

## Original Research Article

# A randomized control trial: effect of tranexamic acid on the need of post-operative blood transfusion following total hip replacement surgery

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### ABSTRACT

**Background:** Total hip replacement surgery is one of the most advanced and technically demanding surgeries in orthopaedics in which blood loss is inevitable. Most of the patients are elderly with multiple co morbidities and the estimated one-year mortality is about 25%. Objective of the study was to assess the need of post-operative blood transfusion in total hip replacement surgery in patients given tranexamic acid versus control.

**Methods:** It was a randomized controlled trial. Hundred patients of both sexes undergoing total hip replacement surgery included in study according to inclusion and exclusion criteria after getting written and informed consent. Equal patients 50-50 (50%) divided in two groups tranexamic acid group and control group based on a computer-generated random number table. The tranexamic acid group received two doses of 10mg/kg body weight of tranexamic acid just before surgery and two hours later intravenously. The control group received two doses of 10mg/kg body weight of normal saline at similar intervals. Numbers of blood transfusions required postoperatively were noted based on the postoperative haemoglobin readings.

**Results:** Mean post-op haemoglobin for the tranexamic acid group was  $10.4 \pm 2.6$  g/dl and for the control group it was  $8.6 \pm 2.4$  g/dl ( $p=0.007$ ). Eight patients (16%) in intervention group required blood transfusion compared to 22 (44%) in control group ( $p=0.009$ ). The relative risk (RR) for transfusion was 0.51 when TXA was administered compared to when placebo was administered.

**Conclusions:** Perioperative tranexamic acid is a safe and useful method of reducing intra op bleeding and need of post-operative blood transfusion postoperatively in THR patients.

**Keywords:** Blood transfusion, THR, TXA

### INTRODUCTION

Total Hip Replacement surgery is one of the most advanced and technically demanding surgeries in orthopaedics in which blood loss is inevitable. Most of the patients are elderly with multiple co morbidities and the estimated one-year mortality is about 25%.<sup>1</sup> Around 50% of patients undergoing hip surgery require at least 1100 ml of blood transfusion.<sup>2</sup> Blood transfusion also has its demerits like it can cause severe immunological reactions and also be a source of various blood-borne

infections<sup>3</sup>. Now a days methods used to decrease intraoperative blood loss are permissive hypotension, topical freezing saline, thromboplastic agent and intraoperative administration of anti-fibrinolytic agent like tranexamic acid (TXA).<sup>4</sup>

TXA is a pharmacological agent, and is a derivative of amino acid lysine which occupies lysine sites on the plasminogen molecules and therefore causes reduced formation of activated plasmin which is responsible for the dissolution of clot. This in turn results in stabilization

of clot and decreased blood loss. Use of TXA has been extensively studied in cardiac, spine, maxillofacial and other surgeries and has been proved to be an important factor in decreasing operative blood loss and hence, the need for postoperative blood transfusion.<sup>5,6</sup> With limited literature for TA use in Total Hip Replacement Surgery, the current study was planned to compare the frequency of blood transfusion after THR in patients given TXA versus placebo.

## METHODS

After approval from institutional ethical committee (IEC), hundred patients of both sexes undergoing THR surgery were included in study according to inclusion and exclusion criteria after getting written and informed consent. Patients having ischemic heart disease, pregnant or lactating women, those with known coagulation disturbances, use of warfarin or other anticoagulants and allergy to TXA were excluded from study. Only those providing consent to participate in the study were enrolled in the study.

Equal patients 50-50 (50%) were divided in two groups Tranexamic acid group and control group based on a computer-generated random number table. The Tranexamic acid group received two doses of 10mg/kg body weight of tranexamic acid just before surgery and two hours later intravenously. The Control group

received two doses of 10mg/kg body weight of normal saline at similar intervals. A 2<sup>nd</sup> year Orthopaedic resident not part of the primary surgical team was responsible for administration of the placebo or TXA while keeping the investigator and primary surgery team blinded. Neither the patient nor the investigator knew of the group allocation. Haemoglobin (Hb) was measured preoperatively (pre-op Hb) and at 24 hours postoperatively (post-op Hb). All the patients were operated by the authors only. Patients who were required to receive blood transfusion were noted. Blood was transfused if the postoperative Hb was <8g/dl.

## Statistical analysis

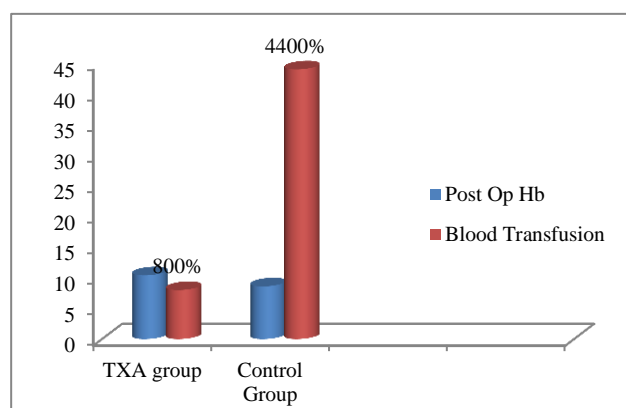
The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. Continuous variables were expressed as mean  $\pm$  standard deviation (SD) and categorical variables were expressed as frequencies and percentages. For comparison of means, Independent sample t-test was used and Chi-square test was used for comparison of categorical variables.  $P < 0.05$  was considered significant.

## RESULTS

Out of 100 participating patients in study equal number of 50-50 (50%) divided in two groups Tranexamic acid group and control group.

**Table 1: Baseline data.**

	TXA Group	Control	P value
<b>Age</b>	58.6 $\pm$ 9.7 years	57.9 $\pm$ 9.2 years	0.6
<b>Female/ Male</b>	28/22	29/21	0.5
<b>Site R/L</b>	27/23	30/20	0.4
<b>Pre op Hb</b>	11.8 $\pm$ 1.6 gm%	11.6 $\pm$ 1.5gm%	0.7
<b>Post op Hb</b>	10.4 $\pm$ 2.6 gm%	8.6 $\pm$ 2.4gm%	0.007
<b>Blood transfusion</b>	8 (16%)	22 (44%)	0.009



**Figure 1: Post Op Hb and blood transfusion.**

There were no significant differences between the groups in terms of age (58.6 $\pm$ 9.7 years in TXA group ranging from 29-86 years while 57.9 $\pm$ 9.2 years in Control group ranging from 33 years to 81 years  $p=0.6$ ), gender ( F/M 28/22 and 29/21 in respective groups  $p=0.5$ ), site (R/L 27/23 and 30/20 in respective groups  $p=0.4$ ), pre-op Hb (11.8 $\pm$ 1.6 gm% and 11.6 $\pm$ 1.5gm% in respective group) and duration of surgery ( $p > 0.05$  each) (Table 1). Mean post-op haemoglobin for the tranexamic acid group was 10.4 $\pm$ 2.6 g/dl and for the control group it was 8.6 $\pm$ 2.4 g/dl ( $p=0.007$ ). Eight patients (16%) in intervention group required blood transfusion compared to 22 (44%) in control group ( $p=0.009$ ) (Table 1). The relative risk (RR) for transfusion was 0.51 when TXA was administered compared to when placebo was administered.

## DISCUSSION

Benoni G et al. conducted a study to assess the role of TXA in total knee replacement (TKR). Two doses of 10mg/kg body weight of TXA were administered, one before release of tourniquet and the second three hours later. Giving TXA significantly reduced the amount of blood loss and the need for blood transfusion.<sup>7</sup> A meta-analysis of 129 RCTs, carried out in 2012 also concluded that the probability of receiving transfusion after surgery was reduced by one-third after administering TXA.<sup>8</sup> Vijay et al did a RCT in which TXA was administered as an initial bolus dose of 500mg before surgery followed by continuous infusion at 1mg/kg/h for the duration of surgery.

Results showed that the differences in mean reduction in Hb and mean volume of blood loss postoperatively between TXA and placebo groups were significant. In addition, only 7 out of 45 patients in TXA group required blood transfusion compared to 18 out of 45 in placebo group and the difference was again significant.<sup>4</sup> In contrast to this another RCT done by Zufferey et al in 2010 showed that there was no significant difference in blood transfusion rates between TXA and placebo groups after surgery for hip fracture.<sup>2</sup> Therefore, although effectiveness of TXA in reducing post-surgical blood loss and transfusion requirements have been shown by multiple studies, but its effectiveness, specifically in hip surgeries, is yet to be established. Our study showed that in THR the need for blood transfusion was significantly reduced in patients receiving TA, as 16% patients in TXA group versus 44% in control group required blood transfusion our results are comparable to a study of Vijay et al in which 15.5% patients in TXA group and 40% in control group required transfusion after hip fracture surgery.<sup>4</sup>

In present study no complication occurred in the TXA group, which is also supported by a meta-analysis conducted in 2003 which concluded that TXA is not associated with an increased risk of thrombo embolic accidents.<sup>9</sup>

TXA is a low cost and relatively safe alternative to reduce need of post-operative blood transfusion in THR surgery. This ultimately helps in decreasing the financial load on the patients. In spite of the fact that certain confounding factors could have had an effect on the efficacy of results of the study like BMI, but still this study does not fail in proving the usefulness of TXA. The study also takes into account only the post-op Hb measured 24 hours after surgery. To further substantiate the results, the volume of blood loss intra operatively and postoperatively can also be measured. Hb levels can also be measured daily for a week after surgery to evaluate the long-term effect of TXA.

## CONCLUSION

Perioperative tranexamic acid is a safe and useful method of reducing intra operative bleeding and need of blood transfusion post operatively in total hip replacement patients.

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*Ethical approval: The study was approved by the Institutional Ethics Committee*

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