



Prevention of postpartum hemorrhage and hysterectomy in patients with morbidly adherent placenta: a cohort study comparing outcomes before and after introduction of the Triple-P procedure

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ABSTRACT

Objectives To evaluate patient outcomes and need for further interventions in women with a morbidly adherent placenta (MAP), before and after introduction of the Triple-P procedure involving placental non-separation, myometrial excision and reconstruction of the uterine wall.

Methods Between December 2007 and February 2014, 30 patients with MAP were treated at our center. In 2007, we instituted a policy of bilateral prophylactic occlusion balloon catheter placement in both internal iliac arteries followed by Cesarean section with non-placental separation and preservation of the uterus. In 2010, the surgical technique was modified and the Triple-P procedure introduced. As a result, 19 women in our study received the Triple-P protocol (study group) and 11 did not (control group). The quantity of blood replacement products, estimated blood loss, and necessity for uterine arterial embolization and/or hysterectomy were recorded retrospectively and compared between the two groups.

Results Placenta percreta was confirmed in six (54.5%) patients in the control group and 13 (68.4%) in the study group. Estimated mean blood loss during the procedure was lower in the study group than in the control group (1.70 L vs 2.17 L, respectively), but the difference was not statistically significant ($P=0.445$). The risks of postpartum hemorrhage (PPH) and hysterectomy were statistically significantly lower in the study group (PPH, 54.5% vs 15.8%; $P=0.035$; hysterectomy, 27.3% vs 0.0%; $P=0.045$). As a consequence, there was a significant decrease in duration of inpatient stay in the study group ($P=0.044$).

Conclusion Introduction of the Triple-P procedure conveyed a significantly reduced rate of hysterectomy, PPH and duration of hospital stay in patients with MAP. Copyright © 2014 ISUOG. Published by John Wiley & Sons Ltd.

INTRODUCTION

Morbidly adherent placenta (MAP) is a condition associated with massive postpartum hemorrhage (PPH), and is the second highest reported cause of hemorrhage leading to peripartum hysterectomy in the UK¹. As it is a potentially life-threatening risk, the traditional management was Cesarean delivery with peripartum hysterectomy, with or without bowel or bladder resection, depending on the degree of infiltration of these organs. This treatment has been associated with a mean expected blood loss of 7800 mL (range, 2500–17 000 mL) if no antenatal diagnosis was performed² and significant maternal and fetal morbidity and mortality³.

Alternative management options have been proposed to reduce maternal morbidity associated with peripartum hysterectomy⁴. Accurate and timely diagnosis of MAP is required to institute optimal management. MAP can be diagnosed by ultrasound or magnetic resonance imaging (MRI) to help identify women at risk of developing hemorrhage prior to delivery⁵.

In 2007 we introduced a program of prophylactic occlusion balloon catheter (POBC) insertion into both internal iliac arteries before Cesarean delivery in women suspected of having the severest forms of MAP (placenta percreta and increta), the aim of which is to reduce blood flow to the uterus after Cesarean delivery, preventing

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Cesarean hysterectomy and massive hemorrhage by allowing immediate progression to arterial embolization if necessary⁶.

In March 2010 the surgical technique was modified from non-placental separation to placental resection and uterine reconstruction. The Triple-P procedure is a three-step treatment involving the co-operation and expertise of obstetricians, anesthetists, hematologists and interventional radiologists to prevent massive hemorrhage and peripartum hysterectomy. This procedure has been described in detail previously⁷. Step 1 involves the preoperative location of the placenta and delivery of the fetus by an incision above the upper border of the placenta. Step 2 involves pelvic devascularization by inflating pre-placed occlusion balloons in both internal iliac arteries under imaging guidance. Step 3 comprises placental non-separation with myometrial excision and reconstruction of the uterine wall. When placenta percreta invades the bladder wall, the portion of the invading placenta is left *in situ* and a local hemostatic powder (PerClot[®], Starch Medical Inc., San Jose, CA, USA) is used to achieve hemostasis from the placental bed. PerClot is a collagen powder that creates a mechanical barrier over the placental venous sinuses to stop bleeding. In addition, being hydrophilic, it imbibes water, thereby concentrating platelets and fibrinogen at the bleeding site and promoting hemostasis. Placental separation or bladder resection is never attempted in the Triple-P procedure and all cases undergo a transvaginal ultrasound examination within 8 weeks as part of their follow-up to confirm resorption of the placental tissue that was invading the bladder.

Our referral regional care plan includes the options of conservative Cesarean section with POBC insertion or Cesarean hysterectomy. Therefore, the choice of conservative treatment is at the specific request of the patient, who will have consented accordingly.

The aim of this study was to describe this center's experience in women with MAP, comparing outcomes before and after introduction of the Triple-P procedure.

METHODS

Between December 2007 and February 2014, 30 pregnant women were identified as having MAP by ultrasound or MRI and were at high risk of PPH. Women with a diagnosis of placenta percreta and increta were referred for placement of arterial occlusion balloons immediately before Cesarean delivery.

The first 11 patients with MAP were treated, before the development of the Triple-P procedure, with an elective Cesarean delivery, using the classical approach of an incision into the uterine fundus, leaving the placenta in part or entirely in the uterus (control group). The last 19 patients with MAP were treated from March 2010 using the Triple-P procedure (study group); informed consent was obtained from all patients. Our institution did not require local research and ethics committee approval for this variation of surgical technique.

For each woman a date for Cesarean delivery was scheduled by the obstetricians, and all members of the team were notified of the proposed date to ensure availability of personnel and booking of rooms and equipment. On the morning of delivery, an epidural catheter was inserted by the anesthetists before the patient was transferred to the interventional radiology suite for insertion of internal iliac artery occlusion balloon catheters. Bilateral common femoral arterial punctures were performed under local anesthesia and occlusion balloon catheters (7 Fr Standard Occlusion Balloon Catheters, Boston Scientific Corporation[®], Natick, MA, USA) were positioned, with their tips in the anterior divisions of each internal iliac artery under pulsed low-dose fluoroscopic guidance to minimize radiation exposure to the mother and fetus⁸.

The balloons were then stitched and secured in place to minimize the possibility of movement during the patient's transfer to the obstetric theater. The position of the balloons was checked in the obstetric theater using a portable image intensifier to exclude balloon migration immediately prior to commencement of Cesarean section. Immediately after the baby had been delivered and the umbilical cord clamped, the interventional radiologist inflated each occlusion balloon catheter to reduce blood flow while the obstetrician performed myometrial excision and closure of the uterine incision.

If significant hemorrhage occurred immediately, the patient was transferred to the interventional radiology suite or, if deemed too unstable for transfer, the interventional radiologist could proceed immediately to embolization with a gelatin sponge through the occlusion balloon catheters⁹, as this enables rapid proximal embolization and is a temporary agent. Embolization of the uterine arteries was performed if selective catheterization was easy to achieve, otherwise embolization of the anterior division of each internal iliac artery was performed.

If there was no evidence of hemorrhage, the balloon catheters were left *in situ* and the patient was observed overnight at our obstetric intensive care unit (o-ICU), as per protocol. Bilateral pulse oximeters were placed on both innermost toes to identify any signs of limb ischemia. The occlusion balloons remained inflated for 4 h, after which they were deflated if the patient remained stable with no signs of hemorrhage. If bleeding recommenced at any time after delivery the occlusion balloons could be rapidly re-inflated and the patient transferred for embolization. The arterial sheaths and occlusion balloon catheters were removed by the interventional radiologists the next morning. The following parameters were recorded for each procedure: type of MAP, radiographic exposure, volume of blood loss, transfusion requirements, uterine artery embolization, peripartum hysterectomy and any maternal or infant complications including duration of stay in intensive therapy unit and hospital ward.

Histological confirmation of the degree of placental invasion was not possible for patients in the control group, because the placenta was left in part or entirely in the

uterus, unless PPH occurred and peripartum hysterectomy was required. However, surgical confirmation of the type of MAP was recorded. In the study group, because the affected myometrium was excised with the bulk of the placenta, the type of MAP was confirmed histologically if the line of invasion of the trophoblastic tissue did not extend into the posterior wall of the bladder. If the posterior wall of the bladder was involved, histological confirmation was not possible, as the placental tissue invading the bladder was left *in situ* to avoid cystotomy, and the type of MAP was confirmed surgically in these patients.

Descriptive characteristics were calculated for the variables of interest. Statistical analysis comparing both groups was performed using the chi-square test (Fisher's exact test) for categorical variables and the Wilcoxon and Mann–Whitney *U*-tests for continuous variables; $P < 0.05$ was considered to indicate a statistically significant difference.

RESULTS

Thirty women were diagnosed with MAP during the study period. All Cesarean deliveries apart from two in the study group were performed electively. In all cases occlusion balloons were placed successfully prior to Cesarean delivery. The risk factors for MAP described previously in the literature as advanced maternal age, high gravidity and parity, previous Cesarean sections and multiple abortions with curettage^{10,11} were present in the majority of our patients, as summarized in Table 1.

Placenta percreta was confirmed in more than 50% of patients in both groups, six (54.5%) patients in the control group and 13 (68.4%) in the study group. Table 1 shows that no significant differences were found between the groups for age, parity, previous gynecological surgery, degree of MAP or gestational age, permitting comparison of the clinical results of both groups.

Table 2 shows the outcomes of both groups. Mean blood loss during the procedure was lower in the study group than in the control group (1.70 ± 0.95 L vs 2.17 ± 2.46 L, respectively), but this difference was not statistically significant ($P = 0.445$). PPH occurred in six (54.5%) patients in the control group compared with three (15.8%) in the study group. Thus, the risk of PPH was statistically significantly lower in the study group ($P = 0.035$). Five (45.5%) patients in the control group required emergency arterial embolization to control PPH vs three (15.8%) in the study group, but this reduction in risk was not statistically significant between the two groups ($P = 0.091$). However, the need for emergency peripartum total hysterectomy was significantly lower in patients treated with the Triple-P procedure than in the control group (0/19 (0.0%) vs 3/11 (27.3%), respectively; $P = 0.045$). These outcomes are represented in Figure 1.

While women in the control group had greater mean blood loss during surgery, there was no significant difference between the proportion of women requiring a transfusion in either group (45.5% in the control group vs 47.4% in the study group; $P = 0.61$).

Table 1 Demographic characteristics of pregnant women with morbidly adherent placenta (MAP) according to those who received the Triple-P procedure (study group) and those who did not (control group)

Characteristic	Control group (n = 11)	Study group (n = 19)	P
Age (years)	35 ± 5.06	36.1 ± 5.09	0.363
Age ≥ 35 years	7 (63.6)	12 (63.2)	
Nulliparous	1 (9.1)	0 (0)	0.406
Gravidity	4.36 ± 2.91	3.23 ± 1.30	0.181
≤ 3	5 (45.5)	13 (68.4)	0.194
> 3	6 (54.5)	6 (31.6)	
Parity	3.36 ± 2.91	2.06 ± 1.14	0.104
≤ 2	4 (36.4)	13 (68.4)	0.093
> 2	7 (63.6)	6 (31.6)	
History of gynecological surgery	9 (81.8)	17 (89.5)	0.470
History of curettage	4 (36.4)	7 (36.8)	0.646
History of CS	4 (36.4)	14 (73.7)	0.052
History of MAP or placenta previa	1 (9.2)	2 (10.5)	0.702
Other uterine surgery*	1 (9.1)	4 (21.1)	0.381
Placenta accreta	3 (27.3)	5 (26.3)	0.637
Placenta increta	2 (18.2)	1 (5.3)	0.298
Placenta percreta	6 (54.5)	13 (68.4)	0.354
GA (weeks)	32.9 ± 1.9	35.9 ± 5.8	0.280

Data are given as mean ± SD or *n* (%). *Myomectomy, ectopic pregnancy or circumcision. CS, Cesarean section; GA, gestational age at treatment.

As per protocol, all patients were transferred to the o-ICU immediately after delivery and transferred back to the ward once the patient was stable. The mean stay in the o-ICU was 2.82 ± 2.63 days in the control group and 3.50 ± 1.20 days in the study group, but this difference was not statistically significant ($P = 0.058$). However, patients treated in the study group had a significantly lower mean duration in hospital (4.75 ± 2.02 days) than did the control group (7.73 ± 5.08 days) ($P = 0.044$). A significant reduction in mean radiation dose was observed in the study group (168.91 ± 122.64 mGy in the control group vs 97.59 ± 65.29 mGy in the study group; $P = 0.042$), with no change in radiographic equipment, technique or personnel.

The outcomes were stratified according to the treatment group and type of MAP, and the results are summarized in Table 3. Unfortunately the number of patients included in each section was too small to ensure an adequate sample for achieving a correct statistical confidence level. However, the results show a positive trend in the study group to decreasing the risk of PPH, blood loss, rate of uterine artery embolization and hysterectomy required in each type of MAP and, more specifically, in those with placenta percreta.

One major maternal complication occurred in one woman in the study group. This patient developed a right common iliac and external iliac artery thrombosis after removal of the occlusion balloon catheters and sheaths. The arteries were patent at the time of catheter removal, but she developed right leg claudication during

Table 2 Mode of treatment and result in women with morbidly adherent placenta treated with Triple-P procedure (study group) and those who did not receive this treatment (control group)

Variable	Control group (n = 11)	Study group (n = 19)	P
Radiation dose (mGy)	168.91 ± 122.64	97.59 ± 65.29	0.042
Blood loss during procedure (L)	2.17 ± 2.46	1.70 ± 0.95	0.445
Total blood loss (L)*	3.82 ± 4.09	2.31 ± 1.38	0.454
Hemoglobin reduction immediately post-procedure (g/dL)	3.49 ± 3.93	2.16 ± 1.43	0.195
PPH observed	6 (54.5)	3 (15.8)	0.035
UAE required	5 (45.5)	3 (15.8)	0.091
Cesarean hysterectomy required	3 (27.3)	0 (0)	0.045
Transfusion required	5 (45.5)	9 (47.4)	0.610
Volume of transfused blood products (units)			
Total RBC	54	40	
Total FFP	23	8	
Total PL	7	6	
Total CRYO	4	0	
Maternal complications	0	1	
Infant complications	2	0	
ICU stay (days)	2.82 ± 2.63	3.5 ± 1.20	0.058
Inpatient stay (days)	7.73 ± 5.08	4.75 ± 2.02	0.044

Data are given as mean ± SD, n (%) or n. *Blood loss during procedure and postprocedure in case of postpartum hemorrhage (PPH). CRYO, cryoprecipitation; FFP, fresh frozen plasma; ICU, intensive care unit; PL, platelets; RBC, red blood cells; UAE, uterine artery embolization.

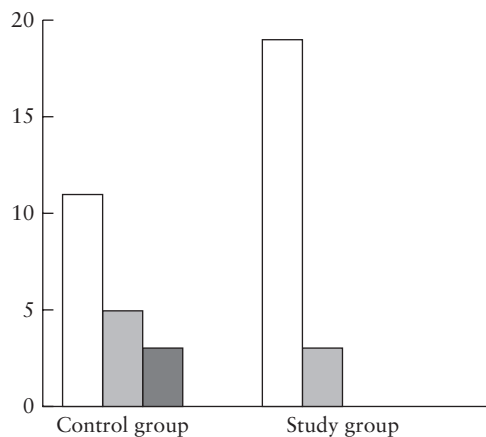


Figure 1 Pregnant women receiving prophylactic occlusion balloon catheter with (study group) or without (control group) Triple-P procedure (□) for treatment of morbidly adherent placenta and those who also required uterine artery embolization (▨) or hysterectomy (■).

mobilization 24 h after delivery, most probably from arterial dissection by a guide wire on removal of the catheters. A duplex ultrasound scan confirmed right iliac arterial thrombosis. She was treated conservatively with anticoagulation and, 3 months later, her symptoms had improved and ultrasound confirmed arterial patency. This complication has been reported elsewhere¹². In the control group, over-distension of the occlusion balloons

led to balloon rupture after Cesarean delivery in one patient. This was the only occasion on which an interventional radiologist was unable to attend the delivery, and a volume 10-times greater than required was inadvertently injected, with consequent bilateral balloon rupture. Without the reduction in blood flow in the uterine arteries, the patient hemorrhaged 12 L during surgery and the obstetrician proceeded to immediate hysterectomy. In two cases in the control group, PPH was controlled inadequately by uterine artery embolization and hysterectomy was required. In one other patient in the control group, a second uterine artery embolization was required 4 months after delivery for secondary PPH. Migration of the balloon catheter during patient transfer to the obstetric theater occurred in two patients in the study group. In both cases, the balloon catheters were repositioned successfully before Cesarean delivery. There were no neonatal complications related to the procedure and there were no urinary tract injuries associated with the Triple-P procedure.

DISCUSSION

MAP is defined as abnormal placental invasion into the myometrium and is associated with severe PPH, high risk of multiple blood transfusions, emergency hysterectomy and maternal morbidity and mortality. The incidence of MAP is increasing, associated with the increasing rate of Cesarean section and increasing maternal age¹³, and one study showed that it is observed in 1 in 533 deliveries¹⁴. Traditionally treated by Cesarean hysterectomy with associated morbidity and hemorrhage, more conservative therapeutic options have been proposed such as non-separation placental hysterectomy, Cesarean section with avoidance of placental removal combined with methotrexate, compression sutures, B-Lynch suture or balloon tamponade with the placenta remaining *in situ*^{15,16}. Nevertheless, delayed hysterectomy may be required with associated infertility, adhesions and related complications¹⁷.

The UK Obstetric Surveillance System performed a nationwide review of peripartum hysterectomies in 2007, and reported MAP as the cause in 38% of cases¹. The role of interventional radiology in the management of PPH was highlighted in the UK Confidential Enquiry into Maternal and Child Health¹⁸. Since the report was published, we have explored the role of prophylactic occlusion balloons with or without uterine artery embolization in an attempt to reduce hemorrhage and avoid hysterectomy at our institution.

Close collaboration between interventional radiologists, obstetricians and anesthetists has led to an increasing use of prophylactic balloon occlusion, with or without arterial embolization, in the conservative management of women with MAP¹⁹. In 2010 this led to the development of a surgical approach with myometrial excision and non-separation of the placenta, the Triple-P procedure.

The Triple-P procedure is a conservative surgical procedure that requires adequate preparation. Anesthetic,

Table 3 Distribution of study population according to degree of morbidly adherent placenta (MAP), mode of treatment and outcome

Type of MAP	Group	Patients			Transfusion required			UAE performed		Hysterectomy required		
		(n)	EBL (L)	P	P	PPH	P	P	P			
Placenta accreta	Control	3	3.4 (2.2–5.0)	0.28	2 (66.7)	0.5	3 (100.0)	0.07	2 (66.7)	0.28	1 (33.3)	0.37
	Study	5	2.4 (1.0–4.5)		2 (40.0)		1 (20.0)		1 (20.0)		0 (0)	
Placenta increta	Control	2	6.4 (0.8–12.0)	*	1 (50.0)	0.66	1 (50.0)	0.66	1 (50.0)	0.66	1 (50.0)	0.66
	Study	1	1		0 (0)		0 (0)		0 (0)		0 (0)	
Placenta percreta	Control	6	7.6 (0.5–10.0)	0.20	2 (33.3)	0.47	2 (33.3)	0.37	2 (33.3)	0.37	1 (16.7)	0.31
	Study	13	2.25 (1.0–4.5)		7 (53.8)		2 (15.4)		2 (15.4)		0 (0)	

Data are given as *n*, mean (range) or *n* (%). *Not possible to perform statistical calculation owing to limited number of patients included in sample. EBL, estimated blood loss; PPH, postpartum hemorrhage; UAE, uterine artery embolization.

obstetric and interventional radiology teams should pre-plan the procedure and have the capability to respond rapidly in case of complications. For this reason, accurate prenatal diagnosis of invasive placentation is necessary.

Ultrasound, including Doppler, examination is the primary modality for the antenatal diagnosis of MAP. There are multiple ultrasound findings described in the literature to make an accurate diagnosis^{20,21}. In our study, bladder involvement was diagnosed antenatally, not only by neovascularization of the bladder base but also by thinning of the myometrium (< 1 mm) and bulging of the posterior bladder wall seen on color-flow Doppler. The authors accept that, in some centers, MRI scans are used to exclude bladder involvement. However, our regional service does not perform routine MRI scans for women with MAP, and such scans are reserved for lateral or posterior placental adhesion to the myometrium. The protocol we used has been published recently²² and is supported by the literature^{20,23}.

This study demonstrates that the Triple-P technique has advantages that are statistically significantly better, despite a larger number of women in the Triple-P group developing the most severe form of MAP, i.e. placenta percreta (68.4%). In both groups, POBCs were placed before Cesarean section and inflated immediately after delivery of the baby to achieve hemostasis. The reduction in blood loss in the study group may be related to the type of Cesarean section performed; in the control group, in which the placenta was left *in situ*, the Cesarean incision was made at the uterine fundus to avoid inadvertent injury to the placenta. This may explain increased blood loss from the more vascular upper segment. In contrast, in the Triple-P procedure group, the incision was made in the lower segment of the uterus and, as the placenta was not separated from the myometrial bed, blood loss was reduced.

These results also demonstrate that with a well-defined conservative treatment protocol, the risk of hysterectomy is reduced significantly even in the severest type of MAP, placenta percreta. The co-operation and presence of the various disciplines during delivery resulted in a more rapid response to complications and the avoidance of intrapartum hysterectomy, with its attendant complications of vesicouterine fistula and bladder and ureteral injuries. Our results have been compared with those of published articles on MAP treated with POBC

and Cesarean hysterectomy, showing improvements in blood loss and risk of blood transfusion, and are summarized in Table 4. Other improvements, such as the significant reduction in radiation dose during placement of the prophylactic occlusion balloons and, consequently, the reduction in fetal radiation dose, can be explained by the cumulative experience of a dedicated team, which supports the principle of hospital-specific specialization to achieve optimal results for the mother and baby^{24,25}.

Further improvements in the technique could be made. The availability of hybrid operating rooms should render transfer of the patient between departments unnecessary, reduce the risk of catheter dislodgement and allow immediate safe embolization without patient movement should hemorrhage occur²⁶. Despite the fact that this is the largest reported study in the literature of women with MAP treated conservatively, the major limitation of this study is the small number of cases. This fact restricts the statistical results and hinders our capability to draw firm conclusions. Further multicenter studies such as PACCRETA²⁷, and including more patients, are necessary to confirm the significantly improved outcomes with fewer re-interventions observed in our study.

In conclusion, MAP is increasing in incidence and is associated with massive PPH. The traditional treatment by Cesarean hysterectomy with associated severe complications in young women can be replaced successfully by conservative and multidisciplinary techniques. The Triple-P procedure is a conservative treatment with myometrial excision along with MAP and uterus-conserving surgery, with reduction in blood flow by the use of occlusion balloon catheters. Our results support the idea that the Triple-P technique has significant improvements in the reduction of massive PPH, hysterectomy and inpatient stay in hospital. Nevertheless, further prospective studies are needed to evaluate better this technique and confirm our findings.

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Table 4 Outcomes in previous literature of patients with morbidly adherent placenta (MAP) treated with prophylactic occlusion balloon catheter (POBC) insertion into the internal iliac artery, with or without uterine artery embolization (UAE) and Cesarean hysterectomy, compared with current study outcomes

Reference	Patients (n)	MAP type*(n)	Treatment	POBC inflated (%)	EBL (mL)‡	Hysterectomy required (n (%))	Blood transfusion (n (%))
Ballas (2012) ²⁸	59	24/0/35/0	POBC placement + Cesarean hysterectomy with/ without POBC inflation	58†	2165 ± 245	59 (100)	46 (78.0)
Carnevale (2011) ²⁹	21	8/2/7/4	POBC + Cesarean hysterectomy	100	1671.5 (200–4000)	21 (100)	13 (61.9)
Shrivastava (2007) ³⁰	19	13/4/2/0	POBC + Cesarean total hysterectomy or supracervical hysterectomy	100	2700 (800–8000)§	19 (100)	10 (52.6)
Bodner (2006) ³¹	6	3/1/2/0	POBC + Cesarean hysterectomy + UAE	100	2783.3 (1000–7000)	6 (100)	4 (66.7)
Kidney (2001) ³²	5	2/0/1/2	POBC + Cesarean hysterectomy	100	2240 (1100–4000)	5 (100)	3 (60.0)
Current study							
Control group	11	3/2/6/0	POBC + CS	100	2170 (500–12 000)	3 (27.3)	5 (45.5)
Study group	19	5/1/13/0	Triple-P procedure	100	1700 (1000–4500)	0 (0)	9 (47.4)

Only first author is given for each study. *In order: placenta accreta/increta/percreta/previa. †If postpartum hemorrhage was noted. ‡Estimated blood loss (EBL) given as mean ± SD or mean (range) unless indicated otherwise. §Median (range). CS, Cesarean section.

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A slide presentation, prepared by Dr Joel Naftalin, one of UOG's Editors for Trainees, is available online.

Chinese translation by Dr Yang Fang. Spanish translation by Dr Masami Yamamoto.