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ORIGINAL ARTICLE

Role of tranexamic acid in reducing blood loss in bipolar hemiarthroplasty in the first 48 hours.

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ABSTRACT… Objective: To find out the efficacy of Tranexamic acid in decreasing intraoperative and postoperative bloodloss in patients going through bipolar hemiarthroplasty (BHA) within the first 48 hours. **Study Design:** Randomized Controlled Trial. **Setting:** Ghurki Trust and Teaching Hospital, Lahore, Pakistan. **Period:** September 15, 2024, to December 15, 2024. **Methods:** Sixty-six patients with femoral neck fractures were randomized into two groups: Group A (TXA, 15 mg/kg intravenously) and Group B (placebo). Bloodloss was measured during and after surgery at 12, 24, and 48 hours using drain volumes. Data were analyzed using SPSS version 27, with Student's t-tests applied to compare outcomes between groups. **Results:** Group A demonstrated significantly lower intraoperative blood loss (534.85 ± 118.48 mL) than Group B (633.64 ± 127.94 mL, $p = 0.002$). Postoperative drain volumes were also lower in Group A at 12 hours (188.79 ± 71.80 mL vs. 225.76 ± 53.97 mL, $p = 0.021$), 24 hours (115.76 ± 43.16 mL vs. 167.58 ± 47.30 mL, $p < 0.0001$), and 48 hours (67.88 ± 39.19 mL vs. 102.12 ± 35.33mL, $p < 0.0001$). Total bloodloss over 48 hours was much lower in Group A (900.91 ± 222.74 mL) compared to Group B (1126.06 ± 216.97 mL, $p < 0.0001$). Subgroup analysis showed consistent benefits across gender, age, and BMI categories, particularly in females and older patients. **Conclusion:** Tranexamic acid significantly decreases intraoperative and postoperative bloodloss in patients goingthrough bipolar hemiarthroplasty (BHA) for the neck of femur fractures. These findings support the inclusion of TXA in surgical protocols to minimize blood loss, lower transfusion requirements, and reduce associated morbidity.

Key words: Bipolar Hemiarthroplasty, Blood Loss, Hip Fracture, Orthopedic Surgery, Postoperative Anemia, Tranexamic Acid.

INTRODUCTION

Hip fractures in older people pose a serious threat to public health. In those 75 years of age or older, they account for around 25% of all fractures. The number of femoral neck fractures worldwide was 1.7 million in 1990; by 2050, that number is expected to increase to 6.3 million.[1]

Hip hemiarthroplasty is one of the most popular treatments for adult hip fractures in old-age patients. Up to 1500mL of blood may be lost due to the fracture and during the procedure. The combination of the fracture and the BHA surgery frequently causes postoperative acute anaemia and the possible need for blood transfusion. Extended hospital stays, delayed functional recovery, and a higher death rate can result from postoperative anaemia. The danger of immunological reactivity, disease transmission, and surgical site infection is increased by allogeneic blood transfusion.[2-3]

Additionally, a higher percentage of patients (20%–60%) may require the administration of blood products due to blood loss, which increases the risk of complications and unfavorable outcomes. The development of controlled hypotensive anaesthesia has reduced the usage of perioperative blood products, various blood salvage procedures, pharmaceutical medications, and other strategies. Patients goingthrough elective total joint arthroplasty (TJA) have been treated with tranexamic acid(TXA), a prominent drug whose cost-effectiveness, clinical

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efficacy, and reduced side effect profiles have been demonstrated in several papers. There is limited data to support the use of TXA in bipolar hemiarthroplasty for intracapsular femoral neck fractures to minimize the bloodloss, although it has been demonstrated to lower bloodloss in elective TJA perioperatively.[4-5]

In orthopaedic surgery, blood-saving measures include tourniquets, fibrinolytic medications such as tranexamic acid, controlled hypotension, avascular procedures, and careful hemostasis. One antifibrinolytic drug that is often used is tranexamic acid (TXA). This drug stops the fibrin clot caused by plasmin from breaking down. It inhibits fibrin binding to plasminogen by competitively and reversibly binding to the binding site of lysine of plasminogen. Thus, it prevents fibrin from dissolving and stabilizes it, which lowers blood loss.[6]

Johansson et al.[7] conducted the study, and the findings reveal that the mean bloodloss in the tranexamine group was 969±434ml, and in the placebo group, 1324±577 was obtained.

The rationale of this study is to provide details regarding the efficacy of tranexamine in minimizing blood loss. Related evidence is scarce in our local population; thus, our inferences will add to the existing knowledge of the efficacy of Tranexamic acid in bloodloss reduction. Hence, it will assist surgeons in developing guidelines to decrease surgery-related bloodloss and thus lower morbidity associated with the surgery. So, this study aimed to compare the mean blood loss between group A receiving TXA vs group B receiving normal saline undergoing bipolar hemiarthroplasty during the first 48 hours.

METHODS

This randomized controlled trial was carried out at Ghurki Trust and Teaching Hospital, Lahore, Pakistan, over four months (September 15, 2024, to December 15, 2024) following the approval of the synopsis. Both outpatient department (OPD) and emergency room (ER) admissions for neck and femur fractures (AO-31B) were assessed through a comprehensive history, clinical examination, and appropriate radiological investigations. Ethical Approval was taken from the Hospital Ethical Review Board (Ref. No 2023/11/R-29 Dated:1-11-23). The sample size was calculated and contained 66 patients, with 33 in each group. This calculation was based on a 95% confidence level, 80% power of the test, and mean bloodloss of 969 ± 434mL in the tranexamic acid (TXA) group compared to 1324 ± 577.7mL in the placebo group.[7] A non-probability purposive sampling technique was employed for patient selection. The inclusion criteria included patients aged 40 to 80 years, weighing between 40 and 90 kilograms, and presenting with a neck or femur fracture as defined operationally. Patients were excluded if they were taking anticoagulants or antiplatelets, had a history of previous surgery for the proximal femur on the same side, or had any coagulation or bleeding disorder, including a haemoglobin level below 10 g/dL.

Surgical Technique and Allocation

Patients were prepared for bipolar hemiarthroplasty (BHA) after anaesthesia clearance. Baseline haemoglobin concentration and hematocrit values were recorded prior to surgery. Each patient received a bolus of 1-litre crystalloid preoperatively. Randomization done by lottery method into two groups. Group A received tranexamic acid (TXA) at a dose of 15mg/kg in 100mL normal saline intravenously, administered 15 minutes before incision.

In contrast, Group B received a placebo in the same manner. Strict aseptic measures were observed throughout the surgical procedure, adhering to WHO scrubbing, gowning, and surgical site preparation guidelines. Tranexamic acid was not routinely administered in clinical practice, and this study aimed to generate evidence to guide its use in reducing intraoperative and postoperative blood loss, potentially informing future surgical guidelines. A subfascial drain was placed in all cases, and postoperative bloodloss was recorded for the first 48hours. Intraoperative blood loss was measured based on suction drain contents, blood-soaked sponges (each fully soaked sponge counted as 100 mL), and spilled blood calculated by the anesthetist. Postoperative blood loss was measured clinically from the suction drain at 12,

24, and 48hours, with the mean blood loss over 48 hours as the outcome measure.

Additional parameters, such as intraoperative fluid replacement using Ringer's solution in a 3:1 ratio for blood volume loss, postoperative haemoglobin concentration on the first day, and blood transfusion requirements during the hospital stay, were recorded but not analyzed as part of this study. The transfusion criteria involved a haemoglobin reduction exceeding 25% of preoperative levels. The researcher noted all demographic data and measurements on an organized proforma on the second postoperative day. Data was analyzed using SPSS version 27. Descriptive statistics were applied to summarize categorical variables, such as gender, in terms of frequencies and percentages. Continuous variables, including BMI, intraoperative blood loss, and drain output, were analyzed using means and standard deviations. Stratification for age, gender, and BMI was conducted to control for potential effect modifiers the Student's t-test assessed group comparisons for postoperative blood loss.

RESULTS

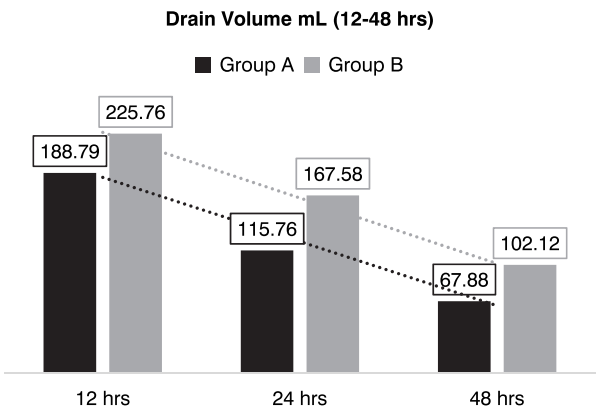

Figure-1. Drain volume over the period

The results show that the gender distribution is relatively balanced between the two groups, with Group A having 52% males and 48% females and Group B having 48% males and 51.2% females. Regarding age, the mean age of patients in Group A is slightly higher at 68.42 years compared to 67.91 years in Group B, which is statistically insignificant (p = 0.850). The Body Mass Index (BMI) is also nearly identical between the two groups (Group A: 28.61 ± 7.11, Group B: 28.58 ± 8.33), with no significant difference observed (p = 0.987).

Variables	Group A (Tranexamic Acid) (n=33)	Group B (Normal Saline) (n=33)	P-Value
Gender			
Male	13(52.0)	12(48.0)	.800
Female	20(48.8)	21(51.2)	
Age(years)	68.42 ± 11.61	67.91 ± 10.40	.850
BMI (kg/m2)	28.61 ± 7.11	28.58 ± 8.33	.987
Intraoperative Blood Loss	534.85 ± 118.48	633.64 ± 127.94	.002
Drain Volume (ml) (12 hrs)	188.79 ± 71.80	225.76 ± 53.97	.021
Drain Volume (ml) (24 hrs)	115.76 ± 43.16	167.58 ± 47.30	<.0001
Drain Volume (ml) (48 hrs)	67.88 ± 39.19	102.12 ± 35.33	<.0001
Total Blood Loss (ml)	900.91 ± 222.74	1126.06 ± 216.97	<.0001

Table-I. Demographic and Clinical Characteristics of Patients in Groups A and B Undergoing Bipolar Hemiarthroplasty (n=66)

Regarding intraoperative blood loss, Group A had significantly less blood loss (534.85 ± 118.48 mL) compared to Group B (633.64 ± 127.94 mL), with a p-value of 0.002. This trend continued in the postoperative period, with Group A exhibiting significantly lower drain volumes at 12 hours (188.79 ± 71.80 mL vs. 225.76 ± 53.97 mL, p = 0.021), 24 hours (115.76 ± 43.16 mL vs. 167.58 ± 47.30 mL, p < 0.0001), and 48 hours (67.88 ± 39.19 mL vs. 102.12 ± 35.33 mL, p < 0.0001). The total bloodloss over the initial 48 hours post-surgery was also significantly lower in Group A (900.91 ± 222.74 mL) compared to Group B (1126.06 ± 216.97 mL), with a p-value of less than 0.0001. These results validate

the hypothesis that Tranexamine minimizes blood loss in patients goingthrough bipolar hemiarthroplasty, highlighting its potential clinical benefit in reducing both peroperative and post-operative blood loss.

Among males, the mean bloodloss was less in Group A (966.92 ± 263.96 mL) than in Group B (1045.00 ± 196.12 mL), but this variation was statistically nonsignificant (p=0.413). In contrast, females in Group A had significantly lower bloodloss (858.00 ± 186.11 mL) compared to females in Group B (1172.38 ± 219.02 mL), with a p-value of <0.0001, indicating a very significant difference. For age, patients between 40–60 years, we found a nonsignificant decrease in bloodloss in Group A (911.67 ± 198.53 mL) compared to Group B (1075.55 ± 243.37 mL) with a p-value of 0.090. However, in the 61–80 age group, Group A experienced significantly lower bloodloss (894.76 ± 239.99 mL) compared to Group B (1151.36 ± 203.76 mL), with a p-value of <0.0001.

Parameters	Group A	Group B	P-Value
Gender			
Male	966.92 (263.96)	1045.00 (196.12)	.413
Female	858.00 (186.11)	1172.38 (219.02)	<.0001
Age			
40-60	911.67 (198.53)	1075.55 (243.37)	.090
61-80	894.76 (239.99)	1151.36 (203.76)	<.0001
BMI			
≤25	981.25 (289.21)	1197.78 (232.31)	.108
>25	875.20 (197.28)	1099.17 (209.66)	<.0001

Table-II. Mean post-operative blood loss based on demographic profile of patients

Regarding BMI, patients with BMI ≤25 had lower blood loss in Group A (981.25 ± 289.21 mL) compared to Group B (1197.78 ± 232.31 mL), although this variation was nonsignificant statistically (p=0.108). Conversely, patients with BMI >25 showed a very significant decrease in blood loss in Group A (875.20 ± 197.28 mL) compared to Group B (1099.17 ± 209.66 mL), with a p-value of <0.0001.

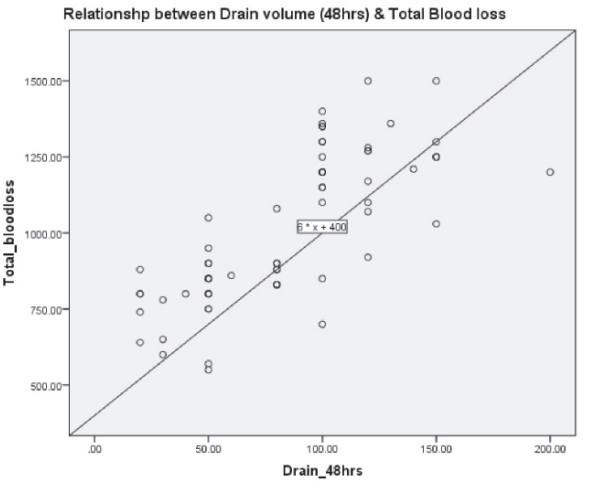

Figure-1 (b)

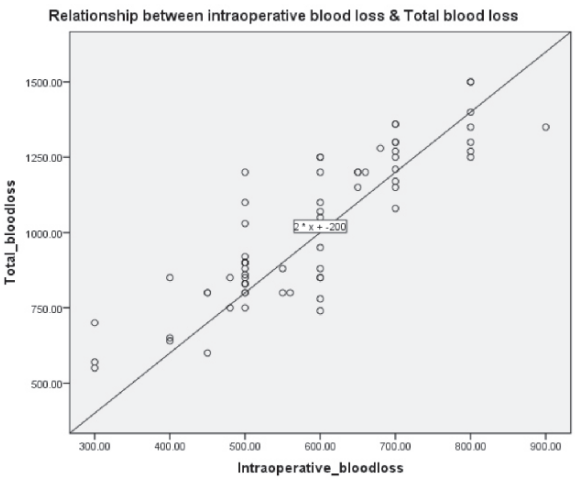

Figure-1 (a)

Figure-1 (a) shows a positive correlation between intraoperative bloodloss and total bloodloss, indicating that higher peroperative bloodloss is associated with greater total blood loss. Figure-1 (b) demonstrates a similar positive relationship between drain volume at 48 hours and total blood loss. Higher drain volumes correspond to greater total blood loss, but most points lie above the equality line, indicating that drain volume captures only a portion.

DISCUSSION

The study under discussion explores the potency of Tranexamic acid (TXA) in minimizing bloodloss during bipolar hemiarthroplasty (BHA) in older people, especially those with neck or femur fractures. High statistics involving hip fractures among older people are estimated to swell from 1.7 million in 1990 to 6.3 million by 2050- demand this research be placed under greater emphasis.[8] The high incidence of blood loss associated with both the fracture and the surgical intervention necessitates effective strategies to mitigate this complication, as postoperative anaemia can lead to extended hospital stays, delayed recovery, and increased mortality rates.[9]

Although there is a lot of data that supports the use of Tranexamic acid in routine total hip replacement there is less is known about its application about its use for patients going through hemiarthroplasty for femoral neck fracture (FNF).[10,11]

The results of our study align with the previously available literature. Both studies demonstrate that tranexamine effectively minimizes blood loss in surgical patients, with statistically significant reductions observed in postoperative blood loss. Husted et al.(2003) reported a postoperative blood loss of 334mL in the Tranexamic acid (TXA) group versus 609mL in the placebo group ($p = 0.001$) and a total bloodloss of 814mL versus 1231mL ($p = 0.001$). Similarly, our study found significantly lower intraoperative blood loss in the TXA group (534.85 ± 118.48mL vs. 633.64 ± 127.94mL, $p = 0.002$) and postoperative drain volumes at 12, 24, and 48 hours, with p-values ranging from 0.021 to <0.0001. total bloodloss over 48 hours was also significantly lower (900.91 ± 222.74 mL vs. 1126.06 ± 216.97mL, $p < 0.0001$).[12]

Kashif et al.[13] carried out a similar study to measure the mean blood loss in patients who underwent hip Arthroplasty, and the results indicate that postoperative mean bloodloss notably rminimize in the Tranexamic acid group in contrast to normal saline 203.8 ± 141.81 vs 281.6 ± 130.31 $p=0.031$ respectively.

Another study's results demonstrate that the mean total bloodloss was 1339mL in I/V administration of Tranexamic acid (TXA), which minimizes the blood transfusion requirements in patients who underwent hemiarthroplasty. Patients who received tranexamic acid had a smaller decrease in postoperative drain volume, indicating reduced blood loss—tranexamic acid minimizes the bloodloss and the transfusion requirement in patients undergoing hemiarthroplasty. Patients who had been given tranexamine had notably less drop in postoperative drain readings (102.50 ± 29.62 vs 274.67 ± 70.01; $P < 0.001$).[14,15]

Selva Kumar et al.'s study demonstrates the voloum accumulated in the drain on postoperative day 1(24 hours) and on the 2nd day (48 hours). In the control group, a mean value of 222.5ml was obtained on day one and 74.2ml on day 2. In the Tranexamic acid group, a mean value of 55.4 was found on day one and 16.7ml on day 2, with a notable difference observed on day 1 ($p=.010$) and an insignificant difference on day 2, i.e., ($p=.960$).[16]

According to a study by Watts et al., the transamine group's mean blood loss was significantly lower than that of the control group. Specifically, the transamine group's mean blood loss was 242mL lower on POD 1 (731 vs. 973 mL, $P = 0.01$), 294 mL lower on POD 2 (830 vs 1124 mL, $P = 0.0002$), and 305 mL lower on POD 3 (902 vs 1205 mL, $P = 0.0005$).

The domized clinical trials revealed that Tranexamic acid (TXA) administration safely lowers the bloodloss in those Patients having hip hemiarthroplasty for acute neck of femur fracture and also minimizes the transfusion rate and the use of total blood product in such patients.[17]

A key strength of our study is that all bipolar hemiarthroplasties were performed using a single surgical approach. Secondly, patients with multiple risk factors for thromboembolic events were excluded. Like other studies, this study has limitations as the number of operating surgeons was not restricted. We did not follow the patients for long-term complications.

CONCLUSION

In conclusion, the current study would be valuable evidence for using Tranexamic (TXA) in neck or femur fracture surgeries. The notable decrease in blood loss associated with TXA administration supports its clinical efficacy and emphasizes the need for its consideration in surgical protocols for elderly patients undergoing hemiarthroplasty. Future studies should focus on larger sample sizes and long-term outcomes to further interpret the benefits and safety of TXA in this population.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Awais Nawaz Khan:** Conceptualization and frame work of research.
2	**Bilal Zaib:** Draft of study data collection.
3	**Haseeb Elahi:** Help in discussion section.
4	**Usman Mushtaq:** Data collection.
5	**Muhammad Kramat Majeed:** Data collection.
6	**Ijaz Ahmad:** Supervision, critical review.