GYNECOLOGY

Cesarean scar pregnancy: noninvasive and effective treatment with high-intensity focused ultrasound

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OBJECTIVE: The aim of this preliminary study was to investigate whether ultrasound-guided high-intensity focused ultrasound (HIFU) can play a role in treating cesarean scar pregnancy (CSP).

STUDY DESIGN: Between November 2011 and December 2012, 16 patients with CSP were treated with ultrasound-guided HIFU ablation. Successful treatment was defined as disappearance of CSP mass, undetectable serum beta human chorionic gonadotropin, and no serious complications such as severe bleeding, uterine rupture, or hysterectomy.

RESULTS: All patients were successfully treated in the outpatient department and none required readmission. After 2-5 treatment sessions, the mean time for achieving undetectable serum beta human chorionic gonadotropin was 4.94 ± 2.32 weeks, and the mean time for CSP mass disappearance was 6.69 ± 3.36 weeks. Three patients experienced moderate abdominal pain that subsided in 1-2 days, and nine patients experienced mild vaginal bleeding (<30 mL) that resolved within 2-3 days. All 16 patients had recovered their normal menstruation function at follow-up.

CONCLUSION: These preliminary results suggest that ultrasound-guided HIFU ablation is a noninvasive, feasible, and effective method for the treatment of CSP.

Key words: cesarean scar pregnancy, high intensity focused ultrasound, noninvasive treatment

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Cesarean scar pregnancy (CSP) is a rare form of ectopic implantation that refers to the implantation of the myometrium at the site of a previous cesarean scar. The incidence of CSP ranges from 1 in 2216 to 1 in 1800 pregnancies, and CSP represents 6.1% of all ectopic pregnancies with a history of at least 1 cesarean section. The incidence is likely to rise substantially in the future, as the cesarean delivery rate increases steadily,[1,2] especially in China. Presently, almost half of all infants in China are delivered by cesarean section.[3] With the widespread use of improved ultrasound imaging and clinician awareness, CSP could be controlled with an appropriate method.[4] The first case of CSP was reported by Larsen and Solomon in 1978, and since then, many cases have been reported.[5] Because of the risk of uterine rupture and catastrophic hemorrhage that may be life-threatening and compromise future fertility, the effective termination of a CSP is crucial to achieve the optimal effect. Because of the rare incidence of CSP worldwide, there is no consensus on the treatment of CSP at present. The traditional operative treatments for CSP include hysterectomy and excision of trophoblastic tissues using either laparotomy or laparoscopy.[6-8] Conservative management approaches for CSP include systemic or local administration of methotrexate, dilatation and curettage, uterine artery embolization, and others.

However, the traditional courses of treatment are associated with serious potential side effects, hysterectomy and infertility. Laparotomy or laparoscopy can cause intestinal adhesion and damage to the uterus and endometrium. Methotrexate damages the hematopoietic system of both the liver and kidneys,[9] and uterine artery embolization can cause ovarian dysfunction, endometrial atrophy, and sepsis, requiring the use of ionizing radiation.[10-11] In recent years, a noninvasive therapy called high intensity focused ultrasound (HIFU) has been applied to many tumors including breast tumor, hepatocellular carcinoma, bone malignancy, pancreatic cancer, etc.[12-15] The wave energy of ultrasound can penetrate the intact skin and function in the tumor tissue to generate a temperature of 60°C to 90°C at the focal spot and induces cellular death and vascular obliteration in tumor tissue.[16] Because removal of a CSP is similar to that of cancerous lesions (tumor or embryonic tissues), we hypothesized that HIFU therapy can be used to remove the trophoblastic tissues in CSP. In the present study, we used ultrasound-guided HIFU therapy to treat CSP patients and examined the efficacy and safety of HIFU treatment in CSP.

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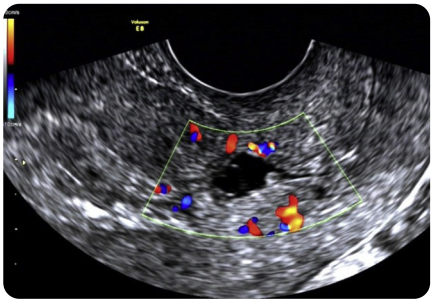
Materials and Methods

Patients

This prospective study was approved by the ethics committee of Jiangxi Maternal and Child Health Hospital. This study was carried out from September 2011 to December 2012. Sixteen patients with CSP were enrolled in this clinical study. Written informed consent was obtained from all patients. None of the patients had uncontrolled vaginal bleeding, ruptured CSP, or other gynecologic diseases. Patients with abnormal coagulation and active infection were excluded from this study. Based on considerations of the newness of the therapy and the safety of patients, patients at gestational age greater than 65 days and with a sac/mass with a largest diameter exceeding 40 mm were excluded from this study. The diagnosis of CSP was based on patients' history of cesarean delivery, clinical manifestations, positive serum beta human chorionic gonadotropin (β-hCG) levels, physical examination, and ultrasonography findings[17]: (1) an empty uterine cavity and cervical canal, without contact with the sac; (2) a gestational sac with or without cardiac activity at the anterior wall of the isthmic portion; (3) a gestational sac embedded at the lower uterine segment, within the myoetrium and the fibrous tissue of the cesarean section scar; (4) a visible myometrial defect between the bladder and the sac; and (5) functional trophoblastic/placental circulation surrounding the gestation sac. All 16 cases matched these criteria (Figure 1).

FIGURE 1
Transvaginal sonogram of a cesarean scar pregnancy



Transvaginal sonography showed a 16 × 8-mm gestational sac that was implanted into a previous cesarean scar, with surrounding vascularity.

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Equipment and HIFU treatment procedures

This study was performed with a HIFU device (Model FEP-BY-01; Yuande Bio-Medical Engineering Ltd., Beijing, China) equipped with a 3.75-MHz diagnostic ultrasound probe (Model SSA-240A, TOSHIBA, Sunrise, Japan) for guiding ultrasonic power deposition and assessing coagulation necrosis during the treatment. The probe was in the center of the HIFU transducer, which was mounted in a tank filled with degassed deionized water. The therapeutic ultrasound energy was launched with a frequency of 1 MHz by the transducer, which focused on a 14-cm focal point. The treatment procedure was carried out as previously reported.[18] One hour before the therapy, patients were given 500 mL water to drink to fill the bladder. The patients lay on the treatment table in prone position so that the skin of the lower abdomen could be easily placed in contact with the degassed water. Then treatment was started using the HIFU system, and the treatment parameters were adjusted according to the gestational sac depth and size. The gestational sac/mass was centered in the focal spot of ultrasound energy. The gestational sac or the embryo and yolk sac were divided into sections with 6-mm separation, and the dimensions of the focal region were 3 × 3 × 6 mm. Whereas the HIFU beam was scanning, each section was ablated in a manner similar to cutting slices of potato. The ablation proceeded from the innermost section to the section outside of body, until the entire mass was covered. This process was repeated section-by-section.

The instrument was mobile in 3-dimensional (3-D) with 1-mm precision. The average therapeutic acoustic power was 1200 W (1000-1300 W), the firing time was 0.15 seconds, and the interval of time between shots was 0.18 seconds. Each treatment lasted 40-60 minutes, and the average number of treatments per patient was 3.25. The average interval between treatments was 1−2 days. The number of treatment sessions was determined by the size of the sac/mass. If the diameter of the sac/mass was less than 20 mm, patients were usually treated in 2 sessions. If the diameter of the sac/mass was greater than 25 mm, patients were treated over four sessions. Accordingly, the greater the volume, the more treatment sessions were needed. During treatment, no anesthesia was used. The HIFU system was managed by 2 doctors (W.F. with 13 years of experience in HIFU ablation and Z.J.S. with 3 years of experience). The entire treatment process was carried out in an out-patient department with planned transfer to the operating suite for uterine artery embolization or hysterectomy if uncontrollable vaginal bleeding occurs.

Safety assessment

The risks of the therapy were discussed with each patient. After HIFU ablation, patients were closely observed and checked for possible immediate complications related to HIFU, such as life-threatening hemorrhage, gastrointestinal perforation, skin burn, peritonitis abdominal pain, and uterine rupture. If such severe complications did not appear, the patients were allowed to go home. Complications were recorded in each patient by 3 observers together (Z.X., H.J.S., and Z.S.H.).

Posttreatment observation and follow-up

No patients were lost to follow-up. Transvaginal color Doppler scanning was used to verify the evidence of residual pregnancy tissue and to assess changes in tissue size over time. Serum β-hCG levels were determined before the intervention, on days 1, 3, and 7 after the complete ultrasound treatment, and every week until recovery to normality. At the same time, the size of the retained gestational products was measured by transvaginal ultrasound. Transvaginal color Doppler US was performed jointly by 2 radiologists (X.J.H. and W.Y.Q., with 7 and 15 years experience with color