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Evaluating pregnancy outcomes in women with uterine fibroids treated with high-intensity focused ultrasound: insights from a single-institution study

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Abstract

Objective This study aims to assess the safety and effectiveness of High-Intensity Focused Ultrasound (HIFU) ablation on pregnancy outcomes among women with uterine fibroids wishing to conceive, focusing specifically on short-term pregnancy outcomes immediately following HIFU treatment.

Methods A retrospective analysis was conducted on 210 women who underwent HIFU treatment (Group I) at our institution between January 2018 and December 2022 and subsequently conceived. Pregnancy outcomes were compared with two control groups: 510 patients who delivered vaginally (Group II) and 278 who underwent cesarean sections (Group III) during the same period. Statistical analyses included multivariable logistic regression to adjust for confounding factors. The study only considered outcomes related to the immediate pregnancy following HIFU treatment and did not include data on subsequent pregnancies or long-term effects.

Results The natural conception rate post-HIFU was 93.81% (197/210), with a miscarriage rate of 19.05% (40/210). Group I had significantly lower rates of gestational diabetes mellitus (8.24%) and precipitate labor (0%) compared to Group II but higher rates of mild anemia (31.18%) and adherent placenta (10.59%). Compared to Group III, Group I had lower rates of gestational diabetes mellitus (8.24% vs. 20.86%) and moderate anemia (4.71% vs. 16.55%) but a higher incidence of premature rupture of membranes (18.82%). Neonates in Group I had lower birth weights compared to Groups II and III ($p < 0.05$), with no cases of low birth weight in Group I. Multivariable analysis identified fibroid location as a predictor of preterm birth, while maternal age and mode of delivery influenced the risk of incomplete uterine rupture.

Conclusion HIFU ablation is a safe and effective fertility-preserving treatment for women with uterine fibroids, demonstrating favorable short-term pregnancy outcomes. It does not increase perinatal risks, but its impact on pregnancy duration and certain complications suggests that careful patient selection and management are crucial. Future studies should investigate the long-term effects of HIFU on subsequent pregnancies.

Keywords Uterine fibroids, High-intensity focused ultrasound, Pregnancy outcomes, Fertility preservation, Obstetric complications

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Background

Uterine fibroids are the most common benign tumors affecting the female reproductive system and pose significant reproductive challenges for women of childbearing age globally.These tumors are associated with various adverse reproductive outcomes, including increased risks of infertility, miscarriage, preterm birth, and postpartum hemorrhage, as well as complications such as abnormal placental placement and fetal growth restriction [1–3]. Current management strategies include surgical interventions, such as myomectomy and hysterectomy, and pharmacological treatments aimed at symptom relief and fibroid reduction [4]. These approaches, however, carry considerable risks, including significant blood loss, potential damage to surrounding uterine tissue, and implications for future fertility. Additionally, pharmacological treatments, while effective in reducing fibroid size and alleviating symptoms temporarily, do not offer a permanent solution and may have side effects that limit long-term use [5].

High-Intensity Focused Ultrasound (HIFU) has emerged as a promising non-invasive treatment for uterine fibroids, addressing the limitations of traditional therapies by preserving uterine integrity and function [6]. By utilizing focused ultrasound waves to generate localized high temperatures, HIFU ablates fibroid tissue through coagulative necrosis, while sparing the surrounding healthy myometrium [7]. This precise application not only ensures targeted treatment of fibroids but also significantly reduces recovery time and postoperative complications [8].

The efficacy of HIFU has been demonstrated in multiple studies, with reported success rates of up to 98.6% in reducing fibroid volume and alleviating symptoms [9]. However, its safety concerning long-term reproductive outcomes remains under investigation, particularly in cases involving submucosal fibroids, where potential impacts on the endometrial cavity are a concern [10]. Although HIFU is non-invasive and effective in fibroid reduction, debates persist regarding its influence on pregnancy outcomes, necessitating further research to establish robust clinical guidelines [11]. Robust, large-scale longitudinal studies are needed to assess the impact of HIFU on fertility, pregnancy viability, and the incidence of obstetric complications.

With the increasing prevalence of uterine fibroids and a rising demand for fertility-preserving treatments, this study aims to provide detailed insights into pregnancy outcomes after HIFU. By examining a large cohort with advanced statistical methodologies, we seek to assess HIFU's safety and efficacy in maintaining fertility and reducing adverse obstetric outcomes.

Materials and methods

Study population

This retrospective study analyzed patients diagnosed with uterine fibroids who underwent HIFU treatment at our institution between January 2018 and December 2022. A control group was established, consisting of patients without uterine fibroids who delivered at the same institution during the same period.The HIFU group included 210 patients, while the control group comprised two subgroups: 510 patients who delivered vaginally (vaginal delivery group) and 278 patients who underwent repeat cesarean section (cesarean delivery group).

This dual-control design was implemented to separately evaluate the impact of HIFU treatment on pregnancy outcomes under different delivery modes.The vaginal delivery group was used to assess maternal and neonatal safety during natural delivery, focusing on outcomes such as preterm birth, placental abnormalities, and labor complications. The cesarean delivery group included patients with scarred uteri and aimed to evaluate whether HIFU treatment increases the risk of pregnancy complications, such as uterine rupture and placental adhesion.This dual-control approach enables a comprehensive analysis of the adaptability and potential risks associated with HIFU treatment under varying delivery modes. By investigating outcomes specific to vaginal and cesarean deliveries, this study provides critical scientific evidence to guide clinical decision-making regarding optimal delivery methods for patients with uterine fibroids post-HIFU treatment.

Data collection

Data for this study were collected through outpatient visits, telephone follow-ups, and systematic reviews of medical records. The variables recorded included demographic information (age, BMI, and medical history), HIFU treatment details (fibroid size, location, treatment parameters, and number of sessions), pregnancy outcomes (conception method, gestational age, delivery mode, and complications such as gestational diabetes mellitus and preeclampsia), and newborn data (birth weight, Apgar scores, and neonatal complications). Each variable was clearly defined and systematically recorded to ensure the accuracy and comprehensiveness of the analysis of maternal and neonatal outcomes following HIFU treatment.

It is important to note that this study only evaluates the short-term outcomes of pregnancies immediately following HIFU treatment, and no data on subsequent pregnancies or long-term follow-up were collected. The focus is on the immediate pregnancy following the HIFU procedure, with no tracking of additional pregnancies within the two to three years post-treatment. Additionally, the HIFU group included only singleton pregnancies. No

cases of multiple pregnancies (twin or higher order) were included in this study.

Inclusion and exclusion criteria

The inclusion criteria for this study were as follows: women aged 20–42 years, a desire for fertility, regular sexual activity without contraception post-treatment, a history of ≤ 2 deliveries for patients in the vaginal delivery group, and a second cesarean section for patients in the cesarean delivery group. Exclusion criteria included submucosal uterine fibroids due to their potential impact on pregnancy outcomes, significant dysfunction of vital organs (heart, liver, lungs, or kidneys), coagulation disorders, a spouse with a history of infertility, and incomplete follow-up data.

Patients with significant submucosal fibroids were excluded to minimize the direct impact of fibroid location on the endometrium, ensuring that the outcomes analyzed were primarily attributable to HIFU treatment. The age range of 20 to 42 years was chosen to target women of reproductive age actively seeking fertility while excluding potential pregnancy-related complications associated with younger (< 20 years) or older (> 42 years) maternal age. The control group was restricted to patients with a history of two cesarean deliveries to ensure homogeneity and comparability in obstetric history, as these patients represent a high-risk population prone to complications such as uterine rupture and placental adhesion. This alignment with the characteristics of the HIFU-treated group allowed for a meaningful comparison of pregnancy outcomes in high-risk populations.

For patients with prior cesarean sections, the trial of labor after cesarean (TOLAC) was considered based on clinical assessments, including evaluations of uterine scar condition and post-HIFU uterine structure. However, most patients opted for cesarean delivery to minimize the risk of uterine rupture. This study design provides clinically relevant evidence for managing pregnancies after HIFU treatment, particularly in high-risk cases.

Ethical approval

This study was approved by the Ethics Committee of the Mianyang Central Hospital (Approval No.: S20240378-01), and was conducted in accordance with the principles outlined in the Helsinki Declaration.

Outcome measures

The primary outcomes evaluated in this study were pregnancy complications and neonatal outcomes across the three groups of patients. Pregnancy complications included conditions such as preterm birth, gestational diabetes mellitus, preeclampsia, uterine rupture, and placental abnormalities. Neonatal outcomes included birth weight, Apgar scores, and neonatal complications.

In this study, 'placental adhesion' referred to conditions within the placenta accreta spectrum, including placenta accreta, increta, and percreta, where the placenta is abnormally adherent to the uterine wall. This was distinct from 'retained placenta,' which requires manual removal after delivery without abnormal adherence to the uterine wall. This distinction was critical for the analysis of placental-related complications and their association with HIFU treatment.Fibroid location, categorized based on imaging results, was included as a key variable in the statistical analysis. The documented locations of fibroids, including subserosal, intramural, and submucosal, were analyzed to assess their potential influence on pregnancy outcomes, particularly the risk of preterm birth. The categorization and analysis of fibroid locations aimed to elucidate whether specific fibroid characteristics significantly contributed to adverse maternal or neonatal outcomes in the study population.

It is important to note that in the HIFU-treated group, residual fibroids were present in some patients after treatment. These residual fibroids, varying in size, number, and location, may have influenced the pregnancy outcomes and serve as a potential confounding factor in this analysis.

Statistical analysis

Data were analyzed using SPSS version 26.0. Continuous variables were expressed as mean ± standard deviation (SD) and compared between groups using the independent t-test. Categorical variables were presented as frequency (percentage) and analyzed using the chi-square test to determine group differences.

To assess the independent effects of HIFU treatment on pregnancy outcomes, multivariable logistic regression models were employed. These models adjusted for potential confounding factors, including fibroid size, location, and number, ensuring a robust evaluation of the treatment's impact. This approach minimized the influence of residual fibroids and allowed for a clearer isolation of the potential effects of HIFU treatment on maternal and neonatal outcomes.

All statistical tests were two-tailed, and a significance level of $p < 0.05$ was considered indicative of statistical significance.

Results

Participants' demographic characteristics

This study involved 958 pregnant women, divided into three groups: Group I (n = 170) consisting of patients with uterine fibroids who underwent HIFU, Group II (n = 510) including pregnant patients without uterine

fibroids who delivered vaginally, and Group III (n = 278) comprising pregnant patients without uterine fibroids who underwent cesarean sections.Out of the 210 patients in the HIFU-treated group, 170 gave birth and 40 (19.05%) terminated their pregnancies early. Among these, 51 cases (30.0%) were associated with pregnancy complications. All 170 births involved single pregnancies, resulting in 170 live newborns.

The average age of participants in Group I was 32.35 ± 3.80 years. Age distribution in Group I was as follows: 60 patients (35.29%) were ≤ 30 years old, 52 patients (30.59%) were between 31 and 34 years old, and 58 patients (34.12%) were between 35 and 40 years old. None of the patients in Group I were over 40 years of age.The average number of pregnancies in Group I was 2.66 ± 1.28, with 84 primiparous women (49.41%) and 86 multiparous women (50.59%). Natural conception was observed in 158 cases (92.94%), and 12 patients (7.06%) conceived using assisted reproductive technologies (ART).The average gestational age at delivery for Group I was 267.25 ± 8.89 days, significantly lower than Groups II and III ($p < 0.05$). Gestational age categories showed that 34 patients (20.00%) in Group I delivered before 37 weeks, while 136 patients (80.00%) delivered at or after 37 weeks.Mode of delivery varied significantly among the groups ($p < 0.05$). All deliveries in Group I involved single pregnancies, resulting in live newborns. (Table 1).

Between Group I (HIFU-treated) and Group II (vaginal delivery without fibroids), no statistically significant differences were noted in age, mode of conception, parity, or incidence of preterm delivery ($p > 0.05$). However, a significant difference in gestational weeks at delivery was observed ($p < 0.05$).Between Group I (HIFU-treated) and Group III (cesarean section without fibroids), no significant differences were identified in age and mode of conception ($p > 0.05$). However, significant differences were present in gravidity, parity, and gestational age at delivery ($p < 0.05$).(Table 1).

In Group I (HIFU-treated), 27.06% (46/170) of patients experienced spontaneous labor, 72.94% (124/170) had cesarean sections. In Group III (cesarean control), 71.22% (198/278) of deliveries were elective cesarean sections, while 28.78% (80/278) were emergency cesarean sections.

Comparison of pregnancy complications and neonatal outcomes

When comparing pregnancy complications between the HIFU-treated group (Group I) and the vaginal delivery group (Group II), several statistically significant differences were observed. Precipitate labor was reported in 21 patients (4.12%) in Group II but was absent in Group I ($p < 0.05$). The incidence of gestational diabetes mellitus was significantly lower in Group I (14 patients, 8.24%) compared to Group II (107 patients, 20.98%) ($p < 0.05$). Incomplete uterine rupture occurred in 8 patients (4.71%) in Group I, while no cases were reported in Group II ($p < 0.05$). Mild anemia was more frequent in Group I (31.18%) than in Group II (17.06%) ($p < 0.05$),

Table 1 Comparison of General Conditions of Pregnant Women (n = 958)

Variable	Group I (n = 170)	Group II (n = 510)	Group III (n = 278)	*P*-value
Age (years)	32.35 ± 3.80	32.54 ± 3.86	32.44 ± 3.85	> 0.05
Age Categories				< 0.05
≤ 30	60 (35.29%)	174 (34.12%)	89 (32.01%)	
31–34	52 (30.59%)	162 (31.76%)	108 (38.85%)	
35–40	58 (34.12%)	174 (34.12%)	76 (27.34%)	
41–42	0 (0%)	0 (0%)	5 (1.80%)	
Gravidity	2.66 ± 1.28	2.63 ± 1.46	3.48 ± 1.42	< 0.05
Parity				< 0.05
Primipara	84 (49.41%)	224 (43.92%)	0 (0%)	
Multipara	86 (50.59%)	286 (56.08%)	278 (100.00%)	
Gestational week of delivery (days)	267.25 ± 8.89	276.96 ± 13.72	272.55 ± 5.09	
Gestational week Categories				< 0.05
32–36 + 6 week	34 (20.00%)	102 (20.00%)	4 (1.44%)	
≥ 37 week	136 (80.00%)	408 (80.00%)	274 (98.56%)	
Mode of conception				> 0.05
Naturalpregnancy	158 (92.94%)	492 (96.47%)	266 (95.68%)	
ART	12 (7.06%)	18 (3.53%)	12 (4.32%)	

Data was described as mean ± SD or n (%)

Group I: HIFU-treated fibroid patients, Group II: Vaginal delivery patients without fibroids, Group III: Cesarean section patients without fibroids

whereas moderate anemia was less common in Group I (4.71%) compared to Group II (12.94%) ($p < 0.05$). Additionally, adherent placenta was significantly more prevalent in Group I (10.59%) than in Group II (3.73%) ($p < 0.05$). (Table 2).

When comparing Group I to the cesarean section group (Group III), significant differences were also identified. Premature rupture of membranes occurred more frequently in Group I (18.82%) compared to Group III (1.44%) ($p < 0.05$). The incidence of gestational diabetes mellitus was lower in Group I (8.24%) than in Group III (20.86%) ($p < 0.05$). Incomplete uterine rupture was less common in Group I (4.71%) than in Group III (11.15%) ($p < 0.05$). Moderate anemia was significantly lower in Group I (4.71%) compared to Group III (16.55%) ($p < 0.05$). Adherent placenta was present in 10.59% of Group I and 12.95% of Group III, with significant differences noted when comparing Group I to

Table 2 Comparison of gestational complications and neonatal conditions(n = 958)

	GroupI(n = 170)	**Group II(n = 510)**	**Group III(n = 278)**	***P*1-value**	***P*2-value**
Hemorrhage at delivery(ml)	335.47 ± 67.79	253.78 ± 93.60	337.12 ± 179.16	< 0.05	> 0.05
Postpartum hemorrhage	8(4.71)	9(1.76)	17(6.12)	> 0.05	> 0.05
Precipitate labour	0	21(4.12)	0	< 0.05	/
Premature rupture of fetal membranes	32(18.82)	115(22.55)	4(1.44)	> 0.05	< 0.05
Gestational diabetes mellitus	14(8.24)	107(20.98)	58(20.86)	< 0.05	< 0.05
Hypertensive disorders in pregnancy	4(2.35)	8(1.57)	2(0.72)	> 0.05	> 0.05
Intrahepatic cholestasis of pregnancy	0	11(2.16)	11(3.86)	> 0.05	< 0.05
Threatened rupture of uterus	0	0	3(1.08)	/	> 0.05
Incomplete uterine rupture	8(4.71)	0	31(11.15)	< 0.05	< 0.05
Hypothyroidism and Hashimoto's thyroiditis	20(11.76)	61(11.96)	40(14.39)	> 0.05	> 0.05
Hyperthyroidism	0	1(0.20)	11(3.96)	> 0.05	< 0.05
Cooley's anemia	0	20(3.92)	20(7.19)	< 0.05	< 0.05
Mild anemia	53(31.18)	87(17.06)	67(24.10)	< 0.05	> 0.05
Moderate anemia	8(4.71)	66(12.94)	46(16.55)	< 0.05	< 0.05
Thrombocytopenia	21(12.35)	59(11.57)	39(14.03)	> 0.05	> 0.05
Chorioamnionitis	0	2(0.39)	0	> 0.05	/
Chorioamnionitis	0	2(0.39)	18(6.47)	> 0.05	< 0.05
Fetal growth restriction	0	2(0.39)	0	> 0.05	/
Prethrombotic state	0	4(0.78)	2(0.72)	> 0.05	> 0.05
Sail placenta and racket placenta	0	10(1.96)	19(6.83)	> 0.05	< 0.05
PAS	18(10.59)	21(4.12)	40(14.39)	< 0.05	> 0.05
Mazischesis	0	1(0.20)	0	> 0.05	/
Placental abruption	0	1(0.20)	2(0.72)	> 0.05	> 0.05
Uterine inertia	0	1(0.20)	/	> 0.05	/
Prolonged latency	0	1(0.20)	/	> 0.05	/
Fetal distress	0	2(0.39)	1(0.36)	> 0.05	> 0.05
Neonatal length(cm)	49.47 ± 0.81	49.72 ± 1.92	49.66 ± 1.46	< 0.05	> 0.05
Neonatal weight(g)	3209.53 ± 387.67	3319.06 ± 460.88	3361.33 ± 392.80	< 0.05	< 0.05
Fetal macrosomia	8(4.71)	32(6.27)	22(7.92)	> 0.05	> 0.05
Low birth weight infant	0	29(5.69)	1(0.36)	< 0.05	> 0.05
VLBWI	0	0	0	/	/
Asphyxia neonatorum	2(1.18)	7(1.37)	3(1.08)	> 0.05	> 0.05
Neonatal deformity	1(0.59)	5(0.98)	5(1.80)	> 0.05	> 0.05

Data was described as mean ± SD or n (%)

P1: Group I compared with Group II

P2: Group I compared with Group III

PAS:Placenta Accreta Spectrum Disorders, refers to conditions in the placenta accreta spectrum, including placenta accreta, increta, and percreta, in contrast to retained placenta

Group I: HIFU-treated fibroid patients, Group II: Vaginal delivery patients without fibroids, Group III: Cesarean section patients without fibroids

Group II ($p < 0.05$), but not between Groups I and III. Placental abnormalities, such as velamentous or battledore placenta, were more frequently observed in Group III (6.83%) compared to Group I, where no cases were reported ($p < 0.05$). (Table 2).

In terms of neonatal outcomes, significant differences were observed in neonatal weight and length. Neonates in Group I had a lower average weight (3209.53 ± 387.67 g) compared to Group II (3319.06 ± 460.88 g) ($p < 0.05$) and Group III (3361.33 ± 392.80 g) ($p < 0.05$). Similarly, neonatal length was shorter in Group I (49.47 ± 0.81 cm) compared to Group II (49.72 ± 1.92 cm) ($p < 0.05$), while no significant difference was observed when compared to Group III. The prevalence of low birth weight infants was also lower in Group I (0 cases) compared to Group II (5.69%, $p < 0.05$), but no significant difference was observed between Group I and Group III ($p > 0.05$). Other neonatal complications, such as fetal distress and neonatal deformities, showed no significant differences between the groups ($p > 0.05$). (Table 2).

Multivariable risk factors affecting adverse pregnancy outcomes

A logistic regression analysis was conducted to evaluate the risk factors influencing adverse pregnancy outcomes, specifically preterm birth, premature rupture of membranes (PROM), and incomplete uterine rupture. Independent variables included maternal age, gravidity, parity, gestational age, mode of delivery, pregnancy complications, neonatal weight and length, fibroid location, number of fibroids, and fibroid size post-HIFU ablation. The dependent variables for analysis were the occurrence of preterm birth, PROM, and incomplete uterine rupture.

The analysis identified fibroid location as a significant independent predictor of preterm birth ($p = 0.005$, OR = 0.189, 95% CI 0.059–0.610; Table 3). Patients with fibroids located in specific uterine regions, such as the lower uterine segment, were associated with a markedly lower risk of preterm birth. This suggests that fibroid location influences uterine mechanics and pregnancy maintenance.In addition, mode of delivery showed a trend toward significance ($p = 0.058$, OR = 0.773, 95% CI 0.094–6.337), indicating a potential association that warrants further investigation. Other variables, including maternal age, gravidity, and fibroid size, did not exhibit significant associations with preterm birth ($p > 0.05$).

None of the examined variables, including fibroid location, mode of delivery, and pregnancy complications, were identified as significant predictors of PROM (Table 4). While pregnancy complications demonstrated statistical significance ($p = 0.035$, OR = 1.000, 95% CI 0.998–1.001), the odds ratio and confidence intervals suggest that the effect size was negligible and clinically insignificant. This finding indicates that PROM may be influenced by other unmeasured factors outside the scope of the current analysis.

For incomplete uterine rupture, maternal age emerged as a significant predictor ($p = 0.048$, OR = 0.768, 95% CI 0.591–0.998; Table 5). Younger maternal age was associated with an increased risk, potentially reflecting differences in uterine tissue resilience or labor management practices among younger patients.Mode of delivery was also significantly associated with incomplete uterine rupture ($p = 0.016$, OR = 0.930, 95% CI 0.300–2.881; Table 5), suggesting that delivery method plays a critical role in uterine integrity.

These findings underscore the importance of fibroid location as a critical factor in predicting preterm birth. Proper assessment of fibroid characteristics during pregnancy management could improve risk stratification and outcomes. Additionally, the role of maternal age and delivery method in incomplete uterine rupture

Table 3 Logistic Regression Analysis of Factors Influencing Preterm Birth

Variable	Regression Coefficient (β)	Wald Statistic	*P*-value	Odds Ratio (OR)	95% Confidence Interval (CI)
Maternal Age	0.030	0.251	0.616	1.031	0.916–1.160
Number of Pregnancies	0.126	0.406	0.524	1.135	0.769–1.674
Number of Births	0.014	0.001	0.979	1.014	0.373–2.758
Mode of Delivery	− 0.258	1.220	0.058	0.773	0.094–6.337
Pregnancy Complications	0.001	0.197	1.022	0.797	0.292–2.173
Weight	− 0.227	1.867	0.172	0.695	0.413–1.171
Height	− 0.364	1.867	0.172	0.695	0.413–1.171
Fibroid Location	− 1.665	7.766	0.005	0.189	0.059–0.610
Number of Fibroids	1.357	2.796	0.094	3.830	0.792–19.044
Size of Fibroids	− 0.015	0.862	0.353	0.985	0.953–1.017

Table 4 Logistic Regression Analysis of Factors Influencing Premature Rupture of Membranes

Variable	Regression Coefficient (β)	Wald Statistic	P-value	Odds Ratio (OR)	95% Confidence Interval (CI)
Maternal Age	− 0.038	0.440	0.507	0.963	0.960–1.078
Number of Pregnancies	− 0.027	0.018	0.892	0.973	0.660–1.436
Number of Births	0.585	1.332	0.248	1.795	0.665–4.849
Mode of Delivery	− 0.901	0.640	0.424	0.406	0.045–3.694
Pregnancy Complications	0.000	0.011	0.035	1.000	0.998–1.001
Weight	− 0.051	0.000	0.011	0.950	0.368–2.451
Height	− 0.255	0.978	0.322	0.775	0.468–1.284
Fibroid Location	− 0.655	1.648	0.199	0.519	0.191–1.412
Number of Fibroids	0.258	0.085	0.771	1.294	0.229–7.329
Size of Fibroids	− 0.005	0.093	0.761	0.995	0.963–1.028

Table 5 Logistic Regression Analysis of Factors Influencing Incomplete Uterine Rupture

Variable	Regression Coefficient (β)	Wald Statistic	P-value	Odds Ratio (OR)	95% Confidence Interval (CI)
Maternal Age	− 0.264	3.904	0.048	0.768	0.591–0.998
Number of Pregnancies	0.585	1.541	0.215	1.794	0.713–4.515
Number of Births	17.997	0.000	0.996	6.544E7	0.000-
Mode of Delivery	− 0.073	− 17.621	0.016	0.930	0.300–2.881
Pregnancy Complications	0.000	0.477	0.113	0.999	0.996–1.003
Weight	− 0.793	0.000	0.477	0.453	0.048–4.293
Height	− 0.060	0.009	0.922	1.061	0.320–3.523
Fibroid Location	− 0.608	0.211	0.646	0.544	0.040–7.318
Number of Fibroids	− 18.189	0.000	0.999	0.000	0.000-
Size of Fibroids	0.024	0.465	0.495	1.024	0.957–1.096

emphasizes the necessity for individualized delivery planning to mitigate risks.In contrast, the lack of significant associations for PROM suggests that other, possibly extrinsic, factors might play a larger role in its development. Further investigations should explore additional variables and mechanisms to deepen understanding of these relationships and optimize pregnancy outcomes in post-HIFU patients.

Discussion

This study corroborates the efficacy and safety of HIFU as a treatment for uterine fibroids, highlighting its suitability for women with fertility aspirations. Our findings demonstrate several significant benefits of HIFU, including a favorable safety profile and a high rate of full-term deliveries. In this study, 80% of patients who underwent HIFU treatment were able to deliver at full term, a result consistent with previous studies reporting full-term delivery rates ranging from 76.3% to over 90% [2, 12, 13]. These findings reaffirm that HIFU is a reliable treatment option for preserving fertility in women with uterine fibroids.

Preterm birth and delivery mode

The relationship between delivery mode and preterm birth emerged as a key finding. Multivariate logistic regression analysis identified mode of delivery as an independent factor influencing preterm birth rates in patients after HIFU treatment. Specifically, the preterm birth rate was significantly lower in the cesarean delivery group (1.44%) compared to the vaginal delivery group (20.0%), suggesting that cesarean delivery may mitigate the risk of preterm birth in post-HIFU pregnancies. Additionally, the gestational duration was generally shorter in the HIFU group than in both the vaginal delivery and cesarean delivery groups. These findings align with prior research suggesting that cesarean delivery may serve as a protective factor in high-risk pregnancies; however, further studies are warranted to confirm this hypothesis.

Previous studies have indicated that delivery mode significantly impacts the risk of preterm birth. For instance, one study found that women undergoing cesarean section during the second stage of labor have a twofold increased risk of spontaneous preterm birth in subsequent pregnancies. This increased risk is likely due to cervical trauma caused by fetal head compression on the fully dilated cervix or the surgical procedure itself, leading to cervical incompetence in subsequent pregnancies [12, 13].

However, the use of cesarean section as a means to reduce preterm birth risk should be carefully evaluated. While cesarean delivery may provide protective effects in certain high-risk pregnancies, it is associated with risks such as postoperative infection, hemorrhage, and endometriosis. Therefore, clinical decision-making should take into account the patient's individual characteristics, including obstetric history, fibroid characteristics, and personal preferences.

In conclusion, the findings of this study highlight the importance of delivery mode in determining pregnancy outcomes after HIFU treatment. Although cesarean delivery appears to offer certain advantages in reducing the risk of preterm birth, its potential risks and long-term impacts must be considered. Future research should focus on further elucidating the effects of different delivery modes on pregnancy outcomes after HIFU treatment to provide comprehensive guidance for clinical practice.

Miscarriage rates and delivery mode variability

Our study reported an early miscarriage rate of 19.05% post-HIFU, which falls within the range documented in previous studies (10–31%) [2, 13]. Factors contributing to miscarriage include patient age, pre-treatment health status, and fibroid characteristics. Additionally, the cesarean delivery rate in our study was 72.94%, significantly higher than the 41.6–64.7% reported in other studies [12, 14, 15]. This may reflect patients' concerns about potential pregnancy complications following HIFU, prompting a preference for cesarean delivery. While cesarean delivery appears to reduce certain risks, further research is warranted to better understand the long-term implications of this trend.

Pregnancy complications and neonatal outcomes

Our findings revealed no significant differences in key pregnancy complications—such as pregnancy-induced hypertension (PIH), eclampsia, thyroid dysfunction, or placental abnormalities—between the HIFU and vaginal delivery groups. Similarly, neonatal outcomes, including rates of neonatal asphyxia, congenital anomalies, macrosomia, and fetal growth restriction, were comparable across groups. These results confirm that HIFU treatment does not adversely affect maternal or neonatal health. Notably, placental adhesion was more prevalent in the HIFU group (10.59%) than in the vaginal delivery group (3.73%, $p < 0.05$), which may be related to the higher frequency of pregnancies in HIFU-treated patients.

Recent studies have investigated the impact of High-Intensity Focused Ultrasound (HIFU) treatment for uterine fibroids on pregnancy complications and neonatal outcomes. A systematic review and meta-analysis published in 2023 analyzed reproductive and obstetric outcomes following HIFU treatment. The study found that the miscarriage rate was 19.2% in the UAE group, with USgHIFU associated with a higher rate of placental abnormalities compared to UAE (2.8% vs. 1.6%) [14]. Another review from 2021 reported that HIFU treatment for uterine fibroids and adenomyosis resulted in favorable pregnancy rates and live birth rates, with a lower natural abortion rate. However, the proportion of cesarean section deliveries after HIFU treatment was relatively high, and cases of gestational uterine rupture have been documented [15]. These findings suggest that while HIFU is a promising fertility-preserving treatment, careful monitoring for potential complications such as placental abnormalities and uterine rupture is essential.

Uterine rupture and fibroid characteristics

Incomplete uterine rupture was observed in 11.15% of cesarean deliveries in the cesarean control group and 4.71% in the HIFU-treated group. The higher rate of uterine rupture in both groups is likely attributed to the inclusion of high-risk patients with a history of multiple cesarean deliveries, known to significantly increase the likelihood of uterine rupture.In the HIFU-treated group, incomplete uterine rupture was associated with advanced maternal age, a history of multiple pregnancies, and fibroid characteristics, particularly fibroid sizes exceeding 5 cm. These findings underscore the importance of enhanced prenatal monitoring for older patients and those with larger residual fibroids after HIFU treatment.

Despite the observed risks, multivariable analysis did not identify HIFU treatment itself as an independent predictor of uterine rupture. This suggests that the increased rate of uterine rupture is primarily related to patient-specific factors, such as obstetric history and fibroid characteristics, rather than the HIFU procedure.To address these challenges, future research should focus on optimizing delivery strategies for patients with scarred uteri post-HIFU treatment. Investigating the impact of delivery methods, such as elective cesarean versus trial of labor, on pregnancy outcomes is crucial. Moreover, prospective studies evaluating uterine scar integrity and structural changes after HIFU treatment will provide

valuable insights into managing pregnancies in this high-risk population more effectively.

Recent studies have examined the relationship between uterine rupture and fibroid characteristics, particularly in patients with a history of multiple cesarean deliveries. A 2023 study reported that the risk of uterine rupture increases with the number of prior cesarean sections, emphasizing the need for careful monitoring in such high-risk populations [16]. Additionally, a 2022 study found that uterine rupture is more frequent in low-income countries compared to high-income countries, with the primary risk factor being a scarred uterus, typically resulting from a previous cesarean delivery [17]. Similarly, a 2023 study confirmed the heightened risk of uterine rupture with multiple cesarean deliveries [18], while another study underscored regional disparities in uterine rupture rates, attributing them to differences in healthcare access and cesarean section management [19]. These findings collectively underscore the importance of enhanced prenatal monitoring for older patients and those with larger residual fibroids after HIFU treatment. Future research should focus on optimizing delivery strategies for patients with scarred uteri post-HIFU treatment, investigating the impact of delivery methods on pregnancy outcomes, and evaluating uterine scar integrity and structural changes after HIFU treatment to better manage pregnancies in this high-risk population.

Anemia and gestational diabetes mellitus

HIFU treatment demonstrated a lower risk of anemia and gestational diabetes mellitus (GDM) compared to other delivery groups, highlighting its favorable impact on maternal health. The incidence of mild anemia in the HIFU group was 31.18%, with moderate anemia at 4.71%, both significantly lower than in the cesarean and vaginal delivery groups. Similarly, the incidence of GDM in the HIFU group was 8.24%, markedly lower than the rates observed in cesarean delivery (20.86%) and vaginal delivery groups (20.98%). These findings suggest that HIFU treatment may offer protective effects against these common pregnancy-related complications, likely due to reduced surgical trauma and preservation of uterine vascularization. This supports the use of HIFU as a fertility-preserving treatment with positive maternal health outcomes. Further studies could investigate the underlying mechanisms contributing to the lower risks of anemia and GDM in HIFU-treated patients, potentially informing enhanced prenatal care strategies.

HIFUtreatment has been associated with a reduced risk of anemia and GDMcompared to other treatment modalities for uterine fibroids, underscoring its favorable impact on maternal health. A study published in 2024 evaluated changes in ovarian reserve and quality of life in women treated with ultrasound-guided HIFU for uterine fibroids. The findings indicated that HIFU treatment led to significant improvements in quality of life, with minimal adverse effects on ovarian function, suggesting a positive influence on overall maternal health outcomes [20].Additionally, a 2023 study focused on predicting the efficacy of HIFU treatment for uterine fibroids. The research developed diagnostic models to accurately predict ablation rates and volume reduction rates, assessing both short-term and long-term treatment outcomes. While the study primarily addressed treatment efficacy, the implications for maternal health, including potential reductions in anemia and GDM, were considered significant [21].These studies suggest that HIFU treatment may offer protective effects against common pregnancy-related complications, likely due to its minimally invasive nature and preservation of uterine vascularization. This supports the use of HIFU as a fertility-preserving treatment with positive maternal health outcomes. Further research is warranted to investigate the underlying mechanisms contributing to the lower risks of anemia and GDM in HIFU-treated patients, potentially informing enhanced prenatal care strategies.

Limitations and future directions

This study has several limitations. First, the high cesarean delivery rate among HIFU-treated patients may limit generalizability. Additionally, while efforts were made to control for fibroid characteristics, their interaction with pregnancy outcomes remains unclear. The relatively small sample size also underscores the need for larger, randomized controlled trials to validate our findings. Future studies should focus on the long-term effects of HIFU, particularly on recurrent fibroids and subsequent pregnancies.While this study demonstrated favorable outcomes in the HIFU-treated group, the presence of residual fibroids may have contributed to the observed results. Residual fibroid characteristics, such as size and location, are known to influence pregnancy outcomes and could serve as confounding factors. Therefore, caution should be exercised when attributing these outcomes solely to the effects of HIFU treatment. Future studies should aim to isolate the effects of residual fibroids through more rigorous matching or stratification techniques.

The incorporation of AI technology into HIFU procedures offers promising avenues for improving precision and effectiveness. Future research should explore these advancements to optimize treatment outcomes. Additionally, studies examining management strategies for pregnancies with scarred uteri post-HIFU and their impact on delivery outcomes are critical for advancing clinical guidelines.

Conclusion

The findings from this study suggest that HIFU is a viable and safe treatment option for uterine fibroids in women seeking to preserve fertility. Our data demonstrate that HIFU does not increase the risk of adverse perinatal outcomes, such as preterm birth or pregnancy complications, and may offer advantages over traditional surgical methods, including shorter recovery times and reduced risks associated with invasive procedures. Additionally, HIFU appears effective in maintaining full-term pregnancies and managing fibroid-related symptoms, making it a promising fertility-preserving alternative.

However, this study also highlights limitations that warrant further investigation. The potential influence of residual fibroids on pregnancy outcomes and the high cesarean delivery rate observed among HIFU-treated patients underscore the need for careful patient monitoring and counseling. Future research should focus on larger, multicenter trials with matched control groups to better isolate the effects of HIFU and evaluate its long-term impact on fertility and pregnancy outcomes. Although the findings of this study support the safety and efficacy of HIFU as a fertility-preserving treatment for uterine fibroids, the potential influence of residual fibroids on pregnancy outcomes must be acknowledged. These results highlight the need for further research to disentangle the effects of HIFU treatment from those of residual fibroids and to optimize clinical protocols for managing pregnancies in this population.

This study contributes to the growing body of evidence supporting HIFU as an effective and fertility-preserving treatment for uterine fibroids. To optimize clinical practice, further studies—particularly single-cohort descriptive analyses—are needed to explore the long-term safety and efficacy of HIFU treatment, as well as its role in managing recurrent fibroids and scarred uterine conditions. The integration of advanced technologies, such as artificial intelligence, into HIFU protocols may further enhance its precision and outcomes, warranting additional research in this area.

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Author contributions
All authors have seen and approved the final version of this article. Min Zhao: designed the study, gathered, and collected the data, wrote the manuscript, and contributed to the critical discussion. Yong Zhang and Ligang Wang collected the data. and Dan Wang an revised the manuscript.

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Availability of data and materials
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study was approved by the ethics committee of the hospital and the ethical approval document has been uploaded to the supplementary document.

Competing interests
The authors declare no competing interests.

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