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Original Research Article

Role of intravenous tranexamic acid in reducing blood loss during and immediately after caesarean section: A randomized controlled study

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Abstract
Background: One of the leading causes of maternal morbidity and mortality globally, especially in developing nations, is remains postpartum haemorrhage (PPH). Compared to vaginal delivery, Caesarean sections are linked to an increased risk of excessive blood loss. By preventing fibrinolysis, the antifibrinolytic drug tranexamic acid (TXA) has been demonstrated to reduce surgical blood loss. The purpose of this study was to assess the safety and effectiveness of intravenous tranexamic acid in reducing intraoperative and postoperative blood loss during caesarean section.
Methods: This randomized controlled trial was conducted in the Department of Obstetrics and Gynaecology, Durgapur Steel Plant Hospital, West Bengal, from December 2019 to January 2021. Two groups (n = 50 each) of 100 term pregnant women undergoing caesarean sections were randomly assigned. Group 1 received intravenous tranexamic acid (1 g before skin incision followed by 500 mg 8-hourly for 2 days), while Group 2 received standard care without TXA. Blood loss was objectively measured intraoperatively and up to 2 hours postoperatively. Hemoglobin levels before and after surgery, incidence of PPH, need for additional uterotonics, maternal complications, and neonatal outcomes were assessed. SPSS version 21.0 was used for the statistical analysis, and $p<0.05$ was deemed significant.
Results: The TXA group had a significantly lower incidence of PPH than the control group (10% vs. 24%, $p=0.04$). 12% of the TXA group and 64% of the control group experienced blood loss above 500 ml ($p<0.001$). The TXA group experienced a significantly lower mean percentage decline in haemoglobin (7.32% vs. 16.7%, $p<0.001$). No significant maternal or neonatal adverse effects related to tranexamic acid were observed.
Conclusion: Intravenous tranexamic acid significantly reduces blood loss and hemoglobin decline during and after caesarean section without increasing maternal or neonatal complications. TXA is a safe and effective adjunct for the prevention of postpartum haemorrhage in caesarean deliveries.\

Keywords: Tranexamic acid, caesarean section, postpartum haemorrhage, blood loss, antifibrinolytic therapy

Introduction

Postpartum haemorrhage (PPH) is the leading cause of maternal mortality globally, accounting for about 35% of all maternal deaths. It is one of the most devastating complications of childbirth [1]. The World Health Organisation (WHO) defines severe PPH as blood loss of ≥1000 ml within 24 hours of delivery, but PPH is typically described as blood loss of ≥500 ml within that time frame [2]. Primary PPH is defined as PPH that occurs during the first 24 hours, while secondary PPH is defined as haemorrhage that occurs after 24 hours and up to six weeks postpartum [3-4]. Despite its clinical importance, postpartum blood loss is rarely measured accurately, and even modest blood loss may lead to hemodynamic instability, particularly in anaemic women. Uterine atony is the most common cause of PPH, followed by genital tract trauma, retained placental tissue, uterine rupture, and coagulation disorders [5]. Globally, maternal mortality rates remain disproportionately high in developing countries, accounting for nearly 99% of maternal deaths, with the highest burden seen in sub-Saharan Africa and South Asia [6]. PPH alone is responsible for approximately 25% of maternal deaths, with an estimated 14 million women affected annually [7].

The routine use of uterotonic agents, particularly oxytocin, has significantly reduced the incidence of PPH; however, haemostatic drugs are not commonly used as first-line therapy. In addition to mechanical haemostasis achieved by uterine contraction, pharmacological

modulation of coagulation and fibrinolysis may further reduce blood loss, especially during and after lower segment caesarean section (LSCS) [8].

A synthetic lysine analogue called tranexamic acid (TXA) prevents fibrin from degradation and reduces bleeding by reversibly blocking plasminogen binding sites. TXA has been widely used to minimize blood loss in various surgical specialties and gynaecological procedures, including menorrhagia and hysterectomy. Its favourable safety profile and superior antifibrinolytic potency compared to other agents support its potential role in obstetrics [9, 10].

Aims and Objectives

This study aims to evaluate the safety of tranexamic acid in obstetrical practice as well as its potential to reduce intraoperative and postoperative blood loss in women undergoing caesarean delivery. Tranexamic acid's effectiveness in reducing blood loss during and after caesarean sections is the primary objective, while evaluating and comparing maternal outcomes and the adverse impact profile linked to its use in the obstetric population is the secondary objective.

Materials and Methods

Study Design

This study was conducted between December 2019 and January 2021 as a randomized controlled trial in the Department of Obstetrics and Gynecology at Durgapur Steel Plant Hospital, Durgapur, West Bengal. The study population consisted of pregnant women at term who presented to the obstetrics and gynecology department and required caesarean section. In order to assess the results, eligible participants who met the predetermined inclusion and exclusion criteria were enrolled in the study and randomly assigned groups.

Inclusion and Exclusion Criteria

The study included pregnant women with a singleton pregnancy who were at term and scheduled for caesarean section. Women were excluded from the study if they had a known allergy to tranexamic acid; underlying liver or renal disorders; coagulopathies; preeclampsia or eclampsia; a previous history of seizure disorders; multiple pregnancies; suspected macrosomia ; or polyhydramnios.

Sample Size Calculation

The sample size is calculated for a randomized controlled trial. In order to estimate the size of sample for each group, the difference in the response rates of the two groups is to be taken into consideration and the sample size is estimated from the following formula:

$$n = 2\ t\alpha 2 s2 / d2$$

Where n is each group's necessary sample size. The two groups' combined standard deviation is denoted by s.

The expected smallest difference between the estimations for the two groups is denoted by d. Typically, tα is regarded as the 5% level of significance.

For example, pooled standard deviation s = 5.0 and t0.05 = 2 if d is the smallest expected difference in the rise of mean between two groups, which is 2%.

Therefore, required sample size n = [2 x (2)2 x (5.0)2] / (2)2 = 50 in each group

Thus, a total of 100 sample was determined and 50 sample in each group were included [2].

Data Collection Tools

Data were collected using a structured case record form that included patient demographic details, obstetric history, clinical examination findings, and laboratory investigation reports. Laboratory tools comprised blood investigations such as complete blood count, hemoglobin with red blood cell indices, kidney function tests, liver function tests, and coagulation profile. Intraoperative blood loss was measured using calibrated weighing scales to assess the weight of surgical mops and by volume measurement. Follow-up hemoglobin estimation was performed using EDTA blood samples.

Data Collection Procedure

Eligible patients who met the inclusion criteria were enrolled in the study after providing written informed consent in the local vernacular language. Baseline data including detailed history, clinical assessment, and screening blood investigations were recorded preoperatively. Patients in the intervention group received a single intravenous loading dose of tranexamic acid (1 g diluted in 5% dextrose) 20 minutes prior to skin incision, followed by a maintenance dose of 500 mg intravenously every 8 hours for two days starting immediately after placental delivery. Intraoperative blood loss during caesarean section was assessed by calculating the difference between the dry and soaked weights of surgical mops and measuring the collected blood volume. All participants were followed up until postoperative day 2, when blood samples were collected in EDTA vials to estimate hemoglobin levels and red blood cell indices in both groups.

Statistical Analysis

IBM's Statistical Package for the Social Sciences (SPSS) version 21.0 was used to enter and analyse all of the data. Proportions were used to describe qualitative factors, while the mean, median, range, and standard deviation are used to describe quantitative data. Prior to performing the appropriate tests of significance, the data were examined for normality. The independent t test was used to determine the significance of the mean difference. The p-value was considered significant if it was less than 0.05.

Results

Table 1: Baseline sociodemographic and obstetric characteristics of study participants (N = 100)

Variable	Group 1 (TXA) n=50	Group 2 (Control) n=50
Mean age (years)	28±2.96	29±2.93
Primigravida	40 (80%)	38 (76%)
Multigravida	10 (20%)	12 (24%)
Urban residence	41 (82%)	39 (78%)
Rural residence	9 (18%)	11 (22%)

Table 1 shows that both groups were comparable with respect to age, gravida status, and place of residence, indicating adequate baseline matching between the intervention and control groups.

Table 2: Associated obstetric and medical conditions among participants

Condition	Group 1 n=50	Group 2 n=50
Gestational hypertension	4 (8%)	19 (38%)
Gestational diabetes mellitus	3 (6%)	2 (4%)
Preeclampsia	0	0

Table 2 observes a higher prevalence of gestational hypertension in the control group, while gestational diabetes mellitus showed similar distribution in both groups. No cases of preeclampsia were observed.

Table 3: Fetal characteristics and presentation

Parameter	Group 1	Group 2
Longitudinal lie	50 (100%)	50 (100%)
Vertex presentation	45 (90%)	47 (94%)
Breech presentation	5 (10%)	3 (6%)

Table 3 shows that fetal lie and presentation were similar in both groups, with longitudinal lie being universal and vertex presentation predominating.

Table 4: Preoperative anthropometry, vital parameters, and baseline laboratory values

Parameter	Group 1 (Mean ± SD)	Group 2 (Mean ± SD)
Height (cm)	161±8.9	161±10
Weight (kg)	63±12	61±12
Hemoglobin (g/dL)	11.9±1.5	12.4±1.4
Heart rate (/min)	109±23	108±24
Systolic BP (mmHg)	129±19	130±19

Table 4 demonstrates comparable anthropometric measurements, vital signs, and baseline hematological parameters between the two groups.

Table 5: Intraoperative blood loss and postpartum hemorrhage

Outcome	Group 1 n=50	Group 2 n=50	p value
Blood loss <500 ml	44 (88%)	18 (36%)	<0.001
Blood loss >500 ml	6 (12%)	32 (64%)	
PPH occurrence	5 (10%)	12 (24%)	0.04

Table 5 shows significantly reduced intraoperative blood loss and a lower incidence of postpartum hemorrhage in the tranexamic acid group compared to the control group.

Table 6: Change in hemoglobin levels before and after caesarean section

Parameter	Group 1	Group 2	p value
Hb before CS (g/dL)	11.94±1.5	12.4±1.42	—
Hb after CS (g/dL)	11.1±1.34	10.6±1.06	—
Mean Hb drop (%)	7.32±5.2	16.7±6.8	<0.001

Table 6 illustrates that the percentage drop in hemoglobin following caesarean section was significantly lower in the tranexamic acid group, indicating effective reduction in blood loss.

Table 7: Neonatal outcomes

Outcome	Group 1 n=50	Group 2 n=50	p value
NICU admission	2 (4%)	4 (8%)	0.001
Respiratory distress syndrome	2 (12%)	6 (8%)	0.14
APGAR at 1 min (Mean ± SD)	7.84±0.58	5.5±1.41	—
APGAR at 5 min (Mean ± SD)	8.96±0.49	7.38±1.42	—

Table 7 shows better neonatal outcomes in the tranexamic acid group, with higher APGAR scores and lower NICU admission rates, though respiratory distress syndrome did not differ significantly.

Discussion

In order to assess the effectiveness of intravenous tranexamic acid (TXA) in reducing intraoperative and postoperative blood loss in women undergoing caesarean sections, the current randomised controlled trial was carried out. A total of 100 term pregnant women were enrolled and equally allocated to two groups: Group 1 received tranexamic acid, while Group 2 received standard management. The two groups were comparable with respect to baseline demographic and obstetric characteristics, ensuring minimal confounding and reliable comparison of outcomes.

The participants in this study were between the ages of 20 and 35 years on average, and there was no discernible difference between the two groups. Primigravida women from metropolitan areas made up the majority of both groupings. These findings are consistent with the demographic patterns reported in similar Indian studies evaluating tranexamic acid use during caesarean delivery [2, 11]. The distribution of indications for caesarean section was also comparable, with non-progress of labour being the most common indication in both groups.

The study's main finding showed that tranexamic acid significantly decreased blood loss both during and after surgery. In Group 1, 88% of women had blood loss of less than 500 ml, compared to only 36% in the control group. Postpartum haemorrhage occurred in 10% of women in the tranexamic acid group, whereas 24% of women in the control group developed PPH, and this difference was statistically significant. These results provide compelling evidence for tranexamic acid's antifibrinolytic function in reducing surgical blood loss during caesarean sections.

Similar observations were reported by Mayur G *et al.* [2] who demonstrated a significant reduction in blood loss from placental delivery to 2 hours postpartum among women receiving tranexamic acid. Simonazzi G *et al.* [3] in their systematic review and meta-analysis, also concluded that prophylactic use of tranexamic acid during caesarean delivery significantly reduced postpartum blood loss, the incidence of PPH, and severity of haemorrhage without increasing adverse events.

The present study also revealed a significantly lower drop in hemoglobin levels in the tranexamic acid group compared to the control group. The percentage fall in hemoglobin following caesarean section was markedly lower in Group 1, indicating better preservation of maternal blood volume. This observation aligns with the findings of Sekhavat L *et al.* [10] and Zhang *et al.* [12] who reported significantly smaller declines in postoperative hemoglobin and hematocrit levels among women receiving tranexamic acid.

In a major double-blind randomised controlled trial, Chandraharan *et al.* [11] also showed that tranexamic acid considerably lowered the mean estimated blood loss and the percentage of women who lost more than 1000 millilitres. These results' stability across several trials supports tranexamic acid's ability to lessen perioperative haemorrhage during caesarean sections.

Neonatal outcomes in the present study were largely comparable between the two groups. Although NICU admissions were higher in the control group, respiratory distress syndrome did not differ significantly. APGAR scores at 1 minute and 5 minutes were higher in the tranexamic acid group, suggesting no adverse neonatal impact. These results are in agreement with studies by Abdel-Aleem H *et al.* [13] and Ahmed MR *et al.* [14] which reported no significant differences in neonatal outcomes following tranexamic acid administration.

Importantly, no maternal adverse effects or thromboembolic complications were observed in either group during the study period. This finding supports the safety profile of tranexamic

acid, as also reported in multiple randomized trials and meta-analyses [3, 15]. The absence of complications further strengthens the justification for its prophylactic use during caesarean delivery. The findings of the present study are consistent with existing literature and demonstrate that tranexamic acid effectively reduces intraoperative and postoperative blood loss, decreases the incidence of postpartum haemorrhage, and limits haemoglobin decline without increasing maternal or neonatal morbidity.

Conclusion

In conclusion, this study included 100 women undergoing caesarean section, equally divided into a tranexamic acid group and a standard management group, with comparable age distribution between 20 and 35 years. Women who received tranexamic acid experienced significantly lower intraoperative and postoperative blood loss and a smaller decline in hemoglobin levels compared to the control group. The administration of tranexamic acid during lower segment caesarean section effectively reduced blood loss without any observed maternal adverse effects or immediate complications, indicating that tranexamic acid is a safe and effective adjunct in the management of blood loss during caesarean delivery.

Author Contribution

Dr. Arindam Mitra (1st author) was responsible for conceptualization, investigation, case management, and overall supervision of the study. Dr. Sujoy Sankar Bhattacharjee (2nd author) contributed to manuscript writing through critical review and editing. Dr. Shreyashi (3rd author) was involved in data collection, patient management, preparation of the original draft, and literature review.

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