How to boost an obstetrician’s confidence in vaginal delivery after high-intensity focused ultrasound: a comparison study on delivery outcomes

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ABSTRACT

Objective: To assess the feasibility of vaginal delivery after HIFU.

Methods: A total of 37 women who met the trial of labor after HIFU (TOLAH) inclusion criteria and 368 women who met the trial of labor after cesarean delivery (TOLAC) inclusion criteria gave birth at Shanghai First Maternity and Infant Hospital between 14th June 2018 and 24th September 2021. The delivery outcomes of the two groups were compared. Multivariable logistic regression analysis was used to estimate the adjusted risk of postpartum hemorrhage (PPH).

Results: In the Qualified Candidates for TOLAH group, vaginal delivery is substantially less common ($p = 0.000$). The prevalence of PPH in the Qualified Candidates for TOLAH group is lower than in the Candidates for TOLAC group ($8.22\%$ vs $12.51\%$, $p = 0.534$; $0\%$ vs $2.51\%$, $p = 0.418$). Hemoglobin drop in the Qualified Candidates for TOLAH group is also lower ($7.03 \pm 7.39$ vs $12.11 \pm 12.62$, $p = 0.001$). The rate of using more than two types of uterotonic medications to promote contraction is significantly lower in the Qualified Candidates for TOLAH group ($54.05\%$ vs $69.84\%$, $p = 0.04$), and the percentage of abnormal uterine contraction is lower in the Qualified Candidates for TOLAH group ($35.14\%$ vs $49.18\%$, $p = 0.072$). PPH is strongly predicted by abnormal uterine contraction (aOR: $17.177$, 95% CI: $5.046$–$58.472$, $p = 0.000$), but not by HIFU (aOR: $1.105$; 95% CI: $0.240$–$5.087$, $p = 0.898$). No uterine rupture occurred in the cases after HIFU.

Conclusions: No uterine rupture occurred in our study group after HIFU. HIFU is not a risk for PPH. It is promising for those after HIFU to choose vaginal delivery.

Introduction

Many women choose to postpone motherhood while taking on other roles and taking into account political, economic, and cultural contexts. Unfortunately, ultrasound examination reveals a fibroids incidence of up to 60% in African-American women by the age of 35 years [1]. Adenomyosis affects 2 out of every 10 women before the age of 40, while it affects 8 out of every 10 women between the ages of 40 and 50 [2]. Evidence suggests that both uterine fibroids and adenomyosis are linked to infertility [3,4]. Fibroids are also associated with recurrent miscarriage [3], premature delivery, placenta previa, placental abruption, and postpartum hemorrhage [5]. Myomectomy was the most common surgical treatment for women with uterine fibroids of child-bearing ages, during myomectomy, the continuity of the normal myometrium was interrupted, and the formation of myometrial scars, which may exert a negative effect on uterine contractions and increase the risk of uterine rupture during pregnancy and labor [6,7]. Adenomyosis has traditionally been treated medically and/or surgically. It is difficult to completely remove the lesion, and conservative surgery has been shown to be effective in only about half of the patients, with a very high recurrence rate [8]. Currently, hysterectomy remains the definitive cure. There is no specific treatment available for patients who want to keep their uterus or remain fertile. As a result, it is critical to investigate new, more effective, safe, and less invasive treatment strategies for these patients of child-bearing ages.

High-intensity focused ultrasound (HIFU) is a new minimally invasive treatment option for benign tumors. It has been considered a uterine-sparing option in gynecology for women seeking alternatives to hysterectomy for uterine fibroids and adenomyosis. It is a technology that directs ultrasound wave beams to a single point where the most energy is deposited. The tumor’s growth is to be stopped by ensuring adequate HIFU power delivery and ablation of selected tumors, and then the uterus is to gradually absorb or expel the tumor. Fibroid shrinkage of around 70% to 90% can typically be achieved in 12 months [9,10]. The uterine volume reduction rates (%) for adenomyosis were 43.99%, 47.01%,...
and 53.98% by 3, 6, and 12 months, respectively [11]. Results obtained by various research groups have shown that HIFU in the treatment of fibroids and adenomyosis is safe, effective and highly acceptable to patients [12,13]. Additionally, previous research has confirmed that HIFU neither damage the surrounding myometrium nor impair ovarian function [14,15].

In the year 2000, Chinese authorities approved the ultrasound-guided (USg) HIFU for clinical treatment. Korea and Singapore have gradually accepted it as a treatment for fibroids and adenomyosis. The UK approved USgHIFU for the treatment of uterine fibroids in 2019 [16]. As the number of women who successfully conceived after HIFU increases, obstetricians are eager to investigate pregnancy and delivery complications. According to the findings of studies, patients who receive USgHIFU treatment can have full-term pregnancies with few perinatal complications and no additional obstetric risks [17,18]. However, Studies show a high rate of cesareans in all subsequent pregnancies, based on the view that Li’s research, the rate of cesarean section now is similar to post-myomectomy (72.0% vs 66.7–78%) [19]. What factors influence an obstetrician’s confidence in vaginal delivery after HIFU? Uterine rupture, Postpartum hemorrhage (PPH) are the most dreadful complications of delivery, and they are also the primary considerations of an obstetrician when deciding whether or not to choose vaginal delivery after HIFU. Just like vaginal birth after cesarean delivery (VBAC)a century ago, the delivery mode after HIFU is at the beginning to be investigated.

The aim of our study is to know the safety of vaginal delivery after USgHIFU by comparing the delivery outcomes after USgHIFU to those of TOLAC, who are assessed by obstetricians more likely to have a successful vaginal birth and have a low risk of obstetric dangers during or after delivery.

Methods

Data sources

A retrospective study was conducted to analyze post-HIFU delivery outcomes at Shanghai First Maternity Infant Hospital, one of three specialized hospitals for obstetrics and gynecology in Shanghai. It is not only an academic hospital affiliated with Shanghai Tongji University, but it also has a high number of births, with an annual average of 30,000 deliveries. Data were obtained from the Obstetrics departmental electronic medical records; The first post-HIFU patient gave birth on 14th June, 2018, and our study included 37 post-HIFU women and 368 good candidates for TOLAC who gave birth in our hospital between 14th June 2018 and 24th September 2021.

The Ethics committee of hospital approved this study (KS211191). The requirement for informed consent was waived by our ethics committee.

Definition of variables

Trial of labor after cesarean delivery (TOLAC) refers to a planned attempt to deliver vaginally by a woman who has had a previous cesarean delivery, regardless of the outcome. This method provides women who desire a vaginal delivery the possibility of achieving that goal—a vaginal birth after cesarean delivery (VBAC).

Trial of labor after HIFU(TOLAH) refers to a planned attempt to deliver vaginally by a woman who has had a HIFU, regardless of the outcome.

A vaginal birth after HIFU(VBAH)

In our hospital, TOLAC and TOLAH were performed in accordance with the recommendations of the American College of Obstetricians and Gynecologists (ACOG) [25]. Assessing the likelihood of VBAC as well as the individual risks is important when determining who is an appropriate candidate for TOLAC to avoid maternal and perinatal morbidity or to avoid obstetric risks such as PPH and uterine rupture. Women with one previous cesarean delivery with a low-transverse incision who desire a vaginal delivery should get admission for TOLAC in our VBAC clinic.

Good candidates for TOLAC

(Those who got admission to TOLAC from obstetricians):

Inclusion:(1) Women who have had one previous cesarean delivery with a low-transverse incision want a vaginal delivery (2) Interdelivery interval of more than 19 months (3) The fetus has a good relationship with the birth canal (4) Ultrasound regularly monitored the scar of uterine condition, and the continuity and thickness were satisfactory

Exclusion:(1) Vaginal delivery contraindications, such as placenta previa, abnormal fetal position, severe hypertension, and so on. (2) There was no previous cesarean section procedure
abnormality, such as a myometrial tear. (3) Having had more than one cesarean delivery in the past (4) Following myomectomy (5) Patients refuse to understand or accept the rare risk of uterine rupture. (6) Those who have previously undergone a traditional or T-incision, uterine rupture.

Qualified candidates for TOLAH (Those who could get admission to TOLAH):

Inclusion: after HIFU

Exclusion (1) Vaginal delivery contraindications, such as abnormal fetal position, severe hypertension, and so on. (2) After myomectomy

Delivery outcomes

Our primary outcome of interest was defined as mode of delivery (vaginal delivery or cesarean delivery). Secondary outcomes included uterine rupture and postpartum hemorrhage (PPH). We recommend using the WHO definition of PPH: Blood loss ≥500 mL within 24 hours after birth. Severe PPH: Blood loss ≥1000 mL within the same time frame [26]. Blood loss was calculated using a weighing method combined with obstetricians’ visual assessment. Hemoglobin (Hb) drop is by subtracting the Hb at time of the next day (median of 24h after delivery) from the pre-delivery Hb. The following were the third outcomes: postpartum blood transfusion, intrauterine balloon tamponade, and surgical procedures to control bleeding requiring laparotomy (uterine artery ligation, uterine compression sutures).

Statistical analysis

Statistical analysis was performed using SPSS version 16.0 (SPSS, Chicago, IL, USA). Descriptive data such as complications during pregnancy and delivery were expressed as a range or rate. Quantitative data are presented as arithmetic mean ± standard deviation (SD). Differences between the two groups were analyzed using the Student’s t-test and Chi-square test or Fisher exact probability analysis. Multivariable logistic regression analysis was used to adjust the likelihood of the measured outcomes for potential confounding variables. Statistical significance was determined at p < 0.05.

Results

Over the study period, there were 90,685 deliveries in our hospital.

40 patients (0.044%) had previously received HIFU, while 8,899 patients (9.81%) had previously undergone a low transverse cesarean delivery. 368 (4.14%) individuals with a previous low transverse cesarean delivery were identified as good candidates for TOLAC (Candidates for TOLAC group). After HIFU, 37 patients (92.5%) were eligible for admission to TOLAH (Qualified Candidates for TOLAH group).

Table 1 compares the mother characteristics and pregnancy outcomes of two groups. The mean age of Qualified Candidates for TOLAH is significantly greater than that of Candidates for TOLAC (35.57 ± 4.81 vs 33.24 ± 3.53, p = 0.007), while more people in Candidates for TOLAC had parity more than twice (24.32% vs 52.99%, p = 0.001). The difference in pregnancy mode and BMI between the two groups is
statistically significant \((p = 0.000\) and \(p = 0.01\), respectively). There were two twins in the Qualified Candidates for TOLAH group and none in the Candidates for TLOAC group \((p = 0.008)\), but no uterine rupture occurred during pregnancy in the Qualified Candidates for TOLAH group.

Table 2 compares the two groups' delivery outcomes. In the Qualified Candidates for TOLAH group, vaginal delivery is substantially less common \((p = 0.000)\), with 36 patients undergoing cesarean section, 11 for obstetric factors (2 with twins, 3 with breech, 2 with suspected fetal distress, 1 with preecclampsia, 1 with shortness of breath, 2 after HIFU + CS), and 25 for obstetricians' recommendation (4 patients aging over 35, 21 patients had received a recommendation from obstetricians who took a conservative approach to managing labor in pregnant women with a history of HIFU ablation treatment). The prevalence of PPH (blood loss \(\geq 500\)) and severe PPH (blood loss \(\geq 1000\)) is lower in the Qualified Candidates for TOLAH group than in the Candidates for TOLAC group \((8.82\% \pm 10.51\%, p = 0.534; 0\% \pm 2.51\%, p = 0.418)\), Hemoglobin drop in the Qualified Candidates for TOLAH group is also lower \((7.03 \pm 7.39 vs 12.11 \pm 12.62, p = 0.001)\). The rate of abnormal uterine contractions reported in the delivery files is lower in the Qualified Candidates for TOLAH group \((35.14\% \pm 7.61\%, p = 0.04)\), however, the rate of uterine artery ligation is greater in the Qualified Candidates for TOLAH group \((35.14\% \pm 7.61\%, p = 0.000)\), interestingly. Among 13 patients undergoing procedure of uterine artery ligation, only one patient had blood loss over 500 ml. No uterine rupture occurred in the cases after HIFU, while 2 cases of uterine rupture occurred in the Candidates for TOLAC group.
strates that today social reasons. Our research, like previous research, demonstrated that undergoing caesareans, 49 patients demanded cesarean for ery versus 56 cases of cesarean, among the 56 patients after HIFU, there were only 15 cases of normal vaginal delivery. Zou et al. [5] reported that among the 71 patients and the remaining 41.8% (28/67) for the advice of obstetricians). Zou et al. [5] reported that among the 71 patients with HIFU, of the 93 full-term deliveries that occurred LM group had a greater incidence of postpartum hemorrhage than the USgHIFU group; Although Li [19] reported six cases after HIFU, Of the 93 full-term deliveries that occurred with heavy hemorrhage, four of those were associated with resection of an intramural fibroid during cesarean section. We believe that HIFU is not a risk for PPH.

**Uterine atony**

Common causes of PPH include uterine atony, trauma, retained placental tissue, and failure of the blood coagulation system, with uterine atony accounting for the majority of cases (75–90%) [32]. Uterine atony is defined as the inability of the uterus to contract after the fetus has been expelled [33]. According to our research, contraction of the uterus is associated with PPH (aOR: 17.177, 95% CI: 5.046–58.472, p = 0.000), and this finding is consistent with the expert consensus. The rate of using more than two types of uterotonic medications to promote contraction is significantly lower in the Qualified Candidates for TOLAH group (54.05% vs 69.84%, p = 0.04), and the percentage of abnormal uterine contraction is lower in the Qualified Candidates for TOLAH group (35.14% vs 49.18%, p = 0.072). We believe that the uterine contraction ability is unaffected by HIFU, which explains the low incidence of PPH after HIFU. The ability of uterine contraction after HIFU has received less attention in prior literature. Only one case of PPH due to uterine atony after HIFU was found in Li’s analysis of 93 full-term births [19]. Following HIFU, the reduction of myoma volume or the ablation inside myomas is beneficial to contraction ability. This point of view needs more studies to concentrate on.

**Uterine rupture after HIFU**

Our study shows that no uterine rupture after HIFU occurred during pregnancy and/or delivery. According to previous studies, uterine rupture after HIFU rarely happens [17,19,34,35]. Three studies did not contain any cases of uterine rupture during pregnancy or labor after HIFU treatment [17,19,35]. Wu et al. reported one case of incomplete uterine rupture after HIFU (1/178) in their study [31]. This can be explained by the procedure of HIFU. HIFU ablation treatment is a noninvasive tissue ablation technique, it means there is no scar. During the treatment, to avoid heat damage to surrounding structures, the distance between the focal point and the endometrium was at least 1.5 cm, and the distance between the focal point and the subserosal surface of the uterus was 1 cm [20,36]. However, during myomectomy, the continuity of the normal myometrium was interrupted, and the formation of myometrial scars, may exert a negative

| Table 3. Multivariable regression analysis PPH (blood loss >500). |
|------------------------|--------|----------------|--------|
|                      | aOR    | 95%CL          | p Value |
| Age                   | 1.098  | 0.991–1.218    | 0.075  |
| BMI                   | 1.105  | 0.240–5.087    | 0.898  |
| Parity                | 0.601  | 0.374–0.966    | 0.036  |
| Weeks                 | 0.983  | 0.951–1.016    | 0.322  |
| Fetal weight          | 1.000  | 1.000–1.100    | 0.329  |
| Placental abnormality | 0.570  | 0.223–1.460    | 0.242  |
| Abnormal contraction  | 17.177 | 5.046–58.472   | 0.000  |
| Cs                    | 1.547  | 0.678–3.527    | 0.300  |
| After HIFU            | 1.105  | 0.240–5.087    | 0.898  |
| Pregnancy mode        | 0.678  | 0.103–4.450    | 0.686  |

Table 3 shows the adjusted odds ratios (aORs) and 95%CLs for relevant factors. PPH is strongly predicted by abnormal uterine contraction (aOR: 17.177, 95% CI: 5.046–58.472, p = 0.000), but not by HIFU (aOR: 1.105; 95% CI: 0.240–5.087, p = 0.898). Liu [20] reported that no postpartum hemorrhage occurred among the 21 successful vaginal deliveries after HIFU. Wu et al. [31] compared the incidence of postpartum hemorrhage in the HIFU and Laparoscopic myomectomy (LM) groups, finding that the LM group had a greater incidence of postpartum hemorrhage than the USgHIFU group; Although Li [19] reported six cases after HIFU, Of the 93 full-term deliveries that occurred with heavy hemorrhage, four of those were associated with resection of an intramural fibroid during cesarean section. We believe that HIFU is not a risk for PPH.

**Postpartum hemorrhage (PPH) after HIFU**

After HIFU, why do today’s obstetricians have less faith in vaginal birth? One of the most significant reasons is that there is little information or research available on the PPH following HIFU. Postpartum hemorrhage (PPH) is the most common cause of maternal mortality worldwide [29]. Blood loss is calculated using a weighing method combined with obstetricians’ visual assessment, and measuring Hb levels early and repeatedly is recommended in patients with PPH [30]. The prevalence of PPH in the Qualified Candidates for TOLAH group is lower than in the Candidates for TOLAC group (8.82% vs 10.51%, p = 0.534; 0% vs 2.51%, p = 0.418). Hemoglobin drop in the Qualified Candidates for TOLAH group is also lower (7.03 ± 7.39 vs 12.11 ± 12.62, p = 0.001). Multivariable regression analysis demonstrates that PPH is strongly predicted by abnormal uterine contraction (aOR: 17.177, 95% CI: 5.046–58.472, p = 0.000), but not by HIFU (aOR: 1.105; 95% CI: 0.240–5.087, p = 0.898). Liu [20] reported that no postpartum hemorrhage occurred among the 21 successful vaginal deliveries after HIFU. Wu et al. [31] compared the incidence of postpartum hemorrhage in the HIFU and Laparoscopic myomectomy (LM) groups, finding that the LM group had a greater incidence of postpartum hemorrhage than the USgHIFU group; Although Li [19] reported six cases after HIFU, Of the 93 full-term deliveries that occurred with heavy hemorrhage, four of those were associated with resection of an intramural fibroid during cesarean section. We believe that HIFU is not a risk for PPH.

**Discussion**

The mode of delivery after HIFU

The World Health Organization identifies that a CS rate above the ideal rate of 10–15 percent in any region is unjustified and unnecessary, which in turn leads to morbidity and mortality that is the result of CS [28]. Every new technology used in the clinic requires time for doctors to fully comprehend numerous studies to confirm the safety of using or the complications to avoid, as well as the vaginal delivery mode after HIFU. Li et al. ’s [19] research indicate that the rate of cesarean section after HIFU is 72%, fourteen people (20.9%, 14/67) chose delivery by cesarean section for obstetric factors, while 79.1% chose delivery by cesarean section for social factors (37.3% (25/67) for the fear of pain during labor, and the remaining 41.8% (28/67) for the advice of obstetricians). Zou et al. [5] reported that among the 71 patients after HIFU, there were only 15 cases of normal vaginal delivery versus 56 cases of cesarean, among the 56 patients undergoing caesareans, 49 patients demanded cesarean for social reasons. Our research, like previous research, demonstrates that today’s obstetricians and patients are less confident in vaginal birth following HIFU.
effect on uterine contractions and increase the risk of uterine rupture during pregnancy and labor [20]. It is reported that the overall incidence of uterine rupture after myomectomy was 0.93% (0.45–1.92%); specifically, it was 0.47% (0.13–1.70%) in women undergoing trial of labor after myomectomy, and 1.52% (0.65–3.51%) in women before the onset of labor [37]. We believe that, based on existing research, the overall risk of uterine rupture after HIFU is rare, but it should be investigated further with a large sample population.

**Other delivery outcomes after HIFU**

In our study, something interesting has happened. Although the rate of PPH is lower in the Qualified Candidates for TOLAH group (8.82 percent vs 10.51 percent, \(p = 0.534\)) and there were only three patients with PPH, 13 patients underwent uterine artery ligation. Among these 13 patients, only one patient had blood loss over 500 ml. 92.31% (12/13) cases receiving procedure of uterine artery ligation were for prevention rather than treatment, because obstetricians had not any confidence on the uterine contraction ability after HIFU. This procedure was performed to prevent bleeding after patients exited the operating room and prevent second entry to the operating room. It means that there is less data and research on blood loss in post-HIFU deliveries, and obstetricians have little notion or trust in the safety of post-HIFU deliveries.

**Limitation**

There remain limitations to this study. First, because of our data collection approach and the retrospective character of the study, we are unable to detect certain aspects that may influence pregnancy and delivery following HIFU, such as obstetrics policy. A future prospective study with proper controls will be required. Second, this study did not find any unusual complications, such as uterine rupture during pregnancy or labor. We can’t say if this is related to HIFU or a result of the small sample size. Third, measurement bias may occur, which is the most significant disadvantage of a retrospective study. Finally, the age range of women in the study population is large. A future prospective study would be needed to address the potential influence of age on the outcomes described here.

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**Data availability statement**

The data that support the findings of this study are openly available in Science Data Bank at https://www.scidb.cn/anonymous/Yk12SUpq

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