Original Article

Evaluation of Intravenous Tranexamic Acid for Reduction of Perioperative Blood Loss and Transfusion Requirements in Total Knee Arthroplasty: A Prospective Randomized Double-Blind Study

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Abstract

Background: Total knee arthroplasty (TKA) is frequently associated with significant perioperative blood loss and increased transfusion requirements. Tranexamic acid (TXA), an antifibrinolytic agent, may reduce these risks. **Material and Methods:** A prospective, randomized, double-blind controlled trial was conducted at MIOT Hospitals, Chennai, between July 2015 and September 2016. Sixty patients undergoing unilateral primary cemented TKA were randomized into two groups: Group A received intravenous TXA (10 mg/kg before tourniquet deflation followed by 1 mg/kg/hour infusion for 12 hours), while Group B received placebo (normal saline). Outcomes assessed included perioperative blood loss, transfusion requirements, and changes in haemoglobin and haematocrit. **Results:** TXA significantly reduced postoperative blood loss compared to placebo (379.17 ± 174.44 mL vs 513.33 ± 143.89 mL; p=0.002). Total blood loss was also lower in the TXA group (543.30 ± 184.85 mL vs 685.83 ± 176.74 mL; p=0.003). The mean decline in haemoglobin and haematocrit was significantly less in the TXA group (1.53 ± 0.52 g/dL vs 2.14 ± 0.71 g/dL; 4.41 ± 1.54% vs 6.32 ± 1.93%; p=0.001). Blood transfusions were required in 20% of TXA patients compared to 50% in the placebo group (p=0.03). No serious complications, including thromboembolic events, were observed. **Conclusion:** Intravenous TXA effectively reduces perioperative blood loss and transfusion requirements in TKA without increasing complications. It may be considered a safe, efficient, and economical blood conservation strategy in knee replacement surgery.

Keywords: Antifibrinolytic therapy, blood transfusion, knee replacement surgery, perioperative blood loss, total knee arthroplasty, tranexamic acid.

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Introduction

Total knee arthroplasty (TKA) is one of the most commonly performed orthopaedic procedures for the management of advanced degenerative knee disorders, particularly osteoarthritis and rheumatoid arthritis. The procedure provides substantial pain relief, restores joint function, improves mobility, and enhances the overall quality of life of affected patients. However, TKA is frequently associated with significant perioperative blood loss, occurring both intraoperatively and postoperatively due to surgical trauma, ongoing fibrinolysis, and bleeding from exposed cancellous bone surfaces.[1] Excessive perioperative blood loss may lead to postoperative anaemia, delayed rehabilitation, prolonged hospital stays, increased morbidity, and a higher requirement for allogeneic blood transfusions.[2]

Allogeneic blood transfusions have historically been used to maintain adequate oxygen-carrying capacity and manage perioperative anaemia. However, blood transfusion is associated with several potential risks, including immunological reactions, transmission of infectious diseases, transfusion-related lung injury, circulatory overload, and increased healthcare costs.[3] Furthermore, concerns regarding limited blood bank resources and the judicious use of blood products have highlighted the need for effective blood conservation strategies in major orthopaedic procedures such as TKA.[4]

Perioperative bleeding in TKA is influenced by both surgical and physiological mechanisms. Surgical trauma activates the coagulation and fibrinolytic pathways, resulting in increased plasmin activity and accelerated fibrin degradation.[5] Additionally, the use of a pneumatic tourniquet during knee arthroplasty contributes to enhanced fibrinolytic activity following tourniquet release because of tissue hypoxia and endothelial release of tissue plasminogen activator.[6] This transient hyperfibrinolytic state significantly contributes to postoperative blood loss and increases the likelihood of blood transfusion.

Various blood conservation strategies, including meticulous

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surgical techniques, autologous blood transfusion, controlled hypotension, normovolemic haemodilution, and pharmacological interventions, have been developed to reduce perioperative blood loss.[7] Among the available pharmacological agents, antifibrinolytic drugs have gained widespread acceptance because of their proven efficacy, ease of administration, and favourable safety profile. Tranexamic acid (TXA), a synthetic lysine analogue, is one of the most extensively studied antifibrinolytic agents in orthopaedic surgery.[8]

Tranexamic acid acts by competitively inhibiting the activation of plasminogen to plasmin, thereby preventing fibrin degradation and stabilising blood clot formation.[9] Its effectiveness in reducing perioperative blood loss has been demonstrated across several surgical specialties, including orthopaedic, cardiac, spinal, and hepatic surgery.[10] In patients undergoing TKA, intravenous administration of TXA has been shown to reduce postoperative drain output, minimise postoperative haemoglobin decline, and decrease the requirement for allogeneic blood transfusions.[11]

Several randomized controlled trials and meta-analyses have confirmed the efficacy and safety of TXA in total knee arthroplasty. Konig et al. and Wang et al. demonstrated that TXA significantly reduced perioperative blood loss and transfusion requirements.[12,13] Similarly, Kakar et al. and Majumdar et al. reported lower postoperative blood loss and reduced allogeneic transfusion rates among patients receiving TXA during knee replacement surgery.[14,15] Furthermore, meta-analyses conducted by Zufferey et al. and Gandhi et al. confirmed that TXA effectively reduces perioperative blood loss without significantly increasing the risk of thromboembolic complications.[16,17]

Although considerable evidence supports the efficacy of TXA, variations in dosage regimens, timing of administration, and routes of administration continue to be debated. Moreover, evidence from the Indian population remains relatively limited, where effective blood conservation strategies are particularly important because of resource constraints and concerns related to blood transfusion. Therefore, further evaluation of intravenous TXA in Indian patients undergoing total knee arthroplasty is warranted.

This study evaluated the efficacy of intravenous TXA in reducing blood loss and transfusion requirements in primary TKA.

Materials and Methods

This prospective, randomized, double-blind, placebo-controlled study was conducted in the Department of Anaesthesiology, MIOT Hospitals, Chennai, between July 2015 and September 2016 to evaluate the efficacy of intravenous tranexamic acid in reducing perioperative blood loss and blood transfusion requirements in patients undergoing unilateral primary cemented total knee arthroplasty. Approval for the study was obtained from the Institutional Ethics Committee of MIOT Hospitals,

Chennai, before commencement of the study. Written informed consent was obtained from all participants after explaining the study protocol in their native language.

The sample size was estimated using postoperative reduction in haemoglobin concentration as the primary outcome variable. Sample size calculation was performed using the formula for comparison of two independent means:

$$n = \frac{2(Z_{\alpha/2} + Z_{\beta})^2 \sigma^2}{d^2}$$

where n represents the required sample size in each group, Zα/2 = 1.96 corresponding to a 95% confidence interval, Zβ = 0.84 corresponding to 80% statistical power, σ represents the pooled standard deviation of postoperative haemoglobin reduction obtained from previously published literature, and d represents the expected difference in postoperative haemoglobin reduction between the two groups.

Using an anticipated mean difference of 0.8 g/dL in postoperative haemoglobin reduction with a pooled standard deviation of 1.4 g/dL, the minimum required sample size was calculated as follows:

$$n = \frac{2(1.96 + 0.84)^2 (1.4)^2}{(0.8)^2}$$

$$n = \frac{2(2.8)^2 (1.96)}{0.64}$$

$$n = \frac{2 \times 7.84 \times 1.96}{0.64}$$

$$n = \frac{30.73}{0.64}$$

$$n = 48.0$$

To compensate for possible dropouts and protocol deviations, approximately 20% additional participants were included, resulting in a final sample size of 60 patients, with 30 patients allocated to each study group.

Reference for sample size calculations:

1. Chow SC, Shao J, Wang H, Lokhnygina Y. Sample size calculations in clinical research. chapman and hall/CRC; 2017 Aug 15.
2. Shinde A, Sobti A, Maniar S, Mishra A, Gite R, Shetty V. Tranexamic acid reduces blood loss and need of blood transfusion in total knee arthroplasty: a prospective, randomized, double-blind study in Indian population. Asian journal of transfusion science. 2015 Jul 1;9(2):168-72.

Patients aged between 20 and 80 years with American Society of Anaesthesiologists (ASA) physical status I or II who were scheduled for unilateral primary cemented total knee arthroplasty were screened for eligibility. Patients willing to provide written informed consent were included in the study.

Patients who refused to participate, had a known hypersensitivity to tranexamic acid, renal or hepatic dysfunction, coagulation disorders, severe cardiac or respiratory disease, malignancy, previous surgery on the operative knee, bilateral total knee

arthroplasty, long-term anticoagulant therapy, or contraindications to regional anaesthesia were excluded from the study.

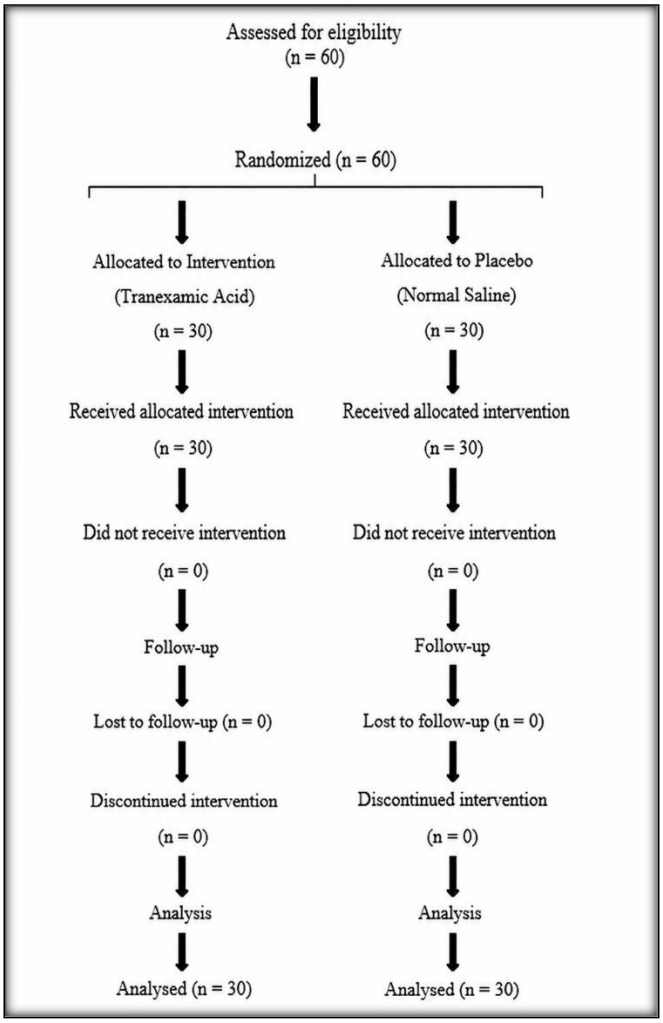
Eligible participants were randomly allocated into two equal groups using a computer-generated randomization sequence. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes prepared by an independent investigator who was not involved in patient recruitment or data collection. Both the patients and the investigators responsible for administering anaesthesia, perioperative management, data collection, and postoperative assessment remained blinded to the treatment allocation throughout the study.

Patients assigned to Group A (Tranexamic Acid Group) received intravenous tranexamic acid at a dose of 10 mg/kg administered slowly over 10 minutes, 30 minutes before tourniquet deflation, followed by a continuous infusion of 1 mg/kg/hour for the subsequent 12 hours. Patients assigned to Group B (Placebo Group) received an equivalent volume of normal saline according to the same schedule.

All patients underwent unilateral primary cemented total knee arthroplasty under standardized regional anaesthesia and identical perioperative management protocols. Intraoperative monitoring, surgical technique, tourniquet application, postoperative analgesia, thromboprophylaxis, and rehabilitation protocols were standardized for all participants to minimize potential confounding variables.

The primary outcome measure was perioperative blood loss assessed by postoperative reduction in haemoglobin concentration and total drain output. Secondary outcome measures included the requirement for allogeneic blood transfusion, postoperative haemoglobin levels, duration of hospital stay, incidence of thromboembolic complications, adverse drug reactions, and other perioperative complications.

The collected data were entered into Microsoft Excel and analysed using Statistical Package for the Social Sciences (SPSS) software version XX. Continuous variables were expressed as mean ± standard deviation and compared using the independent Student's t-test. Categorical variables were expressed as frequencies and percentages and analysed using the Chi-square test or Fisher's exact test wherever appropriate. A two-tailed P value of less than 0.05 was considered statistically significant.



Results

The research comprised sixty patients receiving unilateral primary cemented total knee replacement. Sixty eligible participants were randomly allocated in a 1:1 ratio to receive either intravenous tranexamic acid (n=30) or placebo (n=30).

There were no significant differences in baseline demographics, including age (p>0.05) and preoperative haemoglobin (p>0.05) [Table 1]

Table 1: Baseline Characteristics of Study Participants

Parameter	Group A (TXA)	Group B (Placebo)	p-value
Number of patients	30	30	—
Mean age (years)	63.63 ± 7.44	64.40 ± 6.86	>0.05
Male/Female	11/19	10/20	>0.05
Mean weight (kg)	72.17 ± 8.44	71.93 ± 7.96	>0.05
Duration of surgery (min)	118.83 ± 11.52	121.17 ± 10.74	>0.05
Preoperative Haemoglobin (g/dL)	12.36 ± 1.18	12.18 ± 1.14	>0.05
Preoperative Hematocrit (%)	37.01 ± 3.46	36.74 ± 3.21	>0.05

Patients who received tranexamic acid experienced considerably less postoperative blood loss than the placebo group. Group A's average postoperative drain output was 379.17 ± 174.44 mL, whereas Group B's average blood loss was 513.33 ± 143.89 mL. At p = 0.002, this difference was statistically significant.

Additionally, the tranexamic acid group lost much less blood overall than the placebo group (685.83± 176.74 mL vs 543.30 ± 184.85 mL; p = 0.003).

Table 2: Comparing Blood Loss Across Groups

Parameter	TXA (Grp-A)	Placebo (Grp-B)	p-value
Intraoperative loss of blood (mL)	164.13 ± 49.54	172.50 ± 56.73	>0.05
Postoperative blood loss (mL)	379.17 ± 174.44	513.33 ± 143.89	0.002
Total loss of blood (mL)	543.30 ± 184.85	685.83 ± 176.74	0.003

Table 3: Haemoglobin and Hematocrit Changes

Parameter	TXA Group (Mean ± SD)	Placebo Group (Mean ± SD)	p-value
Fall in Haemoglobin (g/dL)	1.53 ± 0.52	2.14 ± 0.71	0.001
Fall in Hematocrit (%)	4.41 ± 1.54	6.32 ± 1.93	0.001

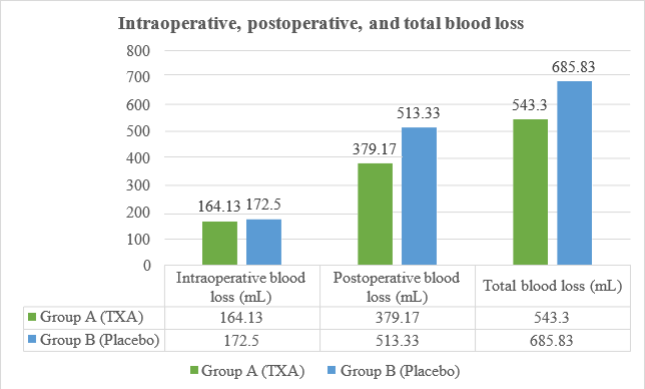


Figure 1: Comparison of intraoperative, postoperative, and total loss of blood between study groups.

[Figure 1] illustrates the comparison of intraoperative, postoperative, and total blood loss between the TXA and placebo groups. Postoperative and total blood loss were significantly lower in the TXA group, while intraoperative blood loss was comparable between groups.

Compared to the placebo group (2.14 ± 0.71 g/dL), the TXA group saw a reduced mean decline in haemoglobin (1.53 ± 0.52 g/dL). In a similar vein, the TXA group saw a lower decrease in haematocrit (4.41 ± 1.54%) compared to the placebo group (6.32 ± 1.93%). The considered statistically significant reductions (p = 0.001) show that intravenous tranexamic acid effectively reduced perioperative blood loss in patients having total knee replacement.

Patients receiving tranexamic acid had a much lower need for allogeneic blood transfusions. Just six patients (20%) in Group A needed blood transfusions, compared to fifteen patients (50%) in Group B (p = 0.03).

Furthermore, the tranexamic acid group transfused less packed red blood cell units on average.

Table 4: Comparing the Needs for Blood Transfusions

Parameter	Group A (TXA)	Group B (Placebo)	p-value
Individuals requiring transfusion	6 (20%)	15 (50%)	0.03
Mean PRBC units transfused	0.27 ± 0.45	0.67 ± 0.71	0.01

Neither group encountered any serious issues during the experiment, such as myocardial infarction, pulmonary embolism, deep vein thrombosis, or allergic reactions. Most patients had an uncomplicated postoperative recovery.

Discussion

For patients receiving total knee replacement, perioperative blood loss continues to be a serious issue. It is frequently associated with postoperative anaemia, prolonged hospital stays, increased need for allogeneic blood transfusions, and delayed mobility. This investigation examined the effectiveness of systemic tranexamic acid in lowering transfusion needs and perioperative blood loss in patients undergoing total knee replacement. Tranexamic acid significantly decreased postoperative blood loss, overall blood loss, postoperative haemoglobin and haematocrit levels, and the need for blood transfusions without making postoperative issues worse, according to the findings.

Demographic and baseline clinical data, such as age, sex distribution, body weight, length of operation, preoperative haemoglobin, and haematocrit levels, were similar across the two groups in this study. Baseline clinical data were similar across both groups, ensuring comparability. Fillingham et al. (2018) reported baseline comparability that was comparable.[18]

The primary result of the study was that tranexamic acid dramatically decreased postoperative blood loss in the patients. The mean blood loss during surgery was 379.17 ± 174.44 mL for the tranexamic acid group and 513.33 ± 143.89 mL for the group receiving a placebo (p = 0.002). Furthermore, the tranexamic acid group lost significantly less blood overall (543.30 ± 184.85 mL) than the placebo group (685.83 ± 176.74 mL; p = 0.003). These results are in line with Wang et al.'s 2018 study, which found that tranexamic acid administration during total knee arthroplasty significantly reduced perioperative blood loss.[19] Jia et al. published similar findings in 2019, showing that tranexamic acid successfully lowers both obvious and concealed blood loss during knee replacement surgery.[20]

Tranexamic acid's antifibrinolytic activity may be responsible for the decrease in blood loss seen in this investigation. Fibrinolysis was activated during knee arthroplasty due to surgical stress and tourniquet removal, which resulted in rapid fibrin breakdown and postoperative haemorrhage. Tranexamic acid reduces bleeding by stabilizing fibrin clots and preventing the conversion of plasminogen to plasmin.[21]

There were not any statistically significant variations in blood loss during the procedure between the groups in this study. The mean intraoperative blood loss was 164.13 ± 49.54 mL for the tranexamic acid group and 172.50 ± 56.73 mL for the placebo group. Seo et al. (2017) observed similar results, concluding that

tranexamic acid mostly affects postoperative fibrinolysis rather than intraoperative surgical haemorrhage.[22]

The much less postoperative fall in haemoglobin and haematocrit levels in individuals taking tranexamic acid was another major finding of the current investigation. Group A's mean decrease in haemoglobin was 1.53 ± 0.52 g/dL, whereas Group B was 2.14 ± 0.71 g/dL (p = 0.001). The tranexamic acid group saw a considerably smaller decline in haematocrit (4.41 ± 1.54%) compared to the placebo group (6.32 ± 1.93%; p = 0.001). Similar results were noted by Zhang et al. in 2016, who showed that patients who received tranexamic acid following total knee replacement had a much lower postoperative haemoglobin drop.[23]

Furthermore, the investigation's tranexamic acid group needed reduced blood transfusions. Compared to 15 patients (50%) in Group B, only 6 patients (20%) in Group A needed transfusions (p = 0.03). Additionally, compared to Placebo (0.67 ± 0.71 units), Group A had a significantly reduced mean number of packed RBC transfusions (0.27 ± 0.45 units). Tranexamic acid substantially decreases exposure to allogeneic transfusions of blood in patients after total knee replacement, according to research by Fillingham et al. and Fu DJ et al. in 2013, which both showed similar reductions in transfusion requirements.[18,24]

Several new meta-analyses and systematic reviews have demonstrated the advantages of tranexamic acid in orthopaedic surgery. Tranexamic acid drastically decreases transfusion rates and perioperative blood loss, regardless of administration mode. (Fillingham et al., 2018).18 In a similar vein, Mi et al. (2017) showed that using tranexamic acid locally and intravenously simultaneously lowers blood loss without creating new issues.[25]

Tranexamic acid safety is still a serious concern since fibrinolysis inhibition may potentially put patients at risk for thromboembolic events. However, this study did not find any significant adverse effects, such as myocardial infarction (MI), thrombosis of deep veins, cardiac embolism, or allergic responses. These results are in line with Borsinger et al.'s 2024 literature review, which showed that tranexamic acid did not substantially raise patients' risk of venous thromboembolism or additional serious adverse reactions after total joint replacement.[26]

The results of this study corroborate the mounting evidence that tranexamic acid is a useful blood-saving technique when used routinely in total knee replacement. Improved surgical recovery, fewer transfusion-related problems, shorter hospital stays, and lower healthcare costs can all be achieved by reducing perioperative blood loss and transfusion needs. Due to its ease of use, affordability, and clinical efficacy, intravenous tranexamic acid is a useful adjuvant in the perioperative care of patients having knee replacements.

Nevertheless, there were several limitations to the current study. The follow-up period was restricted to the immediate postoperative period, and the sample size was somewhat small. There was no long-term surveillance for thromboembolic consequences. To determine the ideal dosage recommendations and long-term safety of tranexamic acid in orthopaedic surgery, more thorough interdisciplinary studies with longer follow-up periods are recommended.

Conclusion

The current study showed that patients having total knee replacement can significantly reduce perioperative blood loss by using intravenous tranexamic acid. Compared to the placebo group, patients receiving tranexamic acid had much lower postoperative and total blood loss, smaller declines in postoperative haemoglobin and haematocrit levels, and a reduced need for allogeneic blood transfusions.

Additionally, the study discovered that tranexamic acid had a favourable safety profile as it did not raise the frequency of thromboembolic events or postoperative sequelae. Reducing the need for transfusions may assist lower overall healthcare expenditures, enhance postoperative recovery, and lower transfusion-related hazards.

According to the findings of this study, intravenous tranexamic acid may be considered a safe, effective, and economical blood conservation approach in total knee arthroplasty and may be routinely incorporated into perioperative treatment guidelines for patients undergoing knee replacement surgery.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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