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Original Research Article

Efficacy of Tranexamic Acid in Hemorrhage Control among Acute Trauma Cases: A Prospective, Placebo-Controlled Study

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Abstract:

Background: Acute trauma is a leading cause of preventable mortality, with hemorrhage being a significant contributor to early deaths. Tranexamic acid (TXA), an antifibrinolytic agent, has shown promise in reducing bleeding and improving outcomes in trauma patients. This study aims to evaluate the efficacy of TXA in controlling bleeding compared to placebo in acute trauma cases.

Methods: This prospective, randomized, double-blinded study was conducted in the Department of Anaesthesiology, Katihar Medical College, Al-Karim University, Katihar, Bihar, India. A total of 120 acute trauma patients presenting with signs of hemorrhage were enrolled and randomly assigned into two groups: Group A (n=60) received tranexamic acid, and Group B (n=60) received a placebo. Patients were assessed for total blood loss, requirement of blood transfusions, hemodynamic stability, and clinical outcomes over a 24-hour observation period and up to 7 days post-admission.

Results: Patients in the TXA group showed a statistically significant reduction in total blood loss ($p<0.05$) and fewer blood transfusion requirements compared to the placebo group. Hemodynamic parameters remained more stable in the TXA group, and fewer complications were observed. There were no significant adverse events related to TXA use.

Conclusion: Tranexamic acid is effective in reducing bleeding and the need for transfusion in acute trauma patients without increasing the risk of complications. Its early administration can be a valuable adjunct in trauma care in resource-limited settings.

Keywords: Tranexamic Acid, Acute Trauma, Hemorrhage Control, Placebo, Blood Loss, Antifibrinolytic, Trauma Care, Randomized Controlled Trial.

Introduction

Trauma continues to be one of the leading causes of morbidity and mortality worldwide, particularly among individuals in the productive age group. In low- and middle-income countries like India, the burden of trauma is further magnified due to inadequate prehospital care, delayed transport, and limited access to definitive trauma management [1]. Among the multiple factors contributing to trauma-related deaths, uncontrolled hemorrhage stands out as a critical and potentially preventable cause of early mortality, especially within the first few hours following injury [2].

Hemorrhage leads to hypovolemia, coagulopathy, and multi-organ failure, creating a vicious cycle that, if not interrupted promptly, results in death. Therefore, early control of bleeding is paramount in improving survival outcomes in trauma patients [3]. In this context, tranexamic acid (TXA) has emerged as a promising pharmacological intervention. TXA is a synthetic derivative of the amino acid lysine and acts as a potent antifibrinolytic agent. It exerts its effect by reversibly blocking the lysine binding sites on plasminogen, thereby preventing the breakdown of fibrin clots [4].

The utility of TXA in trauma has been highlighted by large-scale international trials, most notably the CRASH-2 trial, which demonstrated that early administration of TXA significantly reduced all-cause mortality in bleeding trauma patients without increasing thromboembolic events [5]. These findings have influenced clinical guidelines globally, advocating for the inclusion of TXA as part of early trauma management protocols.

However, despite the strong evidence base, the implementation and outcomes of TXA use in trauma settings in India, particularly in resource-limited areas such as Bihar, remain underexplored [6]. Local patient demographics, variations in injury patterns, and healthcare infrastructure can influence the generalizability of global findings to regional

contexts. Therefore, it is essential to generate local evidence to guide context-specific clinical decisions [7].

This study was undertaken at Katihar Medical College, Al-Karim University, Bihar, with the objective of prospectively comparing the efficacy of tranexamic acid versus placebo in controlling bleeding among acute trauma patients. Through this study, we aim to assess not only the hemostatic effectiveness of TXA but also its impact on transfusion requirements, hemodynamic stability, and early clinical outcomes in a tertiary care hospital in Eastern India.

By contributing to the growing body of literature on TXA use in trauma, especially from an Indian perspective, this study seeks to inform clinical practice, promote rational drug use, and ultimately, improve trauma care outcomes in similar healthcare settings.

Methods

This prospective, randomized, double-blinded, placebo-controlled study was conducted in the Department of Anaesthesiology at Katihar Medical College, Al-Karim University, Katihar, Bihar, India, over a period of six months. A total of 120 adult patients presenting with acute trauma and clinical signs of active bleeding were enrolled after obtaining written informed consent from the patients or their legal guardians. Inclusion criteria included patients aged between 18 and 60 years, admitted within three hours of trauma, with systolic blood pressure <90 mmHg and/or heart rate >110 bpm, indicating significant hemorrhage. Patients with known bleeding disorders, on anticoagulant therapy, with a history of thromboembolic disease, or pregnant women were excluded from the study.

Participants were randomly allocated into two equal groups using computer-generated random numbers. Group A (n=60) received an intravenous loading dose of 1 gram of tranexamic acid diluted in 100 ml of normal saline over 10 minutes, followed by an infusion of 1 gram over the next 8 hours. Group B (n=60), the control group, received an identical volume of placebo (normal saline) following the same administration protocol to maintain blinding. Both the patient and the treating medical team were unaware of group allocations throughout the study.

Baseline demographic data, vital signs, injury characteristics, and initial laboratory parameters were recorded. The primary outcomes assessed were total blood loss estimated over 24 hours and the number of blood transfusion units required. Secondary outcomes included changes in hemodynamic parameters, incidence of thromboembolic complications, duration of hospital stay, and mortality within the first 7 days of admission. Standard trauma care and resuscitation protocols were followed for all patients as per institutional guidelines.

All data were recorded in a structured proforma and analyzed using SPSS version 25. Descriptive statistics were used to summarize demographic data. Continuous variables were compared using the Student's t-test or Mann-Whitney U test, as appropriate, while categorical variables were analyzed using the Chi-square test or Fisher's exact test. A p-value of <0.05 was considered statistically significant.

Result

A total of 120 patients were included in the study, with 60 patients each in the tranexamic acid (TXA) group and the placebo group. Baseline demographic and clinical parameters were comparable between both groups. The TXA group demonstrated significantly lower mean blood loss, reduced transfusion requirements, and more stable hemodynamic profiles during the observation period. The incidence of complications and short-term mortality was also lower in the TXA group.

Table 1: Age Distribution of Patients in Both Groups

Age Group (Years)	TXA Group (n=60)	Placebo Group (n=60)
18–30	21	19
31–40	17	18
41–50	12	13
51–60	10	10
Mean ± SD	34.8 ± 10.4	35.1 ± 9.7

Table 2: Gender Distribution in Study Groups

Gender	TXA Group (n=60)	Placebo Group (n=60)
Male	44	42
Female	16	18

Table 3: Type of Trauma Among Study Participants

Type of Trauma	TXA Group (n=60)	Placebo Group (n=60)
Road Traffic Accident	39	41
Fall from Height	13	11
Assault	8	8

Table 4: Mean Estimated Blood Loss (ml)

Group	Mean Blood Loss (ml) ± SD
TXA Group	620 ± 150
Placebo Group	910 ± 180

Table 5: Number of Blood Transfusion Units Required

Number of Units	TXA Group (n=60)	Placebo Group (n=60)
0	26	9
1–2	24	28
3–4	8	17
>4	2	6
Mean Units	1.4 ± 1.2	2.7 ± 1.6

Table 6: Mean Systolic Blood Pressure at Admission and After 6 Hours

Time Point	TXA Group (mmHg)	Placebo Group (mmHg)
At Admission	88 ± 11	87 ± 10
After 6 Hours	108 ± 12	98 ± 14

Table 7: Mean Pulse Rate at Admission and After 6 Hours

Time Point	TXA Group (beats/min)	Placebo Group (beats/min)
At Admission	114 ± 14	116 ± 15
After 6 Hours	92 ± 10	100 ± 12

Table 8: Hemoglobin Levels at Admission and 24 Hours

Time Point	TXA Group (g/dL)	Placebo Group (g/dL)
At Admission	11.2 ± 1.3	11.1 ± 1.4
After 24 Hours	10.7 ± 1.2	9.3 ± 1.5

Table 9: Requirement of Vasopressor Support

Requirement	TXA Group (n=60)	Placebo Group (n=60)
Yes	8	18
No	52	42

Table 10: Duration of Hospital Stay

Duration (Days)	TXA Group (n=60)	Placebo Group (n=60)
<5	22	15
5–7	30	28
>7	8	17
Mean ± SD	5.6 ± 1.9	6.8 ± 2.1

Discussion

The findings of this prospective, randomized, placebo-controlled study provide strong evidence supporting the efficacy of tranexamic acid (TXA) in reducing blood loss and improving hemodynamic stability in acute trauma patients. Our study aligns with existing global literature, including the landmark CRASH-2 trial, and adds valuable region-specific evidence from a tertiary care center in Bihar, India.

The significant reduction in total blood loss observed in the TXA group (620 ± 150 ml) compared to the placebo group (910 ± 180 ml) underlines TXA's potent antifibrinolytic action in the acute trauma setting [8]. The preservation of clot integrity and prevention of fibrinolysis likely contributed to reduced bleeding and subsequent clinical benefits. These findings are consistent with those reported by Shakur et al., where early administration of TXA reduced all-cause mortality and bleeding-related deaths in trauma patients [9].

Another major finding was the reduced need for blood transfusions in the TXA group. Fewer patients in this group required more than two units of blood, which has significant implications in resource-limited settings like ours [10]. Blood products are often scarce, and minimizing transfusion requirements can reduce costs, prevent transfusion-related complications, and lower the risk of transfusion-transmissible infections. The hemodynamic profile of patients in the TXA group showed greater stability [11]. Mean systolic blood pressure improved significantly within the first six hours, and the pulse rate decreased more effectively compared to the placebo group. This reflects more effective bleeding control, leading to improved circulatory dynamics and reduced vasopressor dependency [12]. Notably, only 13.3% of TXA group patients required vasopressors, compared to 30% in the placebo group.

Additionally, hemoglobin levels remained more stable in the TXA group after 24 hours, reinforcing the role of TXA in minimizing ongoing blood loss. Fewer patients in the TXA group developed complications such as sepsis or thromboembolic events [13,14]. Although TXA has been associated with theoretical thrombotic risks, our findings and those from the CRASH-2 trial suggest that the drug is safe in the trauma population when used appropriately and early.

Shorter hospital stays in the TXA group (mean 5.6 ± 1.9 days) also emphasize improved recovery, with patients demonstrating quicker stabilization and discharge readiness [15,16]. This is crucial in high-burden healthcare systems where reducing length of stay can significantly alleviate pressure on hospital infrastructure.

Most importantly, mortality within 7 days was markedly lower in the TXA group (3.3%) compared to the placebo group (11.6%), indicating that TXA's early administration may have life-saving potential in acute trauma settings [17,18]. While this study did not follow patients beyond one week, the initial mortality reduction provides compelling support for TXA use during the critical early window after trauma [19].

This study has several strengths, including its prospective design, balanced randomization, and real-world applicability in a tertiary care setting. However, it is not without limitations. The follow-up period was limited to 7 days, and long-term complications or mortality beyond discharge were not assessed. Furthermore, advanced imaging or laboratory confirmation of thromboembolic events was not universally available, which may have led to underreporting.

Despite these limitations, the study provides strong local evidence for the integration of TXA into standard trauma protocols, especially in resource-limited hospitals across India. Given its low cost, ease of administration, and favorable safety profile, TXA offers a practical solution to a major challenge in trauma care—hemorrhage control.

Conclusion

This study demonstrates that early administration of tranexamic acid in acute trauma patients significantly reduces blood loss, decreases the need for blood transfusions, improves hemodynamic stability, and lowers short-term mortality. The drug was well-tolerated, with no significant increase in thromboembolic complications. These findings underscore the effectiveness and safety of TXA as a valuable adjunct in the initial management of trauma, particularly in resource-limited settings. Incorporating tranexamic acid into routine trauma protocols can enhance patient outcomes and contribute to more efficient use of critical care resources.

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