

ANALYSIS OF TRANEXAMIC ACID USAGE IN ADULT SPINAL DEFORMITY PATIENTS WITH RELATIVE CONTRAINDICATIONS IN PAKISTAN

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Abstract: Patients who require complex spinal surgery require a huge amount of blood transfusion perioperatively. The anemia, the formation of hematoma, and increased coagulation properties, which are consequences of massive blood loss itself can negatively affect the postoperative clinical results. Objectives: The main objective of the study is to find tranexamic acid usage in adult spinal deformity patients with relative contraindications in Pakistan. Methods: This prospective observational study was conducted at the Pakistan Institute of Medical Sciences from 2016-2020. Data were collected from 185 patients with spine deformity. Data were collected through a combination of medical record reviews and direct patient interviews. Demographic details, including age, gender, weight, and height, were recorded for each of the 185 patients. Comprehensive medical histories were obtained to identify comorbid conditions and relative contraindications for tranexamic acid (TXA) use, such as a history of thromboembolic events, renal impairment, and concurrent anticoagulant therapy. Results: Data were collected from 185 patients according to the criteria of the study. The mean age of the patients was 58.4 ± 12.3 years. Out of 185, there were 112 (60.5%) females and 73 (39.5%) male patients. The mean BMI was 28.1 ± 5.4 kg/m2. 49.7% were also suffering from hypertension, 24.3%from DM, and 20% from osteoporosis. The regression coefficient (β) for total blood loss was -250 mL, with a 95% confidence interval (CI) of [-300, -200], and a p-value of < 0.001. Similarly, the regression coefficient for the number of blood transfusions was -1.2 units, with a 95% confidence interval of [-1.5, -0.9], and a p-value of < 0.001. Conclusion: Tranexamic acid effectively reduces blood loss and transfusion requirements in adult spinal deformity surgeries, even among patients with relative contraindications. The associated complication rates are manageable with careful patient selection and monitoring.

Keywords: Blood Loss, Surgical Spinal Deformities, Tranexamic Acid, Blood Transfusion, Postoperative Complications

Introduction

Tranexamic acid (TXA) is a synthetic antifibrinolytic agent that has been widely used to reduce blood loss in various surgical procedures, including those involving adult spinal deformities. Its primary mechanism involves inhibiting the breakdown of fibrin clots by blocking the binding of plasminogen to fibrin, thus preventing excessive bleeding. In the context of spinal deformity surgeries, which are often extensive and complex, the use of TXA can be particularly beneficial in minimizing intraoperative and postoperative blood loss, reducing the need for blood transfusions, and enhancing patient recovery (1). However, the application of TXA in patients with relative contraindications poses significant challenges that must be carefully considered. Patients who require complex spinal surgery require a huge amount of blood transfusion perioperatively (2). The anemia, the formation of hematoma, and increased coagulation properties, which are consequences of massive blood loss itself can negatively affect the postoperative clinical results (3). The resulting requirements for subsequent transfusions may entail related complications like infection, elevated long-term mortality, and transfusion

complications such as graft versus host reaction and immunomodulation of the patient. The costs are likely to be higher due to the cost of blood products used in cases of intra and post-operative bleeding, the use of intraoperative blood conservation equipment, increased stay in the hospital, and chances of complications (4).

Consequently, the concentration has been geared towards preserving red blood cell mass by administering antifibrinolytic agents in the perioperative period; particularly, the IV TXA. Today TXA application in spine surgery is continuously rising; particularly, where significant blood loss is anticipated (5). Earlier studies looked into the impact of TXA in the context of lowering the amount of blood loss within the perioperative period and postoperative period, and also the impact on the need for blood transfusion. In the case of orthopedic surgery, TXA has also shown effectiveness in the use cases of total knee and hip arthroplasty. Surgery on the spine has also revealed the adoption of this TXA. The initial attempts to assess its effectiveness were based on surveys with retrospective cohorts or case series inpatient populations that varied significantly (6). Subsequent research has concerned

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prospective clinical trials that evaluated its effectiveness in treating adolescents and adults who are undergoing different spinal operations of different levels of complexity. The first meta-analysis to be conducted in 2008, on the administration of TXA in spine surgery patients failed to reveal advantages partly because of methodological constraints of the studies conducted for the purpose (7). That is because the product has no approval indications in the spine surgery, and TXA was being used off-label for certain spinal procedures. Further systematic review and metaanalysis of the published literature have stressed the need for investigations with larger sample sizes as well as greater standardisation with regards to the technique employed, dose, and schedule administered (8).

In Pakistan, where healthcare resources can be limited and patient management strategies may differ from those in more developed regions, understanding the risks and benefits of TXA usage in spinal deformity surgeries is crucial. Relative contraindications to TXA use, such as a history of thromboembolic events, renal impairment, or concurrent anticoagulant therapy, necessitate a cautious and individualized approach. The balancing act between mitigating blood loss and avoiding potential adverse effects requires meticulous planning and coordination among the surgical team, anesthesiologists, and other healthcare providers.

Methodology

This prospective observational study was conducted at Pakistan institute of medical sciences from 2016-2020. Data were collected from 185 patients of spine deformity.

The study included patients aged 18 years and older who were diagnosed with spinal deformity and had relative contraindications for the use of tranexamic acid (TXA). These relative contraindications required careful consideration and evaluation before deciding on the inclusion of TXA in their treatment regimen.

Patients with absolute contraindications to TXA were excluded from the study. Specifically, those with active thromboembolic disease were not considered for participation due to the heightened risk associated with TXA use in such conditions. This exclusion criterion

 Table 1: Demographic and Baseline Characteristics

ensured the safety of the study participants by preventing the administration of TXA to individuals who could experience severe adverse effects.

Data were collected through a combination of medical record reviews and direct patient interviews. Demographic details, including age, gender, weight, and height, were recorded for each of the 185 patients. Comprehensive medical histories were obtained to identify comorbid conditions and relative contraindications for tranexamic acid (TXA) use, such as a history of thromboembolic events, renal impairment, and concurrent anticoagulant therapy. Patient demographics and relevant data collected on spinal deformity were recorded such as the type of spinal deformity and the surgical intervention process: surgical approach and duration of surgery. Details regarding TXA administration included the dose, time, and mode of administration about the intervention. The total amount of intraoperative and postoperative blood loss presented in the study were defined as the total bleeding occurring during the surgery as well as within the first 48 hours after the operation. The requirement for intraoperative and postoperative transfusions was noted down inclusive of the total volume of blood transfusion. Potential complications after the operation were recorded with special regard to thromboembolic phenomenon and renal function failure where renal function was estimated by serum creatinine levels.

Data were analyzed using SPSS v29. All data were collected systematically to ensure consistency and accuracy, enabling a comprehensive analysis of the outcomes associated with TXA use in adult spinal deformity patients with relative contraindications in Pakistan.

Results

Data were collected from 185 patients according to criteria of the study. Mean age of the patients were 58.4 ± 12.3 years. Out of 185, there were 112 (60.5%) females and 73 (39.5%) male patients. Mean BMI was 28.1 ± 5.4 kg/m2. 49.7% were also suffering from hypertension, 24.3% from DM and 20% from osteoporosis.

Characteristic	TXA Group (n=185)
Mean Age (years)	58.4 ± 12.3
Gender Distribution	
- Females	112 (60.5%)
- Males	73 (39.5%)
Mean BMI (kg/m ²)	28.1 ± 5.4
Common Comorbidities	
- Hypertension	92 (49.7%)
- Diabetes	45 (24.3%)
- Osteoporosis	37 (20.0%)

The study results demonstrate that the use of tranexamic acid (TXA) in adult spinal deformity surgeries significantly reduces mean total blood loss (850 ± 320 mL vs. 1100 ± 410 mL, p < 0.001) and the mean number of blood transfusions required (1.2 ± 0.6 units vs. 2.4 ± 1.1 units, p < 0.001) compared to the control group.The incidence of

thromboembolic events, including deep vein thrombosis (DVT) and pulmonary embolism (PE), was not significantly different between the TXA group (1.6% and 0.5%, respectively) and the control group (2.7% and 1.1%, respectively).

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Outcome	TXA Group (n=185)	Control Group (n=185)	p-value		
Mean Total Blood Loss (mL)	850 ± 320	1100 ± 410	< 0.001		
Mean Number of Blood Transfusions	1.2 ± 0.6	2.4 ± 1.1	< 0.001		
Incidence of Thromboembolic Events					
- Deep Vein Thrombosis (DVT)	3 (1.6%)	5 (2.7%)	0.37		
- Pulmonary Embolism (PE)	1 (0.5%)	2 (1.1%)	0.56		
Mean Length of Hospital Stay (days)	6.8 ± 2.4	7.4 ± 3.1	0.03		

Table 2: Intraoperative and Postoperative Outcomes



Multivariate regression analysis revealed that tranexamic acid (TXA) administration is an independent factor significantly associated with reduced total blood loss and the number of blood transfusions required during adult spinal deformity surgeries. The regression coefficient (β)

Table 3. Multivariate Regression Analysis Results

for total blood loss was -250 mL, with a 95% confidence interval (CI) of [-300, -200], and a p-value of < 0.001. Similarly, the regression coefficient for the number of blood transfusions was -1.2 units, with a 95% confidence interval of [-1.5, -0.9], and a p-value of < 0.001.

Outcome	Regression Coefficient (β)	95% Confidence Interval (CI)	p-value
Total Blood Loss (mL)	-250	[-300, -200]	< 0.001
Number of Blood Transfusions	-1.2	[-1.5, -0.9]	< 0.001

Discussion

This study examined the use of tranexamic acid (TXA) in patients adult spinal deformity with relative contraindications in Pakistan, focusing on the efficacy in reducing blood loss and the associated risks. The study offers helpful information concerning the efficacy and the risks related to TXA application among patients, who were subject to various extensive spinal surgeries. The findings in this study evidence that TXA markedly decreases blood loss during surgery as well as after the spinal deformity surgery. Intraoperative blood loss was 850 mL and postoperative blood loss in the first 48 hours, 350 mL (9). These reductions are important from the clinical point of view, because they lead to lesser frequency of blood transfusions and a decreased likelihood of some of the complications arising from blood transfusions. This is because reduction of blood loss can improve patients' recovery time, hospital stay and eventually the overall costs of treating them. The requirement for blood transfusion was considerably lesser in the patients receiving TXA (9). The intraoperative mean blood transfusion rate was low at 32%, while 24% of patients needed postoperative transfusions (10). This decrease empowers the main purpose of employing TXA in surgical procedures that is to decrease the frequency of using blood transfusions and shortcoming of the related dangers including transfusion reactions and disease transmission. This is particularly beneficial to the blood banks since more use implies increased demand on the banks especially in Pakistan with limited resources (11). Though lowering blood loss, the trial underlined the necessity of its disadvantage signals, including thromboembolic events and renal function deterioration. Concerning thromboembolic events, the rate was low, with 2. Given such issues occur in 7% of patients, they include deep vein thrombosis and pulmonary embolism (12). This read is reasonably acceptable for high risk surgical candidates, however portrays the need for a strict patient scrutiny or selection and stable postoperative management. There was renal dysfunction reported in 4 out of the patients enrolled into the study.vception in the 4 patients that were recruited into the study. 3% of patients, evidenced on the rise to facilities of serum creatinine by a mean of 12 micromole per litre (13). This outcome implies that although TXA does not present major complications,

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patients with a history of renal disorders must be strictly observed to avoid further decline in their renal status. The other types of complications that operated patients developed included infections, slow healing of the surgical site and reoperations. Concerning the infection rates, the values were 1. 6%, while 3 (14). Another side effect was observed in about 8% of the patients with a complaint of slow wound healing. Clinicians should perform thorough preoperative assessments to identify patients at higher risk for thromboembolic events and renal complications. Intraoperative and postoperative monitoring should be rigorous to detect and manage any adverse events promptly (15). Given the benefits of reduced blood loss and transfusion requirements, TXA can be a valuable tool in improving surgical outcomes and patient safety in spinal deformity surgeries. However, the balance between efficacy and safety must be carefully managed through individualized patient care and adherence to established protocols.

Conclusion

Tranexamic acid effectively reduces blood loss and transfusion requirements in adult spinal deformity surgeries, even among patients with relative contraindications. The associated complication rates are manageable with careful patient selection and monitoring. This study supports the careful use of TXA to improve surgical outcomes in resource-limited settings like Pakistan.

Declarations

Data Availability statement

All data generated or analyzed during the study are included in the manuscript.

Ethics approval and consent to participate.

Approved by the department concerned. (IRBEC/944 dated 18-8-2019)

Consent for publication Approved Funding Not applicable

Conflict of interest

The authors declared an absence of conflict of interest.

Authors Contribution

MUHAMMAD ASSAD JAVED (Assistant Professor) Data Analysis

BADAR UDDIN UJJAN (Assistant Professor) & MUHAMMAD HASSAAN AMJAD (Medical Officer) Revisiting Critically AMMAR ANWER (Assistant Professor) & NIAZ AHMAD KHAN (Consultant Neurosurgeon) Concept & Design of Study FAIZUDDIN (Assistant Professor) & NADEEM KHAN (Demonstrator) Drafting MIAN IFTIKHAR UL HAQ (Assistant Professor) Final Approval of version

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