ORIGINAL RESEARCH

Assessment of the Effectiveness of Tranexamic Acid on Postpartum Blood Loss Reduction within the First Two Hours after Vaginal Delivery: A Randomised Controlled Trial

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ABSTRACT

Background: The study aimed to evaluate the effectiveness of tranexamic acid (TXA) in reducing postpartum blood loss within the first two hours after vaginal delivery.Postpartum haemorrhage (PPH) remains one of the leading causes of maternal morbidity and mortality worldwide, particularly in low-resource settings.

Material and Methods: A randomized controlled trial was conducted on 120 pregnant women who met the inclusion criteria and were undergoing vaginal delivery at a tertiary care hospital. Participants were randomly assigned to either the intervention group, which received 1 gram of intravenous TXA immediately after delivery in addition to standard active management of the third stage of labour, or the control group, which received only standard active management. Blood loss was measured using a calibrated drape over two hours post-delivery. Secondary outcomes included changes in haemoglobin levels, the need for additional uterotonics, and adverse effects. Statistical analysis was performed using SPSS software, and a p-value of <0.05 was considered significant.

Results: The mean blood loss was significantly lower in the TXA group (290.6 ± 58.4 mL) compared to the control group (423.2 ± 76.1 mL, $p < 0.001$). The post-delivery haemoglobin levels were significantly higher in the intervention group (11.2 ± 1.3 g/dL) compared to the control group (10.4 ± 1.2 g/dL, $p < 0.001$). The requirement for additional uterotonics was significantly lower in the TXA group (8.33%) than in the control group (30.00%, $p = 0.003$). There was no significant difference in adverse effects, with no thromboembolic events reported in either group.

Conclusion: Tranexamic acid is highly effective in reducing postpartum blood loss following vaginal delivery, minimizing haemoglobin decline, and reducing the need for additional uterotonics without increasing adverse effects. These findings support the routine use of TXA in the management of postpartum haemorrhage.

Keywords: Postpartum haemorrhage, tranexamic acid, blood loss, vaginal delivery,

INTRODUCTION

Postpartum haemorrhage (PPH) remains one of the leading causes of maternal morbidity and mortality worldwide, particularly in low-resource settings. Defined as blood loss exceeding 500 mL after vaginal delivery or 1000 mL after caesarean section, PPH poses significant risks, including hypovolemic shock, organ failure, and death if not managed promptly. Despite advances in obstetric care, the prevention and management of excessive bleeding remain critical priorities in maternal health. Various interventions have been explored to reduce postpartum blood loss, including uterotonics, surgical techniques, and

pharmacological agents. One such agent, tranexamic acid (TXA), has gained attention for its potential to minimize bleeding and improve maternal outcomes following childbirth.[1]

Tranexamic acid is an antifibrinolytic agent that works by inhibiting the breakdown of fibrin clots, thereby promoting haemostasis and reducing bleeding. Initially developed to manage excessive bleeding in surgical and trauma patients, TXA has demonstrated significant efficacy in reducing haemorrhagic complications in various clinical scenarios. Its role in obstetric care has been increasingly recognized, particularly in preventing and treating PPH. Given that PPH results from a failure of normal haemostatic processes following delivery, TXA's ability to stabilize clot formation presents a promising therapeutic avenue for reducing blood loss in the immediate postpartum period.[2]

The prevention of PPH is especially critical in vaginal deliveries, which account for the majority of births worldwide. While active management of the third stage of labour, including uterotonic administration, controlled cord traction, and uterine massage, has been widely adopted, some women continue to experience excessive bleeding despite these interventions. This highlights the need for additional strategies to enhance haemostatic control in the crucial first two hours after birth, when the risk of severe blood loss is highest.[3]

Randomized controlled trials (RCTs) provide the highest level of evidence when evaluating medical interventions. In the context of TXA use for reducing postpartum blood loss, RCTs have aimed to assess its safety, efficacy, and overall impact on maternal outcomes. Several studies have examined the timing and dosage of TXA administration, with particular focus on its prophylactic use immediately after vaginal delivery to mitigate early postpartum bleeding. Understanding its effectiveness in this specific timeframe is crucial for determining its potential integration into standard postpartum care protocols.[4]

While TXA has been widely used for the treatment of established PPH, its role in the prevention of significant postpartum blood loss following vaginal delivery is still under investigation. The primary concern with routine TXA administration is the balance between its haemostatic benefits and potential adverse effects, including thromboembolic events. Therefore, rigorous clinical evaluation is necessary to determine its overall risk-benefit profile for routine use in obstetric practice.[5]

This study aims to evaluate the effectiveness of tranexamic acid in reducing postpartum blood loss within the first two hours following vaginal delivery. By conducting a randomized controlled trial, this research seeks to provide robust evidence on the impact of TXA in preventing excessive bleeding, thereby contributing to improved maternal health outcomes. The findings may inform clinical guidelines and policies regarding the use of TXA as a preventive measure against PPH, ultimately enhancing postpartum care strategies.

AIM AND OBJECTIVES

Aim:

The primary aim of this randomized controlled trial was to evaluate the effectiveness of tranexamic acid (TXA) in reducing postpartum blood loss within the first two hours following vaginal delivery. Secondary objectives included assessing its impact on haemoglobin levels, the need for additional uterotonic agents, and the occurrence of adverse effects.

Objectives:

Primary Objective: To determine whether TXA administration decreases the volume of blood loss within the first two hours postpartum.

Secondary Objectives:

- To assess changes in haemoglobin levels from pre-delivery to post-delivery.
- To evaluate the necessity for additional uterotonic agents to control bleeding.
- To monitor and compare the incidence of adverse effects between the intervention and control groups.

MATERIALS AND METHODS

Study Design

- A randomized controlled trial (RCT)study.
- A computer-generated randomization sequence was used to allocate participants into two groups:

1. **Intervention group:** Received 1 gram of single intravenous tranexamic acid immediately after delivery, along with routine active management of the third stage of labour.
2. **Control group:** Received only standard active management of the third stage of labour (10 IU of oxytocin intramuscularly).

Study Population

Total participants: 120 postpartum women.

Study place

This study was conducted in the Department of Obstetrics and Gynaecology, in collaboration with Department of Anaesthesia, Rama Medical College Hospital and Research Centre, Hapur, Uttar Pradesh, India

Study period

The study was carried out over a period of one year and ten months from January 2016 to October 2017.

Inclusion Criteria

Pregnant women undergoing vaginal delivery

- Singleton pregnancy at term (≥37 weeks of gestation),undergoing spontaneous or induced vaginal delivery, and without contraindications to tranexamic acid.
- No known bleeding disorders
- No history of antepartum haemorrhage

Exclusion Criteria

- Women undergoing caesarean section
- History of coagulopathy or thromboembolicdisorders
- Severe preeclampsia or eclampsia
- Known allergy to tranexamic acid
- Presence of placenta previa, abruption placentae, or other placental abnormalities
- Any contraindications to oxytocin

Ethical consideration

The study was approved by the research and ethical committee, and written informed consent was obtained from all participants before enrollment in the study.

Outcome Measures

Primary Outcome:

Amount of postpartum blood loss measured within the first two hours after delivery

Secondary Outcomes:

- Incidence of postpartum haemorrhage (PPH)
- Need for additional uterotonics or blood transfusion
- Any reported adverse effects of tranexamic acid

Statistical Analysis

- Sample Size Calculation: Determined based on expected reduction in blood loss with 80% power and 5% significance level ($p < 0.05$).
- Comparative Analysis:
  - Descriptive statistics (mean, standard deviation, median, interquartile range) were used to summarize data.
  - Independent t-test (for normally distributed data) and Mann-Whitney U test (for skewed data) were used to compare blood loss between groups.
  - Chi-square test was used to analyze categorical variables (e.g., incidence of PPH).
  - Multivariate logistic regression was performed to adjust for potential confounders.

Statistical Software: Analysis was performed using SPSS software version 21.0.

Blood loss was measured using a calibrated drape placed under the patient immediately after delivery and continued for two hours postpartum. Additional blood loss from soaked pads and linens was estimated and recorded. Hemodynamic parameters, including blood pressure, pulse rate, and haemoglobin levels, were monitored before and after delivery. Any adverse effects, such as nausea, vomiting, or thromboembolic events, were recorded. The primary outcome measure was the total blood loss within the first two hours postpartum. Secondary outcomes included the need for additional uterotonics, haemoglobin drop, and occurrence of any adverse effects.

RESULTS

The results of this study are presented in five tables, covering the baseline characteristics of study participants, blood loss within the first two hours postpartum, haemoglobin changes, the need for additional uterotonics, and adverse effects.

Table 1: Baseline Characteristics of Study Participants

Characteristic	Intervention Group (n=60)	Control Group (n=60)	p-value
Age (years, mean ± SD)	27.5 ± 3.8	27.8 ± 3.6	0.67
Gestational Age (weeks, mean ± SD)	38.4 ± 1.2	38.3 ± 1.1	0.81
Primipara (%)	30 (50.00%)	28 (46.67%)	0.71
Multipara (%)	30 (50.00%)	32 (53.33%)	0.79

The baseline characteristics of participants are summarized in Table 1. The mean age of participants in the intervention group was 27.5 ± 3.8 years, while in the control group, it was 27.8 ± 3.6 years (p = 0.67), indicating no significant difference between the two groups. The mean gestational age was also similar, with 38.4 ± 1.2 weeks in the intervention group and 38.3 ± 1.1 weeks in the control group (p = 0.81). The proportion of primiparous women was 50.00% in the intervention group and 46.67% in the control group (p = 0.71), while the proportion of multiparous women was 50.00% in the intervention group and 53.33% in the control group (p = 0.79). These findings indicate that the two groups were comparable in terms of demographic and obstetric characteristics.

Table 2: Blood Loss within First Two Hours Postpartum (mL)

Group	Mean ± SD (mL)	p-value
Intervention (n=60)	290.6 ± 58.4	<0.001
Control (n=60)	423.2 ± 76.1	<0.001

Table 2 presents the primary outcome of the study—postpartum blood loss within the first two hours. The mean blood loss in the intervention group was 290.6 ± 58.4 mL, whereas it was significantly higher in the control group at 423.2 ± 76.1 mL (p < 0.001). This demonstrates that tranexamic acid was effective in significantly reducing postpartum blood loss following vaginal delivery.

Table 3: Haemoglobin Changes (g/dL)

Time Point	Intervention Group (n=60)	Control Group (n=60)	p-value
Pre-Delivery	11.8 ± 1.2	11.7 ± 1.1	0.74
Post-Delivery	11.2 ± 1.3	10.4 ± 1.2	<0.001

Table 3 reports changes in haemoglobin levels before and after delivery. The pre-delivery haemoglobin levels were comparable between the two groups, with a mean of 11.8 ± 1.2 g/dL in the intervention group and 11.7 ± 1.1 g/dL in the control group (p = 0.74). However, post-delivery haemoglobin levels showed a significant difference, with the intervention group having a mean of 11.2 ± 1.3 g/dL compared to 10.4 ± 1.2 g/dL in the control group (p < 0.001). This suggests that the reduction in haemoglobin levels was more pronounced in the control group, further supporting the effectiveness of tranexamic acid in reducing blood loss.

Table 4: Need for Additional Uterotonics

Need for Additional Uterotonics	Intervention Group (n=60)	Control Group (n=60)	p-value
Yes	5 (8.33%)	18 (30.00%)	0.003
No	55 (91.67%)	42 (70.00%)	0.003

The requirement for additional uterotonics is summarized in Table 4. Only 8.33% (n=5) of patients in the intervention group required additional uterotonics, compared to 30.00% (n=18) in the control group, and this difference was statistically significant (p = 0.003). This suggests that the administration of tranexamic acid reduces the likelihood of requiring further uterotonic agents to control bleeding.

Table 5: Adverse Effects

Adverse Effect	Intervention Group (n=60)	Control Group (n=60)	p-value
Nausea	4 (6.67%)	3 (5.00%)	0.72
Vomiting	2 (3.33%)	1 (1.67%)	0.56
Thromboembolic Event	0 (0.00%)	0 (0.00%)	1.00

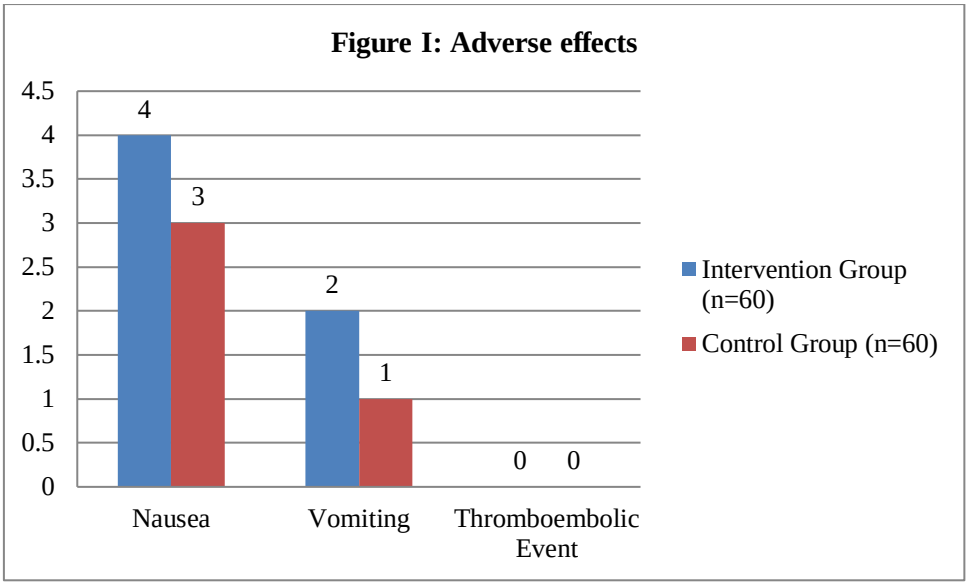

Table 5 and figure I, provides details on adverse effects. The incidence of nausea was slightly higher in the intervention group (6.67%) compared to the control group (5.00%) (p = 0.72). Vomiting occurred in 3.33% of patients in the intervention group and 1.67% in the control group (p = 0.56). No thromboembolic events were reported in either group (p = 1.00). These findings indicate that tranexamic acid was well tolerated, with no significant increase in adverse effects.

DISCUSSION

The findings of this study are consistent with previous research on the effectiveness of tranexamic acid (TXA) in reducing postpartum haemorrhage (PPH). The baseline characteristics of the participants, including age, gestational age, and parity, were similar in both groups, ensuring that any observed differences in outcomes could be attributed to the intervention rather than confounding variables.

In this study, the mean blood loss within the first two hours postpartum was significantly lower in the TXA group (290.6 ± 58.4 mL) compared to the control group (423.2 ± 76.1 mL) (p < 0.001). These findings are in line with those of Gai et al. (2004), who conducted a randomized controlled trial and found that TXA administration reduced blood loss from 439.3 ± 179.3 mL in the control group to 262.4 ± 142.3 mL in the TXA group (p < 0.001).[6] Similarly, Ducloy-Bouthors et al. (2011) demonstrated that TXA significantly decreased blood loss in postpartum women with moderate-to-severe haemorrhage. These studies support the hypothesis that TXA plays a crucial role in reducing postpartum bleeding and preventing severe hemorrhage.[7]

The haemoglobin levels in this study further confirm the efficacy of TXA. The post-delivery haemoglobin level was significantly higher in the TXA group (11.2 ± 1.3 g/dL) compared to the control group (10.4 ± 1.2 g/dL) (p < 0.001), suggesting that TXA effectively minimizes haemoglobin decline. This result is consistent with findings from Mirghafourvand et al. (2015), who reported a significantly smaller reduction in haemoglobin levels among women receiving TXA compared to those in the control group.[8] Additionally, Yang et al. (2001) found that the haemoglobin drop was significantly lower in the TXA group, further supporting its role in preserving maternal haemoglobin levels after delivery.[9]

The need for additional uterotonics was significantly lower in the TXA group (8.33%) compared to the control group (30.00%) (p = 0.003). This result is consistent with studies conducted by Sekhavat et al. (2009), who found that TXA administration significantly reduced the need for additional uterotonic agents.[10]Similarly,Movafegh et al. (2011) observed that the use of TXA decreased the requirement for further uterotonic therapy, which is a critical factor in managing PPH. This suggests that TXA not only reduces blood loss but also decreases the burden of additional interventions required to control postpartum bleeding.[11]

Regarding adverse effects, this study found no significant differences between the two groups. The incidence of nausea (6.67% vs. 5.00%, p =

0.72) and vomiting (3.33% vs. 1.67%, p = 0.56) was slightly higher in the TXA group, but the differences were not statistically significant. Most importantly, no thromboembolic events were reported in either group. This aligns with the findings of Bonnar and Gjorstrup (1997), who reported that TXA did not increase the risk of thromboembolic complications when used for PPH.[12]Similar results were observed by Mayur et al. (2013), who found that TXA was well tolerated, with no significant increase in adverse effects compared to standard management.[13]

LIMITATIONS OF THE STUDY

Single-Centre Design: Conducted at a single institution, which may limit the generalizability of the findings to other settings with different patient populations or healthcare infrastructures.

Short Follow-Up Period: The study focused on outcomes within the first two hours postpartum; longer-term effects of TXA, such as on maternal morbidity or mortality, were not assessed.

Sample Size: While the study included 120 participants, a larger sample size might provide more robust data and enhance the statistical power to detect differences between groups.

CONCLUSION

This study demonstrates that tranexamic acid (TXA) is highly effective in reducing postpartum blood loss within the first two hours after vaginal delivery. The significant reduction in mean blood loss, lower haemoglobin decline, and decreased need for additional uterotonics highlight its clinical benefits in preventing postpartum haemorrhage. Additionally, TXA was well tolerated, with no significant increase in adverse effects such as nausea, vomiting, or thromboembolic events.

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