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A retrospective analysis of the treatment on abdominal aortic balloon occlusion-related thrombosis by continuous low-flow diluted heparin

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Abstract

Thrombosis is one of the serious complications related to prophylactic balloon occlusion of the abdominal aorta (PBOAA). This study aims to retrospectively analyze the efficacy and safety of continuous low-flow infusion of diluted heparin saline to prevent this complication related to PBOAA and further to provide the theory and evidences for using PBOAA.

A study was carried out at our hospital from March 2016 to December 2018. Women with pernicious placenta previa (PPP) were treated PBOAA to prevent massive bleeding during CS. According to whether continuous low-flow infusion of diluted heparin saline was used to prevent catheter-related thrombosis or not, they were divided into 2 groups, the test group and the control group. The incidence of thrombosis between the 2 groups was compared and the effective treatment of thrombosis was also discussed. The comparison of nonparametric values was accomplished by using Fisher exact test. Statistical significance was set at $P < .05$.

There were 31 women with PPP who received PBOAA during CS who were included in our study. Six of 19 women in control group (31.6%) developed thrombotic complications, while none of 12 women in test group. There were statistically significant differences in the incidence of thrombosis between the 2 groups ($P = .037$). There was no statistically significant difference in the amount of estimated blood loss and blood transfusion during CS between the 2 groups, nor was there statistically significant difference in the hospital days after CS ($P > .05$). All 6 women with thrombotic complications had no positive symptoms and thrombotic sequelae. The managements of thrombus included systemic anticoagulation, catheter-directed thrombolysis, and catheter-directed anticoagulation. One of the 6 women was lost to follow-up, and the thrombus of the other 5 women were completely dissolved. No other adverse outcomes or complications related to PBOAA were observed in all women in this study.

Continuous low-flow infusion of diluted heparin saline is a safe procedure when PBOAA is performed for patients with PPP. It can effectively reduce or even avoid thrombosis without increasing intraoperative blood loss during CS for PPP patients.

Abbreviations: CS = caesarean section, CSE = combined spinal-epidural anesthesia, DSA = digital subtraction angiography, IR = interventional radiology, MDT = multiple disciplinary team, MRI = magnetic resonance imaging, PBOAA = prophylactic balloon occlusion of the abdominal aorta, PPP = pernicious placenta previa, UAE = uterine artery embolization.

Keywords: abdominal aortic balloon occlusion, catheter-directed thrombolysis, diluted heparin, pernicious placenta previa, placenta accreta, thrombosis

1. Introduction

Abnormal placental implantation is a serious complication of pregnancy. It is an important cause of postpartum hemorrhage, perinatal emergency hysterectomy, or even maternal death. It can be divided into 3 types (accreta, increta, percreta) according to the depth of placental implantation.[1–3] Placenta accreta refers to the abnormal placenta direct attachment onto the myometrium, and the placental increta means the abnormal placenta invades into the myometrium, while placenta percreta means the abnormal placenta invades into or through the uterine serosa. For ease of description, "placenta accreta" is usually used for the above 3 types.[4] One in every 533 pregnant women was reported with placenta accreta. High increased rate of placenta accreta is associated with high caesarean section (CS) rate.[5] When the placenta attaches to the scar of the previous CS, the risk of placenta accreta increases, especially when combined with placenta previa.[6] After 28 weeks of gestation, if the placenta is attached to the lower margin of the uterine segment and reaches or even covers the cervix, its position is lower than the fetal presentation, which was named as placenta previa. The current

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placenta previa placing at the scar caused by previous CS is named pernicious placenta previa (PPP). Previous cesarean delivery increases this risk to 3% for the first delivery, and to 40% and 67% for the third and fifth deliveries, respectively.[7–8]

PPP is the main cause of obstetric bleeding and hysterectomy. Massive bleeding during CS can lead to hypovolemic shock or even maternal death. Therefore, how to control massive hemorrhage in PPP is a difficult problem and still a challenge to obstetricians. So, it is necessary to take effective preventive measures to ensure the safety of mothers and fetuses. In the last decade or so, intra-arterial balloon occlusion has been used by obstetricians and interventional radiologists for women with PPP during CS, especially in China. Although studies have shown that this technique can effectively reduce the amount of bleeding and the rate of hysterectomy during CS, there is still no consensus.[9] The incidence of balloon catheter related complications is relatively low, but serious complications may still occur. Among them, balloon catheter related thrombosis may lead to limb ischemic, or even amputation and the incidence of thrombosis reported in the literature is about 0.9% to 10%.[9–15]

We performed prophylactic balloon occlusion of the abdominal aorta (PBOAA) for women with PPP during CS from March 2016. And several women have developed lower extremity vascular thrombosis. In order to decrease this serious complication, we have used continuous low flow pumping of diluted heparin saline. And we have achieved remarkable results. To date, we have not retrieved a controlled study on how to prevent balloon catheter-associated thrombosis. Therefore, this study will explore the prevention and management of thrombosis related to PBOAA, and provide further evidence for the safety and efficacy of PBOAA.

2. Methods and materials

2.1. Patients

A retrospective study was carried out at our hospital from March 2016 to December 2018. The protocol of this study was approved by Medical Research Ethics Committee of our hospital, and written informed consent was waived due to the study with retrospective nature. The inclusion criteria of our study are as follow:

(1) patients suspected placenta accreta were diagnosed by Doppler ultrasonography and/or magnetic resonance imaging (MRI), and subsequently confirmed by intraoperative and/or postoperative pathologic examination,
(2) multiple disciplinary team (MDT) discussion was carried out before the operation, and then, the operative plan of CS with PBOAA was confirmed,
(3) preoperative consent of patients and their families was obtained,
(4) the balloons were inflated during CS.

The above 4 needed to be satisfied at the same time before they could be included in the study. The exclusion criteria of our study are as followed:

(1) patients were suspected placenta accreta without a history of previous CS,
(2) CS was performed in an emergency situation,
(3) the balloon was not inflated because of a small amount of bleeding during CS,
(4) the purpose of CS was to terminate the pregnancy.

CS of all patients was performed by the same team of experts (Junhui Wan and his colleagues).

2.2. Interventional operation

Because of the absence of a hybrid operating room equipped with C-arm for digital subtraction angiography (DSA) in our hospital, women were transferred to the interventional radiology (IR) suite for presetting abdominal aortic balloon catheter before CS. After right groin disinfection and surgical draping, puncture of the right femoral artery was taken under local anesthesia by 2% lidocaine. The placement of a 5-French gauge vascular sheath was followed by a pigtail catheter introduced into the upper abdominal aorta to identify the origins of the renal arteries with reference to lumbar vertebrae and to measure the diameter of the lower abdominal aorta. And then, a 12-French gauge vascular sheath (RCF-12.0–38-J, Cook Medical Inc., Bloomington, IN) replaced the 5-French gauge vascular sheath under the support of a stiff guide wire (Amplatz^{TM}). After that, a compliant balloon catheter (Reliant Stent Graft Balloon Catheter, Medtronic Inc., Parkmore Business Park West, Galway, Ireland) was just inserted into the infrarenal abdominal aorta above the aortic bifurcation under fluoroscopy guidance. The volume required to occlude the blood flow of the abdominal aorta was calculated based on the volume of the cylinder according to the length of balloon and the diameter of the lower abdominal aorta and a check inflation of balloon was avoided. Finally, the sheath and the balloon catheter were fixed to the skin, and the length of the balloon catheter outside the body was marked so as to confirm whether the balloon catheter was dislodged during transportation and combined spinal-epidural anesthesia (CSE) or not.

2.3. Operative procedure

After prepositioning the abdominal aortic balloon catheter, patients were transferred to the surgery room for continuous monitoring of arterial waveform and invasive blood pressure. According to whether the management of preventing thrombosis was adopted or not, all women were divided into 2 groups, non-prevention group (control group) and prevention group (test group). The control group was not infused with diluted heparin saline, and the left dorsalis pedis artery was punctured by an anesthesiologist to monitor the arterial waveform and blood pressure to evaluate the occlusive effect. For the test group, an extension tube was connected to the right femoral artery sheath side arm followed by a tee. One of its branches was connected to a monitor for continuous monitoring of the right femoral artery waveform and blood pressure with continuous infusion of diluted heparin saline (about 2 mg/hour). The last branch of the tee was connected to a syringe. In this way, according to the changes of waveform and blood pressure, we could determine whether arterial thrombosis developed, and at the same time, the thrombus could be aspirated and another small amount of diluted heparin saline was injected through the syringe for anticoagulation during CS, so as to avoid thrombosis.

After preparation, CS was performed under CSE. Intraoperatively, the balloons were inflated with 0.9% sodium chloride solution at the obstetrician's request, either before uterine incision or immediately after delivery of the fetus and umbilical cord clamping. Successful occlusion was assumed if the arterial waveform appeared as a straight line. With the balloon

occlusion, the obstetricians stripped the placental tissue and sutured the uterine wound for hemostasis. After the completion of hemostasis operations, the balloon pressure was released to check for bleeding. If the bleeding was controlled, the balloon remained deflated. If the uterine wound continued to bleed, the interventional radiologist (Rongguang Luo) reflated the balloon. Continuous balloon occlusion was limited in 30 minutes. If suturing the uterine wound was not completed within 30 minutes, we still deflated the balloon for at least 1 minute to prevent lower limb ischemia and necrosis, and then we repeated to inflate the balloon again. Once hemostasis for the uterine wound were adequate, the obstetricians sutured the uterus layer by layer.

2.4. Postoperative care

After CS, the women in the control group were transferred back to the interventional operation room for DSA angiography to check whether there was uterine bleeding and arterial thrombosis, and uterine artery embolization (UAE) and the treatment of thrombosis were determined based on the angiography. For the test group, balloon catheter and sheath were directly removed in the operating room. UAE would be performed if there was postpartum hemorrhage. Six hours after surgery, color doppler ultrasonography of both lower limbs was performed to diagnose the thrombosis. In the 2 groups of women, following the balloon extraction, the sheath was removed after the side arm suction with confirmation that there was no thrombus extraction, and then pressure hemostasis followed by dressing (Some patients in the control group, the vascular suture device was used). The dorsalis pedis artery pulse and skin temperature of both lower limbs were closely monitored after patients returning to the ward.

2.5. Data acquisition

By searching the electronic medical records of our hospital, the patients' data were collected and imported into a Microsoft excel for analysis. Data such as patients' age (years), gestational age (days), number of gravidity, number of parity, number of previous CS, operation duration (min), occlusion duration (min), cases of women developed thrombosis (n, %), estimated blood loss (mL), blood transfusion (mL), hospital days after CS, and the treatment of thrombosis were collected. All patients were followed up by telephone or outpatient after the delivery.

2.6. Statistical analysis

The differences in measurement data between 2 groups were presented as mean ± standard deviation (SD), or as median (with interquartile range), and were analyzed using two independent samples t test and the Mann–Whitney U test if the data were not normally distributed. Categorical variables were presented in the form of a rate and the difference between the 2 groups was compared by using Fisher exact test. SPSS 22.0 software (IBM, Armonk, New York, NY) was used, and $P < .05$ was considered statistically significant.

3. Results

3.1. Thrombosis in two groups

A total of 31 patients were enrolled in the study. All of those were confirmed to have placenta accreta after surgery. Among them, thrombosis occurred in 6 of 19 patients in the control group, all of them located in the right lower extremity, and the incidence was 31.6% (6/19). No thrombosis was developed in the test group, and the incidence was 0% (0/12). The incidence was 19.4% (6/31) for all 31 patients. Most common site of thrombosis was found to be common femoral followed by superficial femoral (Table 1). All 6 women with thrombotic complications had no serious positive symptoms and thrombotic sequelae. The managements of thrombus included systemic anticoagulation, catheter-directed thrombolysis, and catheter-directed anticoagulation (Table 1). One of the 6 women was lost to follow-up, and the thrombus of the other 5 women were completely dissolved. No other adverse outcomes or complications related to PBOAA were observed in all women in this study.

3.2. Comparison between the 2 groups

There was no significant difference in baseline data (patients' age, gestational age, number of gravidity, number of parity, number of previous CS) between the 2 groups (Table 2). The difference of operation duration between the 2 groups was not significant ($P = .670$). No single balloon inflating lasted more than 30

Table 1

Characteristics of the six women with thrombotic complications in the control group.

Case No.	Gravidity (n)	Parity (n)	Previous CS (n)	Gestational age (weeks)	Diagnosis	Surgical procedure	Operation duration (min)	Occlusion duration (min)	Postoperative diagnosis of thrombosis	Location of thrombosis	Treatment
1*	4	1	1	36 + 1	PI + MPP	CS + LR + UAL	125	13	8 d	R SF A	CDT + Anticoagulation
2	2	1	1	35 + 3	PI + CPP	CS + LR + UAL	70	9	<48 h	R CF/ SF A	CDT
3	6	2	2	37+3	PI + CPP	CS + hysterectomy	260	19	4 d	R superficial V	Anticoagulation
4†	2	1	1	39	PP+CPP	CS + SH +UAL	226	21	<48 h	R EI A	Anticoagulation
5‡	9	3	3	35 + 3	PP + CPP	CS + LR + UAL	180	30	<48 h	R CF A	CDT
6	6	2	2	34 + 2	PI + CPP	CS + LR + UAL + UAE	170	13	<6 h	R CF A	CDAC

A = artery, CDAC = catheter-directed anticoagulation, CDT = catheter-directed thrombolysis, CF = common femoral, CPP = complete placenta previa, CS = cesarean section, EI = external iliac, LR = local resection, MPP = marginal placenta previa, PA = placenta accreta, PI = placenta increta, PP = placenta percreta, R = right, SF = superficial femoral, SH = subtotal hysterectomy, UAE = uterine artery embolization, UAL = uterine artery ligation, V = vein.

* During the process of CDT, the thrombolytic catheter was displaced and the thrombus did not dissolve. The patient had no symptoms and refused thromboembolectomy, and asked for discharge from our hospital. Ultrasound examination was performed 5 months later and the thrombus dissolved with the treatment of systemic anticoagulation.

† The right external iliac artery was occluded, and the lateral branch of the internal iliac artery was supplied to the right superficial femoral artery. The super-selective intubation was unsuccessful, and the patient refused thromboembolectomy because of non-symptom and absent of lower limb ischemia, and she was treated by systemic anticoagulation and was lost to follow-up after discharge from our hospital.

‡ During the process of CDT, there was a small amount of bleeding in the abdominal incisions.

Table 2

Comparison of the non-prevention group and prevention group.

	Non-prevention group (n = 19)	Prevention group (n = 12)	*P*
Age (years)*	32.2 ± 5.4	31.3 ± 4.5	.643
Gestational age (days)*	253.5 ± 14.3	252.2 ± 12.6	.798
Number of gravidity*	4.7 ± 2.5	3.5 ± 1.5	.133
Number of parity*	1.5 ± 0.8	1.8 ± 0.8	.305
Number of previous CS (n)*	1.4 ± 0.7	1.8 ± 0.8	.147
Operation duration (min)*	140.3 ± 53.6	148.6 ± 45.6	.670
Occlusion duration (min)*	16.3 ± 6.9	18.6 ± 9.1	.437
Cases of women developed thrombosis (n, %)†	6, 31.6%	0, 0%	.037
Estimated blood loss (mL)‡	500 (800)	700 (650)	.652
Blood transfusion (mL) ‡	0 (1200)	400 (1200)	.214
Hospital days after CS‡	8.1 ± 3.5	8.1 ± 2.5	.592

CS = cesarean delivery.
* Independent samples *t* test.
† Fisher exact test.
‡ Mann–Whitney *U* test.

minutes in either group. The difference of balloon occlusion duration between the 2 groups was not significant ($P = .437$). Due to incomplete hemostasis within 30 minutes or still bleeding after deflated the balloon, 2 patients in both groups needed to reflate the balloon. The 2 patients in test group were inflated the balloon three times, with a total duration of 39 minutes and 31 minutes, respectively. And 2 patients in control group were inflated the balloon 2 times, with a total duration of 31 minutes and 30 minutes, respectively. The incidence of thrombosis in test group was significantly lower than that in the control group, and the difference was statistically significant (Fisher exact test, 1-sided, $P = .037$). There was no statistically significant difference in the amount of estimated blood loss (mL) and blood transfusion (mL) during CS between the 2 groups, nor was there statistically significant difference in the hospital days after CS ($P > .05$) (Table 2).

4. Discussion

4.1. Incidence of thrombosis compared between the 2 groups

This study showed that the incidence of thrombosis in the test group (0/12, 0%) was significantly lower than that in the control group (6/19, 31.6%), As we know, PPP is a kind of life threatening disease because of the risk of massive blood loss during CS. Heparin is an anticoagulant and may increase the risk of bleeding during CS for patient with PPP. Although heparin was used in the test group, our results still showed that he difference of intraoperative blood loss and transfusion, and the days of hospitalization after CS between the test group and the control group has no statistically significant (Table 2). Our small sample study suggested that continuous low flow diluted heparin saline infusion may effectively prevent the occurrence of PBOAA related thrombosis, without increasing adverse consequences such as intraoperative blood loss and transfusion. Therefore, we believe that continuous low flow diluted heparin saline infusion is safe and effective for preventing thrombosis in CS with PBOAA.

4.2. Reason for continuous low flow infusion of dilute heparin saline

It is reported that PBOAA during PPP has a risk of thrombosis, and the incidence is about 0.9% to 10%.[9–15] However, in our study, 6 of the 19 patients initially treated developed thrombosis with high incidence of 31.6% (6/19). Although the total incidence was 19.4% (6/31) for all 31 patients. It is still higher than that reported in literatures. Though all the 6 patients were cured and discharged after treatment, the potential adverse consequences should not be ignored, which prompted us to reflect on the reasons for the high incidence of thrombosis and how to prevent thrombosis. At first, parturient women are usually in high coagulation state, while the anticoagulant effect of heparin can reduce and avoid thrombosis. Slow blood flow after balloon occlusion and platelet aggregation after arterial intima injury are potential risks of thrombosis, and continuous diluted heparin saline infusion ensures unobstructed blood vessels may prevent thrombosis. Secondly, general anesthesia may cause respiratory depression in the fetus. Therefore, CS is usually performed under CSE in our hospital. But heparinization is not permitted by anesthesiologists because bleeding and hematoma may be caused by puncture during CSE. At the same time, patients with PPP have the risk of fatal bleeding, which is another reason to ban heparinization. That is, only small dosage of heparin can be used during CS. Hence, continuous infusion of diluted heparin saline with low flow was used in our study. Our results suggested that continuous low-flow infusion of diluted heparin saline was effective in reducing or even avoiding thrombosis and did not increase the risk of intraoperative bleeding. That is to say, the method used in test group is feasible.

4.3. Other factors for thrombosis

Some other factors may cause thrombosis. Firstly, the operation is not skilled in the early stage, and we did not pay enough attention to thrombosis because there were no obvious positive symptoms, therefore, effective preventive measures were not taken. Secondly, we do not have a composite operating room equipped with DSA, so the patients were needed to be moved from the intervention room to the operating room, then the placement duration of balloon and catheter sheath was prolonged. Thirdly, a large catheter sheath (12F) was used, which limits the speed of blood flow. And the procedure of CSE required patients to present arch position, which might cause friction between catheter sheath and artery wall and then damage intima of artery, or even contribute to thrombosis. These may be the reasons why we observed thrombosis mainly occurred about the puncture side. Hence, we chose the catheter sheath side arm for infusing diluted heparin saline to prevent thrombosis in test group. The results of this study show that our method in test group is safe and effective.

4.4. Balloon catheter selection and thrombosis

The balloon catheter is mainly divided into compliant and non-compliant. However, which kind of balloon catheter is more suitable to be used in PPP has not yet reached consensus. Currently, non-compliant balloons are available in a variety of types, and it is easy to obtain a balloon that is consistent with the diameter of the abdominal aorta. However, since most hospitals lacked a composite operating room, inflating the balloon in operating room would be performed without fluoroscopy. If non-compliant balloon catheter dislodged is not found, balloon-inflation may cause serious adverse consequences such as arterial rupture. In contrast, displacement of compliant balloons did not always result in serious adverse consequences. But most currently available compliant balloons require a larger arterial sheath,

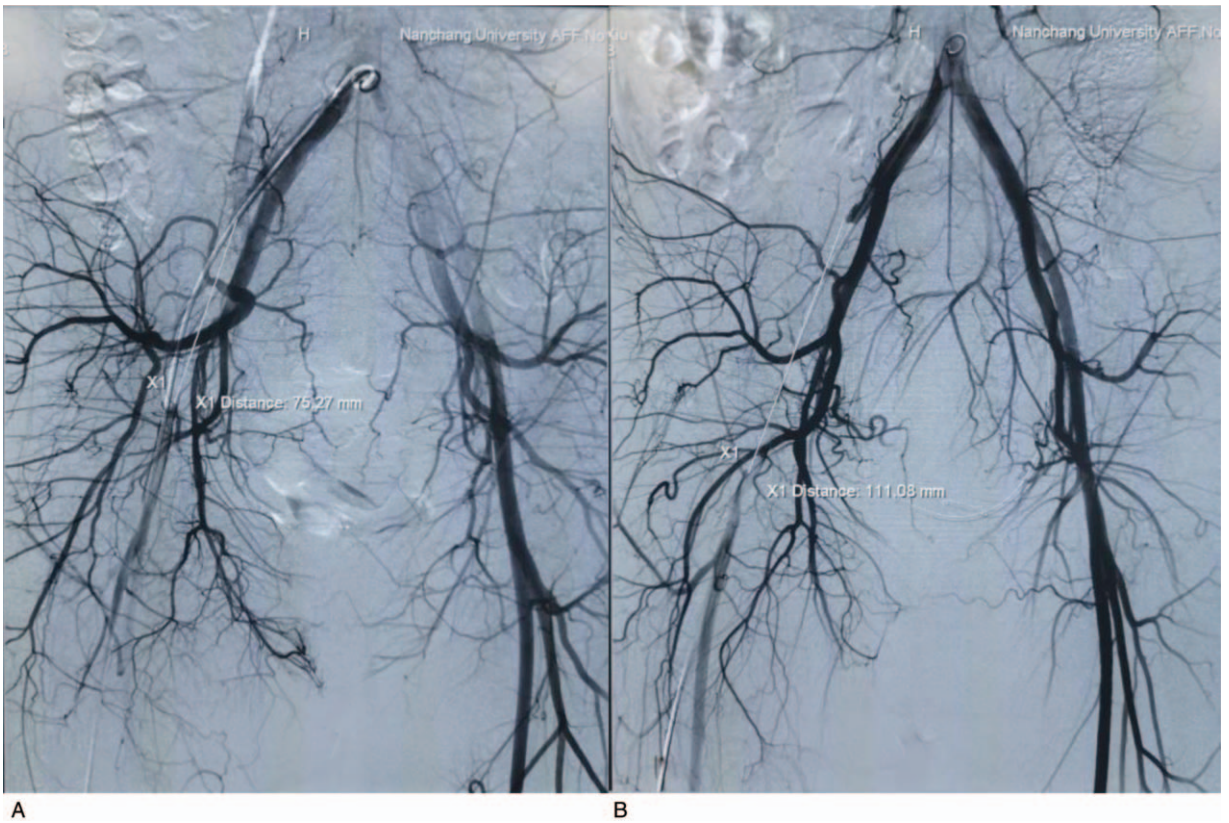

Figure 1. There are the DSA images of the 2 women in the control group after CS. Both of them showed the filling defect of the right common iliac artery. A. The filling defect is approximately 7.5 cm in length. There was no thrombosis was found in postoperative ultrasound examination. B. The filling defect is approximately 11 cm in length. The woman was diagnosed thrombosis of the right external iliac artery by postoperative ultrasound examination.

typically 12F. The squeezing action of the fetus during delivery may result in the displacement of the balloon catheter without being detected during CS. Therefore, we chose a kind of compliant balloon catheter (Medtronic's), but it requires using 12F arterial sheath. It has been reported in the literature that prolonged placement of 12F arterial sheath can lead to lower limb ischemia and have a risk of amputation.[16] The causes of thrombosis were not completely defined, but removal of the catheter sheath as early as possible may reduce the incidence of thrombosis. Therefore, in response to these factors that may lead to thrombosis, we have made great progress, that is, improving the level of technical operation, taking precautions and removing the catheter sheath early. At the same time, due to the large femoral sheath (12F) used, DSA angiography sometimes fails to accurately diagnose the presence or absence of a thrombus, even if there was a filling defect (Fig. 1). Therefore, in test group, ultrasound was used instead of DSA to diagnose thrombus. Hence, the large femoral sheath was removed immediately as CS was accomplished in test group, while the patients were transferred back to IR suite to perform angiography after CS and then the balloon catheter was removed in control group. The longer time of the balloon catheter remains in the body may also be a cause of high incidence of thrombosis in control group. But this needs to further study.

4.5. Treatment of thrombus

Six patients with thrombosis had no lower limb ischemia and were treated with anticoagulation postoperative. Originally, transcatheter thrombolysis is mainly used for the rapid dissolution of thrombus due to the lack of experience in the treatment of iatrogenic arterial thrombosis. However, PPP is a contraindication to thrombolysis and has a risk of bleeding. After continuous exploration, the intubation anticoagulation method achieved remarkable results. Whether the systemic use of urokinase affects the neonatal coagulation function through breast milk is not yet clear. Therefore, we believe that intubation anticoagulation is better than whole body anticoagulation. To date, there is no study of thrombosis associated with balloon catheters, and still no consensus on the treatment of thrombosis. Systemic anticoagulation, thrombectomy, angioplasty were mainly used nowadays.[9] There was bleeding risk in thrombolytic therapy after CS, while systemic anticoagulation was slow onset. Intubation anticoagulation may be prefer for it can quickly restore blood flow to the spot of thrombus and prevent new thrombosis. In our study, 6 patients with thrombosis had no obvious lower limb ischemia and necrosis due to collateral compensatory. We mainly used catheter-directed thrombolysis (3 patients), but one patient had a small amount of bleeding in the abdominal incisions (Table 1). In view of this situation, we switched to catheter-directed anticoagulation, which also achieved good results. And because of maternal hypercoagulation, we recommend intubation anticoagulation when thrombosis occurs. In other words, when thrombus is formed without lower limb ischemia, catheter-directed anticoagulation therapy can be used. After the body recovery, if the thrombus remains undissolved, thrombectomy can be performed. For patients with

lower limb ischemia, thrombectomy or endovascular stenting is recommended to quickly restore blood flow to the lower extremities as early as possible to avoid amputation.

4.6. Limitation of this study

There are also some shortcomings in the study. Firstly, the 2 groups of women were in different periods of abdominal aortic balloon occlusion technique. When the test group was treated, the technical skill had significantly improved, which may be one of the factors of thrombus reduction. Secondly, although we noticed that the longer time of the balloon catheter remained in the body may also be a factor of high incidence of thrombosis, but we failed to record the duration of balloon catheter placement in patients' medical records. And most importantly, the sample size of this study is small, and the sample size needs to be increased later to confirm the result.

5. Conclusion

Continuous pumping of the diluted heparin saline through the femoral artery sheath during PBOAA can significantly reduce thrombosis without increasing blood loss and blood transfusion, and also does not prolong the hospital stay after CS. It is a safe and effective prevention of thrombosis during PBOAA.

Author contributions

Data curation: Rongguang Luo, Fen Wang, Wentao Zhang, Zhifeng Duan.
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