Section: Anesthesiology

Original Research Article

EFFECTIVENESS OF INTRAVENOUS TRANEXAMIC ACID IN REDUCING BLOOD LOSS DURING AND AFTER EMERGENCY CAESAREAN SECTION - A PROSPECTIVE RANDOMISED DOUBLE-BLIND PLACEBO-CONTROLLED STUDY

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Abstract

Background: Maternal mortality from postpartum haemorrhage after lower segment caesarean sections (LSCS) is one of the common causes. As an anti-fibrinolytic medication, tranexamic acid injection lowers blood loss during and after surgery. The primary goals of this trial were to determine if tranexamic acid, at a dosage of 15 mg/kg body weight, is useful in reducing blood loss during and following emergency caesarean sections and can able to prevent serious side effects to a pregnant mother. **Materials and Methods:** One hundred pregnant women were randomly assigned to two groups: placebo (5% dextrose) and injectable tranexamic acid (15mg/kg). ANOVA was used to compare the means of three or more numerical samples (using the F distribution). The Z2 test was employed to see whether the proportions differed significantly. Pearson correlation analysis was used to calculate the correlation. **Result:** In this study we found that there was no change in blood pressure and heart rate before and after operation. But there was decrease in haemoglobin percentage as well as haematocrit value in post-operative period. But these two values (haemoglobin percentage & haematocrit) were more decrease in placebo group than other group. In tranexamic acid group, two hours after surgery the haemoglobin percentage was 31.6980±1.1494. In placebo, two hours after surgery the haemoglobin percentage was 30.7551±3.2236. These changes in haemoglobin percentage and haematocrit were statistically significant. But we did not find any serious side effect. **Conclusion:** We achieved from our study that tranexamic acid @15 mg /kg body weight given before 15 minute of skin incision reduced obstetric blood loss during LUCS without any serious side effects.

INTRODUCTION

Maternal mortality (MMR) has been a source of worry in every developing country, including India, for many years. Lower segment caesarean section (LSCS) is now commonly used to deliver a healthy baby or to overcome maternal pregnancy complications. However, the most prevalent consequence of LSCS is obstetric haemorrhage.[1,2] The expected blood loss in LSCS is roughly 1000ml. Uterotonic medicines such as oxytocin, methyl ergometrine, prostaglandin E1, and Prostaglandin F2α are effective in preventing and managing post-partum bleeding following caesarean section.[3] Tranexamic acid inhibits fibrinolysis by reversibly blocking lysine binding sites on plasminogen molecules. Tranexamic acid, administered 15 minutes before skin incision, reduces blood loss during and after surgery due to its antifibrinolytic action. Our goal was to investigate the effectiveness of tranexamic acid at 15 mg/kg body weight administered 15 minutes before skin incision in minimizing blood loss during emergency LSCS.[4,5] During our analysis, we also sought to identify the most prevalent side effects of the drug within study period. Interventions targeted

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at avoiding postpartum haemorrhage (PPH), a prominent cause of maternal death globally, should be prioritized.[6] Over 80% of reported haemorrhage fatalities were classified as PPH.[7] Several studies were undertaken on different dosages of tranexamic acid ranging from 10 mg/kg body weight to 15 mg/kg body weight.[8,9,10,11]

MATERIALS AND METHODS

After gaining approval from the institutional ethics committee and obtaining written informed permission from each pregnant female, a prospective randomised double blinded control research was conducted. The research was conducted between December 2020 and May 2022. The research was conducted in accordance with the principles of the Declaration of Helsinki. We included one hundred mother who were between the ages of twenty to forty, had a gestational age of 38 weeks, and had asa grades I and II when having emergency LSCS. Sample size is calculated by using the formula

$$N = \frac{2x\left[Z_{\left(1-\frac{\alpha}{2}\right)} + Z_{\beta}\right]^2 x\, \sigma^2}{\Delta^2} \quad (1)$$

From the above formula we took significance level α as 0.05, the desired power β as 0.08, standard derivation σ as 1 and minimal clinically important difference (Δ) as 0.55. So, putting all the values in the equation we got the sample size as 50.36 which could be rounded off to 50 females in each group. Therefore, we took one hundred pregnant mothers of 38 weeks of gestation undergoing for emergency LSCS as our study population (Figure 1). The study population were randomly allocated in two groups: - group A and group B. Group A (study population) contained of fifty population who were received injection tranexamic Acid at a dose of 15 mg/ Kg body weight intravenously fifteen minutes prior to skin incision. Group B (control group) also consisted of fifty population who were received same amount of 5% dextrose fifteen minute prior to skin incision. The infusion of study drug (tranexamic acid or 5% dextrose) was started after all the fundamental mandatory monitoring had been attached. Through a syringe infusion pump, the study drug was administered as an infusion. The pump was configured to produce the desired infusion rate based on the patient's weight. In order to prevent the assessor from learning about the grouping of the patients, the infusion pump was covered with black fabric after being set up. As a result, the syringe and volume of the prepared solution were same; the rate of injection, however, varied depending on the patient's weight and group. The group was therefore unknown to the evaluator and the patient. All the caesarean sections were performed under spinal anaesthesia. Lactated ringer solution was used to maintain intraoperative fluid balance. After the delivery of baby, both groups were received 10-units oxytocin as uterotonic. Patient's heart rate, respiratory rate and blood pressure were noted in every ten-minute interval for 1st hour. After that monitoring was done at an interval of twenty minutes for next one hour. Estimated blood loss was calculated using the difference in haematocrit values taken prior and after caesarean delivery, according to following formula:

$$\text{Estimated blood loss} = \frac{\text{preoperative hematocrit} - \text{post operative hematocrit}}{\text{preoperative hematocrit}} \quad (2)$$

All the patients were carefully look for any adverse effect for next four postoperative days.

Inclusion and exclusion Criteria:

Inclusion criteria of this study were age between twenty to forty years, singleton pregnancy, term pregnancy. Exclusion criteria was grand multipara, multiple pregnancies, foetal macrosomia, polyhydramnios, placenta previa, pre-eclampsia, patients on anti- coagulants drug therapy, previous history of deep vein Thrombosis (DVT).

Haemoglobin and haematocrit, prothrombin time was estimated before and after caesarean section. Estimated blood loss was calculated from the above equation.

Statistical analysis:

For statistical analysis, data were input into a Microsoft Excel sheet and analysed using Graph Pad Prism version 5 and SPSS (version 27.0; SPSS Inc., Chicago, IL, USA). For numerical variables, the data had been summarised as mean and standard deviation, while for categorical variables, count and percentages had been used. For numerical data, one-way analysis of variance (one-way ANOVA) was used to compare the means of three or more samples. The significance of the proportional difference was examined using the Z_2test. The Pearson correlation analysis was used to determine correlation. A p-value was calculated from Student's t-distribution. A p-value of 0.05 or less was regarded as statistically significant.

RESULTS

We got that before placental delivery, pulse rate of Group A was 78.8 ± 7.7854 where as in Group B pulse rate was 74.62 ± 7.5347. As the p value was 0.0076 (less than 0.05) we concluded that distribution of pulse before placental delivery among two groups was statistically significant. But p value for pulse immediately after placental delivery, one hour after LSCS and two hours after LSCS were 0.0701, 0.3594 and 0.9091(more than 0.05). These data were statistically insignificant [Table 1]. Prior to placental delivery, immediately following placental delivery, one hour after LSCS, and two hours after LSCS, the mean values of Group A's respiratory rate were sequentially 12.74±0.7508, 12.80 ±0.8485, 12.82±0.7475, and 12.78±0.7900. These values were 12.80±0.7559, 12.86±0.8084, 12.90±0.7890, and 12.82±0.8003 for Group B. P values were sequentially 0.6913, 0.9042,

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0.6039, and 0.8019 before placental delivery, immediately following placental delivery, one hour after LSCS, and two hours after LSCS. Therefore, every p value was more than 0.05. As a result, we concluded that these numbers were statistically unimportant [Table 2]. Distribution of p values in systolic, diastolic and mean blood pressure one hour after LSCS and two hours after LSCS between two groups were not statistically significant [Table 3, Table 4, Table 5]. Before placental delivery, hemoglobin levels in both groups were higher than 11 gm/dL. However, the hemoglobin percentage in both groups decreased following placental delivery. Both groups following LSCS (after one and two hours) exhibited the trend of declining hemoglobin percentage. The p values following LSCS for one and two hours were less than 0.05. Thus, we concluded that results were meaningful one and two hours after LSCS [Table 6]. Before placental delivery, the hematocrit value was more than thirty-three in both groups. The hematocrit, however, started to decline in both groups following placental delivery. Both groups exhibited the trend of declining hematocrit following LSCS (after one and two hours). The p values were more than 0.05 across the board. Thus, we might conclude that the facts were not important. However, two hours after LSCS, the p value of hematocrit was less than 0.05. This number was statistically significant in this instance [Table 7].

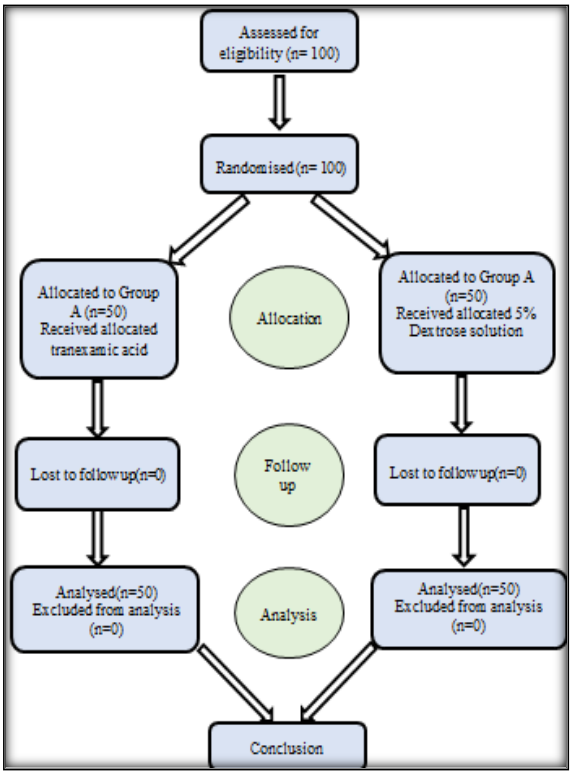

Figure 1: Flow chart of consolidated standards of reporting trials (CONSORT)

Table 1: Distribution of mean, median and p value of pulse among that two Groups

		Number of patients	Mean	Standard deviation	Minimum	Maximum	Median	p-value
Pulse before placental delivery	Group A	50	78.8	7.7854	60	92	78	.0076
	Group B	50	74.62	7.5347	62	90	72.5	
Pulse immediate after placental delivery	Group A	50	92.5	2.9875	92	99	92	.0701
	Group B	50	94.36	3.9474	96	99	96	
Pulse after one hour after LSCS	Group A	50	88.76	4.5291	78	98	90	.3594
	Group B	50	87.96	4.1500	76	97	88	
Pulse after two hours after LSCS	Group A	50	84.86	4.7078	70	93	86	.9091
	Group B	50	84.76	4.0029	78	92	86	

Table 2: Distribution of mean, median and p value of respiratory rate among two groups

		Number of patients	Mean	Standard deviation	Minimum	Maximum	Median	p-value
Respiratory rate before placental delivery	Group A	50	12.74	0.7508	12	14	13	0.6913
	Group B	50	12.80	0.7559	12	14	13	
Respiratory rate immediate after placental delivery	Group A	50	12.88	0.8485	12	15	13	0.9042
	Group B	50	12.86	0.8084	12	14	13	
Respiratory rate after one hour after LSCS	Group A	50	12.82	0.7475	12	14	13	0.6039
	Group B	50	12.90	0.7890	12	14	13	
Respiratory rate after two hours after LSCS	Group A	50	12.78	0.7900	12	14	13	0.8019
	Group B	50	12.82	0.8003	12	14	13	

Table 3: Distribution of mean, median, standard deviation and p value of systolic blood pressure among (SBP) Group A & Group B

		Number of patients	Mean	Standard deviation	Minimum	Maximum	Median	p-value
SBP before placental delivery	Group A	50	123.36	6.5458	110	130	120	0.455
	Group B	50	121.50	6.2760	118	132	124	2
SBP immediate after placental delivery	Group A	50	100.00	7.1701	128	110	110	0.547
	Group B	50	100.00	6.7370	128	110	110	4
SBP after one hour after LSCS	Group A	50	107.72	5.4811	100	120	110	0.808

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	Group B	50	107.44	6.0073	100	120	108	2
SBP after two hours after LSCS	Group A	50	114.00	6.0339	100	122	112	0.077
	Group B	50	111.92	5.6128	100	122	110	4

Table 4: Distribution of mean, median, standard deviation and p value of diastolic blood pressure among (DBP) Group A & Group B

		Number of patients	Mean	Standard deviation	Minimum	Maximum	Median	p-value
DBP before placental delivery	Group A	50	76.84	6.9293	68	90	80	0.5558
	Group B	50	76.02	6.9414	62	90	79	
DBP immediate after placental delivery	Group A	50	71.16	11.3648	60	90	70	0.9181
	Group B	50	71.40	11.9129	60	90	70	
DBP after one hour after LSCS	Group A	50	71.16	5.2230	60	82	70	0.2256
	Group B	50	69.96	4.5980	60	80	70	
DBP after two hours after LSCS	Group A	50	73.20	8.2015	60	90	70	0.6206
	Group B	50	72.44	7.0600	60	90	70	

Table 5: Distribution of mean, median, standard deviation and p value of mean blood pressure among Group A & Group B

		Number of patients	Mean	Standard deviation	Minimum	Maximum	Median	p-value
MBP before placental delivery	Group A	50	92.1760	6.3389	80	111	93.3	0.5779
	Group B	50	91.5120	5.5258	80	100	92.3	
MBP immediate after placental delivery	Group A	50	85.4560	5.8836	73.3	100	83.3	0.9041
	Group B	50	85.3100	6.1845	73.3	100	83.3	
MBP after one hour after LSCS	Group A	50	83.2720	4.8611	71.3	94	83.3	0.2256
	Group B	50	82.1000	4.7488	71.3	96	82.95	
MBP after two hours after LSCS	Group A	50	86.9060	5.9903	76.6	100	86.6	0.2738
	Group B	50	85.5900	5.9671	70.0	100	85.65	

Table 6: Distribution of mean, median, standard deviation and p value of hemoglobin in gram per deciliter among Group A & Group B

		Number of patients	Mean	Standard deviation	Minimum	Maximum	Median	p-value
Haemoglobin before placental delivery	Group A	50	11.02	0.3875	10.40	11.90	10.90	0.2604
	Group B	50	11.11	0.4072	10.40	12.00	10.90	
Hemoglobin immediate after placental delivery	Group A	50	10.8240	0.3910	10.20	11.70	10.70	0.7321
	Group B	50	10.8540	0.4786	10.10	11.80	10.70	
Hemoglobin after one hour after LSCS	Group A	50	10.7760	0.3723	10.20	11.70	10.70	0.0430
	Group B	50	9.0260	0.4823	10.00	11.80	10.60	
Hemoglobin after two hours after LSCS	Group A	50	10.5660	0.3831	10.00	11.50	10.50	0.0349
	Group B	50	10.4020	0.3836	9.80	11.40	10.20	

Table 7: Distribution of mean, median, standard deviation and p value of hematocrit among Group A & Group B

		Number of patients	Mean	Standard deviation	Minimum	Maximum	Median	p-value
Hematocrit before placental delivery	Group A	50	33.0400	1.1879	31.1	35.7	32.7	0.1732
	Group B	50	33.3840	1.3162	31.1	36.0	33.0	
Hematocrit immediate after placental delivery	Group A	50	32.4840	1.1722	30.6	35.1	32.25	0.6267
	Group B	50	32.6140	1.4750	30.3	35.8	32.25	
Hematocrit after one hour after LSCS	Group A	50	32.0860	1.9089	31.2	35.1	32.1	0.3291
	Group B	50	31.4078	4.5010	30.8	35.1	31.8	
Hematocrit after two hours after LSCS	Group A	50	31.6980	1.1494	30.0	34.5	31.5	0.0445
	Group B	50	30.7551	3.2236	30.0	34.2	30.6	

DISCUSSION

One of the main causes of mortality and disability among women in reproductive age in developing countries are complications during pregnancy and delivery. The danger involved with each pregnancy is represented by the maternal mortality ratio. Maternal mortality ratio, or MMR, is a measure of fatalities connected to pregnancy and delivery. It illustrates the ability of the health systems to deliver quality medical treatment that prevents and treats issues that might arise during pregnancy and labour. In the USA, there are about 2.2 maternal deaths for every 100,000 caesarean births. About 0.2 in 100000 vaginal births result in maternal mortality.[12] In the United States, bleeding is the

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main factor in significant maternal morbidity. Certain conditions preceding a caesarean, such as prolonged labour, foetal macrosomia, polyhydramnios etc. may increase the risk of uterine atony and subsequent haemorrhage. Some intraoperative condition like extensive adenolysis, bladder injury, broad ligament hematoma, injury to uterine artery leads to profuse bleeding. Haemorrhage during delivery may lead to need for blood and blood products transfusion, which itself has risks of complications. Sheehan syndrome is a known complication of hemorrhage at delivery. Approximately ten per cent of maternal mortality in the United States is secondary to obstetric haemorrhage.[13] This was a randomised double blinded controlled trail to evaluate efficacy of tranexamic acid in reducing blood loss during caesarean section. For our study, we had one hundred mothers undergone for emergency LSCS. The data from our investigation was statistically examined. Following analysis, we discovered that the values of the pulse rate, systolic, diastolic, mean blood pressure, and respiration rate were statistically insignificant before, after, and one and two hours after LSCS, respectively, placenta delivery, and one hour after placenta delivery. However, based on the results of our study, we concluded that the haemoglobin percentage after one and two hours of LSCS was statistically significant. Additionally, we learnt that the haematocrit number was important two hours after LSCS. Therefore, it was reasonable to predict that following emergency LSCS, the haemoglobin percentage and haematocrit levels decreased. Surgery and blood loss during the placenta were to blame for this blood loss. We found that blood loss was significantly less in group A compare to group B in our study. So, we assessed that injection tranexamic acid given fifteen minutes prior to skin incision can reduce blood loss during LSCS. Gungorduk K et al. (2011),[14] found that they sought to determine the efficacy and safety of Tranexamic acid (TA) in reducing blood loss during elective caesarean section (CS). They performed a randomized, double-blind, placebo-controlled study of 660 women who underwent elective caesarean section. The patients were randomly selected to receive an intravenous infusion of either tranexamic acid (1 g/10 mL in 20 mL of 5% glucose; N = 330) or 30 mL 5% glucose prior to surgery. The primary outcome was the estimated blood loss following caesarean section. No demographic difference was observed between groups. The mean estimated blood loss was significantly lower in women treated with tranexamic acid compared with women in the placebo group. Shahid A et al,[15] (2013) showed that to determine the effectiveness of tranexamic acid (TXA) in reducing blood loss during and after caesarean section (CS), as well as its safety. A randomized double-blind placebo-controlled study. Women undergoing lower segment caesarean section (LSCS) were enrolled. The patients were randomized to receive either injection Tranexamic acid or distilled water just before the surgery. Blood loss was collected and measured. First from the time of placental delivery to the end of LSCS and later from the end of LSCS to two hours postpartum; Haemoglobin, urine analysis, liver and renal functions were tested in both the groups. The mean haematocrit before placental delivery haematocrit immediate after placental delivery, haematocrit one hour after LUCS were not statistically significant and haematocrit two hours after LUCS were statistically significant between two Groups. Ray I et al,[16] (2016) observed that post-partum haemorrhage (PPH) is a major cause of maternal mortality globally. Tranexamic acid, an anti-fibrinolytic agent, is used to prevent this dreadful complication of post-partum haemorrhage. This study aims to document the efficacy of intravenous Tranexamic acid in reducing blood loss during and after caesarean section (CS). In this prospective randomized placebo-controlled open-label study, 100 mothers scheduled for elective CS were randomly selected and divided into two groups (study and control) of 50 each. The study group received 1 g IV Tranexamic acid and the control group received IV placebo. Following delivery, all mothers received ten units of oxytocin in 500 ml of normal saline. They also noticed that blood loss is much less in group received injection Tranexamic acid prior to skin incision compare to the placebo group. Our result also corroborate with the studies of Bhavana G, Abhishek MV, Mittal S,[17] Bhatia SK, Deshpande H,[18] Kamel HE et al.[19] In this study any mother did not show any noticeable adverse effects.

CONCLUSION

We can conclude from our study that decrease haemoglobin and haematocrit due to obstetric haemorrhage in the group A (Tranexamic acid given 15 mg/kg body weight, before 15 minutes of skin incision) was significantly less compare to group B placebo group. So, injection Tranexamic acid can reduce blood loss during caesarean section without significant side effect.

Limitations

In spite of every sincere effort our study has some lacunae. The notable short comings of this study are:

1. The sample size was small. Only 100 cases are not sufficient for this kind of study.
2. The study has been done in a single centre. The study was carried out in a tertiary care hospital, so hospital bias cannot be ruled out.

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