

# Intraoperative infrarenal aortic balloon occlusion in pregnancies with placenta accreta spectrum disorder

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Background: The objective of this study was to evaluate the efficacy of intraoperative aortic balloon occlusion (IABO) during caesarean section for placenta accreta, increta or percreta and explore the relationship between different profile balloon catheters and catheter-related complications. Methods: This retrospective case control study included 295 patients with pathologically confirmed placenta accreta spectrum (PAS) disorder at the Sichuan Academy of Medical Sciences & Sichuan Provincial People's Hospital between 2013 and 2019. The characteristics of 162 patients who had aortic balloon occlusion (balloon group) were compared with those of 133 patients who had no catheterization (control group). Results: There were significant differences between the two groups in estimated blood loss, calculated blood loss, number of transfusions, transfused packed red blood cells (PRBCs), haemoglobin reduction, operation time and caesarean hysterectomy (P < 0.05). Regarding different PAS disorders, the estimated blood loss among women with placenta accreta and placenta increta was lower in the balloon group (n = 32 and 102, respectively) than in the non-balloon group (n = 33 and 85; P = 0.04 and P < 0.01, respectively). Only the placenta increta group showed a significant difference (P < 0.01) in transfused PRBCs. In patients who used the low-profile balloon catheters, we found a significant reduction in catheter-related complications compared with the highprofile group (n = 52 vs. 110, P = 0.04). Conclusions: Our study demonstrated that intraoperative infrarenal aortic balloon occlusion was effective in both reducing intraoperative haemorrhage and blood transfusion, and in preventing hysterectomy during caesarean section for pathologically diagnosed placenta accreta and increta. Lowprofile balloon catheters can reduce catheter-related complications.

#### Keywords

Aortic balloon occlusion; Caesarean section; Interventional therapy; Placenta accreta; Thrombus

#### 1. Introduction

Abnormal placental implantation is defined as the invasion of placental villi into the myometrium to varying degrees. FIGO has redefined it as Placenta accreta spectrum (PAS) disorder in 2018, and as Luke *et al.* first defined, the

PAS disorder was classified into three forms based on the depth of villous invasion. Placenta accreta is characterized by the placental villi penetrating through the thinned decidua basalis and adhering directly to the myometrium. Placenta increta is characterized by the invasion of the placenta into the myometrium. Invasion through the myometrium reaching or penetrating the serosa is termed placenta percreta [1–3]

PAS disorder can lead to difficulties in placental separation, which has become an important cause of postpartum haemorrhage, perinatal hysterectomy, and even maternal death. In previous studies, the approach most often recommended for managing PAS disorder was caesarean hysterectomy with no attempt to detach the placenta [4–6]. Hysterectomy, however, results in catastrophic fertility loss, and recent studies have attempted to preserve the uterus by manual removal of the placenta with resection of the invaded area or conservative management while leaving the placenta *in situ* [7, 8].

In recent years the prophylactic placement of endovascular balloon catheters has become popular for controlling intraoperative haemorrhage in women with PAS disorder. In our previous study, intraoperative aortic balloon occlusion (IABO) was demonstrated to effectively reduce intraoperative haemorrhage during caesarean sections of patients with PAS disorder. This effect has been confirmed by other studies [9–12]. This technique can prevent hysterectomy in patients with placenta increta. In a previous study at our institution, 10% of patients who underwent IABO developed arterial thrombus [13].

In the current study, we accumulated a greater number of patients with PAS disorder, and low-profile devices were employed in IABO to reduce thrombotic complications. The clinical data for a group of pathologically diagnosed PAS disorder patients who underwent manual placenta removal during caesarean section were retrospectively analysed. We

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aimed to further evaluate the clinical efficacy of IABO, both in terms of reducing intraoperative haemorrhage and in fertility retention. This efficacy was also evaluated in different types of PAS disorder.

#### 2. Materials and methods

This retrospective case control study was conducted between 2013 and 2019 among women in our Hospital diagnosed with PAS disorder by postoperative pathology. The study protocol was approved by the Institutional Ethics Committee of the Sichuan Academy of Medical Sciences and Sichuan Provincial People's Hospital, Chengdu, China. Patients with accidental discovery of PAS disorder during surgery were excluded because of insufficient preoperative preparation. Patients with surgical diagnosed PAS disorder but with a lack of pathological evidence were excluded. Patients with gestational hypertension, intrahepatic cholestasis, acute fatty liver, acute pancreatitis, asthma, and cardiopulmonary insufficiency were also excluded. As a result, a total of 295 patients with PAS disorder were enrolled. Each pregnant woman was informed about her clinical symptoms, treatment options and associated risks. Patients were asked to sign an informed consent for the reception of prophylactic aortic catheterization or other options.

The infrarenal aortic balloon catheterization procedures were performed on all the hemodynamically stable patients by two experienced interventional radiologists in an interventional operating room. At the beginning of the study, we used a 12-F sheath (RCF-12.0-38-J, Cook Medical Inc., Bloomington, IN, USA, diameter: 3.96 mm), and a catheterguided 10-F (maximum diameter after dilatation: 46 mm) occlusion balloon for the IABO procedure (the high-profile group). After 2017, a 8-F (RS\*A80K10SQ, RADIFOUS Medical Inc., Hanoi City, Vietnam, diameter: 2.78 mm) sheath and a 7-F (12TLW807F, Edwards Lifesciences Medical Inc., Puerto Rico, USA, maximum diameter after dilatation: 14 mm), occlusion balloon were employed to reduce the thrombotic complications (the low-profile group). The IABO procedures were as previously described [13]. Before caesarean delivery, patients were transferred to the interventional radiology (IR) suite for abdominal aortic balloon catheterization. The catheterization was the same in both high and low groups. A vascular closure device was placed through the (preferred) right femoral artery, under local anaesthesia. A vascular sheath was inserted and the balloon was filled with the injected contrast and determined to be stable at the level just caudal to the renal artery bifurcation. Then, angiography of the proximal aorta should show abundant blood flow within both renal arteries after the balloon is inflated. Finally, the angiogram should show no blood flow in the L3 to L5 lumbar arteries and the distal aorta and record the volume. The balloon was deflated, and the balloon catheter was filled with 5 mL of diluted heparin solution. The sheath/balloon catheter system was fixed to the skin.

Patients were then transferred to the operating room, and caesarean delivery was performed under general anaesthesia or combined spinal-epidural anaesthesia (CSE). Intraoperatively, the balloons were inflated at the obstetrician's request, either before uterine incision or immediately after delivery and umbilical cord clamping. If it was necessary for occlusion to continue for 40 minutes, the balloon was deflated for 10 minutes to prevent lower limb ischemia and necrosis. After caesarean delivery, the patients were transferred to the ward, post-anaesthesia care unit, or intensive care unit, based on their type of anaesthesia and general condition. The sheath system was removed by an interventional radiologist. Compression haemostasis at puncture points was achieved using a vascular compression device, and this device was removed after the punctured lower limb had been immobilized for eight hours. The dorsalis pedis artery pulse and skin temperature of both lower limbs were closely monitored after surgery, and vascular colour ultrasound were used to detect thrombosis. The diagnose of thrombus is artery stenosis (blood flow signals decrease) or even artery occlusion (blood flow signals disappear).

As requested by the obstetricians, the balloons were inflated immediately after delivery and umbilical cord clamping or before uterine incision. For the safety of the patient, the balloon usually needed to be deflated for 10 minutes after filling for 40 minutes, and the maximum duration of persistent balloon blocking was no more than 60 minutes. The duration of occlusion was recorded for all patients. Before abdominal closure, the balloon was routinely deflated to monitor for active bleeding. If no life-threatening bleeding occurred, uterine artery embolization (UAE) could be performed in an interventional operating room. As soon as there was no fresh uterine bleeding, the catheters were immediately removed by the radiologist. When the patient returned to the ward, Colour Doppler ultrasound of the lower limb was arranged to determine whether there was thrombus formation.

The 162 patients who received intraoperative aortic balloon occlusion were categorized as the balloon group, and the other patients did not undergo balloon placement (control group). In both groups, we analysed patient demographic characteristics and clinical data. The intraoperative and postoperative blood loss was estimated based on the volume of suction containers, the weight of the surgical pads, and a visual estimation of vaginal blood loss. The duration of surgery was defined as the time from the initial incision to the completion of wound closure. The preoperative and day 1 postoperative haematological data for each patient were obtained for both groups. Surgery-related and catheterizationrelated complications were also reported. The main perinatal outcomes included estimated blood loss (EBL), the rate of caesarean hysterectomy, the amount of packed red blood cells (PRBCs) transfused, duration of surgery and decreases in haemoglobin after surgery; these outcomes were further analysed according to the forms of PAS disorder.

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Table 1. Baseline characteristics and the distribution of different types of PAS disorder for all eligible patients treated with or without aortic balloon catheters.

Variable	Balloon group	Control group	P value	
	(n = 162)	(n = 133)	1 varue	
Maternal age (years)	$30.2 \pm 4.2$	$31.3 \pm 4.7$	0.73	
Body mass index (kg/m <sup>2</sup> )	$25.4 \pm 3.6$	$25.7 \pm 3.1$	0.84	
Gravidity (n)	4 (1-7)	3 (1–6)	0.45	
Parity (n)	1 (0-2)	1 (0-3)	0.62	
Gestational age at delivery (weeks)	$36.8 \pm 3.5$	$36.1 \pm 4.0$	0.58	
Prior caesarean section	129 (79.6%)	98 (73.7%)	0.23	
Pathologic diagnosis			0.26	
Placenta accreta	32 (19.8%)	33 (24.8%)		
Placenta increta	102 (63.0%)	85 (63.9%)		
Placenta percreta	28 (17.2%)	15 (11.3%)		
Emergency operation	31 (19.1%)	29 (21.8%)	0.57	

Values are shown as the mean  $\pm$  SD, or as a number with the respective percentage in brackets.

Table 2. Maternal and neonatal outcomes for all patients treated with or without aortic balloon catheters.

	Balloon group	Control group	P value	
	(n = 162)	(n = 133)	1 value	
Estimated blood loss (mL)	$1239.5 \pm 752.8$	$1728.6 \pm 985.4$	< 0.01	
Calculated blood loss (mL), RBCs	$1352.1 \pm 662.2$	$1902.5 \pm 931.47$	< 0.01	
Received Transfusion	110 (67.9%)	115 (86.5%)	< 0.01	
Transfused PRBCs (U)	$5.5\pm3.2$	$9.5 \pm 4.6$	0.01	
Haemoglobin reduction (g/L)	$12.3 \pm 12.2$	$21.4\pm14.2$	0.01	
Operation time (min)	$97.4 \pm 45.7$	$120.49 \pm 42.81$	< 0.01	
Caesarean hysterectomy	24 (14.8%)	34 (25.6%)	0.02	
Admission to ICU	27 (16.6%)	37 (27.8%)	0.04	
Hospital days (days)	$6.5\pm2.8$	$7.1\pm3.2$	0.80	
Surgery-related complications	11 (6.8%)	9 (6.7%)	0.99	
Catheterization-related complications	18 (11.1%)	0	N/A	
Neonatal birth weight (g)	$2768.8 \pm 502.4$	$2958.3 \pm 602.5$	0.78	
Apgar scores at 5 min	10 (9–10)	10 (10–10)	0.48	

Values are shown as the mean  $\pm$  SD, or as a number with the respective percentage in brackets, or as a median with the interquartile range in brackets. PRBCs, packed red blood cells; ICU, intensive care unit; N/A, not applicable.

Normally distributed data were described as mean  $\pm$  standard deviation (SD); non-normally distributed data were reported as median and interquartile range (lower quartile to upper quartile). Categorical variables were reported as proportions (%). According to the distribution of the variables, the continuous variables were compared using Student's t-test or the Mann-Whitney U-test. Categorical variables were compared using Chi-squared or Fisher exact tests. All analyses were performed using SPSS 22.0 (SPSS Inc., Chicago, IL, USA). The results were considered statistically significant at P < 0.05.

#### 3. Results

In total, 295 patients with pathologically confirmed PAS disorder were enrolled into this study. Sixty-five patients were diagnosed as having placenta accreta (22.0%), 187 had placenta increta (63.4%), and 43 had placenta percreta

(14.6%), during the study period. A total of 162 patients (54.9%) had aortic balloon catheters placed before caesarean section (balloon group), and all balloons were inflated intraoperatively. The remaining 133 patients (45.1%) underwent caesarean section directly without prophylactic intervention (control group).

There were no between-groups differences regarding maternal age, body mass index, gravidity, parity, gestational age at delivery, patients with prior caesarean section, emergency operation and the distribution of different forms of PAS disorder (Table 1). In comparison, significant differences were observed in estimated or calculated blood loss, the amount of transfused PRBCs and the number of transfusions (Table 2). In addition, patients in the control group had a significantly longer operation time and a greater decrease in haemoglobin value after surgery than those in the balloon group. There were significant differences in the percentage of caesarean

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hysterectomy and the rate of admission to the intensive care unit (ICU) between the balloon group and the control group (14.8% vs. 25.6%, P=0.02; 16.6% vs. 27.8%, P=0.04, respectively). No significant differences were found in hospital days, surgery-related complications, and neonatal outcomes. There were 18 patients who had catheterization-related complications, including one case of hematoma in the front wall of the right common femoral artery, 2 cases of venous thrombosis of the right lower limbs and 15 cases of artery thrombosis of the right lower limbs. There were no differences for neonatal outcomes such as neonatal birth weight or Apgar scores at 5 min (Table 2).

We further compared intraoperative outcomes by placenta accreta, placenta increta, and placenta percreta. Interestingly, different results were obtained when women with different forms of PAS disorder were assessed separately. For estimated blood loss, significant differences were found between groups for women with placenta accreta and placenta increta, but no significant differences were found in placenta percreta. For transfused PRBCs, only the placenta increta group, showed a significant difference between groups. In comparison, significant differences were observed in operation time and caesarean hysterectomy for women with placenta accreta or placenta increta (Table 3).

In patients who received the low-profile balloon catheter, we found a significant reduction in catheter-related complications compared with the high-profile group (P = 0.04). In the high-profile group, sixteen patients (14.5%) had catheterization-related complications, including one case of hematoma in the front wall of the right common femoral artery, two cases of venous thrombosis of the right lower limbs and 13 cases of artery thrombosis of the right lower limbs. The thrombosis locations of these patients were the internal iliac artery (n = 1), common femoral artery (n = 4), popliteal artery (n = 6), and both the common femoral artery and the popliteal artery (n = 2). All patients with an arterial thrombosis had symptoms of weakening or disappearance of the dorsalis pedis artery pulse and reduction of skin temperature. Four cases presented with lower limb swelling after several hours of surgery. Five cases had lower limb pain, combined with numbness. However, there were only 2 cases of lower limb arterial thrombosis in the low-profile group. There was no significant difference in estimated blood loss, transfused PRBCs, caesarean hysterectomy and time of balloon occlusion (Table 4).

## 4. Discussion

This study shows that the IABO was effective in reducing EBL, PRBCs units transfused, haemoglobin reduction, calculated blood loss, the number of patients requiring blood transfusion, and preserving fertility in patients with PAS disorder.

Endovascular interventional modalities for haemorrhage control during caesarean section are increasingly used in cases that are complicated by PAS disorder. However, there is no consensus regarding the safety and effectiveness of these modalities. Prophylactic balloon occlusion of the internal iliac arteries (PBOIIA), common iliac arteries (PBOCIA), abdominal aorta (PBOAA) and uterine arteries (PBOUA) with or without embolization of the UA have been used. The preventative role of interventional radiology procedures in cases of PAS disorder has been discussed [14]. According to a previous study, the incidence of hysterectomy is 0–81.8% in PAS disorder. Improvement in medical technologies have made it possible to avoid obstetric hysterectomy in the management of major obstetric haemorrhage and as more patients expect to retain the uterus, so the clinical management of such patients has changed [10, 15–22].

Since IABO can also occlude the collateral circulation of uterus, more and more obstetricians have introduced IABO during caesarean section in patients with PAS disorder. According to previous studies, IABO can effectively reduce the incidence of intraoperative haemorraghia and hysterectomy in patients with PAS disorder [9, 10, 12]. Qinghua Wu *et al.* [12] reported that in all 88 patients with placenta percreta, the uterus was successfully conserved using IABO; only 2 of the patients required further UAE. But these studies lacked a pathological diagnosis and had a limited number of cases.

In our previous case-control studies, IABO was found to reduce EBL, similar to other studies [11, 23]. But the technique was equivocal in reducing the rate of hysterectomy because of the limited number of cases studied. In this study, more cases of PAS disorder were accumulated, and patients with intraoperatively found PAS disorder were excluded. All patients were pathologically diagnosed, which made this study more accurate.

This study once again confirmed the efficacy of IABO in reducing EBL and blood transfusion volume, and also confirmed the role of IABO in uterine preservation and reduction of operation time. When the data were analysed according to different subtypes of PAS disorder, we found that the technology was successful in cases that were complicated by placenta accrete and increta. However, in cases that were complicated by placenta percreta, the technique reduced EBL, transfused PRBCs, and operation time, but no statistically significant difference. That was partly because although IABO could theoretically reduce bleeding, severe bleeding often occurred when we tried to remove as much of the deep invasive placenta as possible. In other cases, the uterus cannot be repaired because a large area of the placenta-uterine wall has been excised. In these cases, hysterectomy was still necessary. Involvement of the cervix was another unavoidable reason for caesarean hysterectomy.

In this study, all patients were diagnosed by pathology after the surgery, but effective prenatal diagnosis and evaluation were still essential for the management of such patients. New imaging technology played an increasingly important role in prenatal diagnosis of PAS disorder. Ultrasound was the most commonly used examination method for prenatal diagnosis of these patients. Despite the widespread use of

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Table 3. Surgical outcomes for women with different forms of PAS disorder treated with or without aortic balloon catheters.

	Accreta (n = 65)			Increta (n = 187)		Percreta (n = 43)			
	Balloon group $(n = 32)$	Control group (n = 33	) P value	Balloon group (n = 102)	Control group (n = 85	) P value	Balloon group (n = 28)	Control group (n = 15)	P value
EBL (mL)	600 (400–1000)	950 (600–1600)	0.04	1200 (800–2000)	2000 (1000–2500)	< 0.01	3100 (2450–4500)	3600 (2600–5050)	0.27
Transfused PRBCs (U)	3 (2–6)	3.5 (2-7)	0.72	5 (2.5–8)	9 (4–14)	< 0.01	12 (6–16)	14 (6.5–18)	0.15
Operation time (min)	$90.3 \pm 36.1$	$122.3 \pm 39.8$	0.04	$99.1 \pm 46.9$	$144.1 \pm 40.9$	0.01	$124.1 \pm 52.6$	$149.1 \pm 47.3$	0.85
Caesarean hysterectomy	0	2 (6.0%)	N/A	8 (7.8%)	16 (18.8%)	0.02	17 (67.9%)	11 (73.3%)	0.40

Values are shown as the mean  $\pm$  SD, or as a number with the respective percentage in brackets, or as a median with the interquartile range in brackets. EBL, estimated blood loss; PRBCs, packed red blood cells; N/A, not applicable.

Table 4. Surgical outcomes and catheterization-related complications for patients using different type of balloon catheters.

	High-profile group	Low-profile group	P value	
	(n = 110)	(n = 52)	1 value	
Estimated blood loss (mL)	$1150.5 \pm 682.3$	$1285.4 \pm 760.5$	0.85	
Transfused PRBCs (U)	5.0 (4-10)	6.0 (4–12)	0.55	
Caesarean hysterectomy	16 (14.5%)	9 (17.3%)	0.65	
Catheterization-related complications	16 (14.5%)	2 (3.8%)	0.04	
Time of balloon occlusion (min)	25 (5–50)	24 (6–55)	0.64	

Values are shown as the mean  $\pm$  SD, or as a number with the respective percentage in brackets, or as a median with the interquartile range in brackets. PRBCs, packed red blood cells.

magnetic resonance imaging (MRI), its role in placental management and improved pregnancy outcomes of PAS disorder has not been clearly documented. The reported sensitivity of colour Doppler for diagnosing PAS disorder was 92% and the specificity was 67%, and the corresponding values for MRI were 84% and 78%, resulting in no significant difference [24]. Few studies have aimed to use these techniques to distinguish between different forms of PAS disorder antenatally, but MRI was found to be better at detecting the depth of infiltration [25]. Although diagnostic accuracy is limited, necessary prenatal imaging can provide obstetricians with sufficient evidence for planning the delivery, thus avoiding unnecessary catheterization and improving peripartum outcomes.

In our prior studies, the high-profile balloon catheters were significantly associated with thrombus [26]. From 2017 onwards, low-profile balloon catheters were introduced. In this paper, we have identified a relationship between balloon size and catheter-related thrombosis. Possible reasons for thrombosis include slow blood flow distal to the balloon occlusion, platelet aggregation induced by foreign stimuli and arterial intimal injury, the hypercoagulable state, and elevated vascular wall pressure due to the increased blood volume during pregnancy. Severe blood loss during surgery, unstable haemodynamics, blood transfusion, and secondary coagulation dysfunction might also contribute. Although it is difficult to ascertain the exact cause for the thrombosis in each case, many investigators consider that low-profile devices and early sheath removal can reduce the incidence of thrombus. Our new study confirmed this opinion. With a similar occlusion time, patients who received the low-profile balloon catheters had a significantly lower incidence of thrombus and no increase in EBL, transfusion amount, or incidence of hysterectomy.

Our research analysed the effectiveness of IABO among 3 different types of PAS disorders, indicating when the choice of IABO is most appropriate. Our study noted the relationship between balloon size and catheter-related thrombosis, which supports the use of a low-profile balloon that can not only block blood flow but also reduce complications.

There are several limitations to the present study. The present conclusions must be constrained by the limited number of patients included, by the retrospective design of the study and by potential bias in the selection of cases and controls. However, with the severity of this emergency condition a prospective randomized control trial would be difficult. Another limitation is that this study does not provide any conclusion regarding the total blood loss of the patients. It is well established that visual estimation of blood loss is not reliable and there can be doubt about the accuracy. A prospective, randomized, controlled study with a larger number of patients is warranted to support the wider generalisability of the proposed method.

#### 5. Conclusions

Our study demonstrated that intraoperative infrarenal aortic balloon occlusion was effective in both reducing intraoperative haemorrhage and blood transfusion, and in preventing hysterectomy during caesarean section for pathologically diagnosed placenta accreta and increta. Further prospective randomized trial should be performed to assess the validity of IABO in percreta. A low-profile balloon catheter is recommended for this procedure to reduce the risk of thrombus. IABO is recommended in those patients with placenta increta; however, the use of IABO does not benefit women with placenta percreta and other optimal managements are required to decrease their blood loss.

## **Author contributions**

JM and MDL contributed to the conception of the study. JXL, MWH and QH contributed significantly to data analysis. MDL, JXL and XFY wrote the manuscript. XFY, MWH and QH provide help on data collection. JM perform the analysis with constructive discussions. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

## Ethics approval and consent to participate

All subjects gave their informed consent for inclusion before they participated in the study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of Sichuan Provincial People's Hospital (approval number: \$17064).

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#### Conflict of interest

The authors declare no conflict of interest.

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