Minimally Invasive Treatment of Cesarean Scar and Cervical Pregnancies Using a Cervical Ripening Double Balloon Catheter

Expanding the Clinical Series

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Abbreviations

CCRB, Cook® double cervical ripening balloon catheter; CDs, cesarean deliveries; CSP, cesarean scar pregnancy; CxPs, cervical pregnancies; MTX, methotrexate

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The efficacy of treating cesarean scar pregnancies and cervical pregnancies with the Cook® cervical ripening balloon catheter, in a multicenter office-based setting is reported. Thirty-eight women were treated. Insertion of the catheter was performed under real-time ultrasound guidance. Patients received adjuvant systemic methotrexate, prophylactic oral antibiotics, and oral pain medication. Serum human chorionic gonadotropin and ultrasound scans were followed serially until resolution. Thirty-seven patients were successfully treated, requiring no further procedures. We found that the Cook cervical ripening balloon technique is a simple, effective, outpatient, minimally invasive treatment with few complications noted in this expanded series.

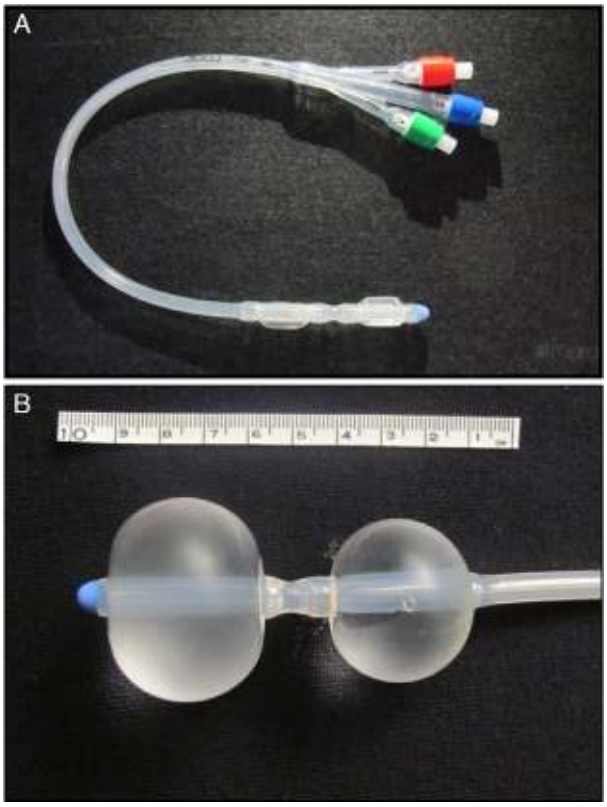
Key Words—cervical pregnancy; cesarean scar pregnancy; double balloon; minimally invasive

The overall rate of cesarean deliveries (CDs) has been above 30% since 2005.[1] This has resulted in a substantial number of women at risk of a cesarean scar pregnancy (CSP). At present, the exact incidence of CSP is unclear. Some authors have suggested 1:1800 to 1:2500[2] of all with a history of a previous CD; others have estimated it to be 0.15%.[3] More recent estimates suggest that the rate of CSP is 1:531 women with at least 1 CD.[4]

In the literature, there are more than 31 procedures described to treat CSPs,[5] and that list is increasing with additional and mostly invasive techniques that do not appear to reduce their complication rates. The treatments with the lowest complication rates are those in which potassium chloride or methotrexate (MTX) is directly injected into the gestational sac or into the embryo under real-time ultrasound guidance. In a recent review of 63 cases of CSP that were treated by local injection, the complication rates ranged from 0% to 5.8%.[6–13] Adjuvant use of systemic MTX appears to improve success rates. Nevertheless, excessive bleeding during or after the procedure continues to be a common complication. As reported in 2015,[14] bleeding during or after the treatment was seen 1 of 10 patients. Using a Foley catheter as an adjuvant therapy to prevent or control bleeding after local

injection with potassium chloride or MTX was first reported by our group in 18 patients.[15] The major complication encountered with this approach was that in 3 patients the balloon was expelled before its scheduled removal.[15] We attempted to eliminate this complication by using the Cook® double cervical ripening balloon (CCRB) catheter (J-CRBS 18400–G19891; Cook Medical, Winston-Salem, NC)[14] (Figure 1). After introduction of this catheter into the uterine cavity, the upper balloon is inflated in the uterine cavity and then, guided by transvaginal sonography (TVS), the second balloon is positioned and inflated at the level of the targeted gestational sac containing the embryo. The balloon in the uterine cavity serves as an anchor to "hold" the catheter in place, enabling the lower balloon to stay in its required position.[14] In the initial report, 10 patients (7 CSP and 3 cervical pregnancies [CxPs]) were treated using the CCRB catheter. Using this catheter, we found that this treatment method has several advantages over previously described minimally invasive, local, intragestational injection treatment for CSP or CxP. It effectively stopped embryonic cardiac activity and at the same time prevented bleeding complications. The aim of this article is to validate the efficacy of treating CSPs and CxPs using the CCRB catheter and to report the experience of additional centers.

Figure 1. Cervical ripening double balloon catheter. **A**, The catheters with its 3 ports: red—feeding the upper balloon, close to the tip of the catheter, to be inflated in the uterine cavity; green—leading to the lower balloon to be inflated and compress the cesarean scar pregnancy (CSP) or the cervical pregnancy (CxP); blue—accommodates the malleable stylet, which at insertion renders sturdiness to the catheter. **B**, The inflated balloons. The upper balloon is inflated with 25 cc and the lower balloon with 15 cc of saline.



Materials and Methods

This is a retrospective case series of patients diagnosed and treated with a CSP or CxP using the previously published technique[14] using the CCRB catheter. Cases were collected from patients with CSPs or CxPs referred to 7 centers (New York University Langone Health; Carnegie Imaging for Women, PLLC; Lenox Hill Hospital [Northwell Health]; Spectrum Health; University of Texas at Houston; and Arnas Civico Hospital [Palermo, Italy]; Albert Einstein College of Medicine). Patients were eligible to undergo the treatment after evidence-based counseling presenting them with surgical, other minimally invasive treatment using local, intragestational MTX injection or the presently used double balloon technique. After considering the above options to terminate the CSP, if they were hemodynamically stable and they fulfilled the double balloon treatment protocol criterion (a confirmed CxP or CSP by published sonographic evaluation),[2,16] patients were given a detailed description of the procedure and signed an informed consent form.

Two hours before the procedure, most patients were given a 600- to 800-mg nonsteroidal noninflammatory agent (ibuprofen) for pain management; 2 patients received intravenous conscious sedation. The CSP or CxP was localized using both transabdominal sonography and TVS. The gestational sac size and the presence of cardiac activity were assessed (Figure 2). A speculum was placed in the vagina, and the cervix and vagina were cleaned using antiseptic

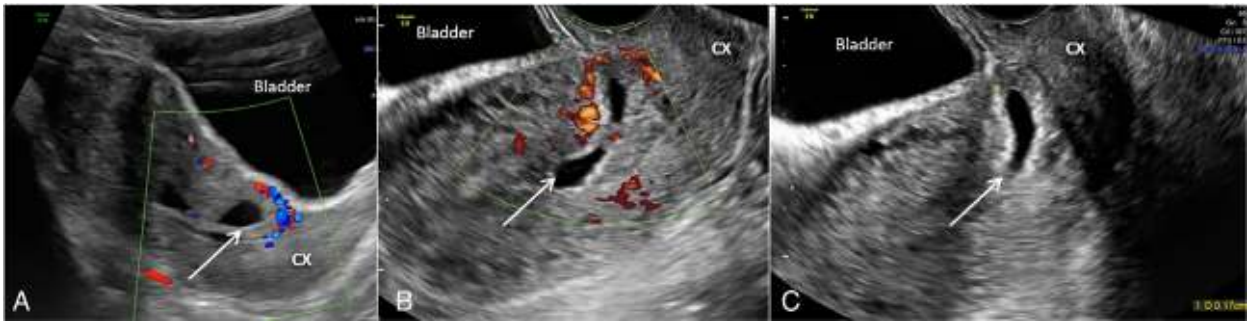
solution. The external cervical os was evaluated for the capacity to accept the catheter. In cases in which the cervix was closed and firm, it was mechanically dilated using Hegar or Pratt cervical dilators until it accommodated the catheter under transabdominal ultrasound guidance. Using a sponge forceps to assist, the tip of the catheter was passed through the cervical canal and into the fundal region of the uterine cavity under real-time transabdominal sonography. Once in place, the upper balloon was inflated with 10 to 25 mL of sterile saline under continuous transabdominal ultrasound evaluation. The speculum was removed, and using real-time TVS the lower balloon was inflated with about 10 to 20 mL of sterile saline, resulting in compression of the gestational sac in the lower uterine segment for CSP. The instilled volumes within the 2 balloons were adjusted as needed under continuous TVS for proper position and pressure effect upon the CSP or CxP. After the balloons were inflated, cessation of fetal embryonic activity and most often collapse of the CSP or CxP sac was confirmed by sonography (Figure 3). Placement of the catheter for CxP is the same as for CSP; the only difference is that the pressure (lower) balloon can be inflated in the endocervical canal or just below the external os of the cervix in the vagina.

Several patients received intramuscular MTX (1 mg/kg body weight, or a single 100-mg injection) before their referral. All but 4 of the patients without previous MTX treatment received the drug immediately after the procedure. In addition, patients received antibiotics (azithromycin 250 mg daily for 5 days) and acetaminophen and/or ibuprofen for pain management. Patients were observed for 1 to 2 hours in the sonography office and subsequently discharged and provided with postprocedure instructions, a 24/7 contact (cell phone) number for possible emergencies, pain medications, and a scheduled appointment for follow-up in 24 hours and subsequently in 3 to 7 days.

The catheter remained in place for 1 to 3 days based on the providers preference and assessment of the pregnancy at the 24-hour scan. The balloon deflation and catheter removal were performed as follows (Figure 4). The lower balloon was always deflated first under TVS, and the gestational sac was searched for embryonic heart activity. If there was none and during a 2-hour additional observation period there was no bleeding, the upper balloon was deflated. The catheter was removed only if during an additional 2-hour observational period there was no fresh "red" vaginal bleeding seen, and the uterine cavity did not fill up with blood. This procedure ensured that in case of any bleeding there was still the possibility to control it (ie, reinflate the balloons) while the catheter was still in place. Baseline blood tests included quantitative serum human chorionic gonadotropin (hCG), complete blood count, and liver and renal function tests as needed. Serial hCG and sonograms were initially performed weekly or as determined by the provider until resolution was achieved.

The entire procedure of placing the catheter, inflating the upper and lower balloons, and deflating them is demonstrated in Video 1.

Figure 2. Ultrasound images of a 6-week 3-day live cesarean pregnancy (single arrows) with the low, anterior location of the sac. CX, cervix. **A**, Transabdominal color Doppler sonogram emphasizing the already increased flow at the placental implantation. **B**, Transvaginalsonogram, color Doppler flow signals at the placental implantation. C, Transvaginal sonogram of the thin 1.7-mm myometrial layer between the placenta and the anterior uterine surface below the bladder.

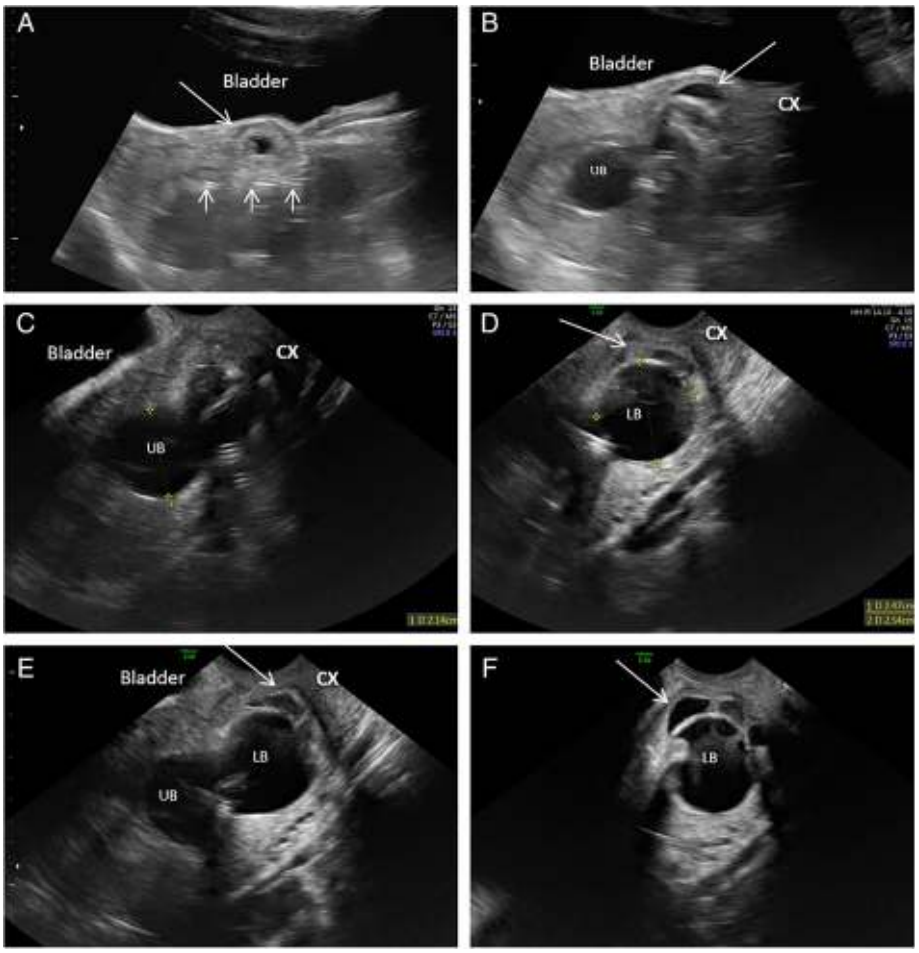


Results

Seven centers provided the 38 cases. One center treated 17 patients (one was CxP), the second treated 7 patients, the third center treated 6 patients, the fourth center treated 4 patients, the fifth center treated 2 (one a CxP), and the sixth and seventh centers treated 1 patient each. Among the CSP cases, 20 of 38 patients had one CD, 8 of 38 had 2 prior CDs, 5 had 3 prior CDs, and 1 each 4 and 5 CDs. There were 5 patients with recurrent CSPs; 4 had 1 prior CSP (2 with 1 prior CD, 1 with 3 prior CDs, and one with 5 prior CDs); and 1 with 2 prior CSPs (and 2 prior CDs); all had been treated previously with a combination of treatments (local intragestational sac injection, single Foley balloon, and intramuscular MTX). There was 1 patient with an incomplete septated uterus and a recurrent CSP. The gestational ages ranged from 5 0/7 to 10 1/7 weeks, and 1 had a sac containing a set of twins. Table 1 is a comprehensive summary of the pertinent clinical information about presentation and outcomes of the cases.

Thirty-seven procedures were performed in an outpatient setting. Thirty-four of the 38 patients were

Figure 3. Ultrasound images of the subsequent and main steps of inserting double balloon catheters and inflating the balloons. The arrows point to the gestational sac. **A**, Transabdominal sonogram of the catheter (small arrows) in the uterine cavity. **B**, Transabdominal sonogram of the inflated upper (anchor) balloon. **C**, Transvaginal sonogramof the inflated upper balloon. **D**, Transvaginal sonogramof the inflated lower (pressure) balloon. **E**, Transvaginal ultrasound image of both the inflated upper and lower balloons. The flattened gestational sac is already evident. **F**, Transverse transvaginal sonogram of the lower balloon flattening the gestational sac. CX, cervix; LB, lower balloon; UB, upper balloon.



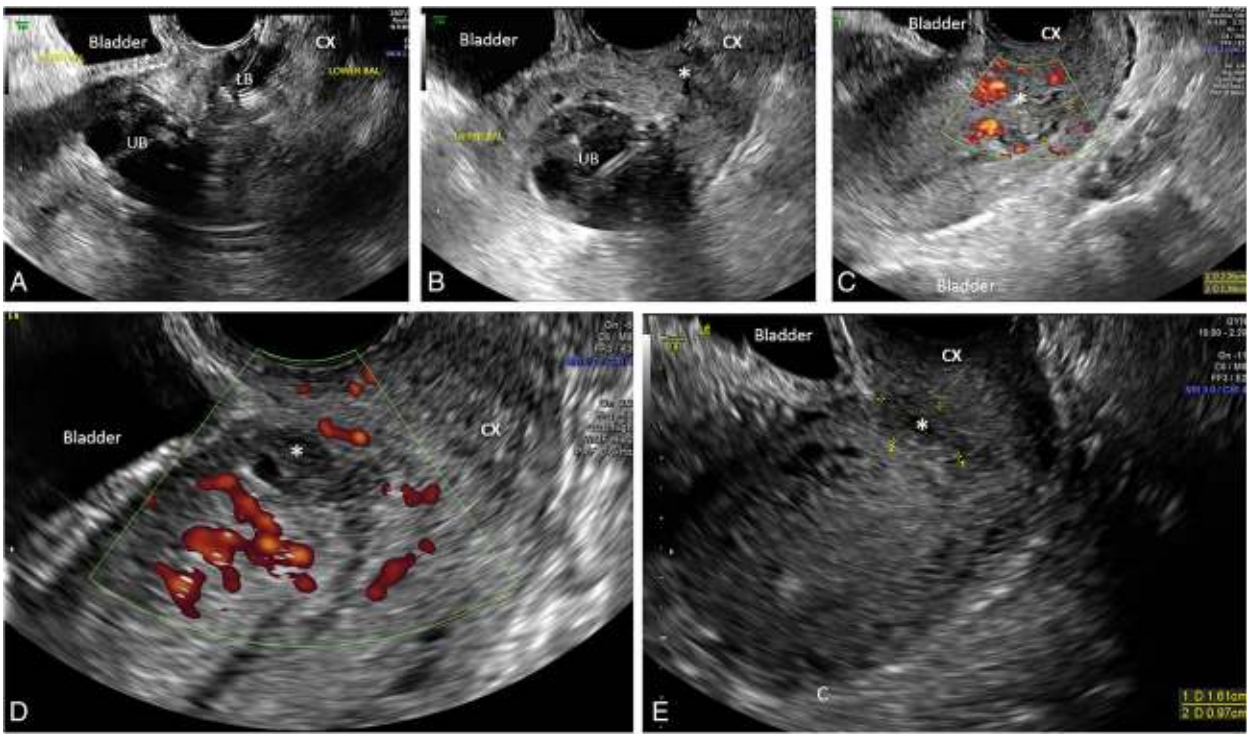
managed as outpatients after the procedure, and 4 patients were admitted overnight at the discretion of their providers, with no apparent complication noted. During the catheter placement there was no bleeding; cervical dilatation was not associated with bleeding.

After adjustments of the fluid volumes in the balloons, the upper balloon was filled with 7 to 25 cc of sterile saline, while the lower balloon was filled with 3 to 20 cc. The median value of the hCG at the time of the procedure (Table 2) increased with increasing gestational age (6493 IU/mL, 16,047 IU/mL, 34,772 IU/mL, and 140,000 and 77,289 IU/mL for gestations at 5, 6, 7, 8, and 10 weeks, respectively). The median number of days to a negative hCG was similar across all gestational ages (50, 41, 50, 49, and 49 days for pregnancies of 5, 6, 7, 8, and 10 weeks, respectively). Thirty-four patients received an intramuscular injection of MTX before or the day of the procedure. As per the patients, preprocedure ibuprofen was effective; however, cramping and pressure while the catheter was in place was the most common complaint among the treated patients. This was ameliorated by additional oral pain management. All catheters were removed as planned; none required early removal because of pain. After removal of the catheter, the most common complaint was dark vaginal spotting. None of the patients required reinflation of the balloons because of bleeding. Of the 38 patients treated, 1 patient with a CSP required a total abdominal hysterectomy on day 27 because of sudden excessive bleeding.

Discussion

Before providing an objective evaluation of the treatment modality used in this series, one must realize that CSP and CxP are extremely dangerous clinical entities if left untreated. Regardless of the gestational

Figure 4. Transvaginal ultrasound images of the subsequent steps of deflating and removing the double balloon catheter. The asterisk marks the site of the treated gestational sac. **A**, After 24 hours the 2 balloons in place.. **B**, The lower balloon was deflated. **C**, Three hours later the catheter was removed. Sonogram of the uterus after catheter removal. **D**, Color Doppler sonogram of the uterus 1 week after treatment. **E**, Gray scale sonogram of the uterus 3 weeks after treatment. CX, cervix; LB, lower balloon; UB, upper balloon.



age, a CSP compromises the integrity of the uterus and thus risks the lives of patients throughout all 3 trimesters.

In 2012, Timor-Tritsch and Monteagudo[5] published a review highlighting 2 significant consequences following a CD: the pathologically adherent placenta and the CSP. In this review, 31 primary treatments for CSP were identified, which included surgical interventions (dilation and curettage, hysteroscopic excision, laparoscopy, laparotomy, and hysterectomy), radiologic interventions (uterine artery embolization), and medical intervention (systemic or local methotrexate), as well as a combination of these methods. Of the 751 cases in this review, 98 (13%) required an emergent secondary treatment (36 total abdominal hysterectomies, 40 laparotomies, and

Table 1. Clinical Information of the Cases by Gestational Age at Presentation

No.	GA (wks)	CD (Prior CSP), n	Presence of Cardiac Activity	hCG at Procedure	Days Catheter in Place	Days to Negative hCG	Comments
1	5	1	Yes	3,146	1	78	
2	5 3/7	5 (1)	Yes	8,800	1	66	Cramping, spotting
3	5 3/7	2	Yes	6,493	1	21	No MTX
4	5 4/7	2	Yes × 2	2,900	1	50	Twin pregnancy; light bleeding
5	5 5/7	1	Yes	3,353	2	78	Cramping
6	5 5/7	1	Yes	16,229	1	40	Dark spotting
7	5 5/7	0	No	11,713	1	37	Cervical pregnancy
8	6 1/7	1 (1)	Yes	36,779	1	41	
9	6 1/7	1	Yes	4,602	1	30	No MTX
10	6 2/7	1	Yes	1,748	2	14	
11	6 2/7	1	Yes	29,828	1	39	
12	6 2/7	1	Yes	25,500	1	36	
13	6 2/7	3 (1)	Yes	13,884	1	65	
14	6 3/7	1	Yes	12,466	1	58	Bleeding 200–300 cc during scan; double balloon placed emergently
15	6 3/7	0	Yes	9,646	1	42	Cervical pregnancy
16	6 3/7	1	Yes	433	1	13	
17	6 4/7	1	Yes	5,600	1	NA	Last hCG 614; pressure pain
18	6 4/7	1	Yes	22,065	1	106	Small EMV
19	6 4/7	1	Yes	18,209	1	28	Minimal bleeding
20	6 4/7	1	Yes	30,194	1	48	
21	6 4/7	1 (1)	Yes	874	1	28	Septated
22	6 5/7	2	Yes	41,007	1	85	
23	6 6/7	3	Yes	26,914	1	76	No MTX
24	7	1	No	1,453	1	NA	Last hCG 494; failed termination by D&C
25	7 1/7	1	Yes	5,198	1	36	
26	7 1/7	3	Yes	72,455	1	NA	Last hCG 737; bleeding 27 days after treatment; TAH
27	7 2/7	2	Yes	22,704	3	20	Spotting
28	7 2/7	1	Yes	40,194	2	65	No MTX
29	7 3/7	2	Yes	40,000	1	55	
30	7 4/7	2	Yes	50,700	1	50	Pressure, dark spotting
31	7 5/7	4	Empty sac	7,061	1	44	Spotting
32	7 6/7	1	Yes	29,543	2	32	Pain, moderate bleeding before placement; dark spotting afterwards
33	7 6/7	2	Yes	27,064	1	NA	Last hCG 503
34	7 6/7	1	Yes	78,423	1	105	Spotting
35	7 6/7	3	Yes	62,685	1	97	Bleeding 100 cc at insertion
36	8 3/7	3	Empty sac	17,913	2	21	Dark spotting
37	8 3/7	2(2)	Yes	262,086	1	77	
38	10 1/7	4	Yes	77,289	1	49	

CD indicates cesarean delivery; D&C, dilation & curettage; EMV, enhanced myometrial vascularity; GA, gestational age; hCG, human chorionic gonadotropin; MTX, methotrexate; and TAH, total abdominal hysterectomy.

22 uterine artery embolizations) because of excessive bleeding. Additionally, over 40% of patients reported various maternal complications when treatment was administered in the first trimester.

Management and treatment options for CSPs are numerous; however, choosing the least invasive treatment with the fewest maternal risks can be quite challenging. The CCRB catheter appears to be an effective, simple, and well-tolerated outpatient treatment of CSPs and CxPs. In the initial report, all 10 cases (3 CxPs and 7 CSPs) were successfully treated.[14] This treatment allows preservation of fertility for women who have not yet completed their obstetric goals, as well as to decrease the potential morbidity associated with other treatment methods. Recently, this catheter was used to prevent bleeding in a case series of CSPs managed by suction and dilation.[17]

In the present case series, the double balloon was placed in 4 patients with nonviable pregnancies. Although we clearly advocate that CSPs and CxPs with no demonstrable cardiac activity can and should be conservatively followed up, in these 2 patients the area of the CSP or CxP was richly vascular, as judged by color Doppler; therefore, the rationale for placing the balloon was to prevent the potential for significant bleeding. The justification for nonintervention in cases of nonviable pregnancies is based upon a previously published case series of 60 cases of CSP in which, among 12 cases with no cardiac activity managed expectantly, all but 2 resolved without complications.[18]

In the present case series, 4 of the 38 patients did not received intramuscular MTX (patients declined); the outcome and the days to a negative hCG were similar to those who received methotrexate. Given the relatively small number of patients, we are unable to evaluate the influence of adjuvant use of systemic MTX on the time of resolution or the rate of drop of the serum hCG. Of note, in our initial case series, all 10 patients were managed with the double balloon and none of the patients received MTX. The reason for this was to evaluate the selective effect of the balloon treatment.[14] However, our experience leads us to believe that adjuvant use should be considered part of every case to expedite resolution As previously reported, bleeding during or after the treatment from a CSP requiring a secondary procedure was seen in 98 of 751 (13%) cases.[5] In the present case series, only 1 of the 38 (2.6%) patients treated with the double balloon had significant bleeding requiring a secondary treatment, in this case a hysterectomy 27 days after the procedure. Of note, this patient was not followed for a period of several days and then had an episode of heavy bleeding requiring hysterectomy. If we combine this case series with our original series of 10 cases,[14] the significant bleeding complication requiring a secondary treatment is 2.1%.

Table 2. Summary of Outcome

GA (wks)	*Patients, n*	*Median hCG (Procedure)*	*Mean Days Balloon in Place*	*Median Days to Negative hCG*
5–5 6/7	7	6,493	1.1	50
6–6 6/7	16	16,047	1.1	41
7–7 6/7	12	34,772	1.3	50
8–8 6/7	2	140,000	1.5	49
9–10 6/7	1	77,289	1	49

GA indicates gestational age; and hCG, human chorionic gonadotropin.

At this point it is important to mention acquired enhanced myometrial vascularity of the uterus (also called acquired arteriovenous malformations), an often underrecognized complication following failed intrauterine pregnancies or treated pregnancies such as CSPs. Although it is difficult to speculate on the frequency of this complication following the treatment for a CSP, when it occurs, these patients are the ones that require the most interventions and have the highest rates of morbidity. In a series of 27 cases of enhanced myometrial vascularity published in 2016, there were 5 minimally invasive treated CSPs, none of them treated with the current technique; 4 required additional MTX, 3 underwent uterine artery embolization, and ultimately 2 of the 5 women underwent a hysterectomy.[19]

In a recent letter to the editor,[20] we described several important observations and clinically useful "pearls" when applying the CCRB. We subsequently incorporated them into the technique. These "pearls" may help the readers to successfully use this treatment method. First, a history of previously dilated cervix, either by a prior vaginal delivery or a cesarean section performed with some degree of cervical dilation, as well as a history of a prior dilation and curettage usually enable easier catheter introduction.

Patients who do not fall in this category will need a minimal cervical dilatation (the catheter diameter is 18 French) that can be achieved by cervical dilators under paracervical block. Second, reducing the catheter tip diameter by aspirating all the air from the balloons using an empty small syringe (3–5 cc) through the 2 (red and green) ports prior to placement further decreases catheter tip diameter, making insertion easier. Third, pain management by premedicating the patients with 600 to 800 mg of ibuprofen 2 hours before and subsequently 400 to 600 mg q 6 to 8 hours, alone or in conjunction with acetaminophen as needed, markedly reduces pain caused by balloon distention. Fourth, shortening catheter dwell time can also decrease discomfort. In our initial series, the catheter was kept in place for several days (median, 3 days). Currently, we have shortened the time to its extraction without losing the benefits of the double balloon. In pregnancies at 7 weeks' gestation or less, the lower balloon was deflated after 5 to 6 hours or the next morning once sonography has confirmed absence of cardiac activity and no bleeding is present. In the absence of cardiac activity, the upper balloon was deflated and then the lower balloon deflated, and the catheter was removed if no bleeding is observed throughout a 2-hour observation time. Finally, informing the patient during the initial consultation that spotting and bleeding can last several weeks can help manage patient expectations. We suspect the reason for the prolonged spotting is the nature of the treatment: It has "created" retained products of conception with all its clinical consequences (spotting, bleeding). We do not recommend surgical removal of the tissue remnants because forceful removal of the deeply invading trophoblast by opening the vessels that invaded the scar and the myometrium may cause severe bleeding. During the resolution phase, the area of the CSP may increase in size and vascularity before it begins to decrease in size; therefore, ultrasound imaging lags in appearance when compared to the clinical resolution of the condition based on dropping hCG. As noted with treatments of tubal ectopic pregnancies, the hCG may first increase before it begins to resolve.[2] Expectant management will result in gradual resolution of both the size and vascularity paralleling the disappearance of the serum hCG. Finally, to ensure patient satisfaction, easy access to the treating team for support, reassurance, and answering questions is key to a successful treatment and avoidance of potentially unnecessary emergency room visits.

In conclusion, this method provides a safe-as-it-can-be and effective treatment modality for these 2 types of pregnancies when compared to other, more aggressive and invasive managements described in the literature. The simplicity and the outpatient applicability of this technique may become especially relevant because many patients presenting with CSP or CxP may live far away from tertiary centers and can thus be effectively managed in their community. Five of the 7 centers in this report had no prior experience in treating CSPs or CxPs. Although we do not have complete data, there are other centers both in the United States and abroad that have used this technique successfully to treat these 2 types of pregnancies. All centers found the technique relatively easy to apply because most physicians had experience in placing this type of catheter for cervical ripening in the labor room setting. In this and in the previous series, this technique was used for pregnancies at or before 10 weeks of gestation; therefore, its success in treating pregnancies beyond this gestational age has not been studied at this time. We speculate that it could be useful as an adjuvant therapy in cases beyond 10 weeks that were treated with local intragestational sac injection. Further research into this treatment modality with an ongoing registry to determine whether the optimistic results obtained thus can be applied to a larger population is advised.

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