E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.48047/ijprt/16.02.379

Research Article

COMPARITIVE STUDY OF EFFICACY OF TRANEXAMIC ACID AND HEMOCOAGULASE IN REDUCING PERIOPERATIVE BLOOD LOSS IN MAJOR ORTHOPAEDIC LOWER LIMB SURGERIES: A DOUBLE BLIND RANDOMIZED CONTROL STUDY

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Received date: 10-08-2026, Date of acceptance: 17-08-2026, Date of Publication: 24-08-2026

Abstract

Background and Aims: Major orthopaedic surgeries are associated with significant perioperative blood loss and necessitate blood transfusion. Aim was to evaluate and compare blood loss and need for blood transfusion in the perioperative period between the two groups receiving tranexamic acid and hemocoagulase. Secondary objective was to compare the coagulation indices in the two groups by comparing PT, APTT, INR values preoperatively and 24 hours postoperatively.

Methods: Prospective randomized double blinded comparative study was undertaken in 120 patients aged 18 to 75 years of ASA 1, 2 undergoing major lower limb orthopedic surgeries. Group T received Tranexamic acid 10 mg /kg intravenously 15 minutes prior to incision followed by 1mg/kg/hour till closure. Group H received Hemocoagulase 1 ml intravenously 15 minutes prior to incision followed by 0.5ml IM at the time of closure. Total amount of perioperative blood loss, transfusion requirements were noted. Haemoglobin, haematocrit, PT, INR, APTT values were compared preoperatively and postoperatively after 24 hours in both groups.

Results: Total perioperative blood loss in group T was 428.4 ± (65.2) ml and Group H was 417.4 ± (47.9) ml which was not statistically significant (p=0.291). There was no statistically significant difference observed for fall in hemoglobin (p=0.371), hematocrit (p=0.602) and perioperative transfusion requirements (p=0.486) in both the groups. The change in PT, APTT and INR values when compared preoperatively versus postoperatively showed no statistically significant difference ($p > 0.05$).

Conclusion: Tranexamic acid and Hemocoagulase are equally effective in reducing perioperative blood loss in major orthopedic lower limb surgeries. Transfusion requirement and change in

coagulation profile was similar in both the groups.

Key words: Tranexamic acid; Hemocoagulase; Blood Loss.

INTRODUCTION

Orthopaedic surgeries are often associated with significant blood loss due to nature of the surgeries that require dissection through bone and fibrotic tissues. These tissues may be vascular and haemostasis would be difficult to establish on account of friability and diffuse nature of bleeding. Exposure and decortication of bone also leads to significant bleeding. Controlling bleeding in these areas may be difficult by routine haemostatic measures like cautery or use of ligatures[1]. Blood loss associated morbidities can be direct, including hypotension, organ damage, particularly cardiac, pulmonary, renal, and coagulopathy. Excessive blood loss needs necessitate allogeneic blood transfusion, which may result in acute lung injury, hypersensitivity reactions, infections, and immune suppression.[2]

Hence various methods have been employed such as hypotensive anaesthesia, haemodilution, autologous blood transfusion, cell salvage methods, erythropoietin and use of antifibrinolytic agents like tranexamic acid, EACA, aprotinin to reduce the blood loss in these surgeries thereby mitigating need for allogenic blood transfusion.[3]

Tranexamic acid has shown safety and efficacy in orthopaedic surgery, especially TKA, THA, and spine surgery, for controlling perioperative and postoperative bleeding[3]. Hemocoagulase is a thrombin like enzyme (TLE) extracted from snake venom that, accelerates the formation of fibrin monomers and hastens fibrin clot formation.[4] TLEs have drawn attention due to their outstanding features of low toxicity, fast onset of action, long-lasting efficacy, and no intravascular embolism.[5] Evidence has accumulated that, hemocoagulase significantly reduces bleeding in patients undergoing abdominal, urological, thyroid, orthopaedic, obstetric, and gynaecological surgeries.[6] However, there are very few studies that comparing the efficacy of tranexamic acid with hemocoagulase in reducing blood loss and transfusion requirement in major orthopaedic surgeries.[7]

Our study was designed to compare and assess the efficacy of two drugs, tranexamic acid and hemocoagulase in reducing perioperative blood loss in patients undergoing major orthopaedic lower limb surgeries. A prospective double blind randomized control study was designed comparing the above mentioned drugs.

AIM OF THE STUDY

To compare the effectiveness of Tranexamic acid and Hemocoagulase in reducing perioperative blood loss in lower limb surgeries under neuraxial anaesthesia

MATERIALS AND METHODS

SOURCE OF DATA:

The present study was conducted on patients between 18 – 75 years of age belonging to ASA grade 1and 2, of either sex, posted for orthopaedic elective surgeries of lower limb under neuraxial anaesthesia at Karnataka

Institute of Medical Sciences, Hubli from December 2019 to 2020.

METHODS OF DATA COLLECTION:

After ethical committee approval and after obtaining informed valid consent, 120 patients belonging to ASA physical status 1 and 2 in the age group of 18-75 years who were undergoing elective orthopaedic surgeries of the lower limb under neuraxial anaesthesia were included in the study and were randomised into two groups.

Group T (n= 60) - Patients receiving Tranexamic acid

Group H (n=60) -Patients receiving Hemocoagulase

INCLUSION CRITERIA:

- Patients belonging to ASA physical status 1 and 2
- Age 18 – 75 years belonging to either sex
- Patients giving informed and valid consent
- Patients undergoing elective major lower limb surgeries under neuraxial anaesthesia.

EXCLUSION CRITERIA:

- Patients posted for emergency surgeries
- Patients with cardiac, renal, hepatic and cerebral diseases
- Patients with history of DVT and thromboembolic episodes
- Patients on anticoagulant and antiplatelet agents.
- Patients with a known allergy to any to the study drugs.
- Pregnant and lactating females.

METHOD OF STUDY: A prospective randomized double blinded comparative study was planned. Pre anaesthetic evaluation of all patients was performed by an anaesthesiologist a day before surgery. An informed written and valid consent was taken from 120 patients who satisfied the inclusion criteria and they were randomly allocated to two groups according to computer-generated randomized number table. The two groups were Group T and Group H. Each group ha 60 patients. Group T patients received Tranexamic acid 10 mg /kg intravenously 15 minutes prior to incision followed by 1mg/kg/hour till closure and group H patients received Hemocoagulase 1 NIH unit intravenously 15 minutes prior to skin incision followed by 0.5ml IM at the time of closure. The study drugs were drawn and diluted in identical 100 ml solution of crystalloids by an anaesthetist who did not take part in the study. Patients and investigators were blinded to the study medication. All patients in two groups were kept nil per oral for 6 hours before surgery. Patients underwent surgery under spinal or combined spinal epidural anaesthesia. Hemodynamic parameters (heart rate, systolic, diastolic and mean arterial blood pressure, respiratory rate), haemoglobin concentration, platelet count, coagulation profile were noted preoperatively. Total amount of blood loss was calculated as amount of blood in suction jar excluding amount of normal saline used for irrigation, surgical site spillage and the amount of blood soaked in surgical sponges, swabs and surgical drapes. The amount of blood soaked in surgical sponges, swabs and surgical drapes was calculated by weighing the soaked sponges and subtracting their dry weight. Post operatively blood present in the drain at 24 hours was also included in the total blood loss. The total duration of surgery will be noted. The number of units

of whole blood /PRBC transfused intraoperatively and postoperatively during the hospital stay was noted. The criteria for blood transfusion was hypotension due to haemorrhage, blood loss more than 20% of patient's total blood volume or fall in haemoglobin levels below 8 g/dl.

PARAMETERS OBSERVED

Intra operative blood loss, Postoperative drain output , Total number of whole blood /PRBC transfused – intraoperatively and postoperatively , Preoperative and Postoperative haemoglobin , Preoperative and Postoperative haematocrit, Preoperative and Postoperative PT, INR APTT values.

STATISTICAL ANALYSIS

Sample Size Estimation Formula:

Sample Size: Sample size was estimated by using the difference in Mean blood loss in a study done by Ankit Singh and Deepesh Gupta with title "Comparative Evaluation of Tranexamic Acid and Hemocoagulase on Blood Loss in Orthopaedic Hip Surgeries" published in "Global Journal for Research Analysis Volume-8, Issue-8, August-2019." Using these values at 95% Confidence limit and 80% Power, sample size of 54 was obtained in each group by using the below mentioned formula and Med calc sample size software. With 10% non-response-sample size of 60 cases will be included in each group.

$$\text{Sample size} = \frac{2SD^2(Z_{\alpha/2}+Z_{\beta})^2}{d^2}$$

SD – Standard deviation = From previous studies or pilot study

$Z_{\alpha 2} = Z_{0.05/2} = Z_{0.025} = 1.96$ (From Z table) at type 1 error of 5%

$Z_{\beta} = Z_{0.20} = 0.842$ (From Z table) at 80% power

d = effect size = difference between mean values

So now formula will be

$$\text{Sample size} = \frac{2SD^2(1.96+0.84)^2}{d^2}$$

STATISTICAL ANALYSIS: Data was entered into Microsoft excel data sheet and was analysed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. Chi-square was the test of significance. Continuous data was represented as mean and standard deviation. Independent t test was the test of significance to identify the mean difference between two groups. p value < 0.05 was considered as statistically significant.

Sampling method: Randomisation by computer generated tables.

RESULTS

Age distribution of the study subjects compared between the two study groups (n=120)

Table 1: Distribution of Age (Years)

	Group T (n=60)	Group H (n=60)	p-value
Mean (SD) Age in years	43.8 (16.5)	41.3 (16.4)	0.559*
Age group (in years)			
18 – 30	11 (18.3%)	17 (28.3%)	0.413#
31 – 45	24 (40.0%)	18 (30.0%)	
46 – 60	11 (18.3%)	14 (23.3%)	
More than 60 years	14 (23.3%)	11 (18.3%)	

* independent sample t-test

Chi-square test

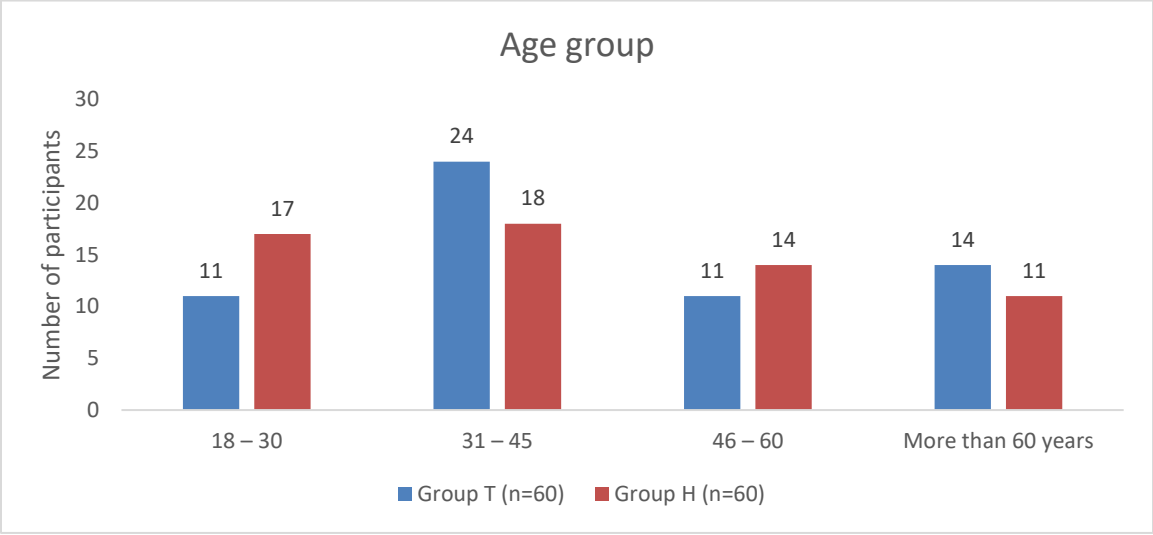

Chart 1: Distribution based on age (n = 120)

Both the groups were comparable in terms of age distribution. Tranexamic group (Group T) had 60 patients with mean age 43.8 years with SD of 16.5. Hemocoagulase group (Group H) had 60 patients with mean age 41.3 years with SD of 16.4. The p value for age distribution is 0.559 which is more than 0.05 which is statistically insignificant.

Comparison of patient characteristics – gender wise distribution of the participants between the two study groups (n=120)

Table 2: Distribution of Gender

Gender	Group T (n =60)	Group H (n = 60)	p value
Male	44 (73.3%)	47 (78.3%)	0.522#
Female	16 (26.7%)	13 (21.7%)	

* independent sample t-test

Chi-square test

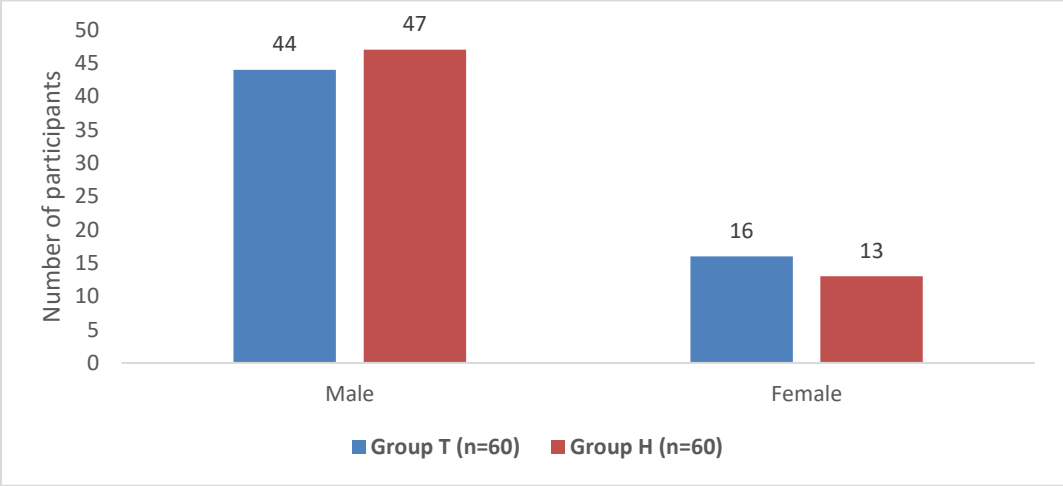

Chart 2: Distribution of gender between the two groups (n=120)

The above table and figure shows the gender distribution of the study subjects between the two groups. Group T had 44 (73.3 %) male patients and 16 (26.7 %) female patients while Group H had 47 male patients (78.3 %) and 13 female patients (21.7%). The p value obtained was 0.522 which was statistically insignificant. Thus both the study groups were comparable in terms of gender distribution. (Table 2, Chart 2)

Comparison of patient characteristics-Comparison of BMI between the two study groups (n=120)

Table 3: Distribution of BMI

BMI	Group T	Group H	p value
Mean (SD)	22.3 (2.7)	21.9 (2.6)	0.5078*

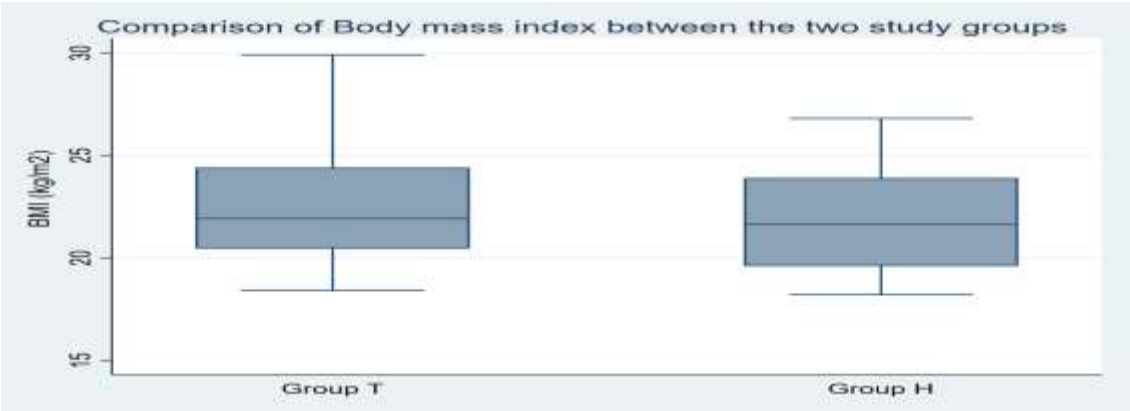

Chart 3: Distribution Based On Body Mass Index (BMI) In Kg/m 2

The test used for compare BMI between the two groups was unpaired t test. Group T had mean BMI of 22.3 kg / $m^2$with SD of 2.7 kg/m^2 while Group H had mean BMI of 21.9 kg / $m^2$with SD of 2.6 kg/m. The p value was 0.5078 which is statistically insignificant. Thus both the groups are comparable in terms of BMI. (Table 3, Chart 3)

Comparison of Group T and Group H showing ASA status

Table 5 – DISTRIBUTION BASED ON ASA STATUS

ASA status	**Group T**	**%**	**Group H**	**%**	**Total**	**%**
1	38	63.33	42	70.00	80	66.67
2	22	36.67	18	30.00	40	33.33
Total	60	100.00	60	100.00	120	100.00
Chi-square=0.6000 P = 0.4390						

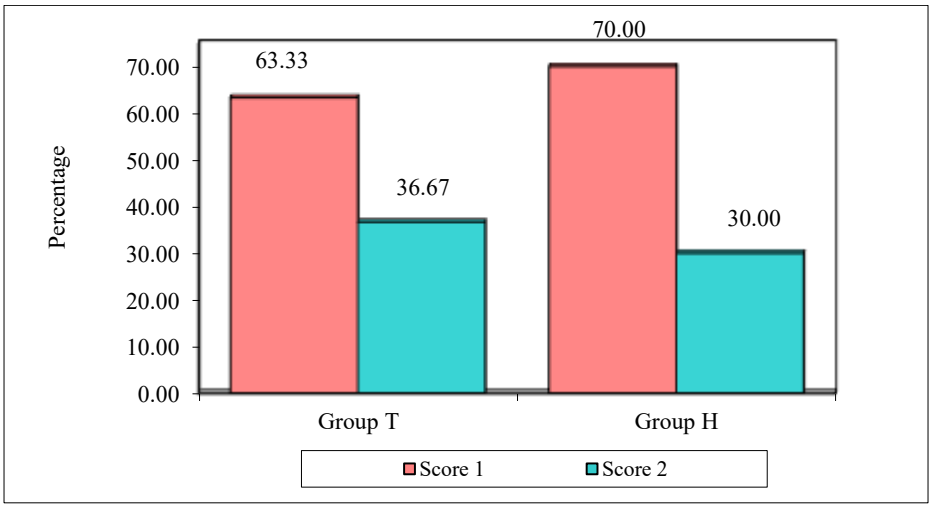

Chart 4: Distribution Based On ASA Status

On applying Chi Square test, the 2 groups were found similar with regards to ASA grade of the patients. Group T had 63.33% patients with ASA grade 1 while Group H had 70 % patients with ASA grade 1. In group T 36.67 % patients were belonging to ASA grade 2 while 40 % patients of Group H belonged to ASA grade 2. The p value obtained was 0.493(Table 5, Chart 4)

Comparison of patient characteristics – mean duration of surgery the participants between the two study groups (n=120)

Table 6: Distribution of Mean Duration of Surgery

Duration of surgery (in minutes)	Group T	Group H	p value
Mean (S D)	135.8 (21.9)	131.3 (19.0)	0.232*

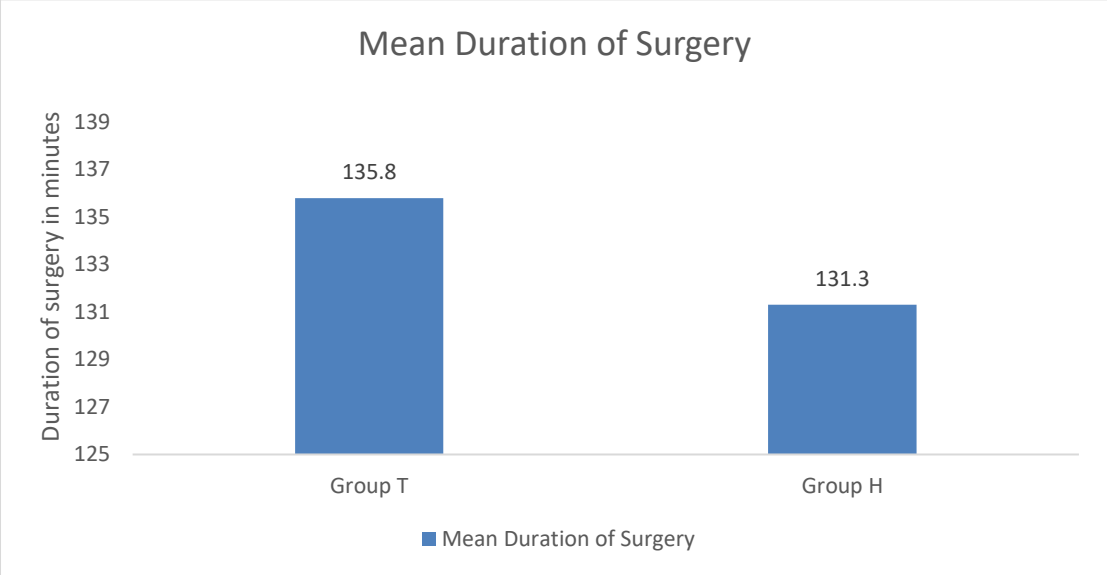

Chart 5: Distribution of Mean Duration of Surgery

Both the groups were comparable in terms of duration of surgery. Group T had mean duration of surgery 135.8 minutes with S D of 21.9 minutes while Group H had mean duration of surgery of 131.3 minutes with S D of 19 minutes. The p value obtained was 0.232 which was statistically insignificant. (Table 6, Chart 5)

Table 7: Comparison of Total Blood Loss between The Two Study Groups (N=120)

	Group T (n=60)	Group H (n=60)	p-value
Blood loss - drain	76.1 (8.0)	70.9 (14.3)	0.097*
Blood loss – intra op	393.5 (61.2)	383.1 (44.6)	0.289*
Total blood loss	428.4 (65.2)	417.4 (47.9)	0.291*

* independent sample t-test, # Chi-square test

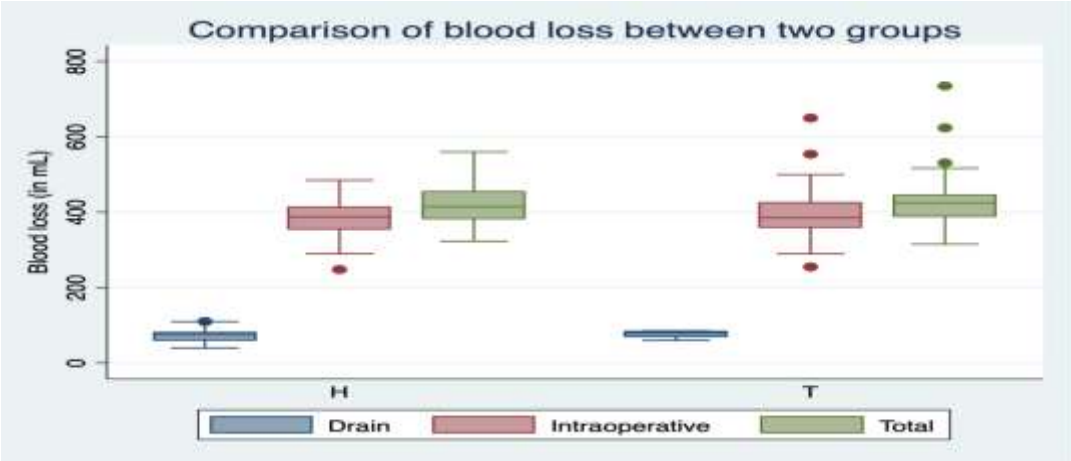

Chart 6: Comparison of Blood Loss Between The Two Groups

For comparison of blood loss between two study groups unpaired t test was applied. Mean blood loss intraoperatively in Group T was 393.5 ml with SD of 61.2 ml while in Group H mean blood loss intraoperatively was 383.1 ml with SD of 44.6 ml. The mean postoperative drain output was 76.1 ml with SD of 8 ml in group T. Group H had 70.9 ml mean postoperative drain output with SD of 14.3 ml. The p value obtained was 0.291 by applying independent sample t test. (Table 7, chart 6)

Table 8: Comparison of Haemoglobin before and After Surgery between The Two Study Groups (N=120)

	Group T (n=60)	Group H (n=60)	p-value
Pre-operative Haemoglobin (g%)	12.1 (1.7)	12.7 (1.8)	0.057*
Post-operative Haemoglobin (g%)	10.0 (1.5)	10.4 (1.5)	0.120*
% Reduction in haemoglobin	17.2 (4.2)	17.8 (3.4)	0.371*

* independent sample t-test, # Chi-square test

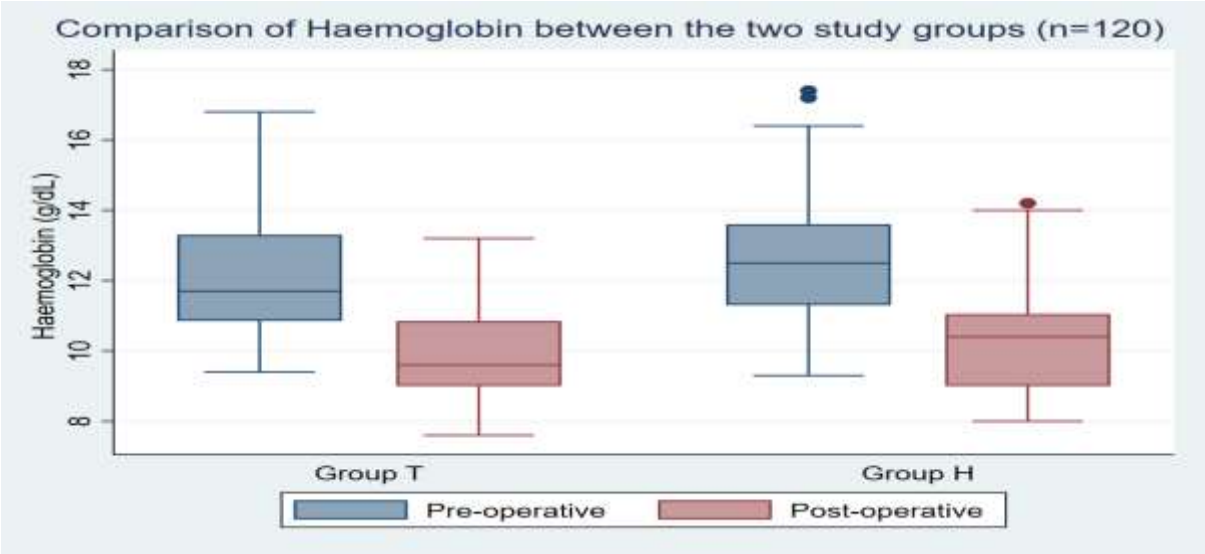

Chart 7: Comparison of Preoperative and Postoperative Haemoglobin between the Study Groups

Preoperative mean haemoglobin value was 12.1 g/ dl with SD of 1.7 g /dl in Group T and in Group H preoperative mean haemoglobin was 12.7 g/dl with SD of 1.8 g/dl. The two groups were comparable in terms of preoperative mean haemoglobin values with p value of 0.057.

Postoperative mean haemoglobin value was 10 g/ dl with SD of 1.5 g /dl in Group T and in Group H preoperative mean haemoglobin was 10.4 g/dl with SD of 1.5 g/dl. The two groups were comparable in terms of postoperative mean haemoglobin values with p value of 0.120.

The percentage reduction in haemoglobin in Group T 17.2 g /dl with SD of 4.2 g/dl and in Group H percentage reduction in haemoglobin was17.8 g/dl with SD of 3.4 g/dl. Independent student t test was used to compare percentage reduction between the two groups which was not statistically significant and p value was 0.371 (Table 8, Chart 7)

Table 9: Comparison of Haematocrit Before and After Surgery Between The Two Study Groups (N=120)

	Group T (n=60)	**Group H (n=60)**	**p-value**
Pre-operative Haematocrit (%)	34.0 (5.0)	35.8 (5.5)	0.061*
Post-operative Haematocrit (%)	27.9 (4.2)	29.3 (4.6)	0.093*
% Reduction in Haematocrit	17.8 (4.5)	18.2 (3.6)	0.602*

* independent sample t-test

Chi-square test

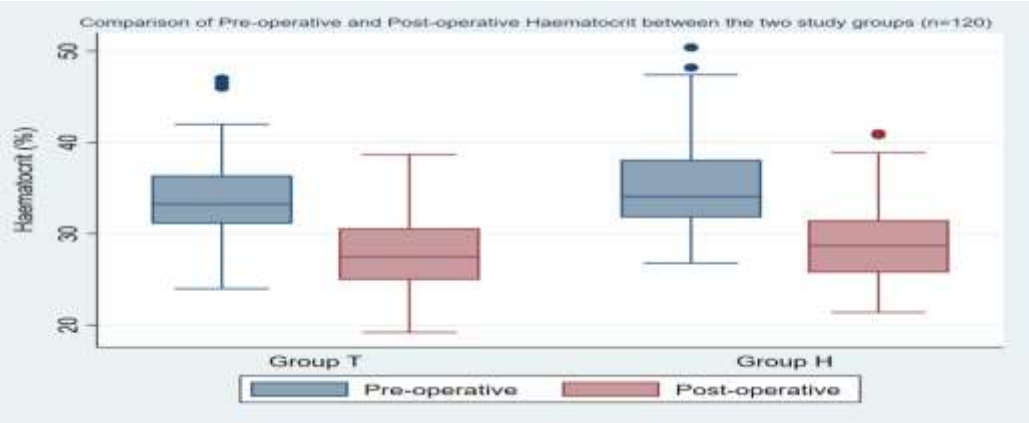

Chart 8: Comparison of Pre-Operative and Post-Operative Haematocrit between The Study Groups (N=120)

Preoperative mean haematocrit value was 34.0 % with SD of 5 % in Group T and in Group H preoperative mean haematocrit was 35.8 % with SD of 5.5 %. The two groups were comparable in terms of preoperative mean haematocrit values with p value of 0.061.

Postoperative mean haematocrit value was 27.9 % with SD of 4.2 % in Group T and in Group H preoperative mean haematocrit was 29.3 % with SD of 4.6 %. The two groups were comparable in terms of postoperative mean haematocrit values with p value of 0.093

The percentage reduction in haematocrit in Group T 17.8 % with SD of 4.5 g/dl and in Group H percentage reduction in haematocrit was 18.2% with SD of 3.6 %. Independent student t test was used to compare percentage reduction between the two groups which was not statistically significant and p value was 0.602 (Table 9, Chart 8)

Table 10: Comparison of Intra-Operative, Post-Operative, and Total Blood Transfusion between the Two Groups (N=120)

	Group T (n=60)	Group H (n=60)	p-value
Intra-operative transfusion			
1 unit	11 (18.3%)	5 (8.3%)	0.107#
Not transfused	49 (81.7%)	55 (91.7%)	
Post-operative			
1 unit	28 (46.7%)	24 (40.0%)	0.486#
2 unit	0	1 (1.7%)	
Not transfused	32 (53.3%)	35 (58.3%)	
Total units transfused			

1 unit	27 (45.0%)	25 (41.7%)	0.472#
2 unit	6 (10.0%)	3 (5.0%)	
Not transfused	27 (45.0%)	32 (53.3%)	

* independent sample t-test

Chi-square test

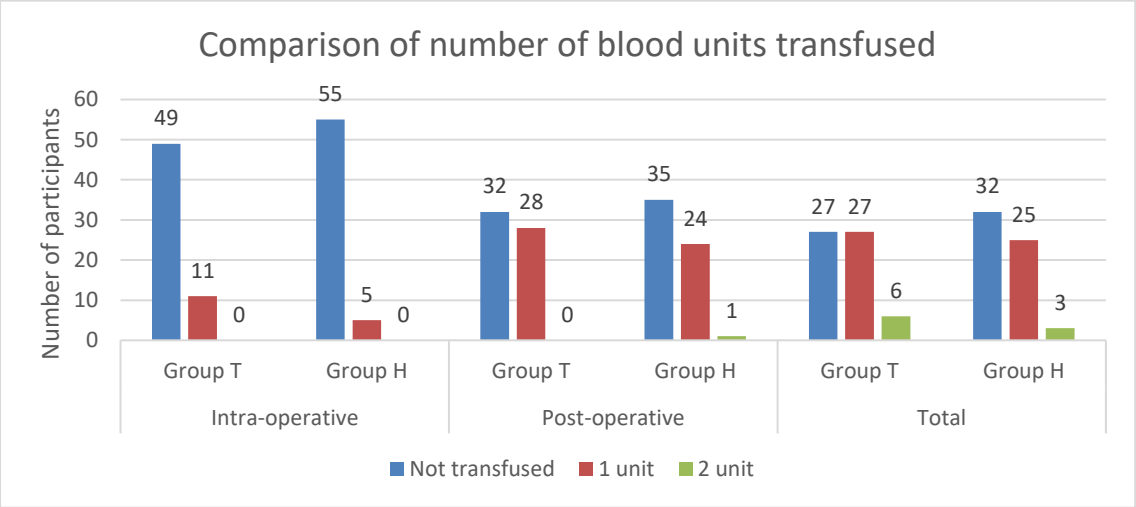

Chart 9: Comparison of Intra-Operative, Post-Operative, and Total Blood Transfusion Between the Two Groups

In Group T 18.3% patients received 1 unit of blood transfusion intraoperatively while in Group H 8.3% patients received 1 unit of Blood transfusion. Chi square test was used to compare the difference in need for blood transfusion between the two groups and it was not statistically significant (p = 0.107)

In Group T 46.7% patients received 1 unit of blood transfusion postoperatively while in Group H 40.0%% patients received 1 unit of blood transfusion postoperatively. Only one patient in Group H received 2 units of blood transfusion. The two groups were comparable in terms of number of units of blood transfused post operatively. Chi square test was used to compare the difference in need for blood transfusion between the two groups post operatively and it was not statistically significant (p = 0.486)

The difference in number of units of blood transfused intra operatively and post operatively between the 2 groups was not statistically significant with p value of 0.472.

Table 11: Comparison of Prothrombin Time Before and After Surgery Between The Two Study Groups (N=120)

	Group T (n=60)	Group H (n=60)	p-value
Pre-operative Prothrombin time (s)	13.1 (1.2)	13.1 (1.1)	0.869*
Post-operative Prothrombin time (s)	12.3 (1.0)	12.4 (1.2)	0.964*
Reduction in Prothrombin time	0.76 (0.9)	0.71 (1.10)	0.813*

* independent sample t-test

Chi-square test

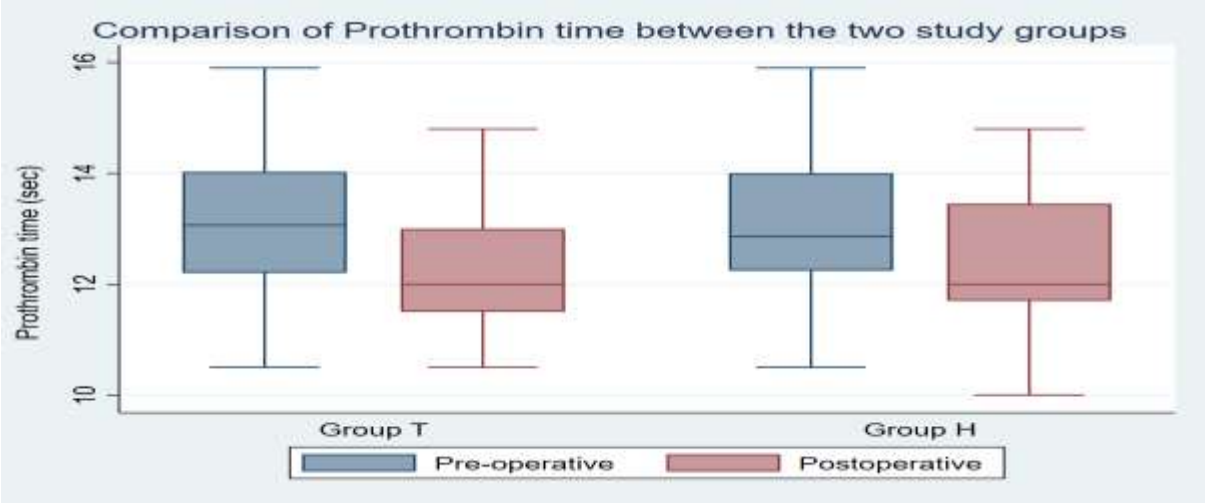

Chart 10: Comparison of Prothrombin Time before And After Surgery Between The Two Study Groups (N=120)

Preoperative Prothrombin time (PT) was comparable in both the groups. Group T had preoperative mean PT of 13.1 seconds with SD of 1.2 seconds. Group H had preoperative mean PT of 13.1 seconds with SD 1.1 of seconds. Independent t test was applied and difference between both the groups was statistically insignificant with p value of 0.869.

Similarly, postoperative PT values in both groups were comparable with p value of 0.964.Group T had mean postoperative PT value of 12.3 seconds with SD of I second whereas Group H had postoperative PT value of 12.4 seconds with SD of 1.2 seconds.

Thus comparing mean PT values preoperatively versus postoperatively, the reduction in PT values was not statistically significant. The independent sample t test was applied for the above said comparison and p value obtained was 0.813.

Table 12: Comparison of PT-INR before and After Surgery between the Two Study Groups (N=120)

	Group T (n=60)	Group H (n=60)	p-value
Pre-operative PT-INR	1.12 (0.15)	1.14 (0.14)	0.321*
Post-operative PT-INR	1.07 (0.16)	1.09 (0.15)	0.554*
Reduction in PT-INR	0.05 (0.16)	0.06 (0.13)	0.686*

* independent sample t-test, # Chi-square test

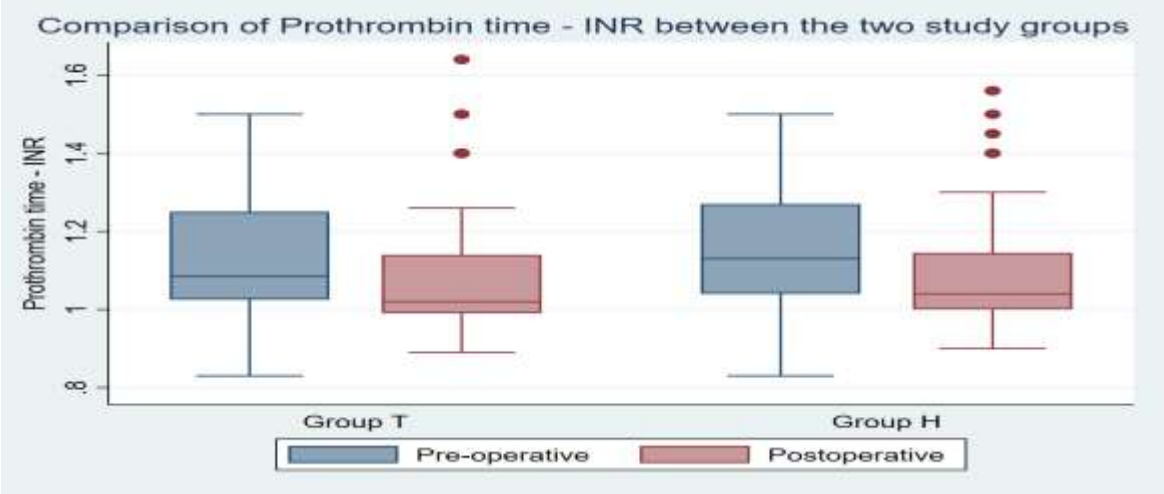

Chart 11: Comparison of PT-INR before and After Surgery between The Two Study Groups (N=120)

The preoperative mean PT INR value in Group T was 1.12 with SD of 0.15 while in Group H preoperative mean PT INR value was 1.14 with SD of 0.14.Both the groups were comparable in terms of preoperative PT INR values with p value of 0.321

Group T had mean postoperative PT INR value of 1.07 with SD of 0.16 and Group H had mean postoperative PT INR value of 1.09 with SD of 0.15. Using independent t test p value obtained was 0.554, thus making both the groups comparable in terms of postoperative PT INR value.

No statistically significant reduction in PT INR was observed when comparing preoperative values and postoperative values between both the groups. The independent sample t test was applied and p value was 0.686. (Table 12, Chart 11)

Table 13: Comparison of APTT (Activated Partial Thromboplastin Time) Before and After Surgery between the Two Study Groups (N=120)

	Group T (n=60)	Group H (n=60)	p-value
Pre-operative aPTT (sec)	29.9 (3.8)	30.4 (3.2)	0.364*
Post-operative aPTT (sec)	29.4 (4.6)	29.9 (3.6)	0.541*
Reduction in aPTT (sec)	0.42 (2.93)	0.54 (1.67)	0.785*

* independent sample t-test

Chi-square test

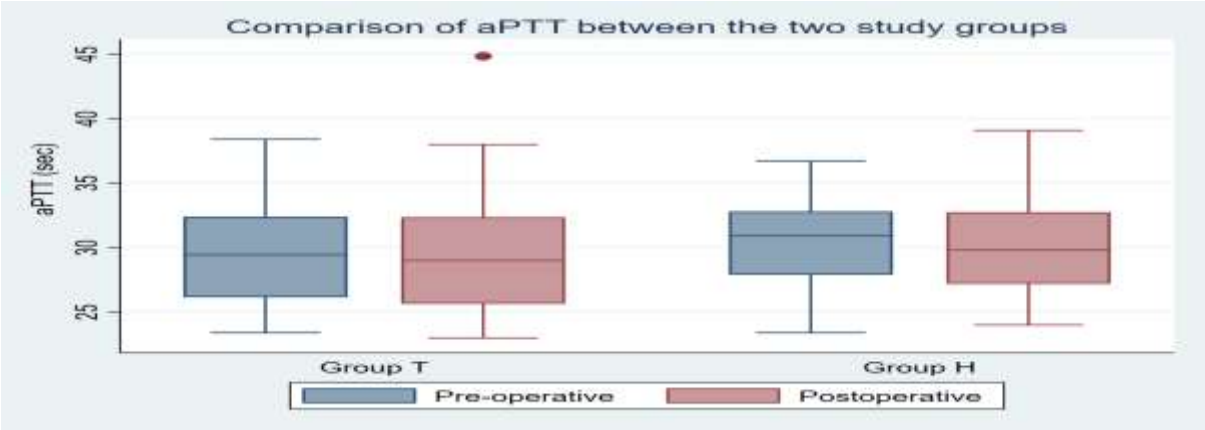

Chart 12: Comparison of APTT (Activated Partial Thromboplastin Time) Before and After Surgery between the Two Study Groups (N=120)

The preoperative mean aPTT (Activated Partial Thromboplastin Time)value in Group T was 29.9 with SD of 3.8 while in Group H preoperative mean aPTT value was 30.4 with SD of 3.2.Both the groups were comparable in terms of preoperative aPTT values with p value of 0.364

Group T had mean postoperative aPTT value of 29.4 with SD of 4.6 and Group H had mean postoperative aPTT value of 29.9with SD of 3.6. Using independent t test p value obtained was 0.541, thus making both the groups comparable in terms of postoperative aPTT value.

No statistically significant reduction in aPTT was observed when comparing preoperative values and postoperative values between both the groups. The independent sample t test was applied and p value was 0.785. (Table 13, Chart 12)

DISCUSSION

Significant blood loss is anticipated with major orthopaedic surgeries as it is with all major surgical procedures. However, when a patient is posted for elective orthopaedic surgeries, it becomes even more vital on the part of the treating and operating physicians to employ strategies to reduce bleeding and to maintain the patient's haemodynamic balance. Higher perioperative blood loss leads to increased transfusion requirements which in turn increase the morbidity and mortality in these patients. Reduced bleeding at surgical site carries with it a major benefit of ensuring a clear surgical field to the operating surgeon. Various orthopaedic surgeries especially complex reconstructive arthroplasties and spinal surgeries are often associated with significant intraoperative blood loss.[8]

Numerous techniques have been employed to reduce the perioperative blood loss like autologous or allogenic blood transfusion, cell salvage methods, hypotensive anaesthesia, fibrin sealants as well as antifibrinolytic agents like EACA, tranexamic acid, hemocoagulase. However, none of these techniques are devoid of complications.[9]

Tranexamic acid is an antifibrinolytic that acts on lysine binding sites of plasminogen and prevents formation of plasmin and thus it inhibits dissolution of clots. One of the earliest uses of tranexamic acid was in cardiothoracic surgery and its use expanded in gynaecologic surgeries to reduce haemorrhage as well as in cases of acute trauma. It is also used in gastrointestinal, hepatic, urologic and ear, nose, and throat surgeries to reduce intraoperative blood loss. Multiple studies have studied various dosing regimens and different routes of administration of TXA in orthopaedic surgeries that include fixed or weighted IV doses, a single IV dose or multiple IV doses, continuous IV infusion and, intra-articular application by direct wash or injection, with or without drain clamping.[10]

Hemocoagulase is derived from snake venom of snakes like Bothrops atrox or Bothrops jararaca and has thrombin like enzyme activity. It cleaves fibrinogen into fibrin monomers like thrombin does. But it has an advantage of not being inhibited by thrombin inhibitors. According to a meta-analysis done by Yao Y.T et al hemocoagulase has shown to be effective in reducing transfusion requirements in patients undergoing cardiac surgeries. They also reported that postoperatively hemocoagulase treated patients had higher Hb levels while hemocoagulase did not influence intraoperative heparin or protamine dosage or platelet counts. Hemocoagulase has also been effective in patients undergoing transurethral bipolar plasma kinetic prostatectomy by reducing prothrombin time, hospital stay time and its effectiveness is not influenced by prostate volume. It is also effective in reducing blood loss in orthopaedic surgeries, dental procedures and in preventing pulmonary haemorrhage in mechanically ventilated neonate when used prophylactically.[11]

Different studies have used hemocoagulase in varied dosages and routes. Qui M et al in

their study used hemocoagulase at the dose of 1 U 10-12 hours preoperatively and then 1 ml IV 30 minutes prior to surgery and again repeated the same dose 12 hours postoperatively. Also they gave intra articular 1 U of hemocoagulase at the site of incision prior to closing. In their study done in patients undergoing idiopathic scoliosis surgery Xu C et al administered hemocoagulase in dose of 0.02 U /kg with a maximum dose of 1 U intravenously 20 minutes prior to incision and then repeated the same dose every 2 hours till the end of surgery. Gupta D et al used hemocoagulase in the dose of 1 U IV 10 minutes prior to incision. In our study, we administered hemocoagulase 1 ml (1 NIH Unit) which was diluted in 100 ml of normal saline IV 15 minutes prior to skin incision and then 0.5 ml hemocoagulase was given IM at the time of closure which was similar to study done by N Roopa, Prasad A et al in patients undergoing spinal fusion surgeries.[12]

The present study was conducted on 120 patients belonging to ASA physical status 1 and 2 between the age 18-75 years belonging to either sex giving informed and valid consent and who were undergoing elective major lower limb surgeries under regional anesthesia. Using computer generated tables patients were randomly allocated into 2 groups.

Group T (n = 60)-Tranexamic acid group.

Group H (n = 60)-Hemocoagulase group.

The sample size of 120 patients was obtained using statistical analysis which included 10 % non -response sample. We did not have any drop outs in our study.

Baseline demographics were comparable between the two groups and there was no statistical significance between both the groups was observed with regards to age, sex, BMI, ASA status, duration of surgery. ($p < 0.05$)

Likewise, p value of 0.686 was obtained when preoperative and postoperative INR values of the 2 groups was compared and p value of 0.785 was obtained when we compared preoperative and postoperative APTT values.[13]

Our findings are similar to study done by Gupta D et al who reported no statistically significant difference in PT, INR, APTT values between the tranexamic acid and hemocoagulase groups pre and postoperatively.[14]

Hui M et al who conducted their study on patients undergoing spinal fusion surgeries reported that no difference was observed in postoperative PT and APTT values between batroxobin group and control group ($p = 0.543$ for PT, $p = 0.649$ for APTT).[15]

We did not observe any adverse events or side effects in any of the patients belonging to tranexamic acid group or hemocoagulase group during our study.

LIMITATIONS OF THE STUDY

- We did not have a control group to compare our study drugs with.

CONCLUSION

We conclude that Tranexamic acid and Hemocoagulase are equally efficacious in reducing perioperative blood loss as well as transfusion requirement in patients undergoing major orthopaedic lower limb

surgeries. Change in coagulation indices such as PT, APTT, INR values in the two groups were similar both preoperatively and 24 hours postoperatively.

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