> Furthermore, an increase in blood lipids and glucose has been associated with the occurrence of MCs.<sup>[32,33]</sup>

The response of the bone marrow often depends on the composition of the bone marrow itself; if there is more fatty tissue in the bone marrow of the vertebral body, it can activate some signaling pathways and inflammatory factors. As a result, the local inflammatory reaction of the bone marrow is enhanced, resulting in alterations to the structure or regional microenvironment of the bone marrow and MCs in the vertebral body. We analyzed blood lipids from the two groups. Although none of the blood lipids were significantly different, the mean values of patients with MCs were larger than those of patients without MCs. Therefore, we tried to identify differences in vertebral fat infiltration between the two groups by measuring data using imaging-related techniques.

There was no significant difference in VBQ between the MC and NMC groups; the MCs mainly occurred near the endplate. The EBQ was used to measure the ROI of 3 mm in the upper and lower endplates; there were no significant differences in the other vertebral bodies.

Interestingly, the SI of the upper and lower endplates of each vertebral body in patients with MCs was more significant than the SI in the center of the vertebral body. In contrast, the opposite was observed in patients without MCs. Therefore, we compared the ratio of the ROI. The ratio of the ROI was the ratio of the SI in the endplate 3 mm to the central SI in the vertebral body; that is, the endplate SI/bone marrow SI in the vertebral body. The ratio of each vertebral body was significantly different, according to a t-test. Therefore, it can be concluded that the SI of the upper and lower endplates is higher in patients with MC, indicating that fat infiltration in the endplate is more evident than in NMC patients. According to relevant studies, fat distribution in the vertebral body is high in the middle and low on both sides.<sup>[34-36]</sup> Additionally, it is common in the middle, high on both sides, and can occur with aging.<sup>[37]</sup> Therefore, the abnormal distribution and metabolism of fat will occur earlier in patients with MCs. Excessive fatty tissue and inflammatory cells infiltrate the upper and lower endplates of the vertebral body. Moreover, local arteriosclerosis of small blood vessels will appear earlier and cause fat embolism, leading to earlier degeneration of the intervertebral disk.

This study has some limitations. First, this is a single-center retrospective study. Therefore, the sample size needed to be larger. The number of cases of type 1 and 3 MCs were inadequate. Second, the study focused on the phenotypic analysis of endplate changes on MRI scans rather than the study-related histopathological and mechanical analyses. Third, there were errors in SI value measurements due to subjective measures. Further studies may be needed in the future.

In conclusion, the occurrence of MCs in the lumbar spine may be associated with abnormal fat distribution, particularly in the vertebral body. The distribution of vertebral fat in patients with MCs is distributed earlier in the upper and lower endplates of the vertebral body, whereas this trend is not significant in patients without MCs. The thickness of subcutaneous fat tissue is a key factor in the occurrence of MCs.

**Ethics Committee Approval:** The study protocol was approved by the Third Hospital of Hebei Medical University Ethics Committee (date: 25.10.2022, no: Ke 2022-115-1). The study was conducted in accordance with the principles of the Declaration of Helsinki.

**Patient Consent for Publication:** A written informed consent was obtained from each patient.



**Data Sharing Statement:** The data that support the findings of this study are available from the corresponding author upon reasonable request.

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