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Maternal and perinatal outcomes in placenta accreta spectrum disorders with prophylactic internal iliac artery balloon catheterization and embolization

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ABSTRACT

Objectives: To summarize our five-year experience with managing patients diagnosed with wide range of PAS disorder and treated with prophylactic internal iliac balloon implantation prior to cesarean section and to assess maternal and fetal outcomes.

Material and methods: Retrospective cohort study.

Results: A total of 30 patients were included in the study. Hysterectomy was performed in 10 cases — partial hysterectomy in six and total hysterectomy in four. Median estimated blood loss was 1.18 L. In two cases technical complications were noted. In one case bilateral internal iliac artery thrombosis requiring urgent surgical intervention occurred. A total of 30 live infants were delivered. Mean birth weight was 2435 g and mean Apgar score at 1', 5' and 10' minutes was 6.8, 8 and 8.7 respectively. After average 30 days of hospitalization all infants and their mothers were discharged in good clinical condition.

Conclusions: Placenta accreta spectrum remains a challenge for obstetricians and gynecologists and despite interdisciplinary approach is associated with numerous

complications with life-threatening postpartum hemorrhage being the most serious one. Prophylactic placement of iliac balloons is a minimally invasive and safe endovascular technique which allows rapid and effective control of postpartum bleeding in patients with PAS, with low complication rate for both mother and the child.

Key words: abnormally invasive placenta; postpartum hemorrhage; high-risk pregnancy; hysterectomy; surgical techniques

INTRODUCTION

Placenta accreta spectrum (PAS) is adversely impacting maternal health outcomes worldwide and its prevalence is likely to rise rapidly. The term PAS refers to the range of pathologically adherent or invasive placentas and includes placenta accreta, placenta increta and placenta percreta [1]. This classification is based on the depth of placental invasion into the myometrium and surrounding tissues. Placental tissue implants onto the myometrium (accreta), into the myometrium (increta) or through the myometrium to surrounding organs (percreta) [2]. The most common risk factor is multiple previous cesarean deliveries, with observed rise over the last decades leading to a considerable increase in the incidence of PAS disorders that now occur approximately in up to 1 of 272 patient with a birth-related hospital discharge diagnosis [3, 4]. In a large systematic review, the rate of placenta accreta spectrum increased from 0.3% in women with 1 previous cesarean delivery to 6.7% in women with six previous cesarean deliveries [5]. Other risk factors include history of uterine surgery causing damage to the uterine wall integrity (operative hysteroscopy, surgical termination and endometrial ablation or curettage), multiparity, advanced maternal age, Asherman syndrome, assisted reproduction techniques and prior or current placenta abnormalities, especially placenta previa (PP) [6, 7]. In most PAS disorders (more than 90%) women have also PP–*praevia* PAS [8].

Clinical signs during the delivery are like those of placental retention: lack of placental separation within 20–30 minutes after childbirth despite active management of the third stage of labor, difficulties with manual or piecemeal placental removal requiring instrumental intervention and heavy bleeding from the placental bed after placental removal during cesarean section [9, 10]. Prenatal diagnosis of PAS is invaluable to reduce the risk of perioperative bleeding and improve management strategy. It enables early, prompt referral of suspected cases to tertiary center that beyond experienced multidisciplinary team is equipped with facilities such as immediate availability of blood products and intensive care unit [11]. Routine ultrasonography in the second and third trimester is the primary imaging tool for

screening women at risk of PAS, although it can be also suspected at a very early stage during the first trimester of pregnancy. In highly specialized centers, the diagnostic accuracy of ultrasound in identifying previa PAS is over 90% but recent series show that up to a third of cases of PAS are not diagnosed antenatally [12]. In order to confirm the depth of invasion and delineate its topography, or in doubtful cases such as localization of the placenta at the posterior wall, magnetic resonance imaging (MRI) should be performed to add valuable information [13] (Fig. 1).

Guidelines from International Society for PAS recommend fully individualized timing of delivery, based on personal risk assessment of emergent cesarean section. Patients in stable condition with diagnosis of PAS should be scheduled for elective cesarean delivery at around 34 to 37 weeks depending on their history of preterm birth, vaginal bleeding or PROM [14]. However, the optimal surgical approach to PAS disorders is not determined yet and different management options are available: from cesarean hysterectomy persisting the definitive treatment method, to one-step conservative operations and the triple P procedure, focused on removing only this part of the uterine wall invaded by the placenta [15, 16]. Still, surgical management of PAS disorders remains a challenge for obstetricians and all measures taken in aim to reduce maternal mortality and improve the quality of perinatal care are invaluable [17, 18]. Hence several surgical methods and various additional techniques ranging from uterine cavity compression with balloon tamponade or sutures, to pelvic devascularization with uterine artery or internal iliac artery ligation aiming to control bleeding in patients with PAS have been suggested [19–21]. With the introduction of interdisciplinary hybrid operating rooms equipped with digital subtraction angiography (DSA) minimally invasive endovascular radiology methods performed in order to reduce peri-operative blood loss and improve visualization of the operative field were proposed [22–25].

Objectives

The purpose of our study was to summarize our five-year experience with managing patients diagnosed with wide range of PAS disorder and treated with prophylactic internal iliac balloon implantation prior to cesarean section and to assess maternal and fetal outcomes. At our institution this procedure has become a routine part of preparation for scheduled cesarean section in patients diagnosed with PAS.

MATERIAL AND METHODS

In this retrospective, single-center study we investigated the medical records of patients with PAS who underwent prophylactic internal iliac balloon implantation prior to cesarean section from January 2015 to October 2020. Clinical information including age, history of deliveries/cesarean sections and additional risk factors (*e.g.*, diabetes mellitus, smoking and endocrine disorders) was collected. All patients were evaluated by a multidisciplinary board consisting of obstetrician, anesthesiologist, interventional radiologist, urologist and neonatologist. Diagnosis of PAS was based upon US and/or MRI examination. Elective cesarean delivery was scheduled at 34 to 37 weeks. In case of rapid and severe antepartum hemorrhage or clinical deterioration the procedure was carried out without any delay. Antenatal corticosteroids were administered to all patients before the delivery.

All procedures were performed in hybrid operating room. Firstly, in local anesthesia, bilateral vascular access was obtained and both internal iliac arteries were catheterized with 5-Fr Cobra catheters (Cook, Bloomington, IN) simultaneously by two interventional radiologists. Afterwards, PTA balloon catheter was placed on each side and inflated with a mixture of saline and contrast media. Control angiography confirmed proper balloon placement and complete vessel occlusion. All measures were taken in order to reduce the radiation dose to the mother and the fetus according to the as low as reasonably achievable (ALARA) principle (short fluoroscopy pulses, optimization of X-ray tube and detector position, tight collimation etc.). Bilaterally, balloons were deflated, the sheaths were dressed and sutured to the skin. Following the endovascular part, the cesarean procedure was carried out in general anesthesia. After the delivery of the infant, the balloons were inflated (3AT up to 60 minutes) on both sides in order to reduce the bleeding. In case of uneventful detachment and removal of the placenta and successful hemostasis the uterus was sutured, balloons deflated, and abdominal wall was closed. In case of extensive postpartum hemorrhage despite the inflated balloons, hysterectomy was performed if deemed necessary. Afterwards, angiographic control of internal iliac arteries was performed. If sign of contrast extravasation was observed, endovascular embolization was carried out (Fig. 2).

Finally, both balloons and vascular sheaths were removed, and puncture sites were closed using closing devices or manual compression. After the surgery all patients remained under intensive surveillance for at least 24 hours.

Procedural details (radiation dose, hysterectomy rate, estimated blood loss, volume of blood products transfused, duration of the surgical procedure and complications) as well as fetal information (Apgar at 1', 5' and 10' minute, birth weight, postpartum complications and hospitalization duration) were recorded.

Consent for publication was obtained for every individual person's data included in the study. The institutional review board approved the study.

RESULTS

A total of 30 patients were included in the study. The mean age of the patients was 35 years (from 26 to 45) and median gestational age at the time of delivery was 34 weeks (from 27 to 38). The median number of previous pregnancies was 3 (from 1 to 7) while median number of previous caesarean deliveries was 1.7 (from 0 to 5). Additional risk factors during the pregnancy included diabetes mellitus (20%), hypothyroidism (17%), anemia (10%) and nicotinism (7%). Routine blood analysis including red blood cells count (RBC) and hemoglobin were performed before and after the cesarean section. Average RBC was $3.8 \times 10^6/\mu\text{L}$ (from 3.1 to $4.6 \times 10^6/\mu\text{L}$) and average hemoglobin level was 12 g/dL (from 8.1 to 13.7g/dL) before the procedure. Patients' demographics are presented in Table 1.

As far as the antenatal diagnosis of placenta accreta spectrum and the degree of placental invasion was concerned, the preoperative imaging examinations disclosed placenta accreta in 12 patients (40%), placenta increta in 17 patients (56%) and placenta percreta in one patient (4%). Median radiation dose during balloon placement was 37 mGy (from 10 to 75). Median duration of balloon occlusion was 38 min (from 15 to 60 min) whereas median obstetric surgery duration was 84 min (range 20 to 200 min). Hysterectomy was performed in 10 cases (33%) — partial hysterectomy in six and total hysterectomy in four. From this group histopathological examination of hysterectomy specimens identified three cases of placenta accreta (25% of all patients with placenta accreta), six cases of placenta increta (35%) and one case of placenta percreta (100%). Median estimated blood loss (EBL) was 1.18 L (range 0.25–4.5 L). Median number of blood products transfused during the surgery (red blood cells and fresh frozen plasma) was 1.6 and 1.4 respectively. Median RBC count drop was $0.6 \times 10^6/\mu\text{L}$ and median hemoglobin concentration drop was 1.4 d/dL after the delivery. On average, patients spent 30 days in hospital (including pre-cesarean stay) (range 5–76 days).

In two cases (7%) technical complications occurred — in one patient balloon rupture was observed in control angiography and in one patients balloon migration to external iliac artery was noted. Both patients required partial hysterectomy. In one case (3%) bilateral internal iliac artery thrombosis requiring urgent surgical intervention occurred. This patient underwent total hysterectomy. Control angiography disclosed minor post-cesarean contrast extravasation in three cases (10%). In all three patients, successful embolization of uterine arteries was performed with gelatin sponge powder.

A total of 30 live infants were delivered. Mean birth weight was 2435 g (range 950–3450 g) and mean Apgar score at 1', 5' and 10' minutes was 6.8, 8 and 8.7 respectively. From this group 13 (43%) neonates required continuous positive airway pressure (CPAP) therapy for 12-24 hours after delivery. Additionally, in two (15%) infants exogenous surfactant therapy was implemented. All 13 infants were admitted to the neonatal ICU for observation. No further complications were observed. Eventually, all 30 infants and their mothers were discharged in good clinical condition. Procedural details and clinical outcome are shown in Table 2.

DISCUSSION

Placenta accreta spectrum (PAS) remains a challenge for obstetricians and gynecologists and despite interdisciplinary approach is associated with numerous complications with life-threatening postpartum hemorrhage (PPH) being the most serious one. According to authors of meta-analysis reported maternal mortality rate is up to 7% in patients with PAS [26, 27]. That is why, minimally invasive techniques of interventional radiology aiming to reduce intra-operative bleeding were gradually adopted in many centers worldwide. First use of endovascular methods in control of PPH was described by Brown et al. in 1979 [28]. Since then, the technique evolved and became an effective method especially in situations where preservation of fertility is desired [29]. The aim of our study was to analyze maternal and neonatal outcomes among patients diagnosed with PAS treated with prophylactic internal iliac balloon implantation prior to cesarean section.

In our study, median estimated blood loss (EBL) during cesarean section was 1.18 L which remains within the range of EBL described by other authors [22, 23, 30–35]. According to WHO recommendations blood loss of ≥ 1.0 L is defined as severe PPH however this definition is based on historical findings and from our experience such blood loss is fully manageable with blood products transfusion [36]. Massive PPH defined by a blood loss > 2.5 L occurred in two patients (7%). Both required significantly more blood products (7 of red blood cells and six of freshly frozen plasma compared to median of 1.6 and 1.4 in other patients) and underwent total hysterectomy. Nevertheless, they were eventually discharged in good clinical conditions with healthy infants. In case of massive PPH despite inflated balloons one should always remember about non-uterine arteries which do not originate from internal iliac arteries but might be major sources of PPH [37]. Therefore, some authors recommend abdominal aorta occlusion rather than blockage of internal iliac arteries [22, 31]. According to Cui et al. this type of balloon placement blocks most of the pelvic blood supply and

significantly aids hemodynamic stability [31]. In our center however, abdominal aorta occlusion is reserved for emergency cases (*e.g.*, ruptured abdominal aorta aneurysms) rather than for elective procedures.

In our institution all cesarean deliveries in patients with PAS are performed in general anesthesia. Hong et al. compared the maternal hemodynamics, EBL and neonatal outcome of general versus epidural anesthesia for cesarean section among patients with morbidly adherent placenta [38]. The authors concluded that general anesthesia may increase blood loss without improving the safety of the procedure. On the other hand, in the event a hysterectomy is necessary, the conversion from regional to general anesthesia might take some time and increase the intraoperative blood loss.

Despite comparable EBL the hysterectomy rate was higher than described by above-mentioned authors (33% in our study). Possible explanation is that in some cases, after discussion with the patient and obtaining an informed consent, the hysterectomy was performed in order to prevent further potentially life-threatening pregnancies in multiparous patients – median number of previous pregnancies in hysterectomy group was four compared to 2.6 in non-hysterectomy group. As expected, the rate of hysterectomy increased with the degree of placental invasion and severity of PAS — 25% of patients with placenta accreta, 35% of patients with placenta increta and 100% of patients with placenta percreta.

Authors of other studies reported a rate of maternal complications up to 16% due to balloon placement [22, 23, 30–35]. Complication rate documented in our study was significantly lower — 10%. Exact causes for these particular complication rates are difficult to ascertain but there are two possible explanations. First, in our center all procedures were performed in hybrid room which eliminates the need of patient's transfer to the delivery suite and enables quick angiographic control if needed. Secondly, the catheter placement was performed simultaneously by two experienced interventional radiologists with minimal number of attempts which reduces the probability of luminal trauma. Unfortunately, similarly to Cui et al. and Shrivastava et al. an internal iliac artery thrombosis occurred in one patient [31, 35]. The patient was managed with surgical means. This confirms that the decision of balloon implantation should always be made based on a comprehensive analysis of the patient's general condition as the pregnancy and balloon occlusion are risk factors for venous thrombosis [39, 40].

As far as neonatal complications are concerned, apart from large group of infants requiring continuous positive airway pressure (CPAP) therapy for 12–24 hours after delivery (14–43%, median gestation age — 32 weeks) no serious complications were observed. This

stays in line with observations made by Nicholson et al. who did not find any evidence for balloon-induced ischemic complications for the neonates [23].

In terms of radiation, all measures were taken in order to reduce the radiation dose to the mother and the fetus (median dose achieved in our patients was 0.037 Gy). According to Yoon et al. dose lower than 0.5 Gy is generally considered safe for the fetus during the second and third trimester [41]. Doses greater than 150 mGy, which are viewed as the minimum dosage at which negative fetal consequences will occur, were not achieved in any of our patient. Semeraro et al. who conducted a study on fetal radiation dose during prophylactic balloon placement in patients with morbidly adherent placenta concluded that the most significant dose reduction might be obtained with pulsed fluoroscopy rate which were routinely performed in our center [42].

We are aware that our research has several limitations. The main limitation is the retrospective nature of the data collected from a single center and consequently small sample size due to rarity of the condition. Secondly, umbilical cord pH which could provide additional information on neonate condition was not routinely acquired in all patients. Finally, lack of control arm consisting of patients undergoing cesarean section without prophylactic balloon placement for direct comparison might be perceived as a drawback.

CONCLUSIONS

In conclusion, prophylactic placement of iliac balloons is a minimally invasive and safe endovascular technique which allows rapid and effective control of postpartum bleeding in patients with a wide range of disorders from placenta accreta spectrum, with low complication rate for both mother and the child.

Conflict of interest

The authors declare that they have no conflict of interest.

Financial founding

The authors received no financial founding.

Ethical approval

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

Informed consent

Informed consent was obtained from all individual participants included in the study.

Contributions

All authors contributed significantly to the paper: MSZ, KP and WDK evaluated the data and prepared the manuscript. KP, MSZ, WDK, GP, PD and MG participated in described procedures. All authors approved the final version of the manuscript.

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Table 1. Demographic characteristic of the patients

Patients n = 30	
Demographic data	
Mean age [years] (min–max)	35 (26 to 45)
Average gestational age [weeks] (min–max)	34 (27 to 38)
Average gravidity (min–max)	3 (1 to 7)
Previous cesarean section [mean] (min–max)	1.7 (0 to 5)
Additional risk factors	
Diabetes mellitus (n, %)	6 (20%)
Hypothyroidism (n, %)	5 (17%)
Anemia (n, %)	3 (10%)
Nicotinism (n, %)	2 (7%)

Laboratory results before the delivery	
Red Blood Cells (RBC) [mean] (min–max)	$3.8 \times 10^6/\text{ul}$ (3.1 to $4.6 \times 10^6/\text{uL}$)
Hemoglobin (Hgb) [mean] (min–max)	12 g/dL (from 8.1 to 13.7 g/dL)

Table 2. Procedural details and clinical outcome

Patients n = 30		
Radiological details		
Mean radiation dose (min–max)	37 mGy (10 to 75 mGy)	
Mean duration of occlusion (min–max)	38 min (15 to 60 min)	
Embolization rate (n, %)	3 (10%)	
Endovascular complication rate (n, %)	3 (10%)	
Procedural details		
Median duration of surgery (min–max)	84 min (20 to 200 min)	
Hysterectomy rate (n, %)	Partial — 6 (20%)	Total — 4 (13%)
Median estimated blood loss (EBL) (min–max)	1.18 L (0.25 to 4.5 L)	
Median number of blood products transfused (n)	Red blood cells — 1.6	Freshly frozen plasma — 1.4
Median laboratory values drop	Red blood cells count — $0.6 \times 10^6/\text{uL}$	Hemoglobin — 1.4 d/dL
Neonates details		
Mean birth weight was (min-max)	2435 g (950 to 3450 g)	
Mean Apgar score at 1' 5' and 10' minutes	6.8, 8, 8.7	
Neonates requiring CPAP (n,%)	13 (43%)	

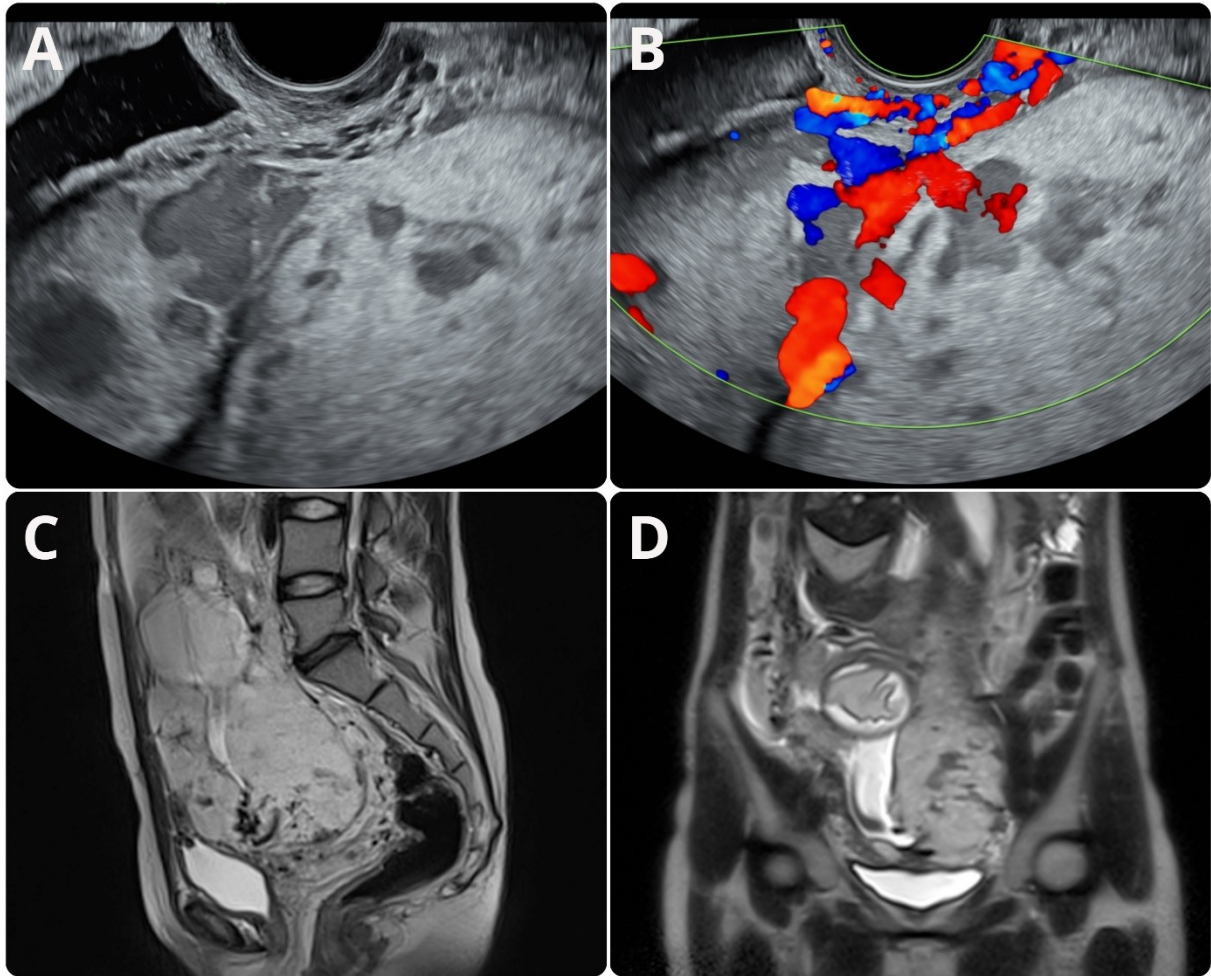


Figure 1. Imaging examination of a 20-year old patient with praevia PAS; **A.** Presence of numerous abnormal placental lacunae, undetectable myometrium and bladder wall interruption on grayscale ultrasound; **B.** Doppler mode showing vascular supply; **C, D.** T2-weighted MRI sequences (sagittal and coronal) confirming the diagnosis

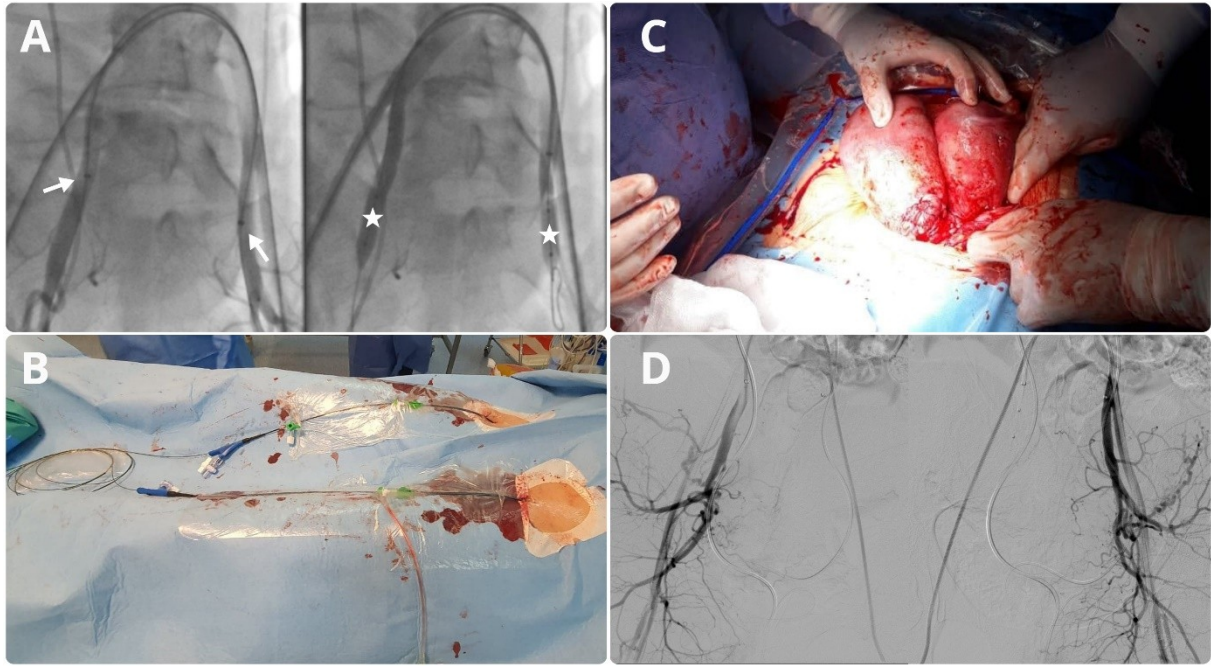


Figure 2. Prophylactic internal iliac arteries balloon placement in a patient with PAS and uterus didelphys; **A.** Radiological part of the procedure — initial angiography from vascular sheaths in internal iliac arteries (white arrows). Control contrast injection after inflating of the balloons confirms occlusion of internal iliac arteries (white stars); **B.** After balloon placement, the sheaths were dressed and sutured to the skin; **C.** Intra-operative picture after the delivery; **D.** Control angiography showing no signs of contrast extravasation