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Comparison of the safety and efficacy of PABO above or below the ovarian artery during cesarean delivery in patients with coexisting placenta accreta and placenta previa

Hiroyuki Tokue [a,*], Azusa Tokue [a], Yoshito Tsushima [a], Takeshi Kameda [b]

[a] Department of Diagnostic and Interventional Radiology, Gunma University Hospital, Gunma, Japan
[b] Department of Obstetrics and Gynecology, Gunma University Hospital, Gunma, Japan

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ABSTRACT

Purpose: To determine the effect of ovarian arteries on the use of prophylactic abdominal aortic balloon occlusion (PABO) in patients with coexisting placenta accreta and placenta previa.

Methods: Thirty-two pregnant women with coexisting placenta accreta and placenta previa treated with PABO in our hospital during 2013–2020 were retrospectively analyzed. The patients were divided into two groups: one with infra-renal abdominal aortic balloon occlusion above the ovarian artery (Group A, n = 15) and the other with occlusion below the ovarian artery (Group B, n = 17). Medical records and relevant imaging of all patients were reviewed. All Cesarean deliveries were scheduled and we decided to perform hysterectomy based on the surgical findings.

Results: Patients in both groups were similar in terms of age, gravidity history, and status of placenta. Regarding their outcomes, estimated blood loss was not significantly different in both groups, although it was lower in Group B than in Group A (3949.5 vs. 4333.8 ml). The other tested parameters did not show any difference. The uterus was preserved in 13 (41%) patients. No access-related or balloon occlusion-related complications occurred in either group.

Conclusions: PABO was safe. However, the balloon location (above or below the ovarian arteries) did not influence the outcomes. Further evaluation and prospective studies are required to evaluate the safety and efficacy of balloon occlusion above or below the ovarian artery in patients with coexisting placenta accreta and placenta previa.

1. Introduction

With the global increase in the cesarean delivery rate, the incidence of placenta accrete spectrum (PAS) and placenta previa during second pregnancy has increased [1,2]. PAS is a severe obstetric complication that can lead to postpartum hemorrhage, disseminated intravascular coagulation, shock, and even life-threatening debilitations. PAS is classified into three types based on the depth of invasion. Placenta accreta refers to the placental villi that penetrate the thinned decidua basalis and adhere directly to the myometrium. Placenta increta is characterized by the invasion of the placenta into the myometrium. Invasion through the myometrium and reaching or penetrating the serosa is termed as placenta percreta [1]. Placenta previa is a placental malposition that is a risk factor for various life-threatening conditions, including perinatal bleeding. Placenta previa and placenta accreta may be associated with high morbidity and mortality for both mothers and fetuses [2].

Hysterectomy, which would permanently affect fertility, had been the major therapeutic choice, when life-threatening bleeding occurred with placenta accreta subsequent to cesarean delivery. However, in the

Abbreviations: CTCAE, common terminology criteria for adverse events; EBL, estimated blood loss; MAP, morbidly adherent placenta; PABO, prophylactic abdominal aortic balloon occlusion; US, ultrasound.

* Corresponding author at: Department of Diagnostic and Interventional Radiology, Gunma University Hospital, 3-39-22 Showa-machi, Maebashi, Gunma, 371-8511, Japan.

E-mail addresses: tokue@s2.dion.ne.jp (H. Tokue), azusa45@yahoo.co.jp (A. Tokue), yoshitotsushima@gunma-u.ac.jp (Y. Tsushima), tkame@gunma-u.ac.jp (T. Kameda).

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past few decades, prophylactic abdominal aortic balloon occlusion (PABO) before cesarean delivery has been employed by surgeons to prevent intraoperative and postoperative hemorrhage [3]. PABO may be safe and effective in treating patients with placenta accreta, which might control hemorrhages during cesarean delivery and reduce hysterectomy-associated risks [4–12]. When placental removal and uterus reconstruction is needed to prevent hysterectomy, PABO may be useful. Conversely, the clinical efficacy of PABO has been described by various authors with different results. Among them, the adequate position of the aortic balloon has not been sufficiently evaluated. Many studies described it only as "below the level of the renal artery" or "under the origin of renal artery" [4–12].

The uterine arteries are major centers that can sustain hemorrhage during cesarean delivery in patients with placenta accreta. While various collaterals develop in addition to the uterine arteries, there have been limited studies on the role of the ovarian arteries in patients with coexisting placenta previa and placenta accrete [4–12].

This study retrospectively compared the safety and efficacy of PABO above or below the ovarian arteries for cesarean delivery in patients with coexisting placenta accreta and placenta previa.

2. Material and methods

2.1. Patients

In the data base in our institution between January 2013 and September 2020, we found 35 pregnant women with coexisting placenta accreta and placenta previa treated with interventional procedures followed by cesarean section. If the interventional radiologist determined that PABO was anatomically difficult to place above the ovarian artery, the occlusion balloon was placed above bifurcation. In this study, the general term placenta accreta refers to all three grades of abnormal trophoblastic invasion unless otherwise specified. All Cesarean deliveries were scheduled and we decided to perform hysterectomy based on the surgical findings. We planned placental removal and uterus reconstruction. PABO was used for preserving the uterus as much as possible.

The inclusion criteria were: 1) diagnosed as coexisting placenta accreta and placenta previa based on ultrasound (US) or magnetic resonance imaging and confirmed based on intraoperative findings (The diagnostic criteria were the presence of at least one of the following US findings: marked thinning or loss of the retroplacental hypoechoic zone, interruption of the hyperechoic border between the uterine serosa and bladder, presence of mass-like tissue with echogenicity similar to that of the placenta, visualization of prominent vessels or lakes within the placenta or myometrium); 2) absence of hemorrhage before surgery, 3) gestational weeks >28 weeks; 4) availability of patient history of previous cesarean delivery; 5) placenta previa, with placenta covering the previous cesarean scar, 6) preoperative hemoglobin level >10.0 g/L. The exclusion criteria were: 1) severe obstetric complications, especially hematological system diseases or coagulation disorders, gestational hypertension, intrahepatic cholestasis, acute fatty liver, acute pancreatitis, asthma, or cardiopulmonary insufficiency; 2) use of drugs, including aspirin, that would affect coagulation functions; 3) fetal anomaly, fetal growth restriction, or fetal distress; 4) planned hysterectomy. All assessments were completed by two individuals, and any disagreement was arbitrated by a third party (Fig. 1).

PABO was performed above the ovarian arteries from 2013 to 2016, and PABO was performed below the ovarian arteries from 2017 to 2020. From 35 patients recorded, 32 patients matched the criteria, and patients were divided into two groups: one group comprising patients with PABO above the ovarian arteries (Group A) and the other comprising patients with PABO below the ovarian arteries (Group B).

The study was approved by the institutional ethics committee, and informed consent of the patients was waived.

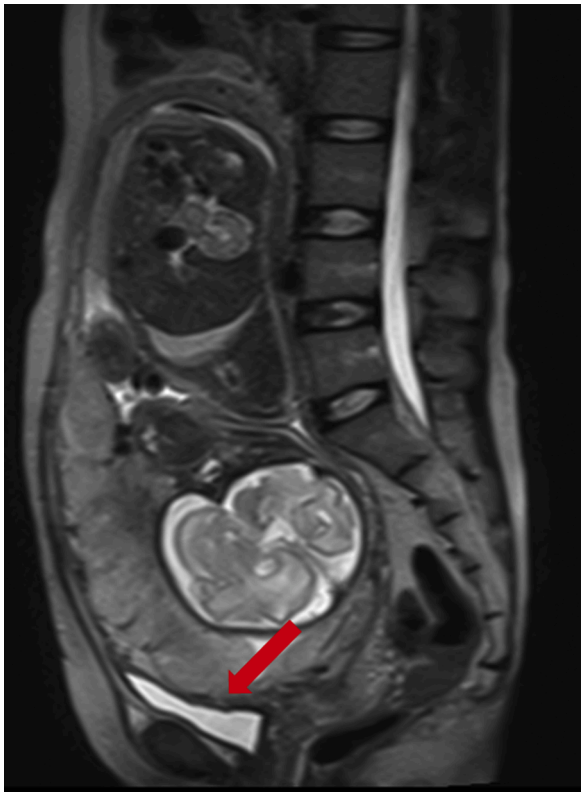

Fig. 1. Coexisting placenta accreta and placenta previa. Sagittal MR image (T2-weighted image) showing the abnormal placental tissue abutting the bladder wall (arrow).

2.2. Maternal characteristics and outcomes

For each patient, clinical data, including estimated blood loss (EBL), amount of packed RBC transfusions, and operative time, were obtained from electronic medical records system. We followed up on any ensuing complications and menstruation cycle of the patients, and the average follow-up time was 1 year (range, 6–18 months).

The main outcome parameters included EBL volume, RBC transfusion volume, hysterectomy, operative time, postoperative hospital days, neonatal status, including fetal radiation dose, and other clinical complications. The operation time for cesarean section was defined as the time from the initial incision to the completion of wound closure, including hysterectomy if performed. EBL was quantified using the volume of suction containers, weight of swabs, and visual estimation of vaginal blood loss. PABO-related complications were evaluated daily by an interventional radiologist and gynecologist until the time of discharge, and were recorded and classified as per the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. Maternal characteristics and outcomes were also reviewed.

2.3. Interventional procedure

If the placental adhesion to the uterus was severe or bleeding persisted during Cesarean delivery, the patient gave consent to undergo hysterectomy. After taking due consent from the patient, multidisciplinary treatment plans were designed by interventional radiologists, anesthetists, and obstetricians for patients. All intravascular interventional therapies were performed by interventional physicians. On the day of cesarean delivery, PABO was performed in the digital subtraction angiography operating room. On administering a local anesthesia, the right femoral artery was accessed using the Seldinger technique and a 7-French introducer sheath for placing a 7-French aortic occlusion balloon

catheter (Rescue BalloonR, 12−14 mm diameter, Tokai Medical Product, Aichi, Japan). Using a guidewire, we inserted a 4-F catheter into the abdominal aorta and performed angiography to visualize the blood flow of the abdominal aorta, renal artery opening, ovarian arteries, and position of the common iliac artery bifurcation.

In Group A, the occlusion balloon was placed between the renal and ovarian arteries. In Group B, the occlusion balloon was placed between the ovarian artery and bifurcation. If the ovarian artery originated from the renal artery, it was treated similarly as that patients in Group B. Accurate balloon placement was angiographically confirmed using a contrast agent. The balloon was inflated with saline until the patient's pulse and oxygen saturation in the great toe could not be detected. To minimize radiation exposure to the mother and fetus, images were obtained at 3 frames/s. The decision regarding the position of the

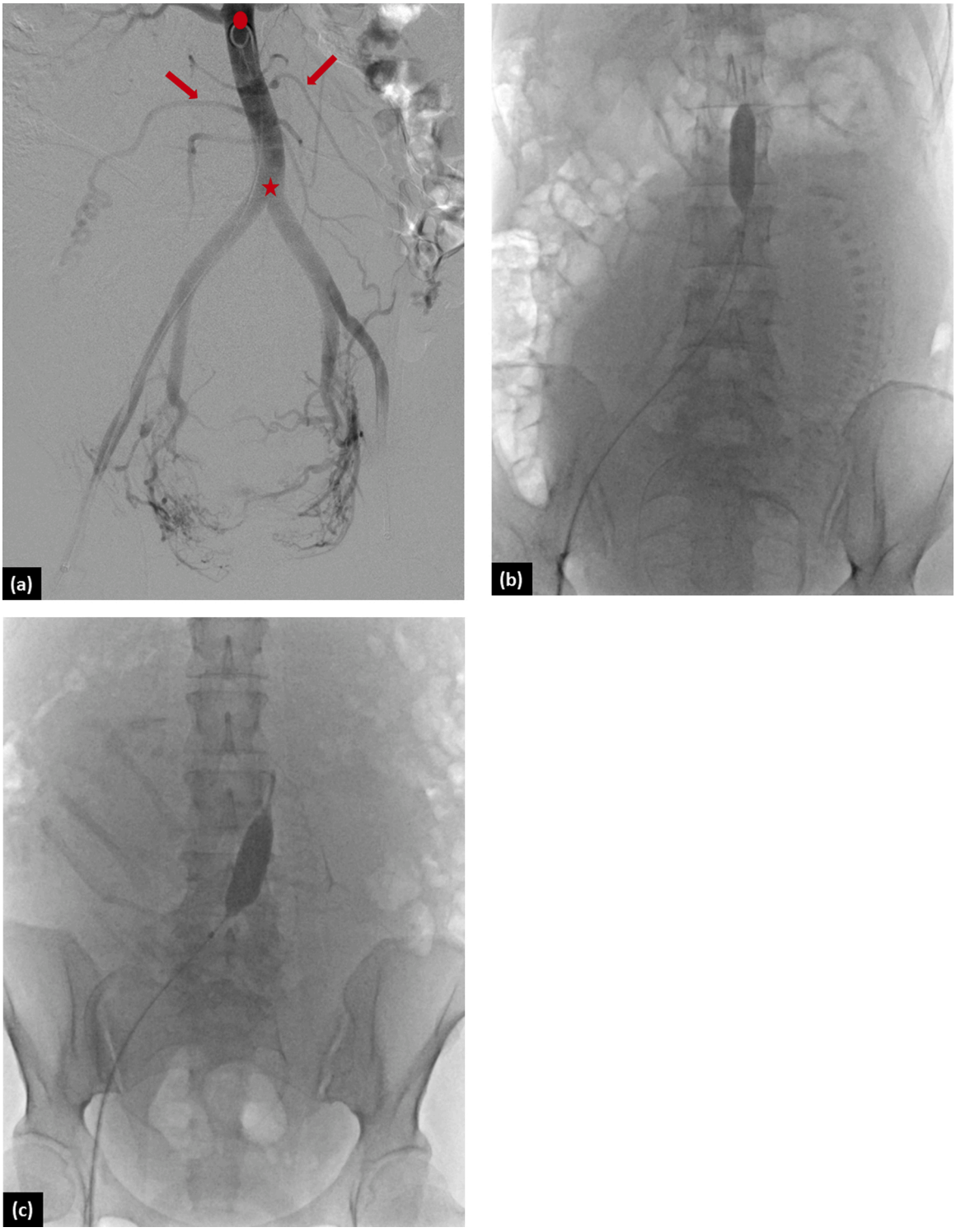

Fig. 2. Prophylactic balloon occlusion of the intra-abdominal aorta in patients with coexisting placenta accreta and placenta previa. (a) A digital subtraction abdominal aortogram was performed via the right femoral approach prior to the placement of an aortic occlusion balloon. Angiography showed the renal artery opening (circle), ovarian arteries (arrows), and position of the common iliac artery bifurcation (star). (b) In Group A, the occlusion balloon was placed between the renal and ovarian arteries. (c) In Group B, the occlusion balloon was placed between the ovarian artery and bifurcation.

abdominal aortic balloon occlusion was made after consultation between interventional radiologist and gynecologist (Fig. 2).

Once the catheter was placed in the correct position, it was securely taped to the skin. After placing the aortic balloon, the patient was transferred to the surgical operating room for cesarean delivery under spinal anesthesia. Just before cesarean delivery, it was ensured that the catheter position was correct using the mobile C-arm X-ray machine. If necessary, fluoroscopy was performed during cesarean delivery. As requested by obstetricians, after delivering the infant and clamping the umbilical cord, the occlusion balloon was inflated by interventional physicians. Thereafter, the obstetrician surgically excised as much of the placenta as possible along with any myometrium and reconstructed the uterus under general anesthesia with tracheal intubation. The aortic balloon was alternately inflated for 30 min and then deflated for 10 min. If hemorrhage from the uterus persisted, the blockage was repeated until the bleeding stopped. The placenta was manually removed as far as possible. If it was difficult to manually remove the placenta, it was left in situ, and hysterectomy was performed immediately in patients from both groups. Furthermore, hysterectomy was performed when it was difficult to control bleeding in patients during cesarean delivery. After that, patients were observed in the recovery room for 60 min. The balloon catheter was withdrawn after completing the entire procedure. The arterial sheath was removed 6 h after completing the procedure. Manual external compression was performed for arterial access by interventional physicians.

2.4. Fetal radiation dose

The radiation dose (mGy) was determined at the end of the procedure in the total of DSA and Carm fluoroscopy. The entrance skin radiation dose in the region of the irradiated field was defined as the fetal radiation dose.

2.5. Statistical analysis

Clinical data analyses were performed using SPSS 24.0 (IBM Corporation, Amon, NY). Continuous variables with normal distribution were presented as mean ± standard deviation, and independent sample *t*-test or the Mann-Whitney *U*-test were used to determine differences. Categorical data were expressed as frequency and percentages using the *Chi*-square test to compare differences. *P* values <0.05 were considered statistically significant.

3. Results

Thirty-two of 35 patients recorded in our data base met the inclusion criteria of our study. Group A comprised 15 cases, and Group B comprised 17 cases. One patient was treated as per the protocol for Group B because the ovarian artery originated from the renal artery. There were no differences in age, gravidity history, and status of placenta between two groups (Table 1).

EBL tended to lower in Group B than Group A (3949.5 vs. 4333.8 ml), but this difference was not statistically significant. The other outcomes were also not different in both groups (Table 2). There were no PABO-related complications until discharge, and no observational damage was noticed in the adjacent pelvic organs during the operation in patients of both groups.

The uterus was preserved in 13 (41%) patients. There were two cases of postoperative complications of CTCAE grade 3 or higher. One patient in group A required transcatheter arterial embolization two days after cesarean delivery because of continuous bleeding from the adherent part of the placenta. Bilateral uterine artery embolization with a gelatin sponge was performed, and bleeding was stopped immediately. Another patient in Group B developed hematoma near the postoperative site with associated infections, but the condition was resolved due to antibiotics administration. Subsequently, the patient was discharged 23 days after the operation. All mothers and babies were healthy at the time of discharge. Moreover, all the women who completed breastfeeding had recovered their menstruation cycle with in a year.

Table 1
Baseline characteristics and distribution of different types of placenta accreta spectrum disorder in patients of Groups A and B.

	Group A (N = 15)	Group B (N = 17)	p value
Age (years)	35.3 ± 5.4	34.6 ± 4.7	0.68
BMI	26.8 ± 4.6	24.5 ± 5.8	0.13
Parity (n)	1.4 ± 0.8	2.0 ± 1.0	0.26
Number of previous cesarean sections	1.2 ± 0.7	1.8 ± 1.1	0.070
Degree of placental adhesion (n)			0.70
Accreta	12	14	
Increta	2	1	
Percreta	1	2	
Gestational age (d)	252.0 ± 9.1	248.5 ± 13.0	0.73
Placenta position (n)			0.71
Anterior	9	12	
Posterior	6	5	
Type of placenta previa (n)			0.15
Previa totalis	3	8	
Previa partialis and marginalis	12	9	

Table 2
Maternal and neonatal outcomes of Groups A and B.

	Group A (N = 15)	Group B (N = 17)	p value
Apgar score (5 min after delivery)	7.5 ± 1.1	7.9 ± 0.90	0.28
Birth weight infant (g)	2517.7 ± 341.1	2473.8 ± 457.0	0.62
Operation time (min)	226.5 ± 126.0	249.3 ± 115.2	0.65
Estimated blood loss (ml)	3949.5 ± 1684.0	4333.8 ± 1974.8	0.71
Hysterectomy (n)	8 (53%)	11 (65%)	0.72
Amount of packed RBC transfusions (units)	12.5 ± 4.8	14.7 ± 6.8	0.92
Postoperative hospital stay (days)	8.4 ± 2.1	10.5 ± 4.6	0.074
Total time of balloon occlusion (min)	65.8 ± 39.7	70.6 ± 29.2	0.76
Fetus radiation dose (mGy)	18.6 ± 3.2	17.6 ± 5.2	0.46

4. Discussion

In our patients' groups, PABO was safely performed, although our study included a limited number of patients and was a non-randomized retrospective single-center study. When performing PABO in patients with coexisting placenta accreta and placenta previa, the occlusion of blood flow of the ovarian arteries did not affect outcomes.

Recently, PABO for patients with placenta accreta has become an important method for controlling intraoperative hemorrhages. This technique has the advantage of being simple, and involves low radiation dosages for pregnant women and fetuses. The clinical effects of PABO have been described by different authors and have varying results [4–12]. We suspected that this may be due to the different inclusion and diagnostic criteria for placenta accreta in different studies. There are four possible PABO positions from the distal to proximal abdominal aorta [13]: 1) at the aortic bifurcation, 2) between the inferior mesenteric and ovarian arteries, 3) between the renal and ovarian arteries, and 4) at the renal artery. The position of the balloon has not been evaluated in previous studies.

We performed a literature review of available reports on prophylactic abdominal aortic balloon occlusion for patients with placenta accreta and placenta previa through December 2020 using the key terms "aortic balloon occlusion," "placenta previa," and "placenta accreta" from PubMed and Google Scholar. For inclusion, the reports needed to

(1) have a description of the evaluation of EBL and blood transfusion, as well as a description of the position of the aortic balloon, (2) be publications in English; (3) be studies including >40 patients; and (4) be reports comparing prophylactic abdominal aortic balloon occlusion with some treatment. We did not include case reports.

The results of the literature review are summarized in Table 3. The description of the position of prophylactic abdominal aortic balloon was ambiguous, e.g., "below the level of the renal artery" or "under the origin of renal artery." There was a necessity for further consideration to ascertain the appropriate position of the aortic balloon occlusion.

Occlusion above the level of the ovarian arteries can lead to wider ischemia and greater complications. However, in our study, occlusion above the ovarian artery did not increase complications. Nonetheless, there was no change in the outcome when compared with the occlusion below the ovarian arteries. Liu et al. reported that balloon occlusion at the renal artery reduced hemorrhage in women with placenta increta without causing ischemic renal damage [14]. The most serious complication is acute renal failure owing to the displacement of the balloon catheter and occlusion of the renal artery. A retrospective study of prophylactic abdominal aortic balloon occlusion reported postoperative complications of approximately 4.4%, including arterial thrombosis and femoral nerve ischemic injury [15]. Moreover, balloon occlusion at the renal artery has a wide ischemic area and requires a short inflation time. The position of the aortic occlusion balloon might depend on the balance between the merit and demerit of possible ischemic organ damage.

Additionally, it is important to minimize the fetal radiation exposure dose when prophylactic abdominal aortic balloon is used. The International Commission on Radiological Protection suggests that when the radiation dose is <100 mGy, the fetal teratogenic risk does not increase [16]. In the present study, the mean fetal radiation exposure dose was 17.6 mGy, which is far less than the dose of 100 mGy. DSA of abdominal angiography and insertion of the balloon into the aorta were performed rapidly in all patients by experienced interventional radiologists to minimize radiation exposure.

This study had several limitations. First, the study was limited by a small sample size because the condition of coexisting placenta accreta and placenta previa is rare. Second, the decision regarding the position of the abdominal aortic balloon occlusion was left to the discretion of the interventional radiologist; therefore, there was selective bias and the interventional radiologists' experience could have affected the decision. Third, this study lacked a long-term follow-up because of its retrospective design. In the future, larger investigations involving multiple centers and large numbers of patients should be performed with longer follow-up periods to provide accurate assessment and validation of the clinical efficacy. Finally, the prophylactic use of balloon occlusion of the abdominal aorta was compared with a control group and no comparisons were made between this method with other treatments to avoid hemorrhage.

In conclusion. PABO was safely performed in all patients with coexisting placenta accreta and placenta previa. The balloon location (above or below the ovarian arteries) did not influence the outcomes.

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Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

This study has obtained IRB approval from Gunma university hospital and the need for informed consent was waived.

Consent for publication

Consent for publication was obtained for every individual person's data included in the study.

Transparency document

The Transparency document associated with this article can be found in the online version.

CRediT authorship contribution statement

Hiroyuki Tokue: Conceptualization, Formal analysis, Investigation, Methodology, Project administration. **Azusa Tokue:** Data curation, Formal analysis, Validation. **Yoshito Tsushima:** Supervision, Writing -

Table 3
Literature review of prophylactic abdominal aortic balloon occlusion for patients with placenta accreta and placenta previa.

Reference	Treatment comparison	N (PABO, comparison)	Description of the position of aortic balloon	Items with significant lower in IABO group	Complication related to IABO
Peng et al. [4]	Common iliac artery BO	252,38	Below the level of the renal artery	No	Femoral arteriovenous fistula (1) thrombus in the upper femoral artery (7)
Wei et al. [5]	Internal iliac artery BO	52,71	Under the origin of renal artery	Apgar score at 1 min >7 Iodoform gauze packing of the uterine cavity	no
Li et al. [6]	Cesarean section alone	24,32	At the level of the renal artery	Hysterectomy	Thrombus of the right external iliac artery (1)
Duan et al. [7]	Cesarean section alone	22,23	Under the origin of renal artery	Operation time EBL Blood transfusion Stuffing uterine cavity followed by UAE Uterine artery ligation Hysterectomy Postoperative days	No
Wang et al. [8]	Cesarean section alone	10,33	Between the iliac bifurcation and the renal arteries	EBL Blood transfusion Complications in the mother Hemorrhage shock	No
Cui et al. [9]	Cesarean section alone	38,31	Below the level of the renal artery	EBL >1000 ml	Right iliac artery thrombosis (1)
Wu et al. [10]	Cesarean section alone	230,38	At the level of T12	Operation time EBL Blood transfusion Hemodynamical abnormality Admission to ICU Postoperative days	no
Panici et al. [11]	Cesarean section alone	15,18	Iliac bifurcation and the renal arteries	Hysterectomy EBL Blood transfusion Admission to ICU Postoperative days	no
Tokue et al. [12]	Internal iliac artery BO	28,32	Infra-renal abdominal aorta	Operation time Total time of BO Fetal radiation dose	no

review & editing. **Takeshi Kameda:** Resources.

Declaration of Competing Interest

The authors report no declarations of interest.

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