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Original Research Article

COMPARISON OF SINGLE INTRAVENOUS BOLUS AND PERIOPERATIVE CONTINUOUS INFUSION OF TRANEXAMIC ACID ON BLOOD LOSS IN LOWER LIMB ORTHOPEDIC SURGERY: A RANDOMIZED DOUBLE-BLIND STUDY

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ABSTRACT

Background: Tranexamic acid (TXA) is widely used to reduce perioperative blood loss in orthopedic surgery. However, the optimal intravenous dosing regimen remains uncertain. This study compared the effectiveness of a single intravenous bolus with a bolus followed by continuous perioperative infusion of TXA in reducing blood loss during lower-limb orthopedic surgery.

Materials and Methods: This prospective, randomized, double-blind study included 60 adult patients of American Society of Anesthesiologists physical status I–II undergoing elective lower-limb orthopedic surgery. Patients were randomly allocated into two groups of 30 each. Group B received TXA 10 mg/kg intravenously 10 minutes before surgical incision, followed by normal saline infusion for 4 hours. Group C received TXA 10 mg/kg intravenously 10 minutes before incision followed by continuous TXA infusion at 1 mg/kg/h for 4 hours. Intraoperative and postoperative blood loss were assessed at predefined time intervals. Hematocrit was measured at baseline, 6 hours, and 24 hours postoperatively. Blood transfusion requirements and adverse events were also recorded.

Results: Baseline demographic characteristics and duration of surgery were comparable between the groups. Mean intraoperative blood loss was significantly lower in Group C than Group B (180 ± 72.2 vs. 263 ± 11.38 mL; $p < 0.001$). Blood loss at 10 hours postoperatively was also significantly lower in Group C (41 ± 14.77 vs. 60 ± 18.9 mL; $p < 0.001$). No significant difference was observed at 6 hours ($p = 0.431$) or 24 hours ($p = 0.269$). Hematocrit was significantly higher in Group C at 6 hours (30 ± 1.2 vs. 29 ± 1.5%; $p = 0.006$) and 24 hours (28 ± 0.8 vs. 27 ± 1.5%; $p = 0.002$). Four patients in Group B and one in Group C required transfusion. No major adverse events were observed.

Conclusion: Continuous perioperative infusion of TXA following an initial bolus was associated with lower intraoperative and early postoperative blood loss and better preservation of hematocrit compared with a single bolus in lower-limb orthopedic surgery.

Keywords: Lower limb surgery, Orthopedic, Fracture, joint replacement, tranexamic acid, blood loss.

INTRODUCTION

Lower limb orthopedic surgeries are frequently associated with substantial perioperative blood loss, which may increase the need for allogeneic blood transfusion and contribute to postoperative morbidity, prolonged hospitalization, and increased healthcare costs. Procedures such as total knee arthroplasty, total hip arthroplasty, and major fracture fixation can result in significant visible and hidden

blood loss. Therefore, effective strategies for reducing perioperative bleeding while maintaining patient safety are an important component of modern orthopedic and anesthetic practice.[1-3]

Tranexamic acid (TXA), a synthetic lysine analogue, is an antifibrinolytic agent that reduces bleeding by competitively inhibiting the activation of plasminogen to plasmin and thereby stabilizing fibrin clots. Its use in orthopedic surgery has been associated with reduced perioperative blood loss and decreased requirements for blood transfusion. Because of its effectiveness, intravenous TXA has become an important blood-conservation strategy in major orthopedic procedures.[4,5]

Several dosing regimens of intravenous TXA have been described, including administration as a single preoperative or intraoperative bolus and administration as a bolus followed by a continuous perioperative infusion. A single bolus is simple, convenient, and requires minimal drug administration, whereas continuous infusion may provide sustained antifibrinolytic activity throughout the perioperative period. However, the optimal intravenous administration strategy remains uncertain, particularly regarding whether continuous infusion provides additional reduction in blood loss compared with a single bolus.[6,7]

Although previous studies have demonstrated the effectiveness of TXA in reducing blood loss during orthopedic surgery, evidence directly comparing different intravenous dosing strategies remains variable. Differences in surgical procedures, dosing protocols, timing of administration, and patient characteristics may contribute to these inconsistencies.[8] Establishing whether continuous perioperative infusion offers a clinically meaningful advantage over a single intravenous bolus could help optimize TXA use while avoiding unnecessary drug administration.[9,10]

Therefore, the present randomized double-blind study was designed to compare the effect of a single intravenous bolus of tranexamic acid with perioperative continuous infusion on perioperative blood loss in patients undergoing lower limb orthopedic surgery.

MATERIALS AND METHODS

A prospective, randomized, double-blind comparative study was conducted in an orthopedic center. A written informed consent was obtained from the participant. The study included 60 adult patients of either sex, classified as ASA physical status I or II, who were scheduled for elective lower-limb orthopedic procedures. Patients were excluded if they had a known bleeding or coagulation disorder, previous or active deep vein thrombosis or pulmonary embolism, a known hypersensitivity to tranexamic acid and patient on preoperative anticoagulant treatment. Patients receiving medications that could significantly affect perioperative bleeding were managed according to the hospital protocol. Patients fulfilling the eligibility criteria were allocated to one of the groups using a computer-generated randomization sequence.

Group B – Bolus group: Patients received tranexamic acid 10 mg/kg intravenously approximately 10 min before skin incision. This was followed by an intravenous infusion of normal saline through a syringe pump, continued until 5hr after surgery.

Group C – Continuous infusion group: Patients received tranexamic acid 10 mg/kg intravenously approximately 10 min before skin incision, followed by a continuous intravenous tranexamic acid infusion at 1 mg/kg/h through a syringe pump, maintained until 5hr after surgery.

The solutions for administration were prepared by an independent individual who was not involved in patient care, outcome assessment, or statistical analysis. The identity of the study medication was concealed from the anesthesiologist managing the patient and from the investigator responsible for recording perioperative observations. To preserve blinding, the study solutions were prepared in identical syringes and the total volume administered was standardized between the two groups.

Preoperative hemoglobin and hematocrit concentrations were measured and documented. All patients underwent a standardized anesthetic technique. All patient received combined spinal and epidural anesthesia as per the hospital protocol. The drug used for the spinal anesthesia was Inj Bupivacaine (Heavy, 0.5%) along with Inj Fentanyl 1mcg/kg in all patients. The epidural was secured for all the patients to prolong intraoperative anesthesia period or for the post-operative analgesia. The vitals are monitored and recorded accordingly, and the hypotension and bradycardia were treated with Inj Mephentermine in graded doses and Inj Atropine 0.6mg respectively. The primary outcome was perioperative blood loss. Total blood loss was estimated from the volume collected in the suction bottle (deduction of irrigated fluid was considered) and the weight of blood-soaked gauze pieces or pads. Hourly urine output was also recorded throughout the perioperative period. The duration of surgery, volume and type of intravenous fluids administered, and requirement for blood or blood-product transfusion were documented for every patient. Surgical duration was calculated from the time of skin incision until completion of wound closure.

The need for perioperative blood transfusion was determined using predefined criteria, taking into account the patient's preoperative hemoglobin concentration, estimated blood loss, hemodynamic status, and clinical condition. The decision to administer blood or blood products was made by the attending anesthesiologist according to these criteria. Postoperative blood loss was assessed from the surgical drain output, where drains were used, at predetermined intervals of 6, 10 and 24h after surgery. Hematocrit measurements were repeated at

6 and 24hr postoperatively. The total drain output and requirement for postoperative blood transfusion were recorded.

Patients were followed clinically throughout the postoperative period for adverse events potentially associated with tranexamic acid or any other complications. Patients received thromboprophylaxis according to the hospital protocol. Any clinically suspected thromboembolic event was investigated and documented appropriately.

Sample size calculation: Based on findings from previous similar studies, a mean difference of 225 mL in perioperative blood loss with a standard deviation of 200 mL was considered clinically relevant. Assuming an effect size of 0.54, a two-sided significance level of 5%, and 95% statistical power, the required sample size for comparison between two independent groups was calculated to be 48 participants (24 per group). Allowing for approximately 10% attrition or protocol deviations, the sample size was increased to 54 participants, with 27 patients allocated to each group. However, due to heavy patient load the sample size is rounded upto 30 per group.

RESULTS

Demographic data and the mean duration of surgery, were comparable in both groups, as shown in [Table 1]. The types of surgeries performed in the both the groups are presented in [Table 2].

Table 1: Distribution of patients according to demographic data

Variable	Group B (n=30)	Group C (n=30)	p
Mean age± SD (years)	57.2 ± 1.1	59.3 ± 9.3	0.229
Male: Female	17:13	19:11	0.792[a]
Mean weight ± SD (kg)	69 ± 9.1	66.5 ± 8.3	0.271
ASA status (1:2)	18:12	13:17	0.301[a]
Mean duration of surgery ± SD (min)	210.5 ± 7.5	213.2 ± 4.8	0.103

Continuous variables are presented as mean ± SD and were compared using a two-sided Welch independent-samples t-test. Categorical variables are presented as counts and were compared using two-sided Fisher's exact test. [a]Fisher's exact test. A p value <0.05 was considered statistically significant.

Table 2: Distribution of patients according to type of surgery performed

Name of surgery	Group B (n=30)	Group C (n=30)
Fracture IT femur	11	10
Fracture shaft femur	7	8
Fracture tibia	3	3
Total hip replacement	4	5
Total knee replacement	5	4

Table 3: Perioperative blood loss in both groups at different time intervals

Time interval	Group B (Mean± SD) (n=30)	Group C (Mean± SD) (n=30)	p value
Intraoperative period	263 ± 11.38	180 ± 72.2	<0.001*
6 hours postoperatively	38 ± 15.2	35 ± 14.1	0.431
10 hours postoperatively	60 ± 18.9	41 ± 14. 77	<0.001*
24 hours postoperatively	12 ± 10.33	9.1 ± 9.8	0.269

Statistically significant at $p < 0.05$.

Perioperative blood loss was compared between Group B and Group C at different time intervals. A statistically significant difference was observed during the intraoperative period and at 10 hours postoperatively ($p < 0.001$ for both), with Group B showing higher mean blood loss than Group C. However, there was no statistically significant difference in blood loss at 6 hours ($p = 0.431$) or 24 hours postoperatively ($p = 0.269$). Overall, these findings indicate that Group C was associated with significantly lower blood loss during the intraoperative period and at 10 hours after surgery.

Table 4: Hematocrit in the both groups at different time intervals

Time interval	Group B (Mean± SD) (n=30)	Group C (Mean± SD) (n=30)	p value
Baseline	31.3±5.1	31.9±7.1	0.708
6 Hours	29±1.5	30±1.2	0.006*
24 Hours	27±1.5	28±0.8	0.002*

Hematocrit (Hct) values were compared between Group B and Group C at baseline, 6 hours, and 24 hours postoperatively. The baseline Hct values were comparable between the two groups, with no statistically significant difference observed (31.3 ± 5.1 vs. 31.9 ± 7.1; $p = 0.708$). However, Group C demonstrated significantly higher Hct values at both 6 hours (30 ± 1.2 vs. 29 ± 1.5; $p = 0.006$) and 24 hours postoperatively (28 ± 0.8 vs. 27 ± 1.5; $p = 0.002$). These findings suggest a significantly better preservation of hematocrit levels in Group C during the postoperative period.

In group B a total of 4 patients received blood transfusion, 1 unit each while in group C one patient received blood transfusion intraoperatively. None of the patient received blood products for first 24hours. None of the patient had any adverse events like hypersensitivity reactions, significant hypotension requiring vasopressors or bradycardia requiring atropine. There were no nausea or vomiting episodes noted among patients in both the group for first 24 hours.

DISCUSSION

The demographic characteristics of the two groups were comparable. There were no statistically significant differences in age, sex, body weight, ASA physical status, or duration of surgery. The distribution of surgical procedures was also broadly comparable between the groups. This baseline similarity is important because perioperative blood loss may be influenced by patient characteristics, duration of surgery, and the type and extent of orthopedic procedure. The comparability of these variables therefore strengthens the interpretation that the differences observed in blood loss were primarily related to the different TXA administration regimens.

The present randomized double-blind study compared the efficacy of a single intravenous bolus of tranexamic acid (TXA) with a bolus followed by continuous perioperative infusion in patients undergoing lower-limb orthopedic surgery. The principal finding was that patients receiving continuous infusion (Group C) had significantly lower intraoperative blood loss than those receiving a single bolus (Group B). Blood loss was also significantly lower in Group C at 10 hours postoperatively, whereas no statistically significant difference was observed between the groups at 6 and 24 hours. In addition, hematocrit values were significantly better preserved in Group C at both 6 and 24 hours postoperatively. These findings suggest that maintaining antifibrinolytic activity beyond the initial bolus may provide additional benefit in reducing perioperative blood loss in lower-limb orthopedic surgery.

The blood-sparing effect of TXA in orthopedic surgery has been demonstrated in several randomized controlled trials. Thipparampall et al. specifically evaluated different TXA dosing regimens in patients undergoing hip surgery and compared a single 10 mg/kg dose with a 10 mg/kg bolus followed by an infusion of 1 mg/kg/h for 4 hours postoperatively. They reported intraoperative blood losses of 456 ± 156 mL in the single-dose group and 400 ± 133 mL in the bolus-plus-infusion group, with the overall comparison showing a statistically significant difference among the study groups. The 6-hour postoperative drain collection was also significantly lower in the infusion group (31 ± 14 mL) than in the single-dose group (46 ± 14 mL). At 24 hours, blood loss remained lower in the infusion group (107 ± 37 mL) compared with the single-dose group (120 ± 76 mL). These findings are particularly relevant to the present study because the dosing regimen used in that study was similar to the regimen used in our continuous-infusion group. Our findings are consistent with this previous study, as Group C demonstrated lower intraoperative blood loss and lower postoperative blood loss at the intermediate assessment compared with Group B.[11]

In the present study, intraoperative blood loss was significantly lower in Group C than in Group B (180 ± 72.2 mL vs. 263 ± 11.38 mL; $p < 0.001$). The difference of approximately 83 mL between the groups indicates a clinically meaningful reduction in measured intraoperative blood loss with continuous infusion. The findings of Thipparampall et al. similarly favored the bolus-plus-infusion regimen, although the absolute blood-loss values in their study were higher than those observed in the present study. This difference may be attributable to differences in the type of orthopedic procedures included, surgical techniques, patient characteristics, and methods used to estimate blood loss. Nevertheless, the consistent direction of effect supports the possibility that maintaining TXA exposure during the early postoperative period may provide additional blood conservation compared with a single bolus.

The findings of the present study, however, are not consistent with all previous studies comparing single-dose and continuous TXA administration. Hourlier et al. conducted a randomized double-blind trial involving 106 patients undergoing primary total knee arthroplasty. Patients received either a single intraoperative dose of 30 mg/kg or a 10 mg/kg loading dose followed by continuous infusion of 2 mg/kg/h for 20 hours. The mean blood loss was 1148 ± 585 mL in the single-dose group and 1196 ± 614 mL in the continuous-infusion group, with no statistically significant difference between the groups ($p = 0.68$). The authors concluded that a single dose was as effective as continuous infusion.[12]

The difference between the findings of Hourlier et al. and those of the present study may be explained by differences in the study population and TXA dosing protocols. Hourlier et al. included only patients undergoing primary total knee arthroplasty, whereas the present study included several lower-limb orthopedic procedures, including fracture fixation, total hip replacement, and total knee replacement. In addition, the duration and dose of continuous infusion differed considerably between the studies. Hourlier et al. continued the infusion for 20 hours, whereas our infusion was administered at 1 mg/kg/h for 4 hours postoperatively. Therefore, the present findings cannot be directly extrapolated to prolonged 20-hour infusion regimens. The difference also highlights the possibility that the optimal duration of TXA administration may depend on the type and extent of surgical trauma.

A similar randomized clinical trial by Hourlier and Fennema evaluated single-dose versus continuous TXA administration in patients undergoing primary

total hip replacement. Patients receiving a single 30 mg/kg dose had a mean blood loss of 1107 ± 508 mL, compared with 1047 ± 442 mL in those receiving a 10 mg/kg loading dose followed by a continuous infusion of 2 mg/kg/h for 20 hours. The difference was not statistically significant (p = 0.43), and no major thromboembolic events were observed.[13] This study therefore supports the view that prolonged administration may not always provide additional benefit over a sufficiently effective single dose. In contrast, the present study demonstrated a significant advantage with the bolus-plus-infusion regimen. The discrepancy may again reflect differences in the dose of the initial bolus, duration of infusion, surgical population, and methods used for assessment of blood loss.

Further evidence has also suggested that the dose of a single TXA administration may influence its effectiveness. In a double-blind randomized controlled trial involving patients undergoing total hip arthroplasty, a 15 mg/kg single intravenous dose significantly reduced both bleeding and transfusion requirements compared with placebo, whereas the 10 mg/kg regimen reduced blood loss but did not significantly reduce transfusion requirements.[14] This finding is relevant to the interpretation of the present study because Group B received a 10 mg/kg single bolus. It is possible that the additional exposure provided by continuous infusion in Group C maintained effective antifibrinolytic concentrations for a longer period, thereby contributing to the lower intraoperative and early postoperative blood loss observed in our study.

A randomized controlled trial by Fillingham et al. provides another important perspective. In patients undergoing primary hip arthroplasty, patients received a preoperative intravenous bolus followed by either a continuous TXA infusion or placebo for 8 hours. The study was designed to determine whether additional perioperative TXA administration could provide further reduction in blood loss compared with a single bolus. This study is particularly relevant because it addresses the same underlying question as the present investigation—whether continued antifibrinolytic therapy after an initial bolus provides additional blood-conservation benefits. The differences between the results of individual trials indicate that the benefit of continuous administration may depend on the surgical procedure and the specific TXA regimen used rather than being universal across all orthopedic operations.[15]

In the present study, postoperative blood loss demonstrated a time-dependent pattern. At 6 hours, blood loss was comparable between Group B and Group C (38 ± 15.2 mL vs. 35 ± 14.1 mL; p = 0.431). However, at 10 hours, Group C demonstrated significantly lower blood loss than Group B (41 ± 14.77 mL vs. 60 ± 18.9 mL; p < 0.001). By 24 hours, the difference was no longer statistically significant (9.1 ± 9.8 mL vs. 12 ± 10.33 mL; p = 0.269). The significant difference at 10 hours but not at 24 hours suggests that the benefit of continuous TXA administration may be most apparent during the intraoperative and early postoperative periods. This observation is consistent with the study by Thipparampall et al., in which the bolus-plus-infusion regimen resulted in lower 6-hour drain collection and lower 24-hour blood loss than the single-dose regimen.

The hematocrit findings further support the observed blood-loss pattern. Baseline hematocrit values were comparable between the groups (31.3 ± 5.1% in Group B vs. 31.9 ± 7.1% in Group C; p = 0.708), indicating similar preoperative hematological status. At 6 hours postoperatively, Group C had a significantly higher hematocrit than Group B (30 ± 1.2% vs. 29 ± 1.5%; p = 0.006). Similarly, at 24 hours, hematocrit remained significantly higher in Group C (28 ± 0.8% vs. 27 ± 1.5%; p = 0.002). The better preservation of hematocrit in the continuous-infusion group is compatible with the lower measured blood loss in this group. However, hematocrit is influenced not only by blood loss but also by intravenous fluid administration and postoperative hemodilution. Therefore, the hematocrit findings should be interpreted together with the direct blood-loss measurements.

The requirement for blood transfusion was numerically lower in Group C. Four patients in Group B required one unit of blood each, whereas only one patient in Group C required one unit intraoperatively. Although this finding favors the continuous-infusion regimen, the number of transfusion events was small and the study was not specifically powered to detect differences in transfusion requirements. Previous studies have demonstrated that TXA can reduce transfusion requirements in orthopedic surgery. In the randomized study by Thipparampall et al., the group receiving the bolus-plus-infusion regimen had lower blood loss and favorable transfusion outcomes compared with the single-dose and control groups. Similarly, randomized evidence in total hip arthroplasty has demonstrated that higher-dose intravenous TXA can reduce both blood loss and transfusion requirements.

The safety findings in the present study were favorable. No patient developed a hypersensitivity reaction, significant hypotension requiring vasopressor support, or bradycardia requiring atropine. No episodes of nausea or vomiting were reported during the first 24 hours. The favorable safety profile is consistent with previous randomized studies. Hourlier et al. reported no adverse events during TXA treatment in their comparison of single-dose and continuous-infusion regimens in total knee arthroplasty. Similarly, the total hip replacement study by Hourlier and Fennema reported no major thromboembolic events during follow-up. Nevertheless, the relatively small sample size of the present study means that it cannot reliably detect uncommon complications such as venous thromboembolism or seizures.

The apparently conflicting results between previous studies may be explained by differences in TXA

dose, timing, duration of infusion, type of orthopedic procedure, and methods of blood-loss estimation. The study by Thipparampall et al., which used a 10 mg/kg bolus followed by 1 mg/kg/h for 4 hours, is particularly comparable to the present study and reported lower blood loss with the infusion regimen. In contrast, the studies by Hourlier et al. used a higher single dose of 30 mg/kg and a substantially longer continuous infusion, and found no additional benefit from continuous administration. These differences suggest that the effectiveness of continuous TXA administration may depend on whether the initial bolus provides sufficient antifibrinolytic exposure for the entire period of clinically important bleeding.

Limitation of the study: The sample size was relatively small and the study was conducted at a single center, which may limit the generalizability of the findings to other patient populations and healthcare settings. Although a standardized anesthetic and surgical protocol was followed, variations in the type and extent of lower-limb orthopedic procedures may have influenced perioperative blood loss. Estimation of blood loss using suction collection and soaked surgical gauze may also be subject to measurement variability. Furthermore, the study evaluated the effects of the two tranexamic acid regimens during the immediate perioperative period and therefore may not have been adequately powered to detect uncommon adverse events or differences in thromboembolic complications. Larger, multicenter studies with longer follow-up and standardized surgical procedures are warranted to confirm these findings.

CONCLUSION

The present study demonstrates that continuous perioperative infusion of tranexamic acid following an initial intravenous bolus was more effective than a single intravenous bolus alone in reducing blood loss during lower-limb orthopedic surgery. Patients receiving the continuous-infusion regimen had significantly lower intraoperative blood loss and blood loss at 10 hours postoperatively, along with better preservation of hematocrit at 6 and 24 hours. Although the requirement for blood transfusion was numerically lower with continuous infusion, the difference was not sufficient to establish a definitive transfusion benefit. Both regimens were well tolerated, with no major adverse events observed during the study period. Thus, a bolus followed by short-duration continuous infusion may be a useful strategy for perioperative blood conservation in lower-limb orthopedic surgery. Further larger, multicenter randomized studies are warranted to validate these findings and establish the optimal dose and duration of tranexamic acid administration.

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