

The Clinical Evaluation of IIA Balloon Occlusion for Pernicious Placenta Previa Patients with Placenta Accreta: A Retrospective Study

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Abstract

Objective: This study aimed to evaluate the clinical efficacy of internal iliac artery (IIA) balloon occlusion in patients with pernicious placenta previa coexisting with placenta accreta.

Background: Pernicious placenta previa is frequently reported to be complicated with placenta accreta, which contributes to serious consequences such as severe obstetric postpartum hemorrhage or even maternal mortality.

Methods: Fifty-eight pernicious placenta previa patients complicated with placenta accreta were retrospectively reviewed. The balloon group consisted of 23 patients, who underwent a caesarean delivery with internal iliac artery occlusion. 35 patients were in the control group, who had a standard caesarean delivery. The primary outcomes were estimated blood loss (EBL), cesarean hysterectomy, and blood transferring volume. The secondary outcomes were operating time, intraoperative hemostatic approaches, surgical complications, balloon catheter-related complications, length of maternal stay, cost of hospitalization, and neonatal outcomes.

Results: No difference was observed in estimated blood loss (EBL), blood transferring percentages and volume, additional measures to secure hemostasis, surgical complications, hospital stay postoperatively and newborn outcomes. More than 40% of the balloon group underwent hysterectomy because of uncontrollable postpartum bleeding (10[43.48%] vs. 11[31.43%], $P=0.350$). Complications related to occlusion of IIA did not occur. The duration of the surgery of the balloon group was significantly longer than that of the control group (123.52 min \pm 74.76 versus 89.17 \pm 48.68, $P=0.038$), and the total hospitalization cost was also significantly higher than that of the control group (45116.67 \pm 9358.67 yuan versus 30615.41 \pm 11587.44 yuan, $P=0.000$).

Conclusion: IIA balloon occlusion in patients with pernicious placenta previa coexisting with placenta accreta did not reduce the hysterectomy rate during cesarean section, nor did it reduce blood loss and blood transfusion, but it prolonged the duration of the surgery and increased the total cost.

Background

Pernicious placenta previa (PPP), the attachment of placental previa to the previous cesarean delivery scars, was first proposed by Chattopadhyay et al^[1], and it is often related to placenta accreta. In past decades, women increasingly preferred to deliver by cesarean section, leading to the increasing incidence of pernicious placenta previa^[2]. It is reported with an incidence of 1 per 533 pregnancies^[3]. One of the main and deadliest complications of pernicious placenta previa with placenta accreta is massive bleeding. The average blood loss in these cases has been estimated to range between 2 and 3 liters^[4]. Therefore, strategies to prevent and treat bleeding are paramount to manage this pathology. Various approaches have been employed in controlling intraoperative blood loss in cases of abnormal placentation. These include inserting uterine tamponade balloons, applying uterine gauze packing, placing uterine brace or isthmic compression sutures, and performing a hysterectomy.

The arterial occlusion balloon was introduced and used in pernicious placenta previa, recently, and the role of intraoperative internal iliac artery (IIA) balloon occlusion to improve hemorrhagic outcomes in women with placenta accreta has been evaluated in many studies, most of which showed some benefit^[5-9], but others failed to demonstrate any^[10-12]. In this retrospective study, we aimed to evaluate the clinical efficacy of IIA balloon occlusion in patients with pernicious placenta previa coexisting with placenta accreta.

Methods

Fifty-eight pernicious placenta previa patients who were complicated with placenta accreta underwent balloon occlusion of IIA between January 2015 and June 2018 at Ningbo Women and Children's Hospital were retrospectively reviewed in this study. The Institutional Review Board of Ningbo Women and Children's approved this study, and the need for informed consent was waived because of retrospective nature of this study.

Cases were identified using the electronic medical record system. The inclusion criteria were a diagnosis of pernicious placenta previa with placenta accreta and having caesarean sections performed by the same experienced surgeon. The following patients were excluded: those who had a history of gynecological cancers or other solid cancers, hematological malignancies, gynecological surgeries (such as myomectomy, cervicoplasty and uterine rupture repair); those severe platelet disorders; twin pregnancy, those who underwent emergent delivery and cases with missing data. For all women included in this study, a diagnosis of placenta accreta had been made on prenatal imaging with either ultrasound and/or magnetic resonance imaging (Figure 1) and abnormal placental status was confirmed clinically, or histopathologically, after delivery. Each clinical case was discussed in multidisciplinary meetings with interventional radiologists, obstetricians, neonatologists, and urologist. Finally, whether to accept IIA balloon occlusion is determined according to patients' willingness, which were subsequently divided into the balloon group and the control group. There were 23 patients in the balloon group and 35 patients in the control group. Occlusion balloon placement was performed by one of two senior interventional radiologists, who each had more than five years of experience with the similar procedure of uterine artery embolisation for caesarean scar ectopic pregnancy.

Procedure for the management of IIA balloon catheters was as follows. Arteriopuncture of bilateral femoral arteries via the Seldinger technique was performed after local anesthesia; 6-French sheaths were then put in place. Next, selective contralateral IIA catheterization was performed with fluoroscopy guidance, and a PTA catheter (Abbott, USA) was inserted into the IIA. The balloon (Abbott, USA), which was approximately 8-10 mm in diameter, was exchanged by using a 0.035-inch super-hard exchange guide wire and then positioned in the IIA with the head pointing to the branch of the anterior IIA, as confirmed by angiography (Figure 2). After the insertion, The balloon was briefly inflated, and contrast injected to verify occlusion of the artery. Once positioning was satisfactory, the balloon catheter and its sheath were fixed on the skin. Patients were then transferred to the operating room for cesarean delivery. After the baby was delivered, the occlusion balloons were inflated immediately. The placenta was then

delivered and cesarean delivery was continued in the usual manner. Balloons were deflated before skin closure. Balloon catheters and wires were removed after surgery, and 1 sheath was left in place to allow for resuscitation and emergency embolization if needed. Perioperative management was similar in the two groups except for catheter placement and balloon occlusion of bilateral internal iliac arteries.

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The primary outcomes were estimated blood loss (EBL), cesarean hysterectomy, and blood transferring volume. The secondary outcomes were as follows: operating time, intraoperative hemostatic approaches (such as intrauterine tamponade, compression suturing, uterine artery ligation), surgical complications, balloon catheter-related complications (including puncture site hematoma, thrombosis, embolic events, and vascular rupture), length of maternal stay, cost of hospitalization, and neonatal outcomes. Statistics Statistical analysis was performed using SPSS 20.0 software. Data were presented as mean \pm SD, median (range) or count (percentage). Comparison between 2 groups was determined by t test, Wilcoxon rank sum test or chi-square test. $p < 0.05$ was considered significant.

Result

Fifty-eight women were included. Twenty-three women were in the balloon group and thirty-five women were in the control group. Baseline characteristics are summarized in Table 1. There was no significant difference between the two groups with respect to patient age at delivery, gestational age, gravidity, parity, type of pregnancy, number of previous uterine surgeries and abdominal surgeries, number of previous cesarean deliveries, types of placenta accretion and hemoglobin before cesarean section.

Table 1
Demographic characteristics and incidence of different forms of placenta accretion in the two study groups.

Characteristic/Outcome	Balloon Group(n=23)	Control group(n=35)	p-value
Mean age, years	33.00±3.77	33.37±4.44	0.742
gestational age, weeks	34.86±1.05	35.47±1.20	0.113
Gravidity	3.70±1.11	3.91±1.29	0.508
Parity	2.13±0.55	2.14±0.43	0.924
number of previous uterine surgeries	1.52±1.47	1.74±1.17	0.528
number of previous cesarean deliveries	1.09±0.29	1.14±0.36	0.531
Hemoglobin before cesarean section, g/dl	11.23±1.33	11.19±1.25	0.914
Depth of Placenta percreta			
accreta	4	11	0.232
Increta	9(56.52%)	16(77.14%)	0.620
Percreta	10(43.48%)	8(22.86%)	0.097

The intraoperative and postoperative outcomes for the two groups are summarized in Table 2, 3. The median EBL was 2500ml (range,1750-5750ml) in the balloon group versus 2000ml (range, 1500-3350ml) in the control group ($p=0.171$). There was no statistically significant difference observed between the groups with intraoperative hemorrhage volumes of 2500 mL and above ($p=0.421$). More than 40% of the balloon group underwent hysterectomy because of uncontrollable postpartum bleeding (10[43.48%] vs. 11[31.43%], $p=0.350$). The need for additional measures to secure hemostasis similarly showed no difference between the groups (Table 3).

Table 2
Blood loss and transfusion requirements between the two study groups.

Parameters	Balloon Group(n=23)	Control group(n=35)	p-value
Estimated blood loss, ml [#]	2500(1750-5750)	2000(1500-3350)	0.226
Blood loss≥2500ml, n(%)	13(56.52%)	16(45.71%)	0.421
Transfusion, n(%)	21(91.30%)	35(100%)	0.076
Autologous blood transfusion, n(%)	20(86.96%)	34(97.14%)	0.134
Autologous blood transfusion, ml [#]	600(335-1050)	500(278.5-745.5)	0.347
RBC transfusion, n(%)	12(52.17%)	17(48.57%)	0.788
RBC, units [#]	3(0-6)	0(0-4.5)	0.486
FFP transfusion, n(%)	18(78.26%)	20(57.14%)	0.098
FFP, units [#]	1080(555-1200)	500(0-1160)	1.000
Cryoprecipitate transfusion, n(%)	12(52.17%)	10(28.57%)	0.070
Cryoprecipitate, units [#]	5(0-10)	0(0-9.75)	0.343
Decrease in Hb after surgery [#]	1.3(-1.5-1.7)	1.35(0.1-2.45)	0.266
RBC, red blood cells; FFP, fresh frozen plasma; Hb, haemoglobin concentration.			
#Data were presented as median (range). Comparison between 2 groups was determined by Wilcoxon rank sum test.			

Table 3
Surgical details and postoperative outcomes between the two study groups.

Parameters	Balloon Group(n=23)	Control group(n=35)	p-value
Cesarean hysterectomy, n(%)	10(43.48%)	11(31.43%)	0.350
Additional measures to secure hemostasis, n(%)	15(65.22%)	27(77.14%)	0.320
Iodoform gauze packing of the uterine cavity, n(%)	14(60.87%)	26(74.29%)	0.280
Balloon tamponade, n(%)	8(34.78%)	20(57.14%)	0.096
Uterine artery ligation, n(%)	2(8.70%)	2(5.71%)	0.661
uterine artery embolization, n(%)	6(26.09%)	12(34.29%)	0.509
Partial excision of the invaded uterine wall, n(%)	3	2	0.303
Duration of the surgery, min*	123.52±74.76	89.17±48.68	0.038
Hospital stay postoperatively, days	7.96±2.14	7.74±1.90	0.692
Hospitalization cost, yuan*	45116.67±9358.67	30615.41±11587.44	0.000
Surgical complications, n(%)	14(60.87%)	22(62.86%)	0.879
Fever, n(%)	11(47.83%)	20(57.14%)	0.487
DIC, n(%)	2(8.70%)	4(11.43%)	0.738
Pneumonodema, n(%)	0	1(2.86%)	0.414
Bladder injury, n(%)	3(13.04%)	1(2.86%)	0.134
Relaparotomy, n(%)	2(8.70%)	3(8.57%)	0.987
Maternal death	0	0	-
Balloon related complications			
Hematoma puncture	0	0	-
Vein thrombosis	0	0	-
Neonatal outcome			
Neonatal birth weight, g	2540±480	2740±360	0.074

DIC disseminated intravascular coagulation

*P<0.05

Parameters	Balloon Group(n=23)	Control group(n=35)	p-value
Apgar score of 1min	8.70±0.56	8.46±1.12	0.349
Apgar score of 5min	9.78±0.42	9.69±0.93	0.642
Neonatal mortality	0	0	-
DIC disseminated intravascular coagulation			
*P<0.05			

Twenty-one women in the balloon group and all women in the control group received blood transfusions. No significant differences were noted both in the percentages and volumes of autologous blood transfusion, red blood cell transfusion, fresh frozen plasma transfusion and cryoprecipitate transfusion between the two groups. There was no significant difference in the Hb decrease between the two groups (1.3 (range, -1.5-1.7) vs 1.35 (range, 0.1-2.45), $p=0.266$).

The duration of the surgery of the balloon group was significantly longer than that of the control group (123.52 min±74.76 versus 89.17±48.68, $p=0.038$), and the total hospitalization cost was also significantly higher than that of the control group (45116.67±9358.67 yuan versus 30615.41±11587.44yuan, $p=0.000$). There was no significant difference in surgical complications, postoperative hospital stay, newborn weight, Apgar scores at 1 and 5 minute between the two groups. No still births or maternal death were observed in either group. No balloon related complication occurred in the balloon group.

Discussion

This study showed that balloon occlusion of IIA in patients with pernicious placenta previa coexisting with placenta accreta did not reduce the hysterectomy rate during cesarean section, nor did it reduce blood loss and blood transfusion, but it prolonged the duration of the surgery and increased the total cost.

Although advances in obstetric care have led to a substantial improvement in pregnancy outcomes, the death rate from placenta accreta remains as high as 7%, largely due to massive haemorrhage^[13, 14], which may then lead to disseminated intravascular coagulation, fluid overload, acute respiratory distress syndrome and infection. It seems logical that occlusion of the internal iliac arteries with prophylactically-placed balloon catheters would be a more effective treatment option, but reported results are controversial. Some retrospective studies^[6-9] reported that intraoperative IIA balloon occlusion had benefits in reducing blood loss and the amount of blood transfusion. Some previous systematic reviews also reported that intraoperative IIA balloon occlusion had benefits in reducing blood loss, the volumes of blood transfusion and even the percentages of cesarean hysterectomy in women with accrete^[5, 15]. Nicholson et al. also reported that patients with IIA balloon occlusion had a decreased rate of

hysterectomy compared to those without it^[16]. Recently, Yao FAN and Soo BuemCho 's two randomized controlled studies also agree with this view^[15,17]. However, randomized controlled studies^[10,18]and several case control studies^[11,12,19]did not find any benefit. Our findings accord with the previous randomized controlled trial conducted by Meng Chen et al^[18].

In our study, we selected the most serious type of disease in the placenta previa spectrum—pernicious placenta previa with placenta accreta, and tried to exclude the heterogeneity caused by the study subjects; In addition, in our study, all patients are operated by the same surgeon, who has more than 20 years of experience and performs nearly 1,000 cesarean sections a year. They also received the same standard peripartum care apart from the insertion of iliac artery balloons which also eliminate the surgical procedural heterogeneity between surgeons and teams. This is the most significant advantage of our research, which has not been reported in other studies.

It is unclear why occlusion of the internal iliac arteries failed to reduce haemorrhage in our study. The uterine arteries account for most of the blood supply to the uterus, but the extensive collateral supply from the ovarian arteries will not be affected^[20]. It may also be possible that IIA balloon occlusion does not provide enough arterial flow attenuation in cases of severe abnormal placentation. In a recent case report, escalating from IIA balloon occlusion to common iliac artery balloon occlusion was found to be more effective in reducing operative blood loss during cesarean hysterectomy for morbidly adherent placenta^[21] probably because common iliac artery balloon occlusion occluded more collateral arteries than IIA balloon occlusion. In addition, there may be a risk of balloon displacement. As the women were transferred from the interventional unit to the operating theatre after balloon insertion, and we were unable to perform real-time balloon imaging during the caesarean section, the possibility of balloon migration cannot be excluded. Teixidor has confirmed this in his research^[22]. In order to avoid catheter displacement as much as possible, we used general anesthesia in the balloon group.

In our study, the transfusion rate was 91.3% in the balloon group and 100% in the control group, which was much higher than the 50% or so reported in the literature^[23]. In our hospital, autologous blood transfusion is one of the necessary means to reduce the bleeding during the operation of pregnant women with placenta accreta spectrum. Therefore, nearly every pregnant woman in our study underwent autologous blood transfusion during cesarean section, which may be the reason for the increased transfusion rate in our study.

Our results show that the duration of surgery in the balloon group is significantly longer than in the control group, which should be interpreted with caution. Pregnant women in the balloon group needed an interventional surgeon to remove the balloon after surgery, whereas women in the control group did not.

This study has several limitations, including the retrospective, single-center nature of the investigation. The lack of randomization in the outcome could lead to more complex cases being selected for balloon placement while the less severe cases may have tended to undergo standard caesarean delivery. Blood

loss was estimated, and transfusion was performed based on surgeon preference, which may have varied based on practice.

Conclusion

IIA balloon occlusion in patients with pernicious placenta previa coexisting with placenta accreta did not reduce the hysterectomy rate during cesarean section, nor did it reduce blood loss and blood transfusion, but it prolonged the duration of the surgery and increased the total cost.

Abbreviations

PPP: Pernicious placenta previa; IIA: internal iliac artery; EBL: estimated blood loss; RBC: red blood cells; FFP: fresh frozen plasma; Hb: haemoglobin concentration;

DIC: disseminated intravascular coagulation.

Declarations

Ethics approval and consent to participate

The Institutional Review Board of Ningbo Women and Children's approved this study , and the need for informed consent was waived because of retrospective nature of this study. (EC2019–043). All methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication

Not applicable for this publication.

Availability of data and materials

The research data used to support the findings of this study were supplied by Ms.Zhang under license and so cannot be made freely available. Requests for access to these data should be made to Ms.Zhang (Email:zhangli00501465@outlook.com).

Competing interests

We declare that we don't have competing interests with publication of this article.

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Author contributions

LH: data collection and analysis; primary author of manuscript. AC: evaluation design; Surgeon of cesarean section; JC: Imaging technical guidance, image collection. XL, ,YS,QD: data analysis and interpretation; manuscript preparation and review. WZ: obtaining funding and ethics approval. LZ: leads all aspects of this study including study concept and design; obtaining funding and ethics approval; supervision of data collection and implementation; and manuscript supervision and revision for critical intellectual input. All authors have read and approved the manuscript.

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Figures

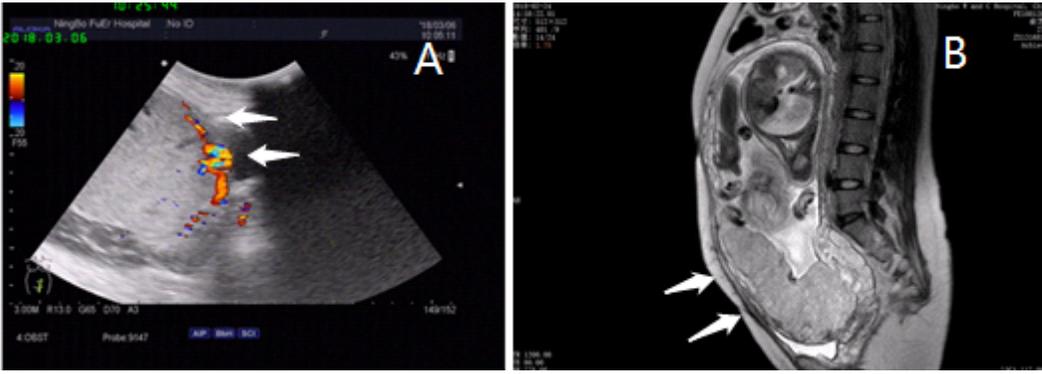


Figure 1

A: Color Doppler images. The arrow indicates evidence of placenta accreta (indistinct boundary of utero-placental interface); B: MRI. Placenta accreta in the lower uterine segment (indicated by an arrow).

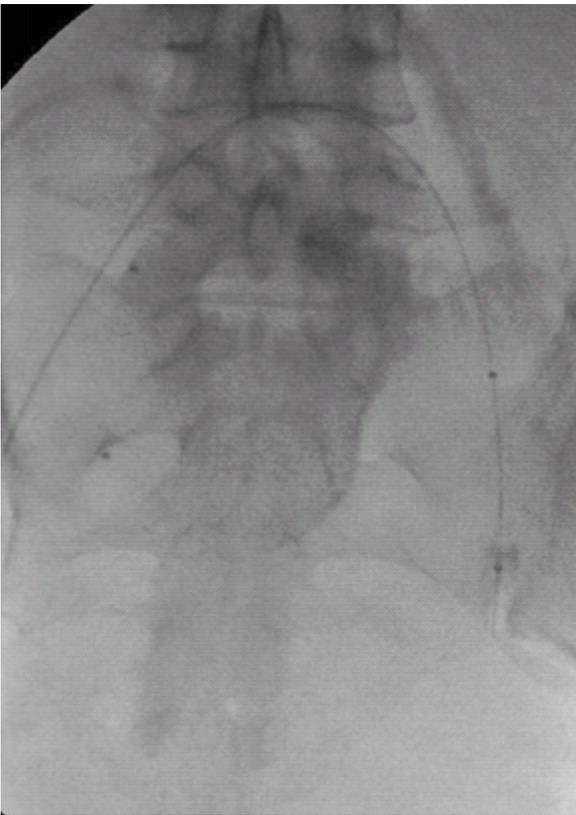


Figure 2

Fluoroscopy showing the balloon catheters positioned in the main lumen of the internal iliac arteries bilaterally.