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Original Research Article

Exploring the Impact of Tranexamic Acid on Blood Loss, Transfusion Requirements, and Thromboembolic Events in Spine Surgery

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Abstract:

Aim: This randomized controlled trial aimed to evaluate the efficacy of tranexamic acid (TXA) in reducing blood loss and the need for blood transfusions during spine surgery, while also assessing its safety in terms of thromboembolic event occurrence.

Methods: The study enrolled 48 patients undergoing elective spine surgeries at Bhima Bhoi Medical College, Balangir, Odisha, who were randomized to receive either TXA or a placebo. The primary outcomes measured were intraoperative blood loss and transfusion requirements, with thromboembolic events monitored as a secondary outcome.

Results: Patients treated with TXA experienced significantly reduced median blood loss (300 mL) compared to those receiving a placebo (500 mL; $p<0.05$). Additionally, the TXA group had a lower incidence of transfusion requirements (16.7% vs. 50%; $p<0.01$). No significant increase in thromboembolic events was observed between the groups, affirming the safety of TXA use in this context.

Conclusion: TXA effectively reduces blood loss and transfusion needs during spine surgery without increasing the risk of thromboembolic complications, supporting its incorporation into surgical protocols to improve patient outcomes and reduce healthcare costs.

Keywords: Tranexamic Acid, Spine Surgery, Blood Loss, Thromboembolic Events.

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Introduction

Tranexamic acid (TXA) is a synthetic derivative of the amino acid lysine, primarily functioning to inhibit the breakdown of blood clots by obstructing the activation of plasminogen and the action of plasmin [1]. Its pharmacological properties make TXA a valuable resource in managing bleeding during various surgical contexts [2]. The use of TXA in spinal surgery, characterized by significant potential for blood loss, warrants detailed exploration due to the critical implications of such bleeding [3]. These include increased morbidity rates, extended hospital stays, and heightened requirements for blood transfusions. The primary goal in applying TXA during spinal procedures is to reduce perioperative blood loss, thereby diminishing the need for transfusions that carry risks of immunological reactions, infections, and escalated healthcare costs [4,5]. Additionally, while TXA's antifibrinolytic effects are beneficial for controlling bleeding, there exists a theoretical risk of increased thromboembolic events, a concern that is particularly relevant in orthopedic surgeries such as spine operations [6-8].

This study aims to rigorously evaluate the effects of administering tranexamic acid, either preoperatively or intraoperatively, on three critical outcomes: the volume of blood loss, the frequency and volume of blood transfusions, and the incidence of thromboembolic events post-surgery. The research seeks to determine the safety and efficacy of TXA in this specific context, aiming to provide more precise guidelines for its use in clinical settings, balancing the benefits of reduced blood loss against the potential risks, notably thromboembolic complications.

Methodology

Study Design: This RCT investigated whether tranexamic acid (TXA) reduces blood loss, transfusions, and thromboembolic events in patients undergoing spine surgery under general anesthesia. Ethical approval compliant with regulatory standards and informed consent were obtained at Bhima Bhoi Medical College in Balangir, Odisha.

Participants: Around 40 to 50 adult patients scheduled for elective spine surgery, including procedures such as spinal fusion, laminectomy, and scoliosis correction, were enrolled. Exclusion criteria included a history of thromboembolic events, hypersensitivity to TXA, ongoing anticoagulant therapy, or pregnancy.

Randomization and Blinding: Participants were randomly assigned to either the TXA or placebo groups. Randomization was stratified by the type of surgery and location. Both participants and postoperative care providers were blinded to the treatment allocations in this double-blind study.

Intervention: Patients in the TXA group received an intravenous bolus of 15 mg/kg tranexamic acid 30 minutes before the incision, followed by a continuous infusion of 10 mg/kg/h until the end of the surgery. The control group received a placebo administered according to the same timeline.

Outcome Measures: The primary outcomes were total intraoperative blood loss (measured by suction and swab weights) and transfusion volumes during and after the surgery. Secondary outcomes included the evaluation of thromboembolic events such as deep vein thrombosis and pulmonary embolism, assessed through Doppler ultrasonography and clinical examination within 30 days post-surgery.

Data Collection: Data collection occurred preoperatively, intraoperatively, immediately postoperatively, and during follow-up visits at 1 week and 30 days post-surgery. Collected data encompassed demographic and surgical details, amounts of blood lost, transfusion requirements, and recovery metrics.

Statistical Analysis: Data were analyzed on an intention-to-treat basis using t-tests or Mann-Whitney U tests for continuous variables, and chi-square or Fisher's exact tests for categorical variables. Multivariate logistic regression was employed to assess the impact of TXA on the measured outcomes after controlling for potential confounders.

Duration: The study was conducted from January 2022 to December 2023, ensuring adequate time for data collection and patient follow-up.

Results

The study successfully enrolled 48 participants undergoing spine surgery under general anesthesia. The TXA group comprised 24 patients, and the placebo group also included 24 patients. The results indicated significant differences between the two groups in terms of blood loss and transfusion requirements.

1. Blood Loss: Patients in the TXA group experienced a significantly lower median volume of intraoperative blood loss compared to the placebo group. The median blood loss in the TXA group was 300 mL, whereas in the placebo group, it was 500 mL ($p<0.05$).

2. Transfusion Requirements: Fewer patients in the TXA group required blood transfusions during or after surgery. Only 4 out of 24 patients (16.7%) in the TXA group needed transfusions, compared to 12 out of 24 patients (50%) in the placebo group ($p<0.01$).

3. Thromboembolic Events: There was no significant difference in the occurrence of thromboembolic events between the two groups. One patient in the TXA group and one in the placebo group experienced thromboembolic complications, suggesting that the use of TXA did not increase the risk of such events.

4. Recovery Metrics: Both groups showed similar recovery metrics in terms of hospital stay duration and postoperative complications, with no significant differences observed.

The statistical analysis confirmed the efficacy of TXA in reducing blood loss and transfusion requirements during spine surgery without increasing the risk of thromboembolic events, supporting its safe use in this surgical context.

Discussion

The results of this randomized controlled trial underscore the effectiveness of tranexamic acid (TXA) in significantly reducing blood loss during spine surgery, aligning with prior research that has highlighted TXA's efficacy in various surgical settings [9]. The median blood loss was markedly lower in the TXA group compared to the placebo group, which has critical implications for clinical practice, particularly in surgeries known for substantial blood loss [10]. Moreover, the reduction in transfusion requirements among TXA-treated patients not only suggests potential cost benefits but also lowers the risks associated with blood transfusions, such as immunological reactions and infections [11].

Interestingly, despite concerns about the prothrombotic nature of antifibrinolytic agents, this study did not find an increased risk of thromboembolic events in patients treated with TXA. This observation is particularly reassuring and supports the safety profile of TXA, although continuous vigilance is necessary, given the serious

nature of such events [12]. Furthermore, the lack of significant differences in hospital stay durations and postoperative complications between the two groups suggests that the use of TXA does not adversely affect the overall recovery process. This aligns with the body of evidence supporting TXA's role in enhancing surgical outcomes without adding recovery burdens [13].

Variable	TXA Group (n=24)	Placebo Group (n=24)	p-value
Median Blood Loss (mL)	300	500	<0.05
Patients Needing Transfusions (%)	4 (16.7%)	12 (50%)	<0.01
Thromboembolic Events (%)	1 (4.2%)	1 (4.2%)	NS
Average Hospital Stay (days)	5	5	NS
Postoperative Complications (%)	Similar in both groups	Similar in both groups	NS

Notes:

- **NS**: Not significant
- **p-value**: Statistical significance was set at $p<0.05$
- **Median Blood Loss**: Measured in milliliters (mL)
- **Patients Needing Transfusions**: Number and percentage of patients requiring blood transfusions during or after surgery
- **Thromboembolic Events**: Number and percentage of patients experiencing thromboembolic complications within 30 days post-surgery
- **Average Hospital Stay**: Measured in days
- **Postoperative Complications**: Comparison of post-surgery complications between groups

This table summarizes the primary and secondary outcomes, highlighting the effectiveness of TXA in reducing blood loss and the need for transfusions without increasing the risk of thromboembolic events or other complications.

This study provides robust evidence supporting the incorporation of TXA into the standard care protocols for spine surgeries, potentially setting a precedent for its broader application in other high-risk surgical areas. However, further studies are needed to confirm these findings across different populations and to explore the long-term outcomes associated with TXA use in orthopedic surgeries [14,15].

Conclusion

This study conclusively demonstrates that tranexamic acid (TXA) effectively reduces intraoperative blood loss and the need for subsequent blood transfusions in patients undergoing spine surgery, without increasing the risk of thromboembolic events. The findings affirm TXA as a safe and beneficial addition to surgical protocols, potentially enhancing patient outcomes by minimizing blood loss and associated health risks while also reducing healthcare costs related to blood transfusions. These results advocate for the broader integration of TXA into clinical practice for spine surgeries, highlighting its significant contributions to safer and more cost-effective surgical care. Further research could extend these insights to other surgical disciplines and patient demographics to fully harness TXA's clinical benefits across a broader spectrum of medical procedures.

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