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Foley Balloon Catheter Application to Prevent Bleeding During Treatment for Cesarean Scar Pregnancy

Sezaryen Skar Gebeliği Tedavisinde Kanamayı Önlemek İçin Foley Balon Kateter Uygulaması

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ABSTRACT Objective: To demonstrate the efficacy of application of Foley balloon catheter (FBC) prophylactically to prevent, or as an adjuvant therapy to control, bleeding in women undergoing treatment of suction currettage (S&C) for Cesarean scar pregnancy (CSP). **Material and Methods:** This is a retrospective study was done by using prospectively collected data of patients diagnosed with CSP. Between 1 January 2007 and 31 December 2015, 24 Turkish women with CSP underwent by S&C in Necmettin Erbakan University, Meram Medical Faculty. Subsequently, under ultrasound guidance, the FBC was inflated with 20 mL sterile saline to secure its position sonographically documented inside the uterine cavity. Successful outcome was defined as normalization of serum beta-human Chorionic Gonadotropin (β-hCG) levels, disappearance of CSP mass, and avoidance of major complications (uterine rupture, hemorrhage, and conversion to laparotomy). **Results:** Twenty-one patients were successfully treated and 3 subjects failed treatment. The mean estimated blood loss of all 24 patients was 103.12±52.18ml (range, 30-250ml). The mean time for the β-hCG values to return to non-pregnant levels was 5.58±1.10 weeks (range, 4-8 weeks). Finally, the treatment rate of S&C with FBC tamponade was 87.5% (21 of 24 women). **Conclusion:** We explored the feasibility and effectiveness of treating early 6-9 week CSP by invasive treatment (S&C) using a previously known FBC. We evaluated its ability to treatment of CSP by S&C and at the same time to prevent possible local bleeding by FBC. This application was found to be simple, safe, and effective with high patient acceptance.

Keywords: Cesarean section; pregnancy, ectopic

ÖZET Amaç: Sezaryen skar gebeliği (SSG) tedavisi sırasında vakum küretaj (V&K) yapılan kadınlarda kanamanın tedavisi ya da önlenmesi için Foley balon kateter (FBK) yerleştirmenin etkinliğini göstermek. **Gereç ve Yöntemler:** Bu retrospektif çalışma SSG'li hastaların prospektif olarak toplanan verileri kullanılarak yapıldı. Çalışma 1 Ocak 2007 ile 31 Aralık 2015 tarihleri arasında Necmettin Erbakan Üniversitesi Meram Tıp Fakültesinde SSG tanısı alan ve V&K ile tedavi edilen 24 Türk kadın değerlendirildi. Bu hastalara ultrason kılavuzluğu altında 20 ml steril salin ile şişirilen FBK yerleştirildi ve yeri ultrason ile dokümente edildi. Serum beta-human koryonik gonadotropin (β-hCG) düzeylerinin normale dönmesi, SSG kütlesinin kaybolması ve majör komplikasyonlarla karşılaşılmaması (uterin rüptür, kanama ve laparotomi gerekliliği) başarılı sonuç olarak değerlendirildi. **Bulgular:** Hastalardan 21'i başarılı bir şekilde tedavi edilirken 3 hastanın tedavisi başarısız oldu. Yirmi dört hastanın tahmini ortalama kaybı 103.12±52.18ml (30-250ml arasında) idi. β-hCG düzeyinin gebe olmayan seviyelere dönmesi için gereken ortalama süre 5.58±1.10 haftaydı (4-8 hafta arasında). Son olarak, FBK sonrası V&K ile tedavi olma oranı %87.5 idi (24 hastanın 21'i). **Sonuç:** Biz bu çalışmada 6-9 hafta arası SSG hastalarında invaziv tedavi (V&K) sonrası FBK uygulamasının uygulanabilirliği ve etkinliğini araştırdık. SSG'nin V&K ile tedavisi sırasında FBK ile lokal kanamanın önlenmesindeki başarısını da değerlendirdik. Bu uygulamayı kabul eden hastalarda basit, güvenli ve uygulanabilir bir yöntem olduğu görüldü.

Anahtar Kelimeler: Sezaryen; gebelik, ektopik

A cesarean scar pregnancy (CSP) is defined as the localization of a fertilized ovum surrounded by uterine muscular fiber and scar tissue.[1] The incidence of CSP is unknown; however, some workers in the field set it at 1 in 1800-2500 cases of previous cesarean deliveries.[2] Larsen

and Solomon reported the first case of a CSP in 1978 and successfully treated the patient with laparotomy, hysterotomic resection, and uterine scar dehiscence repair.[3]

There are a number of treatment options for CSP, including sporadic and individual approaches which depend on the specialty, and has led to a lack of universal treatment guidelines.[4] The options for management of CSPs; expectant management, medical treatment, surgical treatment, uterine arterial embolisation and a combination of these options. Successful attempts of those therapies individually or in combination have also been reported.[4,5]

Among the 751 treated CSPs, 331 cases (44.1%) reported complications. The most severe and notorious complication was bleeding at or after the applied treatment.[4] Recently, however, balloon technology has been suggested and used to tamponade and control hemorrhage. This involves placement into the uterine cavity or cervical canal of a rubber or silicone balloon which is then inflated with normal saline, exerting pressure upon the bleeding vessel to slow or stop the bleeding until the vessels are occluded and full hemostasis takes place.[4-6] Balloon catheters have been used increasingly in the management of obstetric hemorrhage, post-abortion hemorrhage, CSP, and cervical pregnancy.[7-14]

CSP is two types. CSP I refers to the implantation of the gestational sac on a previous cesarean scar with progression in the cervico-isthmus and the uterine cavity. CSP II refers to a deep implantation of the amniotic sac in a cesarean scar defect with progression towards the myometrium and the uterine serosal layer. In CSP II cases, the thickness of the uterine myometrium between the gestational sac and the bladder wall is usually less than 4 mm.[5]

Many women came to our hospital for further diagnosis and treatment if they were suspected to have CSP, so we were able to make a study of suction curettage (S&C) followed by Foley balloon catheter (FBC) tamponade in the treatment of CSP.

In this study we report our experience on the adjuvant use of an inflatable FBC to prevent blood loss in women undergoing treatment for CSP.

MATERIAL AND METHODS

This is a retrospective study was done by using prospectively collected data of patients diagnosed with CSP I, between 6 and 9 weeks' gestations, referred to Necmettin Erbakan University, Meram Medical Faculty with diagnosed or suspected CSP. The study was approved by the Research Ethics Committee of the Necmettin Erbakan University, Meram Medical Faculty and was conducted in accordance with the Declaration of Helsinki.

Between 1 January 2007 and 31 December 2015, 24 Turkish women with CSP I underwent by S&C in our hospital, because preservation of fertility was desired. Women were enrolled in the study if they had unruptured CSP I, no uncontrolled vaginal bleeding and no other gynecological disease.

PRELIMINARY MEASUREMENT OF THE INFLATED FBC

To exert the right amount of pressure to prevent bleeding and balloon expulsion, in vitro experiments were performed prior to the actual use of the FBC. By inflating the FBC with increasing volumes of saline, the medical balloon size was measured. Figure 1 depicts the catheter and technique of selected experiments. The FBC should be inflated in the 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 CSP I

In the presence of a positive pregnancy test and in patients with history of previous cesarean delivery, the criteria for a CSP I were, as published earlier, 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 (>2 mm, <4 mm) myometrial layer between the gestational sac/placenta and bladder (Figure 2).[15]

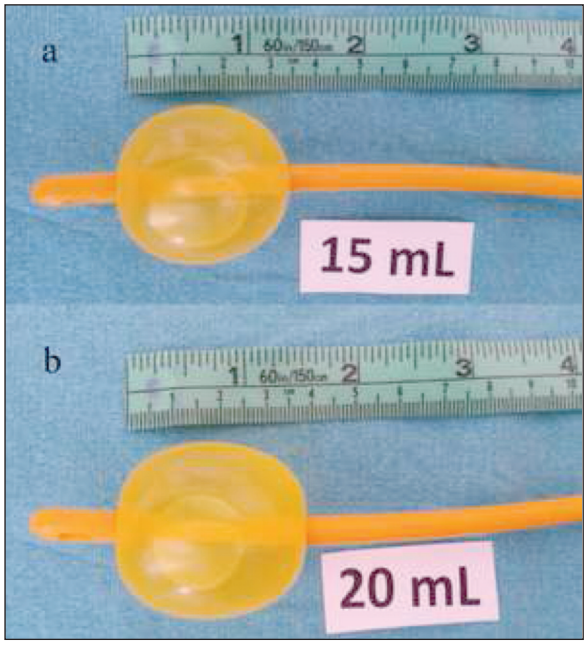

FIGURE 1: FBC inflated with different volumes of saline: **a)** 15mL saline; balloon diameter is about 28 mm; **b)** 20 mL saline; balloon diameter is about 34 mm.
FBC: Folley balloon catheter.

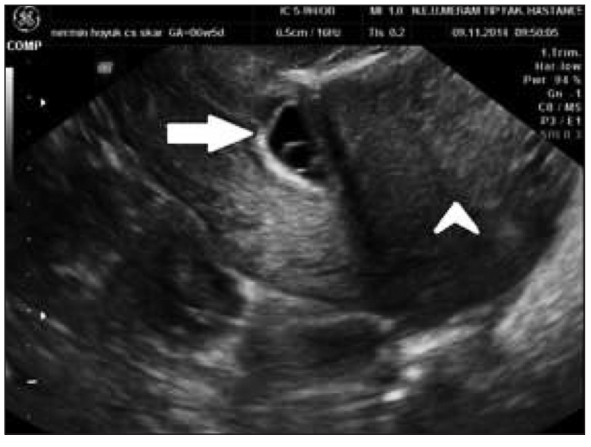

FIGURE 2: CSP, transvaginal ultrasound image of 6 weeks of gestation. A gestational sac (arrow) surrounded by myometrium is seen in the image. Empty endometrial cavity is noted (arrow head).
SP: Caesarean scar pregnancy.

THE INCLUSION CRITERIA

All patients who fulfilled the diagnostic criteria and consented to the FBC treatment after evidence based counseling were included in this study. The diagnosis, therapy, and follow-up of all patients were performed at the Necmettin Erbakan University Meram Medical Faculty Department of Obstetrics and Gynecology.

Inclusion criteria: The diagnosis of CSP I was mainly based on the results of transvaginal ultrasound, including no pregnancy intrauterine, no cervical canal pregnancy, the pregnancy sac was observed in the anterior uterine isthmus, and the non-depressed area was formed in the myometrium between gestational sac and bladder wall. <9 weeks gestation, myometrial thickness between the bladder and gestational sac >2 mm, hemodynamically stable without the need for urgent laparatomy and informed consent signed, including possibilities for urgent laparotomy and hysterectomy.

All patients gave informed consent to undergo the procedure and were aware of the possible complications of treatment.

FIRST-LINE TREATMENT; S&C

S&C was performed as a first-line treatment in patients. The patients were placed in lithotomy position. The vulva and vagina were prepared in a sterile fashion with betadine.[24,25] A speculum was placed, and the exposed cervix was cleaned with betadine. If necessary, patients were applied by gently dilating the cervix to the size of Hegar number 6 to facilitate catheter placement. The uterus is imaged by a transabdominal ultrasound probe. During S&C, excess pressure was avoided against the uterine walls (especially the anterior wall). The process was terminated after obtaining a sample of tissue with disappearance of the CSP I sac on sonography.

DESCRIPTION OF THE FBC APPLICATION

The sterile gel-lubricated, FBC (16 French) was advanced into the uterine cavity under continuous, real time trans-abdominal ultrasound guidance using forceps. Under ultrasound guidance, the FBC was inflated with 20 mL sterile saline to secure its position sonographically documented inside the uterine cavity (Figure 3). The speculum was removed and replaced by the transvaginal ultrasound probe. Under real time and continuous ultrasound observation, the FBC was pulled adjacent to the gestational sac. If needed, its position was readjusted inflating or deflating the anchoring FBC.

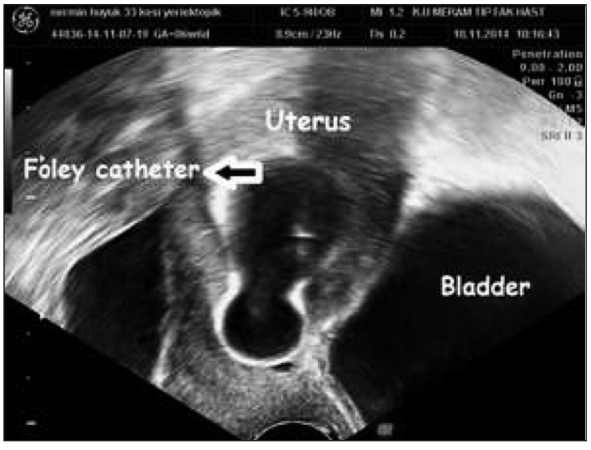

FIGURE 3: FBC used in CSP. Image of a balloon with a diameter of 34 mm, inflated with 20 ml saline in the sagittal transvaginal ultrasound imaging. Balloon presses the surrounding antero-posterior tissues with its ovoid shape.
FBC: Folley balloon catheter; SP: Caesarean scar pregnancy.

The correct position of the balloon was sonographically documented. The FBC was fixed to the leg with traction and uterine tamponade was continued for 48 h.

The area of the gestational sac and the FBC were observed by ultrasound, and if needed, saline was added to the balloon to prevent or stop any possible bleeding. The patient was kept in the service observation for 2 days. Patients were prescribed a 7 day course of antibiotic treatment to be started on the day of treatment. After 2 days, the FBC was deflated under transvaginal ultrasound control. If no visible bleeding was seen, the patient was observed for 1 hour. If no local bleeding was noted, the FBC was removed after 30 minutes later and the patient discharged home.

FOLLOW-UP EVALUATION OUTCOME

Gestational age was calculated based on the last menstrual period and set according to the ultrasound dating. Successful outcome was defined as normalization of serum beta-human Chorionic Gonadotropin (β-hCG) levels, disappearance of CSP mass, and avoidance of major complications (uterine rupture, hemorrhage, and conversion to laparotomy). Blood loss was estimated on the basis of the increase in weight of bloody sponges on a mL/g basis in combination with the method of Dahmani et al.[16]

Weekly serum human chorionic gonadotropin were obtained until nonpregnant values were noted. Birth control for 6 months was strongly suggested.

STATISTICAL ANALYSIS

Statistical analyses were performed with SPSS Statistics 16. Descriptive statistics (means, standard deviation and range) were calculated for: age (years), BMI (kg/m²), gravidity, parity, gestational age at the time of diagnosis (week), pretreatment β-hCG level (mlU/ml), pretreatment Hb value (g/dl), after treatment Hb value (g/dl), time until β-hCG negativity (<5 mIU/ml) (week), time from prior cesarean section delivery (month), number of prior cesarean sections, amount of bleeding (ml), diameter of gestational sac (mm).

RESULTS

During the study period, 32 patients were diagnosed with CSP I at the time of the treatment. After counseling, 8 patients with CSP I preferred others treatment options. Thus, these 8 patients were excluded from study. Twenty-four patients were treated by S&C and FBC application and therefore were eligible for analysis.

The demographic characteristics and clinical findings of the patients are shown in Table 1. Mean gestational age was 7.08 ± 1.21 weeks. The gestational age was calculated based on crown rump length (CRL) measurements; the last menstrual period was used in patients without an embryo. The mean estimated blood loss of all 24 patients was 103.12 ± 52.18 (range, 30-250) ml. Pretreatment mean serum β-hCG at the insertion of the balloons was 8386.7 ± 6088.1 mIU/mL (range, 1180–25611 mIU/mL). The mean time for the β-hCG values to return to non-pregnant levels was 5.58 ± 1.10 weeks (range, 4-8 weeks).

All patients tolerated the placement of the balloons adequately. One patient presented to the emergency department for lower abdominal cramps and severe bleeding. The causes of the pain were the rupture of CSP and severe intra-abdominale hemorrhage. For this patient an emergent laparotomy/hysterotomy was required. We performed a wedge

TABLE 1: Patient characteristics and clinical findings.

Patient characteristics (n:24)	Mean ± SD	Range
Age (years)	30.66 ± 5.29	22–42
BMI (kg/m²)	29.41 ± 3.50	24–34
Gravidity	4.25 ± 1.03	2-6
Parity	2.50 ± 0.78	1-4
Gestational age at the time ofdiagnosis (week of LMP)	7.08 ± 1.21	5-9
Pretreatment hCG level (mIU/ml)	8386.7 ± 6088.1	1180–25611
Pretreatment Hb value (g/dl)	12.13 ± 0.99	10.20–14.00
After treatment Hb value (g/dl)	11.15 ± 1.08	9.60–13.20
Time until hCG negativity (<5 mIU/ml) (week)	5.58 ± 1.10	4-8
Time from prior cesarean section delivery (month)	18.87 ± 10.18	6-48
Number of prior cesarean sections	2.04 ± 0.95	1-4
Amount of bleeding (ml)	103.12 ± 52.18	30-250
Myometrial thickness between gestational sac and urinary bladder (mm)	3.25 ± 0.52	1-4
Diameter of gestational sac (mm)	9.39 ± 1.44	7.60-12.50

BMI; Body mass index, LMP; Last menstrual period, Hb: Hemoglobin, hCG: human Chorionic Gonadotropin, Blood loss was estimated on the basis of the increase in weight of bloody sponges on a mL/g basis in combination with the method of Dahmani et al.[16]

excision of the CSP in the patient. Two patients with plateauing β-hCG levels after S&C and FBC application without bleeding received a systemic single intramuscular dose of methotrexate (MTX) (50 mg/m²).

All patients were compliant and returned for their blood tests and ultrasound examinations as scheduled. The application of S&C and FBC was successful in 21 patients. Finally, the treatment rate of S&C with FBC tamponade was 21 of 24 (87.5%).

Pathology confirmed chorionic villous and trophoblastic tissue in all patients with CSP I.

DISCUSSION

CSP is a rare form of ectopic pregnancy which carries a high risk of uncontrollable bleeding requiring hysterectomy. The reason for this is its basic, underlying histology.[17] It is now clear that CSP is one of the main precursors of morbidly adherent placenta.[17-19] It is important to be able to diagnose the condition as early as possible in order to manage treatment. The treatment objectives with CSP should be to perform prior to rupture, to remove the gestational sac and to retain the patient's future fertility. The majority of the obstetrics and gynecology community almost suggest termination of CSPs. Only a few of articles reported the possibility of continuing a pregnancy implanted in the scar of a previous cesarean delivery.[18,20,21]

It is true that a certain number of CSP, just as intrauterine pregnancies, may terminate on their own. However, waiting for this to happen is not a practical or acceptable option.[4] If termination of the pregnancy is chosen, there is an excess amount of actual options published in the literature. Most treatments are slow to act, invasive, or carry significant complications. One of the most important complications are bleeding.[4] Considerable blood loss takes place in almost 50% patients during or after S&C. So we thought the use of FBC tamponade was necessary in treatment of CSP I. After S&C there was a natural pit in the anterior of the isthmic part of the uterus, and the FBC with 20 ml 0.9% sodium chloride could press the surface of the CSP to decrease the bloodloss.

Treating obstetrical hemorrhage by means of tamponing is well established. Packing the uterus with gauze was one of the old methods.[22,23] Recently different types of inflatable balloons of various shapes were used to slow or stop bleeding by inflating them with saline, which exerted pressure on the blood vessels until full hemostasis is achieved. Examples are the Rush balloon, the Bakri

balloon, and the double cervical ripening balloon.[10,24-28] Placing balloon catheters in cases of postabortal hemorrhage was also published.[11] The adjunct use of balloon catheters were also part of the treatment of cervical pregnancies.[14,29]

Balloon tamponade is used in treating obstetrical hemorrhage by the obstetrical community.[30] We planned to see the results of using FBC tamponade in CSP. All 24 patients included in this study were stable and underwent interventions under elective circumstances. The aim of the CSP treatment is the removal of the gestational sac before a rupture develops and to preserve the future fertility of the patient.[31]

Uterine artery embolization is another method used to decrease the risk of bleeding following the conservative surgery of a MTX injection. In a randomized study including 72 CSP cases in which uterine artery embolization prior to S&C or systemic MTX treatment was performed, a significantly lower blood loss (37 ml vs. 416 ml) and shorter hospital stay (12 days vs. 42 days) were observed in the uterine artery embolization section of the study.[32] However, this approach necessitated an interventional radiology infrastructure to be present. The method we used in this present study on the other hand requires no surgical infrastructure other than routine applications.

A relatively new approach in these cases is the removal of CSP under direct vision using hysteroscopy.[33] In a series of five cases, a FBC application was necessary in one case and MTX treatment was required in one other, due to a plateauing β-hCG level.

S&C provides a rapid treatment option. However, a larger or smaller amount of bleeding may occur from the curettage field and it is impossible to predict which patient will develop serious bleeding. The placement of a FBC as a standard treatment may prevent bleeding before it occurs in patients who had a possibility for bleeding but could not be predicted to bleed. In addition, a 93% success rate was achieved in a study including 45 patients with CSP who received MTX treatment followed by S&C, and the introduction of a FBC.[34] In that study, uterine artery embolization was performed in three patients with treatment failure who had developed vaginal bleeding.

The length of time we left the catheters in place was entirely empirical. Fylstra and Coffey used a single FBC inflated in the cervix to prevent bleeding after local injection of cervical pregnancies, leaving the balloon in place for approximately 24 hours in anticipation of adequate hemostasis.[35] Dildy et al. left their newly tested double balloons to treat postpartum hemorrhage in place for a mean of 20.3 hours.[30] Bakri balloons were kept in place for 22±3 hours in 66 of 71 successful cases to stop postpartum hemorrhage and 3±1 hours in 5 of the unsuccessful cases.[36]

It is difficult to draw meaningful information from the experience of the previously mentioned articles as to the optimal time to remove balloons in place. The main question is, what is the necessary time from the occlusion of potentially bleeding vessels to prevent bleeding after the catheter is removed? Further clinical trials have to be directed to find not only the adequate and minimum time to keep catheters in place but also to find the proper and lowest effective fluid volume in the balloons.

Profile of patients who would be best candidates for the treatment are patients with live CSP between 6 and 8 weeks and a strong desire for future fertility or to preserve the uterus. The patients must be aware that in case of failure, subsequent treatment may call for other treatments such as uterine artery embolization and/or hysterectomy.

The weakness of the study is the low number of patients treated. Therefore, possible rare complications may not be investigated in this study. However, no complications were experienced following the FBC treatment. The length of time for the catheter to be kept in place as well as the optimal inflation volumes has to be studied further.

CONCLUSION

We explored the feasibility and effectiveness of treating early 6-9 week CSP I by invasive treatment (S&C) using a previously known FBC. We evaluated its ability to treatment of CSP I by S&C and at the same time to prevent possible local bleeding by

FBC. Such catheters are frequently used for clinical practice, and there is a wide familiarity by obstetricians. This application was found to be simple, safe, and effective with high patient acceptance. Further evaluation of this technique by treating a larger number of patients.

Conflict of Interest

Authors declared no conflict of interest or financial support.

Authorship Contributions

While the study is being prepared, all authors have contributed equally.

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