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Intraoperative internal iliac artery balloon occlusion versus ligation in cases of placenta previa accreta: A randomized trial

Mohamed Lotfy Mohamed El-sayed, Ahmed Mohamed El-huseiny, Mostafa Abdo Ahmed, Sameh Saber

ABSTRACT

Aims: The aim of the study was to compare the efficacy of intraoperative bilateral internal iliac artery balloon occlusion versus bilateral internal iliac artery ligation before extraction of placenta previa accreta after fetal delivery. **Methods:** One hundred patients with preoperative diagnosis of placenta previa accreta were randomly allocated into two groups each including 50 patients; Group (A) intraoperative internal iliac artery (IIA) balloon occlusion was undergone and Group (B) internal iliac artery ligation was undergone. Then delivery of the fetus and the placenta was removed in a piecemeal manner; any remaining placental bed bleeding was controlled by different surgical techniques. **Statistical analysis:** The collected data were computerized and statistically analyzed using SPSS program (Statistical Package for Social Science) version 20. Qualitative data were represented as frequencies and relative percentages and quantitative data were expressed as mean±SD (Standard deviation). We used two statistical tests for detection of the difference between the two studied groups: The student “t” test for comparison of means of quantitative variables of

two independent groups and chi-square test was used to calculate difference between qualitative variables and find the association between row and column variables. Both tests are used for normally distributed data. **Results:** Satisfactory hemostasis was achieved in 33 patients (33/50 = 66%) in IIA balloon occlusion group while hemostasis was achieved in 29 patients (29/50 = 58%) in IIA ligation group, whereas additional surgical interference were performed in (12/50 = 24%) and (15/50 = 30%) of IIA balloon occlusion group and IIA ligation group respectively. Emergent hysterectomy was performed in (5/50=10%) of IIA occlusion group and (6/50 = 12%) of IIA ligation group. Blood transfusion during operation in 36 patients (36/50 = 72%) and three patients on the first 24 hours after the operation while in IIA ligation group blood transfusion during operation in 39 patients (39/50 = 78%) and five patients on the first 24 hour after the operation. The postoperative hospital stay was shorter with IIA occlusion group. **Conclusion:** Placenta accreta is a potentially life-threatening condition that carries a high rate of maternal morbidity and mortality. Bilateral internal iliac arteries occlusion before extraction of the placenta seemed to be an effective and safe technique to decrease intrapartum and postpartum complications, and to minimize the risk of the emergent hysterectomy.

Keywords: Internal iliac artery balloon occlusion, Internal iliac artery ligation, Placenta previa accreta

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INTRODUCTION

The incidence of placenta accrete was increased and parallel the increasing cesarean section delivery. The incidence of placenta accreta was 1 in 533 pregnancies in the period between 1982–2002 [1]. Placenta accreta becomes problematic during delivery when the placenta does not completely separate from the uterus and is followed by massive obstetrical hemorrhage, leading to different medical and surgical complications [2] resulting in approximately 7% maternal mortality and morbidity as high as 60% [3, 4]. Attempting placental separation for patients who require fertility preservation may increase the risk for hysterectomy in up to 100% [4].

Different techniques that have been developed to minimize intraoperative blood loss and decreasing the risk of cesarean hysterectomy including preoperative catheterization with intraoperative balloon occlusion of the internal iliac arteries and embolization are used to control intraoperative bleeding [5, 6]. Also prophylactic bilateral internal iliac artery ligation before trial of placental removal sometimes to be an effective method to decrease complications and lowering the risk of intrapartum hysterectomy [7].

Placenta previa accreta is a life-threatening condition associated with high risk of maternal morbidity and mortality. So, it is important to select a safe technique to minimize intrapartum and postpartum complications of placenta previa accrete during delivery. Hence, we compare two commonly used methods to control the bleeding after fetal delivery either internal iliac artery balloon occlusion or ligation.

MATERIALS AND METHODS

This prospective, two arm, allocation concealed, randomized study was conducted at the high-risk pregnancy unit of obstetrics and gynecology department, Zagazig University Hospital, Egypt, during the period between March 2014 and January 2016.

The study included 100 patients with placenta previa accreta. Inclusion criteria were:

- (1) preoperative diagnosis of placenta previa accreta
- (2) TVS and color Doppler are methods of diagnosis
- (3) gestational age 28 weeks or more
- (4) cesarean deliveries were planned at 37 weeks of gestation unless there were other obstetrical conditions.

This study protocol was approved by the Institutional Research Ethical Committee. The patients were counseled about the benefits of both management options and written informed consent was obtained from all patients with the risk of intrapartum and postpartum hemorrhage, the need for blood transfusion, and the possibility of hysterectomy if needed to stop massive bleeding.

Ultrasonography (TVS and color Doppler) was used for diagnosis of placenta previa accreta. Loss of retro-placental hypoechoic zone, thinning of the hyperechoic border between bladder and uterine serosa, presence of echogenic masses invading urinary bladder and abnormal placental lacunae (Swiss cheese appearance) are ultrasound findings suggestive of placenta accreta. Color Doppler showed hypervascularity of uterine serosa-bladder interface and vascular lakes with turbulent flow [3].

Patients were randomly allocated to internal iliac artery (IIA) balloon occlusion group (Group A) or IIA ligation group (Group B) (1:1 ratio) using computer generated randomization list and sequentially numbered sealed envelopes containing allocation information written on a card. The sealed envelopes were prepared by statistician not involved in the study. Study nurse opened the sequentially numbered envelopes to allocate patients to assigned group.

Routine evaluation for all patients was carried out according to the unit's policy by assessment of history, clinical examination, and investigations including complete blood count, coagulation profile and organ functions.

A multidisciplinary team including a senior obstetrician and assistant, an anesthesiologist, a urologist and an interventional radiologist were involved in the operation. Cross-matched blood was prepared for each patient at least four units of packed RBCs. Surgical planning regarding incision site and avoiding incising the placenta was performed. After extraction of the fetus, the uterus with the placenta inside was exteriorized outside the incision and the anterior division of the internal iliac artery was ligated or internal iliac artery balloon inflation was done on both the sides. Then, the placenta was removed manually in a piecemeal manner; any bleeding points from the placental bed were then controlled by bilateral uterine and ovarian artery ligation or multiple square hemostatic sutures or both methods, followed by repair of the uterus and the abdominal wall.

In the internal iliac artery balloon occlusion group, bilateral femoral arteries access performed using Seldinger's technique. This involved bilateral femoral arterial punctures and insertion of 8-French vascular sheaths under local anesthesia (Figure 1). Over a 0.035-french hydrophilic guidewire (Terumo), a 5-French diagnostic cobra shaped catheter (Boston Scientific) was used to reach the contralateral internal iliac artery. The hydrophilic guidewire replaced by a stiff one and the diagnostic catheter is then exchanged for 6-10-French occlusion balloon catheter (Boston Scientific). Size

selected according to the vessels caliber. Balloon catheters positioned with their inflatable part within the distal common iliac and the proximal portion of the internal iliac artery (Figure 2A–H). The procedure was repeated on the other side. After both balloon catheters were properly inserted, a test volume of dilute water-soluble contrast material was injected to inflate the occlusion balloons. The catheters were secured, and the patients were subsequently taken into the operating room for planned delivery. After fetal delivery by classical cesarean section, the occlusion balloons were inflated. In patients who underwent hysterectomy or had the placentae delivered, the balloons were deflated just before closure of the rectus sheath after confirming that hemostasis within the pelvis was secured. The balloon catheters were left in place for 24 hours after surgery for fear of primary post-operative bleeding. After 24 hours removal of the balloon catheter and the sheaths, firm dressing compression over the insertion site was performed for at least 20 min in all cases.

In the internal iliac artery ligation group, adequate exposure was obtained by opening the peritoneum over the bifurcation of the common iliac arteries and internal iliac artery ligation was carried 3–4 cm distal to this level to avoid the posterior division. A right-angle clamp was carefully passed just beneath the artery from lateral to medial. Silk suture was passed under the artery with the clamp and the vessel was then double ligated.

Primary outcome measure was the amount of intraoperative blood loss (assessed by shock index which equal heart rate divided by systolic arterial blood pressure [8]) and the secondary outcome measures were number of blood transfusion units, postoperative hemoglobin concentration, cesarean hysterectomy and any other maternal morbidities.

Sample size and calculation

A randomized trial assuming that the mean of RBCs units transfused in bilateral internal iliac artery ligation group is 1.8 ± 1.3 [7] and that of balloon occlusion of internal iliac artery group is 2.9 ± 2.4 so the estimated sample is 98 patients (49 in each arm) using the open

EPI program with power 80% and CI 95%. We choose on arbitrary bases to include 100 patients in each arm of the study. The main aim of the study was to comparing the efficacy of internal iliac artery balloon occlusion versus internal iliac artery ligation in the management of patients with placenta previa accrete, this data could be used in the future meta-analysis for comparing both management options.

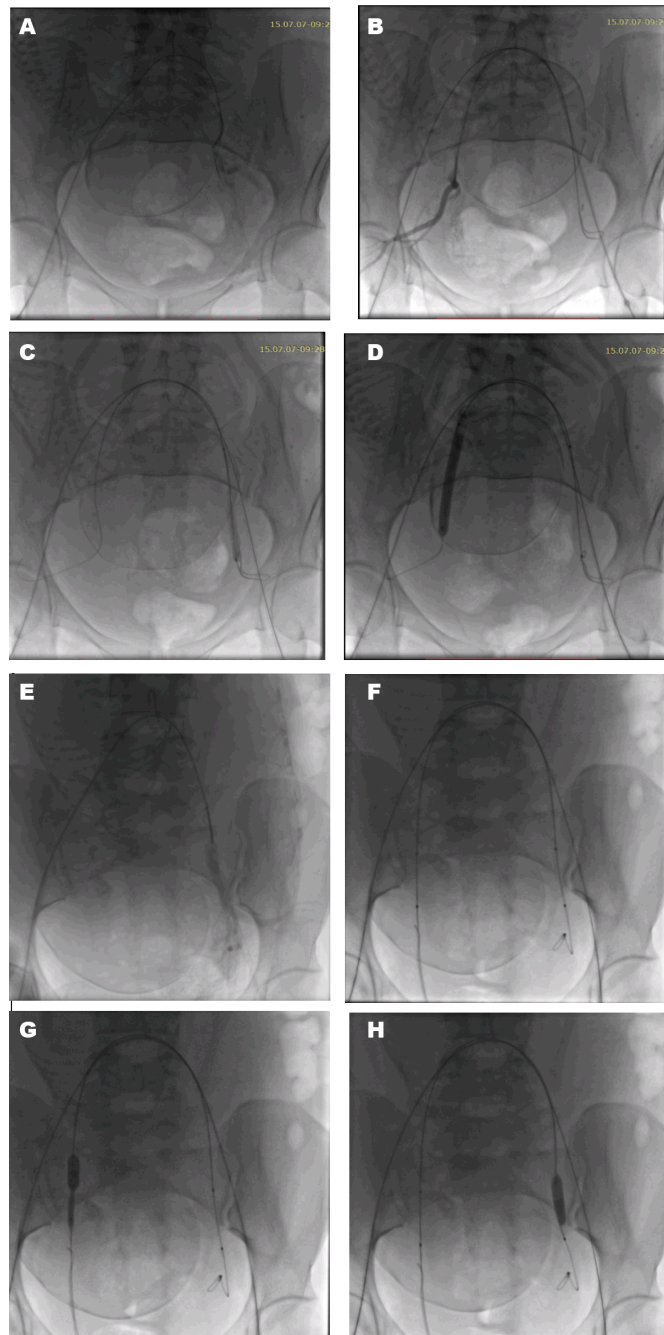


Figure 2: Conventional angiography of a pregnant female during trans-femoral puncture IIA balloon occlusion (A–D). The catheter introduced through the right femoral artery, till the left IIA. Procedure repeated on contralateral side, testing the balloon inside the left IIA then the other on right side. (E–H) Markers of the inflatable parts of the balloons in place, testing the balloon inside the right IIA then the other on left side.



Figure 1: The endovascular instruments used including the vascular sheath, the diagnostic cobra catheter, the stiff wire, the hydrophilic guidewire and the balloon catheter.

Statistical analysis

- The collected data were computerized and statistically analyzed using SPSS program (Statistical Package for Social Science) version 20.
- Qualitative data were represented as frequencies and relative percentages.
- Quantitative data were expressed as mean±SD (Standard deviation).
- The student t test and chi-square are appropriate tests;

The student “t” test for comparison of means of quantitative variables of two independent groups in normally distributed data.

Chi-square test (χ^2)

- Chi-square test was used to calculate difference between qualitative variables and find the association between row and column variables.
- A p-value less than 0.05 was considered statistically significant.

RESULTS

A total number of 100 patients diagnosed by TVS and color Doppler with placenta previa accreta were studied; 72 (72%) of these patients presented with antepartum hemorrhage and 28 were diagnosed during antenatal care by TVS scanning. Ninety-two percent of these patients had undergone previous one cesarean section or more. Six patients had a history of first trimester abortions (8%) and two patients with no known risk factors. As regard age, parity, gravidity and number of previous cesarean section no significant difference between two studied groups (Table 1) (Figure 3).

Bilateral internal iliac artery balloon occlusion was performed in 50 patients with placenta previa accreta and bilateral internal iliac artery ligation was done intraoperative in 50 patients with placenta previa accreta, satisfactory hemostasis was achieved in 33 patients (33/50 = 66%) in IIA balloon occlusion group while hemostasis was achieved in 29 patients (29/50 = 58%) in IIA ligation group, whereas additional surgical interference were performed in (12/50 = 24%) and (15/50 = 30%) of IIA balloon occlusion group and IIA ligation group respectively. Emergent hysterectomy was performed in (5/50 = 10%) of IIA occlusion group and (6/50 = 12%) of IIA ligation group after using of other methods to stop bleeding respectively (Table 2).

Blood transfusion during operation in 36 patients (36/50 = 72%) and three patients on the first 24 hours after the operation while in IIA ligation group blood transfusion during operation in 39 patients (39/50 = 78%) and five patients on the first 24 hours after the operation. The postoperative hospital stay in IIA balloon occlusion group was ranged from 3–12 days (mean 8.4±1.5 days) with an average 7.6 days. However, the

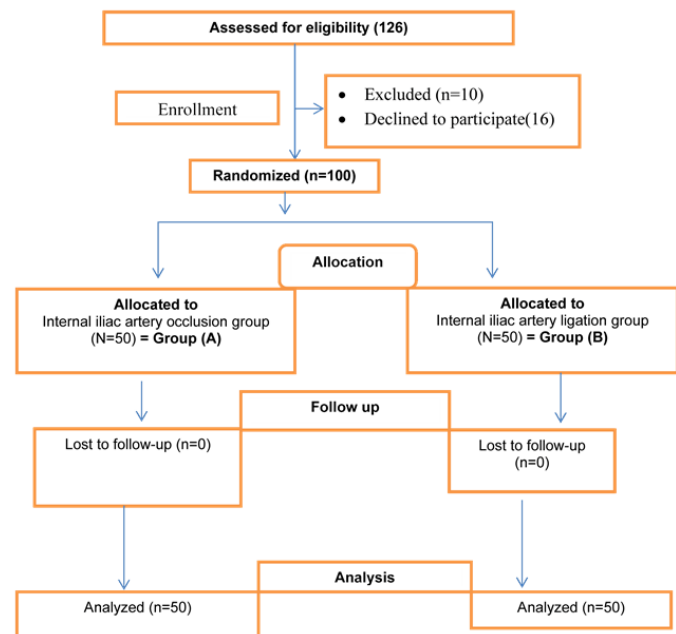


Figure 3: Flow chart of participants.

length of patient hospitalization in IIA ligation group from 3–13 days (mean 9.5±1.7 days) with an average of 10.6 days. Postoperative febrile complications in IIA ligation group were less than IIA balloon occlusion group (12.2±1.9 versus 13.3±2.3 days) (Table 3).

DISCUSSION

The incidence of placental invasion is increasing because of the increased rate of cesarean section [8]. Ninety-three percent patients with reported placenta accreta had undergone previous one or more cesarean section. Up to 88% of these patients had associated with placenta previa [9, 10]. Clark et al. showed that the risk of placenta accreta in patients with previous cesarean section where after the first, second and third cesarean sections, the risk were 0.03%, 0.02% and 0.1% respectively. ACOG committee opinion (2002) reported that the incidence of placenta accreta increased up to 39% for those who had undergone two cesarean sections [7]. Hysterectomy has been the best management option in placenta accreta, but this represents a problem for patients who desire to preserve the uterus for future fertility thus, alternatives management options include leaving the placenta after cesarean delivery with uterine devascularization, uterine artery embolization, uterine compression sutures, and/or under-running sutures of the placental bed [11, 12]. Different techniques have been developed to decrease intraoperative blood loss depend on reducing pelvic circulation, primarily of the internal iliac arteries for disruption of the arterial blood supply to the uterus and preserving the blood supply to other pelvic structures. This has been accomplished either by temporary balloon occlusion or by intraoperative ligation

Table 1: Demographic data of both groups

Variables	Internal iliac artery balloon occlusion group Mean \pm SD (N=50)	Internal iliac artery Ligation group Mean \pm SD (N=50)	p-value
Age	33.54 \pm 4.36	33.62 \pm 3.86	0.9
Parity	2.84 \pm 0.88	2.75 \pm 0.59	0.4
Gravidity	4.02 \pm 1.25	4.03 \pm 1.33	0.9
Number of previous cesarean section	2.54 \pm 1.12	2.3 \pm 1.03	0.3

Table 2: Comparison between intraoperative data of both groups

Variables	IIA balloon occlusion group (N = 50)		IIA ligation group (N = 50)		p-value
	F	%	F	%	
Degrees of placental invasion					0.9
Simple accreta	6	12	5	10	
Increta	28	56	30	60	
Percreta	16	32	15	30	
Needing for further interference;	12	(24%)	15	(30%)	0.01*
Multiple square hemostatic sutures	2	16.7	8	61.5	
Bilateral uterine and ovarian artery ligation	9	75	4	15.4	
Both methods	1	8.3	3	23.1	
Descriptive variables	IIA balloon occlusion group (N = 50)		IIA ligation group (N = 50)		
	F	%	F	%	
Hysterectomy	5	10	6	12	
Urinary tract injuries	1	2	4	8	
Intraoperative blood loss (Shock index)	0.85 \pm 0.02		1.12 \pm 0.0.07		0.000*

Shock index: means heart rate divided on systolic arterial pressure

*p-value <0.05 is significant

Table 3: Comparison between postoperative data of both groups

Variables	IIA balloon occlusion group (N=50) (M \pm SD)	IIA ligation group (N=50) (M \pm SD)	p-value
Blood transfusion Units (Packed RBCs)	1.8 \pm 0.4	2.1 \pm 0.5	0.001**
Hemoglobin concentration (g/dL)	9.8 \pm 1.2	8.6 \pm 1.4	0.001**
Hospital stay (Days)	8.4 \pm 1.5	9.5 \pm 1.7	0.001**
Febrile complications (days)	13.3 \pm 2.3	12.2 \pm 1.9	0.4

*p-value <0.05 is significant

** p-value <0.001 is highly significant

of the internal iliac arteries [13].

In this study, intraoperative bilateral internal iliac artery balloon occlusion was done for group of 50 patients and intraoperative bilateral internal iliac arteries ligation was performed for another group of 50 patients before any attempt to remove the abnormally adherent placenta, which is the main source of severe bleeding that usually occurs in such a situation, a technique to reduce the pulse pressure distal to the level of ligation or occlusion, thus minimizing blood loss during cesarean delivery in placenta previa accreta. Both techniques seemed to be successful in patients with placenta accreta as 10% (5/50) of the patients with internal iliac artery balloon occlusion group required cesarean section hysterectomy versus 10% (5/50) of the internal iliac artery ligation group required cesarean section. hysterectomy, with more blood loss, and one of internal iliac artery balloon occlusion group associated with maternal complications in the form of bladder injury in contrast to three patients of ligation group associated with bladder injuries and one patient with ureteric injury. The amount of blood loss in internal iliac artery balloon occlusion group is less than that with the internal iliac artery ligation group (Shock index, 0.85 ± 0.02 versus 1.12 ± 0.07 respectively). Aggarwal et al. reported massive blood loss in all patients with placenta accreta, with a mean blood loss of 2710 ml, and an average of six units of whole blood were transfused which was reduced in the patients with prophylactic bilateral internal iliac artery ligation. Salim et al. showed that with preoperative suspicion of placenta accreta, preoperative placement of prophylactic balloon catheters associated with no significant differences between the intervention and control groups as regard the number of packed RBC units transfused, the amount of blood loss, 4,950 ($\pm 5,051$) and 4,709 ($\pm 3,434$) mL, duration of surgery, peripartum complications, and hospitalization length. Reversible adverse effects related probably to prophylactic balloon catheter insertion were noted in 2 of 13 (15.4%) women.

In contrast, Berg et al. showed that bilateral internal iliac artery ligation appears to be effective for bleeding due to uterine atony; but less effective for abnormally adherent placenta. Also Refaei et al. showed that prophylactic bilateral internal iliac artery ligation before extraction of placenta accreta an effective method to decrease cesarean section complications and avoid emergency hysterectomy. The impact of ligation on pelvic circulation is limited by rapid collateral development [14, 15]. Carnevale et al. found that internal iliac artery balloon occlusion decreased intraoperative blood loss and transfusion requirements when comparing the patients retrospectively with a control group [16–18]. Balloon occlusion has the advantage of being reversible after the procedure in comparison with the intraoperative internal iliac arteries ligation. However, Internal iliac artery ligation requires an expert obstetrician and a few minutes for bilateral ligation, but intraoperative balloon occlusion procedures require a team approach, timely

actions by the interventional radiologist and access to the internal iliac arteries through a bilateral femoral arteries was gained within 30 min [19]. Preoperative bilateral internal iliac artery balloon occlusion reduces intraoperative blood loss and transfusion requirements in patients with placenta accreta compared with controls [7]. A major benefit of intraoperative internal iliac artery ligation over intraoperative balloon occlusion is prevention of fetal exposure to radiation, save time and team works as interventional radiologist. Also, catheter related complications occur in about 7% of patients including; complications of angiography, pelvic infection, a self-limited pyrexia, and maternal thromboembolic events [20].

Author Contributions

Mohamed lofty Mohamed El-Sayed – Substantial contributions to conception and design, Analysis and interpretation of data, Drafting the article, Revising it critically for important intellectual content, Final approval of the version to be published

Ahmed Mohamed El-huseiny – Substantial contributions to conception and design, Acquisition of data, Analysis and interpretation of data, Drafting the article, Revising it critically for important intellectual content, Final approval of the version to be published

Mostafa Abdo Ahmed – Substantial contributions to conception and design, Acquisition of data, Analysis and interpretation of data, Revising it critically for important intellectual content, Final approval of the version to be published

Sameh Mohamed Saber – Substantial contributions to conception and design, Acquisition of data, Analysis and interpretation of data, Drafting the article, Revising it critically for important intellectual content, Final approval of the version to be published

Guarantor

The corresponding author is the guarantor of submission.

Conflict of Interest

Authors declare no conflict of interest.

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