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A STUDY ON EFFICACY OF TRANEXEMIC ACID IN REDUCING BLOOD LOSS AFTER VAGINAL DELIVERY.

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ABSTRACT **Introduction:** Postpartum blood loss is difficult to evaluate especially in developing countries like India where most of the women are anaemic with poor reserve and these conditions are further aggravated by increased demand during pregnancy and blood loss during third stage of labour. The present study was planned to compare the efficacy of prophylactic 10 IU intramuscular oxytocin and 10 IU intramuscular oxytocin +1g Tranexamic acid in reducing blood loss in the third stage of labour. **Methods:** The present study was carried out on full term pregnancies with singleton pregnancy being delivered vaginally at Tirunelveli medical college were included. For this comparative study, 200 women in labor were included after obtaining informed consent. A detailed obstetric history, history of previous medical illnesses, history of the treatment received earlier, cardiovascular and respiratory system and other systems including thyroid and breast were noted. **Results:** The average total blood loss in IIIrd stage of labour with IM oxytocin was 191 ml and with IM oxytocin + Tranexamic acid was 81 ml, which was statistically significant ($p<0.001$). Oxytocin + Tranexamic acid group had less blood loss when compared to oxytocin group alone at various time period. **Conclusions:** In the active management of IIIrd stage of labour 10 IU intramuscular Oxytocin + one gram of tranexamic acid IV is a better combination in reducing the blood loss at delivery when compared to 10 IU intramuscular oxytocin alone.

KEYWORDS : Oxytocin, Postpartum haemorrhage, Tranexamic acid, Vaginal delivery

INTRODUCTION:

Post-Partum Hemorrhage is the leading cause of maternal morbidity and mortality worldwide. As it is responsible for about 25% of maternal mortality worldwide[1] Post-Partum Hemorrhage not only affects the health of the mothers, but also has a significant impact on the health of the newborns.[2] The WHO defines postpartum hemorrhage (PPH) as "loss of blood more than 500 mL during the first 24 hours after delivery"[3]

Various approaches have been instituted for the prevention and management of Postpartum hemorrhage such as, Mechanical means, replacement of fluid and blood products, embolization, and pharmacologic agents (Oxytocin-First line, Methergine, carboprost, tromethamine and misoprostol.[4]

Drugs used to treat PPH mentioned above were uterotonics aimed at preventing uterine atony. Tranexemic acid (TXA), with its antifibrinolytic properties, aimed correcting the coagulopathy, is increasingly being used worldwide to treat PPH. The following changes occurs during pregnancy related to coagulation such as increased levels of clotting factors, decreased anticoagulation activity and decreased fibrinolysis resulting in a hypercoagulable state peaking at term. It decreases the incidence and amount of bleeding in elective surgeries.[5]Tranexamic acid has been shown to significantly reduce the mortality among patients admitted with trauma. Tranexamic acid does not increase the incidence of vascular occlusive events, and is subsequently recommended in the situations like reduction of blood loss during delivery.

Several studies have demonstrated the effectiveness of tranexamic acid in reducing the blood loss related mortality and morbidity during delivery[6]. This study aims to assess the effectiveness of tranexamic acid in reducing the blood loss in vaginal deliveries and its role of prophylaxis in primigravida among the antenatal mothers.

METHODOLOGY

Primipara undergoing normal vaginal delivery in age group of 19-34 years who were admitted in labor ward at Department of Obstetrics and Gynecology, Tirunelveli medical college hospital were included in the study, for a period of 18 months. Convenient Sampling method was used. Singleton gestation with Hemoglobin level >9gms/dl were included in the study. While patient undergoing caesarean delivery, allergic to tranexamic acid, While patients with age <18 yrs ,>35 yrs, Hb% <9 grams /dl, Complicated pregnancy at risk of PPH, hematologic disorder, history of thrombus or epilepsy were excluded from study. 200 patients divided into two groups were included in our study, 100 in study group and 100 in control group. Sample size was calculated based on Anantha Lakhsmi Satyavathi et al study[7].

The subjects were randomized into two groups, detailed obstetric and medical history were taken. Vital parameters BP,PR, RR, obstetric history were noted USG done to confirm gestational age and to assess liquor status, complete blood count at time of admission and after delivery for study group tranexamic acid is given 15mg/kg in 100 ml of ringer lactate at the time of delivery of anterior shoulder in addition to oxytocin for control group oxytocin alone is given.

Post-delivery vitals, amount of blood loss, need of additional uterotonics, need of blood transfusion are noted and side effects of drugs are noted. Institutional Ethical Committee approval was obtained before the start of the study. Informed written consent was obtained from each participant.

When a numerical variable is associated with the study groups independent t test is used for the significance in mean difference. When a Categorical Variable is associated with a categorical variable for test of significance, chi-square test is used. P values less than 0.05 were considered statistically significant. Data was analyzed using SPSS software version 22.

RESULTS:

The study population comprise of a total of 200. Of which 100 belong to Study group who received Tranexamic acid and 100 Controls. The mean and SD of the age of the study group are 24.6±3.48 and controls is 24.1 ± 3.38 respectively. Among the Study group and control group, 28 and 24 were belonging to Socio economic status IV. Among the Study group and control group, 84 and 80 were booked antenatal mothers. The Booked case details among the study and control groups are represented in the following table and Bar chart,

The mean and SD of the BMI of the study group are 23.2 ± 0.62 and for controls it was 23.32 and 0.62. These differences were not statistically significant with p value of >0.05 using independent t test.

The onset of labor categories among the study and control groups were not statistically significant where spontaneous delivery was in 112 mothers and induced in 88 mothers. The Mode of delivery among the study and control groups is not statistically significant with labor naturalis in 130 mothers while LN with perennial laceration was in 10 mothers, LN with episiotomy in 60 mothers.

We further evaluated vital parameters like respiratory rate, pulse rate, systolic and diastolic BP. The following table represents the Mean and standard deviations of the vital parameters of the study groups pre and post-delivery.

Table 1. Vital parameters of the study groups pre and post-delivery

	Group	N	Mean	Std. Deviation	p-value (t test)
Pre Delivery Pulse Rate	Study	100	82.5000	2.45155	0.917
	Control	100	82.5400	2.92471	
Post Delivery Pulse rate	Study	100	83.8600	3.01518	<0.001 (Significant)
	Control	100	87.0400	2.57384	
Pre Delivery SBP	Study	100	115.46	5.706	0.078
	Control	100	116.88	5.631	
Post Delivery SBP	Study	100	114.28	5.728	0.0764
	Control	100	114.04	5.563	
Pre Delivery DBP	Study	100	75.2800	5.66057	<0.001 (Significant)
	Control	100	78.5000	4.75140	
Post Delivery DBP	Study	100	73.6400	4.98385	.366
	Control	100	74.3200	5.60462	
Pre Delivery RR	Study	100	17.6100	1.00398	0.001 (Significant)
	Control	100	18.0400	.87525	
Post Delivery RR	Study	100	17.8600	.96421	0.031 (Significant)
	Control	100	18.1400	.85304	

The mean duration of the third stage among the study and control group are 4.60 and 4.48 respectively. The differences in mean of the duration of the third stage among the study and control group are not statistically significant.

The mean blood loss between the Time of Delivery to 30 Min among the study and control groups are 81.01 and 191.80 respectively. The mean blood loss between the Thirty Min to Two Hours among the study and control groups are 27.26 and 49.52 respectively. The mean blood loss between the Time of Delivery to two hours among the study and control groups are 108.27 and 241.17 respectively. The decreased blood loss among the study group is statistically significant and is represented in the following table 2.

Table 2. Blood loss among the study and control groups:

	Group	N	Mean	Std. Deviation	p-Value
Time of Delivery to Thirty Min	Study	100	81.0100	41.09652	<0.001 (Significant)
	Control	100	191.8000	55.36728	
Thirty Min to Two Hours	Study	100	27.2600	16.68794	<0.001 (Significant)
	Control	100	49.5200	29.88580	
Time of Delivery to two hours	Study	100	108.2700	57.72236	<0.001 (Significant)
	Control	100	241.1700	85.14614	

In regards to need of uterotonics, among the Study group and control group, 2 and 22 required additional Uterotonics. The decreased need for additional Uterotonics among the study groups is statistically significant using chi square test with a p-value of <0.001.

Next, among the Study group and control group, 2 and 10 were received Blood transfusions. The decreased Blood transfusions among the study groups is statistically significant using chi square test with a p-value of 0.017. Among the Study group and control group, 90 and 88 were having no Maternal Complications. Vomiting was reported equally among the study groups. The differences in maternal complications among the study and Control groups is not statistically significant.

Among the Study group and control group, 2 and 10 were having Duration of Hospital Stay more than 3 hours. This shorter hospital stay of mothers among the study group is statistically significant with a p-value of 0.017.

DISCUSSION

The main objective of the study is to study the effectiveness, Safety, Tranexamic acid in reducing postpartum blood loss after vaginal delivery and its role of prophylaxis in primigravida among the antenatal mother's form Tirunelveli medical college hospital.

In this Study, the mean and SD of the age of the study group are 24.6 and 3.48 respectively. The mean and SD of the age of the Control group are 24.1 and 3.38 respectively. These differences were not statistically significant with p value of >0.05 using independent t test. Maternal age has been associated with PPH and studies have concluded that both the extremes of age cause adverse outcomes with respect to PPH.[8]

In this Study, booking status, Socioeconomic status, onset of labour, mode of delivery and duration of third stage were not statistically significant between the groups. Induction of the labour has been studied for the occurrence of PPH and found no association. But in this study, the induction of the labour proportion was not significantly different in this study.[9]

In this Study, the mean and SD of the BMI of the study group are 23.2266 and 0.62 respectively. The mean and SD of the BMI of the Control group are 23.3204 and 0.62 respectively. These differences were not statistically significant. Various studies have shown that increased BMI is associated with increased incidence of BMI. **AJ Butwick et al** , observed that Being overweight or obese class I, II, or III was related with a decreased odds of severe postpartum haemorrhage.[10]

Moreover, factors such as Age, BMI, booking status, Socioeconomic status, onset of labour, mode of delivery and duration of third stage were not statistically significant between the groups in our study.

In this Study, the mean blood loss between the Time of Delivery to Thirty Min among the study and control groups are 81.01 and 191.80 respectively. The mean blood loss between the Thirty Min to Two Hours among the study and control groups are 27.26 and 49.52 respectively. The mean blood loss between the Time of Delivery to two hours among the study and control groups are 108.27 and 241.17 respectively. The decreased blood loss among the study group is statistically significant.

Anne-Sophie Ducloy-Bouthors et al[11], studied the effectiveness of High dose Tranexamic Acid (loading dose 4 g over 1 hour, then infusion of 1 g/hour over 6 hours) for the reduction of Blood Loss in Vaginal Delivery. High-dose TA can reduce blood loss and maternal morbidity in women with PPH with minimally observed minor side effects. **Mojgan Mirghafourvand et al**, showed that prophylactic tranexamic acid decreases blood loss and associated complications after vaginal delivery in women with a low risk of postpartum haemorrhage and improve maternal health.[12] **Gungorduk, Kemal et al** showed that high-dose TA can reduce blood loss and maternal morbidity in women with PPH with minimally observed minor side effects.[13]

In this Study, Among the Study group and control group, 2 and 22 required additional Uterotonics. The decreased need for additional Uterotonics among the study groups is statistically significant using chi square test with a p-value of <0.001. **Loïc Sentilhes et al**, in his study showed that tranexamic Acid had a lower rate of provider-assessed clinically significant postpartum haemorrhage, received significantly less additional uterotonic agents.[14]

Gabriele Saccone et al, proved that prophylactic tranexamic acid decreases blood loss and associated complications after vaginal delivery in women with a low risk of postpartum haemorrhage and improve maternal health. [15]. The World Health Organization (WHO) recommends primary usage of intravenous tranexamic acid (TXA) within three hours of birth in addition to standard care for women with clinically diagnosed with postpartum haemorrhage (PPH) following vaginal delivery or caesarean section.

In this Study, Among the Study group and control group, 2 and 10 were received Blood transfusions. The decreased Blood transfusions among the study groups is statistically significant using chi square test with a p- value of 0.017. In this Study, Among the Study group and control group, 2 and 10 were having Duration of Hospital Stay more than 3 hours. This shorter hospital stay of mothers among the study group is statistically significant with a p-value pf 0.017.

In this Study, Among the Study group and control group, 90 and 88 were having no Maternal Complications. The Maternal Complications is not statistically significant. among the Study group and control group. **Claes Lindoff et al**, studied the Treatment with Tranexamic Acid during Pregnancy, and the Risk of Thrombo-Embolic

Complications. They concluded that there is no evidence of any thrombogenic effect of Tranexamic Acid[16].

CONCLUSION

Tranexamic acid significantly reduced the amount of blood loss during and after the normal delivery and its use was not associated with any side effects and.or complication like thrombosis. Thus, tranexamic acid can be used safely and effectively in subjects undergoing normal delivery.

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