

Efficacy of Intrauterine Balloon Catheter in Control of Bleeding from Placental Bed during Caesarean Section in Cases of Major Placenta Praevia

Efficacy of
Intrauterine
Balloon Catheter
during Caesarean
Section

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ABSTRACT

Objective: To determine the efficacy of intrauterine balloon catheter in control of bleeding from placental bed during cesarean section in major placenta praevia.

Study Design: A descriptive case series study

Place and Duration of Study: This study was conducted at the Shaikh Zaid Women Hospital, Obstetrics and Gynaecology Unit-III, SMBBMU, Larkana from March 2016 to September 2016

Materials and Methods: Sixty two patients of age 18-35 years, having an alive singleton pregnancy, gestational age of >37 to 42 weeks and diagnosed case of major placenta praevia were consecutively selected. Patients with placenta accrete, uterine anomalies, submucosal uterine fibroids, preeclampsia, instrumental deliveries and hemoglobin concentration <8 g/dL were excluded. Mean \pm SD, frequencies & percentages were calculated. Chi-square was used as a test of significance with a P value <0.05 taken as significant.

Results: Mean age \pm SD was 28.18 ± 5.0 years (Range 18-35). Parity ranged from zero to 3 with a mean parity \pm SD of 1.45 ± 0.18 children. Mean \pm SD gestational age of was 38.65 ± 1.30 weeks (37-42). Mean age \pm SD amount of blood loss was 644.97 ± 418.81 milliliters. (Range: 251-2415ml). The efficacy of balloon catheter in the prevention of bleeding (primary outcome) was 88.7%. The post-stratification analysis showed that efficacy of balloon catheter in the prevention of bleeding was more with elder maternal age, higher gestational age, lower SE status, higher gravida), higher parity and normal weight but statistically non-significant.

Conclusion: The use of intrauterine balloon catheter in cases of major placenta praevia as the first step in order to prevent intractable PPH as well as minimize the chances of undesirable hysterectomy.

Key Words: Placenta praevia, intrauterine balloon catheter, Caesarean section, Postpartum Hemorrhage.

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INTRODUCTION

In pregnancy, placenta praevia complicates up to 3-5% of all deliveries called the most important causes of maternal mortality globally. In placenta praevia, the placenta is attached partially or fully to the myometrium leads to blockage of the uterus at its neck side. It occurs due to deficiency of the decidua and when there is a myometrial invasion by chorionic villi that interfering with normal delivery of a baby.

It is a major cause of obstetrical bleeding that is intrapartum or postpartum¹ and². Postpartum hemorrhage (PPH) on the other hand complicates up to 18% of all deliveries, accounting for 25-30% of all maternal deaths³. According to the Millennium Developmental Goals report, the ratio of maternal mortality is 320 per 100,000 live birth. Postpartum bleeding is usually from the placental bed at the lower uterine segment and occurs immediately after the placenta is delivered⁴.

There have many interventions develop to prevent this hemorrhage⁵. Among these is the use of various uterotonics, such as oxytocin, methylergonovine maleate, 15-methylprostaglandin F₂ α , dinoprostone, and misoprostol. If uterotonics fail, techniques of tamponade include uterine gauze packing or the use of a Foley's intrauterine catheter, Sengstaken-Blakemore tube, and Bakri balloon⁶ and⁷. These are based on the principle of uterine tamponade which requires developing intrauterine pressure so as to stop bleeding⁸. Foley catheter with a 30-ml balloon capacity is easy to acquire and may routinely be stocked on labor and delivery suites. The efficacy of intrauterine balloon

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catheter in control of bleeding from placental bed in cases of placenta praevia was 80⁹. Therefore; the intrauterine balloon catheter is being suggested for stopping the hemorrhage in cases of placenta praevia. Sengstaken-Blakemore tube is expensive while intrauterine balloon catheter is a simple, cheap & quick intervention in preventing hemorrhage in resource-poor settings. Further, it is equally effective¹⁰.

The rationale study is to assess the efficacy of intrauterine balloon catheter in preventing the PPH in cases of placenta praevia which are delivered through cesarean section. Success in this will recommend the use of an intrauterine balloon catheter in all patients thus saving resources and preventing maternal morbidity and mortality. The objective of this study is to determine the efficacy of intrauterine balloon catheter in control of bleeding from placental bed during cesarean section in major placenta praevia.

MATERIALS AND METHODS

A descriptive case series study was conducted for duration of six months from 14-03-2016 to 13-09-2016 at Shaikh Zaid Women Hospital, Obstetrics and Gynaecology Unit-III, SMBBMU, Larkana. In all 62 patients of age 18-35 years, having an alive singleton pregnancy, gestational age of >37 to 42 weeks and a diagnosed case of major placenta praevia were consecutively selected. Patients with placenta accrete, uterine anomalies, submucosal uterine fibroids, preeclampsia, instrumental deliveries and hemoglobin concentration <8 g/dL were excluded.

The data collection was started soon after getting the approval of synopsis from Research Evaluation Unit of CPSP, Karachi. Only booked cases of placenta praevia to the gynecological OPD of Unit III, Shaikh Zaid Women's Hospital Larkana, were taken up in the study after taking valid written consent (& confirming the eligibility as per selection criteria). All patients were delivered through cesarean section once the labor pain starts. Following delivery of the infant, 1 g of ceftriaxone and 5 IU of synthetic oxytocin was administered intravenously and the placenta was removed by controlled cord traction. The consultant obstetrician (having experience of five years) waited until signs of separation before applying traction to the cord, except in the setting of significant bleeding.

Following delivery of the placenta, a No. 24F Foley catheter was placed into the uterine cavity and inflated with 60-80 ml of saline (a volume of 150 ml can be reached before it bursts). Additional Foley catheters can be inserted, if necessary, until bleeding stops. In cases where bleeding did not stop, other standard measures were taken like; intravenous infusions of oxytocin (10–20 U), intravenous ergometrine (0.5 mg), intramuscular prostaglandin F_{2a} or rectal insertion of misoprostol.

The researcher herself assisted the consultant obstetrician as well as collecting the data from patients on a prescribed proforma. The data were collected on demographic variables include name, age, gestational age, parity, address & socioeconomic status. Amount of bleeding was also being noted. The primary outcome variable was the detection of efficacy (achieving

hemostasis) of an intrauterine balloon catheter in major placenta praevia.

Statistical Analysis: The data were entered in MS Excel and analyzed in SPSS version 18. Mean & standard deviation (Mean ± SD) was expressed for the continuous variables like maternal age, gestational age, height, weight, BMI, gravida, parity & amount of bleeding. Frequencies and percentages were expressed for categorical variables like socioeconomic status, address & efficacy of intrauterine balloon catheter in major placenta praevia (i-e; primary outcome variable). To evaluate the effect modification, the confounding factors like maternal age, gestational age, socioeconomic status, BMI, parity & amount of blood were stratified. It was followed by application of chi-square with a p-value < 0.05 taken as significant.

RESULTS

Table No.1: Demographic profile of studied females

N= 62	Mean (S.D)
Age of Patient (Years)	28.18 ±5
Gravida	2.45±0.89
Parity	1.45±0.18
Gestational age (Weeks)	38.65±1.3
Height (Feet)	5.54± 0.3
Height (Meters)	2.86± 0.31
Weight (Kgs)	71.97± 9.51
BMI (Kg/ m ²)	25.08± 3.93
Amount of blood loss (millilitres)	644.97± 418.8

Table No.2: Percentages of studied variables in females

Variables		Percentages (N=62)
Age of Patients	18-20	9.70%
	21-30	53.20%
	31-35	37.10%
Residence	Urban	51.60%
	Rural	48.40%
Gravida	1-2	51.60%
	3-4	48.40%
Parity	Null parity	14.50%
	1-2	74.20%
	3-4	11.30%
Socio-economic Status	Lower	12.90%
	Middle	56.50%
	Upper	30.60%
BMI (Body Mass Index)	Underweight	9.70%
	normal weight	35.50%
	overweight	45.20%
	obese	9.70%
Blood loss in milliliters	<500	54.80%
	501-1000	33.90%
	1001-1500	4.80%
	1501-2000	4.80%
	>2001	1.60%

Total 62 participants of our study have mean age \pm SD was 28.18 ± 5.0 year with a mean parity \pm SD of 1.45 ± 0.18 children. Patients presented a maximum gestational age was 42 weeks while mean \pm SD gravidity recorded was 2.45 ± 0.89 with a range of 1-4. Mean weight of patients was 71.97 ± 9.51 Kgs with a mean height of patients in feet was 2.86 ± 0.31 . Mean Body mass index (BMI) on the basis of these weight & height measurements was 25.08 ± 3.93 . Whereas, mean age \pm SD amount of blood loss was 644.97 ± 418.81 milliliters. (Table 1).

It was observed that more than one half of total-i-e; 53.2% (n=33) belonged to age group of 21-30 years and 48.4% (n=30) were belonging to urban areas. However, 51.60% and 74.20% females were in 1-2 gravidity and

parity group respectively. 56.5% (n=35) females had middle level of socioeconomic status, 45.2% overweight and 54.8% were bled < 500 millilitres (Table 2).

Majority of patients that is 91.9% (n=57) had presented within the gestational age of 37-40 weeks while remaining i-e; 8.1% (n=5) were in their >41 weeks of gestation. (Figure 1).

With this basic data the outcome variable i-e; efficacy of balloon catheter in the prevention of bleeding, it was found that a vast majority responded and 88.7% (n= 55) women were successively saved from PPH. The failure was 11.3% (n=7) which was tackled with other measures. (Figure 2).

Table 3: status of the efficacy of studied variables in females

VARIABLES		Efficacy of the treatment		Total	P- value
		Yes	No		
Maternal age categories (years)	18-20	5 (83.3%)	1 (16.7%)	6 (100%)	0.83
	21-30	29 (87.9%)	4 (12.1%)	33 (100%)	
	31-35	21 (91.3%)	2 (8.7%)	23 (100%)	
	Total	55 (88.700%)	7 (11.3%)	62 (100%)	
Gestational age categories(weeks)	37-40	50 (87.70%)	7 (12.30%)	57(100%)	0.405
	> 41	5 (100%)	0 (0%)	5(100%)	
	Total	55 (88.70%)	7 (11.30%)	62(100%)	
Socioeconomic status	Upper	7(87.5%)	1(12.50%)	8 (100%)	0.988
	Middle	31(88.6%)	4 (11.4%)	35(100%)	
	Lower	17 (89.5%)	2(10.50%)	19(100%)	
	Total	55 (88.70%)	7 (11.30%)	62(100%)	
Gravida	1-2	27(84.3%)	5(15.6%)	32(100%)	0.023
	3-4	28(93.3%)	2(6.67%)	30(100%)	
	Total	55 (88.7%)	7(11.30)	62(100%)	
Parity	Nullparity	7 (77.78%)	2 (22.22%)	9(100%)	0.965
	1-2	41(89.10%)	5 (10.9%)	46(100%)	
	3-4	7(100%)	0 (0%)	7(100%)	
	Total	55 (88.70%)	7 (11.30%)	62(100%)	
BMI	Underweight	6 (100%)	0 (0%)	6(100%)	0.203
	Normal weight	22(100%)	0(0%)	22(100%)	
	Over weight	24 (85.71%)	4(14.29%)	28(100%)	
	Obese	2 (33.33%)	4 (66.67%)	6(100%)	
	Total	55 (88.70%)	7 (11.30%)	62(100%)	
Amount of blood loss in millilitres	<500	34(100%)	0 (0%)	34(100%)	0.0001
	501-1000	21 (100%)	0 (0%)	21(100%)	
	1001-1500	0 (0%)	3 (100%)	3(100%)	
	1501-2000	0(0%)	3 (100%)	3(100%)	
	>2001	0(0%)	1 (100%)	1(100%)	
	Total	55 (88.7%)	7 (11.30%)	62(100%)	

Study found that efficacy of balloon catheter in the prevention of bleeding was more (91.3%) in patients of elder age (31-40 years) compared to (83.3%) among those of younger age (18-20 years) and women with higher gestational age (>41 weeks) had more efficacy of balloon catheter (100%) compared to women presenting with 37-40 weeks gestation (87.7%) but both were statistically non-significant. There was a slight and non-significant difference of efficacy of balloon

catheter between the different SE status women; the lower SE status being more responsive (88.7%) than Upper SE status women (87.5%). Whereas, gravidity's relationship with the efficacy of balloon catheter revealed that women with lower gravida (1-2) had lower efficacy of treatment compared to the higher gravida. Nulliparous women had lower efficacy of treatment compared to the women with higher parity of 3-4 children but statistically non-significant. Women

with underweight & normal weight both had 100% efficacy of balloon catheter compared to overweight and obese women. Result found that women having a lesser bleeding amount (< 1000 ml) had 100% efficacy of balloon catheter compared to those > 1000 milliliters (P-value = 0.0001).

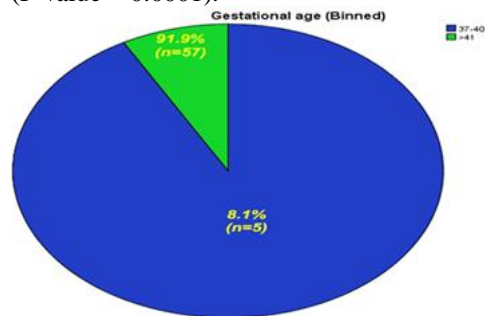


Figure No.1: The frequency of patients as per presenting gestational age.

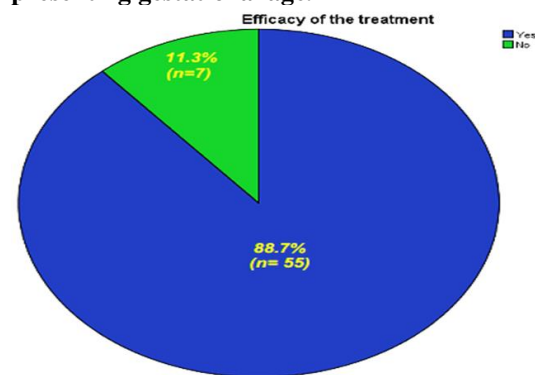


Figure No.2: The frequency of efficacy of balloon catheter in the prevention of bleeding. (n=62)

DISCUSSION

The increase in the recorded incidence of placenta praevia in the past few decades is being contributed to the increase in cases of the postpartum hemorrhage and its related complications. Hysterectomy can be an undesirable action to take, especially in the case of a low parity patient. Usually, this step is taken when other traditional measures to stop hemorrhage fail. Various management options are utilized for control of bleeding caused by this clinical abnormality and conservative approaches are becoming increasingly used instead of a hysterectomy.¹¹

The current study has evaluated the efficacy of intrauterine balloon catheter in control of bleeding from placental bed during cesarean section in cases of major placenta praevia. In a sample of 45 patients diagnosed with the above-mentioned condition, it was found that hemostasis was achieved in a very large proportion of cases (i-e; 88.7%; n= 55) and only in 11.3% (n=7) cases major bleeding occurred (>500 ml) and intervention of balloon catheter failed. Comparing to these results, other contemporary studies have also found almost mimicking outcomes. A local study¹² and another study from Iran have reported the success of intrauterine balloon catheter in achieving hemostasis with a rate of 88% & 80% respectively.¹³ The previous study found

that every 8 out of 10 patients were positively spared from postpartum hemorrhage with use of intrauterine balloon catheter in cases of placenta praevia was 80%. While some of the other studies have reported a slightly lower success rate; yet overall it ranges between 78%-89%.¹⁴ Study report described how he simultaneously placed 5-10 standard Foley balloons in the lower uterine cavity to control PPH. The Bakri balloon alone or with placental bed sutures was effective in 88% of cases.¹⁵

The current study had used the prophylactic approach by giving intervention of intrauterine balloon tamponade and assessed its efficacy in preventing bleeding. The current study also evaluated the loss of blood even after the intervention (as happened in failure cases). The study noted that only 4.8% (n=3) women bled between 1001-1500 milliliters & one (1.6%) woman bled between 1501-2000 milliliters. As per the operational definitions of this study, these 4 cases were severe PPH cases and were then managed with other measures like uterine artery ligation and or hysterectomy. The use of a balloon tamponade in severe PPH due to placenta praevia has been reported only in a small series of a few cases. The previous study reported the first attempt to achieve hemostasis in case of PPH complicated by placenta praevia by compression using a Foley catheter. The study used a self-made original tamponade balloon in two cases of placenta praevia together with additional surgical procedures such as bilateral hypogastric ligation.^{16 and 17}

Further, the study results are in comparison with other studies in terms of other variables. A recent study reported that the mean maternal age of their patients was 28.9 ± 4.4 years which is comparable to current series of patients i-e; 28.18 ± 5.0 years. The median number of gravidity and parity were 3 (range 1-9) and 1.3 (range 0-6), respectively.¹⁸ In the current study, these were found to be gravidity 2.45 ± 0.89 & parity 1.45 ± 0.18 (Range from 0-4). Similarly; the current study reports that mean \pm SD gestational age of was 38.65 ± 1.30 weeks which was reported by another study to be 37.3 ± 1.7 weeks (range 33-40).

The current study noted that efficacy of balloon catheter in the prevention of bleeding was more among women of elder age compared to younger ages (RR = 1.09) however the finding not associated with statistical significance (P value = 0.839). Likewise; it was noted women who presented with higher gestational age, lower SE status, higher gravida, higher parity & normal weight women had more positive results and efficacy success rate of the balloon catheter in the prevention of bleeding than their counterparts. Other studies have found similar results. However, some studies do not match with the current study findings wherein, parity and maternal age are the factors of difference. These studies reported the elder maternal age and high parity both cause higher failure rate of efficacy of balloon catheter in prevention PPH^{19 and 20}. The current study found the use of a balloon catheter in the prevention of bleeding is also very much effective. Hence to prevent intraoperative & postpartum hemorrhage during & after LSCS operation due to major degree placenta praevia can be successively achieved with this. This

intervention is directly useful in lowering the high incidence of maternal mortality and morbidity²¹.

CONCLUSION

The use of intrauterine balloon catheter in cases of major placenta praevia as the first step in order to prevent intractable PPH as well as minimize the chances of undesirable hysterectomy.

Author's Contribution:

Concept & Design of Study: Sania Pirzada
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Conflict of Interest: The study has no conflict of interest to declare by any author.

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