MAK HILL Publications Research Journal of Medical Sciences

Research Article
doi: 10.36478/makrjms.2024.7.370.374

OPEN ACCESS

Key Words
Above-the-knee tourniquet, bleeding, blood transfusion, total knee arthroplasty (TKA), tranexamic acid

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Received: 20 April 2024
Accepted: 20 June 2024
Published: 21 June 2024

Citation: N. Kattu Bava, T. Uvarajan, K.C. Mathew, Mohammed Sheriff and T.T. Annamalai, 2024. Effect of Tranexamic Acid in Reducing Blood Loss and Transfusion in Patients Undergoing Total Knee Arthroplasty Without Tourniquet Usage Safely. Res. J. Med. Sci., 18: 370-374, doi: 10.36478/makrjms.2024.7.370.374

Effect of Tranexamic Acid in Reducing Blood Loss and Transfusion in Patients Undergoing Total Knee Arthroplasty Without Tourniquet Usage Safely

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Abstract
In Total knee arthroplasty (TKA), the loss of blood during and after the surgery can lead to substantial morbidity and the need for blood transfusions. Various methods are applied in TKA to minimize blood loss and to decrease transfusion rates in patients undergoing surgery. Tranexamic acid is an antifibrinolytic agent with known efficacy for achieving this goal of decreasing the morbidity and the transfusion rates. Currently, many surgeons are performing TKA without the use of tourniquet. Hence we aim to study effect of tranexamic acid in reducing blood loss during and after TKA without the adjunctive use of above-the-knee tourniquet. This prospective study was conducted in Sree Mookambika Institute of medical sciences between March 2022 and June 2023. We included the 50 patients with a diagnosis of osteoarthritis undergoing TKA. We divided the 50 patients into two groups as group A and group B with 25 patients each using non-probability technique. The group-A received tranexamic acid 10 mg/kg (diluted in 100 cc of normal saline) 10-minute intravenous infusion three times, the first dose 20 minutes before the induction of anasthetic agents, the second dose during the induction of anesthetic agents and a third dose after three hours. The group B didn't receive tranexamic acid. Surgery was performed without the use of above-the-knee tourniquet. We collected data about demographic and procedural characteristics, hemoglobin and hematocrit values, drain blood loss at 24 hours as well as adverse events. There were no transfusions in the group A, whereas 31% of the control group required transfusion ($p<0.05$). The group A had higher hematocrit and haemoglobin levels at 24, 48 and 72 hours after surgery (all $p<0.05$) and lower drain loss at 24hours (i.e. group A 351.4±151 ml and 614±240 ml in the group B, $p<0.005$). There were no in-hospital or six-month symptomatic thromboembolic complications. A triple dose of tranexamic acid was safe and effective, reducing blood loss and preventing the need of blood transfusion in patients undergoing TKA without the need of above-the-knee tourniquet.

INTRODUCTION

Bleeding from bone and soft tisseus (500-1400 cc) represent the most common cause of postoperative morbidity after Total Knee Arthroplasty (TKA), increasing the requirement of transfusion up to 50% and prolongs the length of hospitalization[1-6]. Also, the use of antiplatelet and anticoagulant agents to reduce the thromboembolic events in patients undergoing TKA has considerably increased bleeding risk. Tranexamic acid is a synthetic amino acid lysine derivative that competitively blocks the lysine-binding sites of plasminogen thereby inhibits fibrinolysis. Various studies have demonstrated that tranexamic acid administration, either topically or systemically, decreases bleeding following surgical procedures[7-10], including TKA[3-11], without predisposing to thromboembolic complications. The application of an above-the-knee pneumatic tourniquet during TKA can also reduce intra operative bleeding[12], nonetheless, this practice does not reduce overall blood loss[13] and provoke considerable tissue damage and postoperative pain[14], which may also slow rehabilitation. In addition, the use of tourniquets for more than 1-2 hours during TKA increases the risk for local arterial and venous thrombosis[15]. Meanwhile, due to the use of modern cementing techniques and tranexamic acid may avoid the need for a tourniquet during TKA[16]. In our institution, we have done this procedure without using a tourniquet. We have not seen many studies that has evaluated the efficacy of tranexamic acid in reducing blood loss in patients undergoing TKA without the use of pneumatic tourniquet. Therefore, we have done a prospective study to evaluate the use of this tranexamic acid in patients undergoing TKA without tourniquet. The primary outcome measure was transfusion rate, secondary outcome measures were drain output, hemoglobin/hematocrit levels.

MATERIALS AND METHODS

This prospective study was conducted in Sree Mookambika Institute of medical sciences between march 2022 and June 2023. We included the 50 patients with a diagnosis of osteoarthritis undergoing TKA with normal preoperative platelet count, normal Prothrombin Time, normal Partial Thromboplastin Time, normal International Normalized Ratio. We excluded patients with allergy to tranexamic acid, history of Deep Vein Thrombosis and Thromboangitis obliterans, congenital or acquired coagulopathies, renal or liver dysfunction, myocardial infarction within the last 6 months or retinopathy. If patients were taking antiplatelet agents they were asked to stop them for at least 7 days before surgery. We divided the 50 patients into two groups as group A and group B with 25 patients each using non-probability technique. The group-A received tranexamic acid 10 mg/kg (diluted in 100 cc of normal saline) 10-minute intravenous infusion three times, the first dose 20 minutes before the induction of anasthesia, the second dose during the induction of anesthetic agents and a third dose after three hours. The group B didn't receive tranexamic acid. Surgery was performed without the use of above-the-knee tourniquet. An anterior skin incision and medial parapatellar aproach was used in all cases. All patients received a posterior stabilized cemented prosthesis. All patients received cemented prosthesis and the patella was not resurfaced in any case. In each patient, one intra-articular drain was used and connected to a high-vacuum drain bottle. Then knees were placed in compressive bandages and splint. The patients were taught and asked to perform a mechanical ankle pumping exercise regimen for deep vein thrombosis prophylaxis as soon as possible. The compressive bandages and the splint were removed on the first day after surgery and the patient could start ambulation with a walker. We also recorded data regarding the total drain output at twenty-four hours and the serial changes in hematocrit and hemoglobin (baseline, first, second and third postoperative days) values for the hospital stay as well as adverse events both related to the wound and to any medical complications. We analyzed group differences in this study by operative time, transfusion requirements, drain loss at 24 hours, serial changes in hemoglobin and hematocrit levels. The data collected was subjected to data entry in MS Excel. The data was analyzed using SPSS (SPSS inc IBM Chicago city, Illinois state, USA) Version 20.0 using Chi square test and Paired t test.

RESULTS AND DISCUSSIONS

In our study the mean age was 71.5±9.4 years (range 43-90 years) in the group A and 72±6.8 years

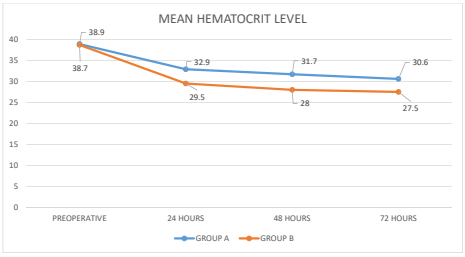

Fig. 1: Mean hematocrit level comparision between two groups during follow up.

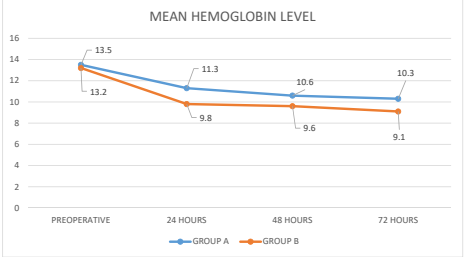

Fig. 2: Mean hemoglobin level comparision between two groups during follow up

Table 1: Mean hematocrit level comparision between two groups during follow up.

	Mean Hematocrit levels (%)	
Period	**Group A**	**Group B**
Preoperative	38.9	38.7
After 24 Hours	32.9	29.5
After 48 Hours	31.7	28
After 72 Hours	30.6	27.5

Table 2: Mean hemoglobin level comparision between two groups during follow up.

	Mean Hemoglobn levels (g/dl)	
Period	**Group A**	**Group B**
Preoperative	13.5	13.2
After 24 Hours	11.3	9.8
After 48 Hours	10.6	9.6
After 72 Hours	10.3	9.1

In our study we had a mean operative time of 90.9±10.5 minutes for group A and 92.2±9.9 minute for (range 61-84) in the group B. Female gender was prevalent in both groups 63% in group A and 75% in group B. the group-B. Hospital stay of the patients had a mean of 4.4±7.3 days (range 4-7 days) and 4.0±9.4 days (range 4-7 days) for the group A and group B, respectively.

Postoperatively, the hemoglobin and hematocrit levels of group A were significantly higher in the group A. After 24, 48 and 72 hours, both hemoglobin and hematocrit were dropped in the group B (Fig.2).

The blood drained during the first 24 hours was lower in the group A i.e 351.4±151 ml and 614±240 ml in the group B ($p<0.05$). This 41% absolute reduction in drain loss resulted into zero transfusion requirement for the group A and 31% (in the group B ($p<0.05$), with 2.06 (range 1-4) transfused units. four out of seven transfused patients had a hemoglobin level <8 g/dl postoperatively, while 3 patients had a hemoglobin <9.5 g/dl associated with significant comorbidities. None of the patients in the treatment group reached these transfusion thresholds. There were no thrombotic, embolic or infectious complications during hospitalization and at six-month follow-up.

TKA is associated with considerable intra operative and postoperative bleeding and the subsequent need for blood transfusion[1-3]. Several studies have demonstrated that blood transfusion carries an excess risk of infections, arterial and venous thrombosis along with untoward immunologic reactions[17,18]. Besides, blood transfusion increases overall procedural cost. Several strategies have been used to diminish transfusion requirements such as the use of pneumatic above-the-knee tourniquet, postoperative blood salvage, hypotensive anesthesia, use of femoral intra medullary plug, cryotherapy or use of Jones bandage[19-22] along with the administration of topical agents (fibrin-based or thrombin-based). Tranexamic acid affects the fibrinolytic system by inhibiting the proteolytic action of plasm in, which stabilizes clot formation and diminishes blood loss. Intravenous administration of this agent has dramatically reduced the rate of bleeding during TKA[23]. Several investigators have also demonstrated its efficacy as a topical agent (i.e. dental procedures in patients with hemophilia or on oral anticoagulation, orthopedic surgeries, or trauma-associated bleeding[24,27]. Nonetheless, Ahlberg *et al.* reported that the drug diffuses rapidly through the synovial membrane, which allows for an immediate antihemorrhagic effect during TKA[28]. In a recent TKA study, five different intravenous drug regimens were tested using 10 mg/kg doses: (1) intra operative single-dose, (2) double-dose, intra operative and postoperative (3 hours after the first dose), (3) double-dose, preoperative (20 minutes before tourniquet inflation) and intra operative, (4) triple dose regimens, preoperative, intra operative and postoperative and (5) placebo. In this seminal study, regimens (3) and (4) showed the best anti-bleeding effect[29]. This study clearly suggests the need for an intravenous preoperative dose of tranexamic acid to obtain the strongest effect.

In line with these results, we used triple-dose scheduled regimen with a preoperative dose and second dose 3 hours after the procedure, but in contrast with prior studies, we did not apply tourniquet. In this setting, the drug regimen was extremely effective in reducing blood loss and transfusion requirements. To our knowledge, this study is the first to test the clinical safety and efficacy of this agent in patients undergoing TKA without above-the-knee pneumatic tourniquet. The absence of cases with symptomatic deep vein thrombosis is reassuring, however, it is not surprising giving the excellent drug profile shown so far. Although speculative, the avoidance of blood transfusion with this agent may reduce thrombosis risk. In our study, transfusion requirements were low (0% with tranexamic acid and 31% without) compared to a recent meta-analysis (29% with tranexamic acid and 55% without)[3], despite similar drain loss (319 and 630 ml with and without tranexamic acid, respectively). There may be differences in clinical threshold for blood transfusion which show discrepancy in transfusion rates between our study and others.

In the present study, there were several limitations which worth naming. Because of the nature of the study, we cannot exclude specific biases regarding surgical decisions during the procedure or the need for blood transfusion. Less sample size didn't allow for better evaluation and comparsion of clinical outcome between groups, however, severe postoperative bleeding after TKA leads to a worst short and long-term outcome. Our findings only apply to this type of TKA surgery, thus, they should not be generalized to other orthopedic procedures. In the present study, to identify deep vein thrombosis below the knee we have used ultrasound scan. This non-invasive imaging tool though has a low sensitivity for deep vein thrombosis. By measuring blood loss in the drains, we quantified only a partial amount of total blood loss. Tranexamic acid should prove cost-effective owing to the dramatic reduction exerted by the drug in terms of postoperative bleeding and the need for transfusion observed.

CONCLUSION

Administration of tranexamic acid reduces postoperative blood loss and the need for blood transfusion in patients undergoing TKA without the adjunctive use of an above-the knee pneumatic compression tourniquet. A triple dose of tranexamic acid was safe and effective, reducing blood loss and preventing the need of blood transfusion in patients undergoing TKA without the need of above-the-knee tourniquet. We observed that there was no increase in the symptomatic thromboembolic events in our patients.

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