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Original Research Paper

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EFFECT OF TRANEXAMIC ACID IN REDUCING BLOOD LOSS DURING THORACOLUMBAR SPINE SURGERY

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ABSTRACT

BACKGROUND: Spine surgeries are usually associated with excessive blood loss, which increases morbidity and mortality due to hemodynamic instability and subsequent blood transfusions. Tranexamic acid (TXA), an antifibrinolytic drug, inhibits the activation of plasminogen, is found to be useful in reducing blood loss.

METHODOLOGY: A prospective observational study conducted in Government Medical College, Kottayam for a period of twelve months, randomly assigned forty-eight adult patients (ASA I or II) undergoing thoracolumbar spine surgery into two groups, who received either a bolus of 10 mg/kg IV TXA after induction followed by an infusion of 1 mg/kg/h of TXA up to closure of skin, or an equivalent volume of normal saline. Blood investigations, surgical parameters, perioperative blood loss and blood transfusions were assessed.

RESULTS: Both groups in the study were comparable with respect to demographic variables, baseline laboratory indices and surgical parameters. The mean perioperative blood loss was 44% less ($P<0.05$) and blood transfusion requirements were 71% reduced ($P<0.05$) in patients who received TXA. Mean surgical duration as well as postoperative hemoglobin drop was significantly reduced in TXA group compared to Normal Saline group (NS).

CONCLUSION: Tranexamic acid reduces perioperative blood loss and blood transfusion.

KEYWORDS : Tranexamic Acid, Blood Loss, Spine Surgery.

INTRODUCTION:

Spine surgery has the potential for massive blood loss, requiring transfusion due to extensive tissue dissection, bone instrumentation and decortications.[1] Patient factors affecting blood loss include severity, type of injury, patient weight and gender. Surgical factors include operating time, procedure performed, surgical approach used, number of vertebrae fused, mean arterial pressure, number of spinal osteotomies performed. Massive hemorrhages can lead to intra operative stroke, cardiac ischemia, shock and epidural hematoma formation, which causes cord compression and permanent neurological deficit.[1]

Allogenic blood transfusion has several risks like transmission of blood borne pathogens, hemolytic and immune mediated transfusion reactions. Homologous blood, when available decreases, but does not eliminate risk associated with transfusions due to immunomodulator effects.[2] Large volume blood transfusions can lead to pulmonary or cerebral edema, coagulopathy as well as acute lung injury. Moreover, costs associated with transfusions are significant.[3]

Okamoto et al. discovered tranexamic acid (Trans-4-aminomethyl cyclohexane-1-carboxylic acid), a potent antifibrinolytic drug.[4] Tranexamic acid is a synthetic lysine analogue and competitive inhibitor of plasminogen and plasmin. Its half-life is about 80 minutes. It acts by reversibly binding four to five lysine receptor sites on plasminogen and plasmin, which prevents plasmin from binding to and degrading fibrin and preserve the framework of fibrin's matrix structure. The adverse effects include headache, weakness, confusion, blurring of vision and allergic reaction and seizures.[4] The main contra-indications are disseminated intravascular coagulation, microscopic hematuria, severe renal failure, hypersensitivity and thrombotic events.

AIM OF THE STUDY:

To evaluate the efficacy of Tranexamic acid in reducing blood loss during thoracolumbar spine surgery and to assess the effect of Tranexamic acid in preventing blood transfusion.

MATERIALS AND METHODS:

The prospective observational study was conducted in Department of Anaesthesiology, Government Medical College, Kottayam for a period of twelve months, after obtaining institutional ethical committee approval and written informed consent from the patients.

Minimum sample size was calculated based on a study conducted by Barger et al,[5] on "*Effect of Tranexamic Acid on Blood Loss and Transfusion Requirements in Lumbar Spine Fixation*" in which mean intraoperative blood loss in TXA group (μ_1) and in control group (μ_2) were 618.53 ± 205.954 and 830.23 ± 208.869 respectively.

$$N = \frac{(Z\alpha + Z\beta)^2 \times SD^2}{(\mu_1 - \mu_2)^2}$$

$Z\alpha$ at 95% CI = 1.96
$Z\beta$ at 80% CI = 0.84
$\mu_1 = 618.53$; $SD_1 = 205.954$
$\mu_2 = 830.23$; $SD_2 = 208.869$
$SD = (SD_1 + SD_2)/2$

$$N = \frac{7.84 \times (207.41)^2}{(211.70)^2} = 7.52 \sim 8$$

Larger the sample size, larger will be the accuracy, so multiples of 8 were considered, hence study was conducted with a minimum sample of 24 in each group allotted by simple random sampling using closed envelope method.

INCLUSION CRITERIA: ASA I and ASA II patients of either sex, 18-65 years of age undergoing elective thoracolumbar spine surgery involving one or two vertebral segments.

EXCLUSION CRITERIA: Emergency surgeries, known case of hypersensitivity to Tranexamic acid, patients with pre-existing hepatic or renal disease, seizure disorder, uncontrolled hypertension, diabetes, anemia, malignancy, coronary artery disease and deep venous thrombosis.

METHODOLOGY:

Patients were kept fasting for eight hours. They were divided into two groups; Group A received a loading dose of 10 mg/kg intravenous tranexamic acid diluted in 100 ml Normal Saline after induction, over 20 min, followed by a maintenance infusion of 1mg/kg/h up to the closure of skin. Group B received equal amount of 0.9% Normal Saline. Electrocardiogram, non-invasive blood pressure and pulse oximetry were connected and baseline values were recorded. Glycopyrrolate 0.2mg, midazolam 0.02mg/kg, fentanyl 2μg/kg IV, propofol 2mg/kg and succinyl choline 2mg/kg were injected. Endotracheal intubation was done and positive pressure ventilation was initiated. Blood-soaked pads and gauzes, number of units of blood transfused, blood in suction bottles and total volume of irrigation saline instilled were recorded. Intraoperative estimated blood loss (EBL) was obtained by measuring volume of blood in suction bottle and counting blood-soaked mops and pads.

All fluids added to the surgical field were quantified and deducted from the measured blood loss. Fully blood-soaked small pad 10 x 10 cm contain 13.5 ml blood, medium sized pad 30 x 30 cm contain 61 ml blood and large pad 45 x 45 cm contain 100 ml blood approximately.[6] Blood was transfused only when the EBL exceeded the maximum allowable blood loss (ABL), blood losing at a higher rate or if any signs or symptoms of anemia had occurred.[7] Maximum allowable blood loss was calculated by using hemodilution method developed by Jeffrey Gross.[8] ABL=EBV x (Hb_i- Hb_f) / Hb_i; EBV is estimated blood volume, Hb_i is pre-operative hemoglobin, Hb_f is lowest acceptable hemoglobin value which is standardized as 10 g/dl in the study. EBV= Body weight (kg) x Average blood volume (ABV). ABV for adult male is 75ml/kg and for female is 65ml/kg.[9]

The residual neuromuscular blockade was reversed with neostigmine 0.05mg/kg and glycopyrrolate 0.01mg/kg and extubation was performed.

Post-operatively hemoglobin, hematocrit and blood in drain were measured for 24 hours. All patients were monitored for side effects, mainly nausea, vomiting, giddiness, seizures, hypotension and deep venous thrombosis.

STATISTICAL ANALYSIS:

The collected data were analyzed using Statistical Package for Social Sciences (SPSS I nc, Chicago, IL, USA, version 16.0 for windows). For comparing qualitative parameters, Chi square (X^2) test was used as nonparametric test, and unpaired student's t test was used for comparing mean values between cases and controls. Paired t test was employed to compare preoperative and postoperative values of different parameters. For all statistical evaluations, p value <0.05 was considered to be significant.

RESULTS:

Parameters	Group	Mean	SD	T value	P value
Preoperative hemoglobin (mg/dl)	TXA	12.58	1.25	0.000	1.000
	NS	12.58	1.06		
Postoperative hemoglobin (mg/dl)	TXA	11.92	1.25	3.95	0.001
	NS	10.63	0.77		
Intraoperative blood loss (ml)	TXA	297.08	71.23	-8.118	0.000
	NS	519.58	104.23		
Postoperative blood loss (ml)	TXA	67.29	18.47	-9.425	0.000
	NS	134.17	30.06		
Total blood loss (ml)	TXA	364.38	80.26	-9.739	0.000
	NS	653.75	106.51		
Duration of surgery (min)	TXA	97.5	23.82	-13.14	0.000
	NS	178.75	18.72		

Figure 1: Comparison of quantitative parameters between tranexamic acid group and normal saline group.

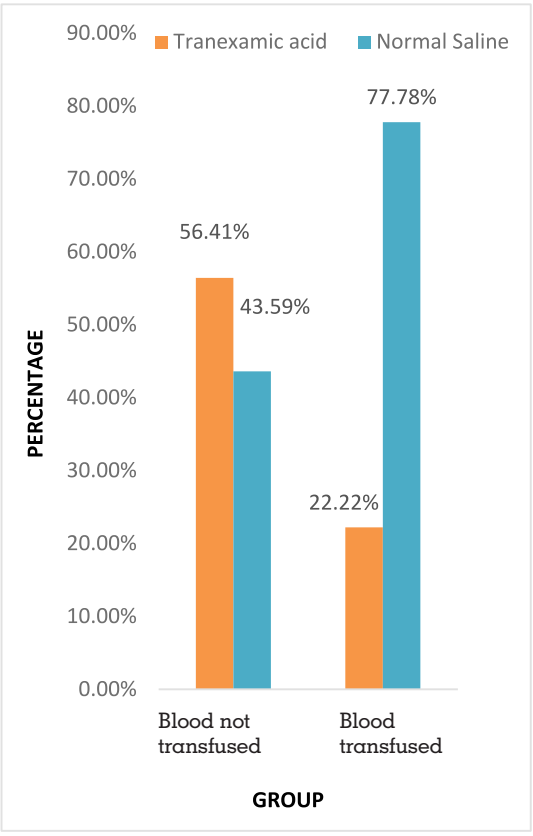

Figure 2: Incidence of PRC transfusion among TXA group and control group

DISCUSSION:

Prevention of blood loss remains as a challenge in complex spine surgery. Massive perioperative hemorrhage adversely affects patient outcome. Allogeneic blood transfusions may lead to potential transfusion reactions and infections. Intravenous administration of the inexpensive but highly efficacious lysine analogue Tranexamic acid (TXA) reduces perioperative hemorrhage and blood transfusions.

Both groups in the study were comparable with respect to age, gender, ASA physical status, pre-operative hemoglobin and hematocrit values. No significant differences were found in the type of surgical procedure done, level of spine operated, number of vertebral segments fused and the baseline laboratory parameters studied. The technique of anesthesia was standardized. The mean intraoperative blood loss and the amount of blood in the drains were less in the TXA group compared to the placebo group (P = 0.000). Thereby, total blood loss (intraoperative plus postoperative) was consequently less in the TXA group (44% reduction in total blood loss with P = 0.000). A significant reduction in blood transfusion was noted in TXA group compared to control group(P = 0.000). The number of units of PRCs received in TXA group and in control group were two and seven respectively.

The difference in the postoperative hemoglobin and hematocrit values of patients in TXA group and control group were significant (P = 0.001). These results were consistent with studies done by Barger et al.[5] and Elwatidy et al.,[10] in which the postoperative hemoglobin and hematocrit values were statistically significant in the TXA group compared to the control group.

The mean duration of surgery was less in TXA group compared to the control group (P = 0.000). The finding was consistent with the study done by Barger et al.[5] Bleeding may obscure the surgical site. Cauterizing and controlling

bleeding is a time-consuming cumbersome task. TXA decrease anesthetic exposure along with surgical duration indirectly. The main concerns in using TXA are the potential for increased risk of thrombotic events, seizures and allergic reactions. None of our patients experienced these.

CONCLUSION:

Prophylactic use of Tranexamic acid is effective and safe in reducing perioperative hemorrhage during major spine surgery. TXA may help in reducing blood transfusion and transfusion related complications.

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