

Axial loading lumbar magnetic resonance imaging with a new device in asymptomatic individuals

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Background: Axial loading magnetic resonance imaging (MRI) of lumbar spine is of great significance in the diagnosis of lumbar diseases. However, the axial loading device used in clinic is unique and has some defects. Therefore, we aimed to investigate the effect and examinee comfort of a new device for axial loading lumbar MRI in asymptomatic volunteers.

Methods: A new axial loading MRI device for the lumbar spine was developed. A total of 30 asymptomatic individuals underwent conventional lumbar MRI and axial loading lumbar MRI sequentially. The dural sac cross-sectional area (DSCA), sagittal vertebral canal diameter (SVCD), and disc height (DH) at L3-4, L4-5, and L5-S1 before and after axial loading were compared by two experienced radiologists. Examinee comfort during the two examinations was assessed.

Results: All 30 volunteers completed the examinations with the new device. No difference in examinee comfort was found between conventional and axial loading MRI. After axial loading, the DSCA, SVCD, and DH showed the largest decreases at L4-5 followed by L5-S1 and L3-4, with the decreases in DSCA and SVCD at L4-5 being significant (P<0.05). Definite imaging-diagnosable disc herniation or bulging was shown at three intervertebral disc levels of three participants.

Conclusions: The new device could effectively implement axial loading of the lumbar spine without causing obvious discomfort for the examinee. The present study has demonstrated that significant changes occur in the lumbar spine of asymptomatic individuals after axial loading.

Keywords: Axial loading; magnetic resonance imaging (MRI); lumbar spine; asymptomatic.

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Introduction

Magnetic resonance imaging (MRI) is currently the best non-invasive examination for the diagnosis of lumbar spine disorders, because it has excellent soft tissue contrast and provides good visualization of anatomical structures (1-3). A conventional lumbar MRI examination is usually performed in the supine position with no load on the lumbar spine, which fails to reflect the real conditions of the lumbar spine

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Figure 1 The axial loading MRI device consists of wearable components and pressure components (A,B). Pressure is applied in the pneumatic mode by the control system, which was placed as far away from the magnet as possible (C). MRI, magnetic resonance imaging.

in the upright position, resulting in the discrepancy between imaging and clinical symptoms (4-8).

To solve this problem, the axial loading MRI technology has been developed to simulate the pathological changes of the lumbar spine in the upright position. Until now, several clinical studies have confirmed that axial loading MRI could improve the accuracy of the diagnosis of lumbar spinal stenosis thus change the clinical treatment strategy (9-12). Currently, the only device for axial loading MRI is the DynaWell L-Spine (DynaWell Diagnostics, NY, USA), which has some defects, including instability in exerting force, complex operation, and high cost (13,14). In an effort to address these deficiencies, we developed a new lumbar axial loading device. The present study aimed to investigate the effect and examinee comfort of this new device for axial loading lumbar MRI in asymptomatic volunteers.

Methods

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Patients

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Institutional Review Board of the 305 Hospital of PLA, Beijing, and informed consent was obtained from all the participants. Thirty asymptomatic volunteers, with an average age of 35.3 years, were included in the study. None of the participants had any history of low back pain or sciatica. The exclusion criteria included previous spinal surgery, severe osteoporosis, severe cardiopulmonary dysfunction, a history of spinal fracture, spinal malignant tumor, lower limb disease, and claustrophobia.

Axial loading device

The new lumbar axial loading MRI device consists of wearable components and pressure components, which achieve lumbar loading by exerting pressure on the shoulders and hips. The pressure is applied in the pneumatic mode. Through the inflation of the control system, air is transmitted from the vent pipe to the cylinder, and the connecting belt is tightened after the cylinder is pressurized, which allows the pressure to be applied stably and measured accurately (*Figure 1*).

The volunteers laid on the examination bed with the wearable components and then the pressure was applied. The pressure adjustment knob was used to control the strength at 40-50% of the body weight, simulating the load weight of the lumbar when the body is upright, and the compression time was 5 minutes (12,15,16). Then, axial loading MRI scanning of the lumbar was performed. During the examination, a small cushion was placed underneath the lumbar spine to achieve lordosis, simulating the upright position.

Imaging technique

All MRI examinations were performed on a 1.5-T system (Signa Optima, GE Medical Systems, Milwaukee, WI, USA) using a surface coil. Sagittal T2-weighted fast recovery fast spin-echo (FRFSE), T1-weighted fast spin-echo (FSE), and axial T2-weighted FRFSE sequences were performed. The repetition time/echo time (TR/TE) was 450–525/9–16 for T1-weighted images and 2,600–3,800/110–130 for T2-weighted images. The field of view (FOV) was 320×320 for

Table 1 Characteristics of the volunteers

Baseline characteristics	Male (n=15)	Female (n=15)	
Age(years) ^a	34±16	38±14	
Height (cm) ^a	177.1±6.0	163.5±6.9	
Body weight (kg) ^a	76.6±9.8	59.6±6.8	
Body mass index (kg/m²) ^a	24.4±2.7	22.3±2.8	
Disc herniation or bulging			
L3-4	-	-	
L4-5	1	1	
L5-S1	1	-	

^a, values are presented as mean ± standard deviation.

sagittal images and 200×200 for axial images, and the slice thickness was 4 mm. The imaging matrix was 320×256 for sagittal images and 320×220 for axial images.

All the participants first underwent conventional MRI scanning, followed by axial loading MRI scanning. All MRI examinations were performed between 6:00 pm and 9:00 pm to exclude the effects of diurnal variations on the lumbar spine.

Image interpretation and measurement

Two experienced radiologists analyzed the images using a workstation (AW, version 4.6, GE Medical Systems). The MRI images were sent to the radiologists with all participant information withheld. The radiologists were also blinded to whether the images had been obtained with or without axial loading. The dural sac cross-sectional area (DSCA), sagittal vertebral canal diameter (SVCD), and disc height (DH) were measured at L3-4, L4-5, and L5-S1. The SVCD, which was the distance from the midpoint of the posterior edge of the intervertebral disc to the base of the spinous process, was measured in the transverse axial image. The DH was averaged from the anterior edge, midline, and posterior edge of the intervertebral space. Three measurements were performed for each disc space and the values were averaged.

Examinee comfort assessment

After undergoing axial loading MRI, the participants were asked to assess the level of comfort of the two examinations on a 5-point scale, as follows: 1 point, no discomfort during the examination; 2 points, only mild discomfort during the examination; 3 points, certain discomfort but the MRI could be undertaken with ease; 4 points, obvious discomfort but the MRI could be completed; and 5 points, intolerable discomfort and the MRI could not be performed.

Statistical analysis

The statistical analyses were performed using the SPSS 25.0 software (IBM Corp., Armonk, NY, USA). The cohort was characterized using means and standard deviations to describe continuous variables and proportions to describe categorical variables. Unadjusted bivariate analyses were conducted using paired *t*-tests for continuous variables. Examinee comfort was compared between the two examinations using the Wilcoxon signed-rank test. Statistical significance was defined as P<0.05. For comparison between the supine and standing positions, a P value with two tails was reported. Inter-observer reproducibility and intra-observer reproducibility for the quantitative radiological measurements were calculated using the intraclass correlation coefficient (ICC) (17). Absolute agreement, two-way random effects, and singlemeasure models were adopted. Poor, moderate, good, and excellent agreement was represented by ICC values of less than 0.4, between 0.4 and 0.74, between 0.75 and 0.9, and exceeding 0.9, respectively.

Results

Study population

All 30 asymptomatic volunteers (15 males and 15 females) completed their examinations successfully, and the image quality was satisfactory. The baseline characteristics of the study participants and obvious changes in the intervertebral disc are summarized in *Table 1*. After axial loading, three intervertebral disc levels of three volunteers had definite imaging-diagnosable disc herniation or bulging, despite having no relevant clinical symptoms (*Figure 2*).

Measurements

The mean DSCA, SVCD, and DH values for all the volunteers at each level tested are listed in *Table 2*. The DSCA and SVCD at the L4-5 level demonstrated a statistically significant difference after axial loading (P<0.05; *Table 2*). The DSCA, SVCD, and DH all showed the greatest reduction after axial loading at the L4-5 level, with



Figure 2 An asymptomatic 35-year-old man. Sagittal T2-weighted FRFSE of conventional MRI (A) and axial loading MRI (B), with disc herniation at L4-5 (arrow). Axial T2-weighted FRFSE of conventional MRI (C) and axial loading MRI (D), also with disc herniation (arrow), and a reduced DSCA from 128.13 to 109.23 mm² after axial loading. FRFSE, fast recovery fast spin-echo; MRI, magnetic resonance imaging; DSCA, dural sac cross-sectional area.

declines of 7.7%, 4.6%, and 2.7%, respectively, followed by L5-S1, with decreases of 6.0%, 3.5%, and 2.4%, respectively, and L3-4, with decreases of 3.6%, 4.1%, and 1.9%, respectively.

Comfort assessment

During the two examinations, no difference in comfort level was reported by the examinees (P=0.83; *Table 3*). Upon questioning, the discomfort of the three high scorers (one with a score of 4 and two with a score of 3) was found to be due to experiences of panic and chest tightness in response to having their heads placed within a magnetic body.

Inter- and intra-observer reliability

The inter-observer ICCs for the DSCA, SVCD, and DH were 0.995, 0.994, and 0.873, respectively, suggesting good to excellent reliability. The intra-observer ICCs for the above measurements were 0.921, 0.972, and 0.953, respectively, suggesting excellent reliability.

Discussion

Previous studies have confirmed that lumbar axial loading MRI plays an important role in the diagnosis of lumbar diseases. The DynaWell L-Spine currently used in clinic achieves lumbar loading by exerting pressure on the

Table 2 The DSCA, SVCD, and DH on conventional MRI and axial loading MRI for each spinal level tested*

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Variables	Conventional MRI	Axial loading MRI	Difference (%)	P value
DSCA (mm ²) ^a				
L3-4	154.18±18.33	148.64±20.11	5.54±4.02 (3.6)	0.274
L4-5	136.18±16.24	125.64±19.06	10.54±9.15 (7.7)	0.026*
L5-S1	128.06±15.22	120.35±17.17	7.71±6.86 (6.0)	0.074
SVCD (mm) ^a				
L3-4	22.89±2.90	21.93±1.78	0.96±0.74 (4.1)	0.129
L4-5	17.78±1.66	16.96±1.32	0.82±1.22 (4.6)	0.039*
L5-S1	16.45±1.27	15.87±1.16	0.58±0.83 (3.5)	0.070
DH (mm) ^a				
L3-4	10.63±0.73	10.44±0.64	0.19±0.33 (1.9)	0.288
L4-5	11.49±0.72	11.18±0.65	0.31±0.39 (2.7)	0.085
L5-S1	11.46±0.71	11.19±0.69	0.27±0.45 (2.4)	0.141

^a, values are presented as mean ± SD; *, P<0.05. DSCA, dural sac cross-sectional area; SVCD, sagittal vertebral canal diameter; DH, disc height; MRI, magnetic resonance imaging; SD, standard deviation.

 $\label{eq:constraint} \begin{array}{l} \textbf{Table 3} \ \text{Comfort scores of the volunteers for conventional MRI} \\ \text{and axial loading MRI} \end{array}$

Score	Conventional MRI	Axial loading MRI
1	14	11
2	13	16
3	2	2
4	1	1
5	-	_

1= no discomfort; 2= mild discomfort; 3= certain discomfort but MRI can be done easily; 4= obvious discomfort but MRI can be done persistently; 5= intolerable discomfort and MRI cannot be done. MRI, magnetic resonance imaging.

shoulders and feet. However, the pressure may vary during the examination due to mild movement of the hip and knee joints, such as slight flexion of the knees. Furthermore, the device uses a manual rotating knob to adjust the tension of the connecting belt mechanically. If the patient is uncomfortable or needs to readjust the pressure during the examination process, the technician is required to return to their bedside to assist (13,14,18-21).

The new device we have developed exerts pressure on the shoulders and hips, which prevents the occurrence of pressure changes due to movement of the knee or hip joint, thus improving the stability of the pressure on the lumbar spine. In the aspect of pressure regulation, we have innovatively adopted the pneumatic mode, which can be perfectly applied to the magnetic field and ensure the stability and accurate measurement of the required pressure applied. The vent pipe connected to the control system is directed through a ground slot to the operation room, where pressurization can be controlled. If conditions do not permit, the control system can be placed as far away from the magnet as possible in the magnet room.

This study recruited 30 asymptomatic volunteers instead of patients with symptoms. Since our device is unprecedented, we needed to study whether it could successfully complete the examination without causing obvious discomfort to the examinee. More importantly, we wanted to determine whether the device could meet the needs of axial load. The test results showed that the device met the requirements in both aspects.

All 30 volunteers completed their examinations successfully, with satisfactory image quality. In the comfort assessment, the volunteers reported experiencing discomfort caused by the MRI, such as discomfort from having their head within a magnetic body, more than discomfort caused by pressure. Two male volunteers reported perineal compression discomfort, and in subsequent device improvements, we added cushions to the perineal wearing components to reduce compression.

The DSCA, SVCD, and DH are the most commonly

used parameters for evaluating changes in lumbar vertebrae after loading, and can most directly reflect the changes in the intervertebral disc and the structure of the spinal canal (22-24). In our study, in most participants, the DSCA, SVCD, and DH at three disc levels changed to a certain extent after axial loading, and the DSCA and SVCD at L4-5 decreased statistically significantly. Some studies have also reported slight changes in the lumbar angle after loading (25,26). A study of asymptomatic individuals using the DynaWell device found that the decrease of DSCA in L4-5 was the most significant, but no other related data, such as SVCD and DH, were measured (27). They also found cases of imaging-diagnosable disc herniation or bulging after lumbar loading in individuals with no clinical symptoms. There were three such cases in our study, which indicates the need to combine clinical symptoms, signs, and imaging findings for the diagnosis of lumbar intervertebral disc herniation.

Axial loading MRI is of great significance. It is the only method that can simulate the stress of the lumbar spine in combination with conventional MRI. Another method is upright MRI, which can truly reflect the pathological changes of the patients under lumbar loading. It is also suitable for studying lumbar changes in complex positions, such as hyperextension and flexion spinal rotation. However, this kind of examination needs to be equipped with special upright MRI equipment, which is expensive, and the magnetic field strength is low (0.25–0.6 T), so the image quality is relatively poor (28-32).

The discussion on whether the axial loading MRI is the same as the upright MRI is of little significance. The state of the lumbar is not fixed when people are upright, and the lumbar also changes dynamically with the extension of upright time and walking distance (33). Moreover, during upright MRI examination, examinees are instructed to lean slightly backward against the examination bench and to rest their arms at a crossing bar to hold, which is still different from the normal upright position (34). Kanno et al. (35) studied the relationship between axial stress MRI and orthostatic myelography. Their results showed a significant positive correlation between the significant reduction in the DSCA in the two examinations. Axial loading MRI could reflect the changes in the DSCA during upright myelography in patients with lumbar spinal stenosis, which has higher sensitivity and specificity than conventional MRI. Some studies have shown that through the use of axial loading MRI, the diagnoses of some patients with spinal stenosis could be confirmed, and the treatment strategy

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changed from conservative treatment to surgical treatment (9,36). Therefore, the significance of lumbar axial loading MRI is that it can make the clinical symptoms of patients conform to the imaging findings and enable clear diagnoses of patients that can further influence clinical decision-making. Mahato *et al.* (37) used upright plus axial loading MRI concurrently. The manifestations of spinal canal stenosis and spondylolisthesis were obvious, representing an increase in the sensitivity of the examination, which might have a noticeable impact on clinical decision-making.

Our study had some limitations. Although we designed and developed a new device and verified its practicability through preliminary experiments, our findings are currently limited to healthy asymptomatic volunteers, and the results might not be easily applied to clinical practice. Therefore, further research on more clinical patients is necessary. Moreover, the sample size of our study was small, and our conclusions might not be clinically convincing enough. In short, our new device needs further clinical research.

Conclusions

The new device we have developed creatively adopts the shoulder-hip compression and pneumatic pressure modes. In our study of asymptomatic volunteers, all individuals completed their examinations successfully, with satisfactory image quality and no significant discomfort caused by the new device. The DSCA, SVCD, and DH at three disc levels changed to a certain extent, with the DSCA and SVCD at L4-5 decreasing significantly. Future studies with clinical patients should be designed to confirm whether the new device can improve the accuracy of diagnosis of lumbar degenerative diseases.

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Footnote

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://qims. amegroups.com/article/view/10.21037/qims-22-283/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related

to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Institutional Review Board of the 305 Hospital of PLA, Beijing, and informed consent was obtained from all the participants.

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