

A prospective observational study evaluating the efficacy of prophylactic internal iliac artery balloon catheterization in the management of placenta previa–accreta

A STROBE compliant article

Yao Fan, MM^a, Xun Gong, MD^a, Nan Wang, MD^b, Ketao Mu, MD^b, Ling Feng, MD^a, Fuyuan Qiao, MD^a, Suhua Chen, MD^a, Wanjiang Zeng, MD^a, Haiyi Liu, MD^b, Yuanyuan Wu, MD^a, Qiong Zhou, MD^a, Yuan Tian, MD^a, Qiang Li, MD^a, Meitao Yang, MM^a, Fanfan Li, MD^a, Mengzhou He, MD^a, Rajluxmee Beejadhursing, MM^a, Dongrui Deng, MD^{a,*}

Abstract

We studied the efficacy of prophylactic internal iliac artery balloon catheterization for managing severe hemorrhage caused by pernicious placenta previa.

This prospective observational study was conducted in Tongji Hospital, Wuhan, China. One hundred sixty-three women past 32-week's gestation with placenta previa–accreta were recruited and managed. Women in the balloon group accepted prophylactic internal iliac artery balloon catheterization before scheduled caesarean delivery and controls had a conventional caesarean delivery. Intraoperative hemorrhage, transfusion volume, radiation dose, exposure time, complications, and neonatal outcomes were discussed.

Significant differences were detected in estimated blood loss (1236.0 mL vs 1694.0 mL, $P = .01$), calculated blood loss (CBL) (813.8 mL vs 1395.0 mL, $P < .001$), CBL of placenta located anteriorly (650.5 mL vs 1196.0 mL, $P = .03$), and anterioposteriorly (928.3 mL vs 1680.0 mL, $P = .02$). Prophylactic balloon catheterization could reduce intraoperative red blood cell transfusion (728.0 mL vs 1205.0 mL, $P = .01$) and lessen usage of perioperative hemostatic methods. The incidence of hysterectomy was lower in balloon group. Mean radiation dose was 29.2 mGy and mean exposure time was 92.2 seconds. Neonatal outcomes and follow-up data did not have significant difference.

Prophylactic internal iliac artery balloon catheterization is an effective method for managing severe hemorrhage caused by placenta previa–accreta as it reduced intraoperative blood loss, lessened perioperative hemostatic measures and intraoperative red cell transfusions, and reduce hysterectomies.

Abbreviations: BC = balloon catheterization, CBL = calculated blood loss, CS = cesarean section, EBL = estimated blood loss, PIIABC = prophylactic internal iliac artery balloon catheterization, RBC = red blood cell.

Keywords: balloon catheterization, cesarean section, internal iliac artery, placenta accreta, placenta previa, postpartum hemorrhage

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YF and XG contributed equally to this work.

The authors have no conflicts of interest to disclose.

^a Department of Gynecology and Obstetrics, ^b Department of Interventional Radiology, Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, Hubei, People's Republic of China.

* Correspondence: Dongrui Deng, Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, Hubei, People's Republic of China (e-mail: dr.deng@tjh.tjmu.edu.cn, dongruideng@hotmail.com).

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1. Introduction

Placenta previa and accreta are 2 forms of abnormal placentation and are accountable for high risk of maternal death worldwide.^[1] Placenta accreta describes a situation where the placenta firmly adheres to the myometrium because of partial or total absence of the decidua basalis. Its variants includes accreta, increta, and percreta which are classified according to the depth of trophoblastic invasion.^[2,3]

Placenta previa and accreta are 2 major reasons for postpartum hemorrhage, which can cause disseminated intravascular coagulation, multiorgan dysfunction syndrome, and other adverse perinatal outcomes.^[4,5] Placenta previa is responsible for ~30.4% of maternal deaths^[6] and they remain a challenge in obstetric practice.^[7] For pregnant women with placenta previa, the odds of placenta accreta are 11% for one prior cesarean section (CS) and 67% for a fifth or more repeated CSs.^[8]

Placental attachment locations uniquely influence perinatal outcomes^[9] and delivery strategies.^[10] Anterior placentation with placenta previa is associated with altered uterine contractil-

ity that leads to intraoperative hemorrhage during vaginal birth.^[9,11] Moreover, studies suggest that a transecting incision can necessitate intraoperative maternal blood transfusion, which is usually adopted intraoperatively for placenta previa with anterior placentation.^[12]

Placenta previa is usually accompanied with accreta or its variants. Conventional management of this situation was cesarean hysterectomy with the placenta left in situ.^[13] However, there is a desire to preserve the uterus and fertility, so alternative to hysterectomy are needed. Presently, attempts to avoid hysterectomy include reducing intraoperative hemorrhage such as uterine compression sutures, intrauterine balloon tamponade, pelvic artery ligation, and spiral suturing of the lower uterine segment. Intrauterine balloon tamponade may increase CS scar dehiscence,^[14] uterine rupture, and infection.^[15] Combined with compression sutures, it may induce uterine necrosis.^[16] Best practices for these methods involve skilled surgeons and obstetricians who have detailed knowledge of pelvic artery anatomy that factors in vascular variations or distortions.^[17] Uterine compression sutures were more likely to induce synechiae, persistent vaginal discharge, pyometra, endometriosis, and ischemic complications.^[18–20] Furthermore, pelvic artery ligation may preclude subsequent embolization of the uterine artery when performed on an internal iliac artery,^[21] and its success was only about 42% due to rich collateral vessels.^[22] Its effect on fertility and pregnancy outcomes is unclear and controversial, so it is considered when other measures have failed.^[20,21]

Since the first case of clinical use of aortic balloon catheter was reported in 1954 in Korea,^[23] the intravascular balloon catheter technique has been widely used to manage uncontrolled hemorrhage.^[24] Recently, obstetrics has partnered with interventional radiology to use artery embolization and balloon catheter occlusion. The reversible nature of prophylactic arterial occlusion makes it useful for reducing intraoperative blood loss. It requires multidisciplinary cooperation among obstetricians,

interventional radiologists, appropriate blood banking facilities, and the availability of gynecological and surgical experts should the need arise.^[25] Previous studies suggest that prophylactic balloon catheterization (BC) of different target arteries offered uncertain efficacy.^[7,26,27]

Target artery catheterization is controversial but BC of the internal iliac artery is less likely to induce complications such as limb and pelvic organ ischemia compared to aortic or common iliac artery BC.^[28] The reversible nature of this technique lessens the probability of affecting a future uterine blood supply and has advantages of controllable temporary uterine blood flow occlusion.

In our study, balloon-tipped catheters were inserted into target arteries before scheduled CS and catheters were inflated to control intraoperative hemorrhage. Primary outcomes included intraoperative estimated blood loss (EBL), calculated blood loss (CBL), and red blood cell (RBC) transfusion. Radiation dose, exposure time, surgical duration, procedure complications, and neonatal outcomes were analyzed as secondary outcomes.

2. Methods

This study was conducted in the Department of Obstetrics and Gynecology, Tongji Hospital, Wuhan, Hubei, People's Republic of China, which is a referral medical center of central China.

This study was supported by the National Science and Technology Pillar program of China during the Twelfth Five-Year Plan Period and the Fundamental Research Funds for the Central Universities. The funds provided only financial supports and played no role in the procedure of the study. The protocol of this study was approved by the ethical committee of Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology (IRB ID: TJ-C20150516).

Between June 2015 and January 2017, 182 women were eligible for this study, and 163 were included (Fig. 1). Women were recruited if there were sonographic or magnetic resonance

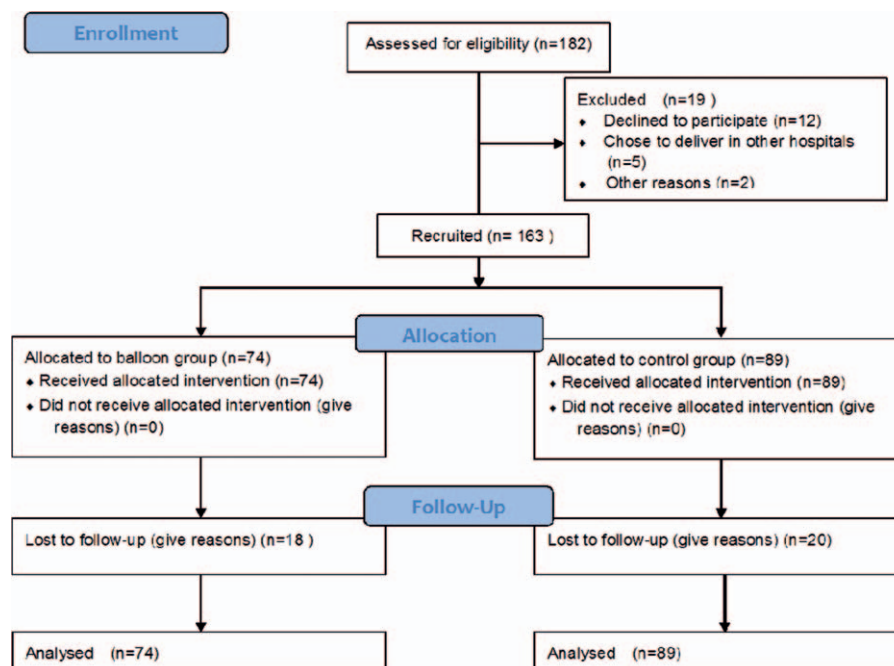


Figure 1. Participant flowchart.

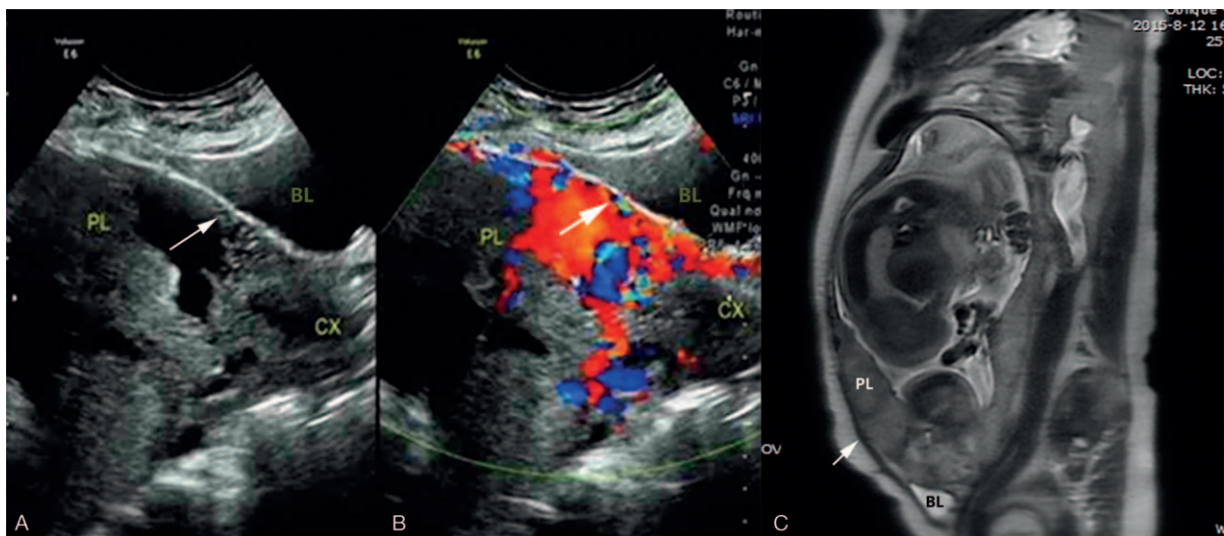


Figure 2. (A and B) Arrow in color Doppler images indicates evidence of placenta accreta (hypervascularity of uteroplacental interface). (C) MRI shows placenta accreta in the lower uterine segment (arrow). BL=bladder, CX=cervix, PL=placenta.

imaging evidence of placenta previa and accreta. Those with a bleeding disorder or who underwent emergency CS or delivered before 32-week’s gestation were excluded. All the women in this study were full informed of the benefits and complications of prophylactic internal iliac artery balloon catheterization (PIIABC) by their doctors, and assigned to either balloon (n=74) or control groups (n=89) based on their willingness for PIIABC. Signed consents were obtained irrespective of treatment approach.

Because participants and doctors were aware of the assignment, the study was not double-blind so the data recorder and analyst were blinded to treatment groups to remove bias.

Patient data were recorded during the study, including maternal characteristics, sonographic or MRI evidence (Fig. 2), intraoperative blood loss, and neonatal information. Fluoroscopy time, radiation dose, and perinatal complications were also recorded and discussed.

About 1 hour before the scheduled CS, the balloon group underwent PIIABC with interventional radiology preoperatively. During the conventional catheterization procedure, both femoral arteries were punctured using a Seldinger technique under local anesthesia and a 6-French vascular sheath (Cook, Bloomington, IN) was inserted. Then a 0.035-in. guidewire (Cook) was inserted into the vascular sheath and under fluoroscopy guidance, a cobra-shaped catheter (Cook) was inserted into the contralateral internal iliac artery. Contrast agent was injected intravascularly to confirm sheath placement and internal iliac artery caliber was obtained via angiography, facilitating catheter size selection. Then, the 0.035-in. guidewire (Cook) was replaced with an exchange guidewire (Cook) and the cobra-shaped catheter was removed. After that, an appropriate balloon catheter was inserted into the contralateral internal iliac artery and the vascular sheath was removed. Balloon catheters on both sides were verified with fluoroscopy to confirm placement (Fig. 3), and then the

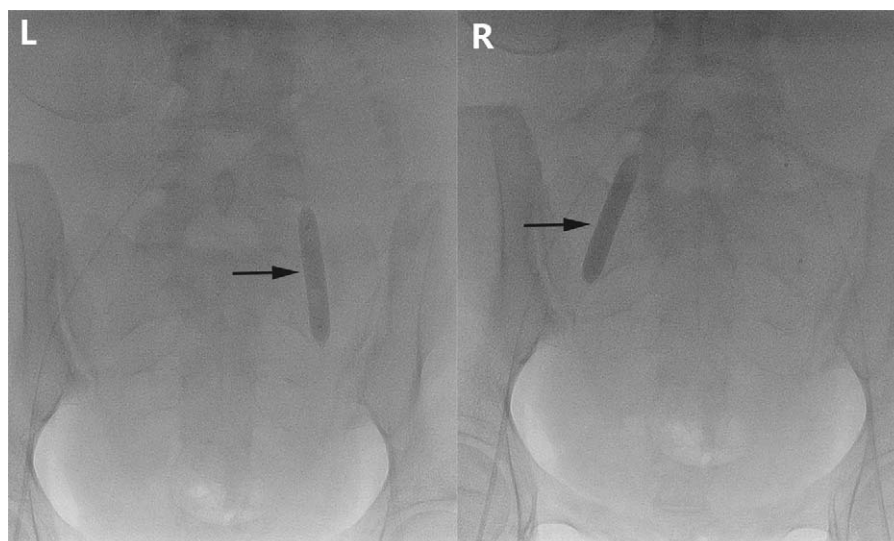


Figure 3. Intravascular catheterization procedure: balloon catheters positioned in the internal iliac arteries (arrows). L=left side, R=right side.

sheaths were attached upper thighs via medical dressings. The radiologist who performed PIIABC had modified catheterization technique after completing 24 cases. The 0.035-in. guidewire was omitted and the exchange guidewire was used inserted after the application of cobra-shaped catheter and fluoroscopy was only performed to confirm the placement of balloon catheters.

After catheterization, the mother was immediately transferred to the operating room for CS, during which balloons were inflated with normal saline as the uterine incision was made. After delivery, the placenta was delivered spontaneously or by cord traction. Once hemostasis was achieved using uterotonic or surgical methods such as uterine compression suture, pelvic artery ligation, or intrauterine balloon tamponade, the balloons were deflated and the uterus was sutured. Catheter removal was done after surgery completion by the same radiologist. Puncture sites were sealed using a closure device. Controls were treated the same way except for PIIABC. Hemostatic uterotonic and surgical methods were used during CS as needed.

Arteria dorsalis pedis pulse, temperature, and color of lower limbs of balloon group subjects were recorded. Follow-up was in February 2017. Postdelivery data included maternal and neonatal complaints, duration of lochia, and first menstruation after delivery. Women who did not return for follow up were called on the phone.

Primary outcomes were EBL, CBL, and intraoperative RBC transfusion. Intraoperative EBL was assessed by combining the weight of compresses and blood volume collected via suction. To minimize bias caused by anthropic factors and amniotic fluid, we used an algorithm proposed by Salim et al.^[25] Women's body mass index (BMI), pre- and postoperative hematocrit and RBC volume transfused during CS were included in the algorithm. Assuming that blood volume remained unchanged in both pregnancy and just after delivery, the following formula was devised to calculate blood loss:

Calculated blood loss = blood volume (hematocrit preoperative – hematocrit postoperative) + mL of transfused RBCs.^[25]

Secondarily, we investigated outcomes including duration of surgery, crystalloid and colloidal solution given intraoperatively, other hemostatic methods used, radiation dose and exposure time for the balloon group and adverse maternal or neonatal effects observed. Differences in radiation dose and exposure time were compared for both techniques.

Study subjects were sorted in to anterior, posterior, and anteroposterior placenta subgroups according to the allocation of placental attachment reported by antenatal sonographic examinations. CBL for each matched subgroup was analyzed accordingly.

Sample size was determined by power analysis using preliminary data obtained in our trial with the following assumptions: to achieve 80% power for a significance level of $\alpha=0.05$ with a confidence level of 95%, difference in EBL of 860 mL. Therefore, a minimum of 32 participants were need in each group. Categorical variables were presented as frequencies and percentage. Continuous variables were presented using mean \pm standard deviation, median, and range. The correlations between groups and categorical variables were examined using the χ^2 test. For continuous variables, Wilcoxon rank-sum test was used. The relative risk along with 95% confidence intervals were presented. Statistical analysis and data processing were performed using Prism 5.

3. Results

Since June 2015 to February 2017, 163 women with placenta previa and accreta were recruited, and the follow-up ended in

Table 1
Women's demographic and obstetric characteristics.

	Balloon group (n=74)	Control group (n=89)	P
Age, y	32.6 \pm 0.6	32.0 \pm 0.4	.45
BMI	26.9 \pm 0.4	27.2 \pm 0.5	.64
Gravida	3.6 \pm 0.2	3.6 \pm 0.2	.92
Para	1.1 \pm 0.7	.9 \pm 0.5	.10
Gestational age, wk	36.5 \pm 0.1	36.4 \pm 0.2	.65
GDM	8/74 (1.8%)	7/89 (7.9%)	.52
Hypertensive disorder	2/74 (2.7%)	9/89 (1.1%)	.06
Previous cesarean sections	0.9 \pm 0.1	0.9 \pm 0.1	.86
Region of placental attachment			
Anterior placentation	20	28	.38
Posterior placentation	18	20	.08
Anteroposterior placentation	36	41	.11

BMI = body mass index, GDM = gestational diabetes mellitus.
Prior uterine operations include myomectomy, uterine curettage, hysteroscopy, etc.

March 2017 (Fig. 1). Seventy-four cases underwent PIIABC and CS (Balloon group) and the remaining 89 cases underwent conventional CS (Control group). Demographic and obstetrical characteristics of women from 2 groups presented no statistical differences (Table 1).

Table 2 shows intraoperative data. Significant differences were observed in EBL ($P=.01$), CBL ($P=.02$), intraoperatively transfused RBC ($P=.02$), and the number of women transfused with any blood product ($P=.02$). CBL estimation was modified to adjust for possible anthropic errors and amniotic fluid to EBL. EBL was not statistically different, but mean EBL in the balloon group was lower than controls.

Figure 4 shows that a prophylactic balloon catheter reduced intraoperative RBC transfusion. Intraoperative plasma or fluid transfusions and surgery duration did not differ statistically

Table 2
Intraoperative data.

	Balloon group (n=74)	Control group (n=89)	P
RBC transfused, mL*	728.0 \pm 113.6	1205.0 \pm 138.7	.01*
RBC transfusion rate*	40/74 (54.1%)	68/89 (76.4%)	.01*
FFP transfused, mL	180.3 \pm 54.2	163.5 \pm 35.0	.54
FFP transfusion rate	12/74 (19.3%)	23/89 (36.8%)	.13
Multiple types of blood products* transfusion rate	12/74 (19.3%)	23/89 (36.8%)	.13
Any transfused blood products intraoperation	40/74 (54.1%)	68/89 (76.4%)	.01*
Colloidal fluid transfused, mL	756.8 \pm 77.7	921.1 \pm 96.8	.18
Crystalloid transfused, mL	1616.0 \pm 98.6	1637.0 \pm 101.4	.88
Total transfused fluid, mL	2441.0 \pm 161.1	2558.0 \pm 165.1	.62
EBL, mL	1236.0 \pm 138.2	1694.0 \pm 144.3	.01*
CBL, mL	813.8 \pm 107.9	1395.0 \pm 143.6	<.001*
Uterine compression suture	73/74 (98.6%)	63/89 (73.7%)	.11
Uterine artery ligation*	22/74 (29.3%)	35/89 (39.3%)	.02*
Intrauterine balloon	5/74 (6.8%)	6/89 (6.7%)	.99
Uterine artery embolization	6/74 (8.1%)	5/89 (5.6%)	.53
Hysterectomy	2/74 (2.7%)	5/89 (5.6%)	.36
2 hemostatic methods [†] or more	20/74 (27.0%)	35/89 (39.3%)	.09
Operation time, min	111.2 \pm 5.2	121.4 \pm 8.5	.29

CBL = calculated blood loss, EBL = estimated blood loss, FFP = fresh frozen plasma, RBC = red blood cell.
* Statistical difference.
[†] Hemostatic methods used in this study include uterine compression suture, pelvic artery ligation, uterine artery embolization.

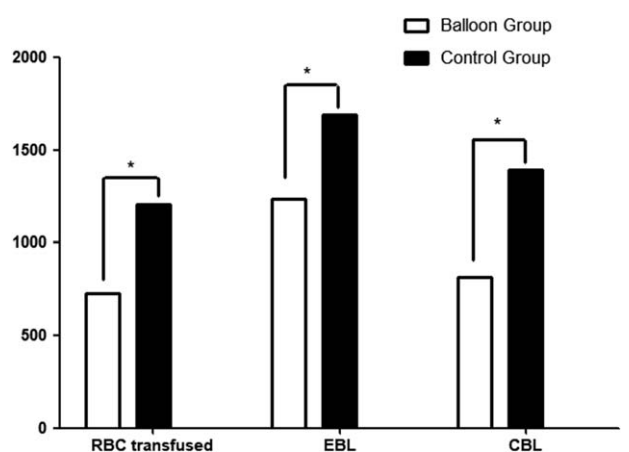


Figure 4. RBC transfused, EBL, and CBL of Balloon group and Control group.

between groups but women receiving plasma or multiple blood products intraoperatively was reduced in the balloon group. No differences in hemostatic methods were noted including uterine compression sutures, pelvic arterial ligation, intrauterine balloon tamponade, uterine artery embolization, or the use of 2 or more hemostatic methods.

Women were sorted into three subgroups (anterior, posterior, and anteroposterior placenta) according to the region of placental attachment and CBL for subgroups were analyzed. Data appear in Table 3. In the balloon group 24 women underwent conventional catheterization and 32 women underwent modified catheterization with a 6-French vascular sheath and less fluoroscopy. Table 4 shows data for radiation doses between groups (mean dose 29.2mGy; mean exposure 92.2 seconds).

Neonatal outcomes were also not significantly different (Table 5). Nine balloon group and 11 control group cases were lost to follow-up and of those who did follow-up, no complaints were noted 42 days after delivery (Table 6). No statistical differences in lochia duration and resumption of menses postdelivery between 2 groups and these data appear in Table 3.

A woman in the balloon group complained of lower limb pain on the second day after delivery. Ultrasound and computed tomography angiography revealed thrombosis in the left external iliac artery and right side femoral artery. Symptoms resolved after 2 weeks low molecular weight heparin (4.25 ku daily). She was discharged 18 days postdelivery, and no other complaints were reported at follow-up.

4. Discussion

Placenta previa and accreta are associated with numerous adverse perinatal outcomes including postpartum hemorrhage and even perinatal death.^[1] Hemostatic surgical methods and uterotonics

Table 4

Radiation dose and exposure time.

	Conventional catheterization (n=30)	Modified catheterization (n=44)	P
Exposure time, s*	187.6 ± 13.2	35.0 ± 5.4	<.001*
Radiation dose, mGy*	61.0 ± 3.8	10.2 ± 1.5	<.001*

Table 5

Neonatal outcomes.

	Balloon group (n=74)	Control group (n=89)	P
Gender, M/F	46/28	46/43	.18
Weight, g	2891 ± 69	2879 ± 52	.89
Apgar-5 min	7.4 ± .2	7.1 ± .2	.38
Apgar-10 min	8.6 ± .1	8.5 ± .2	.80
NICU	6/74 (1.5%)	5/89 (8.8%)	.75

NICU = neonatal intensive care unit.

Table 6

Postdelivery follow-up.

	Balloon group (n=56)	Control group (n=69)	P
Duration of lochia, d	37.6 ± 4.0	3.0 ± 3.1	.14
First menses postdelivery, d	123.1 ± 14.4	135.5 ± 14.3	.55

are routinely used to manage intraoperative hemorrhage and preserve the uterus. Hysterectomy is the ultimate recourse when all other methods fail in controlling hemorrhage. Prophylactic BC is a proposed approach in reducing intraoperative hemorrhage regardless of surgical methods.

Traditional methods evaluating intraoperative blood loss are usually inaccurate.^[29] They include visual inspection and other indirect assessment methods involving hematocrit and hemoglobin. For our study, we adopted CBL to adjust EBL which could be affected by anthropic factors and amniotic fluid. As our results present, the mean CBL is less than mean EBL in both study groups. The discrepancy between CBL and EBL might be on the account of the addition of amniotic fluid collected in vacuum suction.

Prophylactic BC is controversial and the literature reports different efficacies. A retrospective study of balloon catheters application for the abdominal aorta had postoperative complications 4.4% of the time, including arterial thrombosis and femoral nerve ischemic injury.^[27] A Japanese study supported that BC for the common iliac artery was more effective than for the internal iliac artery due to the rich collateral uterine blood supply.^[28] However, Mok et al^[22] stated that PIIABC could reduce intraoperative blood loss and improve the operating field due to decreased pulse pressure distal to the occlusion site. We

Table 3

Intraoperative data of patients with different placental location.

	Balloon group (n=74)	Control group (n=89)	P
CBL in patient with anterior placenta,* mL	650.5 ± 163.0 (n=17)	1196.0 ± 167.5 (n=22)	.03*
CBL in patient with posterior placenta, mL	766.4 ± 197.0 (n=14)	1090.0 ± 262.0 (n=17)	.34
CBL in patient with anteroposterior placenta,* mL	928.3 ± 177.8 (n=35)	1680.0 ± 256.4 (n=33)	.02*

CBL = calculated blood loss.

chose the internal iliac artery due to the unlikelihood of vascular complications such as ischemia and thrombosis.^[28]

There is no universal standard for intraoperative timing of inflation and deflation of balloons but this timing is of great significance for managing placenta previa and accreta, because uncontrollable hemorrhage can occur seconds after uterine incision. Also, the longer the balloons remain inflated, the more likely the complications related to BC. A 2015 study in which balloons were inflated after fetal delivery and deflated 12 hours later reported no benefits of PIIABC for reducing intraoperative bleeding and BC-associated complications were noted in 15.4% of cases.^[25] To minimize hazards, balloon catheters remain inflated as the uterine incision was being made until hemostasis was achieved.

In this study, women from the balloon group had less intraoperative blood loss compared to controls. This would also reduce the uterine blood supply and keep the surgical field clear. Traditional methods for evaluating intraoperative blood loss are not accurate,^[29] and include human error when visually recording data and uncertain assessment methods involving hematocrit and hemoglobin. We used CBL to adjust EBL that could be influenced by anthropic factors and amniotic fluid volumes. Data show that mean CBL was less than mean EBL for both study groups, likely due to amniotic fluid collected by vacuum suction.

PIIABC can reduce transfusions for women with PPP, without causing severe adverse maternal and fetal complications or prolonging surgery. Although controls had more hysterectomies than those in the balloon group, these differences were not significant.

The BC method has been described but the localization of placental attachment is seldom mentioned. The literature suggests that anterior placentation with placenta previa with severe intraoperative bleeding and uterine atony.^[9,11] Moreover, a transecting incision, which is used for placenta previa with anterior placentation can warrant to intraoperative maternal blood transfusion.^[12] We found statistical differences in CBL between matched anterior and anteroposterior placenta subgroups, suggesting that PIIABC may benefit women with anterior or anteroposterior placentas as the former is believed to be a risk factor for massive hemorrhage during CS. This evidence may help clinical decision-making regarding PIIABC but we found no difference in posterior placenta subgroups although the mean CBL from the balloon treatment group was less than in controls. Our sample sizes may have been too small to reveal significant differences that larger samples would show.

The greatest complication of PIIABC is thrombosis. Of all cases in our study, one developed arterial thrombosis after interventional surgery and the mother may have been in a preexisting hypercoagulable state—her BMI before CS was 33.6 (18.5–24.9), and her preoperative D-dimer test was 1.27 g/ μ g/mL FEU (normal \leq 0.5 g/ μ g/mL FEU).^[30] Wang et al.^[31] considered obesity a risk factor for thromboembolism in women with atrial fibrillation. After anticoagulation therapy, symptoms improved and no additional complaints were recorded at follow-up. Arterial thrombosis after removal of the balloon catheter has been reported by Ozkan^[32] so we may assume that arterial injury produced by intravascular radiology may cause thrombus formation.^[33] In our study, intravascular balloon catheter sizes were chosen according to each woman's arterial caliber, and catheters remained in the internal iliac artery as briefly as possible to minimize damage.

Radiation exposure can cause adverse pregnancy outcomes including intrauterine growth restriction, prenatal death, small head size, mental retardation, organ malformation, and childhood cancer.^[34] Exposure to radiation is not an indication for gestational termination if the radiation dose is less than 100 mGy. Neither fetal anomalies nor pregnancy loss are associated with radiation less than 50 mGy.^[34] Malformation risks are significant when radiation exceeds 150 mGy.^[35] After performing 30 PIIABC procedures, the radiologist modified the catheterization procedure, replacing the 6-French vascular sheath for the 5-French cobra-shaped vascular sheath that was directly inserted without a guide wire to reduce fluoroscopic time and mean radiation dose and exposure time. The overall radiation dose of the balloon group was 30.0 mGy, well below 100 mGy. We observed no anomalies for neonates during follow-up.

This study is limited by including one center, but it is strong due to having the same multidisciplinary team to manage all women under the same management protocol. Ideally, this reduced potential operator-dependent bias.

5. Conclusion

Our study revealed that PIIABC can not only significantly reduce intraoperative blood loss for women with PPP, especially with an anterior or anteroposterior placenta, but also can lessen intraoperative RBC transfusion without serious adverse maternal or neonatal outcomes. Furthermore, the modified catheterization technique which was performed for 32 cases reduced exposure time and radiation dose, and subsequently reduced maternal and fetal hazards. More studies are required to address obstetrical interventional radiology.

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