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Original Article

Comparison of Efficacy of Surgical Interventions (Balloon Tamponade versus B-lynch Suture) to Prevent Postpartum Hemorrhage in Patients with Placenta Previa – a Randomized Controlled Trial

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ABSTRACT

Objective: To compare mean blood loss by prophylactic balloon tamponade versus B-lynch suture in patients with placenta previa.

Study Design: Randomized controlled trial (Clinicaltrials.gov: NCT05133167).

Place and Duration of Study: Obstetrics and Gynecology Department, Combined Military Hospital, Jhelum Pakistan, from Apr to Oct 2021.

Methodology: A total of 60 patients with placenta previa, ranging in age from 18 to 40, were included in the study. Computer-generated random sample allocation was used to assign equal number of patients to Groups A and B. In Group-A, balloon tamponade (using Foley catheter 28 Fr) was used intra-operatively to prevent post-partum hemorrhage. Post-operative blood loss within first 24 hours was estimated by measuring the amount of blood collected in Foley balloon tamponade bag, in milliliters. In Group-B, B-lynch suture was used intra-operatively to prevent post-partum hemorrhage. Post-operative blood loss within first 24 hours was estimated by the weight difference of the pads before and after being used by the patient.

Results: The mean blood loss in Group-A (prophylactic balloon tamponade) was 118.97±20.26 ml, while it was 154.13±15.21 ml in Group-B (B lynch suture Group) (*p*-value=0.0001).

Conclusion: In cases of placenta previa, prophylactic balloon tamponade resulted in reduced post-intervention mean blood loss compared to B-lynch.

Keywords: Balloon tamponade, Placenta previa, Postpartum hemorrhage.

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INTRODUCTION

Placenta Previa is the abnormal placentation in the lower uterine segment which covers all or part of the cervix, and is one of the major causes of maternal and fetal morbidity.[1] The condition affects about 1 in every 200 pregnancies.[2] Advanced maternal age, repeated pregnancies, the number of previous caesarean deliveries, and other uterine procedures such as myomectomy and curettage all raise the risk of placenta previa.[3] According to UNICEF, nearly 295,000 women died during pregnancy and childbirth with 94% of all maternal deaths occurred in poor and lower middle-income countries, with South Asia accounting for roughly 86% of all maternal deaths, the majority of which could have been prevented. In European women, associated risks of placenta previa included 54.9% preterm birth, 42.3% antepartum hemorrhage, 35.6% low birth weight <2500g, 30% maternal anemia, 7.1% postpartum hemorrhage, 5.2% hysterectomy, 4% co-existing placenta accreta and 1.5% fetal mortality.[4] Hemorrhage is the most common direct cause of maternal death, accounting for 27.1% of all maternal deaths globally.[5] Although many surgical techniques have been devised for when medical therapy fails to control massive postpartum hemorrhage, the reported hysterectomy rate is still high.

Modern obstetrics aim to preserve uterus especially in cases of low parity by using compression sutures, balloon tamponade, pelvic devascularization, and uterine artery embolization.[6,7] Postpartum hemorrhage is frequently managed with intrauterine balloon tamponade. According to a recent meta-analysis, uterine balloon tamponade has a high (86.8%) success rate in treating severe postpartum bleeding in patients of placenta previa.[8] B-Lynch suturing techni-

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que has been used in patients with postpartum atony[9] and recently used in cases with placenta previa, where all of the patients had a successful outcome.

As no trials in Pakistan have directly compared the two interventions in Placenta Previa, this study was planned with the aim of comparing mean blood loss by prophylactic balloon tamponade versus B-lynch suture to reduce maternal and fetal mortality and morbidity.

METHODOLOGY

The randomized controlled trial was conducted at the Department of Obstetrics and Gynecology, Combined Military Hospital, Jhelum Pakistan, from April to October 2021. Approval (No.02/21) was obtained from the Ethics Review Committee. The trial was registered at Clinicaltrials.gov with the trial number NCT05133167. On the basis of a study conducted by Kavak *et al.*[10], a sample size of 60 was calculated (with 30 participants in each Group) using WHO sample size calculator.

Inclusion Criteria: Patients who were pregnant, between the ages of 18 to 40 years, with singlet pregnancy, at 35 to 39 weeks gestation, diagnosed with placenta previa, defined by American Institute of Ultrasound in Medicine (AIUM)[11] as the placenta that covers the internal cervical os, and admitted for elective caesarean section.

Exclusion Criteria: Patients with pre-existing serious medical or surgical diseases, multiple gestation, placenta accreta spectrum (accreta/increta/percreta), bleeding diathesis and other causes of post-partum hemorrhage i.e., uterine atony, genital tract tears, retained products of conception etc.

Patients fulfilling the inclusion criteria were recruited after taking informed written consent. Patients were allocated to Group A and B using computer generated random sample allocation (Figure). In Group-A, balloon tamponade (using Foley catheter 28 Fr) was used intra-operatively to prevent post-partum hemorrhage. Post-operative blood loss within first 24 hours was estimated by measuring the amount of blood collected in Foley balloon tamponade bag, in milliliters. In Group-B, B-lynch suture was used intra-operatively to prevent post-partum hemorrhage. Post-operative blood loss within first 24 hours was estimated by the weight difference of the pads before and after patient use (1-gram weight difference = 1ml blood volume lost). Mean blood loss within first 24 hours post procedure, was compared in both groups for outcome measurement.

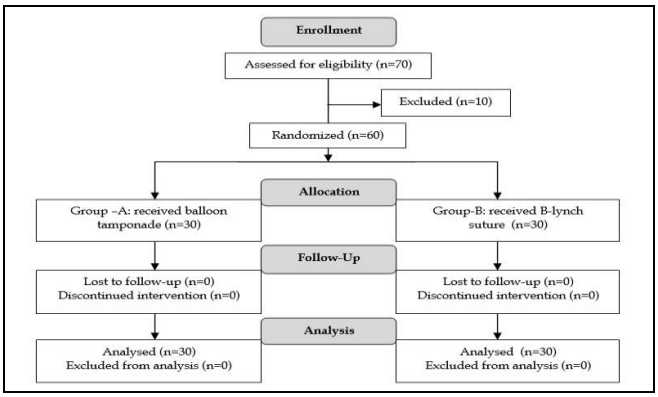

Figure: Patient Flow Diagram (n=60)

The pre-designed proforma was used for recording data of the patients including age, gender, gestational age, parity, and the amount of intra-operative and post-operative blood loss (first 24 hours) by the researcher. Cross match and arrangement of blood products were confirmed before the intervention. To eliminate any bias, the surgical technique, the surgeon performing the procedure, and the use of antibiotics and anesthesia were all standardized.

Statistical Package for the Social Sciences (SPSS) version 23.00 was used to enter and analyze the data. Quantitative variables like age, gestational age, parity & blood loss were calculated using descriptive statistics and presented as mean & standard deviation. The amount of blood lost during surgery in Groups A and B was calculated and compared using an independent sample t-test, where *p*-value of ≤0.05 was considered as statistically significant.

RESULTS

Age range in this study was from 18 to 40 years with mean age of 29.22±6.08 years. The mean age of women in Group-A was 29.30±5.94 years and in Group-B was 29.13±6.31 years. Majority of the patients 35(58.33%) were between 20 to 30 years of age. The mean gestational age in Group-A was 36.43±0.97 weeks and in Group-B was 36.67±0.85 weeks. Mean blood loss in Group-A (prophylactic Balloon tamponade) was 118.97±20.26 ml while in Group-B (B-lynch suture) it was 154.13±15.21 ml as illustrated in Table-I (*p*-value=0.0001). Distribution of the patient groups according to age, gestational age has been shown in Table-II. Mean blood loss with respect to age, gestational age and parity in both groups is shown in

Table-III, illustrating that mean blood loss was higher in Group-B (B-lynch Group).

Table-I: Mean blood loss in Study Groups (n=60)

Groups	Blood Loss (Mean ± SD)	*p*-value
Group-A (n=30)	118.97±20.26 ml	0.001
Group-B (n=30)	154.13±15.21 ml	

Table-II: Distribution of the patients according to Age and Gestational Age (n=60)

Variables	Group-A (n=30)	Group-B (n=30)	Total
	Mean±SD	Mean±SD	Mean±SD
Age (years)	29.30±5.94	29.13±6.31	29.22±6.08
Gestational age (weeks)	36.43±0.97	36.67±0.85	36.51±0.89

Table-III: Mean Blood Loss according to Age, Gestational Age and Parity (n=60)

	Group-A (n=30) Blood Loss (ml) Mean±SD	Group-B (n=30) Blood Loss (ml) Mean±SD	*p*-value
Age (Years)			
18-30	121.69±17.33	155.32±15.34	0.001
31-40	115.86±23.45	152.09±15.50	0.001
Gestational Age (weeks)			
35-37	122.35±18.07	155.19±14.92	0.001
38-39	97.0±22.47	144.67±17.62	0.001
Parity			
Primiparous	122.0±16.79	169.20±5.22	0.001
Multiparous	118.36±21.14	151.12±14.77	0.001

DISCUSSION

Data on the comparison of these two techniques was very scarce in the literature especially in cases of placenta previa. As a result, the current study compared the effectiveness of Balloon Tamponade and B-Lynch suture during caesarean delivery in patients with placenta previa by comparing the post-intervention mean blood loss after the two procedures were performed. In our study, mean blood loss in Group-A (prophylactic balloon tamponade) was 118.97±20.26 ml while in Group-B (B lynch suture Group) was 154.13±15.21 ml (*p*-value=0.001). The outcomes were similar to those of Kavak *et al*., who found that the amount of post-operative bleeding was lower in the balloon tamponade Group than in the hemostatic suture Group in a 2013 study.[10] (120±56 ml vs. 351±70 ml; $p<0.05$).

Patients with placenta previa often experience overwhelming hemorrhage during childbirth. The prevalence of post-partum hemorrhage is 27.4% in cases of placenta previa,[11,12] and this global burden of postpartum hemorrhage (PPH) is increasing due to increasingly high cesarean section rate in Pakistan (22%).[13] Risk of placenta previa is increased by 2 to 5 times in women who have had a previous caesarean delivery, as well as placenta accrete spectrum and the need of obstetric hysterectomy.[14] Previous studies have shown an increased individual effectiveness of balloon tamponade and B-Lynch suture in prevention of PPH during caesarean section for placenta previa. In a randomized controlled study comprising of 52 patients with placenta previa, prophylactic application of Bakri balloon during the caesarean section led to a reduced need of medical and surgical intervention when compared to the control group.[15] In another study, the researchers applied vertical compression suture in 15 patients having placenta previa, with just two patients needing packing.[16] In one study, parallel vertical compression sutures were applied in 95 patients with placenta previa in the experimental group, compared to a control Group comprising of 100 patients, which found compression sutures to be a successful surgical method for the securing of hemostasis and preservation of uterus in patients with placenta previa with no complications.[17] A total of 278 pregnant women were included in another study, with 168 of the 171 women who underwent vertical compression suture, achieving a successful outcome and only three patients undergoing postpartum hysterectomy.[18] A study conducted in Bahawalpur by Fatima *et al*.[19], concluded that in comparison to intrauterine balloon tamponade, the success rate of B-Lynch suture for the management of severe postpartum hemorrhage was found to be greater.

LIMITATION OF STUDY

Our study had some limitations, including a small number of patients and a single-center design. Nonetheless, this is the first trial to compare and examine the effectiveness of balloon tamponade versus B-lynch suture in preventing severe intrapartum bleeding during caesarean section due to placenta previa.

CONCLUSION

Our study concluded that prophylactic balloon tamponade results in lesser post-intervention mean blood loss in cases of placenta previa as compared to B lynch.

Conflict of Interest: None.

Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

SN & SN: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

QZ & MAQ: Data acquisition, data analysis, drafting the manuscript, critical review, approval of the final version to be published.

NHN & MAB: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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