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Orthopaedics Section

Effectiveness of Tranexamic Acid to Prevent Blood Loss in Patients undergoing Hip Arthroplasty: A Randomised Controlled Study

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ABSTRACT

Introduction: The safe and efficient Intravenous (i.v.) administration of Tranexamic Acid (TXA) has been shown to reduce blood loss and transfusion requirements following total hip replacement. However, its effectiveness in hip arthroplasty for femoral neck fractures remains a subject of debate to date.

Aim: To evaluate the effects of TXA in patients undergoing hip arthroplasty to prevent blood loss.

Materials and Methods: The present prospective, double-blinded, randomised controlled study was conducted in in the Department of Orthopaedics, SRM Medical College Hospital and Research Institute (a tertiary care facility), Chengalpattu, Tamil Nadu, India, between August 2023 and January 2024. Study involved 138 participants with hip fractures classified into a TXA group (group A) and a placebo group (group B). The selected participants were monitored for blood loss, haemoglobin levels and blood transfusion volume. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) software version 21.0, with t-tests and chi-square tests employed to compare participant characteristics.

Results: In the present study, 69 of the 138 individuals received TXA in the interventional group, while 69 received a placebo in the control group. The mean±Standard Deviation (SD) age was 44.6±17.6 years in the interventional group and 48.5±16.4 years in the control group. Postoperatively, the interventional group exhibited a smaller decline in haemoglobin levels (12 g/dL vs. 11.0 g/dL). TXA significantly reduced transfusion volume (p-value <0.001). Additionally, blood loss was lower in patients receiving TXA (p-value <0.001).

Conclusion: Treatment for hip fractures with TXA showed a tendency towards reduced blood loss and transfusions, as well as, a shortened total duration of surgery among the study participants. This indicates that TXA is safe and efficient in minimising blood loss during surgery.

Keywords: Blood transfusion, Hip replacement surgery, Neck of femur fracture

INTRODUCTION

The population's average life expectancy in India has been rising over time, leading to an increase in the number of elderly people [1]. This, in turn, has resulted in a rise in unintentional falls and hip fractures [2]. Approximately 40,000 hip arthroplasties are performed annually in India, which equates to 120 per lakh of the population. An estimated 6.3 million hip fractures are predicted to occur annually by the year 2050 [3]. Hip fractures are known to have a high mortality rate and can significantly diminish independence for many affected individuals. For instance, the fracture causes 18% of those affected to restrict their movements and stay at home, while 24% of them pass away within a year [4].

Rapid mobilisation is the primary objective of contemporary surgical treatment approaches, as it lowers complications and increases long-term survival. When an osteosynthetic treatment technique is used for displaced femoral neck fractures, there is a higher chance of femoral head necrosis [5]. For this reason, endoprosthetic approaches are recommended, especially for older patients. The healthcare system is heavily burdened because the majority of these injuries require surgical intervention [6]. In addition to blood loss following surgery, hip fractures are frequently associated with a significant amount of blood loss from the initial injury [7]. After surgery, 20-60% of patients require blood transfusions, which can lead to an increase in postoperative infections, extended hospital stays and potentially higher treatment costs [8].

Postoperative anaemia following hip fracture surgery is associated with various potential side-effects, ranging from mild to severe, including worsened functional recovery and an increased risk of death [9]. If perioperative anaemia prevention measures were implemented, these risks might be mitigated. Transfusions of allogenic blood are costly and carry associated risks. Consequently, a wide range of blood conservation techniques have been studied, such as controlled hypotension, perioperative blood salvage, preoperative blood donation and the use of pharmaceutical agents [10]. Numerous pharmacological techniques are currently being investigated. Although agents that prevent bleeding during surgeries, like epsilon-aminocaproic acid and recombinant human erythropoietin, have demonstrated efficacy [11], their high cost and limited ability to reduce out-of-pocket expenditures in orthopaedic surgery have restricted their use.

The plasminogen-binding antifibrinolytic drug TXA competitively blocks lysine binding sites by interacting with plasminogen. As a result, plasmin-induced fibrinolysis and clot disintegration are inhibited and plasminogen-fibrin interaction is prevented [12]. When surgically damaged tissues produce tissue plasminogen activator and initiate the fibrinolytic system, TXA can begin to work. It is particularly effective in halting microvascular haemorrhage, which poses a significant risk during orthopaedic procedures [13]. Although TXA is being used increasingly frequently to reduce blood loss in elective orthopaedic surgeries involving the hip, there is currently insufficient information regarding its optimal application in

hip fracture repair. The use of TXA can minimise blood loss and reduce the need for postoperative blood transfusions [14].

With this knowledge, a prospective randomised controlled trial was planned with the hypothesis that the administration of i.v. TXA during the perioperative period will result in decreased bleeding in both the intraoperative and postoperative periods, as well as, decreased transfusion rates among participants undergoing arthroplasty for neck of femur fractures. The present study aimed to measure outcomes in terms of blood loss after the administration of i.v. TXA in patients undergoing hip arthroplasty for a fractured neck of the femur.

MATERIALS AND METHODS

The present prospective double-blinded randomised controlled study was carried out in the Department of Orthopaedics, SRM Medical College Hospital and Research Institute (a tertiary care) facility, Chengalpattu, Tamil Nadu, India, from August 2023 to January 2024. The study was initiated after obtaining Institutional Ethical Clearance from the study Institute (Reg. No: EC/NEW/INST/2022/2933 and Ethics Clearance Number: SRMIEC-ST0823-1417). Informed consent was obtained from all the participants and they were assured of confidentiality throughout the study.

Inclusion criteria: The study included all patients aged 18 years or older with a fracture of the neck of the femur requiring hemiarthroplasty or total hip arthroplasty. Each patient underwent a coagulation profile assessment and baseline investigations and only those with haemoglobin levels exceeding 9 g/dL were included.

Exclusion criteria: Patients were excluded from enrollment if they had a creatinine clearance below 30 mL/min, a history of unprovoked or recurrent deep vein thrombosis or pulmonary embolism, a recent cardiovascular or cerebrovascular event within the past 30 days, coronary stent implantation for coronary artery disease within the last six months, hypercoagulable conditions, subarachnoid haemorrhage, pregnancy, or active breastfeeding [15].

Sample size calculation: The sample size was calculated using the formula for two proportions with alpha and beta set at 95% and 80%, respectively. The blood transfusion requirements in the interventional group and control group were assumed to be 8.4% and 31.7%, based on the study by Powell-Bowns MF et al., [16]. The final sample size, accounting for a 1.5% design effect and a 10% non response rate, was determined to be 138 [17].

Study Procedure

Patients were randomised into two groups using computer-generated randomisation lists and permuted blocks of randomly mixed sizes. Randomisation was stratified based on the type of operation the participants were scheduled to undergo. The study employed a double-blind design, with patients assigned to receive one of two i.v. treatments:

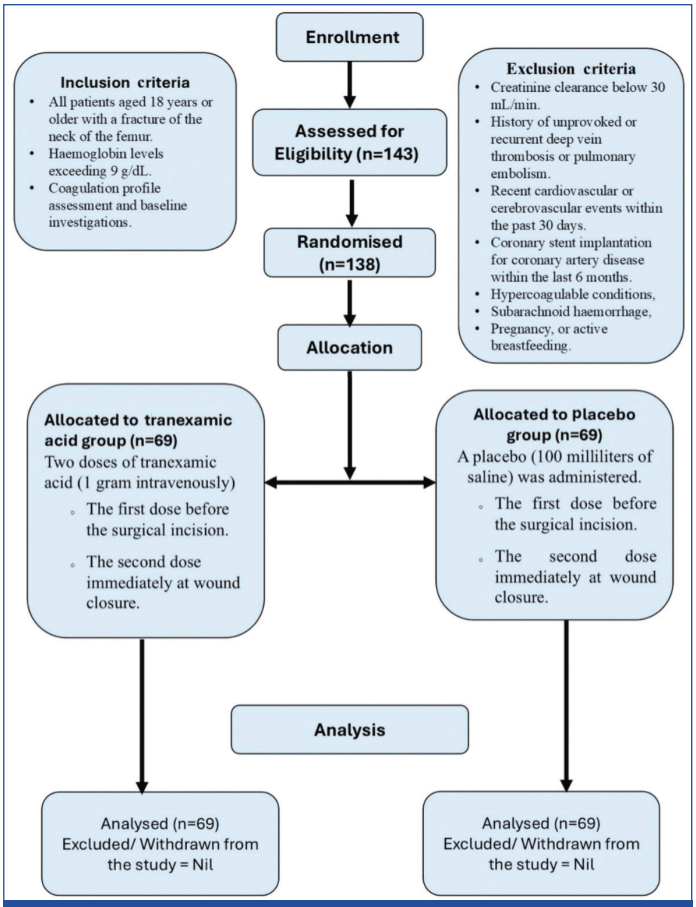
Intervention group/group A: Two doses of TXA (1 gram intravenously), administered as follows [18]:

- The first dose before the surgical incision;
- The second dose immediately at wound closure.

Control group/group B: A placebo (100 millilitres of saline) administered at the same time intervals as the intervention group [Table/Fig-1] [19].

To maintain blinding, a designated staff member prepared the i.v. solutions outside the Orthopaedic Department and delivered them directly to the anaesthesiologist in the operating room. Identical saline drips ensured masking before the procedure. Neither the patient caretakers, data collectors, nor the safety monitoring team were informed of the group assignments.

Monitoring and assessments: The selected participants were monitored for:



[Table/Fig-1]: Study's Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

- **Intraoperative and postoperative blood loss:** The total volume of blood loss for the participants was measured as a whole and no separate measurement for blood loss during and after surgery was monitored.
- **Haemoglobin levels:** Preoperative haemoglobin levels were monitored, recorded and followed by measurements on Postoperative Days (POD) 1, 2 and 3.
- **Blood transfusions:** The total volume of blood transfusions administered in millilitres during the study period was documented.

Calculation of blood loss: Blood loss was calculated using the standard assessment based on the size and number of gauze pads soaked during surgery and the calculations [20].

Calculation of blood volume in participants:

Blood Volume (BV) (mL)=Z_1×{Height (Ht) in m}^{3}+Z_2×(Weight in kg)+Z_3

Z_1=0.366, Z_2=0.032, Z_3=0.604 for men.

Z_1=0.356, Z_2=0.033, Z_3=0.183 for women.

Estimation of the blood loss among participants:

EBL=BV×(Ht_0-Ht_1)×(3-Ht mean)

Ht_0=Preoperative haematocrit

Ht_1=Lowest haematocrit (1st, 2nd or 3rd POD)

Ht_{mean}=Average between the initial and final haematocrits.

Estimation of the total blood loss:

Total Blodd Loss (TBL)=Estimated Blod Loss (EBL)+Transfusion volume (Tv)

Tv=Transfusion volume {each packed Red Blood Cell (RBC) unit contains 300 mL}.

STATISTICAL ANALYSIS

Statistical analysis was performed using the SPSS software version 21.0. Continuous and categorical variables were analysed

appropriately, with categorical variables summarised as proportions. Normality was assessed using P-P and Q-Q plots. Blood loss (measured in millilitres) was reported as the mean and Standard Error (SE). Comparisons of participant characteristics between the TXA group and the control group were conducted using the independent Student's t-test and the Chi-square test.

RESULTS

The study included 138 participants divided into two groups: group A (TXA) and group B (control). The participants' mean±SD age in group A was 44.6±17.6 years, while in group B it was 48.5±16 years (p-value=0.174). In group A, 49 (71.1%) were males, compared to 41 (59.4%) in group B [Table/Fig-2]. There were no statistically significant differences in baseline characteristics, preoperative haemoglobin, haematocrit, or mean International Normalised Ratio (INR) between the groups (p>0.05), indicating comparability. Preoperative antiplatelet therapy was given to 23 (33.3%) of group A and 19 (27.5%) of group B participants [Table/Fig-3].

Demographic and baseline characteristics		Group A	Group B	t-test/Chi-square value	p-value
Age (years) (Mean±SD)		44.6±17.6	48.5±16.4	-1.366	0.174
Gender	Male	49 (71.1%)	41 (59.4%)	2.044	0.152
	Female	20 (28.9%)	28 (40.6%)		
BMI (kg/m^2) (Mean±SD)		22.6±3.7	23.5±3.9	-1.441	0.152

[Table/Fig-2]: Demographic and baseline characteristics of the participants (N=138).

Postoperative day	Group A	Group B	t-value	p-value
Haemoglobin (gm/dL) (Mean±SD)				
Day 1	12±1.2	11±0.6	6.192	<0.001*
Day 2	10.4±0.9	10.1±0.6	2.886	0.005*
Day 3	10.3±0.9	10±0.6	2.204	0.029*
Haematocrit (%) (Mean±SD)				
Day 1	32.6±1.7	32.2±1.6	1.365	0.175
Day 2	36.2±1.7	35.9±1.5	0.849	0.397
Day 3	37.4±2.2	36.3±2.3	2.758	0.007*

[Table/Fig-3]: Comparison of haemoglobin and haematocrit levels between groups postoperatively (N=138).
*The p-value <0.05 was considered statistically significant

The postoperative haemoglobin and haematocrit levels has been presented in [Table/Fig-4]. The mean haemoglobin levels decreased from the preoperative period to the POD 3. The haemoglobin levels were significantly higher in group A compared to group B on POD 1, 2 and 3, with p-values of <0.001, 0.005 and 0.029, respectively. Similarly, haematocrit levels decreased from the preoperative period to POD 3. The haematocrit levels were also significantly higher in group A compared to group B on POD 3, with p-value=0.007. However, the haematocrit levels for both groups remained similar on POD 1 and POD 2, with the differences not being statistically significant on these days, as indicated by p-values of 0.175 and 0.397 respectively.

Variables	Group A	Group B	Chi-square value/ t-value	p-value
Factors (Mean±SD)				
Preoperative haemoglobin (gm/dL)	11.5±1.4	11.2±1.5	1.23	0.221
Preoperative haematocrit (%)	41.3±2.3	41.5±2.5	-0.498	0.62
INR	0.81±0.2	0.87±0.3	0.241	0.81
Length of surgery in hours	1.6±0.3	1.8±0.2	-5.045	<0.001*
Length of anaesthesia in hours	2.1±0.3	2.3±0.41	3.270	0.001
Intraoperative blood loss in mL	395.5±59.7	490.7±59.4	-9.387	<0.001*
Procedure, n (%)				
Hemiarthroplasty	53 (76.8%)	54 (78.3%)	0.042	0.838
Total hip arthroplasty	16 (23.2%)	15 (21.5%)		
Preoperative antiplatelet, n (%)				
No	46 (66.7%)	50 (72.5%)	0.548	0.459
Yes	23 (33.3%)	19 (27.5%)		

[Table/Fig-4]: Comparison of haematology parameters, surgical procedures and anaesthesia duration of participants (N=138).

Group A had a significantly shorter hospital stay (7±1.7 days) compared to group B (9±1.8 days) (p-value <0.05) [Table/Fig-5]. Additionally, group A experienced significantly lower total volume of blood loss (495.9±61.9 mL vs 547.1±64 mL) and required less total volume of blood transfusion (461.8±88.8 mL vs 525.9±82.5 mL) than Group B, with all differences being statistically significant (p-value <0.05) [Table/Fig-6].

Parameter	Group A	Group B	t-value	p-value
Length of hospital stay (days)	7±1.7	9±1.8	-4.686	<0.001*

[Table/Fig-5]: Comparison of length of stay in participants (N=138).

Variables	Group A (in mL)	Group B (in mL)	t-value	p-value
Blood transfusion volume	461.8±88.8	525.9±82.5	-4.389	<0.001*
Total volume of blood loss	495.9±61.9	547.1±64	-4.772	<0.001*

[Table/Fig-6]: Comparison of blood loss and transfusion between groups (mL) (N=138).

DISCUSSION

The present study aimed to evaluate the efficacy of TXA in reducing blood loss and postoperative blood transfusion requirements during total or hemiarthroplasty for hip fractures. To ensure comparability, both groups comprised patients with similar baseline characteristics. Participants in the TXA group received two doses of TXA: one during the perioperative period and another immediately postoperatively. In contrast, the control group received a placebo at the same time points.

The findings indicate that administering one gram of TXA both perioperatively and postoperatively effectively reduced drops in haemoglobin levels, minimised blood loss and decreased the need for postoperative blood transfusions. Observations on POD 1, 2 and 3 showed that the reduction in haematocrit levels was comparable between the groups on days 1 and 2. However, on day 3, the TXA group exhibited a significantly higher haematocrit compared to the control group.

All study participants received a standard dose of 1 gram of TXA during the perioperative and postoperative periods [4]. This dose, equivalent to approximately 20-25 mg/kg, promotes plasmin formation and inhibits clot breakdown through its antifibrinolytic activity [16,21,22]. In contrast, lower doses (10-15 mg/kg) may increase the risk of bleeding due to their reduced capacity to inhibit the conversion of plasminogen to plasmin [22-24]. Therefore, the higher standard dose of TXA is an effective intervention to prevent bleeding in most surgeries and can be reliably used during total or hemiarthroplasty for hip fractures [13].

The findings of the present study align with previous research demonstrating the effectiveness of perioperative and postoperative i.v. TXA in reducing blood loss during and after total or hemiarthroplasty for hip fractures [23-26]. However, some studies have reported contradictory results regarding the use of TXA in other procedures, such as dynamic hip screw fixation and proximal femoral nailing [16,27,28]. These variations may be attributed to differences in the type of surgery, as most studies have focussed on specific procedures or surgical techniques [28,29]. Additionally, several trials have highlighted TXA as a highly cost-effective intervention for minimising blood loss, thereby reducing the financial burden on patients [16,17].

The current study also emphasised that the perioperative and postoperative administration of TXA significantly reduced the need for blood transfusions in patients undergoing total or hemiarthroplasty for hip fractures. This finding aligns with the majority of studies, which suggest that TXA's ability to minimise bleeding from small vessels underpins its efficacy [16,29-31]. The standard dose promotes the conversion of plasminogen to plasmin, enhancing its antifibrinolytic activity [30,31]. This mechanism effectively prevents microvascular bleeding, reducing blood loss and the subsequent need for transfusions. As a result, haemoglobin and haematocrit levels were better preserved in the postoperative period [32,33]. These findings support the conclusion that TXA is a reliable intervention for reducing blood loss in hip fracture surgeries and may be broadly applicable to all types of hip fractures.

Limitation(s)

The current study involved patients with hip fractures from a single setting. It did not evaluate intraoperative and postoperative blood loss as separate entities. Additionally, the long-term side-effects of the management and outcomes were not assessed, as the focus was primarily on the effect of TXA in preventing blood loss.

CONCLUSION(S)

The present double-blinded randomised controlled study demonstrated that the perioperative and postoperative administration of TXA in patients with a fractured neck of the femur managed by total or hemiarthroplasty resulted in significantly less blood loss during the perioperative and postoperative periods. Additionally, the need for blood transfusions was significantly reduced when compared to those who did not receive TXA. Furthermore, there was no evidence of complications during the follow-up period. Hence, it can be concluded that i.v. TXA promises a safe and effective way to reduce operational blood loss and should be recommended for routine use during hip replacement surgeries.

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