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# A Participant-assigned Interventional Research of Precesarean Internal Iliac Artery Balloon Catheterization for Managing Intraoperative Hemorrhage of Placenta Previa and Placenta Accreta Spectrum Disorders After Cesarean Section*

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**Summary**: Placenta accreta spectrum disorder (PASD) and placenta previa (PP) are two of the most hideous obstetric complications which are usually associated with a history of cesarean section (CS). Moreover, women with PASD, PP and/or a cesarean scarred uterus are more likely to have adverse pregnancy outcomes, including blood transfusion, hysterectomy, pelvic organs damage, postpartum hemorrhage, disseminated intravascular coagulation, multi-organ dysfunction syndrome and even maternal or fetal death. This study aimed to investigate the efficacy of precesarean internal iliac artery balloon catheterization (BC) for managing severe hemorrhage caused by PASD and PP with a history of CS. This participant-assigned interventional study was conducted in Tongji Hospital. We recruited 128 women with suspected PASD, PP and a history of CS. Women in the BC group accepted precesarean BC of bilateral internal iliac arteries before the scheduled cesarean delivery. Women in the control group underwent a conventional cesarean delivery. Intraoperative hemorrhage, transfusion volume, radiation dose, exposure time, complications and neonatal outcomes were discussed. There were significant differences in calculated blood loss (CBL) between BC group and control group (1015.0±144.9 *vs.* 1467.0±171.0 mL, $P$=0.04). Precesarean BC could reduce intraoperative red blood cell (RBC) transfusion as compared with control group (799.5±136.1 *vs.* 1286.0±161.6 mL, $P$=0.02) and lessen the rate of using blood products (57.1% *vs.* 76.4%, $P$=0.02). The incidence of hysterectomy was also lower in BC group than in control group. Postpartum outcomes showed no significant differences between the two groups, except that postoperation hospitalization was longer in BC group than in control group (6.7±0.4 *vs.* 5.8±0.2 days, $P$=0.03). Precesarean BC of internal iliac artery is an effective method for managing severe hemorrhage caused by PASD and PP with a cesarean scarred uterus, as it could reduce intraoperative blood loss, lessen intraoperative RBC transfusions and potentially decrease hysterectomies.
**Key words**: nitrosamine; cotinine; urinary sodium excretion; nutrient intake; blood pressure

The term placenta accreta spectrum disorder (PASD) is used to describe the morbidly adherent placenta, which includes placenta accreta, increta and percreta. Excessive trophoblastic invasion and a deficiency of decidua may involve in the development of PASD[1]. PASD could impede placenta to separate from the uterus, and eventually cause massive obstetric hemorrhage[2–4]. Placenta previa (PP) is also a main reason of peripartum hemorrhage. Massive obstetric hemorrhage might lead to blood transfusion, disseminated intravascular coagulation, multi-organ dysfunction syndrome, surgical injury to pelvic organs or structures, adult respiratory distress syndrome, acute

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transfusion reaction, electrolyte imbalance and renal failure[5].

Cesarean section (CS) is the risk factor of both PASD and PP[3, 4]. The rate of CS has risen rapidly in recent decades worldwide[6]. Some researches reported CS in China in 1993 accounted for 14.9% of all deliveries, for 54.1% in 2018[7], and for 54.5% in 2011[7]. Moreover, a study from the World Health Organization regarding CS data for 9 Asian countries reported that China had the greatest number of CS[5]. Consequently, the incidence of PP and PASD increased as the rate of CS rose rapidly[4, 8]. For pregnant women with PP, the incidence of placenta accreta is 11% in the women with one prior CS and 67% in those with five or more repeated CSs[9]. Moreover, with the history of CS, the incidence of PASD had grown from 0.79‰ to 1.06‰ between 2005 and 2010[10]. With the implementation of the two-child policy by the Chinese government since 2016, a secondary pregnancy with history of CS has emerged and consequently raised the incidences of PASD and PP.

In order to reduce intraoperative hemorrhage during CS of women with PASD, PP and the history of CS, obstetricians have applied many surgical methods, including uterine compression suture, pelvic artery ligation, etc.. Hysterectomy would be conducted with the abnormally attached placenta retained in uterus if the intraoperative bleeding is intractable[11], which would deprive woman's fertility permanently. Presently, the precesarean intravascular balloon catheterization (BC) had been introduced into obstetrics for reducing the blood loss during CS of women with PP and PASD. The balloon of the intravascular catheter could be inflated during CS to occlude uterine blood flow and deflated when hemostatsis was achieved. However, the value of BC remains controversial.

This study was conducted to discuss the efficacy of precesarean BC of bilateral internal iliac arteries for reducing blood loss during cesarean deliveries of women with PASD, PP and a history of CS. We studied intraoperative estimated blood loss (EBL), calculated blood loss (CBL) and red blood cell (RBC) transfusion primarily. And the radiation dose, exposure time, operative duration, procedure complications, postoperative hospitalization and neonatal outcomes were analyzed as secondary outcomes.

## 1 MATERIAL AND METHODS

This study was carried out in the Department of Obstetrics and Gynecology, Tongji Hospital, Wuhan, China, and the protocol was approved by the Ethical Committee of Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology (IRB ID: TJ-C20150516).

Between June 2017 and February 2019, 147 women were eligible for this study, and 128 were recruited (fig. 1). Women were recruited if they met the following criteria: (1) CS scarred uterus; (2) diagnosis of PP by antenatal sonographic examination. The women with coagulation disorder were excluded from this study. The informed consent was obtained from all participants. The women were divided into the following two groups: BC group ($n$=56) and control

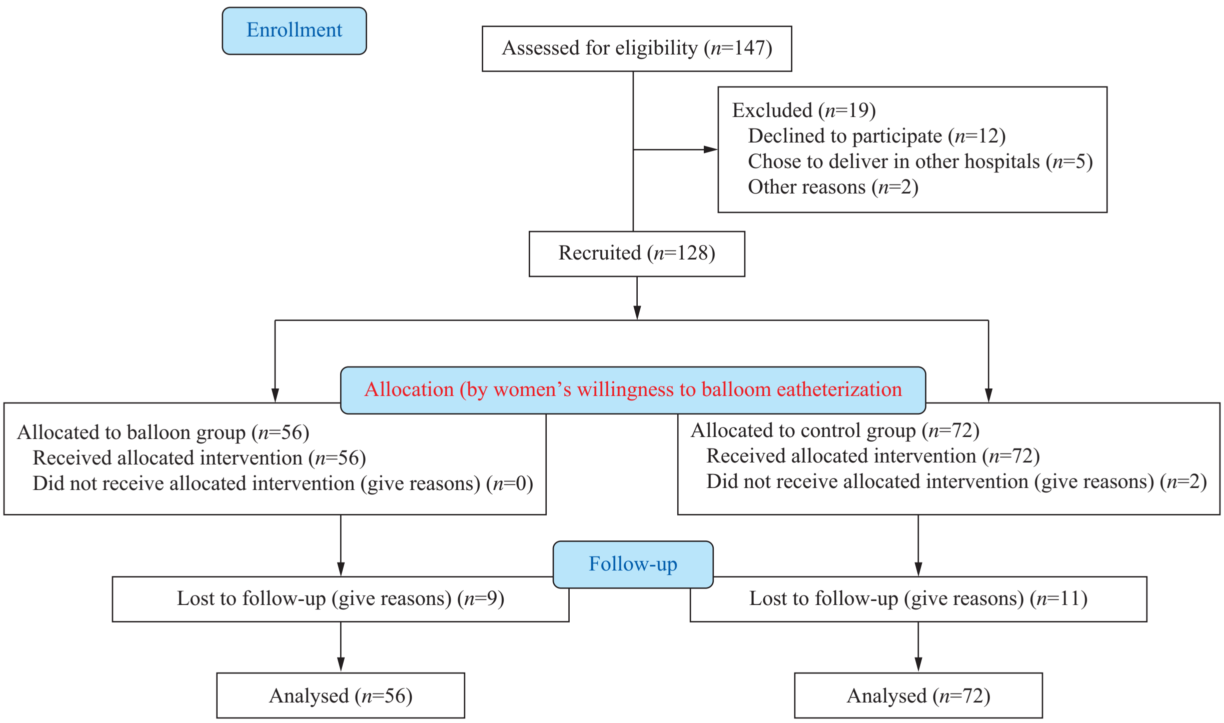


**Fig. 1** Participant flowchart

group (*n*=72). A single surgical team had performed all the cesarean deliveries of our study. Patient data were recorded during the study, including maternal characteristics, sonographic or MRI findings (fig. 2), intraoperative blood loss and neonatal information. Fluoroscopy time, radiation dose, postoperative hospitalization and perinatal complications were also recorded and discussed. The recorders and analysts are blinded to the data in order to minimize the bias.

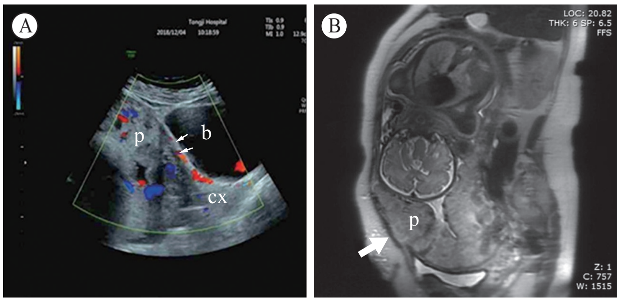


**Fig. 2** A: Color Doppler images. The arrow indicates evidence of placenta accreta (indistinct boundary of utero-placental interface); B: MRI. Placenta accreta in the lower uterine segment (indicated by an arrow). p: placenta; b: bladder; cx: cervix uteri

Women in the BC group received BC of bilateral internal iliac arteries under the guidance of fluroscopy preoperatively. During the conventional BC procedure, both femoral arteries were punctured using a Seldinger technique under local anesthesia and a 6-French vascular sheath (Cook, USA) was inserted. Thereafter, a 0.035-inch guide-wire (Cook) was inserted into the vascular sheath, and a cobra-shaped catheter (Cook) was inserted into the contralateral internal iliac artery under the guidance of the guide-wire and fluoroscopy. Contrast agent was injected into the internal iliac artery to measure internal iliac artery calibre via angiography and confirm cobra-shaped catheter placement. Intravascular catheter size was selected according to the internal iliac artery calibre. Then, an exchange guide-wire (Cook) was inserted and the 0.035-inch guide-wire (Cook) and the cobra-shaped catheter both were removed. After that, a balloon catheter was inserted into the contralateral internal iliac artery and the sheath was removed. The placement of balloon catheters on both sides were verified under fluoroscopy (fig. 3). However, the radiologist had simplified the BC procedure by omitting the 0.035-inch guide-wire and fluoroscopy was applied only to confirm the placement of balloon catheters. Twenty-two women from BC group received conventional BC procedure, and the rest 34 women were given the simplified BC procedure.

After BC, the women were transferred to the operating room for CS immediately. All the women in the BC group underwent the general anesthesia because of immobilization of their lower limbs. The balloon was inflated or deflated by an interventional radiologist during the whole CS. The balloon catheters were inflated immediately with normal saline at the moment when the uterine incision was ready to be made. And the baby was delivered as soon as possible. After delivery of the baby, the placenta was peeled off if spontaneous delivery or umbilical cord traction failed. Intraoperative hemostasis was achieved using uterotonic (20 U of oxytocin) or surgical methods, such as uterine compression suture, pelvic artery ligation, or intrauterine balloon tamponade. The balloon catheters were deflated after hemostasis was achieved. The catheters were removed by the same radiologist as soon as the CS completed. Puncture sites were sealed using a closure device. Women in the control group were treated with the same way except for precesarean BC.

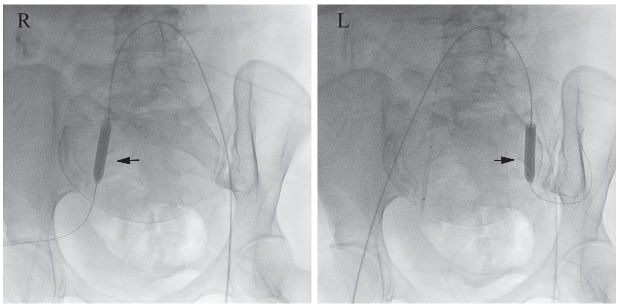


**Fig. 3** Intravascular catheterization procedure
Balloon catheters are positioned in the internal iliac arteries (indicated by arrows). L: left sides; R: right sides

After delivery, all the women received the same postoperative care except the temperature and color of lower limbs were recorded in the women from BC group. All the women in our study received blood routine examination one day after the CS. The vascular sonographic examination of lower limbs was routinely made on each woman in BC group 5 days after the CS.

All the patients in this study were followed up from March, 2019. Maternal and neonatal symptoms after delivery, duration of lochia and first menstruation after delivery were well recorded.

The primary outcomes included intraoperative EBL, CBL and RBC transfusion, and the secondary outcomes included intraoperative fluid transfusion, other hemostasic methods used intraoperatively, duration of CS operation, postoperative hospitalization, radiation dose and exposure time for the BC group and maternal or neonatal adverse outcomes. The weight of compresses and blood volume collected by suction intraoperatively were carefully recorded, and EBL was measured. CBL was assessed using an algorithm proposed by Salim[12], in order to minimize bias caused by anthropic factors. Assuming that blood volume remained unchanged in both pregnancy and just one day after delivery, the following formula was devised to calculate blood loss: CBL = Blood volume (preoperative hematocrit – postoperative hematocrit) + Transfused RBCs (mL)[12].

Continuous variables were presented using means ± standard deviations, median and range. Categorical variables were presented with frequencies and percents. Correlations between groups and continuous variables were examined using a nonparametric Wilcoxon rank-sum test. For categorical variables, $\chi^2$ test was used. The relative risk along with 95% confidence intervals (CI) was presented. Statistical analysis and data management were performed using GraphPad Prism 5 (USA).

## 2 RESULTS

Demographic and obstetrical data in both groups are listed in table 1. Intraoperative data are presented in table 2. There were significant differences between BC group and control group in CBL (1015.0±144.9 *vs.* 1467.0±171.0 mL, *P*=0.04), intraoperatively transfused RBC (799.5±136.1 *vs.* 1286.0±161.6 mL, *P*=0.02) and the number of women with RBCs transfusion (57.1% *vs.* 76.4%, *P*=0.02) and percentage of women given blood product transfusion (57.1% *vs.* 76.4%, *P*=0.02). No significant differences were found between BC group and control group in the percentage of women receiving intraoperative plasma (21.4% *vs.* 27.8%, *P*=0.54) or fluid infusions (21.4% *vs.* 27.8%, *P*=0.54) and operation duration (111.9±6.2 *vs.* 128.7±10.7 min, *P*=0.18). No significant differences in hemostatic methods were noted between the two groups, including uterine compression sutures, pelvic artery ligation, intrauterine balloon tamponade, uterine artery embolization, or usage of two or more hemostatic methods.

Women in the BC group had bruises on bilateral groin because of the BC procedure. Some of them had complained of pain in the puncture sites. But the vascular sonography examination of the lower limbs excluded the possibility of lower limbs artery/vein thrombosis.

Postoperative outcomes are shown in table 3. Postoperative hospital stay in the BC group was significantly longer than that in the control group (6.7±0.4 *vs.* 5.8±0.2 days, *P*=0.03). Nine women in the BC group and 11 in the control group were

**Table 1 Patients' demographic and obstetric characteristics**

| Variables | BC group (*n*=56) | Control group (*n*=72) | *P* |
|---|---|---|---|
| Age (years) | 33.1±0.7 (33.0, 25.0–53.0) | 32.2±0.5 (32.0, 25.0–42.0) | 0.29 |
| BMI | 26.6±0.4 (26.3, 20.7–35.8) | 26.9±0.4 (26.9, 21.0–39.3) | 0.58 |
| Gravida | 3.7±0.2 (4.0, 2.0–7.0) | 3.8±0.2 (4.0, 2.0–10.0) | 0.84 |
| Para | 1.2±0.1 (1.0, 1.0–3.0) | 1.1±0.1 (1.0, 1.0–3.0) | 0.15 |
| Multiple gestation | 1/56 (1.8%) | 2/72 (2.3%) | 1.00 |
| Gestational age (weeks) | 36.5±0.2 (37, 32–39) | 36.3±0.2 (36, 31–40) | 0.52 |
| Previous cesarean section | 1.2±0.1 (1.0, 1.0–3.0) | 1.1±0.1 (1.0, 1.0–2.0) | 0.15 |
| Prior uterine operation | 2.6±0.2 (3.0, 1.0–6.0) | 2.7±0.2 (2.0, 1.0–9.0) | 0.90 |
| GDM | 5/56 (8.9%) | 6/72 (8.3%) | 1.00 |
| Hypertensive disorder | 1/56 (1.8%) | 4/72 (5.6%) | 0.39 |

Prior uterine operations include myomectomy, uterine curettage and hysteroscopy, etc.

**Table 2 Intraoperative data and CBL with different regions of placental attachment**

| Variables | BC group (*n*=56) | Control group (*n*=72) | *P* |
|---|---|---|---|
| Estimated blood loss (mL) | 1326.0±166.7 (850.0, 100.0–5500.0) | 1737.0±164.0 (1200.0, 200.0–6100.0) | 0.08 |
| Calculated blood loss (mL) | 1015.0±144.9 (662.0, 24.0–4867.0) | 1467.0±171.0 (1079.0, 51.0–8739.0) | 0.04 |
| Intraoperative transfused RBC (mL) | 799.5±136.1 (400.0, 0.0–4500.0) | 1286.0±161.6 (800.0, 0.0–8200.0) | 0.02 |
| Intraoperative transfused plasma (mL) | 217.9±70.2 (0.0, 0.0–2300.0) | 168.8±40.1 (0.0, 0.0–1500.0) | 0.54 |
| Women with intraoperative transfused blood products | 32/56 (57.1%) | 57/72 (76.4%) | 0.02 |
| Women with plasma transfusion | 12/56 (21.4%) | 20/72 (27.8%) | 0.54 |
| Colloidal fluid infusion (mL) | 803.6±95.9 (500.0, 0.0–4000.0) | 954.5±118.1 (0.0, 0.0–3500.0) | 0.32 |
| Crystalloid fluid infusion (mL) | 1652.0±114.6 (1500.0, 500.0–4500.0) | 1620.0±106.6 (1500.0, 500.0–4000.0) | 0.84 |
| Total fluid infusion (mL) | 2455.0±188.2 (2250.0, 500.0–7500.0) | 2575.0±196.3 (2500.0, 500.0–7500.0) | 0.66 |
| Uterine compression suture | 40/56 (71.4%) | 52/72 (72.2%) | 1.00 |
| Uterine artery ligation | 17/56 (30.4%) | 31/72 (43.0%) | 0.20 |
| Intrauterine balloon | 3/56 (5.4%) | 5/72 (6.9%) | 1.00 |
| Uterine artery embolization | 6/56 (10.7%) | 3/72 (4.2%) | 0.18 |
| Hysterectomy | 2/56 (3.6%) | 4/72 (5.6%) | 0.70 |
| Pathological inspection of placenta accreta | 9/42 (21.4%) | 11/47 (23.4%) | |
| Hematostatic methods | 20/56 (35.7%) | 34/72 (47.2%) | 0.21 |
| Operation duration (min) | 111.9±6.2 (95.0, 49.0–295.0) | 128.7±10.7 (104.5, 59.0–420.0) | 0.18 |

Hematostatic methods used in this study include uterine compression suture, pelvic artery ligation and uterineartery embolization.

lost to follow-up. During the follow-up period, no complaints were noted 42 days after delivery. No significant difference was found in neonatal outcomes, lochia duration or resumption of menses post-delivery between the two groups.

In the BC group, 22 women underwent conventional BC procedure and 34 women underwent simplified BC procedure. Table 4 shows data for radiation doses in both groups. The exposure time (188.4±14.2 *vs.* 41.8±7.7 s, $P$<0.001) and radiation dose (62.2±3.9 *vs.* 11.9±2.0 mGy, $P$<0.001) were significantly reduced after the simplification of BC procedure.

## 3 DISCUSSION

The WHO reported that number of CSs was increased by three-fold in urban China and more than 15-fold in rural areas from 1993–2008[7]. It aroused public concern because women who already had cesarean delivery are now permitted to have another child under the Chinese government allowance[14]. Prior CS is the risk factor of PP and PASD[3, 9]. PASD with cesarean scar could endanger pregnant woman's surrounding organs[15] and it is associated with many adverse perinatal outcomes such as postpartum hemorrhage and perinatal death[16].

The utility of precesarean BC remains controversial in some researches. Mok *et al* stated that precesarean internal iliac artery BC could reduce intraoperative blood loss and obtain a clear operative field due to decreased pulse pressure distal to the occlusion site[17]. An article supported the precesarean BC for abdominal aorta could reduce intraoperative hemorrhage and prevent hysterectomy[18]. A trial of precesarean BC of internal iliac artery conducted by Salim *et al* reported that precesarean BC could not reduce intraoperative blood loss and blood products transfusion[12]. And a recent Chinese study also stated that BC could not improve the maternal outcomes during cesarean hysterectomy in women with placenta previa accreta[19]. As reported in a study, precesarean BC of abdominal aorta was always associated with induced postoperative complications, such as arterial thrombosis and femoral nerve ischaemic injury[20]. The results of our study demonstrated that precesarean BC of bilateral internal iliac artery could reduce intraoperative blood loss and RBC transfusion without causing serious peripartum complications. By means of temporarily occluding the blood flow of bilateral internal iliac arteries during the CS, the uterine blood supply would be lessened and the operative field would be more clear. Our study also revealed that precesarean BC of bilateral internal iliac arteries could reduce blood products transfusions without prolonging the CS. Moreover, no women had lower limbs thrombosis after BC procedure, yet some of them had complaint of pain or bruises in the puncture sites.

The most severe complication of precesarean BC of bilateral internal iliac arteries is thrombosis. Intravascular radiology may cause arterial injury[21] and potentially lead to arterial thrombosis[22]. The radiologist of our study is very experienced to perform intravascular catheterization, and had chosen appropriate size of intravascular balloon catheter with the help of fluoroscopy. Moreover, the catheters were removed by the radiologist as soon as the CS was finished. Of all cases from BC group of our study, none developed thrombosis.

Radiation exposure might induce adverse pregnancy outcomes, including intrauterine growth restriction, mental retardation, organ malformation, childhood cancer and even perinatal death[23]. As reported by some researchers, fetal dosage lower than 50 mGy was not associated with fetal lethality, anomalies or genetic damage[23, 24]. Fetal malformation might be observed if the dosage exceeds 150 mGy[25]. Woman should not be suggested to terminate her pregnancy if her fetal dosage was less than 100 mGy[25]. And it was recommended that clinically indicated radiation procedures should not be withheld in the consideration

**Table 3 Postpartum data and follow-up information**

| Variables | BC group ($n$=56) | Control group ($n$=72) | $P$ |
|---|---|---|---|
| Postoperative hospitalization | 6.7±0.4 (7.0, 0.0–18.0) | 5.8±0.2 (6.0, 2.0–14.0) | 0.03 |
| Gender(M/F) | 35/21 | 38/34 | 0.29 |
| Weight(g) | 2892.0±56.1 (2850.0, 2220.0–3600.0) | 2966.0±60.8 (2950.0, 1900.0–4100.0) | 0.37 |
| Apgar-5 min | 7.1±0.2 (7.0, 2.0–8.0) | 7.4±0.1 (7.0, 3.0–8.0) | 0.23 |
| Apgar-10 min | 8.4±0.1 (9.0, 3.0–9.0) | 8.7±0.1 (9.0, 4.0–9.0) | 0.10 |
| NICU | 4/56 (7.1%) | 3/72 (4.2%) | 0.70 |
| Women accessble to follow-up | 47/56 (83.9%) | 61/72 (84.7%) | 1.00 |
| Lochia duration (days) | 37.6±4.0 (47/56) (39.0, 25.0–50.0) | 30.0±30.1 (61/72) (35.0, 19.0–45.0) | 0.14 |
| First menstruation time after delivery (days) | 123.1±14.4 (47/56) (135.0, 80.0–270.0) | 135.5±14.3 (61/72) (140.0, 45.0–210.0) | 0.55 |

**Table 4 Radiation dose and exposure time**

| Variables | Conventional catheterization ($n$=24) | Improved catheterization ($n$=32) | $P$ |
|---|---|---|---|
| Exposure time (s) | 188.4±14.2 (176.0, 110.0–239.0) | 41.8±7.7 (20.0, 6.0–76.0) | <0.001 |
| Radiation dose (mGy) | 62.2±3.9 (58.0, 26.3–79.6) | 11.9±2.0 (6.1, 1.4–21.7) | <0.001 |

of fetal radiation exposure[24]. The precesarean BC technique in our study was modified to minimize radiation exposure. The mean radiation dose after modification was 11.9 mGy (1.4–21.7 mGy), while the mean radiation dose of the conventional technique was 62.2 mGy (26.3–79.6 mGy). The overall radiation dose of the BC group was 56.9 mGy, well below 100 mGy. No radiation-related neonatal anomalies were detected during the follow-up period.

Our study was limited because it was designed as a single-center research. But it is still convincing due to that the same multidisciplinary team treated all women under the same management protocol. Ideally, the single-center design had reduced potential operator-dependent bias.

To sum up, our study revealed that precesarean BC of bilateral internal iliac arteries could reduce intraoperative blood loss for women with PASD, PP and a history of CS without inducing serious adverse perinatal outcomes. Intraoperative RBC transfusion was also reduced by precesarean BC. Furthermore, the simplified BC procedure in our study could minimize the damage of fetal radiation exposure.

**Conflict of Interest Statement**

The authors declare that there is no conflict of interest with any financial organization or corporation or individual that can inappropriately influence this work.

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