Predictive value of image indexes of B-mode and power Doppler sonography on the efficacy of high intensity focused ultrasound ablation for uterine fibroids

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\section*{ABSTRACT}

\textbf{Objective:} To investigate the value of the image indexes of B-mode and power Doppler sonography in predicting the therapeutic efficacy of high intensity focused ultrasound (HIFU) ablation for uterine fibroids.

\textbf{Materials and methods:} Two hundred and three patients with a solitary uterine fibroid were enrolled in this study. Every patient underwent transvaginal sonography (TVS) and magnetic resonance imaging (MRI) before HIFU. The patients were divided into hypointense, isointense and hyperintense fibroid groups based on T2 weighted MR imaging characteristics, and ultrasonic image indexes of the fibroids in different groups were compared. Multiple linear regression analysis was used to evaluate the correlation between ultrasonic image indexes and energy efficiency factor (EEF), non-perfused volume (NPV) ratio of uterine fibroids.

\textbf{Results:} Among them, 72 patients had a hypointense fibroid, 70 had an isointense fibroid and 61 had a hyperintense fibroid. Significant differences were observed in the ultrasound imaging gray scale value difference between the myometrium and uterine fibroids (GSmyo-fib), the ultrasound imaging gray scale value ratio of fibroids over the myometrium (Gfib/myo), and the ratio of power Doppler pixel area to fibroid area (PDPA/FA) among the three groups ($p < 0.05$). Linear regression analysis showed that the PDPA/FA and the location of fibroids were the factors affecting the NPV ratio, a model for predicting the NPV ratio was established.

\textbf{Conclusions:} A model with the PDPA/FA for NPV ratio could be used to predict the therapeutic efficacy of HIFU for fibroids.

\section*{Introduction}

Uterine fibroids are the most common benign tumors of the female reproductive system, more common in women aged 30–50 years, with the main symptoms of menorrhagia, urinary frequency, anemia, and infertility [1,2]. The treatment options for uterine fibroids include medication, surgery, uterine artery embolization (UAE), and high intensity focused ultrasound (HIFU) [3,4]. As a non-invasive treatment, HIFU was first utilized in the treatment of uterine fibroids in 2002, and many studies have shown its safety and efficacy [3,5,6]. Magnetic resonance imaging (MRI) has better tissue contrast than CT, the resolutions are comparable. Several studies have revealed that the characteristics of histology and perfusion pattern of uterine fibroids with contrast-enhanced MRI are closely related to the therapeutic efficacy of HIFU ablation [7–9]. Some studies have also proposed the signal intensity of uterine fibroids on T2 weighted imaging (T2WI) of MRI as a predictor of the histological characteristic of uterine fibroids [9,10]. Thus, MRI is often used to predict the efficacy of HIFU for uterine fibroids before the procedure [10]. Over the last ten years, several groups have found that both T2WI and contrast-enhanced MRI have practical value in predicting the efficacy of HIFU ablation for uterine fibroids [11–13]. However, due to the high price of MRI equipment, the coverage rate of MRI is not high. MRI examination often needs to be scheduled and the patients need to wait for a long time, and the cost is relatively high. In contrast, ultrasonography is more convenient and the cost is much less. Therefore, it is worth exploring whether the ultrasound image features of uterine fibroids can be used to predict the therapeutic efficacy of HIFU treatment for uterine fibroids. The purpose of this study was to investigate the value of image indexes of B-mode and power Doppler sonography in predicting the therapeutic efficacy of HIFU ablation for uterine fibroids.

\section*{Materials and methods}

This prospective study was approved by our institute (NO. CQMU-20200520). All patients agreed to participate in this study, and a consent form was obtained from every patient.
Subjects

From May 2020 to June 2021, 203 patients with a solitary uterine fibroid who wanted to have HIFU treatment in the Department of Gynecology of Suining Central Hospital of Sichuan Province in China were enrolled.

Inclusion criteria were as follows: (1) subjects were premenopausal women and 18 years or older; (2) with symptomatic uterine fibroids; (3) with a size of 2–10 cm in diameter.

Exclusive criteria: (1) menstruating, pregnant or lactating women; (2) multiple uterine fibroids or fibroids with adenomyosis; (3) patients with contraindications to MRI (allergic to contrast, metal foreign bodies in treatment area e.g., IUCD, Filchi clips); (4) patients with suspected or confirmed uterine malignancy.

Ultrasonography and image analysis

Every patient underwent transvaginal sonography (TVS) before HIFU treatment. TVS was performed using a DC-60 power Doppler ultrasound diagnostic instrument (Mindray, China), a V11-3 intracavitary probe with a frequency of 2.6–11.4 MHz was used.

A single ultrasound imaging system was used for all patient diagnostic examinations. The gynecological TVS mode was selected. The image resolution and contrast ratio were jointly evaluated by two sonologists with more than 10 years of practice experience in the field of ultrasound. The standardized parameters for B mode ultrasound image were as follows: F (frequency) 3.2–7.9 MHz, D (distance) 7.0 cm, FR (frame rate) 25 frames/s, DR (dynamic range) 115 dB, G (gain) 50 dB. The standardized parameters for power Doppler mode were as follows: F (frequency) 4.4 MHz, WF (wall filtering) 60 Hz, G (gain) 50 dB. The standardized parameters of TVS for B mode and power Doppler mode were jointly evaluated by two experienced attending physicians and were saved in the equipment. All patients who underwent ultrasonic examinations using the standardized parameters in this mode. The sagittal view and transverse view of B mode ultrasound images of the uterus and the fibroids were saved and remained in their original state prior to analysis. The sagittal view of power Doppler ultrasound images of uterine fibroids was also saved for further evaluation.

The ultrasound images in the original DICOM format were obtained from the ultrasound diagnostic equipment. The position of the uterus, the location of uterine fibroids, the maximum diameter of uterine fibroids (measured during ultrasound examination) and the type of uterine fibroids (intramural, submucosal and subserosal uterine fibroids) were recorded. The getcolorpixels analysis software (Institute of Ultrasound Imaging of Second Affiliated Hospital of Chongqing Medical University, Chongqing, China) was used for image analysis. The fibroids and the normal myometrium were respectively delineated as the regions of interest (ROIs) by a sonologist with more than 10 years of practice experience, and then the average gray scale value of the fibroids and the myometrium were obtained (Figures 1C&D, 2C&D, 3C&D).

Magnetic resonance imaging

Every patient underwent an MRI examination before HIFU treatment. All MRI examinations were performed using a 1.5 T Magnetom Avanto MR system (Siemens Healthcare, Erlangen, Germany). Standardized parameters used for T1 weighted image (T1WI) were as follows: TR/400–800 ms, TE/9.4–11 ms, voxel size 1.7 × 1.3 × 5.0 mm, slice thickness 4 mm. Standardized parameters used for T2WI were as follows: TR/3000–6000 ms, TE/75–108 ms, voxel size 1.0 × 1.0 × 4.0 mm, slice thickness 4 mm. Standardized parameters for contrast-enhanced MRI (T1-volumetric interpolated body examination-fat suppression, Ti-VIBE-FS) were as follows: TR/4.9–5.8 ms, TE/2.3–2.7 ms, voxel size 1.7 × 1.2 × 4.0 mm, slice thickness 4 mm.

Uterine fibroids were classified into three types based on the signal intensity of T2WI in the uterine fibroids and surrounding tissues. Hypointense fibroids: the signal intensity of uterine fibroids on T2WI was lower than or equal to that of skeletal muscle; isointense fibroids: the signal intensity of uterine fibroids on T2WI was higher than that of skeletal muscle but lower than that of the myometrium; hyperintense fibroids: the signal intensity of uterine fibroids on T2WI was equal to or higher than the myometrium [14].

High intensity focused ultrasound ablation

Ultrasound-guided HIFU treatment was performed under conscious sedation. A JC 200 HIFU tumor therapeutic system (Chongqing Haifu Medical Technology) was used for the procedure. This system is equipped with an ultrasound imaging probe (Frequency of 1.0–8.0 MHz, MyLab 70, Esaote, Genova, Italy) situated in the center of the transducer to provide real-time imaging for monitoring the treatment. Therapeutic focused ultrasound energy was produced with a 20-cm-diameter transducer with a focal length of 15 cm, operated at a frequency of 0.8 MHz. The acoustic focus dimensions were 5 mm × 3 mm × 3 mm.

The patients were placed in a prone position, with the abdominal wall in contact with degassed water. The sagittal ultrasound scanning mode was chosen for both pretreatment planning and sonication. The distance between treated slices was 5 mm. Point scan energy delivery was used during HIFU. The treatment began on the inferior side of the fibroid, moved toward the superior side, and then from the posterior...
area to the anterior area of the fibroid. The focus was kept at least 1.5 cm away from the endometrium and boundary of the fibroid. The treatment power started from 300 W, the adjustment of energy was based on the hyperechoic grayscale change on the real-time ultrasonographic imaging or the feedback of feeling from the patients [9]. HIFU treatment was terminated when the significant grayscale changed area, defined as coagulative necrosis, covered the entire fibroid [15,16].

To evaluate the therapeutic results, contrast-enhanced ultrasound (CEUS) using a microbubble agent (SonoVue, Bracco, Milan, Italy) was performed before and immediately after HIFU treatment. Briefly, a vial of 25 mg of SonoVue microbubble powder was reconstituted with 5 ml of normal saline. Then, the vial was vigorously shaken to let the microbubble powder fully dissolve. The contrast-enhanced ultrasound imaging was observed and recorded after intravenous injection of 2 ml of SonoVue solution followed by 5 ml of normal saline flushing. The contrast-enhanced ultrasound results were analyzed independently by two senior sonologists. Non-perfused volume (NPV) and the uterine fibroid volume were calculated using the following equation: Volume \( \left( \text{mm}^3 \right) = \frac{4}{3} \pi \times R_1 \times R_2 \times R_3 \). R1 stands for half of the longitudinal diameter (mm), R2 stands for half of the antero-posterior diameter (mm), and R3 stands for half of the transverse diameter (mm) [17]. NPV ratio = NPV/fibroids volume × 100%. Sonication power, treatment time (defined as the time from the first sonication to the last sonication), sonication time, treatment intensity (defined as sonification time per hour) and treatment efficiency (mm\(^3\)/s, ablated volume per second) were recorded.

After HIFU treatment, the energy efficiency factor (EEF), defined as the amount of ultrasound energy needed to ablate fibroids per unit volume, was calculated using the

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**Figure 1.** MRI and ultrasound images obtained from a 47-year-old patient with a hypointense uterine fibroid before HIFU treatment. (A) Transverse view of T2WI showed that a hypointense fibroid located at the posterior wall of the uterus (arrow). (B) Measurement of the ratio of power Doppler pixel area to fibroid area. The border of the fibroid was delineated with dot line. The ratio of power Doppler pixel area to fibroid area of this hypointense fibroid was 0.04. (C) Measurement of the average gray scale value of the myometrium. The border of myometrium was delineated the average gray scale value of the myometrium was 58.55. (D) Measurement of the average gray scale value of fibroid. The border of the fibroid was delineated and the gray scale value of the fibroid was 44.97. The gray scale value difference between myometrium and this hypointense fibroid was 13.58.
following equation: $EEF(J/mm^3) = \eta Pt/V$, $\eta$ stands for focusing coefficient of HIFU transducer ($\eta = 0.7$, reflects the ability of HIFU transducer to converge ultrasonic energy); $P$ stands for therapeutic acoustic power (W); $t$ stands for sonication time (sec); $V$ stands for NPV(mm$^3$) [18,19].

Statistical analysis

The data were analyzed by SPSS 25.0 (IBM, Chicago, USA). Normally distributed data were expressed as mean ± standard deviation, and Skewed-distributed data were reported as median and quartile ranges. Two groups of quantitative indicators were compared by $t$-test or Wilcoxon rank-sum test according to the data distribution. Categorical indicators were by Chi-square test or exact probability method (if the Chi-square test is not applicable). ANOVA or Kruskal-Wallis rank sum test was used to compare the data in multiple quantitative data. Bonferroni method was used to correct the $P$ value in multiple comparisons. Linear regression analysis was used to analyze the correlation of multiple ultrasound image indexes and other factors with EEF and NPV ratio of uterine fibroids, and the regression model was verified by Wilcoxon signed rank-sum test. A $P$ value less than 0.05 was defined as statistically significant.

Results

Patients and uterine fibroids

Patients had a mean age of 43.04 ± 6.20 years (range: 23.00–56.00 years) and a mean body mass index (BMI) of 23.90 (interquartile range: 22.03–25.28). A total of 203 patients with solitary fibroids were divided into three groups based on the signal intensity of uterine fibroids on T2WI of MRI: hypointense group (72/203), isointense group (70/203) and hyperintense group (61/203). No significant differences
were observed among the three groups in age, BMI, uterine position, the maximum diameter of fibroids and type of fibroids. However, a significant difference in the location of uterine fibroids was observed (Table 1). We compared the image indexes of B-mode and power Doppler sonography between different groups of fibroids based on signal intensity on T2WI. As shown in Table 2, significant differences were observed in the GSmyo-fib, the GSfib/myo, and the PDPA/FA among the hypointense, isointense, and hyperintense fibroids. We further performed a pairwise comparison and the results showed that significant differences in the GSmyo-fib, and in the PDPA/FA between any two groups. However, there was no significant difference in the GSfib/myo between isointense fibroids and hypointense fibroids \((p = 0.887)\), and between isointense fibroids and hyperintense fibroids \((p = 0.100)\). Only a significant difference between hypointense fibroids and hyperintense fibroids was observed in the GSfib/myo.

Figure 3. MRI and ultrasound images obtained from a 45-year-old patient with a hyperintense uterine fibroid before HIFU treatment. (A) T2WI showed the signal intensity of fibroid was higher than that of myometrium, which was a hypointense fibroid (arrow). (B) Measurement of ratio of power Doppler pixel area to fibroid area. The border of fibroid was delineated with white dot line. The ratio of power Doppler pixel area to fibroid area was 0.12 (number); (C) Measurement of the average gray scale value of the myometrium. The border of the myometrium was delineated with dot line. The gray scale value was 75.61. (D) Measurement of the average gray scale value of fibroid. The border of the fibroid was delineated with dot line. The gray scale value was 39.10. The gray scale value difference between the myometrium and fibroid was 36.51.

Table 1. Comparison of baseline characteristics of patients with different type of fibroids based on T2WI signal intensity of MRI.

| Variable                       | Hypointense \((N = 72)\) | Isointense \((N = 70)\) | Hyperintense \((N = 61)\) | \(P\) |
|-------------------------------|--------------------------|-------------------------|---------------------------|------|
| Age                           | 45.00 (41.00–48.00)      | 44.00 (38.00–46.00)     | 44.00 (38.00–47.00)       | 0.099|
| BMI                           | 24.28 (22.58–25.84)      | 22.97 (21.48–25.11)     | 23.44 (22.14–25.34)       | 0.229|
| Position of the uterus         | 44/3/25                  | 45/2/23                 | 37/4/20                   | 0.936|
| Location of fibroids           | 41/19/12                 | 32/16/22                | 26/10/25                  | 0.041|
| Maximum diameter of fibroids   | 44.00 (35.00–50.00)      | 46.50 (35.75–59.00)     | 43.00 (35.00–51.00)       | 0.284|
| Type of fibroids               | 28/1/43                  | 28/12/30                | 25/16/20                  | 0.160|

Note: Chi-Square test, ANOVA or Kruskal-Wallis rank sum test was used to compare the data in multiple quantitative data for \(P\) value. The numbers in the parenthesis were interquartile range.
Bold value indicates a significant difference \((P<0.05)\).
Table 2. Comparison of ultrasound indexes among fibroids with different T2WI signal intensity of MRI.

| Variable          | Hypointense | Isointense | Hyperintense | P (Overall) |
|-------------------|-------------|------------|--------------|-------------|
| GSmyo-fib         | 14.16 (8.78–19.20) | 20.29 (11.45–22.63) | 22.68 (15.18–29.65) | <0.001 |
| GSfib/myo         | 0.77 (0.69–0.87) | 0.72 (0.64–0.82) | 0.70 (0.62–0.79) | 0.006 |
| PDPA/FA           | 0.03 (0.01–0.05) | 0.05 (0.02–0.09) | 0.10 (0.03–0.14) | <0.001 |

Notes: *indicated a significant difference between any two groups. ^indicated a significant difference between the hypointense fibroids and isointense or hyperintense fibroids (p < 0.05). The numbers in the parenthesis were interquartile range. GSmyo-fib: gray scale value difference between the myometrium and fibroids; GSfib/myo: gray scale value ratio of fibroids over the myometrium; PDPA/FA: ratio of power Doppler pixel area to fibroid area.

Table 3. Comparison of EEF and NPV ratio of fibroids in different T2 signal intensity of MRI treated with HIFU.

| Variables          | Hypointense | Isointense | Hyperintense | P (Overall) |
|--------------------|-------------|------------|--------------|-------------|
| EEF (J/mm³)        | 5.41 (2.87–7.81) | 6.14 (3.31–11.21) | 18.22 (11.64–21.50)* | <0.001 |
| NPV ratio of fibroids | 86.65% (79.91%–97.22%) | 78.32% (72.25%–88.14%) | 64.48% (54.57%–75.01%) | <0.001 |

Note: *indicated a significant difference between any two groups. ^indicated a significant difference between the hypointense fibroid group and the hyperintense or isointense fibroid group. The numbers in the parenthesis were interquartile range.

Comparison of NPV ratio and EEF of uterine fibroids with different signal intensity on T2WI of MRI treated with HIFU

As shown in Table 3, significant differences were observed in EEF and NPV ratio among the hypointense, isointense, and hyperintense fibroids. A further multiple comparisons was performed and a significant difference in NPV ratio between any two groups was observed. However, there was no significant difference in EEF between the hypointense group and the isointense group. A significant difference in EEF between the other groups was observed (Table 3).

Establishment of regression model for EEF

In this model, EEF was used as a dependent variable, and the other variables included age, BMI, the position of the uterus, location of fibroids, type of fibroids, the maximum diameter of fibroids, GSmyo-fib, GSfib/myo and PDPA/FA were used as independent variables. Firstly, a univariate linear regression analysis was performed between EEF and each independent variable. The correlation between EEF and each independent variable was presented in Table 4. The statistical analysis results showed that the maximum diameter of fibroids and PDPA/FA had a significant relationship with EEF (Table 4). Then we included these two independent variables in a multivariate linear regression analysis. However, only PDPA/FA entered into the model. The maximum diameter of fibroids was excluded from the equation because no significant relationship with EEF was found (p = 0.150). The final regression equation for EEF was $\hat{y} = 133.718 \times 1$, where $\hat{y}$ stands for EEF, X1 stands for PDPA/FA.

According to the equation, EEF = 133.718 x 1, the median predicted EEF was 6.69 (interquartile range: 2.67–12.03)/mm³. The median actual EEF value was 7.57 (interquartile range: 4.22–15.29)J/mm³. A significant difference between the actual EEF values and predicted EEF values was observed (Table 5) (p < 0.05).

Establishment of regression model for NPV ratio

In this model, the NPV ratio of fibroids was used as a dependent variable, and the nine variables included age, BMI, the position of the uterus, location of the uterus, type of fibroids, the maximum diameter of fibroids, GSmyo-fib, GSfib/myo and PDPA/FA were used as independent variables. Firstly, a univariate linear regression analysis was performed between the NPV ratio and each independent variable. The statistical analysis results showed the location of fibroids, GSmyo-fib, GSfib/myo and the PDPA/FA were related to NPV ratio (Table 6). Then we included these four independent variables in a multivariate regression analysis as predictors to predict NPV ratio. The stepwise method was used for multivariate linear regression analysis. The independent variables with a P value lower than 0.05 were entered into the model. The results showed that the PDPA/FA and location of fibroids were significantly related to the NPV ratio. The GSmyo-fib, GSfib/myo were excluded from this model because no significant relationship with NPV ratio was found (p > 0.05). The final equation for NPV ratio was $\hat{y} = 0.852–0.861 \times 1–0.039 \times 2$, where $\hat{y}$ stands for NPV ratio for fibroids, X1 stands for PDPA/FA, X2 stands for the location of fibroids.
A comparison between the actual NPV ratio and predicted NPV ratio was conducted and the results showed no significant difference between the predicted NPV ratio and the actual NPV ratio ($p = 0.230$) (Table 5).

**Discussion**

Many studies have shown that MRI can be used to select patients before HIFU or to predict the therapeutic efficacy of HIFU treatment for uterine fibroids [9,10,19–21]. In this study, we found that several image indexes of B-mode and power Doppler sonography were consistent with the T2WI signal intensity of uterine fibroids on MRI. The GSmyo-fib and the PDPA/FA were significantly higher in hyperintense fibroids than that in hypointense and isointense fibroids. In another ultrasound index, the GSfib/myo was significantly lower in hyperintense fibroids than that in hypointense and isointense fibroids.

Previous studies have shown that the hyperintense uterine fibroids are mainly cellular fibroids [8,19–22]. This type of fibroid has rich cell components, with uniform tissue and less ultrasonic reflection interface, which leads to less ultrasonic absorption [8,19,26]. Therefore, the echo of hyperintense fibroids on the ultrasonic image is lower, the GSmyo-fib becomes larger, and the GSfib/myo was significantly lower than that of the other two types of uterine fibroids. In contrast, the hypointense fibroids have more fibrous tissue, less blood supply than that hypointense fibroids [8,22–25]. Therefore, the echo of ultrasound on hypointense fibroids was higher, the GSmyo-fib becomes smaller, and the GSfib/myo was significantly higher than that of hyperintense fibroids.

In this study, EEF was significantly higher in hyperintense fibroids than that of hypointense and isointense fibroids, and NPV ratio was significantly lower in hyperintense fibroids than that in hypointense and isointense fibroids. The results were similar to the previous studies [9,11]. This phenomenon can be explained by that the hyperintense fibroids have less ultrasonic reflection interface, with lower ultrasonic absorption than that of isointense and hypointense fibroids, which is not conducive to the deposition of ultrasonic energy, resulting in larger EEF compared with hypointense and isointense fibroids [27]. Therefore, NPV ratio achieved in hyperintense fibroids was lower than that of hypointense and isointense fibroids. The previous studies showed that the enhancement degree of cellular fibroids on contrast-enhanced MRI was significantly higher than that of the myometrium [7–10,19]. In this study, we also found that PDPA/FA was higher in hyperintense fibroids than that of hypointense and isointense uterine fibroids, which also demonstrated the blood supply of these fibroids was more abundant. Because the blood flow of the fibroids will take away energy, HIFU ablation for hyperintense uterine fibroids is more difficult than those of isointense and hypointense fibroids [28–30]. Therefore, these image indexes of B-mode and power Doppler sonography might be used in patient selection before HIFU treatment for uterine fibroids.

Previous studies have shown that several imaging factors were associated with HIFU treatment efficacy [14,19]. In this study, we found that the location of fibroids was negatively correlated with the NPV ratio of uterine fibroids. In comparison with the fibroids located in the anterior wall of the uterus, the fibroids located in the posterior wall of the uterus generally had a lower NPV ratio because these fibroids were further from the HIFU transducer and more ultrasonic attenuation occurred. Thus, local ultrasonic energy deposition was not enough, which led to the reduction of the effective ablation volume of fibroids.

### Table 6. Correlation between independent variables and NPV ratio of fibroids with univariate linear regression analysis.

| Independent variable | $p$  |
|----------------------|-----|
| Age                  | 0.227 |
| BMI                  | 0.496 |
| Position of the uterus | 0.472 |
| Location of fibroids | 0.006 |
| Type of fibroids     | 0.497 |
| Maximum diameter of fibroids (mm) | 0.293 |
| GSmyo-fib            | 0.002 |
| GSfib/myo            | 0.013 |
| PDPA/FA              | <0.001 |

Notes: GSmyo-fib: gray scale value difference between the myometrium and fibroids; GSfib/myo: gray scale value ratio of fibroids over the myometrium; PDPA/FA: ratio of power Doppler pixel area to fibroid area.

Bold value indicates a significant difference ($p<0.05$).

Conclusions

Based on the results of our study, we concluded that the GSmyo-fib, the GSfib/myo, and the PDPA/FA might be used...
in patient selection before HIFU treatment. A model with the PDPA/FA for NPV ratio could be used to predict the therapeutic efficacy of HIFU treatment for uterine fibroids. This study is limited because of the relatively small subjects. Further studies with large subjects from different centers to validate the results are needed.

Disclosure statement

Lian Zhang is a senior consultant to Chongqing Haifu. The other authors have no conflict of interests to declare.

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