Research Article

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Modified double balloon Foley catheter treatment for cesarean scar pregnancy at Hung Vuong Hospital in Vietnam

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Abstract

Background: Cesarean scar 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.

Study design: A retrospective study. Patients with diagnosed cesarean scar pregnancy between 6 and 8 weeks' gestation were considered for the treatment. 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. After 1 - 4 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: 50 live cesarean scar pregnancies were successfully treated from 2020 - 2022. Median gestational age at treatment was 6.0 ± 0.71 weeks (range, 6 - 8 weeks). Patients tolerated the double balloon treatment well, despiste reporting initial mild abdominal pressure during balloon. The balloons were in place for a median of 24 hours. Median time from treatment to the total drop of human chorionic gonadotropin was 6.9 ± 3.6 weeks . Successful with balloon inflated 84% (42/50 cases).

Conclusion: The modifier double balloon Foley catheter is a successful, minimally invasive and well-tolerated single treatment for cesarean scar pregnancy. This treatment method has 5 main advantages: it effectively stops embryonic cardiac activity, prevents bleeding complications, does not require any additional invasive therapies, familiar to obstetricians-gynecologists who use the same cervical ripening catheters for labor induction and very cheap. Its wider application, however, has to be validated on a larger patient population.

Key words: Cesarean scar pregnancy, cesarean scar pregnancy treatment, modifier double balloon Foley catheter, ultrasound

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1. BACKGROUND

The frequency of cesarean section (CS) is increasing worldwide. In 2018, Vietnam had CS rates 27.2%, with Hung Vuong hospital in front with a rate of 48.2%. In recent years there has been augmented focus on the complications seen in subsequent pregnancies, of which the more serious include uterine rupture, placenta

accreta/percreta, postpartum hysterectomy, and ectopic pregnancy in a cesarean scar.

Cesarean scar pregnancy (CSP) was first described in 1978 [1], and until 2001 only 19 cases were reported [2]. Since then the frequency of reported cases has dramatically increased [3]. During the last two decades ultrasonography and diagnostics have improved [4] and the techniques for uterine surgery have changed. Today the uterus is often closed in one layer, compared with the previous two-layer technique. All factors may play a role in the increasing prevalence of CSP [5].

Cesarean scar pregnancy is characterized by an empty uterus and cervical canal, a gestational sac located in the anterior uterine wall with diminished myometrium between the sac and the bladder, and a discontinuity in the anterior wall of the uterus adjacent to the gestational sac. Cesarean scar pregnancy can cause severe maternal morbidity and mortality. [6]

Hung Vuong Hospital is one of the two major obstetric and gynecological hospitals in Ho Chi Minh City, every year there are about 1,000 cases of ectopic pregnancy, in which cesarean scar pregnancy is increasing: in 2011 there were 26 cases, in 2012 there were 56 cases, in 2017 there were 98 cases, in 2018 there were 102 cases. At Hung Vuong Hospital, the cesarean scar pregnancy for more than 12 weeks is managed by abdominal surgery to remove the uterine muscle to be hysterectomy in difficult cases. Pregnant women less than or equal to 12 weeks are injected with Methotrexate topically or may be accompanied by systemic methotrexate injection.

We aimed to evaluate efficient and safe treatment of modifier double - balloon Foley catheter for women with CSP.

2. METHODOLOGY

A retrospective case series of patients diagnosed with cesarean scar pregnancy, between 6 and 8 weeks gestations, referred to Hung Vuong Hospital, Vietnam. Center with diagnosed or suspected cesarean scar pregnancy.

Diagnostic criteria for cesarean scar 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, 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 ($\geq$ 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.

3. THE INCLUSION CRITERIA

All patients who fulfilled the diagnostic criteria and consented to treatment using a modifier double- ballon Foley catheter after an evidence based counseling were included in this study. The diagnosis, therapy and follow-up of all patients were performed at Hung Vuong Hospital, Vietnam.

Inclusion criteria were gestational age between 6 and 8 weeks; demonstrable fetal cardiac activity at the time of the ultrasound.

Our patients with live cesarean scar pregnancy 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 the use of systemic methotrexate (50mg injection muscle), laparotomy uterine and/or hysterectomy. The patient must agree to followup frequent blood tests and ultrasound examinations.

Describe about modifier double-balloon Foley catheter

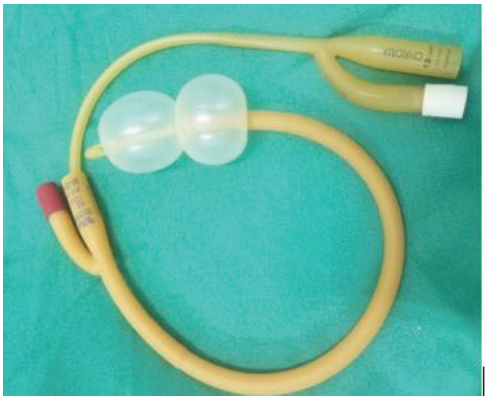

Figure 1. Two Foley catheter 12 Fr and 18Fr interlocked

To exert the right amount of pressure to stop embryonic cardiac activity to prevent bleeding and balloon expulsion. By inflating the upper and lower balloon with increasing volumes of saline, the medical balloon sizes and the interballoon distance was measured. Intrauterine balloon should be inflated with 10-20 mL or less fluid. The lower-treatment balloon should be inflated in the cervical canal with no more than 15-25 mL fluid.

Nonsteroidal anti-inflammatory pain medication was administered orally 1-2 hours before the procedure. Antibiotics were prescribed a 5 days course to be started on the day of treatment.

The patient was placed in a gynecological position. The vulva and vagina were prepped with diluted iodine solution. A speculum was inserted, and the exposed cervix was cleaned with diluted iodine solution. The uterus is imaged by a transabdominal ultrasound. The sterile gel-lubricated, modifier double-balloon Foley catheter was advanced into the uterine cavity. Under ultrasound guidance, the upper anchor balloon (Foley 12 Fr size) was inflated with 10-20 mL sterile saline to secure its position sonographically documented inside the uterine cavity. The lower-treatment balloon (Foley 18 Fr size) was positioned adjacent to the gestational sac. If needed, its position was readjusted inflating or deflating the anchoring upper balloon. The lower-treatment balloon was inflated 15-25 mL by adding saline until the gestational sac was flattened. The correct position of two balloon was sonographically documented. The area of the gestational sac and the lower balloon were observed by ultrasound, and if needed, saline was added to the balloons to prevent or stop any possible bleeding. Sequential and relevant ultrasound images obtained during the treatment of a patient with cesarean scar pregnancy are presented.

The patient was observed for 1 hour after which the uterus was rescanned transabdominally. If no fetal heart beats were seen and there was no sonographic or clinical evidence of bleeding, the patient was followed up at hospital 5 days.

After 2 - 4 days inserted later for evaluation and removal of the catheter. The lower balloon was first deflated under transvaginal ultrasound control. If no fetal heart activity and no visible bleeding was seen, the patient was observed for 30 minutes and then rescanned. If no local bleeding was noted, the upper balloon was deflated. If within an additional 30 minutes no change was detected, the catheter was removed and the patient discharged home with detailed instructions for scheduled repeat blood tests and ultrasound examinations after 3 and 7 days.

4. RESULTS

Table 1. Maternal demographics (n= 50)

Factors	Number/Average
Maternal age (years)	35 ± 5.7
Previous cesarean	
1	27 (54)
2	21 (42)
3	2 (4)
Gestational age at presentation(week's)	
$6^{0/7}$	12 (24)
$6^{1/7} – 7^{0/7}$	30 (60)
$7^{1/7} - 8^{0/7}$	8 (16)
Myometrial thickness (mm)	
1	1 (2)
1.1 – 2	11 (22)
2.1 - 3	38 (76)
Live embryo	
Yes	11 (22)
No	39 (78)

Data presented as n (%) or mean ± standard deviation.

Table 2. Characteristics of treatment with modified double-balloon Foley catheter

Factor	mean ± SD
Interballoon distance (mm)	12.1 ± 2.2
Lower-treatment balloon volume (mL)	20.9 ± 4.4
Upper anchor balloon volume (mL)	16.8 ± 6.8
Time of balloon inflated (hours)	22.8 ± 1.4
Blood loss during balloon inflation (mL)	35.2 ±15.3
Hemoglobin before balloon inflation (g/dL)	100.5 ± 2.3
Hemoglobin after balloon removal and before leaving the hospital (g/dL)	99.66 ± 2.8

Table 3. Outcomes to treat with modifier double balloon Foley catheter characteristics

Factor	mean ± SD	n (%)
Successful with balloon inflated		42 (84)
Combined with use of systemic MTX		8 (16)
Gestational sac disappearance (day)	12.5 ± 5.3 (range, 4 – 18 days)	
Time to negative β-hCG (week)	6.9 ± 3.6 (range, 2 – 12 weeks)	
Time in hospital (days)	4.7 ± 2.8 (range, 3 -17 days)	

Data presented as n (%) or mean ± standard deviation.

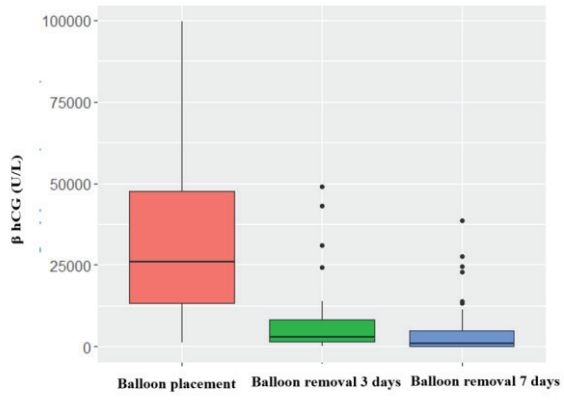

Figure 2. β-hCG levels before and after treatment with double-balloon Foley catheter

5. DISCUSSION

Prenatal counseling of women with a prenatal diagnosis of CSP is challenging, especially in asymptomatic cases. Current evidence is limited and derived mainly from small retrospective series including only highly symptomatic patients, and indicates high rates of adverse maternal outcomes, such as profuse bleeding, uterine rupture and need for hysterectomy [7]. This has led, in turn, to the common practice of offering termination of pregnancy to women with this condition [8]. Evaluation of the gestational-sac implantation site using COS criteria is a simple and reproducible tool for ascertaining the relationship between the ectopic sac, cesarean scar and anterior uterine wall. In the present series, all cases with COS-1 had severe variants of morbidly adherent placenta spectrum, such as placenta percreta or increta, while there were no cases of placenta accreta in this group. It might be speculated that COS-1 represents the most severe variant of CSP characterized by implantation of the ectopic sac within the previous cesarean scar and close to the anterior uterine wall, thus potentially resulting in a higher risk of bladder or parametrial invasion, massive hemorrhage and intrasurgical complications [3].

The cesarean scar pregnancy is one of the main precursors of morbidly adherent placenta. Therefore, cesarean scar pregnancy is a dangerous clinical entity [9, 10]. The majority of the obstetrics and gynecology community strongly recommended suggested termination of CSP.

When termination of the pregnancy is chosen, there is an excessive amount of available options published in the literature. The use of systemic methotrexate are frequently described interventions, either as a single or even multiple doses, was shown to be effective only after several days. [11]

Placing balloon catheters in cases of post-abortion hemorrhage was also published [12]. The adjunctive use of balloon catheters were also part of the treatment of cervical pregnancies [13]. We were further encouraged by the publication by Ilan E. Timor-Tritsch et al, who successfully tested a double balloon catheter in 12 cases of CSP and cervical pregnancy [9].

After inserting the modified double balloon Foley catheter 18F-12F, the study noted that βhCG concentration after 3 days (the day of withdrawal) was greatly reduced compared to before the procedure. This decrease is statistically significant with $p < 0.001$. The concentration of βhCG after 1 week of treatment was much lower than before the procedure, this reduction was statistically significant with $p < 0.001$. The concentration of βhCG 1 week after treatment decreased compared with the concentration of β hCG after 3 days of balloon insertion, however this decrease was not statistically significant with $p = 0.21 > 0.05$.

The amount of blood loss after balloon insertion recorded in our observation was very little, less than 60 mL (Table 2) compared to interventions such as suction curettage or surgery. Infection was also not recorded in the study. Blood loss before and after balloon insertion in the study was

not accurately assessed. However, pre- and post-procedure tests did not show any difference in hemoglobin concentration in blood tests.

The length of time balloon catheters in our observations was usually 24 hours. Dildy et al [14] left their newly tested double balloons to treat postpartum hemorrhage in place for a mean of 20.3 hours (range, 0.3 - 35 hours).

It is difficult to draw conclusive information from the experience of the previously mentioned authors as to the optimal length to leave balloons in place. It seems that the time to stop the heart activity is short and can be measured in hours. 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 optimal and minimum effective fluid volume in the balloons.

The cases considered as failures were those that required additional treatment such as MTX in this study (8 cases in Table 3). These cases also caused the median time of observation to be prolonged (17 days, Table 3). The study also did not record cases of bleeding afterwards, although there were cases of recorded images of the gestational sac persisting for a long time (negative beta-hCG, no bleeding).

In the cases described above, we did not record fever during and after the procedure, and general blood tests did not record an increase in white blood cell count.

The patient was follow - up consisted of weekly ultrasound examinations until the area of the gestational sac demonstrated diminished vascularity and until the gestational sac volume became smaller. Weekly serum human chorionic gonadotropin were obtained until nonpregnant values were noted. At least, birth control for 3 months was strongly suggested.

6. STRENGTH AND LIMITATIONS OF THE STUDY

Because this study is a case series report, it is inevitable that there are shortcomings. For example, in assessing the total blood loss, we only recorded the blood loss around the time of balloon insertion and indirectly the hemoglobin level before intervention and at discharge. The issue of abortion in the group was also not included, so this issue cannot be discussed. Hopefully, in future studies, there will be a more detailed description.

The strength of this study is that it shares experience with a minimally invasive intervention compared to surgery and all patients had the desired positive outcomes with personalized, close follow up by the authors. 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 modified double-balloon Foley catheter 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.

7. CONCLUSION

We explored the feasibility and effectiveness of treating early 6-8 weeks cesarean scar pregnancy by avoiding invasive treatment using a modifier double-balloon Foley catheter (12 Fr combined with 18 Fr). We evaluated its ability to stop the heart activity and at the same time to prevent possible local bleeding. This therapeutic mode was found to be simple, safe, and effective with high patient acceptance. It may be considered in a selective number of patients. Multicenter studies involving a larger number of patients are needed to further evaluate this technique.

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