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ORIGINAL ARTICLE

Intrauterine Inflated Foley's Catheter Balloon in the Management of Abnormally Invasive Placenta Previa: A Case–Control Study

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About the Author

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Abstract

Objective To describe the use of intrauterine inflated Foley's catheter balloon for control of postpartum hemorrhage (PPH) during cesarean section (CS) in cases of abnormally invasive placenta previa aiming to preserve the uterus.

Methods Retrospective case–control study of the data of women who underwent elective CS on abnormally adherent placenta previa was carried out. Women in whom inflated Foley's catheter balloon was used for control of PPH during CS ($n = 40$) were compared with a control group of women who underwent elective CS by the same technique but without use of intrauterine catheter balloon ($n = 38$).

Results Use of intrauterine inflated Foley's catheter balloon significantly reduced the estimated amount of blood loss ($P = 0.008$), amounts of crystalloids, colloids and packed red blood cells transfusion ($P = 0.025$, 0.017 and 0.022, respectively), and the need for bilateral internal iliac artery (IIA) ligation ($P = 0.016$). No significant difference was observed between both groups regarding the use of massive transfusion protocol, performing cesarean hysterectomy, relaparotomy, and admission to the intensive care unit.

Conclusion Application of an intrauterine inflated Foley's catheter balloon during CS in cases of morbidly adherent placenta previa helps to control PPH with preservation of

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the uterus and decreases the need for the invasive IIA ligation.

Keywords Placenta previa · Placenta accreta · Foley's catheter · Cesarean hysterectomy

Introduction

The incidence of placenta previa is increasing nowadays as a result of increasing rate of cesarean deliveries. Placenta previa may be associated with abnormal placental adhesion to the myometrium, a condition known as placenta accreta, increta, or percreta [1]. Abnormally adherent placenta is associated with serious obstetric complications, including life-threatening maternal hemorrhage, transfusion of large amounts of blood products, and peripartum hysterectomy [2]. The major risk occurs after separation of the pathologically adherent placenta, which leads to severe bleeding.

Many authors reported their trials aiming to improve the intraoperative management of abnormally invasive placenta. Fitzpatrick et al. [3] reported that avoiding any attempt to remove the placenta, with the aim of uterine preservation or prior to hysterectomy, reduces the severity of hemorrhage. This is also recommended by the Royal College of Obstetricians and Gynecologists (RCOG) [4]. In women with suspected placenta accreta, planned cesarean hysterectomy with avoiding attempted placental removal was associated with reduced maternal morbidity, but the internal iliac artery (IIA) ligation did not reduce the maternal morbidity [5]. Other authors suggested a stepwise approach, including transverse incision in the uterus at the upper border of the placenta, delayed extraction of the placenta after transient bilateral kinking of the uterine arteries and bilateral ligation of the anterior division of the IIA, proper identification of the lower uterine segment (LUS), and repair of the uterine incision [6].

Insertion of intrauterine balloon tamponade has been suggested in the management of massive postpartum hemorrhage (PPH). The Bakri balloon has a sausage-like spindle shape and a drainage lumen and is made of silicon. It has been used in cases of uterine atony and placenta previa with a success rate of 90% [7]. However, Bakri balloon is not available in all countries.

The aim of this study is to evaluate the efficacy of the use of intrauterine inflated Foley's catheter balloon to control PPH during cesarean delivery in cases of abnormally invasive placenta previa (accrete, increta, and percreta) aiming to preserve the uterus.

Materials and Methods

Study Design

This was a retrospective case–control study conducted during the period from July 2013 through June 2016 in Mansoura University Hospital in Mansoura, Egypt. The study was approved by the Mansoura Faculty of Medicine Institutional Research Board (Code No. R/16.05.30). The main inclusion criterion was women who underwent elective CS on abnormally adherent placenta previa diagnosed by color flow Doppler or magnetic resonance imaging (MRI) in the third trimester of pregnancy, and confirmed intraoperatively (during CS) by difficult separation of the placenta or separation of it in pieces. Women with any of the following criteria were excluded from the study: (1) multifetal pregnancy; (2) medical conditions complicating pregnancy; (3) blood diseases or bleeding tendencies; or (4) moderate or severe antepartum hemorrhage (APH).

As a routine in our hospital, all women diagnosed to have abnormally adherent placenta previa by color flow Doppler and/or MRI were admitted in the third trimester of pregnancy and were subjected to full precise history taking, complete laboratory investigations, fetal surveillance by ultrasound scanning and cardiotocography, and antenatal administration of corticosteroids to enhance the fetal lung maturity. Maternal demographic and clinical characteristics and ultrasound findings were recorded in a database. The operative details and maternal and neonatal outcomes were collected into the same database.

All women were informed about the risk of intraoperative hemorrhage and PPH, the need for blood products transfusion, and the possibility of cesarean hysterectomy if needed to control severe bleeding. A written informed consent was taken from each woman before performing any intervention. Moreover, a written permission was obtained from each woman to use her data for research purposes.

Preparation and Technique of Cesarean Section (CS)

Elective CS was planned at 37–38 weeks of gestation. Adequate amount of blood products was prepared to be available for transfusion. Delivery was performed by a multidisciplinary team, including an expert obstetrician, an assistant, an expert anesthesiologist, and a pediatrician. All participants received general anesthesia. Two 16-gauge intravenous (IV) cannulas were inserted in 2 large forearm veins before induction of anesthesia, and one 16-gauge IV cannula was inserted in the external jugular vein after

induction of anesthesia. An IV infusion of 1000 mg tranexamic acid was done just before induction of anesthesia. An IV infusion of fluids and blood products was done according to our department protocol (discussed below).

A Pfannenstiel incision was performed in the abdomen; then, a transverse incision was performed in the uterus at or above the upper border of the placenta. Ecbolics were administered just before extraction of the fetus then the fetus was extracted, and the umbilical cord was clamped without any attempt to separate the placenta. The uterus with the placenta inside was exteriorized quickly after extraction of the fetus while it was still not contracted to facilitate its exteriorization through the abdominal incision. The uterine artery was ligated bilaterally; then, the placenta was separated. Hemostatic sutures were applied in the uterine wall to control bleeding from the placental bed as much as possible.

After acceptable control of bleeding from the placental bed, the internal os of the cervix was identified and a double-way 20 Fr Foley's catheter with a 30–50-ml balloon (Amecath, Ameco Medical Industries, 10th of Ramadan City, Egypt) was inserted through the internal os to be handled by an assistant through the vagina and fixed to the patient's lower limb after inflation of the catheter balloon by 80 ml warm saline and pulling it against the LUS. Only one catheter was used for tamponade. The uterine incision was then repaired over the inflated balloon. A wide pore drain was then inserted in the Douglas pouch, and the abdominal wall was repaired. The intrauterine inflated Foley's catheter balloon was left in place for 24 h after the operation, and then removed.

A control group was selected from women with abnormally adherent placenta previa who underwent elective CS by the same technique described above, but without use of an intrauterine inflated Foley's catheter balloon, matched for the type of placenta previa and the degree of adherence of placenta. In both groups, if there was intraoperative intractable hemorrhage after performing all the mentioned measures, bilateral ligation of the anterior division of the IIA was performed. Hysterectomy was performed if the intractable hemorrhage continued after bilateral ligation of the IIA.

Measurement of Blood Loss

Blood loss was estimated by a combination of direct measurement and gravimetric method [8]. The direct measurement was performed by collecting most of the lost blood into a suction bottle using a suction apparatus. Care was taken to collect most of (if not all) the amniotic fluid in a separate suction bottle. The gravimetric method was used to estimate the amount of blood loss in the surgical towels. The dry surgical towels (40 by 40 cm) were weighed before surgery. Intraoperatively, the towels were used to dry up all the blood in the surgical field then these towels were collected into a sterile metallic bowl which was weighed empty before surgery. When 5 soaked towels were collected in the bowl, the bowl with the collected soaked towels was handled to the circulating nurse to weigh it by a highly accurate digital balance and then calculate the amount of blood loss in the towels by the following formula: amount of blood loss in the soaked towels (in ml) = weight of the metallic bowl with the collected soaked towels in it (in gm)—[weight of the empty bowel (in gm) + weight of the towels before surgery (in gm)]. The collected blood in the suction bottle was added to the total calculated amount of blood loss in the towels.

Protocol of Fluids and Blood Products Transfusion

An IV infusion of 1500 ml of crystalloids (Ringer's acetate solution) was started at induction of anesthesia until removal of the placenta. Ringer's acetate infusion was continued if there was ongoing bleeding or hemodynamic instability of the patient. An IV infusion of 500–1000 ml of colloids (Voluven®, 6% hydroxyethyl starch 130/0.4 in 0.9% sodium chloride) was performed when 3000 ml of crystalloids were infused. Transfusion of packed red blood cells (PRBCs) was started when 1500 ml of blood (30% of blood volume) was lost. When 4 units of PRBCs were transfused, 4 units of fresh frozen plasma (FFP) were transfused; then, one unit of FFP was transfused for each unit of transfused PRBCs. The targeted hemoglobin level was 9 gm/dl if the patient was stable and 7–8 gm/dl if the patient was unstable. Transfusion of 4–6 units of platelets was performed if the platelet count fell to $<70{,}000/mm^3$; then, the platelet count was repeated, and if it was still $<70{,}000/mm^3$, another 4–6 units of platelets were transfused.

Outcome Measures

The outcome measures of this study were the estimated amount of intraoperative blood loss, the amount of fluids and blood products transfusion, use of a massive transfusion protocol (MTP), the need for IIA ligation, performing cesarean hysterectomy, and relaparotomy. Massive transfusion was defined as transfusion of >4 units of PRBCs in 1 h with anticipation of continued need [9].

Statistical Analysis

Continuous variables were presented as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. The IBM® SPSS® Statistics,

version 20.0, for Windows was used for statistical analysis. P values ≤ 0.05 were considered statistically significant.

Results

A total of 78 women who underwent elective CS on abnormally adherent placenta previa were included in the study. In 40 women, an intrauterine inflated Foley's catheter balloon was applied against the LUS just after removal of the placenta to control bleeding from the placental bed (the study group), while in the remaining 38 women, the CS was performed by the same technique, but without use of an intrauterine inflated Foley's catheter balloon (the control group). Both groups were similar to each other in the mean age, parity, number of previous CS, type of placenta previa by ultrasound, Doppler findings, and preoperative hemoglobin level (Table 1).

There was no significant difference in the gestational age at delivery between both groups, and the degree of placental adhesion was equal in both groups. The need for bilateral IIA ligation was significantly lower in the study group than in the control group (20% vs 47.4%; $P = 0.016$). Both groups were similar to each other in the incidence of urological injuries, performing cesarean hysterectomy, and duration of operation (Table 2).

The estimated amount of blood loss was significantly lower in the study group than in the control group (1657 ± 529 ml vs 1982 ± 523 ml; $P = 0.008$). The percentages of patients received colloids and PRBCs were significantly lower in the study group than in the control group (52.5% vs 76.3%; $P = 0.035$ and 57.5% vs 81.6%; $P = 0.028$, respectively). Also, a significant reduction in the amounts of crystalloids, colloids, and PRBCs transfusion was observed in the study group ($P = 0.025$, 0.017, and 0.022, respectively). No significant difference was observed between both groups regarding the percentages of patients received FFP and platelets, the amounts of FFP and platelet transfusion, and the use of MTP (Table 3).

Both groups were similar to each other in the postoperative hemoglobin level, admission to the intensive care unit (ICU), postoperative hospital stay, incidence of coagulopathy, and incidence of surgical site infection (SSI). No cases needed relaparotomy in either groups (Table 4).

Discussion

Our study has included 78 patients with abnormally invasive placenta previa. The incidence of morbidly adherent placenta in our study group was related to increased parity and number of previous CS. These results agree with the results of Roberts et al. [10], Thurn et al. [11], and many other authors who reported increased incidence of pathologically adherent placenta with

Table 1 Demographic and clinical characteristics of the study and control groups

	Study group ($n = 40$)	Control group ($n = 38$)	P value
Age (years)[a]	32.00 ± 4.33	31.00 ± 4.57	0.326
Parity[b]			
Nulliparous	2/40 (5.0%)	2/38 (5.3%)	1.000
Primipara	6/40 (15.0%)	4/38 (10.5%)	0.738
2nd para or more	32/40 (80.0%)	32/38 (84.2%)	0.770
Previous CS[b]			
No prev CS	3/40 (7.5%)	2/38 (5.3%)	1.000
Prev 1 CS	7/40 (17.5%)	5/38 (13.2%)	0.756
Prev ≥2 CS	30/40 (75.0%)	31/38 (81.6%)	0.587
Type of placenta previa by ultrasound[b]			
Complete centralis	25/40 (62.5%)	26/38 (68.4%)	0.639
Major degree anterior	11/40 (27.5%)	10/38 (26.3%)	1.000
Major degree posterior	4/40 (10.0%)	2/38 (5.3%)	0.676
Doppler findings[b]			
Accreta	17/40 (42.5%)	16/38 (42.1%)	1.000
Increta	23/40 (57.5%)	22/38 (57.9%)	
Preoperative hemoglobin level (gm/dl)[a]	11.72 ± 0.48	11.78 ± 0.44	0.556

CS cesarean section

[a] Expressed as mean ± SD and P value was calculated by the Mann–Whitney U test

[b] Expressed as frequency and percentage and P value was calculated by the Fisher's exact test

Table 2 Operative characteristics of the study and control groups

	Study group ($n = 40$)	Control group ($n = 38$)	P value
Gestational age at delivery (weeks)[a]	37.47 ± 0.51	37.57 ± 0.54	0.575
Degree of placental adhesion[b]			
Focal accreta	8/40 (20.0%)	8/38 (21.1%)	1.000
Partial accreta	4/40 (10.0%)	3/38 (7.9%)	
Total accreta	11/40 (27.5%)	11/38 (28.9%)	
Increta	17/40 (42.5%)	16/38 (42.1%)	
Bilateral IIA ligation[b]	8/40 (20.0%)	18/38 (47.4%)	**0.016**
Ureteric injury[b]	2/40 (5.0%)	5/38 (13.2%)	0.257
Urinary bladder injury[b]	2/40 (5.0%)	4/38 (10.5%)	0.425
Cesarean hysterectomy[b]	3/40 (7.5%)	8/38 (21.1%)	0.110
Duration of operation (min)[a]	105 ± 49	116 ± 51	0.348

IIA internal iliac artery. Bold value indicates statistically significant values

[a] Expressed as mean ± SD and P value was calculated by the Mann–Whitney U test

[b] Expressed as frequency and percentage and P value was calculated by the Fisher's exact test

Table 3 Blood loss and fluid and blood products transfusion in the study and control groups

	Study group ($n = 40$)	Control group ($n = 38$)	P value
Estimated amount of blood loss (ml)[a]	1657 ± 529	1982 ± 523	**0.008**
Amount of crystalloids transfusion (ml)[a]	2875 ± 607	3184 ± 586	**0.025**
Colloids transfusion			
Patients received transfusion[b]	21/40 (52.5%)	29/38 (76.3%)	**0.035**
Amount transfused (ml)[a]	833 ± 242	966 ± 129	**0.017**
PRBCs transfusion			
Patients received transfusion[b]	23/40 (57.5%)	31/38 (81.6%)	**0.028**
Amount transfused (units)[a]	2.87 ± 2.00	4.03 ± 1.99	**0.022**
FFP transfusion			
Patients received transfusion[b]	9/40 (22.5%)	15/38 (39.5%)	0.142
Amount transfused (units)[a]	4.56 ± 2.24	5.60 ± 1.68	0.241
Platelet transfusion			
Patients received transfusion[b]	3/40 (7.5%)	4/38 (10.5%)	0.708
Amount transfused (units)[a]	6.00 ± 2.00	6.00 ± 1.63	1.000
Use of MTP[b]	2/40 (5.0%)	3/38 (7.9%)	0.671

FFP fresh frozen plasma, *MTP* massive transfusion protocol, *PRBCs* packed red blood cells. Bold values indicate statistically significant values

[a] Expressed as mean ± SD and P value was calculated by the Mann–Whitney U test

[b] Expressed as frequency and percentage and P value was calculated by the Fisher's exact test

increased parity and number of previous CS. Deficiency of the decidua basalis at the site of the uterine scar is thought to be the cause of placenta accreta in patients with previous uterine scar [12].

Localization of the placental site in our study has depended on transabdominal ultrasound. When the primary diagnosis was placenta previa, confirmation by transvaginal sonography was done then Doppler study and/or MRI was performed for diagnosis of pathologically adherent placenta. We found that 64% of cases were complete centralis, 28% of cases were major degree anterior, and 8% of cases were major degree posterior. The incidence of morbidly adherent placenta was more in anteriorly situated placentas than in posterior ones. Similar results were obtained by Alchalabi et al. [13] who concluded that scarring of the uterus due to previous CS leads to increased attraction and adherence of the placenta to the scar site.

Cesarean hysterectomy is one of the recommended management options for pathologically adherent placenta [4], but a problem with this management option occurs when future fertility is desired. Many trials were conducted in our department to control severe PPH while at the same

Table 4 Postoperative characteristics of the study and control groups

	Study group ($n = 40$)	Control group ($n = 38$)	P value
Postoperative hemoglobin level (gm/dl)[a]	9.52 ± 0.43	9.48 ± 0.44	0.658
Relaparotomy[b]	0/40 (0.0%)	0/38 (0.0%)	1.000
Admission to ICU[b]	5/40 (12.5%)	12/38 (31.6%)	0.056
Postoperative hospital stay (days)[a]	3.43 ± 1.58	5.24 ± 4.76	0.323
Coagulopathy[b]	3/40 (7.5%)	4/38 (10.5%)	0.708
Surgical site infection[b]			
Superficial incisional infection	3/40 (7.5%)	4/38 (10.5%)	0.708
Deep incisional infection	2/40 (5.0%)	2/38 (5.3%)	1.000
Organ or space infection	0/40 (0.0%)	0/38 (0.0%)	1.000

ICU intensive care unit

[a] Expressed as mean ± SD and P value was calculated by the Mann–Whitney U test

[b] Expressed as frequency and percentage and P value was calculated by the Fisher's exact test

time preserve the uterus in patients with abnormally adherent placenta. These trials included use of hemostatic sutures at the placental bed, uterine, and IIA ligation, and many types of compression sutures. In our study, we tried to preserve the uterus by compressing the placental bed by Foley's catheter balloon filled with 80 ml warm saline, which was held in place against the LUS by an assistant then by its fixation to the thigh of the patient just after removal of the placenta. All other procedures to control bleeding were done as usual when needed. Hysterectomy was performed when there was intractable hemorrhage.

We found a significant reduction in the blood loss in the catheter group than in the control group; therefore, a reduction in the amount of fluids and blood products transfusion was present in the catheter group. In cases of placenta previa, bleeding vessels present in the LUS could not be compressed by uterine contraction; so, it is logic that rapid compression on this part by the inflated balloon just after removal of the placenta could decrease the blood loss during the operation and give us the time needed to do the other conservative measures without deterioration of the patient's general condition. Similar results were obtained when Maher and Abdelaziz [14] used Bakri balloon in cases of placenta previa after occurrence of PPH.

Uterine compression after delivery can be done by many tools and different types of catheters. The Bakri balloon could not be used except after closure of the uterine incision to compress the entire uterine cavity [14]. The Foley's catheter could be used intraoperatively before the occurrence of severe blood loss. It has small capacity, but when it was applied against the LUS only, it was effective in controlling bleeding in cases of placenta previa. The catheter was held in place by an assistant during the operation then by fixing it to the patient's lower limb when there was effective control of bleeding. Also, there was no theoretical risk of occurrence of uterine synechiae when we used this catheter because the application of the balloon was only related to the LUS.

Use of the catheter has significantly reduced the need for performing IIA ligation. Reduction in the need for this invasive procedure which carries the risk of major complications may be due to rapid compression of the placental bed by the inflated balloon just after removal of the placenta. Also, the rate of cesarean hysterectomy in the catheter group was less than in the control group, but the difference was not significant. This may be due to the small number of cases in our study group. Our procedure appeared to be more beneficial in decreasing the rate of cesarean hysterectomy than the procedure performed by Rauf et al. [15] who preserved the uterus in 84.3% of cases with placenta accreta by performing IIA ligation and endouterine hemostatic sutures.

In our study, the need for postoperative admission of the patients to the ICU was lower in the study group than in the control group; however, this was not significant. This lower incidence of ICU admission may be related to less intraoperative blood loss in the study group. The strength of our study lies in being the first study that described the use of intrauterine inflated Foley's catheter balloon for control of PPH during CS in cases of abnormally invasive placenta previa. This catheter is considered a low-cost alternative to the other types of intrauterine catheters and may be suitable for use in low-economic countries. A limitation of our study lies in its retrospective nature, which led to possible bias.

Conclusion

Application of an intrauterine inflated Foley's catheter balloon during CS in cases of morbidly adherent placenta previa helps to control PPH with preservation of the uterus and decreases the need for the invasive IIA ligation.

Compliance with Ethical Standards

Conflict of interest All authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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