OBSTETRICS

A new minimally invasive treatment for cesarean scar pregnancy and cervical pregnancy

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BACKGROUND: Cesarean scar pregnancy and cervical pregnancy are unrelated forms of pathological pregnancies carrying significant diagnostic and treatment challenges, with a wide range of treatment effectiveness and complication rates ranging from 10% to 62%. At times, life-saving hysterectomy and uterine artery embolization are required to treat complications. Based on our previous success with using a single-balloon catheter for the treatment of cesarean scar pregnancy after local injection of methotrexate, we evaluated the use of a double-balloon catheter to terminate the pregnancy while preventing bleeding without any additive treatment. This was a retrospective study.

OBJECTIVES: The objective of the study was to describe the placement of a cervical ripening double-balloon catheter as a novel, minimally invasive treatment in patients with cesarean scar and cervical pregnancies to terminate the pregnancy and at the same time prevent bleeding by compressing the blood supply of the gestational sac.

STUDY DESIGN: Patients with diagnosed, live cervical pregnancy and cesarean scar pregnancy between 6 and 8 weeks' gestation were considered for the office-based treatment. Paracervical block with 1% lidocaine was administered in 3 patients for pain control. Insertion of the catheter and inflation of the upper balloon were done under transabdominal ultrasound guidance. The lower (pressure) balloon was inflated opposite the gestational sac under transvaginal ultrasound guidance. After an hour, the area of the sac was scanned. When fetal cardiac activity was absent and no bleeding was noted, patients were discharged. After 2-3 days, a follow-up appointment was scheduled for possible catheter removal. Serial ultrasound (US) and serum human chorionic gonadotropin were followed weekly or as needed.

RESULTS: Three live cervical pregnancies and 7 live cesarean scar pregnancies were successfully treated. Median gestational age at treatment was 6 6/7 weeks (range 6 1/7 through 7 4/7 weeks). Patients' acceptance for the double-balloon treatment was high in spite of the initial low abdominal pressure felt at the inflation of the balloons. All but 1 patient noted vaginal spotting at the follow-up appointment. Only 1 patient experienced bleeding of dark blood. The balloons were in place for a median of 3 days (range, 1—5 days). Median time from treatment to the total drop of human chorionic gonadotropin was 49 days (range, 28—97 days).

CONCLUSION: The double balloon is a successful, minimally invasive and well-tolerated single treatment for cervical pregnancy and cesarean scar pregnancy. This simple treatment method has 4 main advantages: it effectively stops embryonic cardiac activity, prevents bleeding complications, does not require any additional invasive therapies, and is familiar to obstetricians-gynecologists who use the same cervical ripening catheters for labor induction. Its wider application, however, has to be validated on a larger patient population.

Key words: cervical pregnancy, cesarean scar pregnancy, cesarean scar pregnancy treatment, double cervical ripening balloon, early pregnancy, ultrasound

Cesarean scar pregnancy, an iatrogenic pathological entity, is a direct consequence of a cesarean delivery when the subsequent pregnancy implants on the scar area or in the dehiscence (niche) left behind by the hysterotomy.

Larsen and Solomon[1] reported the first case of a cesarean scar pregnancy in 1978 and successfully treated the patient with laparotomy, hysterotomic resection, and uterine scar dehiscence repair. Since that time, the incidence is rising, paralleling the increasing rate of cesarean delivery. The real incidence of cesarean scar pregnancy is unknown; however, some workers in the field set it at 1 in 1800 to 1 in 2500 cases of previous cesarean deliveries.[2]

In an in-depth review of 751 cases of cesarean scar pregnancies, the literature search yielded a total of 204 publications between 1972 and 2011.[3] In that review, 176 articles reported on first-trimester cesarean scar pregnancies, and another 49 articles described the second-trimester placenta accreta, listing the sometimes devastating complications of these 2 pathologies sharing the same histology.[4] There were 31 described medical, surgical, or radiological treatments, including single or combination therapies.[3]

Among the 751 treated cesarean scar pregnancies,[3] 331 cases (44.1%) reported complications. A large number of these complications were the result of misdiagnosis, others caused by the treatment method applied. The most severe and notorious complication was bleeding at or after the applied treatment. Even the treatment method with the least and the most benign complications (eg, intragestational injection of methotrexate or KCl) encountered 1 complication in 10 treatments.[3]

We previously described the adjuvant treatment of a single Foley balloon insertion and inflation immediately following local, intragestational injection of methotrexate treatment of cesarean scar pregnancy, regardless of presence or absence of bleeding[5]. However, in 3 patients the single balloon was expelled after 1, 2, and 3 days, respectively.[5]

Our hypothesis was, that by using a double-balloon catheter, inflating the

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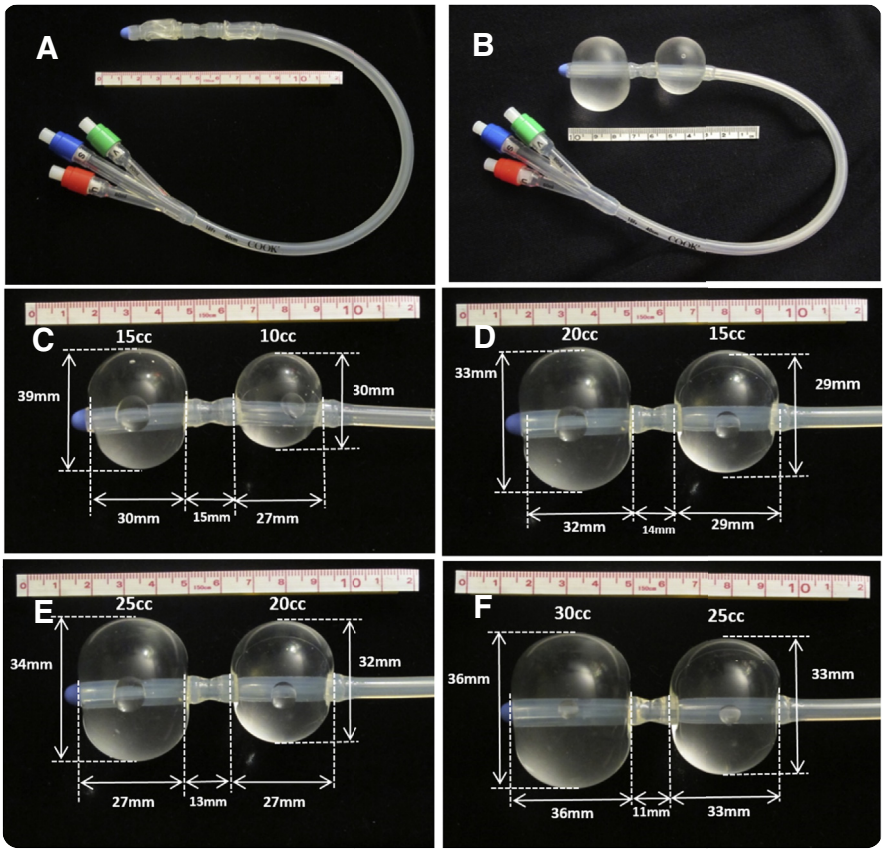
FIGURE 1
Images of the double-balloon catheter



Images of the double-balloon catheter with measurements of balloon sizes and interballoon distances as a function of volume of saline in them. **A,** The cervical ripening double balloon. The upper balloon is that on the left side of the pictures, close to the tip of the catheter. The 3 ports of the catheter are color coded. **B—F,** In vitro measurements of the upper and lower balloons and their interballoon distance as a function of different combinations of volumes instilled. Balloon volumes, their sizes, and interballoon distances are marked on each picture.

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upper one in the uterine cavity to serve as an anchor would prevent expulsion of the lower pressure balloon if positioned and inflated opposite the gestational sac to provide the required tamponade.

Our secondary hypothesis was that the pressure the lower balloon exerted upon the gestational sac and its blood supply would be sufficient to stop embryonic cardiac activity while at the same time prevent bleeding. This therapy would be given without any additional intervention, such as a local intragestational injection of methotrexate or KCl or suction aspiration. We also hypothesized that this treatment method will be successful in some cervical pregnancies.

Should the double-balloon placement result in successfully terminating the pregnancy without causing, but rather preventing, hemorrhage from the cervical pregnancy and cesarean scar pregnancy, this new, minimally invasive treatment modality would present a realistic choice managing these 2 dangerous pathologies.

Materials and Methods

This is a retrospective case series of patients diagnosed with cesarean scar pregnancy or cervical pregnancy, between 6 and 8 weeks' gestations, referred to New York University Langone Medical Center with diagnosed or suspected cesarean scar pregnancy and cervical pregnancy. This study was institutional review board approved (study number s15-01030 by the New York University Review Board).

Preliminary measurement of the inflated double-balloon catheter

To exert the right amount of pressure to stop embryonic cardiac activity to prevent bleeding and balloon expulsion, in vitro experiments were performed prior to the actual use of the double-balloon catheter (Cook Medical; www.Cookmedical.com; number J-CRBS 18400 with stylet). By inflating the upper and lower balloon with increasing volumes of saline, the medical balloon sizes and the interballoon distance was measured. Figure 1 depicts the catheter and technique of selected experiments.

These measurements show that the upper, intrauterine balloon should be inflated with 30 mL or less fluid. The lower-treatment balloon should be inflated in the cervical canal or close to the internal os with no more than 20 mL fluid. Measurements at the actual use of the catheter were also performed to validate the previously mentioned in vitro measurements.

Diagnostic criteria for cesarean scar pregnancy and cervical pregnancy

In the presence of a positive pregnancy test and in patients with history of previous cesarean delivery, the criteria for a cesarean scar pregnancy were, as published earlier,[6] the gestational sac and/or placenta were imaged embedded in the hysterotomy scar with a fetal pole and/or yolk sac containing a live embryo; empty uterine cavity and cervical canal; a thin (<3 mm) myometrial layer between the gestational sac/placenta and bladder and the presence of a rich vascular pattern in the area of the cesarean delivery scar and the placenta.

In patients without a previous cesarean delivery, a gestational sac and placenta seen within the anterior or posterior lip of the cervix, with a live embryo and/or yolk sac, and the presence of a rich vascular pattern around the sac were diagnostic for a cervical pregnancy.