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Bilateral cervix apex clamping procedure can be used as a new noninvasive second line therapy for postpartum hemorrhage

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ABSTRACT

In this study, we present a noninvasive procedure of bilateral cervix apex clamping (BCAC) procedure to control refractory postpartum hemorrhage (PPH) in vaginal delivery as a new second line therapy for refractory PPH. The procedure clamps the anterior and posterior walls of the cervical apex using toothless ovum forceps to arrest bleedingafter the failure of the first line therapy for PPH. 44 women were performed BCAC to control persistent bleeding in 13,359 vaginal deliveries from 1 January 2016 to 31 May 2018. In all of the BCAC, it can reduce bleeding significantly. The bleeding speed after BCAC was far less than that before it (2.64 ± 4.99 ml/min *vs* 20.23 ± 9.40 ml/min $P < 0.001$). The blood loss after BCAC was less than that before it (146.57 ± 170.83 *vs* 797.84 ± 200.73 ml $P < 0.001$). 41 (93.2%) BCACsucceeded and 3(6.8%) failed turned to intrauterine balloon tamponade, 2 succeeded and 1 failed turned to hysterectomy. In the successful group the bleeding speed after the BCAC was 1.38 ± 0.99 ml/min less than that 19.84 ± 6.27 ml/min in the failure group. ($p < 0.001$). The blood loss in the success group is also less than that in the failure ones after BCAC (107.29 ± 78.36mL *vs* 683.33 ± 202.07 ml $P < 0.001$) Even in the failure group, the bleeding speed also reduced after BCAC compared with that before BCAC (19.84 ± 6.27 *vs* 29.17 ± 7.12 ml/min $p = 0.02$). But the blood loss had no statistical difference (683.33 ± 202.07 *vs* 950 ± 132.29 ml $p = 0.27$) In all of the 13,359 vaginal deliveries, the incidence of PPH was 1.21% while the severe PPH was only 0.27%. The BCAC may reduce the incidence of severe PPH (0.27%) and also can reduce the necessity of IUBT (3/13,359 0.22‰), uterine artery embolization (UAE) (0/13,359) and even the exploratory laparotomy hysterectomy (1/13,359). Because it is effective, convenient, cheap and noninvasive, so we think it can be used as a new second line noninvasive treatment for PPH.

Introduction

In the worldwide, the postpartum hemorrhage (PPH) still is the leading cause of maternal mortality [1]. The definition of PPH in vaginal delivery is blood loss ≥500 ml in 24 h after delivery [2].PPH can be divided into minor (500–1000 ml) and severe (more than 1000 ml) [3]. Even in well-developed countries, the prevalence of PPH in vaginal delivery ranges from 0.8% to 7.9% [4–7]. The reasons for PPH in vaginal delivery are uterine atony, placental complication, laceration of soft birth canal and coagulation dysfunction. Because uterine atony was the most common reason for PPH [8], so the first line management for PPH after vaginal delivery is drugs (oxytocin, ergometrine, carboprost, and misoprostol) for uterine contraction and massage of uterus. The second line treatment include the non-invasive management like intrauterine balloon tamponade (IUBT) as Bakri balloon can be used in persistent PPH, it take effect in 72.8%–75% patients [9]. Another second line therapy was invasive uterine artery embolization (UAE). The third line management includes exploratory laparotomy of vessel ligation, uterine compression suture and the last choice of hysterectomy for life saving [10].

We introduced a noninvasive procedure called bilateral cervix apex clamping (BCAC) to arrest refractory bleeding when the bleeding was ineffective of uterine contraction drugs, massage and curettage. BCAC is the clamping of the anterior and posterior walls of the cervix near vaginal fornix from the left and right side with two toothless forceps and there must be space (1.5–2.5 cm) left between the two clamps to ensure the discharge of the blood from the uterine cavity. It was easy to be performed through vagina and we found it can reduce the bleeding speed immediately. In 44 BCAC cases for refractory PPH, 41 (93.2%) took effects. So we think it can be used as a kind of new second line noninvasive management for refractory PPH before the therapy of IUBT. In all of the 13,359 vaginal delivery, only 3(0.22‰) were performed IUBT, Compared to a study in French the utilization of IUBT is 0.12% [11], When combination with IUBT, it can reduce invasive management of UAE.

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There is no UAE in 13,359 vaginal deliveries. 3 IUBT were performed after the failure of BCAC, 2 IUBT performed successfully and 1 turned to hysterectomy because of amniotic fluid embolism.

Methods

From 1 January 2016 to 31 May 2018, 44 patients with refractory PPH after the failure of drugs (oxytocin, ergometrine, carboprost, and misoprostol) and massage received the bilateral cervix apex clamping (BCAC) procedure. This study was approved by the local Ethics Committee of Jiading Maternal and Fetus Care Center in Shanghai, China. To retrospectively analyze the clinical characters of these patients, the difference before and after BCAC and the difference between the successful and failure patients.

Bilateral cervix apex clamping (BCAC) procedure

Conditions

The BCAC will be performed when bleeding persisted and the bleeding speed can not be reduced after failure management of drugs (oxytocin, ergometrine, carboprost, and misoprostol) for uterine contraction combined with uterine massage, The ultrasound examination excluded the placenta remnant in the uterine cavity and the laceration of soft delivery canal was also ruled out

The clamping technique as shown in the following two pictures

Firstly, the space of one side (left or right) apex of the cervix and the fornix of the vagina near the cervical apex must be exposed (Figs. 1 and 2). The assistant pulled vaginal wall with retractor to one side and then pulled the cervix outward and to the opposite side with ovum forcep. The left or right top of the cervix and vaginal fornix will be exposed. Secondly, in the angle of 45–60 vertically upward, one side (left or right) of the anterior and posterior wall at the apex of the cervix and part of the top of the lateral vaginal fornix are clamped together by toothless ovum forceps. At last, the opposite anterior and posterior cervical walls will be clamped in the same way. It is important to note that there must be space (1.5–2.5 cm) left between the two clamps to ensure the discharge of the blood from the uterine cavity. Sometime if the bleeding speed cannot be reduced another two toothless ovum forceps can be used closely and paralleled to the former two forceps downward.occasionally two or three forceps longitudinal clamping the cervix with one or two centimeters distance between every two forceps, even the suturing with absorbable suture in the clamping field have been tried. They all took effect During the clamping, every half an hour ultrasound examination was performed to detect whether blood accumulated in the uterus

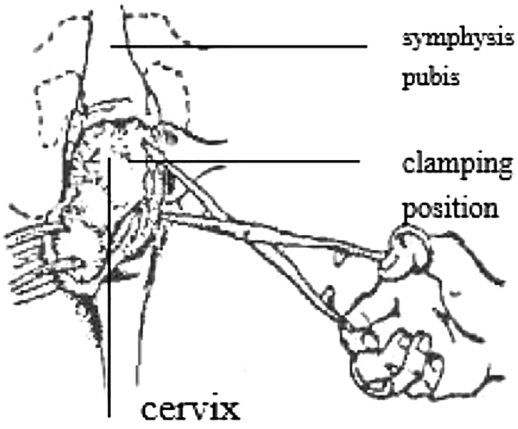

Fig. 1. Diagram of the clamping.

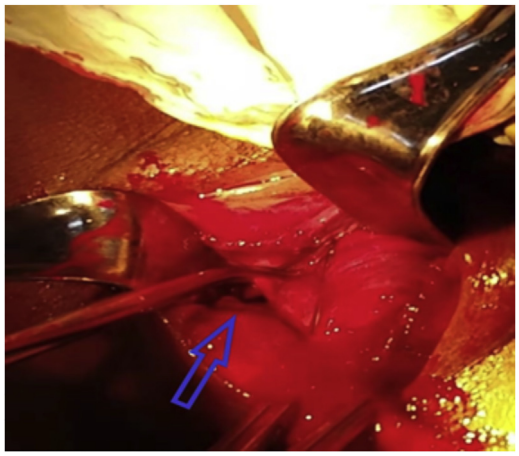

Fig. 2. The image shows the BCAC clamping position (as the blue arrow points) (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

cavity and the forceps were loosened every half an hour to prevent cervical necrosis and to observe whether the bleeding reduced or stopped without the clamping The forceps will be removed gradually in one or two or more hours later according to the bleeding. After the remove of forceps, the estimation of bleeding and monitor of vital signs will be continued in 24 h after delivery. The amount of bleeding was estimated by weighing. At the same time, the ultrasound examination monitoring the bleeding in the uterine cavity every half an hour, the continuous monitoring of vital signs will be started. The blood transfusion, IUBT, UAE and exploratory laparotomy will be prepared too.

Statistical analysis

All statistical numbers were produced on an IBM-PC compatible computer using SPSS (version 19.0, IBM, NY, USA). All descriptive clinical characters were presented as (mean ± SD). *t*-test were performed to compare the difference of the blood loss and the bleeding speed between the successful group and failure group and paired *t*-test for comparing the difference between the blood loss and bleeding speed before and after the BCAC procedure in all 44 patients, failure group and successful group. A value for $p < 0.05$ was considered statistically significance.

Results

Summarization of the characters

In the 13,359 vaginal deliveries during the continuous 17 months in Jiading Maternal and Fetus Care Center in Shanghai.161 (1.21%) PPH occurred, 117 was cure by regular management of uterine massage, uterine contraction drugs, curettage and the suture of the laceration of soft birth canal. Among them 17 were severe PPH(blood loss>1000 ml),44(27.3%)refractory PPH patients were performed by BCAC after failure of the normal management for bleeding, 41 (93.2%) succeeded, 3 failed turned to intrauterine Bakri balloon tamponade (0.22‰) and 2 succeeded and 1 was performed hysterectomy for life saving. There is 19 severe PPH in the 44 patients. Totally, 36 (0.27%) severe PPH, 2 Bakri balloon tamponade and 1 hysterectomy in 13,359 vaginal deliveries.

Analyze of the 44 BCAC patients

In the 44 patients, the average age was 29.0 ± 4.21 years old and the average fetus weight was 3.50 ± 0.48 kg. The BCAC was

Table 1

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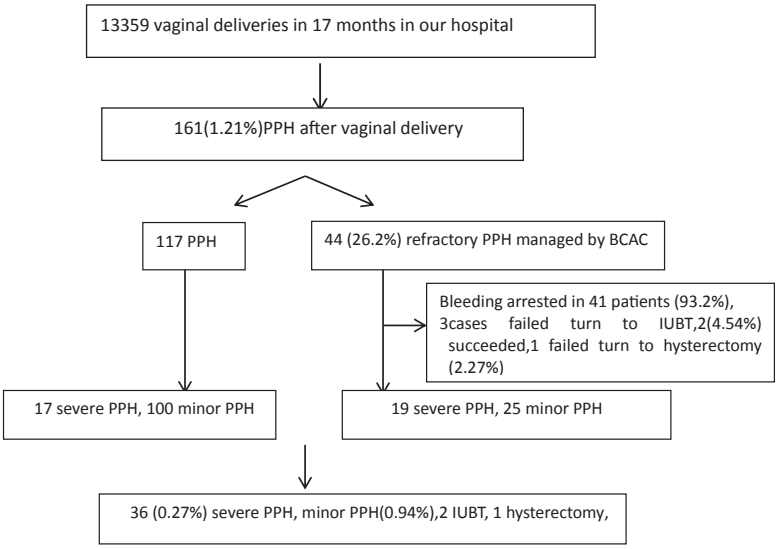

performed after the blood loss between 500-1300ml, the clamping continued for 20–240 minutes. The average blood loss was 797.84 ± 200.73 ml before BCAC and 146.57 ± 170.83 ml after BCAC ($p < 0.001$). The bleeding speed also reduced significantly from 20.23 ± 9.40 to 2.64 ± 4.99 ml/minute ($p < 0.001$). The blood loss and bleeding speed reduced significantly after BCAC in all 44 patients by the paired *t*-test ($p < 0.001$) (Tables 1 and 2).

Analyze differences between the failure and successful group

The failure group had more gravidity 3.67 ± 1.53 than1.85 ± 0.99 in the successful group. p = 0.005. The blood loss before BCAC in the failure group was more than in the successful group(950 ± 132.29 ml *vs* 786.71 ± 201.43 ml p = 0.18, but had no statistical significance.But the bleeding volume and speed after BCAC between the failure group and successful group had statistical significance (683.33 ± 202.07 *vs* 107.29 ± 78.36 ml and 19.84 ± 6.27 *vs* 1.38 ± 0.99 ml/minute $p < 0.001$). The BCAC took effect more significantly in the successful group (Tables 3 and 4).

Analyze the difference before and after BCAC in each group

In the failure group, even the blood loss after BCAC was less than that before BCAC, but it had no statistical significance p = 0.27. The bleeding speed was less after BCAC even in the failure group (29.17 ± 7.12 *vs* 19.84 ± 6.27 ml/minute)p = 0.02. In the successful group the BCAC can reduce the blood loss and bleeding speed perfectly $p < 0.001$.

Table 3
Difference between the failure and successful patients.

	Failure(N = 3)	Success (N = 41)	
	Mean(SD)	Mean(SD)	P(t)
Age(y)	32.33(5.03)	28.76(4.11)	0.16(1.44)
Gravidity	3.67(1.53)	1.85(0.99)	0.005(2.97)
Parity	1.33(0.58)	1.32(0.52)	0.96(0.05)
Term(w)	39.86(1.12)	39.49(1.65)	0.71(0.38)
Fetus weight(kg)	3.29(0.23)	3.52(0.49)	0.44(0.78)
Total blood loss(ml)	2902(1832.14)	958.22(255.2)	0.21(1.84)
Blood loss(ML)			
before BCAC	950(132.29)	786.71(201.43)	0.18(1.37)
after BCAC	683.33(202.07)	107.29(78.36)	<0.001(10.91)
Bleeding speed(ml/min)			
before BCAC	29.17(7.12)	19.57(9.27)	0.08(1.74)
after BCAC	19.84(6.27)	1.38(0.99)	<0.001(18.42)

Discussion

In the study, the incidence of severe PPH was 0.27% in 13,359 vaginal deliveries which was more less than that reported in a study from French (1.5%)in 91,880 vaginal deliveries and Hongkong (1.4%) in 22,860 deliveries [9,11]. In our study the BCAC was

Table 2
Clinical character of all 44 patients and difference before and after BCAC.

	Range	Mean(SD)	p(t)
Age(y)	21–38	29.0(4.21)	
Gravidity	1–5	1.98(1.11)	
Parity	1–3	1.32(0.52)	
Term(w)	31 + 6–41 + 1	39.51(1.61)	
Fetus weight(kg)	2.20–4.43	3.50(0.48)	
BCAC duration (minutes)	20–240	82.75(44.24)	
Blood loss(ml)			<0.001(18.78)
before BCAC	500–1300	797.84(200.73)	
after BCAC	15–900	146.57(170.83)	
Bleeding speed(ml/min)			<0.001(12.79)
before BCAC	6.50–55.0	20.23(9.40)	
after BCAC	0.17–25.0	2.64(4.99)	

Table 4
Difference before and after BCAC each in failure and success group.

	Mean(SD)	p(t)
Failure group blood loss(ml)		0.27(1.51)
before BCAC	950(132.29)	
after BCAC	683.33(202.07)	
Failure group bleed speed(ml/min)		0.02(6.41)
before BCAC	29.17(7.12)	
after BCAC	19.84(6.27)	
Successful group blood loss(ml)		<0.001(21.67)
before BCAC	786.71(201.43)	
after BCAC	107.29(78.36)	
Successful group bleed speed(ml/min)		<0.001(12.47)
before BCAC	19.57(9.27)	
after BCAC	1.38(0.99)	

performed in 44 refractory PPH patients and only 3 failed turned to IUBT.41 (93.2%)BCAC took effect. The IUBT was performed only 3 (0.22‰) and 2 succeeded in 13,359 vaginal deliveries. The utilization rate of successful IUBT is 2/13,359(0.15‰) which is less than 80/91,880 (0.87‰) reported in 2018(11).Without the BCAC, the 44 refractory PPH patients may be treated by IUBT or UAE, So we think the BCAC can reduce IUBT. Combined with IUBT, the BCAC can reduce the invasive second line therapy of UAE (0/13,359). The bleeding speed reduced significantly after BCAC in all of the refractory PPH patients even in the failure group.

70% of PPH happened because of uterine atony [12–15]. In the 44 refractory PPH patients, with the use of uterine contraction drugs, the uterine body contract well but the bleeding still continued, so we think the bleeding may come from the lower segment of uterus muscle atony which is insensitive to the uterotonic agents (oxytocin, carboprost, ergometrine and prostaglandins) and uterine massage or come from the different degree of laceration in the surface of lower segment of the uterus which always cannot be detected by ultrasound, They are both ineffective to the regular management like uterine massage, uterine contraction drugs and curettage with. We think it is dangerous and may be the main reason for refractory PPH [16–20]. But this kind reason for PPH in vaginal delivery is reported little. The clamp can stop the cervical branch of uterine artery [21] which can reduce the bleeding in the lower segment of the uterus and the clamping also can compress the anterior and posterior cervical wall and close the laceration to reduce the bleeding in this region.It also can reduce the flow of uterine artery and stimulate the contraction of uterus. The clamping is easy to be performed especially in vaginal delivery pregnant women because the cervix is more expanded by delivery and becomes more elastic and softer in the influence of hormones produced in pregnant period than in non-pregnant period. Stretching and clamping of the uterine cervix downward may twist the uterine artery. And even can clip part of the uterine artery if tissues lateral to the uterus 2 cm above the apex of the cervix is clamped [22]. Then it can reduce the blood flow and bleeding speed by blocking the uterine artery. The BCAC can clamp more region in the lower segment of the uterus by additional two forceps. It may take effect by clamping the bleeding surface by the same mechanism like the operation of Hwu suture which is used in the placenta previa to stop the bleeding of lower segment in cesarean [23].But in the placental low-lying patients, because more new born vessels in this region the clamping controlling bleeding effect is still limit, the IUBT or UAE is still necessary. Hamdy A reported a new maneuver for prevention of postpartum hemorrhage by sustained traction of the anterior and posterior lips of the cervix by two ovum forceps for duration of 90 s and found it can reduce the incidence of PPH. Also the clamping of the cervix also can continuous tract the cervix downward and outside which may take effect as the new maneuver by Hamdy A. [22,24]. With more and more study on the bleeding in the lower segment of the uterus I think the prevention and success rate for PPH will increase too.

The procedure also has defaults too. I think the procedure can't obtain the best effect to stop bleeding or even can aggravate the bleeding from uterine body atony. Because the clamping of the lower segment of the uterus may hinder the blood flowing out from the uterine cavity which may aggravate the uterine atony. So without so many developed uterine contraction drugs nowadays, this procedure cannot take best effects. Maybe that's the reason why it has been reported little even it had been described 80 years ago as Genkel-Tikanadze method. I think it is still new to most obstetricians and still need improvement through more application. We have modulated the procedure by trying a few new ways to improve it's hemostatic effect.We hope to develop the procedure to a new series including many clamping ways to best control the bleeding in refractory PPH. But the modulated procedure cases is small and the total number of BCAC is small too. The statistical evaluation is still unconvincing and it still needs more clinical verifications. In the 3 failed patient, one is because of the coagulation dysfunction happened quickly (amniotic fluid embolism (25)) and the other 2 cases with the placental previa of 15 mm and 25 mm to the cervical internal ostium. So the BCAC procedure may have little effect in the patients with coagulation dysfunction and placenta abnormal like placental previa or implantation. Even it's effective (93.2% success rate) in refractory PPH, but when the BCAC procedure is performed, the Bakri balloon, the UAE and exploratory laparotomy should be prepared too. The BCAC procedure is effective, convenient, easy, noninvasive and time-saving, it had many advantages compared to the second line therapy of IUBT and UAE for refractory PPH, We hope after a large prospective clinical study, it can be used as a new second line noninvasive management for PPH more credibly.

Declaration of Competing Interest

The author declared there is no conflicts of interest to this work.

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