



International Journal of Orthopaedics Sciences

E-ISSN: 2395-1958
P-ISSN: 2706-6630
IJOS 2019; 5(4): 733-737
© 2019 IJOS
www.orthopaper.com
Received: 04-08-2019
Accepted: 08-09-2019

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Efficacy of intravenous tranexamic acid in reducing perioperative blood loss in patients undergoing hemiarthroplasty

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DOI: <https://doi.org/10.22271/ortho.2019.v5.i4m.1760>

Abstract

Introduction: Femoral neck fractures are frequent injuries in a trauma centre and have a high incidence in the general population. Hip fracture surgeries are associated with substantial blood loss, exposing patients to postoperative anaemia. The severity of anaemia is related directly to post-operative functional recovery of the patients, which is related to long-term mortality. Blood transfusion related adverse effects also can directly influence the recovery. Tranexamic acid is a simple and inexpensive synthetic antifibrinolytic agent, which prevents the degradation of fibrin and delays the breakdown of haemostasis clots. Aim of this study is to assess the efficacy of intra-venous administration of Tranexamic acid in patients undergoing hemiarthroplasty with regards to blood loss at perioperative period.

Materials and Methods: A prospective randomised control study was done in a tertiary care hospital in southern part of India during the period of January 2016 to June 2017. 40 consecutive fracture neck of femur patients were randomised into two group, each group consist of 20 patient, Group 1 patients received placebo of 50 ml of normal saline administered intravenously 10 minutes before starting the surgery. Group 2 patients received Tranexamic acid -1500Mg diluted in 50ml Normal Saline administered intravenously 10 minutes before the surgery. Intraoperative blood loss was assessed by collecting the number of fully soaked mopping pads, fully soaked gauze pieces and quantity of irrigation fluid form suction bottle after subtracting the amount of normal saline used for wash. Post operatively all patients were assessed by evaluating the haemoglobin, Packed cell volume values from patients and blood collected in the negative suction drain of day 1 and day 2. The study group and control group parameters were analysed and compared.

Results: 45 patients were enrolled in our study and 5 patients were excluded from the study due to not giving consent for study. Demographic data like age, gender, side of fracture, type of fracture type of prosthesis were not influenced our study. Requirement of intra operative blood transfusion were significantly reduced in study group in comparison with control group which was statistically significant ($p=0.027$). In study group only 3 patient received blood transfusion, whereas control group 11 patents were received.

Conclusion: In our study, there was significant reduction in the amount of blood loss in tranexamic acid administered group when compared to the placebo group. Tranexamic acid was cost effective and safer when compared to blood components. Tranexamic acid should be considered for routine use in Hemiarthroplasty surgery to decrease blood loss.

Keywords: Fracture neck of femur, anaemia, blood transfusion, tranexamic acid, hemiarthroplasty

Introduction

Femoral neck fractures are frequent injuries in a trauma centre and have a high incidence in the general population ^[1]. Osteoporosis is a major cause of the femoral neck fractures. And treating the fracture alone is not the current line of treatment. The osteoporosis part is also addressed along with the fracture. The World Health Organisation (WHO) criteria for osteoporosis defined as when bone mineral density (BMD) falls 2.5 below the standard deviations the mean found in young adult women ^[2]. Hip fracture surgeries are associated with substantial blood loss, exposing patients to postoperative anaemia. The severity of anaemia is related directly to post-operative functional recovery of the patients, which is related to long-term mortality ^[3]. Most of the patients undergoing hemiarthroplasty

requires 1 to 3 units of blood transfusions post operatively. Blood transfusion related adverse effects also can directly influence the recovery [4-6]. Postoperative anaemia found in 90% of patients after arthroplasty increases the risk of myocardial infarction due to a mismatch between oxygen supply and requirements. During the perioperative period, myocardial infarction is the leading cause of death after major orthopaedic procedures [7, 8]. Tranexamic acid is a synthetic derivative of amino acid lysine that exerts an antifibrinolytic effect through the reversible blockade of lysine binding sites on plasminogen, thereby reducing the conversion of plasminogen to plasmin (fibrinolysis) an enzyme that degrades the fibrin clots and fibrinogen. Tranexamic acid is a simple and inexpensive synthetic antifibrinolytic agent, which prevents the degradation of fibrin and delays the breakdown of haemostasis clots. There by reducing the blood lose by one-third during the surgery a 30% reduction in blood transfusion requirements has been demonstrated with Tranexamic acid in orthopaedic surgery [9]. Our aim of this study is to assess the efficacy of intra-venous administration of Tranexamic acid in patients undergoing hemiarthroplasty with regards to blood loss at perioperative period.

Materials and Methods

This study was a prospective randomised control study done in a tertiary care hospital in south India between the period of January 2016 to June 2017. All patients coming to the casualty with neck of femur fractures above the age of 60 years were included in the study. Patients who were on anti-coagulant therapy, Coronary artery diseases, cerebrovascular accident, uncontrolled hypertension, revision surgeries, patients with neuro-muscular disorders, Pathological fractures were excluded from our study. All patients planned for hemiarthroplasty were included in this study after obtaining informed consent. The study was initiated after getting the approval of Institutional human ethics committee (IHEC). These patients were then grouped into two categories with group 1 and group 2. Group 1 patients received placebo of 50 ml of normal saline administered intravenously 10 minutes before starting the surgery. Group 2 patients received Tranexamic acid -1500Mg diluted in 50ml Normal Saline administered intravenously 10 minutes before the surgery. Patients were prospectively randomized either to the control or intervention group within each stratum by computer-generated permuted block randomization of sizes 2,4, or 6 using SAS 9.4 which was pre-prepared by statistician. Flow chart of our study was given in Figure.

Intraoperative blood loss was assessed by collecting the number of fully soaked mopping pads, fully soaked gauze pieces and quantity of irrigation fluid form suction bottle after subtracting the amount of normal saline used for wash.

Post operatively all patients were assessed by evaluating the haemoglobin, Packed cell volume values from patients and blood collected in the negative suction drain of day 1 and day

2. The study group and control group parameters were analysed and compared.

Statistical analysis

The data was entered in Microsoft Excel and analysed in Epi Data analysis V2.2.2.184 software. The continuous variables age, haemoglobin values (pre and post-surgery), PCV values (pre and post-surgery), litres of suction fluid and washed fluid and drain amount were reported as Mean (SD). The categorical variables such as group (those who received and not received tranexamic acid), gender, side of surgery, mode of injury, Garden type, cement usage, type of prosthesis, number of units of blood transfusion done (pre, intra and post-surgery), number of mops and gauze pads used, were reported as proportions. The association between continuous variables and the groups (those who received and not received tranexamic acid) were assessed using independent t test and the association between categorical variable and groups were assessed using Chi Square test or Fishers exact test. The p value of <0.05 was considered for statistical significance.

Results

A total of 45 patients with neck of femur fracture were assessed for eligibility for this study. Five patients were excluded since they have not consented to take part in the study. A total for 40 patients were included in the study who were randomised in two groups with 20 patients each group. Mean age distribution in control group (group 1) was 65.3 years and study group (group 2) was 68.9 years. Out of 40 patients 22 patients were female and 18 patients were male patients. Most of the patients (n=35) were had slip and fall at home was the mode of injury. Only 5 patients had presented with road traffic accident. 24 patients were classified into gardens type III fracture (Figure.2). Distribution of type of fracture were given in (Table. 1). There was no statistically significant difference found in our study in relation to age, gender, mode of injury and type of fracture, and type of implant and method of implant fixation by with cement or without cementation. In our study we have not studied the blood lose and type of approach for hemiarthroplasty. There was a statistically significant difference noted with intra operative blood transfusion in study group with p value of 0.027 in comparison with control group (Figure.3), (Table.2). Requirement of post operative blood transfusion was nil in study group whereas 2 patients had blood transfusion post operatively with statistical p value of 0.349 which is statistically significant. Post-operative reduction of haemoglobin level in tranexamic acid group was less compared to placebo group which was statistically significant (Table 3). The amount of blood collected in the drain was significantly low in tranexamic acid group (160.5ml) in comparison with placebo group (222.4 ml). detailed description of drain collection was given in (Table.4) and (Figure.4).

ALGORITHM FOR PATIENT SELECTION

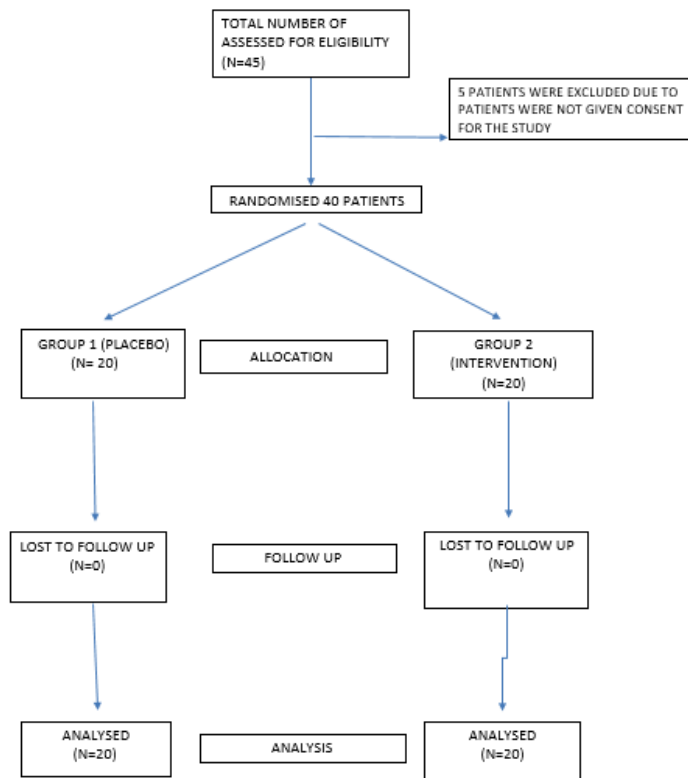


Fig 1: Flow chart of the study

Table 1: Garden type among study participants of both groups

| Garden type | Control group (N=20) | | Study group (N=20) | | Total number of the participants Number | P value # |
|-------------|----------------------|------------|--------------------|------------|--|-----------|
| | Number | Percentage | Number | Percentage | | |
| Type I | 0 | 0.0 | 1 | 5.0 | 1 | 0.723 |
| Type II | 3 | 15.0 | 4 | 20.0 | 7 | |
| Type III | 13 | 65.0 | 11 | 55.0 | 24 | |
| Type IV | 4 | 20.0 | 4 | 20.0 | 8 | |
| Total | 20 | 100.0 | 20 | 100.0 | 40 | |

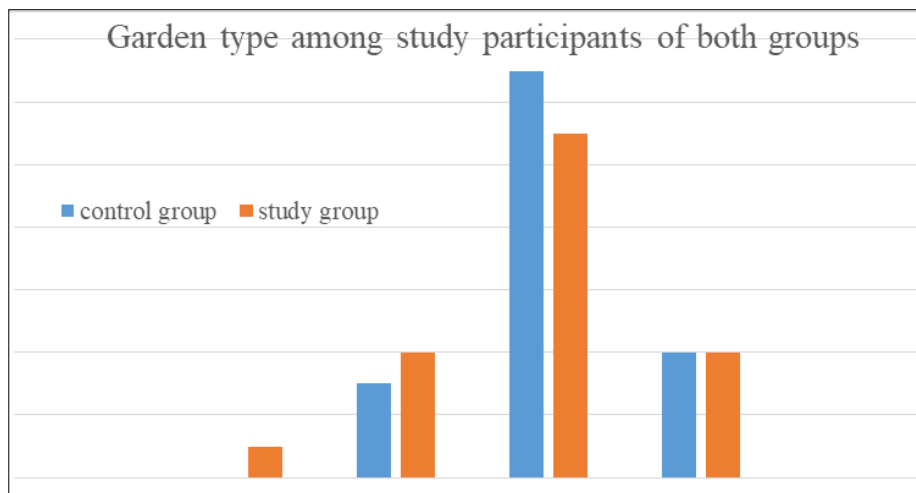


Fig 2: Garden type among study participants of both groups

Table 2: Number of transfusion done intra operatively among the two groups

| Number of blood transfusion done intra operatively | Control group (N=20) | | Study group (N=20) | | Total number of the participants Number | P value # |
|--|----------------------|------------|--------------------|------------|--|-----------|
| | Number | Percentage | Number | Percentage | | |
| 0 | 9 | 45.0 | 17 | 85.0 | 26 | 0.027 |
| 1 | 9 | 45.0 | 2 | 10.0 | 11 | |
| 2 | 2 | 10.0 | 1 | 5.0 | 3 | |
| Total | 20 | 100.0 | 20 | 100.0 | 40 | |

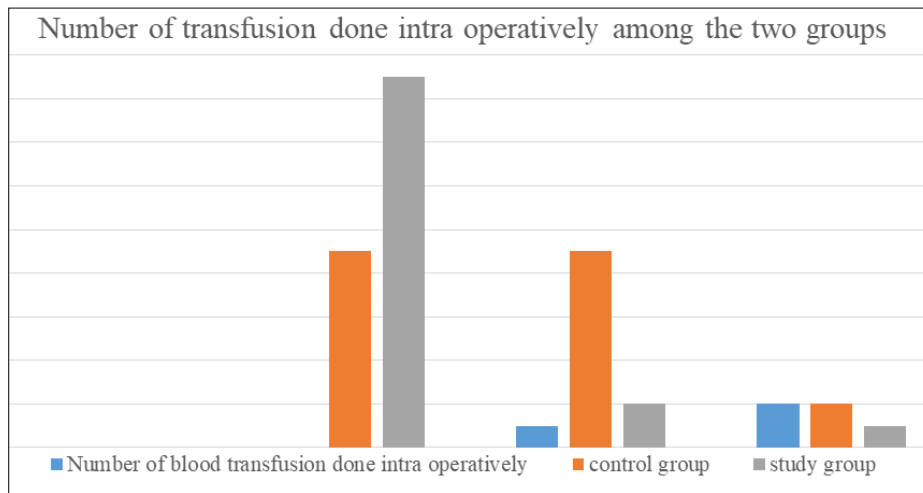


Fig 3: Number of transfusion done intra operatively among the two groups

Table 3: Postoperative Haemoglobin & PCV values of participants of both groups

| | Control group (N=20) | | Study group (N=20) | | P value |
|--|----------------------|--------------------|--------------------|--------------------|---------|
| | Mean | Standard deviation | Mean | Standard deviation | |
| Post-operative Haemoglobin values g/dl | 10.4 | 1.2 | 10.6 | 1.1 | 0.694 |
| Post-operative PCV | 31.0 | 3.4 | 30.5 | 2.8 | 0.622 |

Table 4: Amount of drain collected in day 1 & day 2 among both the groups

| | Control group (N=20) | | Study group (N=20) | | P value |
|---------------------|----------------------|--------------------|--------------------|--------------------|---------|
| | Mean | Standard deviation | Mean | Standard deviation | |
| Drain day one in ml | 222.5 | 85.2 | 160.5 | 55.4 | 0.010 |
| Drain day two in ml | 74.2 | 14.4 | 74.0 | 16.7 | 0.960 |
| Total drain in ml | 296.7 | 93.7 | 234.5 | 66.2 | 0.020 |

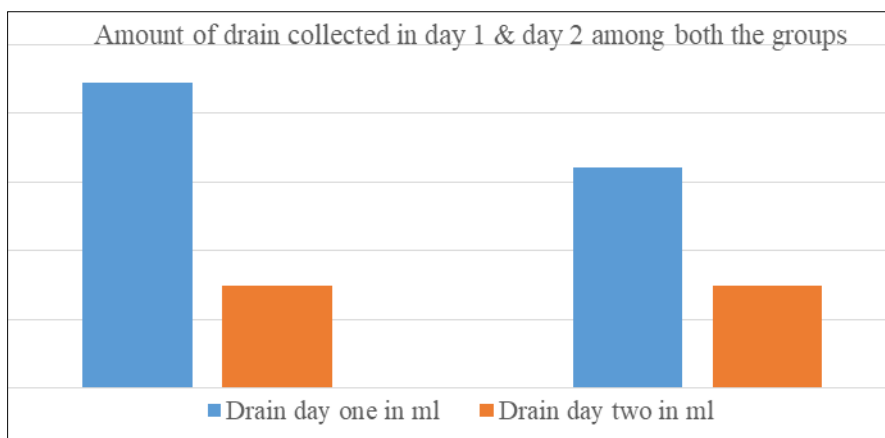


Fig 4: Amount of drain collected in day 1 & day 2 among both the groups

Discussion

Neck of femur fractures are common in older age group for which Hemiarthroplasty is commonly done. It involves significant amount of blood loss because of the extensive soft tissue release and medullary canal opening that are involved in the procedure. Various studies have shown the efficacy of intravenous tranexamic acid in controlling blood loss following hemiarthroplasty and total hip replacement and total knee replacement. Mohib *et al* randomized 100 patients to 2 groups which demonstrated that TA could decrease blood loss and transfusion rates without increasing the rate thrombotic events during the treatment of neck o femur fractures [10]. In our study we randomised 40 patients to 2 groups, in our study also there were decrease in blood transfusion rate and no thrombotic events.

Shiva, Dinakar rai, shyam sundar *et al* experienced a significant reduction of total blood loss and reduction in

number of blood transfusion in hemiarthroplasty surgery using single 15mg/kg dose of tranexamic acid compared with control group. In our study also we have given a single dose of tranexamic acid and there was a significant reduction in the blood loss the intra-operative blood loss between the two treatment groups (Mean-tranexamic acid =264.88 ml, C= 330.52 ml) Postoperative blood loss were significantly less in the Tranexamic Acid group (Mean-T=160.5 ml, C=222.5 ml). Packed red blood cell transfusion requirements were significantly lower in the tranexamic acid group compared with the control group [11]. In our study post-operative blood lose was 160.5ml (Mean) in comparison with control group had 222.4ml (mean) at drain tube collection on day one post operatively.

Raimo O Niskanen *et al* conducted study in tranexamic acid in hip arthroplasty, in their study 39 patients were included and was separated into two groups 20 study group and 19

control group single dose of tranexamic acid were given to the study group they have found that 3 complications occurred in the tranexamic acid group: 1 superficial wound infection, 1 transient dyspnoea on the third postoperative day, and 1 pyelonephritis 1 month later. In our study we administered single bolus tranexamic acid to study group and 50 ml of normal saline was administered to control group and in our study we did not have single complication encountered by us in both the groups until their hospital stay^[12].

Ido. Husted *et al.* have conducted a study in tranexamic acid in hip fractures reported no thromboembolic complications, in our study also we found that no patients were encountered with thromboembolic complications. Sarzaem MM *et al* found that intravenous route was more effective in reducing the post-operative hemoglobin drop and leads to higher post-operative haemoglobin compared to placebo which is consistent with our study^[13].

Wang, Ji, and Zhu *et al* randomized 100 patients to 2 groups which demonstrated that Tranexamic Acid could decrease blood loss and transfusion rates without increasing rate thromboembolism events during the treatment of hip fractures^[14]. In addition, Lee *et al* even suggested that Tranexamic Acid should be widely used in all patients undergoing hip hemiarthroplasty for hip fractures through a retrospectively study^[15]. Our study also there was decreased blood loss in the study group and transfusions, which is consistent with their study.

Limitations of our study

The limitation of this study is the small sample size. Hence there is need for multicentric trial with large sample size to have the statistically significant study.

Recommendation for the future study

Intravenous Tranexamic acid is effective in controlling the intra operative blood loss during hip surgeries. Benefits of Intra articular infiltration of Tranexamic acid in total knee replacement were well documented in literature. Comparative study of intra articular and intravenous administration of Tranexamic acid in hip surgery will be the future progression.

Conclusion

In our study, there was significant reduction in the amount of blood loss in tranexamic acid administered group when compared to the placebo group. Tranexamic acid was cost effective and safer when compared to blood components. Tranexamic acid was useful and effective in reducing peri-operative blood loss and reduces the need for blood transfusion post-operatively. Tranexamic acid decreases the infection risks from blood transfusions, also is very safe regarding the Venous Thromboembolism complications. Tranexamic acid should be considered for routine use in Hemiarthroplasty surgery to decrease blood loss.

Conflict of interest: None

Source of funding: None

Ethical issue: hospital ethical committee approval was obtained before starting the study.

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