

Value of Crossover Sign in Anticipating Under-8-week Cesarean Scar Pregnancy Treatment by Foley Insertion Combined with Suction Curettage in Vietnam

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Abstract

Objectives: An earlier study completed at TuDu Hospital presented the efficacy of Foley insertion combined with fetal suction curettage at a high rate of success in treatment of cesarean scar pregnancy (CSP) of < 8 weeks, but the efficacy of prognosticating factors for this approach has not been specifically addressed yet, especially crossover sign (COS) on ultrasound. We aimed to investigate the correlation between COS on ultrasound and the treatment results of CSP using Foley insertion combined with fetal suction.

Materials and Methods: A case-control study of CSPs ≤ 8 weeks treated at TuDu Hospital during September 2017–April 2019 included 63 failures in the case group and 98 successes in the control group.

Results: COS-2 + increased the likelihood of treatment success by 4.9 times (95% confidence interval: 1.8–13.5) compared with COS-1 cases. In addition, other factors favoring treatment success with statistical significance included no vascularization at cesarean scar on ultrasound (odds ratio [OR] = 7.1), gestational mass volume ≤ 4 cm³ (OR = 3.7), and β-human chorionic gonadotropin at hospital admission ≤ 10,000 mIU/mL (OR = 6.1).

Conclusion: COS imaging played an important role in the prediction of treatment outcomes for CSP ≤ 8 weeks by the combined approach of Foley insertion and fetal suction curettage.

Keywords: Cesarean scar pregnancy, crossover sign, ectopic pregnancy management

INTRODUCTION

Cesarean scar pregnancy (CSP) is a special form of ectopic pregnancy characterized by the implantation of a gestational sac into the myometrium at the location of a cesarean scar. CSP patients may encounter serious complications such as uterine hemorrhage, uterine rupture, and life-threatening massive bleeding, which require hysterectomy and have a negative impact on the patient's future obstetric outcomes.^[1,2] CSP currently has a low incidence rate; however, it has been increasing across the last 10 years in parallel with a rise in

cesarean section incidence.^[3,4] TuDu Hospital recorded a yearly increase of CSP cases, with 287 cases in 2012, up to 827 in 2014, and reaching 1380 in 2017.

Since 2016, crossover sign (COS) has been a new notion in CSP ultrasound diagnosis. On ultrasound of the sagittal uterine plane, we compared the straight line connecting the internal cervical os and uterine fundus through the endometrium (known as the endometrial line) against the anteroposterior diameter of the gestational sac and then

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defined the following scenarios: (1) COS-1 is defined as when the gestational sac is implanted in a cesarean scar and anterior myometrial wall for more than two-thirds of the anteroposterior diameter of the gestational sac and above the endometrial line or (2) COS-2 when the gestational sac is implanted for less than two-thirds of the anteroposterior diameter of the gestational sac and above the endometrial line. In addition, the COS-2 classification was further subdivided into COS-2+ and COS-2-. COS-2+ presented as an intersection between the anteroposterior diameter of the gestational sac and the endometrial line, whereas COS-2- did not have this intersection [Figures 1-3].^[5]

Cali *et al.* conducted two new studies,^[5,6] reviewed the COS images of placenta accreta cases, and found a correlation between COS and other types of placenta accreta, blood loss, and surgery time. Specifically, the placenta accreta patient group with COS-1 needed earlier pregnancy termination, had more blood loss, and experienced longer surgery time than those with COS-2 with statistical significance. As a result, the value of COS might play an important role in assessing the prognosis of CSP cases at the 8th week of pregnancy.

In TuDu Hospital, CSP will be diagnosed at admission and treated with various therapies depending on maternal age, gestational age, and obstetric history. According to Petersen *et al.*, there are numerous therapies for CSP, but none of them are yet considered the optimal treatment in terms of simplicity, effectiveness, and cost-saving.^[7] Since 2014, a new therapy has been introduced into treatment guidelines for CSP ≤8 weeks. Patients underwent Foley balloon catheter insertion at the department of gynecology's inpatient operating suite. Under ultrasound guidance, a 14-Fr Foley balloon was inserted into the uterine cavity at the site of the CSP; the balloon was then inflated up to 40 mL with normal saline in order to slowly compress and push the gestational sac into the uterine cavity. Patients then returned to their rooms for continued observation. If the Foley balloon had slipped before 6 h had elapsed and no evidence of ongoing or impending abortion was present, then the Foley balloon was inflated again; a tampon would be placed to keep the Foley in correct position. If the Foley balloon was in place after 6 h, but the patient exhibited signs of an abortion progress, ultrasound-guided D and C would be performed immediately. Otherwise, the Foley catheter was left in place for 24 h. Afterward, the patient was taken back to the operating room for removal of the Foley catheter, and a D and C with ultrasound guidance was performed. Quantification of hemorrhage was measured by aspiration amount and volume of blood loss measured by the BRASSS-V Drape. Hemorrhage was managed with uterotonic medications such as oxytocin 10 UI and rectal misoprostol 600 µg. Of note, (1) four senior doctors in our research team carried out all procedures of step 3, (2) during the

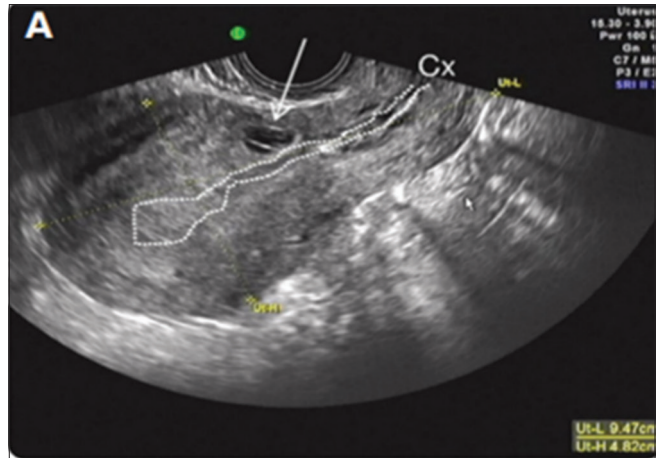


Figure 1: Image of transvaginal ultrasound scanning in a cesarean scar pregnancy case.^[15] The sagittal uterine fundus plane presents the image of a gestational sac with an embryo which is located on the anterior uterine wall, implanted in uterine scar; the uterine fundus and cavity are empty

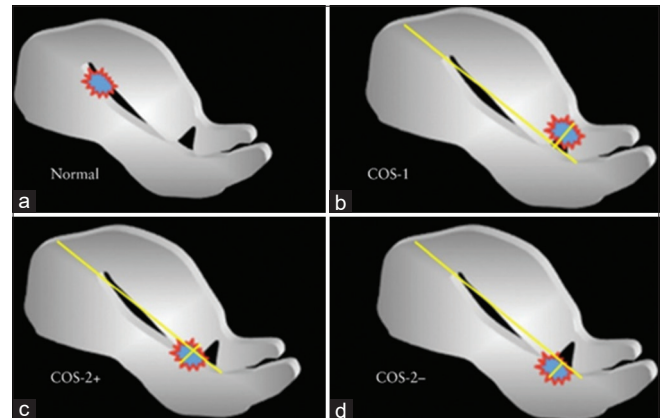


Figure 2: Simulation of correlation between ectopic gestational sac, uterine scar, and endometrium at the anterior uterine wall in crossover sign on ultrasound: (a) Normal (b) COS-1 (c) COS-2+ (d) COS 2-^[5]

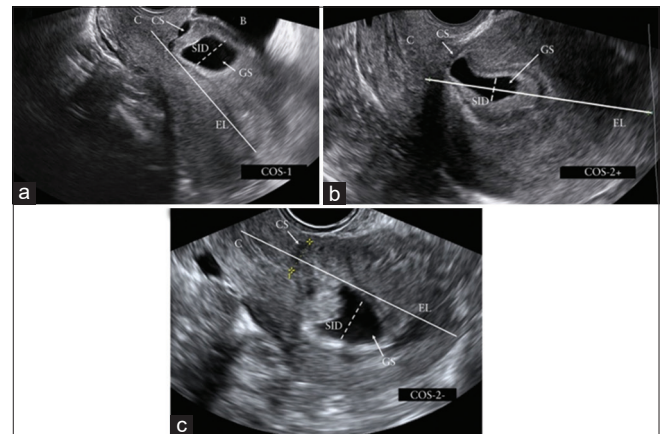


Figure 3: Images of various crossover sign types on ultrasound in cesarean scar pregnancy. (a) Crossover sign-1; (b) crossover sign-2+; (c) crossover sign-2-. B: bladder, C: uterine cervix, CS: cesarean scar, EL: endometrial line, GS: gestational sac, SID: superior-inferior diameter of gestational sac^[5]

Foley catheter insertion, if there was a concern for impending cesarean scar rupture, the procedure would have been terminated immediately due to risk of perforation, and (3) all procedures were performed under local paracervical anesthesia with the patient in the obstetrician-gynecologist (Ob-Gyn) position and the bladder catheterized.

In 2016, a study at TuDu Hospital showed that Foley insertion combined with fetal suction was highly efficacious and produced a high rate of success, but the prognostic factors of this approach have not yet been examined, especially the prognostic value of COS image on ultrasound.^[8] Because of all the aforementioned reasons, we conducted the study for the purpose of assessing the role of COS on ultrasound against treatment results in CSP cases with gestational age ≤ 8 weeks managed with the combined approach of Foley insertion and fetal suction.

MATERIALS AND METHODS

Study subjects

The study was designed as a case control. We conducted the study among individuals with gestational age ≤ 8 weeks diagnosed with a cesarean scar ectopic pregnancy. They were admitted into the hospital and treated with Foley insertion combined with fetal suction at the Department of Gynecology and Endoscopy of TuDu Hospital in the period between September 2017 and April 2019. The sample included patients who were positively diagnosed with CSP Type I by applying CSP criteria on Doppler ultrasound.^[8] The patients with confirmed diagnosis of Type I of CSPs which was caused by implantation of the amniotic sac on the scar with progression toward either the cervicoisthmic space or the uterine cavity (Type I, endogenic type).

All the patients were examined on COS by an imaging doctor who was deputy chair of the Imaging Department of TuDu Hospital. She was an experienced physician in transvaginal ultrasound. She helped us to confirm a diagnosis of CSP following Timor-Tritsch and Monteagudo's criteria.^[9] After signing informed consent of study engagement, they were divided into two groups: (1) case group: patients who failed the treatment and needed another intervention (endoscopic surgery, open surgery, and intervention procedures at surgery theater) and (2) control group: patients who were confirmed for a successful treatment on the same day as case-patients were selected. We excluded the following conditions: (1) gestational sac implantation in other uterine scars than cesarean section (myomectomy, interstitial ectopic pregnancy, etc.); (2) patient's general status was not appropriate for intervention (serious medical illnesses); and (3) patients who had poor memory, societal conscience loss, or refused to participate in the study.

The study was approved by the Council of Scientific Research, the Council of Medical Ethics in Bio-Medical Study of University of Medicine and Pharmacy at Ho Chi Minh city (#348/ĐHYD-HĐĐĐ) and permitted by the TuDu Hospital Council of Scientific Research (#3913/QĐ-BVTD). The study received consent from all patients to use their data.

Applying sample size formula in this case-control study (1:1) with Z value from normal distribution, $\alpha = 0.05$ and $1 - \beta = 0.95$, as per the precedent study by Cali *et al.*,^[5] the proportion of COS-1 in the percreta placenta group was 0.3 (P1) and COS-1 proportion in the nonpercreta placenta group was 0.06 (P2). Therefore, we calculated the minimum sample size to be $n = 126$ cases. The minimal sample size for the case group was 63.

Study procedures

Step 1

Screening and listing individuals: From the list of surgery patients at the Department of Gynecology Endoscopy at TuDu Hospital, we selected all postoperation CSP cases on day 3 who had failed with the combined approach of Foley insertion and fetal suction for gestational age ≤ 8 weeks and placed them into the case group. For the control group, on the same day as case group inclusion, we selected all cases of treatment success confirmed at the last return visit to the department of gynecology and endoscopy if they met inclusion criteria. If there were no cases of success on that day, we would select all cases of success on the following day.

Step 2

Inviting patients to join the study: The researcher contacted eligible patients to counsel them and explain the study, and an informed consent form was read to patients. If patients agreed to participate in the study, they would sign a consent form; otherwise, they would be excluded.

Step 3

Data collection and interview: Patients were interviewed with a closed questionnaire including information on background variables and history-related variables. Then, other information was collected from medical records and outpatient documents to fill in the data collection form.

Step 4

Data entry and cleaning: Exclusion of all ineligible cases, processing data and completing the study.

Evaluation parameters

We determined patients with CSP based on criteria suggested by Timor-Tritsch^[10,11] including (1) empty uterine cavity with no communication with gestational sac, (2) cervical canal clearly seen empty with no communication with gestational sac, (3) discontinuity in the anterior uterine wall was observed in the sagittal uterine plane when ultrasound waves were

directed through the amniotic sac, (4) presence of gestational sac with or without fetal pole and fetal heart (depending on gestational age) at the anterior uterine isthmus, and (5) absence or shortage of myometrial tissue between bladder and gestational sac. All cases diagnosed with CSP would be categorized by COS on ultrasound.

The case group included failures of treatment when they had one of the following: (1) right after Foley insertion and fetal suction, blood loss exceeded 300 mL and did not respond to balloon tamponade and referral to operation theater was required for interventional procedures or surgery; (2) during monitoring period, if there was one of the following factors, such as elevated β -human chorionic gonadotropin (hCG), gestational mass volume increase by more than 15%, profuse vascularization or vaginal bleeding, and therefore another modality of treatment had to be applied.

The control group included all cases with treatment success when they met the following criteria in a maximum 6-month monitoring period after Foley insertion and fetal suction: (1) β -hCG back to negative (<5 mIU/mL), (2) no mixed echo mass existing at uterine scar on ultrasound, and (3) no vascularization at all.

Statistical analysis

Statistical software (STATA 13.0, StataCorp LLC, Lakeway Drive College Station, TX, USA) was used to analyze all the data. Data are presented as the mean \pm standard deviation and n (%). For statistical analyses, a univariate analysis was done for independent variables to find the association with the success of treatment. We completed a univariate analysis for 23 pairs of variables. Then, we collected the variables which had $P < 0.05$ and completed a multivariate analysis. Tests were conducted at a 95% confidence interval (CI).

RESULTS

In the study period of September 2017–April 2019, there were 2295 CSP cases admitted to TuDu Hospital including 1086 CSP cases with gestation ≤ 8 weeks treated with Foley insertion combined with fetal suction 24 h later. There were 63 failures (accounting for 5.8%) that met the sampling criteria. We extracted at random 98 cases of success for study involvement. We expected a 1:1 ratio of case versus control at initiation, but the number of successful cases was not comparable to the number of failure cases on the 3rd day postoperation. To ensure randomization and minimization of bias in our research, we engaged all successful cases on the same day as the failure cases for study sampling. Therefore, there were 63 cases but 98 controls at an approximate ratio of 1:1.5.

The common characteristics and history of patients, clinical and paraclinical parameters including functional

Table 1: Clinical and paraclinical features of study participants ($n=161$)

Features	Frequency (%)
Age (years)	
<35	98 (60.9)
35+	63 (39.1)
Fetal suction history	
No	100 (62.1)
Yes	61 (37.9)
Number of past C-sections	
1	76 (47.2)
2+	85 (52.8)
Functional symptoms	
None	56 (34.8)
Single abdominal pain	24 (14.9)
Single vaginal bleeding	39 (24.2)
Abdominal pain with vaginal bleeding	42 (26.1)
CSP types	
COS-1	109 (67.7)
COS-2+	42 (26.1)
COS-2-	10 (6.2)
Gestational age (weeks)	
≤ 6 weeks	93 (57.8)
6 ± 7	45 (28.0)
7 ± 8	23 (14.2)
Vascularity at cesarean scar	
None	18 (11.2)
Low	64 (39.8)
Moderate	65 (40.4)
High	14 (8.7)
Gestational mass volume (cm^3)	
≤ 4	73 (45.3)
> 4	88 (54.7)
β -hCG levels (mIU/mL)	
$\leq 10,000$	29 (18.0)
$10,000 - \leq 50,000$	65 (40.4)
$50,000 \pm \leq 100,000$	39 (24.2)
$100,000+$	28 (17.4)

COS: Crossover sign, CSP: Cesarean scar pregnancy, hCG: Human chorionic gonadotropin

symptoms, types of CSP, gestational age, gestational mass volume, vascularity at cesarean scar, and β -hCG levels are presented at Table 1.

Treatment results

For the 98 cases of success, the time taken for β -hCG to return to negative was 5.7 ± 2.1 weeks, the shortest being 2 weeks and the longest being 14 weeks after treatment. Most cases quickly returned to negative in < 5 weeks. Time for the disappearance of a mixed echo mass at cesarean scar on ultrasound did not follow normal distribution, with a median at 2 weeks, the longest at 22 weeks and the shortest at 1 week after treatment.

Among 63 cases of failure requiring hospital admission for further treatment, the most common reason for admission was

increased gestational mass volume (57.1%), but only 39.7% of cases received an additional administration of methotrexate injection before the final intervention. Interventional measures included open operation (17.4%), endoscopic surgery (41.3%), and fetal suction in operation theater (41.3%). We were able to conserve the uterus in 96.8% of cases.

Univariate regression analysis for association between COS sonographic image and treatment failures disclosed that cases with COS-2 ± were 3.4 times more likely to be successful compared to those with COS-1 (95% CI: 1.5–7.3). To neutralize confounders and cofactors in the process of COS true value determination, we conducted a multivariate analysis with other factors having $P < 0.25$ by univariate analysis. There were three other factors related to treatment results [Table 2]. After multivariate analysis, ultrasound images of COS-2 ± showed an increased likelihood of treatment success up to 4.9 times (95% CI: 1.8–13.5) compared with the group having COS-1 ultrasound images.

As for COS sonographic images associated with retreatment results in cases of failure, specifically, COS-2 anticipated a less time-consuming operation with lower blood loss as compared with COS-1 cases [Table 3].

DISCUSSION

For the purpose of finding the true association between COS and treatment, we put statistically significant variables by univariate analysis into multivariate analysis to control

confounders and cofactors that could influence the association. The results disclosed that COS-2 images increased the chance of procedural success by 4.91 times ($P = 0.002$) compared to COS-1, demonstrating a high relationship between COS images and treatment prognosis for the combined approach of Foley insertion and fetal suction. Comparing COS-1 with COS-2 groups when operations were performed for cases of failure with Foley insertion combined with fetal suction, it was noted that operation time and blood loss were reduced more in the COS-2 group than in COS-1 ($P = 0.034$ and 0.017 , respectively). This result is in line with Cali *et al.*'s study^[5] where surgery duration, blood loss, and transfused blood units were higher in the COS-1 group than in COS-2 + and COS-2- ($P < 0.05$). Obviously, the deeper the gestational mass implantation into cesarean scar and myometrium, the thinner the myometrial layer and the more difficult the operation due to time spent on adhesion separation and hemostasis.^[12,13] Furthermore, the gestational mass may implant so deeply that the myometrial layer becomes excessively thin, resulting in the wide excision of the myometrial area around sclerotic scar tissue for restorative sutures, profuse bleeding, and poor uterine contraction, which negatively impacts local coagulation and requires blood transfusion for the patient. This message is very important to help the physician in making better prognosis of treatment. It also helps to effectively counsel patients before treatment rather than practice on experimental medicine.

We used transvaginal Doppler ultrasound scanning to examine the uterus and ovaries and diagnose CSP. COS is a new sign

Table 2: Multivariate analysis of treatment-related factors

Features	Success (n=98), n (%)	Failure (n=63), n (%)	OR*	95% CI	P*
COS types					
COS-2±	41 (78.8)	11 (21.2)	1		
COS-1	57 (52.3)	52 (47.7)	4.91	1.790–13.48	0.002
Vascularity at cesarean scar					
None	16 (88.9)	2 (11.1)	1		
Moderate	30 (46.2)	35 (53.8)	7.17	1.261–40.77	0.026
High	3 (21.4)	11 (78.6)	24.74	2.623–233.52	0.005
Gestational mass volume (cm ³)					
≤4	56 (76.7)	17 (23.3)	1		
>4	42 (47.7)	46 (52.3)	3.77	1.399–10.19	0.009
β-hCG level					
≤10,000	25 (86.2)	4 (13.8)	1		
10,000–≤50,000	39 (60.0)	26 (40.0)	6.07	1.373–26.88	0.017

COS: Crossover sign, OR: Odds ratio, CI: Confidence interval, hCG: Human chorionic gonadotropin, (*): Adjusted

Table 3: Correlation between crossover sign image and treatment failures by Foley insertion combined with fetal suction in CSP ≤8 weeks

Factors	COS-1 (n=52)	COS-2± (n=11)	Z	P
Operation time (min)	105	66	-2.117	0.034
Blood loss in surgery (mL)	315	145	-2.381	0.017

COS: Crossover sign, CSP: Cesarean scar pregnancy

of CSP on ultrasound. Since 2016, TuDu Hospital has applied the new knowledge of COS sonographic imaging, and in September 2017, the hospital routinely applied it to clinical practice. The study results found that 67.7% of CSP cases were categorized as COS-1 and COS-2 which accounted for 32.3%, including further classifications into COS-2+ (26.1%) and COS-2- (6.2%). The firm implantation of gestational sacs into uterine scars caused difficulty in treatment. By Cali *et al.*,^[5,6] the severe forms of placenta accreta including placenta percreta or increta progressed to the third trimester more in COS-1 group than the COS-2 group (odds ratio [OR]: 6.67 [95% CI: 1.3–33.3]). In addition, the COS-1 group experienced more blood loss, was administered more blood transfusions, and underwent operations of longer duration.

Through transvaginal ultrasound scan, we additionally applied Doppler ultrasound to improve the diagnostic capacity by assessing blood flow and vascularity around the gestational sac. The study results noted that 57.8% of patients with gestational age ≤ 6 weeks presented with those signs. This rate is equivalent to the 56.6% found in Vo *et al.*'s study.^[8] Early diagnosis at pregnancy ≤ 6 weeks produces high efficacy in treatment. The finding of vascularity at the cesarean scar is the hallmark of fetal implantation at the scar. Our study reported that nearly all cases had vascularization. Pretreatment β -hCG was with the lowest at 521.5 mIU/mL and the highest at 386925.0 mIU/mL. This maximum finding is higher than that of normal pregnancy of the same gestational age, possibly due to fetal implantation at an abnormal site combined with high vascularity, resulting in trophoblastic hypersecretion of β -hCG.

In cases of successful treatment, the time taken for β -hCG to return to negative was 5.7 ± 2.1 weeks, the shortest being 2 weeks and the longest being 14 weeks after the treatment. Most of the cases returned to negative quickly, within < 5 weeks. In our study, time for placental mass vanishment from a cesarean scar was short due to ultrasound-guided fetal suction, and hence, suction was more radical. In almost all cases, the echoic mass disappeared within 2 weeks, at 4 weeks on average, with the shortest taking 1 week and the longest taking 22 weeks.

Treatment result-related factors

Analyzing 24 pairs of single variables detected the following influencers to treatment results: (1) no vascularity on ultrasound increased the likelihood of treatment success to 7.17 and 24.75 times as compared with moderate and high vascularity, respectively ($P < 0.05$). No vascularity meant that the CSP was in the process of degenerating, and the combined approach of Foley insertion and fetal suction increased the rate of success for treatment. (2) Gestational mass volume $V \leq 4 \text{ cm}^3$ had an increased success rate of 3.78 times that

of group $V > 4 \text{ cm}^3$ ($P = 0.009$). According to Vo *et al.*,^[8] gestational mass volume $\leq 4 \text{ cm}^3$ 3 weeks after treatment boosted the success rate to 5 times ($P = 0.05$), and our study results align with the results of that study. Small gestational mass volume helps to easily perform the procedure to remove the whole gestational mass; moreover, with a small gestational mass, the uterine isthmus and cesarean scar zone do not dilate excessively, resulting in good recovery after suction and less risk of bleeding and myometrial injury. (3) Univariate analysis found that the group of β -hCG $< 10,000$ mIU/mL had the success rate of 6.07 times that of group with β -hCG 10,001–50,000 mIU/mL ($P = 0.017$). Vo *et al.*^[8] divided β -hCG levels into two groups: one $> 54,000$ mIU/mL and the other $\leq 54,000$ mIU/mL. Group $> 54,000$ mIU/mL had a higher failure rate of 5.24 times ($P < 0.05$). High β -hCG levels demonstrate trophoblastic activity and imply gestational mass survival. The higher the β -hCG levels, the more strongly the gestational mass develops, and although the treatment has been administered, it continues to grow.^[14]

New point in treatment and applicability

Ultrasound scanning to categorize COS in CSP should be widely applied to help attending physicians in counseling, assessing, managing, and anticipating the condition rationally. On the other hand, in clinical practice, the Foley method combined with fetal suction for CSP ≤ 8 weeks is still the first-line regimen. With the value of COS sonographic images, cases with COS-2 should be counseled on the high likelihood of success of this regimen while COS-1 should be referred for more complex management. For future research, we should focus on finding a more effective method of treatment for the group of CSP with ultrasound image of COS-1.

Restriction

First, the study results would be applied to CSP ≤ 8 weeks in clinical practice. It should be expanded for further study in patients with CSP > 8 weeks. Second, the most challenging encounter was patient follow-up after treatment. The number of fetal sac implants into cesarean scar is increasing year by year, making posttreatment follow-up becomes more difficult due to flexible interval of 2–4 weeks for monitoring β -hCG and Doppler ultrasound. In addition, large geographical distance and difficult travel condition prevent patients from maintaining re-examinations as scheduled.

CONCLUSIONS

COS-2± images increase the chance of treatment success for CSP ≤ 8 weeks by Foley insertion combined with fetal suction by 4.9 times (95% CI: 1.7–13.4) compared to COS-1 images. Meanwhile, COS-2± images can provide information regarding outcomes of expected further intervention in cases of treatment failure, i.e., reduction in mean surgery

time ($P = 0.03$) and blood loss ($P = 0.01$) as compared with cases having COS-1 images.

Data from the study demonstrate that ultrasound assessment of COS should be utilized in the diagnosis and treatment prognosis for CSP as part of routine guidelines at Ob/Gyn practical hospitals.

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Conflicts of interest

There are no conflicts of interest.

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