

A COMPARATIVE STUDY OF ASSESSMENT OF ROLE OF TRANEXAMIC ACID IN CONTROLLING BLOOD LOSS IN ORTHOPAEDIC SURGERIES: A RANDOMISED CONTROL TRIAL.

Dr. Deepak Kumar¹, Dr.(Prof) Santosh Kumar²

¹Senior Resident, Department of Orthopedics, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India

²HOD, Department of Orthopedics, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India

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Corresponding author: Dr. Deepak Kumar

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Abstract

Aim: to study the role of Tranexamic Acid in Controlling Blood Loss In orthopaedic surgeries.

Material & Methods: 50 patients were included in the study during the study period. Patients were randomly allotted to 2 groups of equal participants. The first group (Group A) received Tranexamic Acid. The second group (Group B) was given Normal saline as placebo. The Total Blood Loss (intra operative + post operative) and Fall in Haemoglobin levels were measured post-operatively at 24 and 72 hrs of post-operative period.

Result: The group A had showed significantly reduced total blood loss and fall in Haemoglobin, thus, requiring fewer blood transfusions. No complications were observed.

Conclusions: the present investigation concluded that Tranexamic acid can be effective in reducing blood loss and subsequent fall in haemoglobin.

Keywords: Tranexamic acid, Bleeding, Major Orthopaedic surgeries.

Introduction

Tranexamic acid (TXA), a synthetic derivative of lysine, competitively blocks lysine-binding sites on plasminogen, thus reducing the local degradation of fibrin by plasmin [4].ⁱ TXA has been used successfully to stop bleeding in multiple specialties including liver, cardiac, prostate, and dental surgeries.^{ii,iii}

Tranexamic acid (TXA) has become more commonly used within large orthopedic surgeries with expected significant blood loss, such as total knee and total hip arthroplasties, ORIF of long bone fractures . Many meta-analyses and randomized studies have shown significant reduction in total blood loss and blood transfusions.^{iv}

With the use of TXA, blood transfusion rates have decreased along with many associated risks including postoperative infection, intravascular hemolysis, transfusion induced coagulopathy, renal impairment or failure, and mortality.^{v,vi}

However, the use of TXA is not without its own potential complications. These are not used in suspected myocardial infarction, stroke, deep vein thrombosis, pulmonary embolism, and renal failure.^{vii,viii}

It's widespread use has been affected by concerns regarding its safety, especially the propensity to precipitate an venous thromboembolism.^{ix} Hence the present study was undertaken to assess the of role of Tranexamic Acid In Controlling Blood Loss In orthopaedic surgeries.

Material and Methods

The present randomized control study was conducted in the Department of Orthopaedics Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India from March 2018 – February 2019.

INCLUSION CRITERIA:

1. Patients above 18 years of age of either sex
2. Pt undergoing major surgeries like THR,PHR ,TKR ,LONG BONE ORIF/CRIF

EXCLUSION CRITERIA:

1. Presence of comorbid medical conditions like coronary disease, bleeding disorders, chronic renal failure, previous thromboembolism.
2. Active Infection.

The study protocol was reviewed by the Concerned Ethical Committee and was granted ethical clearance. After explaining the purpose and details of the study, a written informed consent was obtained

Sample selection

The sample size was calculated using a prior type of power analysis by G* Power Software Version 3.0.1.0 (Franz Faul, Universitat Kiel, Germany). The minimum sample size was calculated, following these input conditions: estimated prevalence of 20%, power of 0.80 and $P \leq 0.05$ and sample size arrived were 18 subjects per group. Total sample taken was 25 subjects per group.

Method of Randomisation: Simple Random Sampling – Random number generator

Grouping

The intervention group (Group A) received Tranexamic Acid 500mg intravenous bolus and 500mg slow intravenous infusion which was started just before the surgery.

The control group (Group B) did not receive any Tranexamic Acid during surgery, instead control agent i.e Normal Saline was administered in similar method as to intervention group. The drug was packed into an envelope by an OT nurse. The drug administered by the operating team anaesthetist by opening the envelope.

Surgical Technique

All the operation were performed by a same surgical team.

TOTAL HIP ARTHROPLASTY – A standard lateral approach was used. Cemented and Uncemented THR was decided according to patient profile.

TOTAL KNEE ATHROPLASTY – Performed with medial parapatellar incision.

Standard Bipolar electro-cautery was used for haemostasis during surgery. Wound was closed in anatomical layers with vacuum suction drain placed in-situ. Wound dressing was done on post-op day 2.

Estimation of Total Blood Loss

Total Blood Loss was estimated intraoperatively and post-operatively. Total Blood Loss was estimated to be the sum of Intra-op and Post-op estimated blood losses.

Intra-Op blood loss estimated by weighing all the mops used during surgery (whose dry weight had been standardised and documented using an electronic weighing scale) and total blood loss in the suction drain.

Post-op Blood loss was calculated by the soakage of the incision site dressing at first post op dressing (done using pre-weighed cotton pads) and negative pressure suction drain collection wherever applicable. Suction drain was removed on 2nd post-operative day.

Statistical analysis

The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2010) and then exported to data editor page of SPSS version 19 (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics included computation of percentages and means. The statistical test applied for the analysis was independent sample t-test. The confidence interval and p-value were set at 95% and ≤ 0.05 respectively.

Results

Table 1: demographic profile of the study population

Demographic Characteristics	Group A	Group B
Age (years)	57.1	58.7
Sex – Male/ Female	14 / 11	13 / 12
Height (cm)	159.7	160.5
Weight (kg)	67.6	66.7

Table 2: comparison of mean clinical parameters

Parameters	Group A	Group B
Mean Intraoperative Blood Loss (ml)	158.1	201.2
Mean Postoperative Blood Loss (ml)	369.2	452.6
Mean Total Blood Loss (ml)	527.3	653.8
Mean decrease of Haemoglobin (mg/dl)	2.29	3.61

Discussion

Orthopedic surgeries are associated with severe bleeding because of extensive dissections through bony and fibrotic tissue and inability to cauterize bleeding bony surfaces.^{x,xi} Tissue and vascular damage during surgery or trauma, stimulates cascade of coagulation leading to clot formation to prevent blood loss. However during surgery and trauma the fibrinolytic system is also activated which leads to premature breakdown of the clot and excessive blood loss.^{xii,xiii}

Recently various researchers have tried to study the efficacy and safety of tranexamic acid. In a recent meta-analysis, Huang F.et al.^{xiv} had reported significant reduction in blood loss in major orthopaedic surgeries. It was observed that there was significant reduction in intra-operative and postoperative blood loss in tranexamic acid group. Same was observed in the present study.

It is noted that the effect of tranexamic was seen to be greater if the dose of the tranexamic acid was increased.^{xv} Blood loss could further be reduced by increasing the dose of Tranexamic acid but evidence regarding the safety of the higher dose treatment is lacking. we had established the effectiveness of tranexamic acid in reducing the need for blood transfusion.

Kagoma et al.^{xvi} in a meta-analytical study had concluded that tranexamic acid, including other antifibrinolytics had reduced the blood loss and thus need for blood transfusion. However, they also reported inadequate evidence regarding the safety of these agents in the major surgeries. They reported no increased incidence of VTE in the perioperative period.

There are now reports of safety and efficacy of tranexamic acid in the major surgical procedures.^{xvii,xviii} There is not much reported data in Indian subcontinent. Although the present study has smaller sample size, it is established that TXA can be effectively and safely reduce the blood loss in Orthopaedic Surgeries.

Conclusion

The present study concluded that tranexamic acid administered preoperatively can markedly reduce blood loss and transfusion requirements. It can be an effective tool to reduce blood loss in major orthopaedic surgeries and prevents gross fall in haemoglobin levels thus contributing to the early recovery in the postoperative period. This would help to reduce allogenic blood transfusions and thus avoid transfusion related complications.

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