

# Unintended pregnancies with term delivery following ultrasound-guided high-intensity focused ultrasound (USgHIFU) ablation of uterine fibroid and adenomyosis

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## Summary

**Purpose of Investigation:** This study aimed to assess the pregnancy outcome of patients with uterine fibroid or adenomyosis treated by ultrasound-guided high-intensity focused ultrasound (USgHIFU) ablation. **Materials and Methods:** Treatment was administrated using a focused ultrasound tumor therapeutic system. In this study, there were 23 unintended pregnancies after USgHIFU ablation. **Results:** Twelve patients developed no complication during pregnancy and continued until full term delivery. Vaginal and cesarean section deliveries were also uneventful. The following are the pregnancy outcome of the patients: three patients experienced spontaneous abortions, one patient experienced preterm delivery, and five patients remained pregnant at this point. **Conclusions:** USgHIFU seems to have the effectiveness to precisely treat adenomyosis and uterine fibroid, allowing for normal reproduction. Well-designed prospective trials are needed to ascertain the safety of this treatment with pregnancy due to the lack of large-scaled study.

**Key words:** Adenomyosis; HIFU; Pregnancy; Uterine fibroid.

## Introduction

Uterine fibroid and adenomyosis are frequent diseases at myometrium in women of reproductive age. Recently, reduced fertility and late parturition may be partially attributed to the increased incidence of uterine fibroid and adenomyosis. Various symptoms of the two disorders include dysmenorrhea, menorrhagia, vaginal hemorrhage, and subfertility. To treat uterine fibroid and adenomyosis, myomectomy, and hysterectomy can be considered as operative treatments, and radiofrequency (RF), uterine artery embolization (UAE) and high-intensity focused ultrasound (HIFU) as non-operative treatments [1-3]. HIFU is a non-invasive technique where ultrasound is concentrated on one point and raises its thermal effect to treat the lesion without impairments of skin and peritoneum [3, 4].

The report describes the outcomes of 24 unintended pregnancies of patients with uterine fibroid or adenomyosis treated by ultrasound-guided high-intensity focused ultrasound (USgHIFU) ablation.

## Materials and Methods

Uterine fibroids and adenomyosis were diagnosed referring to medical history, physical examination, ultrasound (US), and MRI. The authors included patients with symptomatic uterine fibroid

and adenomyosis with no evidence of known or suspected extensive pelvic adhesions, such as a history of acute pelvic inflammatory disease, severe pelvic endometriosis, and lower abdominal surgery or an abdominal wall thickness of < 5 cm. The exclusion criteria were pedunculated uterine fibroid, asymptomatic uterine fibroid of < 5 cm in diameter, asymptomatic focal adenomyosis, and suspected malignancy.

HIFU treatment was performed using a focused ultrasound tumor therapeutic system. This study was approved by the Ethics Committee at Incheon Christian Hospital. The authors explained the effect of the procedure, the side effect, and its impacts on pregnancy to the patient prior to administration of HIFU.

All patients received careful bowel and skin preparations prior to treatment. Urinary catheter was inserted into the bladder, which was filled with sterile saline in order to control the bladder volume before treatment. During the procedure, conscious sedation and pain control were achieved by injecting midazolam, propofol, and fentanyl while 300~400 watt (W) levels of energy with HIFU were given to a lesion. The conditions of patients were monitored over 12 hours after procedure, and oral prophylactic antibiotics and anti-inflammatory agents were prescribed before discharge.

The improved symptoms and patients' satisfaction were evaluated before and six months after treatment by the Symptom Severity Score (SSS) and Uterine Fibroid Symptom and Quality of Life (UFS-QOL) questionnaire subscales. The decrease in the lesion volume after HIFU treatment was measured in longitudinal (D1), anteroposterior (D2), and axial (D3) on MRI before and six months after treatment, and the measured data were evaluated by a calculation using the equation below:

$$V = 0.5233 \times D1 \times D2 \times D3$$

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Table 1. — Outcomes of unintended pregnancies after USgHIFU treatment.

Pregnancy outcomes	Uterine fibroid (n=11)	Adenomyosis (n=12)
Normal spontaneous delivery	5	3
Cesarean section	3	1
On-going pregnancy	2	3
Spontaneous abortion	1	2
Premature delivery	0	1
Follow-up loss	0	2
Mean treatment time (minutes)	79.55	51.88
Mean ablation time (minutes)	10.08	10.88
Mean energy (Joules)	458,334.3	189,896.7
Volume reduction rate (% by 6 months)	69.4	39.2
SSS reduction rate (% by 6 months)	20.5	40

USgHIFU: ultrasound-guided high-intensity focused ultrasound; n: number; SSS: Symptom Severity Score.

The effects and recurrences in all participants of this study were examined by T2-weighted MRI imaging (T2WI) and T1-weighted MRI imaging (T1WI) with administration of gadolinium injection at times of pre-, post-, and six months follow-up after treatment. A retrospective analysis was conducted in 1,204 women with uterine fibroid or adenomyosis who underwent USgHIFU ablation from February 2010 to January 2015 at Incheon Christian Hospital, located in Incheon, Republic of Korea. Among these women, there were 23 unintended pregnancies.

## Results

The data of pregnancy outcome of 11 patients with uterine fibroid and 12 patients with adenomyosis after USgHIFU ablation are shown in Table 1.

The mean age of the 11 patients with uterine fibroid was 32.9 (range 26~41) years. Two patients were multiparous. The mean HIFU treatment time and mean HIFU ablation time were 79.55 minutes and 10.08 minutes for uterine fi-

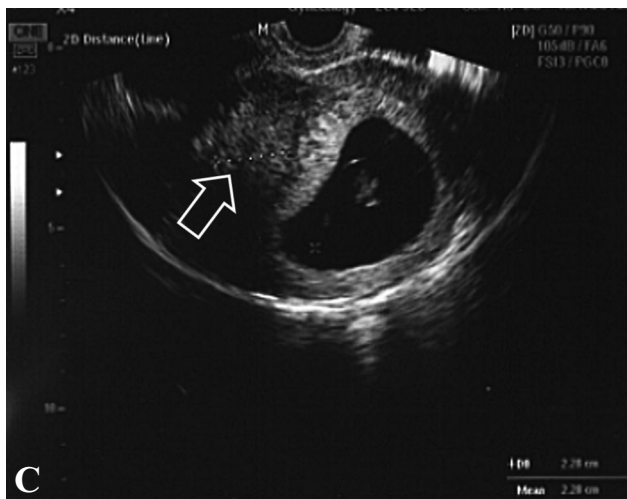
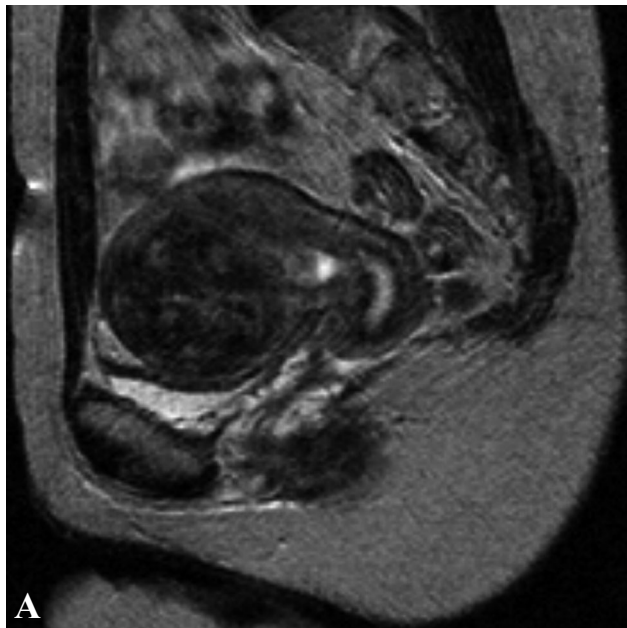


Figure 1. — USgHIFU treatment response in a case of nulliparous uterine fibroid.

(A) MRI scan shows that a 5.2×5.2 cm sized (61.3 cm<sup>3</sup>) uterine fibroid on T2W MRI image sagittal is located at the uterine anterior wall. (B) Six months later, necrotic uterine fibroid is reduced to 3.1×2.5 cm in size (15.1 cm<sup>3</sup>). (C) SSS changed from 48.75 to 31.25 at six-months post-treatment and UFS-QOL scores increased from 54.3 to 71.6 at six-months post-treatment. US scan image of other uterine fibroid patient shows pregnancy 11 months after treatment. The arrow indicates uterine fibroid after USgHIFU. A 3.6-kg living male baby was delivered by cesarean section due to an induction failure at pregnancy 40.5 weeks.

broids, respectively. The mean HIFU treatment energy was 458,334.3 Joules (J). The volume reduction rate and SSS at six months after treatment were 69.4% and 20.5%, respectively.

The mean age of 12 patients with adenomyosis was 34.1 (range 30~42) years. Six patients were multiparous. The mean USgHIFU treatment time and mean USgHIFU ablation time were 51.88 minutes and 10.88 minutes for adenomyosis, respectively. The mean USgHIFU treatment energy was 189,896.7 J. The volume reduction rate and SSS at six months after treatment were 39.2% and 40%, respectively.

In this study, there were 23 unintended pregnancies after USgHIFU (Figure 1). Among these pregnant patients, 12 developed no complication during pregnancy and continued until full term delivery. Eight vaginal and four cesarean section deliveries were also uneventful. Three patients experienced spontaneous abortions; one patient with adenomyosis experienced preterm delivery at 25 weeks of gestation, and five patients remained pregnant at this point. The figure was excluded from this study because the patient was not contacted.

## Discussion

The potential unintended pregnancy after HIFU cannot be excluded despite the present authors' explanation that effect of HIFU on pregnancy is unclear. In a report of 54 pregnancies in 51 women undergoing MRI-guided HIFU treatment for uterine fibroids, live birth rate was 41% of all pregnancies, with a spontaneous abortion rate of 28%, and an elective pregnancy termination rate of 11%. Therefore, there were 11 on-going pregnancies beyond 20 gestational weeks. There were two cases of placenta previa without serious complications [5].

In this report, full term delivery rate was 57.1% (12/21), spontaneous abortion rate was 14.3% (3/21), and on-going pregnancies were five cases. Another study reported the outcome of unintended pregnancies after USgHIFU ablation of uterine fibroids. Pregnancies were progressed to full term in seven women, and all births were via cesarean delivery without complications. Fifteen women underwent induced abortions, and two women experienced spontaneous abortions [6].

Compared to the current authors' previous report [7], the mean age of the 272 patients with uterine fibroids was 40.49 (range 24~54) years. The mean age of 346 patients with adenomyosis was 40.43 (range 24~51) years. However, this study showed that pregnant patients with fibroid after HIFU ablation and with adenomyosis after HIFU were younger by the average of 7.6 and 6.3 years, respectively. As a result, the mean age of the patients in this study is younger than that of the authors' previous study. Informing HIFU effect on the pregnancy to patients before procedure is highly recommended because performing HIFU ablation

to the younger patients increases the possibility of future pregnancy.

In case series of deliveries after RF myolysis, there were three cases of uterine rupture during pregnancies [8] and four cases of term deliveries without any complications [9]. All ruptured cases conceived within three months after the procedure although the data were insufficient to comparing the size and number of fibroids. Three successful cases conceived after 12 months. In the present study, uterine rupture during pregnancy was not observed, but three spontaneous abortions occurred when conceived within one year after ABFU.

Although the preliminary pregnancy experience of USgHIFU is encouraging, this procedure must be approached with caution due to high risk of maternal or fetal morbidity. Intensive surveillance of the mother and fetus is required, and a cesarean section should be performed at the earliest signs and symptoms of uterine rupture.

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