IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 16, Issue 9 Ver. IV (Sep. 2017), PP 29-33
www.iosrjournals.org

Comparison of two Different Dosages of Tranexamic Acid in Spine Fixation Surgery: A Randomized, Prospective Study

[*]Dr. Seena Solomon[1], Dr. Kishan Shetty[2]
Department of Anaesthesiology, Father Muller Medical College/ Rajiv Gandhi University, India[1,2]
*Corresponding Author:*Dr. Seena Solomon*

Abstract:
Introduction: *Perioperative use of tranexamic acid (TXA) in major spine surgeries is known to reduce blood loss and thereby decrease the need for blood transfusion. However the optimal dosing of TXA remains highly controversial. This study was designed to compare the outcome in terms of blood loss and amount of blood transfusion needed in two groups of patients undergoing multilevel lumbar spine fixation surgeries receiving two different doses of TXA.*
Methodology:*A total of sixty patients undergoing multilevel spine fixation surgery were divided equally into two groups and randomized to receive either a low dose of TXA: Group A (15mg/kg loading dose followed by 1mg/kg/hr maintenance infusion) or a high dose of TXA: Group B (30 mg/kg loading dose followed by 2mg/kg/hr maintenance infusion). Outcome measures will be perioperative blood loss, postoperative haemoglobin and haematocrit levels and amount of blood transfused.*
Results:*The mean perioperative blood loss was significantly higher in group A when compared to the Group B. Also, the postoperative haemoglobin level was higher in group B. However, TXA did not significantly reduce transfusion requirements.*
Conclusion:*Higher dose TXA can significantly reduce the perioperative blood loss when compared to low dose TXA.*
Keywords:*tranexamic acid, spine surgery, blood loss*

Date of Submission: 02 -09-2017 Date of acceptance: 13-09-2017

I. Introduction

Considerable blood loss is known to occur during major spine fixation surgeries which is associated with higher need for blood transfusion and this in turn is related to a higher risk of contracting infections, multiple coagulopathies, immune reactions etc. Thus, it has become imperative that we have alternate methods to reduce blood loss perioperatively.One such example is the use of tranexamic acid (TXA), an antifibrinolytic agent which is a synthetic lysine analogue that competitively blocks the lysine binding sites of plasminogen, plasmin and t-PA, thereby retarding fibrinolysis and blood clot degradation. TXA is way cheaper than other antifibrinolytics and has gained popularity in trauma, cardiac surgeries, orthopaedic surgeries, gynaecological surgeries etc.Over the last few years routine use of TXA in major spine surgeries has become a standard of care in many institutions. However, there is debate regarding the ideal dose and timing of TXA administration as well as postoperative benefits of TXA in terms of reduced collection in the suction drain.Hence, to investigate this aspect of TXA, we undertook the study in our hospital with an aim of comparing its two different dosing protocols.

II. Materials and methods

Sixty patients in Father Muller Medical College Hospital, Mangalore who were admitted during November 2015 to December 2016 undergoing elective multilevel lumbar spine fixation surgeries were allotted into groups A or B using a computer generated random assignment.
Group A: 15 mg/kg loading dose followed by 1mg/kg/hr maintenance infusion
Group B: 30 mg/kg loading dose followed by 2mg/kg/hr maintenance infusion

Inclusion criteria:
-Age group between 18-65years
-ASA class I and II
-Weighing 45-75kgs

Exclusion criteria:
-ASA class III and IV
-Coagulopathies
-Allergy to TXA

Method:

Clearance was obtained from the Hospital ethical committee. On the night prior to the surgery, informed consent was obtained and patients were premedicated with T. Diazepam 5 mg and T. Ranitidine 150 mg. Baseline laboratory values and necessary investigations were noted. On the morning of the surgery, patients were shifted to the operating room, monitors connected and baseline vitals noted (non-invasive blood pressure, heart rate, pulse oximeter). A large bore cannula was secured and they were induced for general anaesthesia, after which a loading dose of TXA was administered over 15 minutes followed by maintenance dose depending on the group that they belonged to.Duration of surgery was noted and amount of blood loss intraoperatively was calculated by adding the quantity of blood in the suction canisters and weighing the sponges. Fluids added to the surgical field was deducted from the total measured blood loss. Replacement and maintenance of lost fluids was done with crystalloids, colloids and blood as and when needed. Patients were extubated at the end of the procedure and they were shifted to the postoperative ward where they were observed for at least 24 hours. Quantity of blood in the suction drain was noted. Haemoglobin and haematocrit values were repeated after 12 hours.

Statistical Analysis:

Power analysis from similar studies suggest that a sample size of 30 patients/group was required to get the power of study to 80 %, with 0.05 level of significance. All the data was fed into the IBM SPSS software. Quantitative data was presented as mean and standard deviation. Qualitative data was presented as frequency. Chi square test and student t-test was used for the analyses. P value <0.05 was considered significant.

III. Results

The demographic data of both groups were comparable with respect to age, weight, gender, ASA status and number of levels fixed.Mean duration of surgery in group A was 252.53+/-25.84 min and in group B was 249.67+/-28.17min which was not statistically significant and hence was comparable.

Mean preoperative haemoglobin in group A was 13.6+/-1.6 g/dL and in group B was 13.3+/-1.5 g/dL. With a p value of 0.47, there was no statistical significance and hence the groups were comparable.

Mean preoperative PCV in group A was 40.8+/-4.9% and in group B was 39.9+/-4.6%; p value was 0.48 and hence no statistical significance was observed.

Mean postoperative haemoglobin in group A was 9.05+/-0.9 g/dL and in group B was 9.9+/-1.45 g/dL; with a p value of 0.005, this finding was statistically very significant.

Similarly, the postoperative PCV in group A was 27.+/-2.7 % and in group B was 30.3+/-4.2 % and with a p value of 0.002, this finding too is statistically highly significant.

Total blood loss which was a sum of intraoperative and postoperative blood loss in group A was 1465.17+/-298.4 ml and in group B was 1034.63+/- 207.9 ml; P value was <0.001 which was statistically highly significant.

Number of pints of packed blood cells transfused was 1.63+/- 0.51 in group A and 1.43+/- 0.5 in group B; p value was 0.48 and hence there was no statistical difference between the two groups.

IV. Discussion

Lumbar spine fixation surgery is associated with major blood loss which in turn is dependent on patient factors such as weight, gender and severity of spine deformities and surgical factors such as operating time, number of levels to be fused, blood salvage techniques and use of antifibrinolytics.In order to minimize this blood loss, various surgical and non-surgical techniques have been implemented. Here, we have used a pharmacological intervention in the form of an antifibrinolytic agent, TXA which has been proven to significantly decrease the perioperative blood loss and need for blood transfusion. Although there have been controversies regarding its role in deep vein thrombosis, studies have not given substantial evidence supporting this claim.In the present study, sixty patients undergoing lumbar spine fixation surgery were randomly divided into two groups: one that received a lower dose of TXA and the other, a higher dose. Both groups

werecomparable with regard to demographic and baseline characteristics. Technique of anaesthesia and duration of surgerywas similar for all patients. Spine surgeon was the same for all the cases.

In our study we found that there was significantly lesser blood loss, both intraoperatively and postoperatively in the group that received a higher dose of TXA ($p < 0.001$). Blood transfusion requirement was not statistically significant ($p = 0.48$). However, clinically there was a relative reduction in the need for blood transfusion in group B. Probably this finding could be more evident if a larger sample size was chosen.

V. Figures and tables

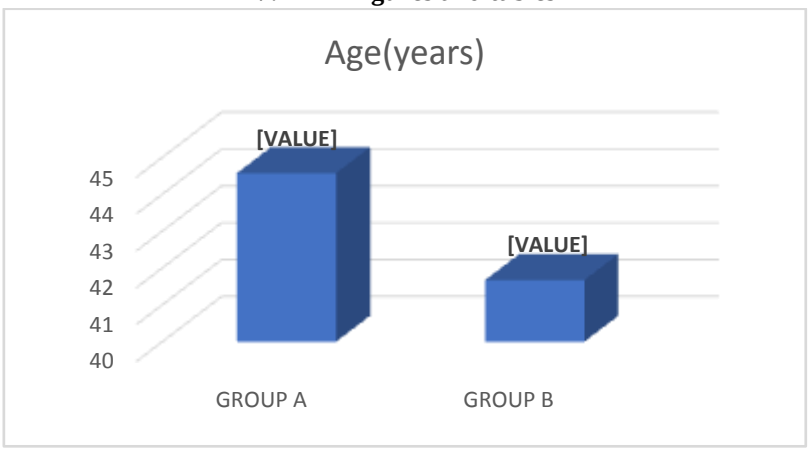

Figure 1. Age distribution

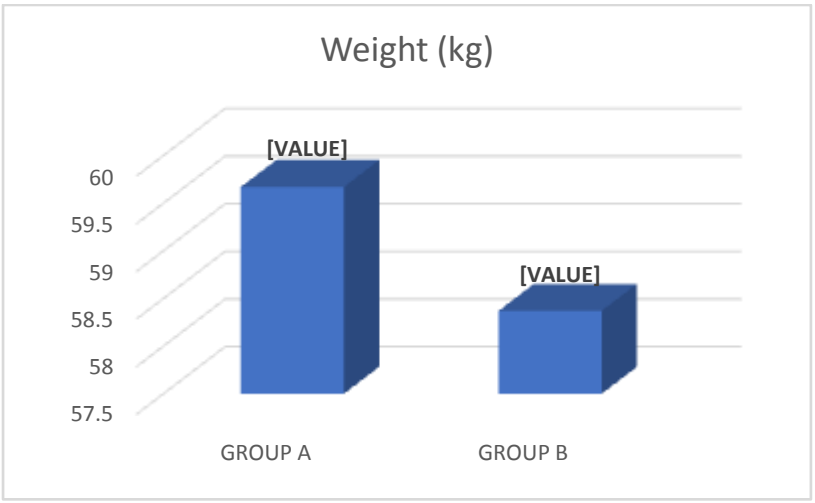

Figure 2. Weight distribution

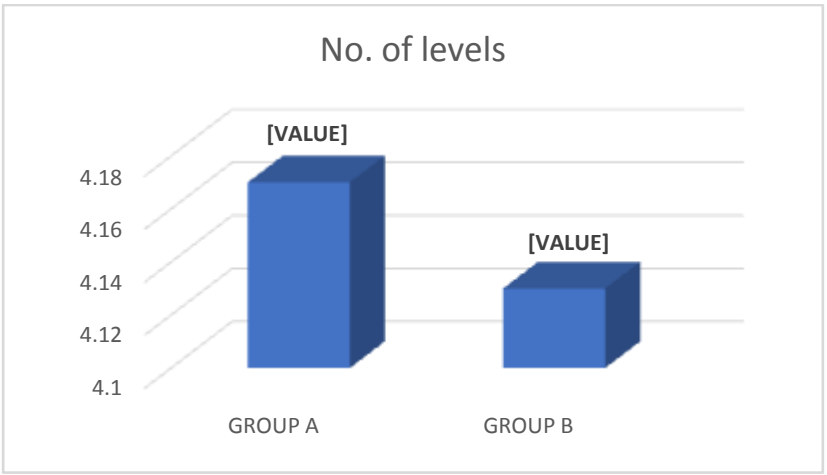

Figure 3. Number of levels

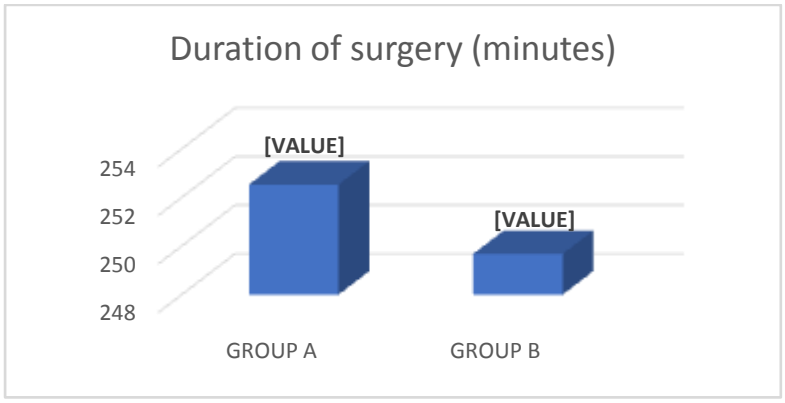

Figure 4. Duration of surgery

Crosstab					
			group		Total
			GROUP A	GROUP B	
Gender (M/F)	F	Count	15	10	25
		% within group	50.0%	33.3%	41.7%
	M	Count	15	20	35
		% within group	50.0%	66.7%	58.3%
Total		Count	30	30	60
		% within group	100.0%	100.0%	100.0%

Table 1. Gender distribution

Crosstab					
			group		Total
			GROUP A	GROUP B	
PRBC transfused	1	Count	3	4	7
		% within group	37.5%	57.1%	46.7%
	2	Count	5	3	8
		% within group	62.5%	42.9%	53.3%
Total		Count	8	7	15
		% within group	100.0%	100.0%	100.0%

Table 2. Number of packed red blood cells (PRBC) transfused

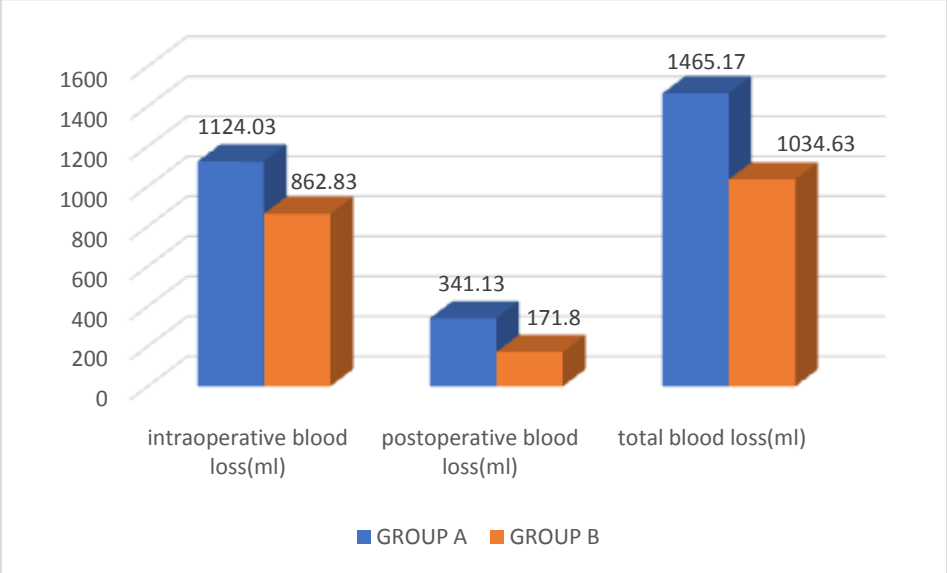

Figure 5. Perioperative blood loss

VI. Conclusion

High dose of TXA (30 mg/kg loading dose followed by 2mg/kg/hr maintenance infusion) administered at induction of general anaesthesia resulted in a significant reduction in intraoperative and postoperative blood loss in patients undergoing lumbar spine fixation surgery. There was no significant reduction in the need for blood transfusion among those who received a higher dose of TXA and this could be due to the small sample size. Also, no significant side effects were seen.

References

[1]. Wong J, El Beheiry H, Rampersaud YR, Lewis S, Ahn H, De Silva Y, Abrishami A, Baig N, McBroom RJ, Chung F. Tranexamic acid reduces perioperative blood loss in adult patients having spinal fusion surgery. Anesthesia & Analgesia. 2008 Nov 1;107(5):1479-86.

[2]. Verma K, Kohan E, Ames CP, Cruz DL, Deviren V, Berven S, Errico TJ. A comparison of two different dosing protocols for tranexamic acid in posterior spinal fusion for spinal deformity: a prospective, randomized trial. International journal of spine surgery. 2015;9.

[3]. Endres S, Heinz M, Wilke A. Efficacy of tranexamic acid in reducing blood loss in posterior lumbar spine surgery for degenerative spinal stenosis with instability: a retrospective case control study. BMC surgery. 2011 Nov 3;11(1):29.

[4]. Colomina MJ, Koo M, Basora M, Pizones J, Mora L, Bagó J. Intraoperative tranexamic acid use in major spine surgery in adults: a multicentre, randomized, placebo-controlled trial. BJA: British Journal of Anaesthesia. 2017 Feb 16;118(3):380-90.

[5]. Yang B, Li H, Wang D, He X, Zhang C, Yang P. Systematic review and meta-analysis of perioperative intravenous tranexamic acid use in spinal surgery. PloS one. 2013 Feb 12;8(2):e55436.

[6]. Huang F, Wu D, Ma G, Yin Z, Wang Q. The use of tranexamic acid to reduce blood loss and transfusion in major orthopedic surgery: a meta-analysis. journal of surgical research. 2014 Jan 31;186(1):318-27.

[7]. Poeran J, Rasul R, Suzuki S, Danninger T, Mazumdar M, Opperer M, Boettner F, Memtsoudis SG. Tranexamic acid use and postoperative outcomes in patients undergoing total hip or knee arthroplasty in the United States: retrospective analysis of effectiveness and safety. Bmj. 2014 Aug 12;349:g4829.

[8]. Li ZJ, Fu X, Xing D, Zhang HF, Zang JC, Ma XL. Is tranexamic acid effective and safe in spinal surgery? A meta-analysis of randomized controlled trials. European Spine Journal. 2013 Sep 1;22(9):1950-7.

[9]. Gautam PL, Katyal S, Yamin M, Singh A. Effect of tranexamic acid on blood loss and transfusion requirement in total knee replacement in the Indian population: a case series. Indian journal of anaesthesia. 2011 Nov;55(6):590.

[10]. Basavaraj K, Hegde R. A randomized prospective study of efficacy of Tranexamic Acid on Perioperative Blood Loss in Thoracic Spine Fixation. Sri Lankan Journal of Anaesthesiology. 2017 Jan 30;25(1).

*Dr. Seena Solomon. "Comparison of two Different Dosages of Tranexamic Acid in Spine Fixation Surgery: A Randomized, Prospective Study." IOSR Journal of Dental and Medical Sciences (IOSR-JDMS) 16.9 (2017): 29-33