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RESEARCH ARTICLE

The intraoperative use of internal iliac artery balloon catheters in cesarean deliveries for abnormal invasive placentation: A 3-year retrospective cohort review in Doha, Qatar.

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ABSTRACT

Background: Abnormal invasive placentation leads to massive intraoperative hemorrhage and maternal morbidity. This study aimed to assess the impact of the preoperative use of internal iliac artery balloon occlusion (IIABO) catheters in patients who had a cesarean delivery (CD) for invasive placentation, commonly known as the placenta accreta spectrum.

Methods: This retrospective cohort study reviewed 67 pregnancies complicated by abnormal invasive placenta and confirmed intraoperatively. Preoperative planned placement of IIABO was performed in 33 women who underwent elective CD. Senior Obstetricians with the necessary expertise performed all CDs. The primary outcome measures were: intraoperative blood loss, blood transfusion requirement, duration of surgery and the need for hemostatic measures. Univariate comparison between the groups and regression analysis of the primary outcome and controlling for confounders, were performed.

Results: No statistically significant difference was observed between the groups with intraoperative hemorrhage volume of above 3000 mL (unadjusted odds ratio [OR] 0.94 [no-IIABO group as the reference]; $p = 0.895$) and the median duration of surgery (median 107, interquartile range [IQR] 80–135 *vs.* median 96, IQR 75–121; $p = 0.3508$). More than 40% of the IIABO group required intraoperative transfusion of packed red blood cells above six units (14 [42.4%] *vs.* 10 [29.4%]; $p = 0.357$]), and 30% required additional postoperative transfusion (10 [30.3%] *vs.* 8 [23.5%]; $p = 0.706$]), although not statistically significant. Multivariate logistic regression

analysis showed that the difference remained non-significant after covariate adjustment (adjusted OR 0.585, $p = 0.456$). Cesarean hysterectomy was performed in fewer cases (seven [21.1%]) in the IIABO group than in the no-IIABO group (10 [29.4%]), although this difference was not significant (unadjusted OR 0.65, $p = 0.442$).

Conclusions: The placement of IIABO catheters is an invasive procedure, which consumes time and resources. Its value as a means of reducing intraoperative blood loss or preserving the uterus in patients with abnormal placental adherence appears questionable. In this cohort study, there was no statistical difference in blood loss, and the need for other steps to control hemorrhage between women with and without IIABO catheters.

Keywords: placenta accreta spectrum, cesarean section, internal iliac artery balloon occlusion catheter, operative hemorrhage

INTRODUCTION

Atonic postpartum hemorrhage is a consequence of ineffective myometrial contractility, primarily at the placental bed site. Abnormal placentation, such as implantation in the noncontractile lower uterine segment (as in placenta previa) and invasion of the placenta into the uterine wall (known as placenta accreta spectrum [PAS]), is a risk factor for major postpartum hemorrhage.[1,2] Uterotonic agents used to facilitate increased uterine tone may be administered as prophylactic or therapeutic interventions for atonic primary postpartum hemorrhage.[3] Still, they may often be insufficient in cases of PAS (including placenta accreta, increta, and percreta, in order of increased uterine wall invasion). Such patients provide a major surgical challenge at the time of cesarean delivery (CD), even when a placental bed problem is anticipated antenatally.[4] An average intrapartum blood loss of between 3 liters and 5 liters, with around 40% of patients requiring at least 10 units blood transfusion, is frequently reported.[5]

Various approaches have been employed in controlling intraoperative blood loss in cases of abnormal placentation. These include inserting uterine tamponade balloons, applying uterine gauze packing, placing uterine brace or isthmic compression sutures, and performing a hysterectomy. Vascular ligation and endovascular occlusion procedures have had varying success rates.[6] The placement of an internal iliac artery balloon occlusion (IIABO) catheter as an alternative to open surgical ligation of a segment of the anterior iliac artery has been advocated in the management of anticipated major postpartum hemorrhage. The catheters are placed preoperatively, inflated following delivery of the baby to restrict blood flow to the surgical field, and deflated upon procedure completion.

Although the pre-operative placement of IIABO catheters provide a logical option in cases of anticipated major hemorrhage, supporting evidence for their routine use is lacking. The International Federation of Gynecology and Obstetrics guideline does not recommend their routine use in the management of massive obstetric hemorrhage associated with the placenta accreta spectrum.[7]

There has been a significant increase in cases of invasive placental disease in the State of Qatar attributable to the increasing CD rates and higher order repeat CDs. The preference for large families in this region has made it necessary for Obstetricians to strive for uterine-preserving surgery and to only perform hysterectomy as a life-saving procedure of last resort. Consequently, there is an incentive for increased use of IIABO catheters in our unit. There are different opinions among Obstetricians regarding its use, with some of the opinion that the technique could help and is therefore worth considering in the management of women with PAS.

This retrospective review of all CDs complicated by invasive placentation over three years aimed to assess the impact of IIABO catheter placement on intraoperative total blood loss. Other outcomes of interest were the massive blood transfusion requirement and additional hemostatic procedures, duration of surgery and postoperative hospital stay. The study intended to explore if there was a clinical benefit of this invasive high-risk procedure in the studied women.

METHODS

Study design and setting

This retrospective descriptive cohort study was conducted in Women's Hospital (WH), Doha, the largest public tertiary care setting in Qatar, delivering an average of 16,000 babies annually. The study was approved by the Medical Research Center, Hamad Medical Corporation, Doha, Qatar (MRC-01-18-093) and was conducted in compliance with the ICH good clinical practice guidelines. Since the data were

collected retrospectively and completely anonymized with secure access, a waiver of informed consent was granted.

The Hospital Central Labor and Delivery Registry was accessed to identify consecutive CDs complicated by intraoperatively confirmed morbidly invasive placenta between January 2013 and October 2016. All singleton pregnancies above 24 weeks' gestation, with an intraoperative diagnosis of one or more of "placenta previa," "placenta accreta," and "morbidly adherent placenta" or "abnormal placentation" (International Classification of Diseases-9-clinical modification 667.0) were included. A total of 67 women who fulfilled the criteria and underwent elective or emergency CDs in this period were identified.

Participants, variables, and data collection

All women in the cohort had an antenatal diagnosis of placenta previa, of whom 70% were suspected of having abnormally adherent placenta by routine antenatal ultrasound scan, supplemented in most cases with a Magnetic Resonance Imaging (MRI) scan. Women who had planned elective CD were admitted to hospital in the third trimester. The placenta previa care bundle was instituted as per the Royal College of Obstetricians and Gynecologists (RCOG)[8] and local hospital guidance, which included the organization of a senior Multidisciplinary team of Obstetricians, Anesthetists, Urologists, Interventional Radiologists and Hematologists with the provision of cross-matched blood and feasibility of Massive Blood Transfusion if needed. Most of the elective patients had preoperative insertion of bilateral IIABO 5-French angiographic catheter under fluoroscopic guidance, by the Interventional Radiology team, before attending the obstetric theater.

The balloons were inflated with saline immediately after the delivery of the baby and before attempting to deliver the placenta. The balloons were deflated before skin closure and removed within 24 hours of surgery. The elective patients who were misdiagnosed antenatally as 'nonadherent placenta previa' did not have IIABO inserted preoperatively.

The remaining patients underwent emergency CD before their planned delivery date, indicated by mild to moderate continuing antepartum hemorrhage. They did not undergo IIABO catheter placement, given the urgency of intervention.

The consent for CD specifically indicated that hysterectomy would only be performed in the presence of life-threatening hemorrhage. All women were operated by senior Consultant Obstetricians with experience in operating on patients with adherent placenta. The standard surgical technique for the CD was as follows: incision of the lower uterine segment, delivery of the baby around or through an unavoidable placenta, and placement of additional hemostatic sutures and/or performance of surgical procedures, including hysterectomy, for hemostasis.

The data were collected from electronic patient health records (CERNER®) including antenatal care sheets, imaging results, preoperative, intraoperative, and postoperative data, Physician and Nurse documentation, laboratory results, progress notes, and discharge summaries. The patient demographic variables collected included age, nationality, body mass index, and obstetric history, including parity and previous CDs. Additionally, gestational age at delivery, additional pregnancy-related comorbidities such as diabetes or hypertension, and preoperative diagnosis of the adherent placenta type (accreta, increta, or percreta as diagnosed by ultrasound and/or MRI) were also extracted.

The primary outcome variable was the total estimated blood loss at the end of CD. Blood loss was measured as the total milliliters of blood measured in the suction apparatus (after accounting for amniotic fluid) plus the estimate from the total gauze count and any significant visible collection on the operating room table or surroundings. The total blood loss was categorized as a binary variable for analysis, and the median blood loss was used as the cut off. Other intraoperative variables were the type of anesthesia used, the number of red blood cell units transfused intra-operatively, intraoperative diagnosis, use of uterotonic and hemostatic agents, and the need for additional surgical hemostatic procedures (Tables 3 and 4), and the duration of surgery in minutes. Any additional requirement for postnatal blood transfusion and the total number of days in the hospital were recorded postoperative variables.

Statistical analysis

The group of women with catheters was compared with that of the group without catheters. The continuous variables are represented as mean/median and standard deviation/interquartile range (IQR) according to the variable distribution, and normality was assessed using a combination of histogram and Shapiro – Wilk test. Categorical variables are

Table 1. Demographic data of women with and without IIABO.

Demographics	IIABO (n = 33)	No-IIABO (n = 34)
Maternal age (years), mean (SD)	34 (3.6)	34 (5.0)
BMI over 35, n (%)	10 (30.3)	11 (34.4)
Parity under 3, n (%)	12 (36.4)	17 (50.0)
Parity 3 or more	21 (63.6)	17 (50.0)
Gestation at delivery—completed weeks, median (IQR)	36 (35 – 37)	35 (33 – 37)
Previous cesarean delivery, n (%)	32 (97.0)	33 (97.0)
3 or more previous cesarean sections, n (%)*	19 (57.6)	9 (26.5)

*$p < 0.05$.
Comparisons were performed using *t*-test, Wilcoxon rank-sum, and Fisher's exact test as applicable. SD, standard deviation; BMI, body mass index; IIABO, internal iliac artery balloon occlusion; IQR, interquartile range.

represented as frequency and percentage of the total number in the group. Comparative analysis was performed using the Student *t*-test or Wilcoxon rank-sum test for continuous variables as applicable and chi-square or Fisher's exact test for categorical variables. An adjusted multivariate regression analysis was conducted for the primary outcome variable to adjust for confounders found to be significantly different in univariate analysis or deemed to be clinically relevant. All statistical analyses were performed using STATA version 16 (StataCorp 1996-2020), and a *p* value of <0.05 was considered statistically significant.

RESULTS

During the three years, there were 48,863 deliveries at WH. There were 67 women with abnormal placentation who met our inclusion criteria. Thirty-three women received IIABO catheter placement, and the remaining 34 did not. There were no statistically significant differences in patient age, BMI, parity, gestational age at delivery and CD history (Table 1). The IIABO group had more women with three or more previous CDs (57.6% *vs.* 26.5%, $p = 0.014$). A difference was noted in the preoperative diagnosis between the groups ($p = 0.005$), with 47% of women in the no-IIABO group not known to have morbidly adherent placenta before surgery (Table 2). The intraoperative diagnosis of accreta, increta, and percreta was equally distributed between the groups (Table 2). The difference between preoperative and intraoperative diagnoses was particularly evident for placenta percreta, in which less than 50% of cases confirmed at the time of surgery were preoperatively suspected.

The intraoperative and postoperative outcomes for the two groups are summarized in Table 3. The total cohort had a median total blood loss of 3000 mL (IQR 1800 – 4535). There was no statistically significant difference between the median blood loss in both

Table 2. Preoperative and intraoperative characterization of the placenta.

Diagnosis	Catheter group IIABO n = 33 No IIABO n = 34	*Number of preoperative suspected diagnoses, n (%)	Number of intraoperative confirmed diagnoses, n (%)
Placenta previa*	IIABO	5 (15.1)	1 (3)
	No IIABO	16 (47)	0
Accreta	IIABO	14 (42.4)	13 (39.4)
	No IIABO	13 (38.2)	18 (53.0)
Increta*	IIABO	11 (33.3)	8 (24.2)
	No IIABO	2 (5.9)	10 (29.4)
Percreta*	IIABO	3 (9.1)	11 (33.3)
	No IIABO	3 (8.8)	6 (17.6)

*$p < 0.05$.
IIABO, internal iliac artery balloon occlusion.
*Preoperative suspected diagnosis by ultrasound with or without MRI

Table 3. Intraoperative and postoperative outcomes in women with and without IIABO.

	IIABO (n = 33)	No-IIABO (n = 34)	Unadjusted OR^	*p* value
General anesthesia, n (%)	26 (78.8)	15 (44.1)*	4.71	0.005*
Duration of surgery (min), median (IQR)#	107 (80 – 135)	96 (75 – 121)		0.351
Estimated blood loss (mL), median (IQR)#	3000 (2000 – 4500)	2650 (1500 – 4800)		0.800
Blood loss > 3000 mL, n (%)	15 (45.5)	16 (47.1)	0.94¥	0.895
Intraoperative blood transfusion (units), n (%)				
0 – 2	10 (30.3)	16 (47.1)		0.58
3 – 5	9 (27.2)	8 (23.5)		
≥ 6	14 (42.4)	10 (29.4)	1.76	0.269
Use of uterotonics**				
Oxytocin only	12 (36.4)	7 (20.6)		
Methergine	11 (33.3)	11 (32.4)		
Carboprost	8 (24.2)	16 (47.1)		
Misoprostol	7 (21.2)	8 (23.5)		
Tranexamic acid	13 (39.4)	16 (47.1)		
Need for additional hemostatic procedure, n (%)	23 (69.7)	25 (73.5)	0.828	0.728
Cesarean hysterectomy, n (%)	7 (21.1)	10 (29.4)	0.65	0.442
Postoperative transfusion, n (%)	10 (30.3)	8 (23.5)		0.706
Number of postoperative inpatient days, median (IQR)#	6 (4 – 7)	4 (3 – 7)		0.1234

^No-IIABO was the comparison group for regression analysis
¥Adjusted OR for blood loss > 3000 mL = 0.585, *p* value 0.455, adjusted for obstetric history, surgical duration, anesthesia used, and intraoperative diagnosis
*$p < 0.05$.
**Some patients required more than one additional uterotonic agent.
#Comparison performed using the Wilcoxon rank-sum test.
OR, odds ratio; IQR, interquartile range; IIABO, internal iliac artery balloon occlusion.

groups (median 3000, IQR 2000 – 4500 in the IIABO group *vs.* median 2650, IQR 1500 – 4800 in the no-IIABO group; $p = 0.80$). There was no statistically significant difference observed between the groups with intraoperative hemorrhage volumes of 3000 mL and above (unadjusted OR [odds ratio] 0.94 [no-IIABO group as reference], $p = 0.895$). More than 40% of the IIABO group required intraoperative transfusion of packed red blood cells above six units (14 [42.4%] *vs.* 10 [29.4%]; $p = 0.357$), and 30% required additional postoperative transfusion (10 [30.3%] *vs.* 8 [23.5%]; $p = 0.706$), although not statistically significant. There was no difference noted in the median duration of surgery (median 107, IQR 80 – 135 *vs.* median 96, IQR 75 – 121; $p = 0.3508$). Patients in the IIABO group were significantly more likely to have received general anesthesia for surgery [26/33 (78.8%) *vs.* 15/34 (44.1%), unadjusted OR 4.71, $p = 0.005$]. Multivariate logistic regression analysis was performed to evaluate the effects of confounders on the main outcome of blood loss (binary), including variables such as obstetric history, intraoperative diagnosis, surgical duration, and anesthesia type in the regression model. The difference between the groups remained not significant after covariate adjustment (adjusted OR 0.585, $p = 0.456$).

The need for additional measures to secure hemostasis similarly showed no difference between the groups (Table 4). More than 70% of women in the total cohort required an additional hemostatic surgical procedure (69.7% vs 73.5% in the IIABO and no-IIABO groups, respectively, OR 0.82; $p = 0.728$). Cesarean hysterectomy was performed less in the IIABO catheter group (seven [21.1%] cases) than in the no-IIABO group (10 [29.4%] patients), although this difference was not significant (unadjusted OR 0.65, $p = 0.442$). Two patients were in the control

Table 4. Additional surgical procedures required to secure hemostasis.

Procedure	IIABO (n = 33) n (%)	No-IIABO (n = 34) n (%)
B-Lynch procedure	5 (15.2)	5 (14.7)
Insertion of Bakri Balloon	4 (12.1)	6 (17.6)
Cesarean hysterectomy	9 (27.3)	7 (20.6)
Reconstruction of the uterine anatomy	5 (15.2)	6 (17.6)
Intrauterine packing	2 (6.1)	3 (8.8)
Uterine artery ligation	2 (6.1)	2 (5.9)
Repair of bladder injury	7 (21.2)	5 (14.7)

group returned to the theater for postoperative hemorrhage. One case was managed by bilateral uterine artery ligation and the other by hysterectomy.

The complications specifically related to the balloon group occurred in women with a BMI greater than 35. They included two cases of femoral access wound hematoma and one instance each of catheter displacement and reinsertion and pelvic deep vein thrombosis on postoperative day 19.

DISCUSSION

This retrospective cohort study has questions the value of IIABO catheter use in the management of anticipated massive obstetric hemorrhage associated with PAS. Around 40% – 50% of women had massive blood loss, with 30% – 40% of them requiring more than five units of blood transfusion. More than 70% required additional hemostatic surgical measures, with one in four ending up having hysterectomy (Table 4).

However, the use of IIABO in our study was associated with a nonsignificant reduction in measures to control the massive hemorrhage. This finding is supported by the study of McGinnis et al.[9] who managed 12 (50%) cases of women who had planned cesarean hysterectomy for an invasive placenta with IIABO catheter placement. Although hysterectomy was immediate and the placenta was not removed, the IIABO catheter group experienced less operative blood loss, particularly in non-elective patients.

Fan et al.[10] presented a recent case-controlled observational study of IIABO. The patients were operated upon in a single center with a single dedicated care team. The use of IIABO was associated with a nonsignificant reduction in obstetric hemorrhage and cesarean hysterectomy.

One drawback of IIABO is the increased reliance on general anesthesia and, therefore, a limitation of patient choice.[11] In our study, almost 80% of women who had IIABO placement received general anesthesia. The main reason was the impracticality of hip-to-torso flexion (for a regional anesthesia) in the presence of femoral artery access site to avoid catheter displacement.

The catheter group also had a nonsignificant increase in the total operative anesthetic times as reported in a previous study.[9] IIABO catheters are not without risk.[12] However, the complications were few in our cohort. The transfer of patients from the Interventional Radiology Unit to the operating theater was a logistical reality, with the potential for catheter displacement or migration. The availability of a "hybrid theater" suite could have avoided this. The use of a hybrid operating room (obstetric and interventional radiology) was successfully demonstrated by Yamada et al.,[13] using embolization techniques performed immediately after the delivery of the baby. Interestingly enough, they also planned a shift from spinal to general anesthesia after the birth of the baby.

In Qatar, the "decision threshold" for resorting to a hysterectomy is remarkably high, as women specifically expect that "the obstetrician does as much as is possible" to preserve the uterus. The RCOG guidance on uterine preservation appears somewhat contradictory.[14] It observes that "there is limited evidence to support uterine preserving surgery in placenta percreta" and that the patient should be informed of the "high risk of peripartum and secondary complications including the need for secondary hysterectomy." But it then goes on to cite a study which suggests that uterine preserving surgery is possible in 9 of 10 instances.[15]

Our clinical perception of the current and future risk of surgical management of PAS,[16] including a 20% recurrence[17] does not appear to be shared by the patients in this setting despite repeated counseling,

often declining tubal ligation. Two senior Obstetricians need to agree on a need for obstetric hysterectomy and to jointly undertake it. The consistency of the decision to perform a hysterectomy is one of the strengths on intervention in this cohort and may underline the validity of our observations.

A similar 2015 retrospective review of conservative management of such cases was conducted by D'Souza et al.,[18] which showed an apparent benefit of placing IIABO. Patients with balloon catheters also received postoperative embolization. However, the numbers were too small in the study, and there was no comparison group. A similar larger study looked at the same combination of methods in 35 women with PAS and found no definite benefit of IIABO combined with embolization.[19]

A few reasons may explain the inconsistencies in the findings on the use of IIABO. There are several confounding clinical variables to contend with, one of which is the depth of myometrial placental invasion.[20] It is plausible that focused antenatal MRI assessment of the myometrial placental interface could predict the degree of blood loss in some cases,[21,22] which could be a potential triaging tool for IIABO management. It may also be possible that IIABO does not provide enough arterial flow attenuation in cases of severe abnormal placentation. In a recent case report, escalating from IIABO to common iliac artery balloon occlusion (CIABO) was found to be more effective in reducing operative blood loss during cesarean hysterectomy for PAS,[23] probably because CIABO occluded more collateral arteries than IIABO. Many recent studies looked at the use of abdominal aorta balloon occlusion to achieve adequate blood flow attenuation. However, it carries higher risks of complications as shown in the retrospective review of 57 women who underwent this procedure, resulting in poor neonatal outcomes, femoral artery thrombosis, and hematoma.[24]

One of the limitations of this study is that it was a retrospective analysis. Data collection was highly dependent on procedural documentation and subjective primary outcome assessment. There were unavoidable differences encountered between the groups that could have led to biased estimates, even though we had controlled for the covariates in a regression analysis.

Furthermore, surgical procedural heterogeneity between surgeons and teams is unavoidable in clinical practice. Although senior Obstetricians with adequate expertise in the area performed all the CDs, we can only assume that the steps, sequences, and procedures were undertaken fairly comparably between the groups.

The lack of statistically significant results may be due to a smaller sample size. However, abnormal placentation and massive obstetric hemorrhage are rare complications in obstetrics, accounting for $<1\%$ of our pregnancies. The only other notable study that had a slightly higher number of patients was by Cho et al.[25] A recent randomized trial of 20 women in the IIABO and no-IIABO groups showed similar results to our observational study.[26]

A multicenter randomized controlled trial of IIABO catheter placement would hopefully provide a more definitive conclusion on the value of IIABO use during cesarean sections in the presence of PAS. The establishment of a Global Registry to collate robust figures toward creating uniform standards of care may eventually pave the way for better surgical outcomes.

There have been suggestions that regional and major maternity hospitals constitute a standing Abnormal Placentation Team, which should comprise multidisciplinary expertise to build on skills, share experiences, and support new intervention studies. We agree with this notion.

CONCLUSION

The placement of IIABO catheters is an invasive procedure, which consumes time and resources. Its value, as a means of reducing intraoperative blood loss or preserving the uterus in patients with abnormal placental adherence, appears questionable. In this cohort study, there was no statistical difference in blood loss and the need for other steps to control hemorrhage between women with and without IIABO catheters.

Conflict of interest

The authors have no conflicts of interest to disclose.

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Previous presentation of contents of this manuscript

The contents of this paper were recently presented as an e-poster at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists, Nashville, USA (May 3 – 6, 2019).

Authors' contributions

HA conceived the idea for the study and supervised data retrieval from the medical records department. AB and KO are the Senior Obstetric Surgeons involved in the care of our patients. AO and his team performed the catheter placements and provided the relevant information. FM performed the data collection and analysis. All authors separately and jointly interpreted the analyzed data. HA, FM, and IB wrote the first draft of the manuscript. FM, HA, IB, and TF updated the manuscript after independent reviews. All authors reviewed and approved the final draft of the manuscript.

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