Evaluation of the Treatment of High Intensity Focused Ultrasound Combined With Suction Curettage for Exogenous Cesarean Scar Pregnancy

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Research Article

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Abstract

Purpose: To evaluate the effectiveness of high intensity focused ultrasound (HIFU) combined with suction curettage in the treatment of exogenous cesarean scar pregnancy (CSP).

Methods: A total of 41 patients diagnosed with exogenous CSP were enrolled in this study. All patients received HIFU treatment combined with suction curettage.

Results: Twenty-nine patients were administered one session of HIFU ablation. In addition, the other 12 patients received 2 HIFU sessions. Suction curettage was performed in all patients after HIFU, and no patient was converted to laparoscopy or hysterectomy. The mean blood loss during suction curettage was 99 ml. Three patients received two sessions of suction curettage. The success rate of our study was 92.68%. The mean time for serum β -HCG normalization was 23.18 ± 3.13 days. The average menstruation recovery time was 29.38 ± 3.34 days. Based on the blood loss during suction curettage, 41 patients were divided into a bleeding group and a control group. The size of the gestational sac in the bleeding group (3.80 ± 0.87 cm) was larger than that in the control group (3.39 ± 0.77 cm) ($P < 0.05$). The thickness of the myometrium between the bladder and gestational sac in the bleeding group (2.37 ± 0.89 mm) was less than that in the control group (2.75 ± 0.75 mm) ($P < 0.05$).

Conclusion: The results suggested that HIFU combined with suction curettage could be considered an effective treatment for exogenous CSP of < 9 weeks. The size of the gestational sac and the thickness of the myometrium between the bladder and gestational sac might be high-risk factors for blood loss during this treatment.

Introduction

Cesarean scar pregnancy (CSP) is a rare variant of ectopic pregnancy in which the gestational sac implants into the site of a previous cesarean scar [1]. With the increase in the cesarean section rate and the improvement of diagnostic technology [2], the incidence of CSP is expected to increase further. The overall principle of CSP treatment is to remove gestational tissue, reduce blood loss and ensure the safety of patients. Various treatments for CSP have been studied before, including methotrexate (MTX), uterine artery embolization (UAE), high intensity focused ultrasound (HIFU) and surgery [3–5]. Although an increasing number of CSP cases have been reported, there is still no consensus on its treatment until now [6].

According to the growth direction and location of gestational sac in uterine scars, CSP is divided into two types: endogenous CSP refers to growth of the gestational sac toward the isthmus and uterine cavity, while the gestational sac of exogenous CSP implants into the deep muscle layer of the cesarean scar and grows toward the bladder and abdominal cavity [7, 8]. Some reports have concluded that there is a higher risk of massive hemorrhage and even death in exogenous CSP because the muscle fibers in previous cesarean scars are relatively insufficient for elastic contractility [9, 10]. Therefore, effective and safe treatment is particularly important for this kind of patient. As reported before, laparoscopy administered

for exogenous CSP has achieved good results [11, 12]. While eliminating pregnancy tissue, laparoscopy could provide an opportunity to repair uterine scar defects, which would be helpful to avoid the recurrence of CSP [13]. However, the exact pathogenetic mechanism of CSP remains unclear. It has been reported that 6%-10% of women after cesarean section have different degrees of scar diverticulum [14], which is significantly higher than the incidence of CSP [15]. CSP patients can have a normal pregnancy again after conservative treatment [16]. These studies suggest that scar diverticulum may not be the only cause of CSP. Although surgery has the advantage of repairing scars at the same time, it might also be complicated by anesthetic complications, postoperative adhesion, and poor healing of local scars [17]. A previous study also concluded that no sufficient evidence was found to elucidate whether reproductive outcomes after CSP are impacted by the management types adopted [18]. In view of the present situation, it seems that effective and less traumatic approaches should be taken. UAE combined with MTX has been reported as an effective treatment for exogenous CSP [19]. However, complications from UAE, such as long-term premature ovarian failure, post thrombotic syndrome, pulmonary embolism, and septic rectal perforation, occur [20–23]. Recently, HIFU has been reported to achieve satisfactory results in the treatment of fibroids and adenomyosis [24, 25]. Several studies have shown that HIFU followed by suction curettage is safe and effective in the treatment of CSP [16, 26]. However, the therapeutic effect of HIFU on different types of CSP has not been reported. In this study, we retrospectively evaluated the treatment of HIFU combined with suction curettage to explore whether it is effective and safe for exogenous CSP patients.

Materials And Methods

Patient collection

In this retrospective study we enrolled 41 patients diagnosed with exogenous CSP from September 2016 to September 2020 at the Second Affiliated Hospital, School of Medicine, Zhejiang University. The research protocol was approved by the ethics committee and institutional review board of our institution. The inclusion criteria were as follows: 1) previous history of a prior cesarean scar, 2) history of amenorrhea < 9 weeks and an increased level of β -human chorionic gonadotropin (β -HCG) (more than 5 mIU/mL), 3) ultrasound (Fig. 1) and magnetic resonance imaging (Fig. 2) meeting the criteria of exogenous CSP recommended by Godin et al [27] and Vial et al [7], with gestational sac implantation into the myometrium of a scar diverticulum and growth toward the bladder and abdominal cavity. Two experienced gynecological radiologists confirmed the sonographic and MRI results of all patients. Patients with heavy bleeding or unstable vital signs were excluded. The clinical characteristics, parameters during treatment, adverse events, and follow-up results were collected.

HIFU ablation

HIFU was performed by using a PRO200 focused ultrasound therapeutic system (Shenzhen PRO Medical Technology Co. Ltd, Shenzhen, China). The B-mode ultrasound used for monitoring was Mylab70 (Esaote, Genoa, Italy). HIFU ablation was performed on every patient without conscious sedation. The patient was

placed in the prone position on the HIFU system. The degassed water bag was positioned on the abdominal wall. During the operation, we used ultrasound to choose the location of the target area in real time, and the sagittal plane of ultrasound scanning was selected (Fig. 3). The pregnant tissue was divided into different treatment levels (the spacing was 3 mm), and the treatment plan was formulated. HIFU ablation was performed from the innermost part and extended to the outside by section. The sound output power was 250–300 W. HIFU ablation was stopped when color Doppler ultrasound revealed that the blood flow signal of the pregnancy tissue disappeared or the gray level of the target tissue changed. Contrast-enhanced ultrasound was performed to examine the blood perfusion of the pregnancy tissue. If a blood supply was found, another session of HIFU ablation was performed the next day.

Suction curettage

Suction curettage guided by ultrasound was performed under general anesthesia one to three days after HIFU ablation. The lithotomy position was employed for all patients. We measured the depth of the uterus and then dilated the cervix gradually with the uterine dilators. A 7 mm suction cannula was inserted into the uterine cavity with a vacuum pressure of 40 Pa. The cannula was moved forth and back and rolled gently to remove the pregnancy tissues. If an ultrasound check showed residual tissue, curettage was performed very gently. If active uterine bleeding > 200 ml occurred during or after suction curettage, we inserted a No. 14 Foley catheter balloon into the intrauterine cavity for compression hemostasis and removed it after 24 hours. The weight of medical gauze was used to measure the blood loss during or after suction curettage.

Follow up

After suction curettage, vital signs and vaginal bleeding of all patients were closely observed for 48 hours, and then they were discharged. A transvaginal ultrasonography examination was performed one week after suction curettage. If remnant tissue was found, the second session of suction curettage was performed immediately. At the same time, the patients underwent serum β -HCG testing every week until exhibiting normal levels. Serum β -HCG levels, the duration of vaginal bleeding, ultrasound assessments, menstruation recovery and adverse effects were followed up.

Successful cases were defined as: (1) no additional methotrexate or surgical intervention; and (2) normalization of serum β -HCG levels and recovery of menstruation.

Statistical analysis

Statistical analysis was performed by SPSS software (SPSS 22.0, IBM Company, Chicago, IL). Patient characteristics are described as proportions for categorical variables and were analyzed by the chi square test. Continuous variables with a normal distribution are reported as the mean $\pm$ SD and were analyzed by Student's *t* test. Continuous variables without a normal distribution are reported as medians and interquartile ranges and were analyzed by the Mann-Whitney U test. Correlation analysis between variables was performed by Spearman rank analysis. A *P* value < 0.05 was defined as a significant difference.

Results

Characteristics of exogenous CSP patients

Patient characteristics are summarized in Table 1. The median age of the patients was 29 years. The mean BMI was 22.62 ± 5.27 kg/m². The average gestational age was 50.31 ± 8.27 days. The median interval from the last cesarean section to CSP was 38 months. Among all patients, 20 patients (48.78%) had one previous cesarean delivery, 18 patients (43.90%) had two such deliveries, and 3 patients (7.32%) had three such deliveries. Thirteen patients (31.71%) had both light painless vaginal bleeding and lower abdominal pain. Twelve patients (29.27%) suffered from abdominal pain without vaginal bleeding. Sixteen patients (39.02%) complained of only light painless vaginal bleeding. Fetal cardiac activity was found in 6 patients (14.63%). Before the treatment the median serum β -HCG level was $26,207 \pm 8492$ mIU/ml. The average gestation sac size was 3.49 ± 0.94 cm. The median thickness of myometrium between the bladder and the gestational sac was 2.65 ± 1.10 mm.

Table 1
Demographic characteristics of exogenous CSP patients (n = 41)

Variables	value
Maternal age (years)	29(25, 39)
BMI (kg/m ²)	22.62 ± 5.27
Gestational age (days)	50.31 ± 8.27
Time interval since last CS (months)	38(21, 84)
Number of previous CS (n)	
1	20(48.78%)
2	18(43.90%)
3	3(7.32%)
Abnormal pain only (n)	12(29.27%)
Light painless vaginal bleeding only (n)	16(39.02%)
Light painless vaginal bleeding and abdominal pain (n)	13(31.71%)
Fetal cardiac activity	6(14.63%)
Pre-treatment serum β -HCG (mIU/mL)	26207 ± 8492
Gestation sac size (cm)	3.49 ± 0.94
Thickness of myometrium between gestation sac and the bladder (mm)	2.65 ± 1.10
β -HCG = β -human chorionic gonadotropin; CS = cesarean section	

HIFU ablation evaluation

HIFU treatment was successfully carried out for all patients (Table 2). One session of HIFU ablation therapy was performed for 29 patients (70.73%). The other 12 patients (29.27%) received 2 HIFU sessions. The average HIFU treatment time was 83 minutes. The median HIFU sonication time was 705 s. After HIFU ablation, no blood perfusion was found in the pregnancy tissue by contrast-enhanced ultrasound (Fig. 4,5). Simultaneously, we could not detect fetal cardiac activity. During HIFU ablation, all patients complained of pain in the sacra or lower abdomen. A 10-point scale was used, and the pain score ranged from 1 to 3 points. The pain was relieved within 1 week without any special medical treatment. A hot skin sensation was complained of by fourteen patients. However, we found no skin burns in those patients.

Table 2

The treatment results

Variables	value
HIFU	
Median treatment time(min)	83(60, 132)
Median sonication time(s)	705 (614,1142)
Session of HIFU ablation	
1	29(70.73%)
2	12(29.27%)
Suction curettage	
The uterus cavity depth(cm)	9.64±1.43
Surgical time(min)	35.45±10.23
Blood loss during curettage (ml)	99 (30, 240)
Treatments for bleeding during suction curettage	
No hemostasis (n)	29(70.73%)
Foley catheter balloon used (n)	12(29.27%)
Session of suction curettage	
1	38(92.68%)
2	3 (7.32%)
Follow up	
Duration of vaginal bleeding post-curettage (days)	9.72±3.92
Time of menstruation recovery(days)	29.38±3.34
Time for serum β -HCG normalization(days)	23.18±3.13
β -HCG= β -human chorionic gonadotropin	

Table 3
Comparison of characteristics of exogenous CSP patients in two groups

Variables	The bleeding group(n = 12)	The control group (n = 29)	<i>P</i>
Maternal age(years)	30(24, 41)	29(25, 38)	0.453
BMI	23.45 ± 3.45	22.87 ± 2.13	0.367
Gestational age	51.23 ± 4.25	49.83 ± 5.15	0.312
Number of previous CS (n)	2(1–3)	2(1–3)	0.419
Time Interval since last CS(m)	42(25, 89)	37(19, 82)	0.187
Pre-treatment serum β-HCG (mIU/mL)	27148 ± 6746	25864 ± 8769	0.328
Gestational sac diameter (mm)	3.80 ± 0.87	3.39 ± 0.77	0.019
Thickness of myometrium (mm)	2.37 ± 0.89	2.75 ± 0.75	0.014
β-HCG = β-human chorionic gonadotropin; CS = cesarean section			

Suction curettage assessment and follow-up

Suction curettage was performed on all patients after HIFU treatment (Table 2). No patient was converted to laparoscopy or hysterectomy. The median blood loss during suction curettage was 99 ml. We inserted the No. 14 Foley catheter balloon into the intrauterine cavity to manage massive vaginal bleeding (> 200 ml) in 12 patients. The catheter balloon was removed 24 hours later. Ultrasound checks were performed by an ultrasound specialist for every patient one week after suction curettage. The pregnancy tissues were successfully removed in 38 patients (92.68%). Three patients (7.32%) received a second session of suction curettage with blood loss of 20 ml for remnant pregnancy tissues.

All patients received follow-up through clinical visits. The median period of vaginal bleeding was 9.72 ± 3.92 days. The mean time for β-HCG normalization was 23.18 ± 3.13 days. The average time of menstruation recovery was 29.38 ± 3.34 days (Table 2). No complications occurred during the follow-up period.

Analysis of risk factors for blood loss during suction curettage

Based on the use of catheter balloons during suction curettage, 41 patients were divided into two groups. The patients who used catheter balloons were considered the bleeding group (blood loss > 200 ml). The other patients were grouped into the control group. Between the two groups, we found no significant difference in terms of age, BMI, gestational age, number of previous cesarean sections, time interval from the last cesarean section, or β-HCG level before treatment ($P > 0.05$). However, the size of gestational sac

in the bleeding group (3.80 ± 0.87 cm) was larger than that in the control group (3.39 ± 0.77 cm) ($P < 0.05$). The thickness of the interval myometrium between the bladder and gestational sac in the bleeding group (2.37 ± 0.89 mm) was less than that in the control group (2.75 ± 0.75 mm) ($P < 0.01$). In all exogenous CSP patients, there was a positive correlation between the size of the gestational sac and blood loss during suction curettage ($r = 0.401$, $P < 0.01$). Meanwhile, the thickness of the interval myometrium between the bladder and gestational sac had a negative correlation with blood loss during suction curettage ($r = -0.423$, $P < 0.01$).

Discussion

To our knowledge, this is the first report on the use of HIFU combined with suction curettage for treating exogenous CSP. The success rate in this study was 92.68% and no patient was converted to laparoscopy or hysterectomy. The median intraoperative blood loss during suction curettage was 99 ml. The average time for serum β -HCG level normalization was 23.18 ± 3.13 days, and the median time for menstruation recovery was 29.38 ± 3.34 days. Although there are some deficiencies in HCG levels and menstrual recovery compared with those after laparoscopy [11, 12], our protocol provides the possibility of one conservative treatment for exogenous CSP patients. We also reviewed the literature about the treatment of UAE combined with suction curettage for CSP. Introspective blood loss ranged from 14 ml to 114 ml, and serum β -HCG returned to normal levels within 15 to 29 days [26, 28, 29]. Our study obtained the similar results as those from the treatment of UAE combined with suction curettage and avoided the complications of UAE.

Theoretically, HIFU mainly uses high intensity ultrasound to focus on the internal target of the body in vitro. We speculate that HIFU contributes to the treatment of exogenous CSP in three ways. First, HIFU ablation can cause necrosis of the corresponding lesion cells. Through the mechanical effect of high intensity ultrasound, the high-temperature thermal effect formed an instantaneous high temperature $> 60^{\circ}\text{C}$, which led to necrosis in the pregnancy tissue. Second, the cavitation effect of HIFU could loosen the adhesion between the myometrium at the uterine scar and the gestational sac, which would be helpful for removing the pregnancy tissue [30]. Finally, HIFU has been reported to be used for the ablation of small vessels with a diameter < 2 mm [31]. The thermal energy deposited in the pregnancy tissue can destroy small blood vessels. As seen on color Doppler assessment, the blood perfusion in the pregnancy tissue disappeared. For the reasons mentioned above, HIFU could make suction curettage a smoother process for removing the pregnancy tissue and reduce the risk of heavy hemorrhage. As reported before, adverse effects, such as sciatic and lower abdominal pain, injury to the bowel and bladder, fever, and skin burns, occur during HIFU ablation [32–34]. In the ablation for exogenous CSP, the target site was located at the anterior wall of the cervix, which was located away from the bowel in the pelvic cavity. Ablation began from the innermost part, which was not near the bladder. With simultaneous ultrasound monitoring, HIFU ablation in our study caused no damage to surrounding organs. Although all patients complained of abdominal or sacral pain during the HIFU ablation, no patients needed further treatment.

Due to the characteristics of exogenous CSP, there is a risk of uterine perforation and substantial hemorrhage during suction curettage. To avoid uterine perforation during suction curettage, we first carried out vacuum suction. If an ultrasound check showed residual tissue, curettage was performed very gently. In our study, no uterine perforations occurred. A previous study reported that perforation of the uterus occurred in a CSP patient during suction curettage after HIFU ablation [35]. The author attributed this event to the 2 mm thickness of the interval myometrium between the bladder and gestation sac. In our study, the thickness of the thinnest interval myometrium was 1.5 mm, but no uterine perforation occurred. Therefore, we deduce that uterine perforation is a result of comprehensive factors. For patients with bleeding greater than 200 ml, we used a Foley balloon catheter to compress the hemorrhage, which avoided the possibility of conversion to laparotomy. However, there were still 3 patients who had to undergo a second suction curettage. We found that all three of these patients were administered Foley balloon catheters during the suction curettage. Thus, the suction curettage was interrupted, which resulted in residual pregnancy tissue.

We also found that the size of the gestational sac and the thickness of the interval myometrium between the bladder and gestational sac were correlated with blood loss during suction curettage. Our results were consistent with those of previous studies [36, 37]. Adhesion between the myometrium at the uterine scar and the gestational sac will form bleeding wounds as the pregnancy tissue is removed [38]. The wound will expand with the increase in the gestational sac, which also elevates the risk of hemorrhage. The weakness of the myometrium is accompanied by poor contractility, which makes it difficult to close the bleeding vessels [39, 40]. We also found no significant difference in terms of age, BMI, gestational age, interval time from last CS, or β -HCG level before treatment between the two groups. We noticed that a previous study considered the β -HCG level to be a risk factor for massive hemorrhage [41]. As a biochemical index representing trophoblastic cell activity, the β -HCG level of exogenous CSP may not be high due to the muscular layer defects and insufficiency of the blood supply. The inconsistency might result from the different grouping standards adopted in different studies.

In conclusion, our results indicate that HIFU combined with suction curettage is effective and safe in the treatment of exogenous CSP of < 9 weeks. We also found that the size of the gestational sac and the thickness of the interval myometrium between the bladder and gestational sac might be high-risk factors for blood loss during this treatment. Limited by the retrospective analysis and the sample number, we should validate our findings by carrying out prospective and large-scale multicenter studies in the future.

Declarations

Competing interests:

The authors declare that they have no conflicts of interest and nothing to disclose.

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Ethics approval:

Institutional Review Board approval waiving informed consent was obtained for this retrospective study (2021-0458).

Authors' contributions:

Lin Mu: Project development, data collection and manuscript writing. HF Weng: Data collection and management. XY Wang: Data analysis.

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Figures

Figure 1

Exogenous cesarean scar pregnancy located in the previous cesarean scar.

Figure 2

Sagittal view of the magnetic resonance imaging showed a gestational sac located in the previous cesarean scar.

Figure 3

Treatment mode of high intensity focused ultrasound ablation.

Figure 4

Abundant perfusion in the myometrium of the surrounding CSP scar was found by contrast enhanced ultrasound before HIFU.

Figure 5

Contrast enhanced ultrasound revealed no enhancement in the myometrium of the CSP scar after HIFU.