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Original Research

A Comparative Study of Intravenous Bolus Versus Bolus With Continuous Infusion of Tranexamic Acid in Reducing Blood Loss in Major Surgical Procedures

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ABSTRACT

Background and Aims: The major surgical procedures are associated with excessive blood loss and necessitate the need for blood transfusion in the absence of blood conservation strategies. Tranexamic acid (TXA) is a synthetic antifibrinolytic drug that competitively blocks the lysine-binding sites of plasminogen, plasmin, and tissue plasminogen activator, thereby inhibiting fibrinolysis and blood clot degradation. The aim of this study was to compare the efficacy of single intravenous bolus dose of tranexamic acid with bolus plus infusion dose of tranexamic acid in reducing intraoperative blood loss.

Methods: This study was conducted as prospective, randomized and controlled.120 patients of either sex, ASA grade I and II and aged between 18 to 65 years were included in the study. These patients were randomly divided into 3 groups i.e. Group A (bolus), Group B (bolus + infusion) and Group C(control).Intraoperative blood loss and blood transfusions were noted. Post operative haemoglobin was done at 6 hours and the results were compared with preoperative haemoglobin levels.

Results: The Placebo group had more blood loss and requirement of transfusion as compared to the TXA (both Bolus and Infusion groups).

The intra-operative blood loss was least in the Bolus group and was maximum in the placebo group.The use of TXA significantly reduced the transfusion requirements in major surgeries with the least amount of transfusion needed in the Infusion group.

Conclusion: The use of TXA (in bolus as well as the infusion) led to statistically significant reduction in blood loss and the requirement of transfusion.

INTRODUCTION

Major surgical procedures are commonly associated with significant blood loss and the need for blood transfusion.[1] A major surgical procedure is known to affect the coagulation systems and the fibrinolytic system shuts down due to increased release of plasminogen activator inhibitor.[2] Plasminogen activator inhibitor is a serine protease inhibitor that functions as the inhibitor of tissue plasminogen activator (tPA), an enzyme responsible for the breakdown of plasminogen to form plasmin.[3] Decrease in haemoglobin following blood loss is associated with a poor surgical outcome, delayed postoperative ambulation, and increased morbidity and mortality.[4] Blood transfusion can lead to transfusion-induced coagulopathy, renal failure and is associated with risk of postoperative infection and also increases the associated costs.[5,6]

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METHODS

The present study was done to study the effect of different drug dose regimens of tranexamic acid (bolus dose of tranexamic acid (10 mg per kg) versus bolus (10 mg per kg) plus infusion dose of tranexamic acid (1 mg per kg per hour) in comparison to the control (placebo) group in reducing blood loss and rate of blood transfusion in major surgeries.

After approval by the Institutional Research committee and Ethics committee, a prospective, randomised and controlled study was conducted in the Department of Anaesthesia and Critical care, Christian medical college and Hospital, Ludhiana. The study included 120 patients of either sex, with ASA status I or II, and in the age group of 18 to 65 years who were admitted in the institution for elective and emergency surgical procedures. Informed consent was taken from the participants and they were divided by virtue of block randomisation with 1:1:1 with block size of 6 and total number of blocks used were 20.

The patients were then allocated into 3 groups i.e. Group A, Group B and Group C.

Group A: Patients in group A received single bolus dose of tranexamic acid (10mg/kg) 10 minutes prior to incision (bolus group) followed by normal saline infusion till 4 hours post-operatively.

Group B: Patients in group B received single bolus dose of tranexamic acid (10 mg/kg) 10 minutes prior to incision followed by infusion of tranexamic acid (1mg/kg/hr) till 4 hours postoperatively (infusion group).

Group C: Patients in group C received bolus of normal saline followed by normal saline infusion (control group).

Patients in group A received single bolus dose of tranexamic acid (10mg/kg) 10 minutes prior to incision (bolus group) followed by normal saline infusion till 4 hours post operatively. Patients in group B received single bolus dose of tranexamic acid (10 mg/kg) 10 minutes prior to incision followed by infusion of tranexamic acid (1mg/kg/hr) till 4 hours postoperatively (infusion group). Patients in group C received single bolus of normal saline followed by normal saline infusion (control group).

In our study, baseline values of haemoglobin and haematocrit were noted pre-operatively. These values were used for comparison with the haemoglobin and haematocrit values done at 6 hours post-operatively.

On arrival of the patient in the operation theatre, a running intravenous line was started. Intra-operative monitoring included SPO2, ECG, blood pressure and heart rate. Total volume of intravenous fluids infused and whole blood units or blood products transfused were noted down. Total duration of surgery in minutes (from skin incision to skin closure) was noted.

Intra-operative blood loss was the primary outcome which was assessed by subtracting the volume of 0.9% saline used as intra-abdominal wash from collection in the suction bottles.

The number of soaked gauzes and sponges by visual assessment were counted. The 5 gm soaked gauzes were counted and according to available literature each gauze piece was estimated to be having 5 ml blood. Then the 25 gm soaked sponges were counted and according to available literature each 25 gm sponge piece was estimated to be having 25 ml blood. Any excessive soakage of drapes was also noted and was taken into consideration.

Intra-operative blood loss as well as the intra-

operative transfusions were recorded and charted. Post-operatively hemoglobin levels were done at 6 hours and the values were then compared with pre-operative hemoglobin levels.

RESULTS AND ANALYSIS

Table 1: Distribution of patients according to type of surgery performed

Name of surgery	Group A (Bolus group) n=40	Group B (Infusion group) n=40	Group C (Control group) n=40	All groups together
Major Gynaecological surgery	16	13	13	42
Major Surgery (plastics, dental, urology and ENT cases)	15	11	13	39
Major Orthopaedic surgery	9	16	14	39
Chi square test	3.044			
P value	0.550			

DISCUSSION

In our study, the mean intra-operative blood loss calculated was 638.79 ± 282.97 ml. When different groups were assessed for intra-operative blood loss, the average intra-operative blood loss calculated in Group A (Bolus group) was 579.75 ± 195.49 ml, whereas it was 639.50

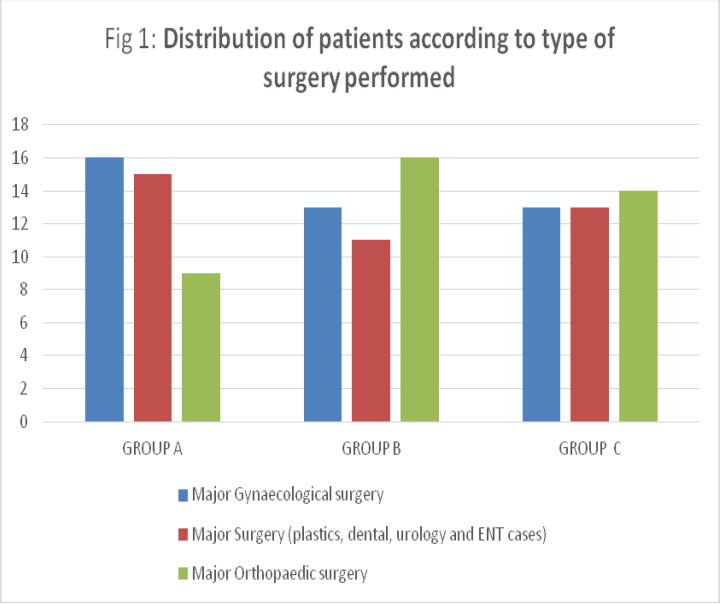


Table 2: Distribution of patients according to intra-operative blood loss

Intra-operative blood loss (in ml)	Group A (Bolus group) n=40	Group B (Infusion group) n=40	Group C (Control group) n=40	All groups together
Mean	579.75	639.50	697.12	638.79
SD	195.49	405.17	186.77	282.97
Minimum	250.00	200.00	500.00	200.00

Maximum	1100.00	2500.00	1200.00	2500.00
95% CI	(517.23,642.27)	(509.92,769.08)	(637.39,756.86)	(587.64,689.94)
P value	0.009*			

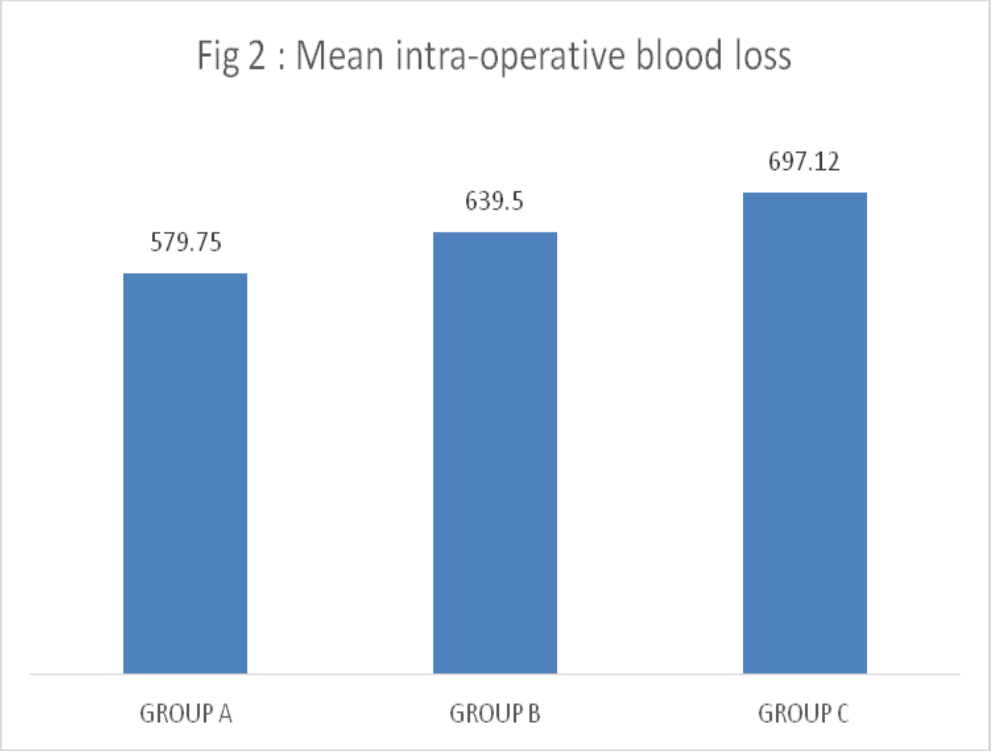
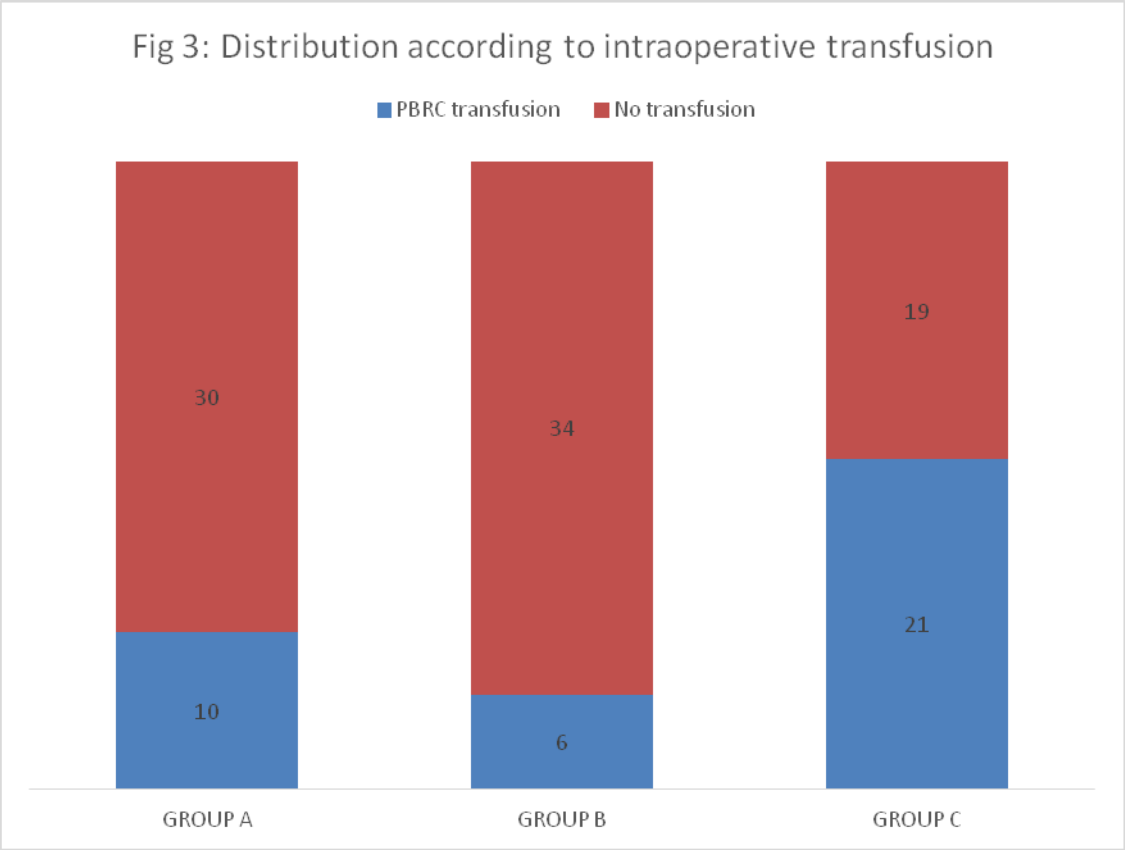


Table 3: Distribution of patients according to intra-operative transfusion

Intra-operative transfusion	Group A (Bolus group) n=40	Group B (Infusion group) n=40	Group C (Control group) n=40	All groups together
PBRC transfusion	10	6	21	37
No transfusion	30	34	19	83
Chi square test	14.145			
P value	0.001*			



± 405.17 ml in Group B (Infusion group) and 697.12 ± 186.77 ml in Group C (Control

group). In our study we found that the average intra-operative blood loss was maximum in the control group followed by the infusion group and was least in the Bolus group. The mean difference among the groups was found to be statistically significant (p- value = 0.009). The findings in our study led us to the conclusion that a single pre-operative bolus dose of tranexamic acid was sufficient and potent enough in reducing the blood loss and the requirement of transfusion in major surgical procedures however administration of a low dose continuous infusion after the allocation of the bolus dose did not improve the results and the blood loss was found to be greater in the Infusion group as compared to the bolus group. In the study conducted by us, a total of 6 patients out of 40 required transfusion in the Infusion group, 10 patients out of 40 needed transfusion in the Bolus group and 21 patients out of 40 required transfusion in the Control group. This comparison among the three groups was statistically significant (p- value = 0.001). We observed that the requirement of blood transfusion was maximum in the Control group and was least in the Infusion group.

CONCLUSION

Major surgical procedures are commonly associated with significant blood loss and the need for blood transfusion.1 Blood loss during

major surgeries can lead to acute anemia thus placing the patients at risk of peri-operative complications.3 Though tranexamic acid has been well researched in the past, there is still no definitive dosing regimen is known till date for reducing blood loss in major surgeries. Hence we undertook this study to compare the effect of different drug dose regimens of tranexamic acid.

Our study showed statistically significant reduction in blood loss with the use of tranexamic acid. In our study, the average intra-operative blood loss was maximum in the control group followed by the infusion group and was least in the Bolus group thereby we inferred that the bolus dose was efficient enough to reduce intra-operative blood loss. Moreover, in our study, we observed that the administration of tranexamic acid decreased transfusion requirements significantly. The need for transfusion was found to be least in the Infusion group in our study.

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Nil

Conflicts of Interest

There are no conflicts of interest.

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