



“ROLE OF INTRAUTERINE BALLOON TAMPONADE IN CONTROL OF INTRAOPERATIVE HEMORRHAGE IN PATIENTS OF PLACENTA PREVIA”

Obstetrics & Gynaecology

Dr. Rujuta Fuke Associate Professor, Government Medical College Nagpur

Dr. Neelam

Harishkumar Shahani* Junior Resident, Government Medical College Nagpur *Corresponding Author

Dr. Nivedita Metagudda Junior Resident, Government Medical College Nagpur

ABSTRACT

Background: Placenta previa describes a placenta that is implanted in the lower uterine segment, either over or very near the internal cervical os. Placenta previa occurs in approximately 4.8 of every 1,000 pregnancies¹ and is associated with maternal mortality and significant increase in maternal morbidities including massive hemorrhage, infection, adjacent organ damage, blood transfusions, emergency hysterectomy and Intensive care admissions.^{2,3} The Bakri Balloon Tamponade (BBT) has been widely used to reduce hemorrhage caused by placental site abnormality, placenta previa, low lying placenta, and focally invasive or adherent placenta. **Methods:** A comparative, prospective study was carried out in women undergoing cesarean section for placenta previa at a tertiary care centre. **Results:** A total of 132 patients (66 in each group) with group 1 consisting of those patients in whom uterine balloon tamponade was inserted for control of intraoperative blood loss and group 2 consisted of those patients in whom other methods were deployed for control of blood loss. The comparison of blood loss between the groups showed that in the Group 1, most of the patients (39.39%) had blood loss in the range of 500-1000 ml and 21.21% of patients had blood loss more than 2000 ml. However, in the Group 2, most of the patients had blood loss of more than 2000 ml (62.12%) and only 3% of patients had blood loss of less than 500ml. The number of complications were also less in group 1 as compared to group 2. The difference between the two groups was statistically significant ($p \leq 0.05$). **Conclusions:** Intrauterine balloon tamponade is an effective tool with a comparable success rate to other treatment modalities for managing massive hemorrhage following cesarean section for placenta previa to preserve uterus.

KEYWORDS

Uterine Balloon Tamponade, Placenta Previa, Post-partum Hemorrhage

INTRODUCTION

The Latin previa means going before - and in this sense, the placenta goes before the fetus into the birth canal. Placenta previa describes a placenta that is implanted in the lower uterine segment, either over or very near the internal cervical os. Placenta previa occurs in approximately 4.8 of every 1,000 pregnancies¹ and is associated with maternal mortality and significant increase in maternal morbidities including massive hemorrhage, infection, adjacent organ damage, blood transfusions, emergency hysterectomy and Intensive care admissions.^{2,3}

There are different types of placenta previa:

Low-lying placenta (type 1): The placenta is near the opening of the cervix, on one side, but does not cover it.

Marginal previa (type 2): The placenta is on one of the edges of the cervical orifice, but does not cover it either.

Partial previa (type 3): The placenta obstructs part of the cervical opening.

Complete previa (type 4): The placenta covers the entire cervical opening, which prevents the exit of the fetus in a normal delivery.

Intraoperative management options deployed to control hemorrhage in placenta previa patients include 1) bimanual uterine compression 2) implantation site compression with sutures 3) uterine arterial ligation 4) pelvic arterial embolization 5) hysterectomy. Current obstetric and midwifery guidelines stress the use of uterotonics (oxytocin, misoprostol) to prevent postpartum hemorrhage (PPH) due to uterine atony.^{4,5} As Cesarean Section rates increase annually, hemorrhage at the site of placental implantation, attributable to placenta previa, remains a serious obstetric complication. Uterine balloon tamponade (UBT) is an approach recommended by the WHO and the International Federation of Gynecologists and Obstetricians (FIGO) for the management of refractory PPH^{5,6} and can be provided using low-cost devices such as a condom tied to the end of a catheter, which is a feasible approach in low-resource settings.⁷ The advantages of BBT are being easy applicable by both vaginal and abdominal routes, more economical than other radiologic and surgical interventional techniques, fertility preserving features, and to have less morbidity and

mortality as compared to hysterectomy. However, the efficacy of the use of intrauterine balloon in PPH after cesarean section complicated by placenta previa remains unclear because only a small series of a few cases have been reported.^{8,9}

AIMS AND OBJECTIVES

- To study the role of intrauterine balloon tamponade in control of intra and post partum hemorrhage during cesarean section in patients of placenta previa.
- To compare the effect of intrauterine balloon tamponade vs other methods of control of blood loss during cesarean section in patients of placenta previa.
- To estimate the number of patients who require other methods in addition to intrauterine balloon tamponade for control of intraoperative blood loss in patients of placenta previa.

METHOD AND MATERIALS

A comparative, prospective study was conducted in women undergoing cesarean section for placenta previa for a duration of 2.5 years on 132 pregnant women at a tertiary care centre after obtaining ethical committee permission.

All patients of placenta previa who were shifted for cesarean section, consent was taken for intrauterine balloon insertion in case of hemorrhage. If the operating surgeon on table feels that the blood loss is excessive by assessing the number of mops soaked, decision to insert UBT or other methods to control blood loss was taken. Various types of UBT were used for eg. Foleys catheter, Bakri balloon, Sengstaken blakemore tube, Condom catheter, Rusch catheter. The easily available UBT like Foleys, Condom, Bakri balloon were used most commonly. Preoperatively, all patients received prophylactic antibiotics.

The UBT generally consists of a balloon, a catheter or some form of tubing to inflate the balloon, and a syringe to inflate the balloon. After performing uterine massage and evacuating the uterine cavity, the deflated balloon was inserted through the cervix into the uterine cavity in a semi-sterile fashion and after proper positioning the balloon was inflated, typically using saline, until bleeding slows or stops. The patient was monitored closely after insertion to observe for any further bleeding or clinical decompensation. If bleeding was ceased, balloons were left in place for 24 hours in order to control postpartum

hemorrhage, or until uterine contraction and subsequent expulsion of the device occurs. For removing the balloon, the tension on the shaft was released and vaginal packing was removed and the balloon deflated gradually with close monitoring of patients, vital signs.

The total blood loss was then measured and tabulated. Those in whom the bleeding was not controlled intraoperatively were treated with other procedures like uterine artery embolization, uterine and internal iliac ligation, compression sutures or hysterectomy and number of patients treated with other methods in addition to UBT were also noted and statistical analysis was carried out with equal number of controls matched for characteristics.

For statistical analysis data was entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. P-value ≤ 0.05 was considered as statistically significant.

Criteria for Study enrollment Inclusion Criteria

Pregnant women undergoing cesarean section for placenta previa and who showed signs of intrapartum hemorrhage more than average by visualising the on table blood loss.

Exclusion Criteria

1. Women with medical conditions complicating pregnancy like preeclampsia, HELLP, SLE, diabetes, etc. 2. Women with coagulopathies. 3. Women with abruptio placentae. 4. Women undergoing vaginal deliveries. 5. Not willing to participate in the study. 6. Patients of placenta previa who do not require any procedure.

OBSERVATIONS AND RESULTS

A total of 132 patients were included in this study and were divided into 2 groups with each group consisting of 66 patients.

Group 1 consists of those patients of placenta previa in whom UBT was inserted intraoperatively to control intra and postpartum hemorrhage and Group 2 consists of those patients of placenta previa who were managed by other methods.

Table 1. Comparison of types of placenta previa

PLACENTAL POSITION	GROUP 1 NUMBER	%	GROUP 2 NUMBER	%	P-Value
TYPE 1	15	22.72	16	24.24	0.000 (Highly-Significant)*
TYPE 2	13	19.69	17	25.75	
TYPE 3	28	42.42	8	12.12	
TYPE 4	10	15.15	25	37.87	
TOTAL	66		66		

Table 2. Comparison of intraoperative findings

INTRAOPERATIVE FINDINGS		Group 1 (TOTAL 66)		Group 2 (TOTAL 66)		P-VALUE
		N	%	N	%	
PLACENTA PREVIA WITHOUT PAS		45	68.18	28	42.42	0.000 (Highly-Significant)**
PLACENTA ACCRETA	ACCRETA	11	16.66	24	36.36	
INCRETA	INCRETA	7	10.6	10	15.15	
SPECTRUM(PAS)	PERCRETA	3	4.54	4	6.06	

Table 3. Comparison of types of balloon tamponade

TYPES OF BALLOON TAMPONADE IN GROUP 1	NUMBER (TOTAL 66)	%
FOLEYS	30	45.45
BAKRI	20	30.30
SENGSTAKEN BLAKEMORE	4	6.06
CONDOM	10	15.15
RUSCH	2	3.03

Table 4. Comparison of complications of procedure in group 1

COMPLICATIONS OF PROCEDURE IN GROUP 1	NUMBER	%
RUPTURE OF BALLOON	4	6.06
DIFFICULTY IN INSERTION	7	10.60
FAILURE	3 (ALL 3 UNDERWENT HYSTERECTOMY)	4.5

REINSERTION	6	9.09
DIFFICULT EXTRACTION	2	3.03
TOTAL	22	

Table 5. Comparison of other procedures in group 2

OTHER PROCEDURES IN GROUP 2	NUMBER (TOTAL 66)	%
MEDICAL MANAGEMENT	12	18.18
COMPRESSION SUTURES	14	21.21
UTERINE ARTERIAL LIGATION	18	27.27
PELVIC ARTERIAL EMBOLIZATION	4	6.06
OBSTETRIC HYSTERECTOMY	18	27.27

Table 6. Comparison of amount of blood loss after the procedure

BLOOD LOSS	GROUP 1 NUMBER	%	GROUP 2 NUMBER	%	P VALUE
<500ML	20	30.3	2	3.03	0.000 (Highly-Significant)*
500-1000 ML	26	39.39	10	15.15	
>1000-2000 ML	6	9.09	13	19.69	
>2000 ML	14	21.21	41	62.12	

Table 7. Comparison of blood and blood products transfusion

Blood products required		Group 1		Group 2		P value
		N	%	N	%	
Whole blood/PRC	1	7	10.6	2	3	0.000 (Highly-Significant)**
	2	9	13.6	4	6	
	3 or more	36	54.54	50	75.75	
FFP	1	0	0	0	0	0.000 (Highly-Significant)**
	2	5	7.57	15	22.72	
	3 or more	29	43.93	45	68.18	
Platelets	1	0	0	0	0	0.000 (Highly-Significant)**
	2	2	3.03	8	12.12	
	3 or more	6	9.09	17	25.75	

Table 8. Comparison of ICU admission

ICU admission	Group 1		Group 2		P value
	N	%	N	%	
Yes	38	57.57	52	78.78	0.000 (Highly Significant)**
No	28	42.42	14	21.21	

Table 9. Comparison of maternal complications

Complications	Group 1		Group 2		P value
	N	%	N	%	
AKI	6	9.09	7	10.06	0.000 (Highly-Significant)**
SEPSIS	7	10.6	10	15.15	
DIC	7	10.6	5	7.57	
Pulmonary edema	2	3.03	6	9.09	
AKI, DIC & Pulmonary edema	1	1.51	2	3.03	
MORTALITY	9	13.63	15	22.72	

There was significant difference in the amount of blood loss between the 2 groups ($p \leq 0.05$) and hence the amount of blood products required was also less in group 1 compared to group 2. There were more complications in group 2 compared to group 1.

DISCUSSION

In INDIA, intra and post-partum hemorrhage due to placenta previa during cesarean section is one of the leading causes of maternal deaths. Many studies reported increasing trends of placenta previa due to increase in rate of cesarean section in the past few years. Simpler techniques like uterine massage, uterotronics drugs, and uterine packing and balloon tamponade can be practiced in low resource settings. Techniques like B-Lynch suturing, stepwise devascularization, internal iliac ligation, uterine artery embolization and hysterectomy are available at higher medical centres. Sometimes women succumb to death just within 1-2 hours after the onset of bleeding. The rapidity with which some women slip into coagulation failure and multiorgan dysfunction syndrome from hemorrhagic shock is alarming. Because of these complex reasons the maternal mortality

is not coming down in developing countries. There is every need for a simpler and sure technique which can stop bleeding or at least stop bleeding temporarily to buy some time to tide over the crisis. The available evidence demonstrates 80%–98% effectiveness of the Bakri balloon for the reduction and control of obstetric hemorrhage.^{12,13}

In our study, 4 types of placenta previa were identified-type 1, type 2, type 3, and type 4. Among them, majority of subjects had type 3 placenta previa. In our study the incidence of placenta previa alone was much higher (68.18%) than morbidly adherent placenta. Among the adherent placenta previa, patients had much higher incidence of placenta accreta (16.66%) than placenta increta (10.6%) and percreta (4.54%).

In a study done by **Krupa BM et al** to evaluate maternal and fetal outcomes in women with placenta previa, the incidence of placenta previa was found to be 0.48%. With respect to types of placenta previa based on classification given by Jauniaux and Campbell, 41% of the cases with PP had type IV or central/complete placenta previa and accounted for majority of cases with placenta accreta (75%). 17.9% of cases had type I PP and least common was type IIb (posterior) PP accounting for 7.7% cases.¹⁴

In our study, we used various types of uterine balloon tamponade (UBT) to control intra and post-partum hemorrhage during cesarean section in patients of placenta previa.

The various types of UBT used included-foleys catheter, bakri balloon, sengstaken blakemore tube, condom catheter and rusch balloon. In majority of cases, Foleys catheter was used as UBT followed by Bakri balloon. The blood loss drastically reduced in those patients in whom UBT was inserted with maximum patients having blood loss <1000ml. Blood and blood products requirement was also very less in patients with UBT compared to patients in whom other methods to control blood loss were used.

In a study by **Tatsuya Arakaki et al** to verify the blood loss control effect of routine prophylactic Bakri balloon tamponade on major and minor placenta previa (PP), all participants were divided into Bakri balloon (underwent routine prophylactic use just after placenta removal) and non-balloon groups, and into major and minor PP groups. Clinical outcomes in major and minor PP were compared between balloon and non-balloon groups. The balloon and non-balloon groups contained 74 and 89 patients, respectively. There were 41 and 33 (balloon group) and 48 and 41 (non-balloon group) major and minor PP cases, respectively. Intraoperative and perioperative blood losses of major PP were significantly lower in the balloon group than the non-balloon group (1045 ml versus 1553 ml, $P=0.016$; and 1189 ml versus 1810 ml, $P=0.006$, respectively). The frequency of massive postpartum hemorrhage (>500 ml) with major PP was lower in the balloon group than in the non-balloon group (2.4% versus 16.7%, $P=0.027$), but with no significant difference with minor PP.¹⁵

In our study the most common complication faced by patients was DIC and SEPSIS. Majority of the patients underwent preterm cesarean sections and preterm live births were maximum.

In a study by **Shilei Bi et al**, to evaluate the effects of different types of placenta previa (PP) on maternal and neonatal outcomes. This study was conducted in The Third Affiliated Hospital of Guangzhou Medical University and Tongji Hospital between January 2009 and 2019. In their study pp was classified into three types which included low-lying placenta, marpartial (marginal and partial) PP, and complete PP. Multivariate logistic regression analysis was performed to determine the effects of different types of PP on maternal outcomes. In total, 4490 singleton pregnancies were complicated with PP. In the four classification method, compared with women with low-lying placenta, women with complete PP had a risk of placenta accrete spectrum disorders, postpartum hemorrhage (PPH), hemorrhagic shock, severe PPH, blood transfusion, hysterectomy, puerperal infection. There was no difference in maternal outcomes between marginal and partial PP. In the two classification method, PP was the risk factor for most of the adverse maternal outcomes, compared with low-lying placenta.¹⁶

The interventions done in group 2 included medical management, uterine arterial ligation, compression sutures, pelvic arterial embolization and obstetric hysterectomy. Among them maximum patients underwent uterine arterial ligation and obstetric hysterectomy.

In a study done by **Krupa BM et al** to evaluate maternal and fetal outcomes in women with placenta previa and assess the demographic features, risk factors, obstetric management and pregnancy outcomes in women with placenta previa. With respect to maternal outcome, 43.6% cases had antepartum and postpartum (mostly atonic) hemorrhage. In terms of surgical interventions, 12.8% of cases with PP had undergone stepwise devascularisation and 15.4% cases required CESAREAN hysterectomy. 15.4% cases required ICU admission out of which 7.7% had hypovolemic shock. 28.2% of patients with PP required hospital stay of more than 14 days. There was no maternal mortality noted in our study. 43.6% cases required blood transfusion majority of which were cases with placenta accreta. Majority of cases recovered with 1-2 units of blood transfusion.¹⁴

CONCLUSIONS

Intrauterine balloon tamponade is an effective tool with a comparable success rate to other treatment modalities for managing massive hemorrhage following cesarean section for placenta previa to preserve uterus.

UBT can also be used not only in tertiary centres but also in limited resource centres, and it may be able to earn time to prepare another procedure with preventing massive bleeding. This cost-effective technique is both life saving and fertility saving by avoiding laparotomy by this simple technique and can become the first defence against massive hemorrhage. However, possible factors related to failure of UBT for placenta previa patients such as prior cesarean section history, anterior placentation, thrombocytopenia, presence of DIC at the time of catheter insertion and catheter drainage volume more than 500ml within 1 hour of catheter placement should be recognized, and the next line management should be prepared in advance.

Conflict of interest- Author declares no conflict of interest in this study.

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