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Tranexamic acid for the reduction of blood loss in total knee arthroplasty

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Abstract

Background: Tranexamic acid (TXA) is antifibrinolytic drug which has the property to reduce intraoperative and postoperative bleeding. There are several studies supporting the use of tranexamic acid in total knee replacements (TKR) and few in total hip replacements. Our study was intended to establish the effects of tranexamic acid in minimizing the intra operative and post-operative blood loss in uncomplicated primary total knee replacement.

Methods: This study was conducted in the department of orthopaedics, SMS Hospital, Jaipur over a period April 2018/ approval by ethical committee to June 2019 or till sample size is reached, whichever is the earliest. The study was considered in the protocol advocated at least 55 patients in each group and henceforth 60 patients were included in each group. (control group and tranexamic acid group).

Results: The blood loss difference between the control group and the tranexamic acid group was significant (P value <.001) in all time interval in comparison between control and tranexamic acid group.

Conclusion: Intravenous route of administration of tranexamic acid seems to be superior to the intravenous administration of normal saline by due need of blood transfusions.

Keywords: Blood loss, tranexamic acid, total knee replacements (TKR).

Introduction

Arthritic knee joints are a common and crippling condition that causes significant pain resulting in disability and change in lifestyle. In advanced disease of osteoarthritis of knee joints Total Knee Arthroplasty (TKA) is the only treatment option.

Total knee arthroplasty is a highly successful procedure that can reduce pain and improve range of motion by providing integrity to articular surfaces.

Several techniques are available to minimize the rate of blood transfusion following the knee arthroplasty. These techniques include autologous blood donation, Intra-operative red cell salvage, hypotensive anaesthesia, controlled hypotension, use of tourniquet with proper haemostasis and use of antifibrinolytics[1-6].

Purpose of our study to find out the usefulness of intravenous tranexamic acid in knee arthroplasty as compare to (placebo)intravenous normal saline following post-operative in drain collection in total knee arthroplasty.

Efficacy of these drugs has been investigated in Orthopaedics, cardiovascular, Hepatic and other surgeries[7].It is significantly reducing post operatively blood loss compared with placebo in variety of surgical procedures including cardiac surgery and total hip and knee arthroplasty.

Tranexamic acid and antifibrinolytic drugs are readily accessible substances promoting haemostasis and reduce bleeding and need for allogenic transfusion. A discussion of antifibrinolytics requires a brief synopsis of the normal haemostatic process.

Material and Methods

Type of study	Randomised Prospective Comparative Study
Study area	Department ofOrthopaedicsSMS Medical College, Jaipur
Study Duration	From April 2018/ approval by ethical committee to June 2019 or till sample size is reached, whichever is the earliest
Sample Size	Sample size was calculated 55 in each of two group alpha error 0.05 and power 80% assuming proportionof case having 50 to 100 ml drain on 1st postoperative day in tranexamic group (control group) 26.67% & 6.67% respective as per seed article. So for study purpose 60 patient use in each group.
Study Subject	Based on Inclusion and Exclusion Criteria

Methodology

1. Patients meeting inclusion criteria were enrolled for study after taking prior consent in orthopedics department by the investigator.
2. All routine pre anesthetic blood and radiological investigations were done .
3. All the patients were subjected to detailed Pre anesthetic checkup.
4. Pre-op antibiotics were given half an hour before incision.
5. Patients were operated in the supine position and tourniquet was applied.
6. All the knees were approached by anterior midline skin incision and medial parapatellar arthrotomy
7. Midline longitudinal incision was given in flexed knee. Medial parapatellar arthrotomy, infrapatellar fat pad and patellofemoral ligaments were excised and patella everted in extended position. Implant were fixed with cement and closure done after putting the drain.
8. Administration of tranexamic acid was done as per decided protocol i.e received normal saline (placebo group) intra-venous and received tranexamic acid (case group) intravenously. Intra-venous-10mg/kg normal saline give 5 minutes before skin incision and tourniquet inflation. Intravenous- 10mg/kg tranexamic acid gives 5 minutes before skin incision and tourniquet

inflation. Clamping of drain for 2 hours to maintain uniformity in the methodology.

9. Post-operatively
   - Amount of blood in the drain at 24 hours was recorded.
   - Quadriceps and hamstring exercises and in bed knee ROM exercises were started as soon the anesthesia effect go.
   - Static quadriceps and closed chain quadriceps exercises were started from next day of the surgery.

Source of Data: Patients admitted in Department of Orthopaedics in S.M.S. Hospital, Jaipur.

Method of Data Collection: Cases were selected by randomization chit & box method

Inclusion Criteria

- Patients giving informed consent to take part in study.
- Age- > 50 years
- Gender- male/female
- Body mass index (18.5 to 24.9-SI Unit)
- Primary osteoarthritis of knee
- Preoperativehaemoglobin value >10 mg/dl
- Normal INR, APTT, PT value

Exclusion Criteria

Patients with h/o-

- Severe Ischemic diseases
- Pulmonary embolism
- Deep vein thrombosis
- Hepatic/renal failure
- Allergy to tranexamic acid
- Bleeding disorders
- Patients receiving anticoagulant therapy

Statistical Analysis

- The collected data will be revised, coded, tabulated and introduced to a PC as master sheet.
- Quantitative variables will be expressed as mean and SD.
- Qualitative variables will be expressed as frequencies and percent's.
- Appropriate statistical tests will be applied to obtain results.
- A significance level of P<0.05 will be used in all tests.

Observation & Results

This study was conducted in the department of orthopaedics, SMS Hospital, Jaipur over a period April 2018/ approval by ethical committee to June 2019 or till sample size is reached, whichever is the earliest. The study was considered in the protocol advocated at least 55 patients in each group and henceforth 60 patients were included in each group. (control group and tranexamic acid group)

Table 1 : Blood loss (in ml) according to Time interval (in hrs) of control &case group

Time interval (in hrs)	Control		Case		P value	Significance
	Mean	SD	Mean	SD		
0-4 hr	116.17	58.72	77.83	42.19	P<0.001	HS
0-8 hr	148.50	58.54	104.50	47.71	P<0.001	HS
0-12 hr	169.67	63.19	132.33	47.38	P<0.001	HS
0-24 hr	198.50	90.94	156.67	62.33	P<0.001	HS

In this study the data are presented as the mean and the standard deviation. The difference between the control group and the tranexamic acid group was significant (P value <.001) in all time interval in comparison between control and tranexamic acid group.

Table 2: Distribution according to age & sex of case & control group

Age Group (in years)	Control Group			Case Group		
	Male	Female	Total	Male	Female	Total
50-60	12 (20.00)	12 (20.00)	24 (40.00)	14 (23.33)	10 (16.67)	24 (40.00)
>60 years	18	18	36	26	10	36

	(30.00)	(30.00)	(60.00)	(43.33)	(16.6)	(60.00)
Total	30 (50.00)	30 (50.00)	60 (100.00)	40 (66.67)	20 (33.33)	60 (100.00)
Mean±SD	64.90±7.01			64.02±7.55		

In our study 12 case male and 12 case female 50-60 years age group in control group and 14 case male and 10 case female 50-60 years age group tranexamic acid group and 18 case male and 18 case female >60 years age group in control group and 26 case male and 10 case female >60 years age in tranexamic acid group.

Discussion

Blood loss in Total Knee Arthroplasty causes significant perioperative morbidity in patients and requires allogenic blood transfusion to compensate for the blood loss. But allogenic transfusion is associated with its own risks of immunological reactions and disease transmission. Therefore, various blood-conservation strategies have been attempted to decrease peri-operative blood loss andpostoperative blood loss, blood transfusion requirement in patients undergoing Total Knee Arthroplasty. Among them, control of bleeding by antifibrinolytic Tranexamic acid (TXA) has appeared as a preferable alternative with proven results in literature. However, the choice of route of administration is still controversial. Therefore, with the aim of finding theefficacious intravenous route of administration of TXA we have embarked upon this study.

The uniqueness of this study is in the fact that all biases have been removed in comparing the efficacy of intravenous normal saline versus intravenous tranexamic acid administrationby doing staged Total Knee Arthroplasty in patient by same surgeon using same implant in identical setting.

Surgery and venous stasis increase the release of tissue plasminogen activator and activate the fibrinolytic system. Binding of TA to plasminogen prevents the breakdown of fibrin even though plasmin is generated. For TA to be effective, it has to interact with the plasminogen binding site before binding to fibrin takes place.

Several studies have investigated the effect of tranexamic acid on intraoperative and postoperative blood loss in patients undergoing total knee arthroplasty but the efficacy of such treatment has not yet been clearly established. In our study postoperative blood loss tends to be higher in association normal saline in totalknee arthroplasty than in association with total knee arthroplasty inintravenous tranexamic acid.

In the meta-analysis they reviewed 19 clinical studies, Alshryda et al found significant decrease in blood transfusion need with TXA application and stated that there was no increase in the risk of DVT and Pulmonary emboli.[7] Another metaanalysis which assessed the efficiency and reliability of TXA showed decreases in the amounts of blood loss without any increase in thrombo emboli rates. [8]

Conclusion

Intravenous route of administration of tranexamic acid seems to be superior to the intravenous administration of normal saline by due need of blood transfusions.

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