Intra-abdominal aortic balloon occlusion in the management of placenta percreta

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Abstract
Background: Massive bleeding is the main concern for the management of placenta percreta (PP). Intra-abdominal aortic balloon occlusion (IABO) is one method for pelvic devascularization, but the efficacy of IABO is uncertain. This study aims to investigate the outcomes of IABO in PP patients.

Methods: We retrospectively reviewed the clinical data of PP cases from six tertiary centers in China between January 2011 and December 2015. PP cases with/without the use of IABO were analyzed. Propensity score matching analysis was performed to reduce the effect of selection bias. Postpartum hemorrhage (PPH) and the rate of hysterectomy, as well as neonatal outcomes, were analyzed.

Results: One hundred and thirty-two matched pairs of patients were included in the final analysis. Compared with the control group, maternal outcomes, including PPH (68.9% vs. 87.9%, ch2 = 13.984, P < 0.001), hysterectomy (8.3% vs. 65.2%, ch2 = 91.672, P < 0.001), and repeated surgery (1.5% vs. 12.1%, ch2 = 11.686, P = 0.001) were significantly reduced in the IABO group. For neonatal outcomes, Apgar scores at 1 minute (8.67 ± 1.79 vs. 8.54 ± 1.68, t = −0.638, P = 0.947) and 5 minutes (9.43 ± 1.55 vs. 9.53 ± 1.26, t = 0.566, P = 0.293) were not significantly different between the two groups.

Conclusions: IABO can significantly reduce blood loss, hysterectomies, and repeated surgeries. This procedure has not shown harmful effects on neonatal outcomes.

Keywords: Placenta accreta spectrum disorders; Placenta percreta; Conservative management; Intra-abdominal aortic balloon occlusion; Propensity score matching

Introduction

Placenta accreta spectrum (PAS) disorders include a spectrum of diseases in which placenta is pathologically adherent to or invade the myometrium. The incidence of PAS disorders has been increasing considerably in the past decades from approximately 0.005% to 0.01%.[1] It may be due to the cesarean delivery rate increase in recent years since previous cesarean delivery is one of the most common risk factors for PAS disorders.[2,3]

In severe cases, such as placenta percreta (PP), the placenta invades through uterine serosa or even into adjacent organs. Massive bleeding is the main concern for the management of PP. For prophylactic interventions, arterial balloon occlusion is one of the most common methods for pelvic devascularization in the past few decades. Nevertheless, the efficacy of intra-abdominal aortic balloon occlusion (IABO) is still uncertain because of lacking larger studies. Thus, we retrospectively analyzed the cases with IABO to investigate the maternal and neonatal outcomes in PP patients.
Methods

Ethical approval

This study was approved by the Ethics Committee of Peking University First Hospital (No. 2013[572]). Informed consent was signed by patients receiving IABO.

Participants

We retrospectively reviewed data from the PAS network consisting of six tertiary centers that performed IABO in China between January 2011 and December 2015. The tertiary centers included the First Affiliated Hospital of Zhengzhou University, Qilu Hospital of Shandong University, Xiangya Hospital Central South University, the Second Xiangya Hospital of Central South University, the Third Affiliated Hospital of Guangzhou Medical University, and Beijing Obstetrics and Gynecology Hospital. Three hundred and twenty one PP cases with/without the use of IABO were confirmed among 537,847 deliveries. All of the centers had experienced multidisciplinary teams composed of maternal-fetal medicine specialists, interventional radiologists, anesthetists, experienced surgeons (gynecologic, urologic, general, and vascular), neonatologists, and intensive care physicians for PAS disorders. Women between 18 and 45 years old and diagnosed with PP were eligible for inclusion. The diagnosis was confirmed by surgical findings and/or histopathologic findings. Patients treated with both IABO and uterine artery embolization, with severe complications (cardiovascular disease, autoimmune disease, malignant tumor, etc.) and those without informed consent were excluded. All the prenatal ultrasound was performed by experienced ultrasound operators or maternal-fetal medicine specialists. The descriptions of ultrasound signs for PAS disorders were standardized in the questionnaire. PAS diagnosis was confirmed in the procedure. Clinical information regarding demographic information, previous obstetric and gynecological histories, current pregnancy and obstetric management, and maternal and neonatal outcomes was collected.

Management of the patients

For women who strongly wish to preserve the uterus, conservative management of PAS disorders should be considered as an option. In our study, scheduled cesarean delivery was planned for these patients. Other surgical techniques were also applied during surgeries, such as tourniquet compression, folding suture, vessel ligation, and uterine packing measures.

IABO procedure

In our study, cases were operated on with abdominal aorta occlusion. After local anesthesia by 2% lidocaine and disinfection of the right groin, the right femoral artery was punctured. After successful vascular catheter placement and replacement, a compliant balloon was deflated, and the proper occlusion place was the infrarenal abdominal aorta above the aortic bifurcation. The catheter was then safely fixed to the skin, and in case of shift and dislodging of the catheter, the length of the catheter outside the body was documented precisely.

Maternal and neonatal outcomes

Postpartum hemorrhage (PPH) was defined as the amount of blood loss greater than 1000 mL within 24 hours after delivery. Blood loss was estimated quantitatively through volume method and/or weighing method. The amount of PPH and the rate of hysterectomy were the primary outcomes. The rate of repeated surgery and neonatal Apgar scores were the secondary outcomes.

Statistical analysis

Statistical analysis was conducted with SPSS 23.0 (SPSS, Chicago, IL, USA). The independent samples t test was used to compare the mean values of continuous variables with normal distribution between the two groups. The Chi-squared test was used to compare categorical variables between the two groups. A P value of <0.05 was considered statistically significant. And then we performed propensity score matching (PSM) between the two groups to reduce the effect of selection bias. Propensity scores were estimated using a logistic regression model. Previous cesarean section history and placenta previa were widely recognized as the most important risk factors for PAS disorders. Taken the inevitable differences of management for PAS disorders in the tertiary centers, we finally set the following characteristics as matching covariates: medical center, number of previous cesarean delivery, and type of placenta previa. The matched data sets were thoroughly checked for balance in terms of an absolute standardized difference near 0 and variance ratios near 1.

Results

A total of 321 patients with PP were enrolled in this study. One hundred and thirty two PP cases with IABO were in the study group whereas 189 PP cases without IABO were in the control group [Figure 1]. Demographic and obstetric characteristics were presented in Table 1. PSM was performed considering the possibilities of selection bias.

After PSM, there were 132 matched pairs of patients between the two groups [Table 1]. Among the 132 matched pairs of cases, the demographic information and obstetric details showed no significant difference (all P > 0.05).

Table 2 showed the maternal and neonatal outcomes of the two groups. For maternal outcomes, significantly reduced rates of PPH, hysterectomy, and repeated surgery were found in the IABO group. In the IABO group, there was 68.9% (91/132) of PPH, whereas the rate was 87.9% (116/132) in the control group (χ² = 13.984, P < 0.001). Hysterectomy was performed in 8.3% (11/132) of cases in the IABO group, and 65.2% (86/132) of cases in the control group (χ² = 91.672, P < 0.001). Repeated surgery contained dilation and curettage and laparotomy. Repeated surgery was performed in 1.5% (2/132) of cases in the IABO group and 12.1% (16/132) of cases in the control group (χ² = 11.686, P < 0.001). For neonatal outcomes, Apgar scores at 1 minute were not significantly different between the two groups (IABO vs. control group: 8.67 ± 1.79 vs. 8.53 ± 1.68, t = −0.638, P = 0.947). Apgar
scores at 5 minutes were not significantly different between the two groups (IABO vs. control group: 9.43 ± 1.55 vs. 9.53 ± 1.26, \( t = 0.566, P = 0.293 \)). Birth weight was not significantly different between the two groups (IABO vs. control group: 2693.98 ± 604.64 g vs. 2699.13 ± 655.38 g, \( t = 0.066, P = 0.568 \)).

**Discussion**

PAS disorders are considered to be one of the most life-threatening diseases that occur during pregnancy. Previously, we reported the rising incidence of PAS disorders in China\(^6\) and the high cesarean delivery rates might be the explanation for the rising trend, especially after the universal two-child policy release.\(^7\)

Planned preterm cesarean hysterectomy is recommended as the standard management by the guidelines published by the American College of Obstetrics and Gynecology, International Federation of Gynecology and Obstetrics, Royal College of Obstetricians and Gynecologists, and Society of Obstetricians and Gynecologists of Canada.\(^8-11\) During the past years, uterus preserving strategy has been gradually chosen by physicians and patients who wish to maintain fertility in China. IABO is one of the most widely applied devascularization methods. Several studies showed that IABO could reduce blood loss in cases of PAS disorders and the rate of hysterectomy.\(^12-17\) Nevertheless, there is a lack of a larger study to confirm the efficacy and safety of IABO. In our study, for women who strongly wish to preserve the uterus, conservative management was considered as an option. In this study, we mainly focused on PPH and the rate of hysterectomy. Our study showed the IABO could significantly decrease blood loss and the rate of hysterectomy. Regarding neonatal outcomes, there was no significant difference in the neonatal Apgar scores. Research showed that the mean radiation exposure dose of IABO was 4.20 ± 1.49 mGy.\(^18\) According to International Commission on Radiological Protection, radiation exposure <100 mGy did not cause adverse effects on the fetus. The radiation exposure dose of IABO was much <100 mGy and was safe for the fetus.\(^19\)
The balloon catheters can be placed into several sites including the abdominal aorta, common iliac, internal iliac, uterine artery, and so on. Recently, a study showed that internal iliac balloon occlusion did not reduce blood transfusion in women with PAS disorders. In 2017, a study from China showed IABO performed better than internal iliac occlusion in reducing blood loss, blood transfusion, balloon insertion time, fluoroscopy time, and fetal radiation dose. It might result from the rich pelvic collateral circulations developed in patients with PAS disorders. Compared with internal iliac occlusion, IABO can block the blood flow at the level of infrarenal. Therefore, IABO may block more pelvic collaterals and prevent severe bleeding more sufficiently than internal iliac balloon occlusion.

Occlusion balloon catheters contribute to a clear operation field and the reduction of intraoperative blood loss and blood transfusion. For patients with high risk, like PP, and patients having strong demand to maintain fertility, IABO could be considered.

A meta-analysis involving 11 clinical studies showed that IABO in patients with PAS disorders was safe and effective. However, cases about severe complications such as arterial damage, infection, and thrombosis were

Table 1: Demographic and obstetric characteristics of cases of placenta percreta with/without the use of IABO before and after PSM.

| Characteristics | IABO (n = 132) | Control (n = 189) | Statistics | P values | IABO (n = 132) | Control (n = 132) | Statistics | P values |
|-----------------|----------------|------------------|------------|----------|----------------|------------------|------------|----------|
| Age (years)     | 32 ± 5         | 34 ± 4           | 3.663\*    | 0.217    | 32 ± 5         | 34 ± 4           | 3.322\*    | 0.247    |
| Gestational week (weeks) | 35.6 ± 2.4    | 35.2 ± 2.6     | -1.323\*  | 0.408    | 35.6 ± 2.4    | 35.3 ± 2.6     | -1.069\*   | 0.442    |
| Number of pregnancies | 3 (1–8)       | 3 (1–9)         | -0.420\†  | 0.675    | 3 (1–8)       | 3 (1–9)         | -0.921\†   | 0.357    |
| Parity          | 1 (1–4)        | 1 (0–4)         | -0.397\†  | 0.692    | 1 (1–4)       | 1 (0–4)         | -0.087\†   | 0.930    |
| Previous cesarean delivery | 0             | 6 (4.5)         | 3.475\‡   | 0.324    | 6 (4.5)       | 7 (5.3)         | -0.525\†   | 0.956    |
| 1               | 79 (59.8)      | 119 (63.0)      | 1.79      | 0.408    | 79 (59.8)     | 82 (62.1)       | 0.103      | 0.827    |
| 2               | 45 (34.1)      | 50 (26.5)       | 0.646     | 0.504    | 45 (34.1)     | 41 (31.1)       | 0.048\‡    | 0.103    |
| ≥3              | 2 (1.5)        | 5 (2.6)         | 0.001     | 0.217    | 2 (1.5)       | 2 (1.5)         | 0.001      | 0.217    |
| Comorbidities   |               |                  |           |          |               |                  |            |          |
| GH              | 1 (0.8)        | 4 (2.1)         | -0.399    | 0.001    | 1 (0.8)       | 2 (1.5)         | -0.399     | 0.001    |
| GDM             | 11 (8.3)       | 19 (10.1)       | 0.446\‡   | 0.504    | 11 (8.3)      | 12 (9.1)        | 0.004\‡    | 0.087    |
| Placenta previa | 132 (100.0)    | 172 (91.0)      | 12.537\‡  | <0.001   | 132 (100.0)   | 129 (97.7)      | 3.034\‡    | 0.333    |
| Marginal        | 6 (4.5)        | 21 (11.1)       | 0.446     | 0.638\†  | 6 (4.5)       | 4 (3.0)         | 0.096      | 0.666    |
| Partial         | 2 (1.5)        | 7 (3.7)         | -0.638\†  | 0.947    | 2 (1.5)       | 2 (1.5)         | 0.001      | 0.001    |
| Complete        | 124 (93.9)     | 144 (76.2)      | 0.947     | 0.333    | 124 (93.9)    | 123 (93.2)      | 0.001      | 0.001    |

Data are presented as mean ± standard deviation, median (minimum–maximum) or n (%). * t values. † Z values. ‡ χ² values. GDM: Gestational diabetes mellitus; GH: Gestational hypertension; IABO: Intra-abdominal aortic balloon occlusion; PSM: Propensity score matching.

Table 2: Maternal and neonatal outcomes of cases of placenta percreta with/without the use of IABO.

| Characteristics | IABO (n = 132) | Control (n = 132) | Statistics | P values |
|-----------------|----------------|------------------|------------|----------|
| PPH             | 91 (68.9)      | 116 (87.9)       | 13.984\*   | <0.001   |
| Blood loss (mL) | 1804.96 ± 1680.45 | 3017.75 ± 1959.84 | 5.397\†    | 0.006    |
| Hysterectomy    | 11 (8.3)       | 86 (65.2)        | 91.672\*   | <0.001   |
| Repeated surgery| 2 (1.5)        | 16 (12.1)        | 11.686\*   | 0.001    |
| Apgar 1 min     | 8.67 ± 1.79    | 8.53 ± 1.68      | -0.638\†   | 0.947    |
| <4              | 5 (3.8)        | 4 (3.0)          | 0          | 1        |
| 4–7             | 15 (11.4)      | 20 (15.2)        | 0.001      | 0.001    |
| ≥8              | 112 (84.8)     | 108 (81.8)       | 0.947      | 0.333    |
| Apgar 5 min     | 9.43 ± 1.35    | 9.53 ± 1.26      | 0.566\†    | 0.293    |
| <4              | 3 (2.3)        | 2 (1.5)          | 0.001      | 0.001    |
| 4–7             | 4 (3.0)        | 3 (2.3)          | 0.001      | 0.001    |
| ≥8              | 125 (94.7)     | 127 (96.2)       | 0.001      | 0.001    |
| Birth weight (g) | 2693.98 ± 604.64 | 2699.13 ± 655.38 | 0.066\†    | 0.568    |

Data are presented as mean ± standard deviation, or n (%). PPH is defined as the loss of >1000 mL (cesarean delivery) of blood within the first 24 hours following childbirth. * χ² values. † t values. Repeated surgery: including dilation and curettage and laparotomy. IABO: Intra-abdominal aortic balloon occlusion; PPH: Postpartum hemorrhage.
reported as well. Carnevale et al [24] described two cases with thrombosis after a quite long operation time who underwent embolectomy after the obstetrics procedure. In 2011, Bishop et al [25] reported a 36-year-old female with PP who ended up with bilateral false aneurysm and right side arterial embolism, leading to unilateral aneurysm rupture, severe hypovolemic shock, and right lower limb ischemia. Gagnon et al [26] in 2013 also reported one case treated with balloon occlusion, who ended up with artery rupture, maternal hemorrhage, and neonatal complication.

To reduce the complications, the procedure should be performed by experienced interventional radiologists. Avoiding balloon catheter overinflation may reduce the incidence of arterial damage. Appropriate occlusion time intraoperatively and early postoperative anticoagulation therapy may prevent thrombosis. In the current study, IABO-related complications are not included in the analysis. Further prospective study will collect more information about the complications, providing an overall assessment of IABO’s risk-benefit ratio.

In conclusion, IABO can significantly lower blood loss and the rate of hysterectomy and repeated surgery. Conservative management with IABO can be an effective strategy for patients diagnosed with PP. This procedure has not shown harmful effects on neonatal outcomes.

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