

# Lumbar Muscle Fat Content Has More Correlations with Living Quality than Sagittal Vertical Axis in Elderly Patients with Degenerative Lumbar Disorders

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**Purpose:** As the most poorly tolerated and debilitating form of spinal malalignment, sagittal imbalance is becoming an increasingly recognized cause of pain and disability in adults. However, there is evidence showing that sagittal imbalance has a weak or no correlation with health-related quality-of-life (HRQoL) outcomes. The objective of this study was to describe the direct factor associated with HRQoL in terms of Oswestry Disability Index (ODI) assessment.

**Patients and Methods:** This study retrospectively evaluated the clinical and radiographic information of 179 elderly patients with degenerative lumbar disorders and suboptimal sagittal standing posture (sagittal vertical axis >50 mm). Patient-reported outcomes were assessed using ODI. Patients with ODI ≥40% were assigned to Group D (disability), while those with ODI <40% were assigned to Group ND (non-disability).

**Results:** Compared with Group ND (n=104), patients in Group D (n=75) had greater thoracolumbar kyphosis, pelvic incidence-lumbar lordosis (PI-LL), sagittal vertical axis (SVA), T1 pelvic angle, and fat infiltration, and smaller LL and muscle mass ratio. Pearson analysis revealed a high correlation between the percentage of fat infiltrated and ODI ( $r=0.768$ ,  $P<0.01$ ) and moderate correlation between SVA and ODI ( $r=0.408$ ,  $P<0.001$ ). Linear regression results indicated that fat infiltration was an independent factor associated with ODI. ODI significantly correlated with SVA in patients with major fat infiltration ( $r=0.328$ ,  $P=0.001$ ), while having no correlation with SVA in those with moderate or minor fat infiltration ( $r=0.083$ ,  $P=0.464$ ).

**Conclusion:** Lumbar muscle fat infiltration is an independent factor associated with the living quality in terms of ODI assessment in the elderly population with degenerative lumbar disorders, which has more correlations with ODI scores than the sagittal imbalance. The relationship between HRQoL outcomes and sagittal imbalance depends on the quality of lumbar muscle.

**Keywords:** elderly patients, living quality, sagittal imbalance, lumbar muscle quality, degenerative lumbar disorders, correlation

## Introduction

Sagittal imbalance, also known as sagittal plane malalignment, usually refers to the spinal deformity that results in forward postural instability, which is now most frequently defined by the position of C7 plumb line >5 cm ventral to the poster-superior margin of sacrum on standing lateral whole spine radiograph.<sup>1,2</sup> As the most poorly tolerated and debilitating form of spinal malalignment, sagittal imbalance is becoming an increasingly recognized cause of pain and disability in adults.<sup>3</sup>

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Previous studies have shown that increasing sagittal vertical axis (SVA) is associated with poor health-related quality-of-life (HRQoL) outcome.<sup>4,5</sup> Therefore, taking this inability to stand upright into consideration is important when assessing the degree of spinal disorders.

However, recent studies do not always show a direct correlation between sagittal imbalance and living quality.<sup>6,7</sup> Faraj et al<sup>6</sup> conducted a multicenter retrospective study including 74 patients with symptomatic de novo degenerative lumbar scoliosis to investigate the influence of sagittal radiographic parameters on preoperative HRQoL. They found a weak correlation between SVA and the Oswestry Disability Index (ODI) scores ( $r=0.296$ ,  $P<0.05$ ). However, no significant correlation was found between SVA and other HRQoL questionnaire scores. Takemoto et al<sup>7</sup> constructed multivariate linear regression models to evaluate the association between pre-operative ODI and sagittal parameters in 204 patients with adult spinal deformity (ASD). When adjusted for demographic and surgical variables, no correlation was observed between SVA and ODI scores. Another prospective radiographic study performed by Araújo et al<sup>8</sup> even found that suboptimal sagittal standing posture had no significant impact on HRQoL in a sex-stratified general population (178 males and 311 females), when adjusted by age, education, and BMI.

Sagittal imbalance is common in the elderly population, which is mainly attributed to the degenerative changes including decreased lumbar lordosis (LL) and increased thoracic kyphosis (TK) in aging spine.<sup>9,10</sup> In clinical practice, however, we also observe a weak correlation between the degenerative sagittal imbalance and quality-of-life in elderly patients that complain with worsening pain and fatigue with activities, while others do not have the same symptoms. Thus, we conducted this study with the following aims: 1) to compare the clinical and radiographic characteristics between elderly subjects with degenerative sagittal imbalance with different suboptimal health statuses, and 2) to describe the direct factor associated with HRQoL in terms of ODI assessment.

## Patients and Methods

### Subjects

Under the approval of the Ethics Committee of Capital Medical University Xuanwu Hospital, a retrospective analysis of clinical and radiographic information of elderly patients with suboptimal sagittal standing posture (SVA>50 mm) between September 2016 to September

2019 was performed. The following inclusion criteria were applied: 1) age $\geq$ 60 years; 2) having primary sagittal imbalance;<sup>1</sup> and 3) with complete radiologic images. Patients with non-degenerative spinal disorders (such as traumas, tumors, and inflammatory spinal arthropathies), hip pathology, and a history of spinal or pelvic surgery were excluded.

## Clinical and Radiographic Evaluation

### Clinical Evaluation

Subjects' age, gender, body mass index (BMI), mean bone mineral density (BMD) of lumbar vertebra, and degenerative spinal disorders were recorded. Curve with a Cobb's angle in the coronal plain of more than 10 degrees was defined as scoliosis and kyphosis with a Cobb's angle in the lateral plain of more than 40 degrees was defined as hyperkyphosis.<sup>11,12</sup> ODI scores<sup>13</sup> were collected at the time of radiographic acquisition.

### Spinopelvic Parameters

Radiographic measurements were performed on long-cassette standing lateral radiographs of the spine and pelvis.<sup>14</sup> The following radiographic parameters were measured using Surgimap software (Nemaris, Inc., New York, NY, USA):

1. TK, the angle between the superior end plate of T5 and the inferior endplate of T12.
2. Thoracolumbar kyphosis (TLK), the angle between the superior endplate of T10 and the inferior endplate of L2.
3. LL, the angle between the upper endplate of L1 and the superior endplate of S1.
4. Pelvic incidence (PI), the angle between the perpendicular to the superior endplate of S1 at its midpoint and the line connecting the point to the middle axis of the femoral heads.
5. Sacral slope (SS), the angle between the sacral plate and the horizontal plane.
6. Pelvic tilt (PT), the angle between the line connecting the midpoint of the superior endplate of S1 to the axis of the femoral heads, and the gravity line.
7. PI-LL mismatch equaled to PI minus LL.
8. Sagittal vertical axis (SVA), the horizontal distance between the C7 plumbline and the posterior-superior corner of the sacrum. Negative values of SVA indicated that the C7 plumbline fell behind the sacrum.

9. T1 pelvic angle (TPA), the angle subtended by a line from the femoral heads to the center of the T1 vertebral body, and a line from the femoral heads to the midpoint of the superior endplate of S1.<sup>15</sup> Negative values indicated that the line from the femoral heads to the center of the T1 was placed behind the line from the femoral heads to the center of the superior sacral end plate.

### Disk Degeneration

The degree of disk degeneration (L1–L2 to L5–S1) was examined on 1.5T MRI (Siemens, Erlangen, Germany) images using Pfirrmann disk degeneration classification.<sup>16</sup> Five grades were comprised on sagittal T2-weighted images, representing a progression from normal disk to severe disk degeneration. Grade I corresponded to no degeneration, whereas grade V represented most severe degeneration. Scoring was calculated for convenient assessment, to grade I a score of 5 score, whereas to grade V a score of 1 given. Higher scores represented better disk conditions. The average value of the five scores was calculated.

### Facet Joint Degeneration

The degree of right facet joint osteoarthritis (FJ OA) (L1–L2 to L5–S1) was evaluated on CT images according to previous studies.<sup>17,18</sup> Four grades of FJ OA were defined: Grade 0 represented no degeneration, whereas grade III represented severe degeneration. Scoring was calculated for convenient assessment, to grade 0 a score of 4 was given, whereas to grade III a score of 1 was given. Higher scores represented better facet joint conditions. The average value of the five scores was calculated.

### Back Muscle Degeneration

The cross-sectional area (CSA) of lumbar paravertebral muscle was assessed on 1.5T MRI (Siemens, Erlangen, Germany) images utilizing Picture Archiving and Communication System (PACS).<sup>19,20</sup> The condition of MRI scan was as follows: matrix size=320×320, slice thickness=4.0 mm, slice per slab=15, number of excitations=2. T2-weighted axial images of the L1–2, L2–3, L3–4, and L4–5 intervertebral disc levels were used to analyze the right muscle size and morphology. The regions of interest (ROI) of back muscle were determined by outlining the fascial boundary of the muscles (the fascia thoracolumbalis was traced down laterally and anteriorly to the dorsal side of the quadratus lumborum, followed by the posterior surface of the facet and lamina, and lateral

margin of the spinous process) (Figure 1A).<sup>19</sup> The signal intensity (in gray scale) of the muscle within the ROI was measured using the measurement function of PACS. The percentage of fat infiltrated area was measured using a pseudocoloring technique (threshold technique) (Figure 1C). In order to decrease the bias caused by body size, the area of back muscle was divided by the disc area of the same level (muscle-disc ratio) (Figure 1B).<sup>19</sup> Mean values of muscle mass and fat infiltration of the four levels were calculated.

All the radiographic data were collected by two independent spine surgeons, who were not involved in the treatment of the patients. The mean values were recorded.

### Groups

All the patients were divided into two groups based on the value of 40 points according to the ODI score.<sup>13,21</sup> Patients with ODI score  $\geq 40\%$  were assigned to the relative disability group (Group D), and those with ODI score  $< 40\%$  were assigned to the relative non-disability group (Group ND).

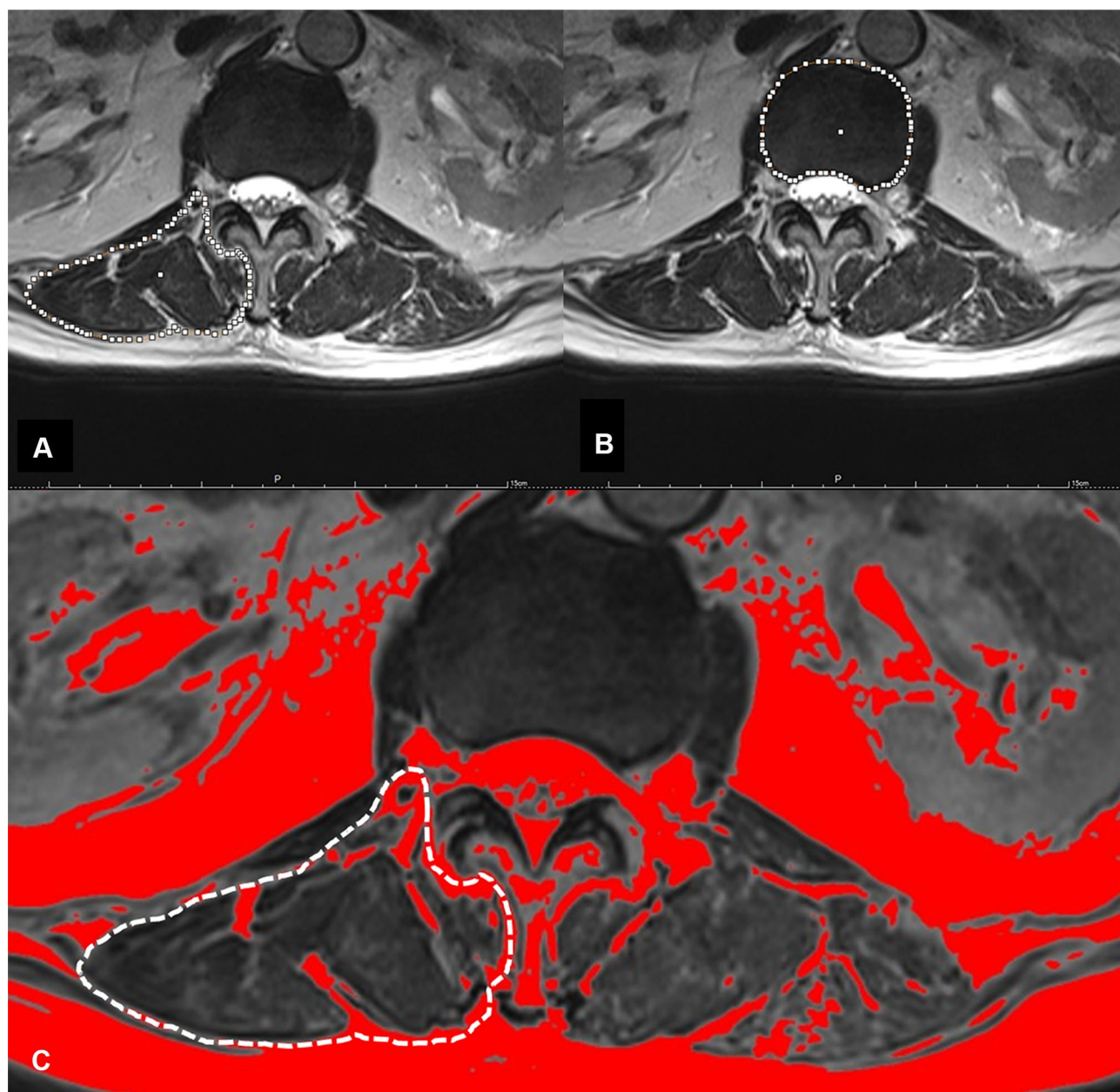
### Statistical Analysis

Values were expressed as mean $\pm$ standard deviation. The intra- and inter-observer reliabilities of the measurement of muscle fat infiltration were analyzed using intra-class correlations (ICC). Chi-square analysis was used for comparisons of categorical variables between groups. Comparisons of continuous variables were performed with independent-samples *t*-test. Correlations between the selected variables from univariate analysis and ODI scores were evaluated. Based on the correlation results, linear regression analysis was performed to identify the factors independently associated with ODI scores. All statistical analyses were performed with SPSS version 19.0 (SPSS Inc, Chicago, IL), and a *P*-value $< 0.05$  was considered significant.

## Results

### Intra- and Interobserver Reliability Analysis

The measurement of muscle fat infiltration had good agreement, with substantial intra- and interobserver reliabilities. The intra- and inter-observer ICC for the measurement was 0.896 (95% confidence interval=0.793–0.950) and 0.852 (95% confidence interval=0.736–0.934), respectively.



**Figure 1** (A) The fascial boundary of lumbar paravertebral muscles (white circle). (B) The boundary of vertebral body (white circle). Muscle–disc ratio was (muscle area)/ (disc area):  $19.53/16.30=1.20$ . (C) Bright pixels of fat tissue in the MR images were colored in red (darker color in the black and white version) using pseudocoloring technique (threshold technique). The percentage of the red pixel area in the white circle was calculated (14.21%).

## Demographic Data of the Whole Cohort

A total of 179 subjects (78 males and 101 females) were included in this study, with an average age of  $70.8\pm 7.7$  years, an average BMI of  $26.1\pm 1.4$  kg/m<sup>2</sup> and an average BMD of  $1.063\pm 0.121$  g/cm<sup>2</sup>. One hundred and thirteen subjects were identified with lumbar disc herniation (1 level: 42, 2 levels: 48, 3 levels: 22, 4 levels: 1), 44 subjects were identified with lumbar spondylolisthesis (1 level: 42, 2 levels: 2), 51 subjects were identified with degenerative

scoliosis, and 21 subjects were identified with hyperkyphosis.

## Comparisons of Demographic and Radiologic Data Between Groups D and ND

Seventy-five patients with ODI scores  $>40\%$  were assigned to Group D, and the others with ODI score  $\leq 40\%$  were assigned to Group ND. As shown in Table 1, patients in the two groups were comparable in age, gender



**Table 1** Comparisons of Demographic Data Between Group D and Group ND

Characteristics	Group D (n=75)	Group ND (n=104)	P
Mean age (years)	72.2±7.4	69.7±8.1	0.217
Gender (M/F)	30/45	48/56	0.413 <sup>†</sup>
Body mass index (kg/m <sup>2</sup> )	25.7±1.3	26.4±1.5	0.712
Bone mineral density (g/cm <sup>2</sup> )	1.012±0.139	1.095±0.115	0.508
Degenerative lumbar disorders			
Disc herniation	1 level: 17 2 levels: 20 3 levels: 9 4 levels: 0	1 level: 25 2 levels: 28 3 levels: 13 4 levels: 1	0.736 <sup>†</sup>
Spondylolisthesis	1 level: 12 2 levels: 0	1 level: 30 2 levels: 2	0.265 <sup>†</sup>
Scoliosis	18	33	0.635 <sup>†</sup>
Hyperkyphosis	14	7	0.014 <sup>†</sup>

**Notes:** Group D indicates the group including patients with ODI score≥40 points; Group ND, the group including patients with ODI score<40 points. <sup>†</sup>Calculated by Chi-square analysis.

distribution, BMI, and BMD. More patients had hyperkyphosis in Group D than Group ND (18.7% vs 6.7%,  $P=0.014$ ). The distributions of diagnoses of lumbar disc herniation, spondylolisthesis, and scoliosis were similar between the two groups.

Compared with Group ND, patients in Group D had greater TLK ( $28.0\pm 10.1^\circ$  vs  $14.4\pm 11.2^\circ$ ,  $P=0.017$ ), PI-LL

( $16.3\pm 4.4^\circ$  vs  $7.5\pm 3.6^\circ$ ,  $P<0.001$ ), SVA ( $116.3\pm 26.8\text{mm}$  vs  $86.5\pm 16.5\text{mm}$ ,  $P=0.008$ ), and TPA ( $22.3\pm 12.3^\circ$  vs  $17.5\pm 8.8^\circ$ ,  $P=0.030$ ) and smaller LL ( $30.6\pm 14.2^\circ$  vs  $42.3\pm 8.8^\circ$ ,  $P=0.014$ ). Assessments of lumbar disc and facet degeneration did not show significant differences between the two groups. With respect to back muscle, patients with ODI>40% had a smaller muscle mass ratio ( $1.15\pm 0.32$  vs  $1.42\pm 0.35$ ,  $P=0.022$ ) and a larger percentage of fat infiltrated ( $40.4\pm 5.0\%$  vs  $25.8\pm 4.3\%$ ,  $P<0.001$ ) than those with ODI≤40% (Table 2).

## Correlation and Regression Analyses in the Whole Cohort

The univariate analysis showed that TLK, LL, PI-LL, SVA, TPA, muscle-disc ratio, and percentage of fat infiltrated might be the associated factors with ODI score. Correlation analyses between these selected variables and ODI score were then performed. Results revealed a high correlation between muscle fat infiltration and ODI ( $r=0.768$ ,  $P<0.01$ ) and a moderate correlation between SVA and ODI ( $r=0.408$ ,  $P<0.001$ ) (Table 3). Significant correlations were not found between other radiologic parameters and ODI assessment. Scatterplots for the relationship of ODI with percentage of fat infiltrated and SVA are shown in Figure 2A and B. Linear regression analysis further indicated that muscle fat infiltration was an independent factor associated with ODI (Table 4).

**Table 2** Comparisons of Radiographic Assessments Between Group D and Group ND

Characteristics	Group D (n=75)	Group ND (n=104)	P
Spinopelvic parameters			
Thoracic kyphosis (°)	29.9±9.3	27.7±8.0	0.612
Thoracolumbar kyphosis (°)	28.0±10.1	14.4±11.2	0.017
Lumbar lordosis (°)	30.6±14.2	42.3±8.8	0.014
Pelvic incidence (°)	46.4±9.1	49.0±9.8	0.206
Pelvic tilt (°)	18.7±8.6	14.3±7	0.107
Sacral slope (°)	28.5±14.9	34.6±12.9	0.081
Pelvic incidence minus lumbar lordosis (°)	16.3±4.4	7.5±3.6	<0.001
Sagittal vertical axis (mm)	116.3±26.8	86.5±16.5	0.008
T1 pelvic angle (°)	22.3±12.3	17.5±8.8	0.030
Disk degeneration			
Facet degeneration	3.45±1.02	3.61±0.99	0.311
Paravertebral muscle degeneration			
Muscle–disc ratio	1.15±0.32	1.42±0.35	0.022
Percentage of fat infiltrated (%)	40.4±5.0	25.8±4.3	<0.001

**Notes:** Group D indicates the group including patients with ODI score≥40 points; Group ND, the group including patients with ODI score<40 points.

**Table 3** The Correlations Between the Selected Radiologic Parameters and ODI Score in the Whole Cohort

		TLK	LL	PI-LL	SVA	TPA	MDR	FI
ODI score	r	0.133	-0.160	0.195	0.408	0.201	0.191	0.768
	P	0.327	0.212	0.102	<0.001	0.088	0.116	<0.001

**Abbreviations:** TLK, thoracolumbar kyphosis; LL, lumbar lordosis; PI-LL, pelvic incidence minus LL; SVA, sagittal vertical axis; TPA, T1 pelvic angle; MDR, muscle-disc ratio; FI, percentage of fat infiltrated.

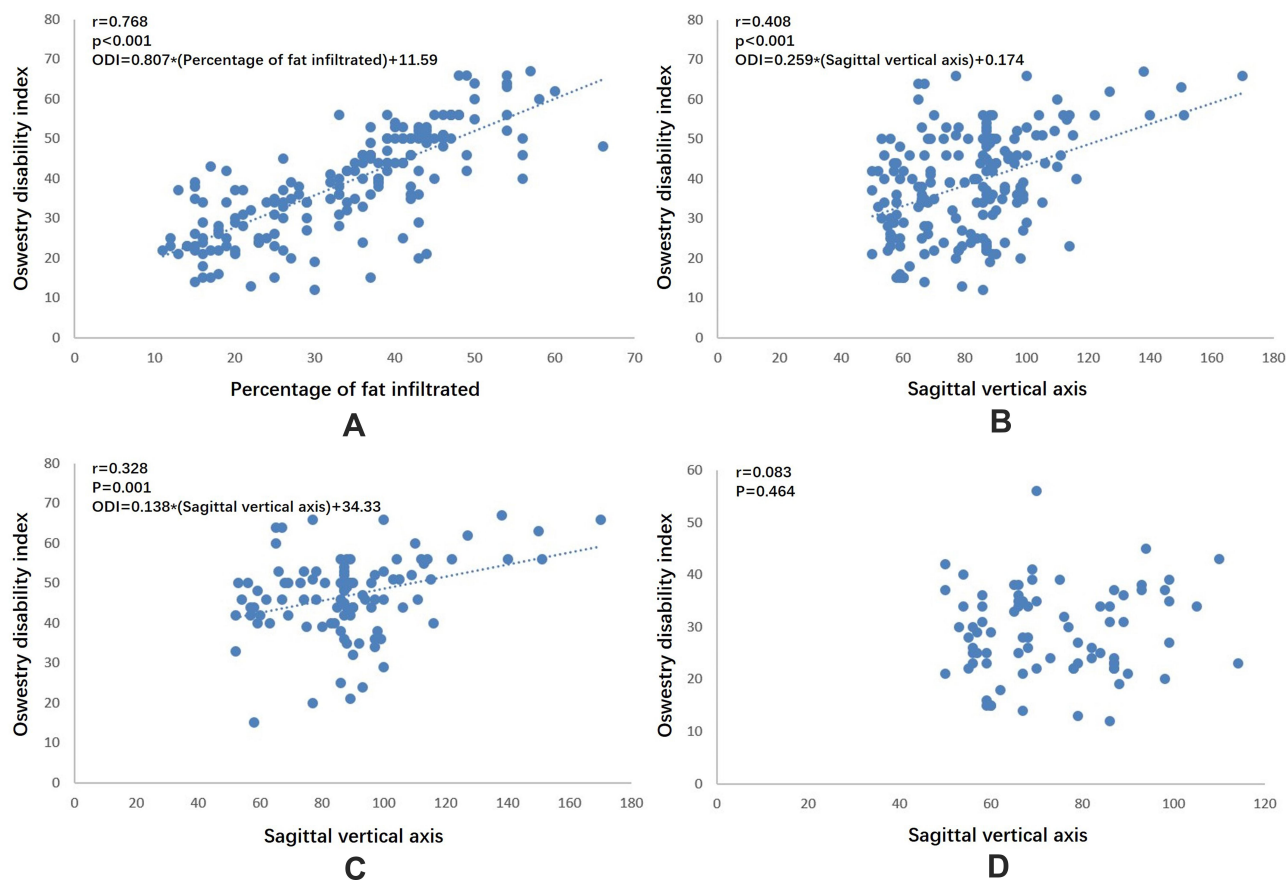
## Correlations Between SVA and ODI in Patients with Major or Moderate Muscle Fat Infiltration

According to the result that muscle fat infiltration was the independent factor associated with ODI, patients were divided into two groups based on the mean percentage of fat infiltrated ( $33.6 \pm 12.3\%$ ). Correlations between SVA and ODI were respectively analyzed in patients with major ( $>33\%$ ) and moderate ( $\leq 33\%$ ) muscle fat infiltration. Results showed that SVA was significantly correlated with ODI in patients with major fat infiltration ( $r=0.328$ ,

$P=0.001$ ), while not correlated in those with moderate fat infiltration ( $r=0.083$ ,  $P=0.464$ ) (Figure 2C and D).

## Discussions

Ideal spinal alignment allows an individual to assume an upright posture with minimal muscular energy expenditure. Positive spinal sagittal imbalance would increase the trunk muscular effort and energy expenditure to maintain a standing position, which then gradually results in low back pain, fatigue, and disability.<sup>22</sup> Numerous studies have reported a relationship between the area or fat infiltration



**Figure 2** Scatterplots for the relationships of ODI with percentage of fat infiltrated and SVA. In the whole cohort of patients with degenerative lumbar disorders, ODI was strongly correlated with the percentage of fat infiltrated (A) and SVA (B). The association between SVA and quality-of-life depends on the quality of paravertebral muscle. ODI was moderately correlated with SVA in patients with major fat infiltration ( $>33\%$ ) of lumbar muscle (C), while not correlated with SVA in patients with moderate or minor fat infiltration ( $\leq 33\%$ ) of lumbar muscle (D).

**Table 4** Linear Regression Analysis for ODI with Percentage of Fat Infiltrated and SVA

Groups	Variables	R <sup>2</sup>	Unstandardized Coefficients	Standardized Coefficients	P
Whole cohort	Percentage of fat infiltrated Sagittal vertical axis	0.594	0.770 0.047	0.732 0.076	<0.001 0.164

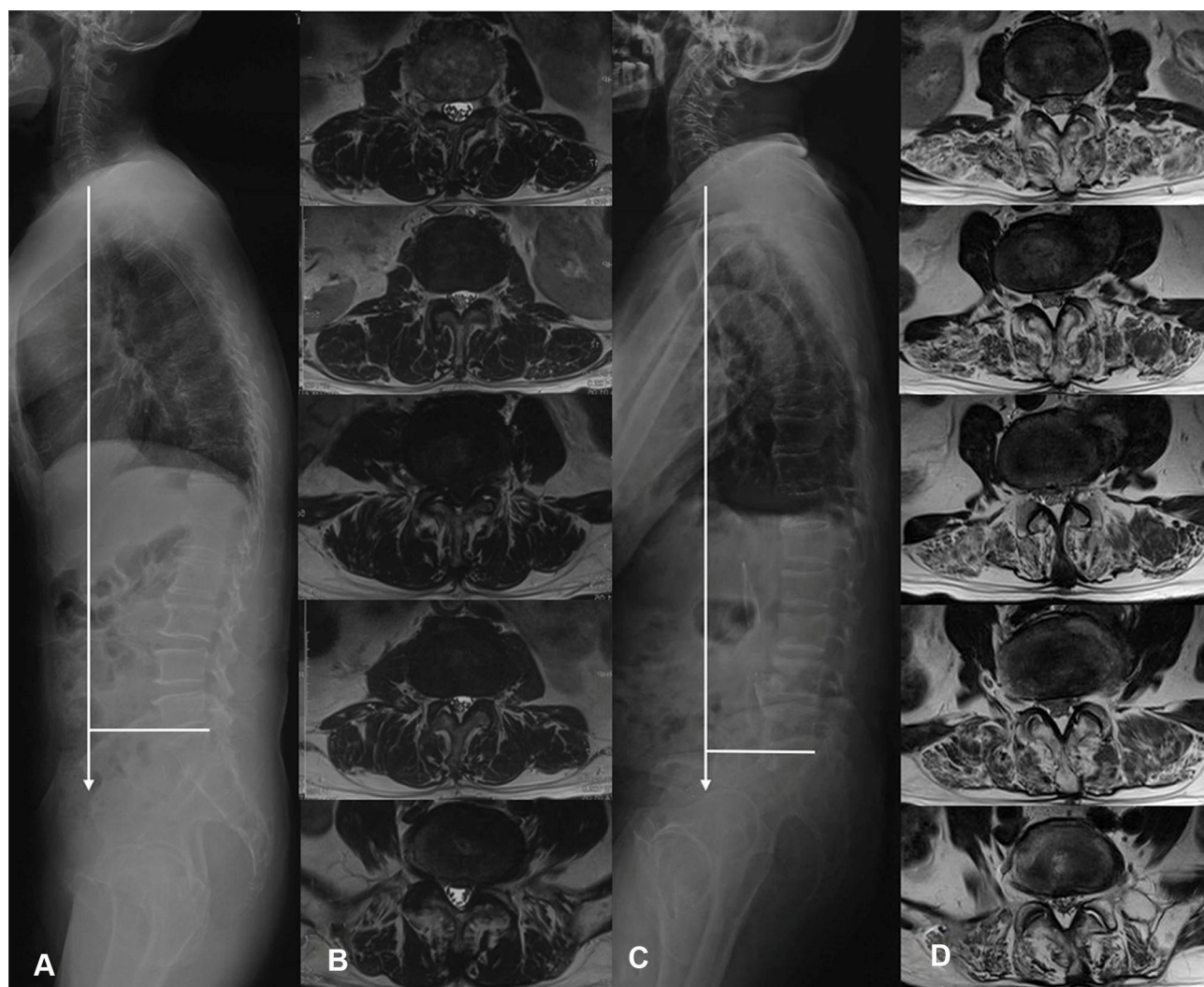
of trunk muscle (especially the paravertebral muscle) and low back pain.<sup>23</sup> Using CT imaging, Danneels et al<sup>23</sup> demonstrated the cross-sectional area of the multifidus at L4 level was statistically smaller in 32 patients with low back pain than the 23 healthy controls. Hebert et al<sup>24</sup> found 401 subjects who were 40-year-old with severe lumbar multifidus fat infiltration had increased odds of ever experiencing low back pain in the past year. In a community-based MRI cohort study including 72 adults with low back pain, a high percentage of fat in the multifidus was associated with an increased risk of high-intensity pain.<sup>25</sup> Although it was hard to determine whether structural abnormalities of the back muscle were a cause or result of low back pain, they thought the muscular atrophy and fat infiltration could permit spinal instability which was an important factor contributing to the occurrence of low back pain.

Low back pain is considered as one of the critical factors jeopardizing healthy life expectancy and a leading cause of years lived with disability.<sup>26,27</sup> Despite paraspinal muscle degeneration has been recognized as a risk factor of low back pain, there is still a rare study on the relationship of paravertebral muscle with quality-of-life. Recently, Hori et al<sup>28</sup> performed a multicenter cross-sectional study to clarify the relationship of trunk muscle mass with low back pain, spinal sagittal balance, and quality-of-life by bioelectrical impedance analysis (BIA) method. Trunk muscles (including the iliopsoas and paravertebral muscles) mass was found to be significantly associated with the ODI, VAS score, SVA, and EQ5D score. In order to identify factors of suboptimal health status and optimize clinical decision-making, we compared the demographic and radiographic characteristics between elderly subjects with degenerative sagittal imbalance and different statuses of living disability. Patients with ODI>40% were found with greater TLK, SVA, TPA, and percentage of fat infiltrated and smaller LL and muscle mass ratio than those with ODI≤40% (Table 2). Pearson analysis revealed that ODI scores were highly correlated with the percentage of fat infiltrated ( $r=0.768$ ,  $P<0.01$ ), while moderately correlated with SVA ( $r=0.408$ ,  $P<0.001$ ). Linear regression results

further indicated that only muscle fat infiltration was the independent factor associated with ODI. Sagittal spinal alignment and balance have also been proven to be related to CSA and fat infiltration of paravertebral muscles.<sup>29,30</sup> In this regard, decreased living quality and sagittal malalignment could be deemed as two different manifestations of the poor back muscle status in the elderly. Therefore, it is reasonable that muscle fat content had more correlations with disability than sagittal imbalance in this study.

Spinal sagittal imbalance is traditionally considered as a common cause of living disability. Recent evidences indicated that sagittal imbalance might not necessarily be associated with quality-of-life.<sup>6-8</sup> In their study, HRQoL questionnaire scores were shown to have a weak or no correlation with SVA in patients with ASD and even in the general population, when adjusted for demographic variables. We speculated that the paravertebral muscle disturbed the relationship of SVA and ODI. A good quality of muscle has the power to compensate for the sagittal imbalance, with minor symptoms. In contrast, a poor quality of muscle would cause major symptoms under moderate sagittal imbalance. In this regard, the association between sagittal imbalance and quality-of-life depends on the quality of paravertebral muscle (Figure 3A–D). Our study confirmed this theory that ODI was significantly correlated with SVA in patients with major fat infiltration ( $r=0.328$ ,  $P=0.001$ ), while not correlated with SVA in those with moderate or minor fat infiltration ( $r=0.083$ ,  $P=0.464$ ). To our best knowledge, this result had never been reported before.

With regard to the associated factors with quality-of-life, most studies paid attention to the spinal sagittal malalignment and imbalance. To date, a rare study focused on the paravertebral muscle in the management of living disability in the elderly. The present study first found back muscular fat infiltration had more significant correlations with living quality than sagittal imbalance in an elderly population with degenerative lumbar disorders. Our results suggested paraspinal muscles should be taken into consideration when evaluating sagittal imbalance disorders and performing the correction surgery.



**Figure 3** A 68-year-old male with an SVA of 88.5mm (A) and a mean percentage of lumbar muscle fat infiltration of 16.3% (B). His ODI score was 24%. Another 66-year-old male with an SVA of 75.7 mm (C) and a mean percentage of lumbar muscle fat infiltration of 48.4% (D). His ODI score was 46%.

This study has several limitations. First, this research was a cross-sectional study, which could not prove the causal relationship. We had no idea whether paraspinal muscle degeneration was the “cause” of spinal sagittal imbalance or the “result” of spinal sagittal imbalance. Second, SVA might be underestimated because of the compensatory mechanism of knee flexion. However, knee flexion could only be evaluated on the full-length radiographs. Third, subjects included were patients who needed an operation in our center, who could not represent the general population. Fourth, muscle strength is also associated with the low back pain and the quality-of-life in patients with lumbar degenerative changes. However, back muscle strength has not been assessed at our center. In spite of this, our

results could also clarify the importance of paravertebral muscles in the management of spinal disorders with sagittal imbalance.

## Conclusion

Lumbar muscle fat infiltration is an independent factor associated with the living quality in terms of ODI assessment in the elderly population with degenerative lumbar disorders, which has more correlations with ODI scores than the sagittal imbalance. The relationship between quality-of-life and sagittal imbalance depends on the lumbar muscle status. ODI evaluation is correlated with SVA in elderly subjects with major fat infiltration, while it is not correlated with SVA in those with moderate or minor fat infiltration.



## Ethics Statement

Patient consent to review their medical records was waived in the present study. The procedure performed in this study involving human participants was in accordance with the ethical standards of the Ethics Committee of Capital Medical University Xuanwu Hospital and/or the national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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## Disclosure

The authors have no conflicts of interest to declare for this work.

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