

# Sacral Muscle Injuries Post-High-Intensity Focused Ultrasound Ablation for Uterine Fibroids: MRI Evaluation and Influencing Factors

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# Abstract

**Objective:** To explore the manifestations of magnetic resonance (MR) imaging-detected muscle injuries around the sacrum following uterine fibroid ablation using ultrasound-guided high-intensity focused ultrasound (USgHIFU) and the factors influencing these injuries. Materials and Methods: A retrospective analysis was conducted on 555 patients with uterine fibroids who underwent USgHIFU ablation therapy. Based on their postoperative MR images, patients with muscle injuries around the sacrum were identified, and the specific locations of these muscles were recorded. The severity of muscle injuries around the sacrum was evaluated imitating the semi-quantitative assessment system for paraspinal muscle infiltration. Thus, the severity of muscle injury was stratified into five groups for comparison of fibroid characteristics and HIFU treatment parameters among the groups. Both univariate and multivariate analyses were employed to analyze all results. Results: Among the 555 patients with uterine fibroids who underwent USgHIFU ablation therapy, 226 patients (40.7%, 226/555) exhibited muscle injuries around the sacrum. Piriformis muscle injury was particularly prevalent, accounting for 97.3% (220/226) of cases, including 20 cases with concurrent gluteus maximus muscle injury. Only 6 cases involved isolated gluteus maximus muscle injury, while no injuries to other muscles were reported. Multivariate analysis revealed that uterine position, fibroid location, T2 signal intensity and HIFU treatment intensity were significantly associated with the severity of piriform is muscle injury (p < 0.05). <u>Conclusion:</u> Following USgHIFU ablation therapy for uterine fibroids, a part of patients may experience muscle injuries around the sacrum, including the piriformis and gluteus maximus muscles, with piriformis muscle injury being the most common. Patients with retroverted uterus, posterior wall fibroids, fibroids with higher T2 signal intensity, and high HIFU treatment intensity may experience more severe piriformis muscle injury postoperatively.

Keywords: ultrasound-guided high-intensity focused ultrasound, MRI, uterine fibroids, sacral injury, adverse events

# 1. Introduction

Uterine fibroids are the most common benign tumors in gynecology (Borah B J, Nicholson W K, Bradley L. et al., 2013), with about 20%-50% of patients exhibiting clinical symptoms such as increased menstrual flow and compressive discomfort, which have adverse effects on their physical and mental health (De La Cruz M S D & Buchanan E M., 2017). With advancements in medical technology, Ultrasound-guided High-Intensity Focused Ultrasound (USgHIFU) has increasingly gained prominence in the treatment of uterine fibroids. As a minimally

invasive therapeutic approach, its safety and effectiveness in treating uterine fibroids have been thoroughly demonstrated in numerous studies (Cheung V Y T., 2013; Liu L, Wang T & Lei B., 2021; Yan L, Huang H, Lin J. et al., 2022; Wang F, Tang L, Wang L. et al., 2014; Zhang L, Zhang W, OrsI F. et al., 2015).

Despite this, a small number of uterine fibroid patients may still encounter adverse reactions following UsgHIFU treatment, with pain being the most prominent issue affecting them (Liu Y, Zhang W W, He M. et al., 2018; Cheng C-Q, Zhang R-T, Xiong Y. et al., 2015). This pain can manifest in areas such as the Sacro coccyx, legs, and lower abdomen, with sacrococcygeal pain being the most prevalent and significantly impacting patients' physical and mental health. These issues highlight the importance of postoperative follow-up.

MRI, with its excellent soft tissue resolution, allows for the assessment of target area and surrounding tissue damage, has been widely used in postoperative follow-up. In postoperative MR images, some patients exhibit damage to tissues such as the sacrum, fascia, and muscles. Numerous studies have indicated that adverse reactions such as postoperative pain are often associated with this type of damage (Cun J-P, Fan H-J, Zhao W. et al., 2018; Zhang Y-J, Xiao Z-B, Lv F-R. et al., 2020). The muscles surrounding the sacrum, such as the psoas major, iliacus muscle, piriformis muscles, are tightly connected to the sacrum, collectively forming a robust support system that ensures the body maintains a stable posture. Notably, the origin of the piriformis muscle is located on both sides of the anterior sacral foramina of the second to fourth sacral vertebrae, making it a crucial muscle that determines the position of the sacrum. The muscles surrounding the sacrum play a pivotal role in human movement. If they are damaged or dysfunctional, it may lead to limited mobility, pain, and other issues, thereby affecting daily activities. Recent research by Li et al. has pointed out that postoperative sacrococcygeal pain is significantly correlated with the volume of muscle soft tissue damage around the sacrum (Li D, Gong C, Bai J. et al., 2020) suggesting that such damage plays an important role in postoperative adverse reactions. However, they did not elaborate on the specific affected area with these injuries, and there are currently no reports on the factors affecting the volume of muscle injuries around the sacrum.

Therefore, this study included a total of 555 patients with uterine fibroids who underwent USgHIFU ablation treatment. Based on postoperative MR images, the specific sites of muscle damage around the sacrum in these patients were recorded, and a semi-quantitative assessment of their damage volume was conducted. Additionally, the factors influencing the volume of this damage were explored. A more comprehensive understanding of these factors will help improve the preoperative evaluation procedure of USgHIFU and predict risk factors for adverse reactions.

# 2. Materials and Methods

# 2.1 Patients

This study has been officially approved by the Ethics Committee of Chongqing Medical University, China (Approval Number: 2021-548). Due to the retrospective nature of the study, we have waived the requirement for informed consent in accordance with regulations. We systematically collected relevant data from 555 women who underwent ultrasound-guided high-intensity focused ultrasound (USgHIFU) ablation treatment for uterine fibroids in our hospital between November 2019 and April 2021.

The inclusion criteria for this study are: (1) confirmed patients with uterine fibroids exhibiting clinical symptoms; (2) patients who meet the criteria for HIFU treatment; (3) patients with altered sacral MR signals after HIFU treatment; (4) patients with complete preoperative and postoperative pelvic MRI imaging data. The exclusion criteria include: (1) history of other gynecological diseases, such as endometriosis or pelvic inflammatory disease; (2) history of radiation therapy for lower abdominal malignancies; (3) excessively large fibroids (maximum diameter > 12 cm); (4) pregnancy.

## 2.2 Magnetic Resonance Imaging Evaluation

Prior to and within 1-2 days post-treatment with USgHIFU, all patients underwent MR imaging using a 1.5T system (Model: uMR570; Manufacturer: United Imaging Healthcare, Shanghai, China). During imaging, patients were positioned supine, with the scanning region extending from the ilium to the inferior margin of the pubic symphysis. The scanning parameters were configured as follows: standard T1-weighted imaging (T1WI; TR/TE = 500/13 ms, axial plane, voxel size =  $1.7 \times 1.3 \times 5.0$  mm<sup>3</sup>, slice thickness = 5 mm), T2WI (TR/TE = 5300/100 ms, axial plane, voxel size =  $1.0 \times 1.0 \times 5.0$  mm<sup>3</sup>, slice thickness = 5 mm), diffusion-weighted imaging (DWI; TR/TE = 4800/98.8 ms, axial plane, voxel size =  $3.0 \times 3.0 \times 5.0$  mm<sup>3</sup>, slice thickness = 5 mm, b-values = 0 and 800 s/mm<sup>2</sup>), and contrast-enhanced sequences (TR/TE = 6.23/2.91 ms, axial plane, voxel size =  $1.7 \times 1.2 \times 5.0$  mm<sup>3</sup>, slice thickness = 5 mm).

Two experienced radiologists independently evaluated the MR images. In cases of disagreement, a consensus was reached through consultation with a senior departmental expert. The three-dimensional diameters of the non-perfused volume (NPV) and uterine leiomyoma were measured on the enhanced images, including the

longitudinal (D1), anteroposterior (D2), and transverse (D3) diameters. Volumes of both the NPV and leiomyoma were calculated using the formula  $V = 0.5233 \times D1 \times D2 \times D3$ . Additionally, several variables were derived from the treatment parameters, including treatment intensity (s/h, representing the hourly ablation rate of the leiomyoma using ultrasound) and NPV ratio (NPV / leiomyoma volume).

The following information was also recorded: leiomyoma count, distances from the dorsal and ventral leiomyoma surfaces to the sacrum and skin, abdominal wall thickness, uterine position (anteverted, mid-position, retroverted), leiomyoma location (anterior wall, posterior wall, lateral wall, fundus), leiomyoma type (intramural, submucosal, subserosal), T2WI signal intensity (hypointense, isointense, hyperintense), and degree of enhancement (slight, moderate, significant). (Yang M-J, Yu R-Q, Chen W-Z. et al., 2020)

Compared to preoperative MR images, MR images of some patients after surgery show muscle injuries such as those to the piriformis and gluteus maximus, typically presenting as mixed patchy hyperintensity or slightly hyperintensity on MRI T2-weighted images (T2WI) and demonstrating weak or no enhancement on contrast-enhanced MRI. This study imitates the semi-quantitative assessment system for paraspinal muscle infiltration (Yazici A, Yerlikaya T & Oniz A., 2022; Wen G, Hou W & Xu G., 2023), a semi-quantitative visual evaluation of the piriformis muscle was conducted on transverse planes, classifying it as unaffected (0 points), mild (1 point): <10% of muscle volume affected; moderate (2 points): 10-30% of muscle volume affected; severe (3 points): 30-50% of muscle volume affected; and extreme (4 points): >50% of muscle volume affected. Thus, 555 patients were divided into five groups: (1) the "Score 0" group (Figure 1a), (2) the "Score 1" group (Figure 1b), (3) the "Score 2" group (Figure 1c), (4) the "Score 3" group (Figure 1d), and (5) the "Score 4" group (Figure 1e). When there is a discrepancy in the piriformis muscle scores between the two sides, priority should be given to the score of the more severely affected side for evaluation.





Figure 1. T2 axial magnetic resonance imaging slices showing degree of piriformis muscle injury severity, with the semi-quantitative assessment system. (The left image is preoperative, and the right image is postoperative)
(a) Score 0, unaffected; (b) Score 1, <10% of muscle volume affected; (c) Score 2, 10-30% of muscle volume affected; (d) Score 3, 30-50% of muscle volume affected; (e) Score 4, >50% of muscle volume affected.

# 2.3 USgHIFU Ablation

All tumor ablation treatments were conducted utilizing the JC-type focused ultrasound tumor treatment system manufactured by Chongqing HIFU Medical Technology Co., Ltd. in China. This system featured an ultrasonic transducer operating at 0.8 MHz, with specifications of a 15 cm focal length and a 20 cm diameter. Real-time guidance during the ablation process was provided by the Mylab 70 ultrasound imaging system from Esaote (Italy), ensuring precise target localization and monitoring of treatment efficacy.

Throughout the procedure, the ablation power was maintained at a constant range of 300-400W, initiating from the posterior aspect of the uterine leiomyoma, with a minimum distance of 10 mm from the tumor's dorsal margin. Treatment parameters, such as ultrasonic power and duration, were dynamically adjusted based on patient feedback and alterations in grayscale observed in the target area's ultrasonography.

Termination of treatment was determined when the monitoring ultrasound indicated the cessation of blood flow perfusion within the target tissue or significant grayscale changes in color Doppler images. At this juncture, various parameters and adverse reaction indicators were documented and analyzed, including sonication power, sonication time, total treatment time, treatment intensity (s/hour), therapeutic dose (TD), negative predictive value (NPV), NPV ratio (NPVR), and energy efficiency factor (EEF; J/mm<sup>3</sup>, representing the energy required per unit volume of fibroid ablation).

During the treatment, the patient was positioned prone on the treatment table, with their abdominal wall in direct contact with the ultrasonic transducer via circulating degassed water maintained at a temperature below 15°C. Conscious sedation was achieved through intravenous administration of fentanyl citrate and midazolam hydrochloride, allowing the patient to remain awake and capable of effective communication with the physician. Throughout the procedure, the patient was instructed to promptly report any discomfort.

## 2.4 Statistical Analysis

Data analysis was conducted using SPSS 26.0 (IBM, USA) statistical software. Normally distributed data were reported as mean  $\pm$  standard deviation, while skewed data were reported as median and interquartile range. Univariate statistical comparisons were performed using ordinal regression. Parameters with significant differences in the univariate analysis were selected and, after satisfying the parallelism test, included in the multivariate analysis, thereby performed ordered multiclass logistic regression analysis. A P-value < 0.05 was considered statistically significant.

# 3. Results

3.1 Baseline Characteristics and Fibroid Features of the Patients

This study included 555 patients with uterine fibroids who underwent USgHIFU ablation treatment. The mean age of the patients was  $40.3 \pm 6.6$  years (range: 33.7-46.9 years). The results showed that 40.7% (226/555) of the patients exhibited muscle injury around the sacrum on MR images. Notably, piriformis muscle damage was particularly prevalent, accounting for 97.3% (220/226) of the cases, with 20 patients also presenting with concurrent gluteus maximus muscle injury, while only 6 cases of isolated gluteus maximus muscle injury was reported, and no other muscles were reported to be injured. To quantitatively assess the most common piriformis muscle injury after the procedure, the semi-quantitative assessment system for paraspinal muscle infiltration was imitated in this study, categorizing the degree of injury into scores ranging from 0 to 4. The statistical results indicated that 3.1% (17/555) of the patients scored 4, 5.9% (33/555) scored 3, 11.8% (66/555) scored 2, 18.7% (104/555) scored 1, and 60.3% (335/555) of the patients showed no significant injury (score 0). In these groups with damage to the piriformis muscle, the proportion of retroverted uterus and posterior wall fibroids was significantly higher than that in the normal piriformis muscle group. The results of the univariate analysis, presented in Table 1, revealed statistically significant differences (p < 0.05, Figure 1) between the degree of piriformis muscle injury (scored 0-4) and fibroid characteristics such as uterine position, fibroid location, fibroid type, T2 signal intensity, distance from fibroid ventral side to the skin, fibroid dorsal side to the sacrum and degree of enhancement for fibroid. Comparisons among groups for other variables showed no significant differences.

Table 1. Univariate analysis to evaluate the relationship between the degree of piriformis muscle injury and fibroid features

Characteristics	0(n=335)	1(n=104)	2(n=66)	3(n=33)	4(n=17)	p value
Age (years)	42(35–45)	41(35–45)	42(37–46)	40(34-45.5)	35(31-47)	0.525
Thickness of abdominal wall (mm)	26.29(21.7 4–31.89)	26.34(22.2 4–30.88)	23.08(19.93–3 0.12)	24.01(20.47–2 8.23)	25.95(21.0 2–29.51)	0.065
Fibroid ventral side to the skin (mm)	40.54(31.5 2–55.78)	50.06(33.1 9–73.15)	53.77(38.46–6 8.19)	46.06(30.63–6 0.27)	45.09(36.2 3–61.46)	0.000
Fibroid dorsal side to the sacrum (mm)	29.69(15.5 7–42.81)	18.82(12.5 9–36.90)	16.47(11.62–2 4.46)	21.43(14.57–3 4.45)	25.79(11.4 0–37.02)	0.000
Maximal diameter (mm)	60.88(50.4 1–74.26)	60.04(48.8 2–72.15)	63.39(51.88–7 4.26)	63.25(55.37–8 0.55)	55.96(47.6 4–67.78)	0.654
Volume of fibroid (cm <sup>3</sup> )	83.50(50.2 7–160.95)	81.29(49.2 0–150.72)	92.18(58.51–1 72.29)	99.37(78.86–2 30.52)	71.20(44.5 2–143.58)	0.937
Number of fibroids	2(1-3)	2(1-3)	2(1-3)	1(1–3)	2(1-2)	0.135
Position of the uterus, n (%)						
anteverted	260(77.6)	58(55.8)	36(54.5)	18(54.5)	9(52.9)	
mid-position	50(14.9)	38(36.5)	22(33.3)	10(30.3)	5(29.4)	0.000
retroverted	25(7.5)	8(7.7)	8(12.1)	5(15.2)	3(17.6)	0.004
Location of fibroids, n (%)						
anterior wall	132(39.4)	31(29.8)	15(22.7)	11(33.3)	4(23.5)	
posterior wall	65(19.4)	43(41.3)	37(22.3)	13(39.4) 8(47.1)		0.000
lateral wall	100(29.9) 28(26.9) 11(16.7) 6(18		6(18.2)	4(23.5)	0.908	
fundus	38(11.3) 2(1.9) 3(4.5)		3(4.5)	3(9.1)	1(5.9)	0.129
Type of fibroid, n (%)						
intramural	28(8.4)	4(3.8)	3(4.5)	2(6.1)	0(0)	
submucosal	252(75.2)	82(78.8)	54(81.8)	29(87.9)	17(100)	0.039
subserosal	55(16.4)	18(17.3)	9(13.6)	2(6.1)	0(0)	0.379
T2WI, n (%)						
hypointense	96(28.7)	15(14.4)	8(12.1)	5(15.2)	1(5.9)	

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isointense	117(34.9)	41(39.4)	24(36.4)	19(57.6)	12(70.6)	0.000
hyperintense	122(136.4)	48(346.2)	34(51.5)	9(27.3)	4(23.5)	0.000
Degree of enhancement, n (%)						
Slight	144(43.0)	43(41.3)	21(31.8)	10(30.3)	6(35.3)	
Moderate	136(40.6)	44(42.3)	24(36.4)	12(36.4)	6(35.3)	0.487
Significant	55(16.4)	17(16.3)	21(31.8)	11(33.3)	5(29.4)	0.002

# 3.2 Comparison of USgHIFU Treatment Parameters Between the Different Groups

A total of 1256 uterine fibroids were ablated in this study, with non-perfusion volume ratios (NPVR) ranging from 11.8% to 100%, with an average of 74.3  $\pm$  17.2%. NPVR, which stands for non-perfused volume ratio, serves as a crucial indicator for evaluating the efficacy of High-Intensity Focused Ultrasound ablation in the treatment of uterine fibroids. It represents the proportion of the non-perfused area (i.e., the coagulative necrosis area) within the entire volume of the uterine fibroid after HIFU treatment. A higher NPVR value indicates a larger volume of coagulative necrosis in the uterine fibroid tissue, thereby signifying a better therapeutic outcome. As shown in Table 2, sonication time, treatment intensity, and total treatment dose TD are highly correlated with the degree of piriformis injury (p<0.05). However, there were no statistically significant differences in parameters such as sonication power, treatment time, EEF, NPV, and NPVR among the groups.

Table 2. Univariate analysis to evaluate the relationship between the degree of piriformis muscle injury and ultrasound ablation parameters

Characteristics	0(n=335)	1(n=104)	2(n=66)	3(n=33)	4(n=17)	p value
Sonication power (W)	400(400–40 0)	400(400–4 00)	400(400-400)	400(400-400)	400(400-400)	0.749
Sonication time (s)	950(615–14 00)	1100(675.2 5–1500)	930(631.75–1 477.50)	1464(775–2000)	1050(884.5–1 532.5)	0.023
Treatment time (min)	101(71–136)	112.5(79.7 5–141)	107(72–136.2 5)	130(81–159.5)	90(76–127.5)	0.255
Treatment intensity (s/h)	582.26±163. 56	615.74±16 0.23	587.30±151.9 3	688.11±167.56	670.45±152.0 4	0.001
TD (KJ)	361.6(235.2 -522.4)	431.60(262 .90–600)	374.96(252.7– 590.01)	580(305.45–800 .00)	412.15(316.4– 613)	0.029
NPV (cm <sup>3</sup> )	60.87(34.06 -112.31)	55.74(31.4 0–122.36)	65.13(40.39–1 08.73)	78.55(45.22–16 8.33)	59.88(31.99–1 26.04)	0.945
NPV ratio (%)	0.77(0.65–0. 88)	0.75(0.60– 0.86)	0.76(0.62–0.8 7)	0.73(0.64–0.84)	0.84(0.68–0.9 2)	0.534
EEF (J/mm3)	4.20(2.85–5. 90)	4.45(3.23– 5.91)	4.24(3.28–5.5 7)	4.92(3.31–9.90)	4.80(3.22–6.2 6)	0.805

Note: TD, therapeutic dose; NPV, non-perfused volume; NPV ratio, the ratio (%) of NPV-to-fibroid volume; EEF, energy efficiency factor.

In each category, numbers in the parentheses indicate the range.

## 3.3 Multivariate Analysis of Influencing Factors on the Degree of Piriformis Muscle Injury

In this study, the results of the parallel lines test indicated that P = 1.000, suggesting that the parallelism assumption was valid, allowing for the use of an ordered logistic process for multivariate analysis. Consequently, uterine position, fibroid location, fibroid type, T2 signal intensity, distance from fibroid ventral side to the skin, fibroid dorsal side to the sacrum, degree of enhancement for fibroid, sonication time, treatment intensity, and TD were included as independent variables in the ordered multinomial logistic regression analysis. Ultimately, among the 10 variables included in the model, uterine position, fibroid location, T2 signal intensity and treatment intensity were significantly associated with the degree of piriformis muscle injury (p < 0.05, Table 3). The higher T2 signal intensity of the fibroid, the greater the risk of causing a more severe degree of piriformis

muscle injury (p = 0.020, odds ratio [OR] 0.506, 95% confidence interval [CI] 0.286-0.898). A retroverted uterus and posterior wall fibroids and higher were HIFU treatment intensity positively correlated with the degree of piriformis muscle injury.

Table 3. Multivariate ordered logistic regression analysis was conducted to evaluate the correlation between the
degree of piriformis muscle injury and significant factors in univariate analysis

Variables	В	SE	Wald	р	Ors[Exp(B)]	95%CI	
						Lower	Upper
Position of the uterus, n(%)							
anteverted*							
mid-position	0.800	0.307	6.781	0.009	0.449	0.246	0.821
retroverted	1.189	0.234	25.691	0.000	0.305	0.192	0.482
Type of fibroid, n(%)							
intramural*							
submucosal	0.458	0.420	1.193	0.275	0.632	0.278	1.439
subserosal	0.346	0.473	0.535	0.464	0.707	0.280	1.789
T2WI, n(%)							
hypointense*							
isointense	1.148	0.272	17.878	0.000	0.317	0.186	0.540
hyperintense	0.680	0.292	5.424	0.020	0.506	0.286	0.898
Location of fibroids, n(%)							
anterior wall*							
posterior wall	1.049	0.267	15.370	0.000	0.350	0.207	0.592
lateral wall	0.090	0.253	0.127	0.722	0.914	0.556	1.502
fundus	-0.498	0.418	1.417	0.234	1.645	0.725	3.732
Degree of enhancement, n(%)							
Slight*							
Moderate	-0.120	0.209	0.330	0.566	1.128	0.749	1.698
Significant	-0.347	0.252	1.893	0.169	0.707	0.431	1.159
Fibroid ventral side to the skin (mm)	-0.003	0.005	0.290	0.590	1.003	0.993	1.013
Fibroid dorsal side to the sacrum (mm)	-0.011	0.006	2.832	0.092	1.011	0.998	1.024
Sonication time (s)	0.000	0.000	0.168	0.682	1.000	0.999	1.001
Treatment intensity (s/h)	0.001	0.001	4.098	0.043	0.999	0.997	1.000
TD (KJ)	0.000	0.001	0.860	0.860	1.000	0.998	1.002

## 4. Discussion

Extensive and prolonged clinical practice and research have confirmed high-intensity focused ultrasound (HIFU) as a relatively safe minimally invasive procedure for the treatment of uterine fibroids. Nevertheless, a minority of patients may experience adverse reactions and complications, attributed to the inherent physical properties (such as thermal effects) and biological effects (such as cavitation effects, among others) of ultrasound during propagation (Jolesz F A & Hynynen K., 2002). These effects can potentially damage the skin, sacrum, and soft tissues along the acoustic pathway, thereby inducing adverse reactions.

This study enrolled 555 patients with uterine fibroids treated with HIFU, with an average non-perfused volume ratio (NPVR) of  $74.3\pm17.2\%$  across all patients, indicating effective thermal ablation of their fibroids (Zheng AQ, Chen JY, Xiao ZB, Zhang R & Bai J., 2023). Postoperative MRI examinations revealed that 40.7% (226/555) of patients experienced muscle damage around the sacrum, including notable damage to the piriformis

muscle and gluteus maximus, with the piriformis muscle being particularly affected.

Recent studies have demonstrated a significant correlation between the degree of soft tissue injury in the muscles surrounding the sacrum and postoperative sacrococcygeal pain (Cun J-P, Fan H-J, Zhao W. et al., 2018). Due to the fact that the piriformis muscle originates from the inner surface of the pelvis, it exits the pelvis through the greater sciatic foramen and enters the buttocks, we hypothesize that postoperative piriformis muscle injury may play a pivotal role in eliciting such pain. Excessive deposition of ultrasonic heat can lead to edema and degeneration of the piriformis muscle. When the injury severity increases, it may result in stenosis of the sciatic nerve at the piriformis foramen outlet, subsequently causing traction and compression on the sciatic nerve, other sacral plexus nerves, and gluteal vessels, ultimately triggering related clinical symptoms.

This study further conducted a semi-quantitative assessment of the severity of piriformis muscle injury among patients, with scores ranging from 0 to 4. The objective was to deeply analyze the multiple factors influencing the degree of piriformis muscle injury. The results indicated significant differences among groups in terms of the uterine position, fibroid location, fibroid type, T2 signal intensity, distance from fibroid ventral side to the skin, fibroid dorsal side to the sacrum, degree of enhancement for fibroid, sonication time, treatment intensity, and TD. However, multivariate analysis revealed that only the position of the uterus, location of fibroids, T2WI signal intensity and treatment intensity were significantly correlated with the severity of piriformis muscle injury.

The T2WI signal intensity of uterine fibroids can reflect their internal tissue composition characteristics. Uterine fibroids with high T2WI signals are rich in water and have low collagen content. These fibroids are less efficient in absorbing ultrasound energy and converting it into thermal energy (Zhao W-P, Chen J-Y & Chen W-Z., 2015), making them relatively less sensitive to HIFU treatment. Higher energy input is required for the ablation of such fibroids. Thus, more energy will propagate along the acoustic pathway, potentially leading to the formation of ectopic small foci in non-target tissues (such as the piriformis muscle). Energy deposition in these areas can produce a heating effect and cause edema.

We found that the degree of piriformis muscle injury may be more severe in cases where the uterus is retroverted or (and) fibroids are located on the posterior wall of the uterus. Previous studies have shown that as the distance between the transducer and the target tissue increases, the ultrasound beam undergoes more significant refraction, reflection, absorption, and scattering during its acoustic path traversal, so an increase in the amount of tissue in front of the focal point will lead to energy decay (Fan H-J, Zhang C, Lei H-T. et al., 2019). Therefore, in cases involving a retroverted uterus or (and) fibroids located on its posterior wall, an increase in energy levels is necessary to ensure satisfactory treatment outcomes due to the relative expansion of the distance between the target and the transducer. As the dosage and propagation distance of the ultrasound beam increase, the interaction between ultrasound and tissue within the acoustic field becomes more complex, elevating the risk of damage to surrounding tissues. Furthermore, due to the proximity of the retroverted uterus and posterior wall fibroids to the piriformis muscle, the piriformis muscle is more susceptible to the biophysical effects of the ultrasound in the far field, causing an increase in thermal energy deposition, thereby increasing the risk of damage.

The principle of High-Intensity Focused Ultrasound therapy leverages the excellent penetration and directionality of ultrasound waves. It involves emitting low-energy ultrasound waves externally and focusing them on a specific region within the body to create a high-intensity, high-energy focal point. The ultrasonic energy at this focal point is sufficient to induce thermal, cavitation, and mechanical effects in the target tissue, leading to coagulation necrosis of the tissue and achieving the therapeutic objective. HIFU treatment intensity refers to the energy density generated by ultrasound within the target region, which is the amount of ultrasound energy per unit area or volume. It indicates the strength of the ultrasound's action on the target tissue. As the treatment intensity increases, the energy density of the ultrasound also rises correspondingly, potentially leading to more intense thermal and mechanical effects on the tissues within the focal area. As an adjacent tissue to the target region, the piriformis muscle may be affected during treatment, thereby increasing the likelihood of damage. During the treatment process, it is crucial to closely monitor the response of both the target tissue and the surrounding normal tissues, and to adjust the treatment intensity in a timely manner based on the actual situation. This helps to avoid the occurrence of either overtreatment or undertreatment.

Research by Yu et al. has confirmed that oxytocin pretreatment can reduce blood perfusion in uterine fibroids (Yu S C-H, Cheung E C-W, Leung V Y-F. et al., 2019), thereby enhancing energy deposition efficiency and lowering the threshold dose (TD) required for ablation. Therefore, for uterine fibroid cases requiring high-energy ablation, preoperative oxytocin pretreatment may be an effective strategy. It holds promise for reducing the total energy demand during ablation, thereby potentially lowering the risk of piriformis muscle damage and postoperative sacrococcygeal pain.

Due to its retrospective design, this study has the limitation of selection bias in data. Additionally, the study did not quantitatively analyze the volume of piriformis muscle damage in patients. Future research could expand the

sample size and conduct prospective quantitative assessments to accurately evaluate the volume of piriformis muscle damage post-surgery using quantitative data.

In summary, a part of patients undergoing uterine fibroid ablation with USgHIFU may experience muscle damage around the sacrum, particularly in the piriformis muscle, which is the most common site of injury. Patients with retroverted uterus, posterior wall fibroids, and T2 high-signal intensity fibroids are at an increased risk of more severe piriformis muscle damage postoperatively, thereby leading to a higher incidence of sacrococcygeal pain. We hope to provide a more comprehensive analysis of postoperative adverse reactions for patients with uterine fibroids undergoing USgHIFU ablation therapy through our research and other studies. Understanding the factors influencing these adverse reactions and finding solutions to minimize such events are ongoing issues that require further exploration.

## **Conflict of Interest**

The authors affirm that the research was conducted without any commercial or financial ties that might be perceived as constituting a potential conflict of interest.

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