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Role of Tranexamic Acid to Reduce Blood Loss at the Time of Placental Separation and Immediate Postoperative Period in Cesarean Deliveries: A Double Blinded Randomised Controlled Trial

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ABSTRACT
Postpartum hemorrhage is a leading cause of maternal morbidity and mortality worldwide. Tranexamic acid has been shown to reduce blood loss in various surgical settings, but its efficacy in cesarean deliveries remains unclear. To evaluate the efficacy of prophylactic tranexamic acid in reducing blood loss and related complications in patients undergoing cesarean delivery. A randomized, double-blinded, controlled study was conducted on 200 term pregnant women undergoing cesarean delivery. Participants were randomly allocated to receive either tranexamic acid (n=100) or placebo (n=100). The primary outcome was total blood loss, and secondary outcomes included the incidence of postpartum hemorrhage and the need for additional interventions to control blood loss. The mean total blood loss was significantly lower in the tranexamic acid group (462.89±142.21 mL) compared to the control group (599.26±221.66 mL, P<0.0001). The incidence of postpartum hemorrhage was also significantly lower in the tranexamic acid group (4% vs. 15%, P=0.0081). The tranexamic acid group required fewer additional interventions, including uterotonics (12% vs. 26%, P=0.0118), blood transfusions (7% vs. 21%, P=0.0044) and surgical interventions (6% vs. 14%, P=0.0600). Prophylactic administration of tranexamic acid significantly reduces total blood loss, the incidence of postpartum hemorrhage and the need for additional interventions in patients undergoing cesarean delivery. This intervention may improve maternal outcomes and decrease healthcare costs associated with the management of postpartum hemorrhage.

INTRODUCTION

Cesarean delivery is one of the most common surgical procedures worldwide, with rates continuing to rise globally[1]. Despite its lifesaving potential, cesarean delivery is associated with significant maternal morbidity, including an increased risk of postpartum hemorrhage (PPH)[2]. PPH, defined as blood loss exceeding 1000 mL or any blood loss leading to hemodynamic instability, is a leading cause of maternal mortality and morbidity[3]. The incidence of PPH is higher in cesarean deliveries compared to vaginal births, with rates ranging from 2%-6%[4]. Tranexamic acid (TXA) is an antifibrinolytic agent that has been extensively studied for its potential to reduce blood loss in various surgical settings[5]. TXA acts by inhibiting the activation of plasminogen to plasmin, thereby preventing the breakdown of fibrin clots and promoting hemostasis[6]. Several randomized controlled trials and systematic reviews have demonstrated the efficacy of TXA in reducing blood loss and the need for blood transfusions in various surgical procedures, including cardiac, orthopedic, and gynecological surgeries[7]. In the context of cesarean deliveries, the timing of TXA administration is crucial. The majority of blood loss during cesarean delivery occurs at the time of placental separation and in the immediate postoperative period[8]. Therefore, administering TXA at the time of placental separation may be more effective in reducing blood loss compared to administration at other time points. Several studies have investigated the use of TXA in cesarean deliveries, with promising results. A systematic review and meta-analysis by Li *et al.* found that prophylactic TXA administration significantly reduced blood loss and the need for blood transfusions in women undergoing cesarean delivery[9]. However, the optimal timing and dose of TXA administration remain controversial, with varying protocols used across studies. The current randomized controlled trial aims to investigate the efficacy of TXA administered at the time of placental separation and in the immediate postoperative period in reducing blood loss during cesarean deliveries. The study employs a double-blinded design to minimize bias and ensure the reliability of the results. By providing high-quality evidence on the optimal timing and dose of TXA administration, this study has the potential to inform clinical practice and improve maternal outcomes in cesarean deliveries. The findings of this trial may have significant implications for the management of cesarean deliveries worldwide. If proven effective, the use of TXA at the time of placental separation and in the immediate postoperative period could become a standard of care, potentially reducing the incidence of PPH and its associated complications. Furthermore, the reduction in blood loss and the need for blood transfusions could lead to significant cost savings for healthcare systems and improve the overall quality of care for women undergoing cesarean deliveries[10]. This randomized controlled trial addresses a critical issue in obstetric practice, aiming to optimize the use of TXA in cesarean deliveries to reduce blood loss and improve maternal outcomes.

Aim and Objectives: The aim of the study was to compare the effect of tranexamic acid in reducing blood loss at the time of placental separation and immediate postpartum blood loss among cesarean deliveries as compared to the one without tranexamic acid, through a randomised controlled trial. The primary objective was to compare the effect of 1 gram intravenous tranexamic acid given preoperatively to women undergoing cesarean with respect to blood loss during placental separation and immediate postpartum (within 2 hours) to women who did not receive tranexamic acid, through a randomised controlled trial. The secondary objectives were to see the incidence of postpartum hemorrhage (PPH) among women undergoing cesarean who received 1 gram intravenous tranexamic acid preoperatively and in women who did not receive tranexamic acid and to study the side effects of tranexamic acid in the intervention group.

MATERIALS AND METHODS

Study Setting and Design: The study was conducted in the Labour Room, Department of Obstetrics and Gynaecology at the Dr Baba Saheb Ambedkar Medical College and Hospital, Rohini, a tertiary care setup. It was a double-blinded, randomized controlled study.

Duration and Study Population: The study was conducted over a period of 9 months after ethical clearance. All term pregnant women admitted to the labour room at Baba Saheb Ambedkar Hospital, having a catchment area of Rohini, were screened for inclusion in the study. The eligible population consisted of all term pregnant women admitted in the labour room undergoing lower segment cesarean section as per the inclusion criteria.

Sample Size: The study of Esmat Jafar beg loo, *et al.* observed that total blood loss in the tranexamic acid group was 616.32±176.87 mL and in the control group was 731.45±178.79 mL. Taking these values as reference, the minimum required sample size with 99% power of study and 5% level of significance was 88 patients in each study group. To reduce the margin of error, the total sample size was considered at 200 (100 patients per group). The formula used for sample size calculation was based on comparing the means of two groups.

Inclusion and Exclusion Criteria: The inclusion criteria were women with a period of gestation equal to or more than 37 weeks undergoing cesarean section. The exclusion criteria were women having multiple pregnancy, polyhydramnios, antepartum hemorrhage, placenta previa, known uterine pathology like fibroid (which are known to be associated with a higher incidence of PPH), allergy to tranexamic acid, history of thromboembolic events and patients already on low molecular weight heparin or antiplatelet agents until the week before delivery.

Study Procedures: A detailed history of the patients was taken and a complete examination, including general physical examination, systemic examination, and obstetric examination, was performed. Blood samples were collected at the time of admission and subjected to routine blood investigations. Block randomization with a sealed envelope system was used for randomizing the patients. Patients were randomized in a series of blocks of ten, with five envelopes each assigned to the tranexamic acid group and the control group. The study was double-blinded, with neither the patient nor the investigator knowing the group allocation. The nursing officer in charge of the maternity operating theater prepared the medication in a 10 mL syringe according to the allocation and labeled it as A or B. The anaesthetist administered the injection just before the surgical incision in the abdomen. Blood loss was measured following the delivery of the baby until the end of surgery and then from the end of the operation to 2 hours after birth. Surgical mops and pads were weighed before and after the surgery and blood in the suction bottle was measured in milliliters. To ensure quality and reduce measurement errors, the cesarean sections included in the study were restricted to those performed during daytime between 9 am and 5 pm.

Outcome Measures: The primary outcome was measured in terms of blood loss, calculated as the weight of gauze pads used after surgery minus the weight of dry gauze pads, plus the volume of blood in the suction bottle after delivery of the baby. Blood loss during the immediate postoperative period (2 hours) was calculated as the weight of wet pads minus the weight of dry pads. One milligram of weight was taken as equivalent to 1 mL of blood [Vitello DJ *et al.,* 2015]. The secondary outcomes were measured in terms of the need for blood transfusion, uterotonics, additional surgical interventions (like uterine artery ligation or uterine compression sutures) and balloon tamponade. All cases where blood loss exceeded 1000 mL were included in this group. Patients' blood pressure and pulse were monitored preoperatively, intraoperatively, and postoperatively. Hemoglobin concentration was measured preoperatively and 48 hours postoperatively and the change in hemoglobin concentration was noted. Patients were followed up until discharge and any maternal morbidity and mortality were also noted.

Statistical Analysis: The data was compiled and analysed using MS Excel (R) Office 365, GraphPad Prism 8.4.2 and SPSS version 25. Descriptive statistics were presented in the form of proportions/percentages for categorical variables and median/interquartile range along with mean and standard deviation for continuous data. Fisher's exact test/chi-square test was used for the comparison of proportions (categorical variables). Continuous variables were analysed using the Mann-Whitney U test (for independent group/unpaired data) and Wilcoxon signed-rank test (for paired data). A p-value of <0.05 was considered statistically significant.

RESULTS AND DISCUSSIONS

The study included a total of 200 patients who were randomized into two groups: the tranexamic acid group (n=100) and the control group (n=100). The demographic characteristics of the patients were similar between the two groups (Table 1). The mean age of the patients in the tranexamic acid group was 24.72±3.24 years, while in the control group, it was 24.20±3.26 years (P=0.2593). The majority of the patients in both groups belonged to the lower socioeconomic status (62% in the tranexamic acid group and 64% in the control group, P=0.7701). Regarding education, a significantly higher proportion of patients in the tranexamic acid group had education up to 10th grade compared to the control group (64% vs. 45%, P=0.0071). The obstetric characteristics of the patients were also comparable between the two groups (Table 2). The proportion of primigravida patients was similar in both groups (33% in the tranexamic acid group and 35% in the control group, P=0.7659). The distribution of patients according to the period of gestation was not significantly different between the groups (P>0.05). The mean hemoglobin levels before delivery (10.50±0.80 g/dL in the tranexamic acid group and 10.53±0.85 g/dL in the control group, P=0.7974) and 48 hours post-operatively (9.81±0.80 g/dL in the tranexamic acid group and 9.72±0.98 g/dL in the control group, P=0.4777) were also similar. The indications for cesarean section were comparable between the two groups (Table 3). The most common indication was fetal distress (35.5% overall), followed by previous LSCS with or without scar tenderness (24.5% overall). There were no significant

differences in the distribution of indications between the groups. The primary outcome, total blood loss, was significantly lower in the tranexamic acid group compared to the control group (Table 4). The mean total blood loss in the tranexamic acid group was 462.89±142.21 mL, while in the control group, it was 599.26±221.66 mL (P<0.0001). The incidence of postpartum hemorrhage was also significantly lower in the tranexamic acid group (4%) compared to the control group (15%) (P=0.0081). Regarding secondary outcomes, the need for additional interventions to control blood loss was lower in the tranexamic acid group. The proportion of patients requiring uterotonics was significantly lower in the tranexamic acid group (12%) compared to the control group (26%) (P=0.0118). Similarly, the need for blood transfusion was significantly lower in the tranexamic acid group (7%) compared to the control group (21%) (P=0.0044). The need for additional surgical interventions, including uterine artery ligation and balloon tamponade, was also lower in the tranexamic acid group (6%) compared to the control group (14%), with the difference approaching statistical significance (P=0.0600). Tranexamic acid-related side effects were reported in 7% of the patients in the tranexamic acid group, while no side effects were reported in the control group, as they did not receive the intervention. In summary, the administration of tranexamic acid significantly reduced total blood loss and the incidence of postpartum hemorrhage in patients undergoing cesarean section. Moreover, the need for additional interventions to control blood loss, such as uterotonics, blood transfusion and surgical interventions, was lower in the tranexamic acid group. The side effects associated with tranexamic acid were minimal and well-tolerated.

Table 1: Demographic Characteristics

Parameter	No Tranexamic Acid	With Tranexamic Acid	P-value
Age (years), mean ± SD	24.20 ± 3.26	24.72 ± 3.24	0.2593
Socioeconomic status			
Lower	64 (64%)	62 (62%)	0.7701
Middle	36 (36%)	38 (38%)	
Education			
Illiterate	26 (26%)	18 (18%)	0.1731
Up to 10th	45 (45%)	64 (64%)	0.0071
Up to 12th	21 (21%)	14 (14%)	0.1938
Graduate and above	8 (8%)	4 (4%)	0.2348

Table 2: Obstetric Characteristics

Parameter	No Tranexamic Acid	With Tranexamic Acid	P-value
Gravidity			
Primigravida	35 (35%)	33 (33%)	0.7659
Gravida 2	28 (28%)	37 (37%)	0.1753
Gravida 3	32 (32%)	25 (25%)	0.2741
Gravida 4	4 (4%)	5 (5%)	0.7337
Gravida 5	1 (1%)	0 (0%)	0.3173
Period of gestation			
37–37+6 weeks	10 (10%)	9 (9%)	0.8099
38–38+6 weeks	23 (23%)	33 (33%)	0.1162
39–39+6 weeks	44 (44%)	35 (35%)	0.1941
40–40+6 weeks	23 (23%)	23 (23%)	-
Hemoglobin (g/dL), mean ± SD			
Before delivery	10.53 ± 0.85	10.50 ± 0.80	0.7974
48 hours post-op	9.72 ± 0.98	9.81 ± 0.80	0.4777

Table 3: Indications for Cesarean Section

Indication	No Tranexamic Acid	With Tranexamic Acid	Total
Fetal distress	29 (29%)	42 (42%)	71 (35.5%)
Previous LSCS ± scar tenderness	24 (24%)	25 (25%)	49 (24.5%)
Breech	12 (12%)	10 (10%)	22 (11%)
Failed induction	12 (12%)	8 (8%)	20 (10%)
Non-progress of labor	9 (9%)	5 (5%)	14 (7%)
Cephalopelvic dis proportion	5 (5%)	5 (5%)	10 (5%)
Contracted pelvis	2 (2%)	2 (2%)	4 (2%)
Oblique lie	3 (3%)	1 (1%)	4 (2%)
Transverse lie	3 (3%)	1 (1%)	4 (2%)
Scar tenderness	1 (1%)	0 (0%)	1 (0.5%)
Oligohydramnios	0 (0%)	1 (1%)	1 (0.5%)

Table 4. Outcome Parameters

Parameter	No Tranexamic Acid	With Tranexamic Acid	P-value
Total blood loss (mL), mean ± SD	599.26 ± 221.66	462.89 ± 142.21	< 0.0001
Postpartum hemorrhage	15 (15%)	4 (4%)	0.0081
Tranexamic acid-related side effects	–	7 (7%)	–
Need for uterotonics	26 (26%)	12 (12%)	0.0118
Need for blood transfusion	21 (21%)	7 (7%)	0.0044
Need for additional surgical intervention	14 (14%)	6 (6%)	0.0600

The present study aimed to evaluate the efficacy of tranexamic acid in reducing blood loss during cesarean delivery. The results showed that the administration of tranexamic acid significantly reduced total blood loss, the incidence of postpartum hemorrhage, and the need for additional interventions to control blood loss compared to the control group. The demographic and obstetric characteristics of the patients in both groups were comparable, with no significant differences in age, socioeconomic status, education, gravidity, period of gestation, or hemoglobin levels before delivery and 48 hours post-operatively. The most common indication for cesarean section was fetal distress, followed by previous LSCS with or without scar tenderness, which is consistent with the findings of other studies[11-12]. The mean total blood loss in the tranexamic acid group was significantly lower than in the control group (462.89±142.21 mL vs. 599.260±221.66 mL, P<0.0001). This finding is in line with several previous studies. Shalaby[13] reported a significantly higher estimated total blood loss in the placebo group compared to the tranexamic acid group (896.81±519.6 mL vs. 583.23±379.62 mL, P<0.001). Similarly, Tiwari[14] found that the mean blood loss from the delivery of the placenta to the end of delivery and from the end of delivery to 2 hours postpartum was significantly lower in the tranexamic acid group (P<0.05). Halifa[15] also observed a significantly lower blood loss from uterine incision to 2 hours post-surgery in the tranexamic acid group (613.05±195.63 mL vs. 751.17±250.66 mL, P<0.001). However, Sentilhes[16] found no significant between-group differences in mean gravimetrically estimated blood loss or in the

percentage of women with provider-assessed clinically significant postpartum hemorrhage. They concluded that tranexamic acid resulted in a significantly lower incidence of calculated estimated blood loss greater than 1000 mL or red-cell transfusion by day 2 than placebo, but it did not result in a lower incidence of hemorrhage-related secondary clinical outcomes. The incidence of postpartum hemorrhage was significantly lower in the tranexamic acid group compared to the control group (4% vs. 15%, P=0.0081). This finding is consistent with the results of Bellos[17], who reported a decreased risk of blood loss >1000 mL (PPH) with tranexamic acid administration in their systematic review of 36 studies. Tiwari[14] also found a significantly higher incidence of PPH in the control group compared to the tranexamic acid group (7% vs. 2%, P<0.05). Similarly, Ifunanya[18] observed a significantly lower incidence of primary postpartum hemorrhage in the tranexamic acid group (11.9% vs. 50%, P<0.0001). The need for additional interventions to control blood loss was significantly lower in the tranexamic acid group. The proportion of patients requiring uterotonics (12% vs. 26%, P=0.0118) and blood transfusion (7% vs. 21%, P=0.0044) was significantly lower in the tranexamic acid group. The need for additional surgical interventions was also lower in the tranexamic acid group, although the difference was not statistically significant (6% vs. 14%, P=0.0600). These findings are in agreement with several previous studies. Shalaby[13] reported a higher need for further ecbolic drugs in the placebo group compared to the tranexamic acid group (46.25% vs. 13.75%, P<0.001). Tiwari[14] also found a significantly higher use of oxytocic drugs in the control group (7% vs. 2%, P<0.05). Sanad[19] observed that more cases in the control group required further ecbolic treatment during the postoperative period compared to the tranexamic acid group (P=0.018). Stortroen[20] reported that tranexamic acid decreased the number of uterotonic agents used (risk ratio, 0.26; P<0.00001) but did not affect postoperative hemoglobin levels (mean difference, 0.41., P=0.10). The present study has several strengths, including its randomized controlled design, double-blinding and the assessment of multiple outcome parameters. However, there are also some limitations. The study was conducted at a single center, which may limit the generalizability of the results. Additionally, the sample size was relatively small and larger studies may be needed to confirm the findings.

In conclusion, the administration of tranexamic acid significantly reduced total blood loss, the incidence of postpartum hemorrhage and the need for additional interventions to control blood loss in patients undergoing cesarean delivery. These findings suggest that tranexamic acid may be an effective prophylactic agent for reducing blood loss and related complications in cesarean deliveries. However, further large-scale, multicenter studies are needed to confirm these results and establish the optimal dosage and timing of tranexamic acid administration.

CONCLUSION

In this randomized, double-blinded, controlled study, we demonstrated that the prophylactic administration of tranexamic acid in patients undergoing cesarean delivery significantly reduced total blood loss, the incidence of postpartum hemorrhage, and the need for additional interventions to control blood loss. The mean total blood loss in the tranexamic acid group was 462.89±142.21 mL, which was significantly lower than that in the control group (599.26±221.66 mL, P<0.0001). The incidence of postpartum hemorrhage was also significantly lower in the tranexamic acid group compared to the control group (4% vs. 15%, P=0.0081). Furthermore, the tranexamic acid group required fewer additional interventions, such as uterotonics (12% vs. 26%, P=0.0118), blood transfusions (7% vs. 21%, P=0.0044), and surgical interventions (6% vs. 14%, P=0.0600), compared to the control group. These findings suggest that tranexamic acid is an effective prophylactic agent for reducing blood loss and related complications in patients undergoing cesarean delivery. The use of tranexamic acid may help to improve maternal outcomes, reduce the need for blood transfusions and potentially decrease healthcare costs associated with the management of postpartum hemorrhage. However, further large-scale, multicenter studies are needed to confirm these results, establish the optimal dosage and timing of tranexamic acid administration and assess the long-term safety and efficacy of this intervention.

In conclusion, the prophylactic use of tranexamic acid in cesarean deliveries appears to be a promising strategy for reducing blood loss and related complications. Obstetric care providers should consider incorporating this intervention into their clinical practice, especially for patients at high risk of postpartum hemorrhage. Nonetheless, the decision to use tranexamic acid should be made on an individual basis, taking into account the patient's specific risk factors and clinical circumstances.

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