Section: Obstetrics and Gynecology

Original Research Article

EFFICACY OF TRANEXAMIC ACID IN DECREASING BLOOD LOSS DURING AND AFTER CAESAREAN SECTION AT A TERTIARY CARE HOSPITAL

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ABSTRACT

Background: Tranexamic acid is effective even when given orally. It is a drug of choice for idiopathic menorrhagia. It can be used in other conditions like placenta previa, abruptio placentae. Some more studies have shown the efficacy of tranexamic acid in decreasing postpartum hemorrhage for women who underwent CS. The objective is to evaluate the effect of tranexamic acid on postoperative bleeding in women undergoing elective caesarean section.

Materials and Methods: Prospective interventional study was carried out. 196 eligible women were divided in two groups. Thorough clinical examination, investigations and Ultrasonography was done. Study group received injection tranexamic acid 1gm intravenously, slowly over 5-minutes, it was given 10-min prior to skin incision and Inj. Oxytocin 20-units in drip following cord-clamping. Control group received only oxytocin after baby delivery as per protocol. Need for blood-transfusion, maternal and neonatal side effects were compared. Postoperative estimation of hemoglobin, PCV was undertaken 24hours post operatively.

Results: Both groups were similar for age, height, weight, number of previous caesarean sections, preoperative hemoglobin, preoperative PCV, duration of surgery in min. Intraoperative blood loss, postpartum blood loss after two hours was significantly more in control group compared to study group. Postoperatively hemoglobin, PCV was significantly better in study group compared to control group. Adverse effects were similar in both the groups.

Conclusion: One-gram Tranexamic acid significantly reduced the amount of blood loss, (331.58±47.503 in the study group compared to 378.32±30.256 in the control group, p=0.001) and after LSCS (54.10±9.131 in study group and 84.30±8.006 in the control group, p=0.001).

Keywords: Efficacy, tranexamic acid, blood loss, caesarean section

INTRODUCTION

Globally around 5,30,000 maternal deaths occur every year and most of them are from developing countries. Most important cause is postpartum hemorrhage. Out of 5,30,000 maternal deaths, it can cause around 300,000 deaths.[1]

Global and Indian trend is towards Caesarean section (CS) instead of normal delivery and its rate is increasing at an alarming rate. Compared to the normal vaginal delivery, it is associated with more complications especially postpartum hemorrhage. There is a need to reduce the blood loss to control the morbidity and mortality associated with CS.[2] It is well known in vaginal delivery around 500 ml blood can occur compared to 1000 ml in CS. This leads to fall of hematocrit by 10% and around 6% more women may require blood transfusion.[3]

To decrease the bleeding at the time of separation of placenta from the wall of the uterus, certain changes occur like contractions of uterine muscles, increase in the activity of the platelets. At the same time, there is increase in the coagulant factors and fibrinolytic activity. As soon as the placenta is removed, the human body increases the levels of fibrin destruction products. Tranexamic acid is an inhibitor of plasminogen activator. Hence, if it is given, it may reduce the bleeding during the postpartum period.[4]

Tranexamic acid is effective even when given orally. It is a drug of choice for idiopathic menorrhagia. It can be used in other conditions like placenta previa, abruptio placentae. Some more studies have shown the efficacy of tranexamic acid in decreasing postpartum hemorrhage for women who underwent CS.[5]

Amino acid lysine's synthetic derivative is tranexamic acid. It blocks the lysine binding sites seen on the plasminogen molecules. Thus, acting as anti-fibrinolytic agent. The plasminogen is prevented of being converted to plasmin by tranexamic acid. It was a common drug of choice in controlling the bleeding in other surgical procedures.[6]

A systematic review was carried out in 2001. It had 18 clinical trials. This review showed that the tranexamic acid was very effective in decreasing the blood loss by 34%.[7] In 2017, World Health Organization recommended use of tranexamic acid in women with postpartum hemorrhage within three hours of child birth.[8]

The main objective of present study is to evaluate the effect of tranexamic acid on postoperative bleeding in women undergoing elective caesarean section with aim of providing a safe and effective pharmacological therapy for reducing blood loss and in reducing maternal morbidity and mortality. The secondary objectives are to assess the efficacy of tranexamic acid is to reduce the need for blood transfusion, post-operative anemia, need for hysterectomy and to asses maternal and fetal outcome.

MATERIALS AND METHODS

A prospective comparative interventional study was carried out at a tertiary care hospital over a period of one year from November 2017 to November 2018.

For sample size calculation, the mean values of blood loss were taken based from a previous study. 9 With 95% of confidence level and 90% of power the sample size came out to be 196 i.e. 98 women in each group.

Primi women 21-29 years of age with singleton pregnancy at 37-39 weeks, hemoglobin of 10 gm% or more with 22-26 of body mass index undergoing elective CS were included in the present study. Those with twin gestation, having polyhydramnios or oligohydramnios, with severe complications, allergic to the drug under study, treated for thromboembolic disorders, with abnormal placenta were excluded.

Institutional Ethics Committee permission was obtained. Written informed consent was taken. Detailed history was recorded. Thorough clinical examination was carried out. Relevant and required investigations were carried out. Ultrasonography was also done. All standard protocols were followed for caesarean section procedure. Once the clamping of the cord was done, they were given oxytocin.

Study group received injection tranexamic acid 1gm intravenously, slowly over a period of 5 minutes and it was given 10 min prior to skin incision and Inj. Oxytocin 20 units in drip following cord clamping. Control group received only oxytocin after baby delivery as per existing hospital protocol. All patients received 20units oxytocin drip and uterine massage after delivery of placenta.

Need for other measures, transfusion of blood or blood products, maternal and neonatal side effects of medications given were compared. Blood pressure, pulse, respiratory rate and blood loss during and within two hours of caesarean section was noted. Postoperative estimation of hemoglobin, PCV was undertaken 24hours post operatively.

The duration of the operation was obtained from the maternal anesthetic record. All the women along with their babies were followed up for 7 days.

Statistical analysis: The data was presented as proportions, mean etc. For comparison of proportions, Chi square test/Fischer exact test was used. For comparison of mean values, t test was used. P value less than 0.05 was taken as statistically significant.

RESULTS

Table 1: comparison of baseline characteristics in study and control groups

Variables		Study group	Control group	P value
Age (years) mean+SD		24.03+3.167	24.05+2.718	0.961
Weight (kg) mean+SD		68.08+5.275	68.03+3.712	0.938
Height (cm) mean+SD		154.48+4.910	154.30+4.135	0.777
Gravida	1	20 (20.4%)	20 (20.4%)	0.879
	2	50 (51%)	53 (54.1%)	
	3	28 (28.6%)	25 (25.5%)	
Number of previous caesarean sections	1	50 (51%)	55 (56.1%)	0.695
	2	28 (28.6%)	23 (23.5%)	
Preoperative hemoglobin (mean+SD)		11.51+0.888	11.51+1.02	0.958
Preoperative PCV (mean+SD)		34.16+2.4	34.05+0.72	0.655
Duration of surgery in min (mean+SD)		44.59+4.66	44.57+1.6	0.976

Both the groups were found to be similar for age, height, weight, number of previous caesarean sections, preoperative hemoglobin, preoperative PCV, duration of surgery in min. The difference was not found to be statistically significant (p>0.05). [Table 1]

Table 2: Comparison of blood loss and other characteristics in two groups

Characteristics	Study group	Control group	P value
Intraoperative blood loss in ml	331.58+47.5	378.32+30.26	0.0001
Postpartum blood loss after two hours	54.1+9.1	84.4+8.01	0.001
Postoperative hemoglobin	10.49+0.89	9.93+0.78	0.001
Postoperative PCV	33.05+2.58	30.18+3.01	0.001

The intraoperative blood loss was significantly more in the control group compared to the study group which received the tranexamic acid. Similarly postpartum blood loss after two hours was also significantly more in control group compared to the study group. Postoperatively the hemoglobin was significantly better in study group compared to the control group. Similarly, after the surgery, the PCV was significantly more in study group compared to the control group. ($p<0.05$). [Table 2]

Table 3: Comparison of perinatal outcome in study and control groups

Perinatal outcomes	Study group	Control group	P value
Delayed cry	2 (2%)	1 (1%)	0.844
Fetal distress	1 (1%)	1 (1%)	
Good	95 (96.9%)	96 (98%)	

Delayed cry was seen in two cases in study group and one case in control group. Fetal distress was seen in one case each. [Table 3]

Table 4: Comparison of adverse effects between the study and control groups

Adverse effects	Study group	Control group	P value
Nil	86 (87.8%)	91 (92.9%)	0.448
Diarrhea	1 (1%)	0	
Nausea	3 (3.1%)	0	
Pyrexia	3 (3.1%)	2 (2%)	
Shivering	2 (2%)	3 (3.1%)	
Vomiting	3 (3.1%)	2 (2%)	

The adverse effects were found to be similar in both the groups. A total of 12 cases had adverse effects in study group compared to seven cases in the control group. But the difference was not found to be statistically significant ($p>0.05$). [Table 4]

DISCUSSION

Postpartum hemorrhage is an important cause of morbidity and mortality in women. The rate of infection increases. There will be increased need for blood products. The hospital stay is prolonged. This leads to enhanced costs. All these can be prevented by decreasing the blood loss.[10] The fibrinolysis process that starts after delivery can be effectively prevented by tranexamic acid action. 1 It blocks the lysine binding focus. It prevents the binding of plasminogen and plasmin to fibrin substrate. Thus, the tranexamic acid reduces the blood loss. It takes 10-15 min to initiate its action and once initiated, the action lasts for three hours.[11]

In the present research design, we tried to study the efficacy of tranexamic acid on decreasing the loss of the blood after CS. Due to some influencing factors, the loss of the blood estimation may be wrong. Hence, we used the hematocrit values before and after CS to estimate the loss of the blood. We had study group which received tranexamic acid in addition to routine protocol and the control group which received the routine protocol. Both the groups were comparable for baseline demographic and clinical characteristics. The vitals and the lab parameters were also comparable for both the groups. Proportion of patients with loss of the blood was more in the control group compared to the study group. Additional uterotonic drugs were required to be given for women in the control group compared to the women in the study group. When the hemoglobin and PCV was compared in two groups after the surgery, it was observed that the women group who received the tranexamic acid had better hemoglobin and PCV levels indicating lesser loss of the blood.

We found that on an average the loss of the blood in the study group was 331.58 ml compared to the 378.32 ml in the control group. This difference was found to be statistically significant ($p<0.05$). The loss of the blood was reduced after the CS. Tranexamic acid was effective in reducing the incidence of postpartum hemorrhage. Similar findings were also reported by Sekhavat et al,[12] A study from China also showed similar results of reduction in the loss of the blood by almost 30% in the tranexamic acid group when compared to the control group.[13] Gohel M et al,[14] observed from their research that during the time right from the CS to two hours postpartum, the mean loss of the blood was lesser in the women who received the tranexamic acid compared to the women who were not given the drug. These differences were found out to be statistically significant ($p<0.05$).

Shahid A et al,[15] in their study observed that from the time starting from the delivery of the placenta to the last stage of the CS, the loss of the blood was significantly reduced in the tranexamic group compared to the control group. In the year of 2013, in a research study by Abdel Aleem et al,[16] with a total

of 740 cases deduced that the loss of the blood was effectively decreased in the tranexamic acid group compared to the women group who were not given the tranexamic acid. One meta-analysis was conducted by Ferrer et al.[4] They used three clinical trials which had 461 cases with two groups where one group was given tranexamic acid. The group in which the tranexamic acid was given, was found to have lesser loss of the blood compared to another group which was not given the tranexamic acid. There were no cases of thrombotic events. No one died. Nausea was the only common complaint after the tranexamic acid was given.

In another meta-analysis having seven clinical trials similar results were reported.[17] One more meta-analysis having 10 clinical trials also had similar results.[18] A systematic review from Cochrane also concluded the similar efficacy of tranexamic acid. Overall, the decrease in the loss of the blood in case of CS was 80.1 ml compared and it was 71.5 ml in case of vaginal delivery.[19]

Limitations: One limitation of the study is the relatively small sample size for looking at parameters such as thromboembolic events. For parameters such as thromboembolic events, it is important to have pooled data from various trials to reach a powerful conclusion. Another limitation of our study is exclusion of high-risk cases for PPH.

Recommendations: From the above study, we recommend the use of 1-gram tranexamic acid intravenously in women undergoing elective LSCS to reduce the maternal morbidity and mortality due to blood loss.

CONCLUSION

One-gram Tranexamic acid significantly reduced the amount of blood loss, (331.58±47.503 in the study group compared to 378.32±30.256 in the control group, p=0.001) and after LSCS (54.10±9.131 in study group and 84.30±8.006 in the control group, p=0.001). The additional need of uterotonic agents and need for the postop blood transfusion was also less in study group who received Tranexamic acid. The use of Tranexamic acid in pregnancy is a safer option as it was not associated with any significant adverse drug reaction. Fetal outcome was evaluated by APGAR score and it was not adversely affected by the use of TXA. Thus, Tranexamic acid can be used safely and effectively in subjects undergoing LSCS for decreasing morbidity and mortality due to blood loss. A careful monitoring of postop vitals is necessary.

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