International Journal of Research in Orthopaedics
Pruthvi KP et al. Int J Res Orthop. 2023 Mar;9(2):256-260
http://www.ijoro.org

Original Research Article

DOI: https://dx.doi.org/10.18203/issn.2455-4510.IntJResOrthop20230286

A prospective randomized control trial of topical tranexamic acid used in elderly patients with femoral neck fractures treated with hemiarthroplasty

Pruthvi K. P.[1]*, Ramesh Chandra Meena[2], Mallikarjun K. Rayanad[2]

[1]Department of Orthopaedics, K. S. Hegde Medical Academy, Mangalore, Karnataka, India
[2]Department of Orthopaedics, SMS Medical College, Jaipur, Rajasthan, India

Received: 25 December 2022
Revised: 16 January 2023
Accepted: 17 January 2023

***Correspondence:**
Dr. Pruthvi K. P.,
E-mail: pruthvishetty2k12@gmail.comn

ABSTRACT

Background: Geriatric hip fracture patients frequently suffer femoral neck injuries. The advantage of using TXA topically over the IV route is that maximum concentration of the drug is attained at the wound/surgical site with minimal systemic side effects of drug and also it is easy to administer locally. Aim of current study was fragmented necks of the femur can be treated with Tranexamic acid to reduce postoperative blood loss.
Methods: Over the course of 20 months from June 2020 to December 2021, the orthopaedics department at SMS Hospital, Jaipur, conducted this study. A total of 174 patients (87 in each group) of age >60 years, presenting with neck of the femur in orthopaedics wards were enrolled in this study.
Results: Compared to the control group, the case group experienced 408 ml more blood loss, which was treated with tranexamic acid. In cases and controls, transfusion was necessary for 31 and 41 patients, respectively.
Conclusions: One dosage of topical tranexamic acid may be given to an older patient undergoing bipolar hemiarthroplasty for a fractured femoral neck in order to minimize post-operative blood loss.

Keywords: Tranexamic acid, Perioperative blood loss, Hemiarthroplasty, Topical tranexamic acid

INTRODUCTION

Hip fractures with a femoral neck break are common in the older population. Hip fractures are expected to account for half of the world's total hip fractures by 2050, and this is a major social and economic problem in emerging Asian countries that are most at risk.[1,2] Femoral neck fractures due to peculiar anatomy and blood supply have unsatisfactory outcomes with internal fixation, especially in the elderly, hemiarthroplasty and recently primary hip replacement have shown relatively good outcome.[3] The control of perioperative blood loss is a critical concern in the care of an older patient who is at a high risk of post-surgical complications. Successful hip operations require proper intraoperative haemostasis to prevent the development of hematomas and reduce blood loss through suction drains. Soft tissue haemostasis also has a role in a patient's ability to move after surgery. Persistent blood loss due to surgical site bleeding after surgery can lead to substandard results of proposed surgeries due to local and systemic effects like pain, hematoma, seroma and chances of infection increases.[4] Tranexamic acid (TXA), an antifibrinolytic drug derived from synthetic amino acids, is used in a variety of chronic conditions to reduce the need for blood transfusions. According to previous studies, this medication is safe and effective at reducing blood loss when administered intravenously or orally.[5,6] TXA is delivered to the bleeding site in a higher concentration with less systemic absorption than intravenous infusion, making it more convenient than intravenous

administration. Objective of our study was to known perioperative blood loss and need for transfusions in acute traumatic neck of femur cases treated with bipolar hemiarthroplasty with or without topical Tranexamic acid.

METHODS

Current study was randomized controlled interventional study. Patients in the orthopaedics department of teaching hospitals affiliated with S.M.S. medical college and hospital were researched from June 2020 to December 2021 with the ethical committee's consent. The sample size was 87 subjects for each of 2 groups in which blood loss of patients receiving topical tranexamic acid (cases) v/s patients not receiving topical tranexamic acid (controls) in femoral neck fracture treated by bipolar hemiarthroplasty was compared. So, for study purposes, 87 patients each were to be taken for the study group and control group.

Inclusion criteria

Inclusion criteria for current study were; patients with age more than 60 years with neck of femur fracture, patient with acute history and fracture neck of femur managed with bipolar hemiarthroplasty.

Exclusion criteria

Exclusion criteria for current study were; pathological neck of femur fractures, patients are medically unfit for surgery and patients with diagnosed bleeding disorders

Procedure

After bipolar prosthesis fixation and reduction, the wash is given with normal saline. The hip joint capsule and the soft tissues surrounding it were injected with TXA (1 gram) using an intraarticular injection syringe. With the drain still in place, the wound was closed layer by layer. Prior to the procedure, the levels of haemoglobin and haematocrit, platelet counts, prothrombin time (PT) and INR were assessed. Prior to surgery, on the day of surgery, and on the first and fifth postoperative days, blood samples were taken to measure haemoglobin and haematocrit levels, as well as the volume of vacuum tube drainage after 48 hours and the number of transfusion and hospital stays. Estimated blood loss (EBL) following surgery was calculated using the formula. Nadler and Mercuriali formulas were used to estimate the total blood loss.[7,8] Blood volume and blood loss was predicted by equation mentioned in (Figure 1).[7,8]

Statistical analysis

The collected data was revised, coded, tabulated and entered in MS excel as the master chart. Quantitative variables were expressed as mean and SD wherein qualitative variable will be expressed as frequencies and percentages. Appropriate statistical tests were applied to obtain results. A significant level of $p<0.05$ will be used in all tests.

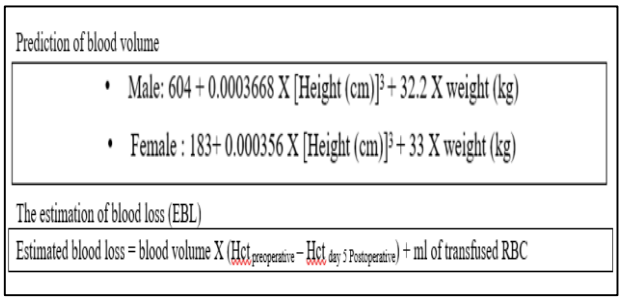

Figure 1: Blood volume and blood loss prediction.

RESULTS

Women were more likely to have a normal coagulation profile and a BMI of 24.47 than men, who were more likely to be in their 60s and 70s (mean 68.126) (Table 1). The mean HB was 11.68 and HCT was 34.61, p values less 0.05 were statistically significant. As shown in (Figure 2) mean EBL were 408 ml, and 518 ml respectively in cases and control.

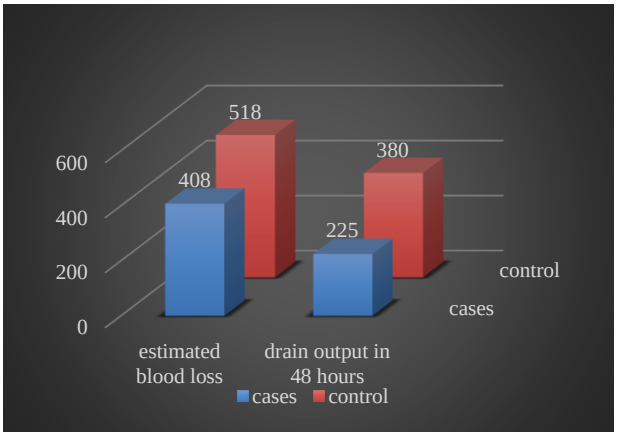

Figure 2: Estimated blood loss in cases and control group.

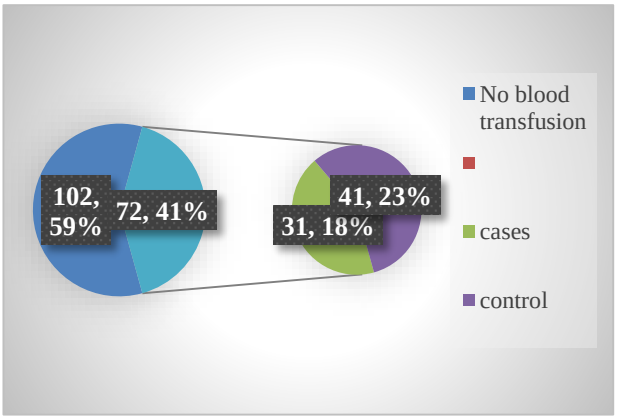

Figure 3: Blood transfusion among cases and controls.

Table 1: Demographic and prospective data in both the groups.

Parameters		Cases	Control	P value
Mean age (years)		68.126	67.713	1.781
Gender (F:M)		59: 28	54:33	-
BMI		24.47±2.86	24.60±2.82	0.098
Coagulation profile	**Platelet**	2.93±0.98	2.83±0.97	0.052
	INR	0.89±0.14	0.88±0.13	0.054
Pre-op HB		11.68±0.89	11.75±0.83	0.056
Pre-op hematocrit		34.61±3.19	34.86±3.23	0.022

Table 2: Mean HB in both study groups at different periods.

Parameters	Group case		Group control		Statistical analysis	
	Mean	**SD**	**Mean**	**SD**	**T test**	**P value**
Pre-operative	11.68	0.89	11.75	0.83	1.771	0.056
immediately post-operative	10.62	0.98	10.66	0.95	1.609	0.098
Post-operative day 1	10.27	0.65	10.38	0.64	1.223	0.051*
Post-operative day 5	9.70	0.66	9.64	0.69	1.425	0.048*

*p value<0.05 is significant

Drain output in cases and control was 225ml and 380 ml respectively. As shown in (Figure 3) 59% of the subjects did not require blood transfusion whereas 41% 23% and 18% in controls and cases respectively required blood transfusion. The mean difference between control and cases Hb was determined to be statistically significant on post-op days 1 and 5 (p value=0.05) using a one-sample t test. However, there was no discernible change between pre-op and immediate post-op.

DISCUSSION

Transfusion volumes and medical complications related to blood transfusions were reduced in elderly patients who had hemiarthroplasty with femoral neck fractures after intraoperative topical injection of TXA. Results from this study suggest that tranexamic acid may be a simple and affordable treatment option for elderly patients with femoral neck fractures. Peri-prosthetic joint infection has been associated in studies to blood transfusions and has been recognised as a risk factor for higher mortality and morbidity on its own.[9,10] The high risk of blood loss and transfusion should be taken into account when performing comment fracture surgical procedures on the elderly and those with coexisting conditions. Studies have found a correlation between tranexamic acid and an elevated risk of deep vein thrombosis.[11,12]

Research on the wound site, however, says that tranexamic acid's impact is stronger than in peripheral venous circulation.[13] This could be due to the wound causing the production of tissue plasminogen activator. Because we chose a topical method of administration, which reduces systemic absorption and hence reduces systemic side effects, none of our research samples had thromboembolic events. In our study, 174 individuals who had a hip hemiarthroplasty for a fractured neck of the femur were included. In all treatments, the average surgery time was 60 minutes. We used a lower TXA dosage of 1 g in our trial due to our concerns about the safety of this drug in elderly patients and the less invasive nature of hemiarthroplasty compared to total hip arthroplasty, especially taking into consideration the fact that the effect of topical TXA is not dose-dependent.[14] Konig et al used topical treatment on the joint by soaking it in 20 ml of TXA solution.[15] Yue et al followed Konig et al by applying gauze soaked in TXA solution to the acetabulum and femoral can.[16] Because we were worried about the length of the surgery, we decided against using the gauze-packing method. In addition, Kang et al rapidly injected a TXA solution into the joint following the drainage tube's closure.[17] The efficacy of the medication may be lowered by this procedure because TXA may have flowed out of the joint through the drain tube. Direct TXA injections were made into the soft tissue around the joint capsule.

Transfusion rates and total amounts were not altered by topical TXA, but perioperative blood loss and vacuum drainage were significantly reduced and transfusion rates and amounts were significantly reduced in our group even though myoglobin and haematocrit transfusion were not altered. Even though there were hardly any variations in haemoglobin and haemoglobin concentration between the two groups, the case group's transfusion rates were much lower. We think that the slight difference in Hb and Hct between the two groups on postoperative days 1 and 5 was the result of the control group receiving more transfusions to make up for the higher blood loss during the early postoperative period.

According to Tuttle et al there was no statistically significant difference between patients who underwent primary hip and knee arthroplasty and those who got topical TXA in terms of the length of hospital stay.[18] Topical TXA, in contrast, increased hospital release to

home rather than a subacute facility, decreased transfusion rates and costs, and was consistent with findings.

The majority of whom were between the ages of 60 and 70. We only included isolated neck of femur fracture instances, regardless of side or mechanism of injury. As the neck of femur fractures in the elderly are 2-3 times higher in women than in men, 60-70 per cent of patients in our study were females compared to 30-40 per cent of males.[15] According to Lee et al transfusion rates for those who received topical TXA were roughly 6% lower than those who did not get TXA, i.e., 19%.[19]

The current study also found that the study group's(cases) transfusion rate was much lower than the control group. In comparison to 7% of cases, roughly 19% of controls were transfused with 2-unit PRBCs. In our hospital, anaesthesiologists make intraoperative transfusion decisions based on the patients' comorbidities and circumstances. Clinical examinations based on blood-soaked gauzes, suction bottles, and vacuum drains are less reliable in determining total blood loss than Hct values and the Gross formula.

Clinical assessments based on blood-soaked gauzes, suction bottles, and vacuum drains were replaced with Hct levels and the Gross formula to calculate the total blood loss. However, there are certain limitations of our study. The follow-up was brief, and the sample size was limited and study was restricted to single institute. Furthermore, the risk of thromboembolism was underestimated because only individuals with clinical symptoms were submitted to diagnostic testing such as ultrasonography or 3-dimensional CT-angiography.

CONCLUSION

A single dose of topical tranexamic acid before closure in bipolar hemiarthroplasty lowers perioperative blood loss and transfusion needs while enhancing safety against thromboembolic events in elderly patients with broken necks of the femur.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Cooper C, Campion G, Melton LJ. Hip fractures in the elderly: a worldwide projection. Osteoporos Int J Establ Result Coop Eur Found Osteoporos Natl Osteoporos Found USA. 1992;2(6):285-9.
2. Gullberg B, Johnell O, Kanis JA. World-wide projections for hip fracture. Osteoporos Int J Establ Result Coop Eur Found Osteoporos Natl Osteoporos Found USA. 1997;7(5):407-13.
3. Hongisto MT, Pihlajamäki H, Niemi S, Nuotio M, Kannus P, Mattila VM. Surgical procedures in femoral neck fractures in Finland: a nationwide study between 1998 and 2011. Int Orthop. 2014;38(8):1685-90.
4. Flohé S, Kobbe P, Nast-Kolb D. Immunological reactions secondary to blood transfusion. Injury. 2007; 38(12):1405-8.
5. Johansson T, Pettersson L, Lysander B. Tranexamic acid in total hip arthroplasty saves blood and money. Acta Orthop. 2005;76(3):314-9.
6. Benoni G, Fredin H, Knebel R, Nilsson P. Blood conservation with tranexamic acid in total hip arthroplasty: a randomized, double-blind study in 40 primary operations. Acta Orthop Scand. 2001;72(5): 442-8.
7. Nadler SB, Hidalgo JH, Bloch T. Prediction of blood volume in normal human adults. Surgery. 1962;51(2): 224-32.
8. Mercuriali F, Inghilleri G. Proposal of an algorithm to help the choice of the best transfusion strategy. Curr Med Res Opin. 1996;13(8):465-78.
9. Innerhofer P, Klingler A, Klimmer C, Fries D, Nussbaumer W. Risk for postoperative infection after transfusion of white blood cell-filtered allogeneic or autologous blood components in orthopaedic patients undergoing primary arthroplasty. Transfusion. 2005; 45(1):103-10.
10. Pulido L, Ghanem E, Joshi A, Purtill JJ, Parvizi J. Periprosthetic joint infection: the incidence, timing, and predisposing factors. Clin Orthop Relat Res. 2008; 466(7):1710-5.
11. Nishihara S, Hamada M. Does tranexamic acid alter the risk of thromboembolism after total hip arthroplasty in the absence of routine chemical thromboprophylaxis? Bone Joint J. 2015;97-B(4):458-62.
12. Myers SP, Kutcher ME, Rosengart MR, Sperry JL, Peitzman AB, Brown JB, et al. Tranexamic acid administration is associated with an increased risk of posttraumatic venous thromboembolism. J Trauma Acute Care Surg. 2019;86(1):20-7.
13. Thipparampall AK, Gurajala I, Gopinath R. The effect of different dose regimens of tranexamic acid in reducing blood loss during hip surgery. Indian J Anaesth. 2017;61(3):235-9.
14. Montroy J, Hutton B, Moodley P, Fergusson NA, Cheng W, Tinmouth A, et al. The efficacy and safety of topical tranexamic acid: A systematic review and meta-analysis. Transfus Med Rev. 2018;32(3):165-78.
15. Konig G, Hamlin BR, Waters JH. Topical tranexamic acid reduces blood loss and transfusion rates in total hip and total knee arthroplasty. J Arthroplasty. 2013; 28(9):1473-6.
16. Yue C, Kang P, Yang P, Xie J, Pei F. Topical application of tranexamic acid in primary total hip arthroplasty: a randomized double-blind controlled trial. J Arthroplasty. 2014;29(12):2452-6.
17. Kang JS, Moon KH, Kim BS, Yang SJ. Topical administration of tranexamic acid in hip arthroplasty. Int Orthop. 2017;41(2):259-63.

18. Tranexamic acid and thrombosis. Prescrire Int. 2013; 22(140):182-3.
19. Lee C, Freeman R, Edmondson M, Rogers BA. The efficacy of tranexamic acid in hip hemiarthroplasty surgery: An observational cohort study. Injury. 2015;46(10):1978-82.

Cite this article as: Pruthvi KP, Meena RC, Rayanad MK. A prospective randomized control trial of topical tranexamic acid used in elderly patients with femoral neck fractures treated with hemiarthroplasty. Int J Res Orthop 2023;9:256-60.