Section: Obstetrics and Gynaecology

Original Research Article

A STUDY ON EFFECT OF PARENTERAL TRANEXAMIC ACID IN PREVENTING PPH FOLLOWING VAGINAL DELIVERY

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Received : 05/01/2025
Received in revised form : 20/02/2025
Accepted : 07/03/2025

Keywords:
Tranexamic acid, oxytocin, labor, vaginal delivery, maternal complications, Apgar score.

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DOI: 10.47009/jamp.2025.7.2.19

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2025; 7 (2); 88-92

Abstract

Background: Labor is defined as regular painful uterine contractions that lead to cervical dilation and effacement. PPH remains the leading cause of maternal death and is often avoidable. Therefore, tranexamic acid may be an effective treatment for high-risk women with PPH. This study aimed to assess the role of TXA in reducing blood loss after vaginal delivery. **Materials and Methods:** This prospective case-control study included 200 pregnant women categorised into two groups: study (n=100) and control (n=100). The study group received oxytocin and tranexamic acid, whereas the control group received oxytocin and placebo. Vital parameters, blood loss, Apgar scores, and maternal outcomes were also recorded. Blood loss was measured using drapes and preweighed pads at delivery and 2 h postpartum. **Result:** Blood loss was significantly lower in the study group than in the control group at all time points ($p<0.05$). The mean blood loss in the study group was 106.27 ml vs. 246.37 ml in the control group ($p=0.02$). The study group had a lower incidence of blood transfusions (2%vs.10%, $p=0.01$) and required fewer additional uterotonics (3%vs.24%, $p=0.01$). Post-delivery, the study group exhibited smaller reductions in haemoglobin and haematocrit levels ($p<0.05$). The study group also had a shorter hospital stay, with 97% of the patients discharged within 3 days ($p=0.02$). No significant differences in maternal complications or Apgar scores were observed between groups. **Conclusion:** Tranexamic acid administered prophylactically via the intravenous route significantly reduced blood loss after vaginal delivery without major complications. It is safe, with no adverse effects on foetal outcomes, although nausea and vomiting are more frequent.

INTRODUCTION

Labor is defined as regular and frequent painful contractions of the uterus that result in the progressive widening and thinning of the cervical space. The World Health Organization (WHO) defines normal birth as "spontaneous in onset, low-risk at the beginning of labor, and continuing so throughout labor and delivery. The baby was born spontaneously in the vertex position between 37 and 42 weeks of gestation. Mother and baby are in good health after birth."[1] Though giving birth is a natural process, complications can arise and even lead to death due to factors such as excessive blood loss.[2] Only about one in every thousand births is complicated by life-threatening obstetric haemorrhage.[3] It is estimated that 1,40,000 women die during childbirth each year. Recent advances in PPH treatment include antifibrinolytics and recombinant factor VIIa.[4] Still, these treatments are limited by their high price and the fact that they are difficult to obtain or store.

Postpartum haemorrhage (PPH) is a major contributor to maternal mortality in developing countries. Most maternal deaths attributed to PPH reported in confidential enquiries into maternal deaths in South Africa (2005-2007, Confidential enquiries 2006) were thought to be avoidable.[5] Uterine atony was the underlying cause of maternal deaths, necessitating the use of uterotonics to stem the flow of blood. Additional causes of maternal death from PPH include caesarean section, retained placenta, inverted uterus, and uterine rupture.[6] Therefore, uterotonic drugs are unlikely to be a solution, and other avenues for investigation and intervention must be explored. As randomised trials

ISSN (O): 2687-5365; ISSN (P): 2753-6556

in pregnant women on PPH are challenging, the efficacy of TXs may be used as a surrogate endpoint in preventing PPH in high-risk women. Tranexamic acid may be effective for high-risk factors that are ineffective for uterotonics, such as placenta praevia and lacerations from instrumental delivery.[7]

Fibrinolysis is a response to local fibrin deposition, as shown by alterations in fibrinolytic components during and after pregnancy. The level of serum fibrinogen degradation products increases one hour after giving birth and remains high throughout the early puerperium period. However, plasma fibrinogen levels decline in both the third and fourth stages of labor and after placental delivery.[8] Thus, reducing blood loss by interacting with the fibrinolytic mechanism. With the help of tranexamic acid, an anti-fibrinolytic agent, this study tracked the progress of decreased blood loss during the third stage of labor.[9]

Aim

This study aimed to assess the effect of parenteral tranexamic acid administration immediately after vaginal delivery on reducing the incidence of immediate PPH in women who received prophylactic oxytocin.

MATERIALS AND METHODS

This randomised controlled study was conducted on 200 pregnant women in the Department of Obstetrics and Gynecology, Madurai Medical College, Madurai, India, for six months. Before the initiation of the study, the Institutional Ethics Committee approved the study, and all patients provided informed consent.

Inclusion Criteria

All term-delivered mothers over the age of 18 had a risk of immediate PPH. Multiparous women, those with pregnancy complications such as anaemia, multiple pregnancies, myoma, polyhydramnios, placenta previa, gestational hypertension, HELLP syndrome, macrosomia, and a previous history of PPH were included.

Exclusion Criteria

Pregnant women with known allergies to tranexamic acid, heart disease, or liver or renal disease. Pregnant women with seizure disorders, those undergoing anticoagulant therapy, those with a history of thromboembolic events, and those with defective colour vision or autoimmune disorders were excluded.

Methods

Using simple random sampling, the participants were categorised into two groups: study (n=100) and control (n=100). The detailed medical and obstetric histories of the patients were recorded. Vital parameters were checked and basic investigations were performed, including patient weight assessment. Detailed general and obstetric examinations were conducted, and the gestational age was confirmed using ultrasonography (USG).

In the study group, within one minute of delivery, patients were given an intramuscular injection of 10 units of oxytocin along with tranexamic acid at a dose of 10 mg/kg through a slow intravenous infusion over five minutes at the time of anterior shoulder delivery. The control group was administered the same 10-unit dose of oxytocin within one minute post-delivery, along with a placebo injection of 5 ml of normal saline, as a slow intravenous infusion over five minutes at the delivery of the anterior shoulder.

The following parameters were recorded for each patient: vital parameters, including pulse rate, blood pressure, respiratory rate, oxygen saturation, urine output (ml/hr), haemoglobin (gm%), and packed cell volume (%); blood loss from the time of delivery to 2 h postpartum; Apgar scores of the newborn; side effects of the administered drug; postpartum vital parameters, including PR, BP, RR, SpO2, urine output (ml/hr), Hb gm%, and PCV%; maternal need for blood transfusion; and maternal outcomes until hospital discharge.

Upon delivery of the baby and draining of all amniotic fluid, the patient was placed at the edge of the table over a disposable conical, graduated plastic collection bag. A drape was used to measure the amount of collected blood. The patient was given preweighed pads, which were then weighed two hours postpartum to assess blood loss. Blood samples were collected and swabs were weighed before and after delivery to quantify blood loss.

Statistical Analysis: Data are presented as means, standard deviations, frequencies, and percentages. An independent-sample t-test was used to compare continuous variables, while Pearson's chi-squared test was used to analyse categorical variables. Statistical significance was determined using a two-tailed test with a p-value of less than 0.05. Data analysis was conducted using the IBM SPSS version 21.

RESULTS

Most patients were aged 20–24 years (48% in the study group vs. 52% in the control group), with a similar distribution across other age categories and no significant difference ($p = 0.6$). Most participants belonged to the upper-lower socioeconomic class (76% vs. 72%), with fewer in the lower-middle class, without a significant difference ($p = 0.06$). Primigravidity was more common in the control group (30% vs. 20%), whereas the study group had more second-time mothers (80% vs. 70%), with no significant difference ($p = 0.65$).

Both groups had comparable proportions of spontaneous and induced labor ($p = 0.82$). However, the study group required significantly fewer additional uterotonics (3% vs. 24%, $p = 0.01$) and blood transfusions (2% vs. 10%, $p = 0.010$) [Table 1].

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Table 1: Comparison of demographic, and clinical characteristics between groups.

		N (%)		P value
		Study group	Control group	
Age (years)	<20	6(6%)	6(6%)	0.6
	20–24	48(48%)	52(52%)	
	25–29	40(40%)	36(36%)	
	≥30	6(6%)	6(6%)	
Socioeconomic Status	Upper lower class	76(76%)	72(72%)	0.06
	Lower middle class	24(24%)	28(28%)	
Obstetric	Primi	20(20%)	30(30%)	0.65
	2nd gravida	80(80%)	70(70%)	
Onset of labor	Spontaneous	49(49%)	47(47%)	0.82
	Induced	51(51%)	53(53%)	
Additional uterotonics	Yes	3(3%)	24(24%)	0.01
	No	97(97%)	76(76%)	
Maternal blood transfusion	Yes	2(2%)	10(10%)	0.010
	No	98(98%)	90(90%)	

There were no significant differences in weight (p=0.12), height (p=0.32), BMI (p=0.9), or labor duration at 3rd stage (p=0.32). The mean blood loss was significantly lower in the study group than in the control group at all time points: from delivery to 30 minutes (71.01 ± 51.39 mL vs. 181.65 ± 40.88 mL, p = 0.009), from 30 minutes to 2 hours (26.27 ± 6.17 mL vs. 52.72 ± 8.90 mL, p = 0.008), and at 2 hours post-delivery (106.27 ± 53.57 mL vs. 246.37 ± 50.07 mL, p = 0.02) [Table 2].

Table 2: Comparison of labor duration, and blood loss between groups

		Study group	Control group	P value
Subjective characters	Weight (kgs)	56.60±2.10	57.10±2.30	0.12
	Height (cm)	156.12±2.80	154.80±2.71	0.32
	BMI	24.50±0.93	24.20±0.93	0.9
Duration of 3rd stage (minutes)		4.90±2.80	4.30±2.60	0.32
Blood loss (ml)	Delivery to 30 minutes	71.01±51.39	181.65±40.88	0.009
	30 minutes to 2 hours	26.27±6.17	52.72±8.90	0.008
	Delivery to 2 hours	106.27±53.57	246.37±50.07	0.02

There were no significant differences in pulse rate (p=0.9), systolic BP (p=0.24), diastolic BP (p=0.5), respiratory rate (p=0.21), SPO2 (p=0.6), or urine O/P (p=0.1) before and after delivery between the groups. The mean haemoglobin level at predelivery was 9.86 ± 1.78 g/dL in the study group and 9.88 ± 2.93 g/dL in the control group. Post-delivery, the mean haemoglobin level was 9.84 ± 2.77 g/dL in the study group and 9.73 ± 2.91 g/dL in the control group. The change in haemoglobin levels from pre- to post-delivery was 0.02 g/dL in the study group and 0.15 g/dL in the control group, with a significant difference between groups (p = 0.001).

The mean PCV at predelivery was 39.04 ± 7.04% in the study group and 38.72 ± 4.56% in the control group. Post-delivery, it was 38.70 ± 7.01% and 37.62 ± 4.53%, respectively, with a reduction of 0.34% in the study group and 1.10% in the control group, showing a significant difference (p = 0.002) [Table 3].

Table 3: Vitals and blood indices comparison at pre and post-delivery between groups

			Study group	Control group	P value
Vitals	Pulse Rate	Pre-delivery	83.38±2.70	82.86±3.60	0.9
		Post delivery	84.86±2.60	87.24±3.61	
	Systolic BP	Pre-delivery	118.52±6.65	109.68±4.61	0.24
		Post delivery	115.40±6.34	103.92±4.29	
	Diastolic BP	Pre-delivery	75.80±7.87	76.92±8.47	0.5
		Post delivery	75.34±7.78	73.64±8.88	
	Respiratory rate	Pre-delivery	17.93±0.30	17.80±0.31	0.21
		Post delivery	18.14±0.98	18.06±1.07	
	SPO2	Pre-delivery	99.90±12.09	99.90±10.13	0.6
		Post delivery	99.66±11.94	98.79±9.64	
	Urine O/P	Pre-delivery	108.10±2.02	109.70±2.12	0.1
		Post delivery	106.90±1.97	106.50±1.86	
Blood Indices	Hb	Pre-delivery	9.86±1.78	9.88±2.93	0.001
		Post delivery	9.84±2.77	9.73±2.91	
	PCV	Pre-delivery	39.04±7.04	38.72±4.56	0.002
		Post delivery	38.70±7.01	37.62±4.53	

There was no significant difference in maternal complications (p=0.9) such as vomiting, fever, and Apgar scores (p=0.09) between the groups.

Regarding hospital stay, 97% of the study group stayed ≤3 Days compared to 85% of the control group. A higher proportion of the control group (15%) required hospitalisation for >3 days, indicating

ISSN (O): 2687-5365; ISSN (P): 2753-6556

a significantly longer stay (p = 0.02) and better recovery or treatment effectiveness in the study group [Table 4].

Table 4: Comparison of maternal complications, and neonatal outcomes between groups

		N (%)		P value
		Study group	Control group	
Maternal complications	Vomiting	7(7%)	6(6%)	0.9
	Fever	5(5%)	6(6%)	
	Nil	88(88%)	88(88%)	
Apgar scores	≥ 8 / 10	96(96%)	94(94%)	0.09
	< 8 / 10	4(4%)	6(6%)	
Duration of hospital stay	≤ 3 days	97(97%)	85(85%)	0.02
	> 3 days	3(3%)	15(15%)	

DISCUSSION

In our study, between 18 and 35 years old, most individuals were aged 20–24 years, with 48% in the study group and 52% in the control group being the majority age group. These findings align with studies by Yang H. and Shi C., where the average age was around 23.5 years.7 The study by Roy et al., with most participants being between 21 and 24 years old.[10]

In our study, both the study and control groups had a high percentage of upper-middle class members, while the middle class had 24% and 28. Similar distributions were seen in the study by Bibi et al., where socioeconomic class V was represented by 76% and 72% of the study group and control group, with 24% and 28% representing class IV.[11]

In our study, multigravida women outnumbered primigravida women (80% vs. 20% in the study group; 70% vs. 30% in the control group). This aligns with the study by Gungorduk et al., where 72% of the participants were multigravida.[12] Similarly, Roy et al. found parity indices to be comparable between groups.[10]

In our study, a higher proportion of women in both groups received booked antenatal care (80% vs. 84%). These findings are consistent with those of Peitsidis and Kadir, who reported similar rates (86% and 88%).8 Early risk identification in the antenatal period remains crucial for reducing the incidence of PPH.

In our study, the mean pulse rate of the control group was 5.38/min, while that of the study group was 1.48/min. The mean SBP decrease was 1.12 mmHg in the study group compared to 3.76 mmHg in the control group, while DBP fell by 0.46 mmHg vs. 3.28 mmHg. These results align with those of Novikova et al., who reported significant reductions in PR and BP in a control group.[13]

In our study, the Hb and PCV levels were significantly lower in the study group. The study group experienced a decrease in mean Hb of 0.02 gm% while the control group experienced a decrease of 0.15 gm%, while hematocrit dropped 0.34% vs. 1.10%. Similar findings were observed in the study by Arab et al., showing postpartum blood loss was significantly higher in the control group.[14]

Ali et al. reported that the study group showed a significant increase in postoperative haemoglobin concentration compared to the control group ($p<0.001$), while the control group experienced a significant reduction in haemoglobin levels compared to the study group ($p<0.001$). The preoperative hematocrit was not significantly different between the study and control groups ($p=0.967$), In the study group, the level of postoperative hematocrit was higher than in the control group (p0.015), and the Reduction in hematocrit levels was less in the study group than the control group ($p<0.001$).[15] Additional uterotonics were required in 3% of the study group vs. 24% of the control group, similar to the findings from Shekhavat et al., where TXA reduced the need for uterotonics.[16]

The third-stage labor duration showed no significant difference (4.6 minutes in the study group vs. 4.48 minutes in the control group). The mean blood loss at 2 h was 106 mL in the study group vs. 246 mL in the control group, indicating a significant reduction with TXA use. Studies conducted by Ducloy-Bouthors et al. found that the average total blood loss in the study group was 120 ml compared to 232.45 ml for the control group.[17] The meta-analysis by Wang et al. showed that The TXA group experienced a lower percentage of blood loss during and after CS, with a mean difference of -141.61 ml compared to the control group ($p<0.01$). There was a significant reduction in intraoperative and postpartum blood loss in the TXA group as compared with the control group (MD -143.36 ml, $p<0.01$; and MD -38.20 ml, $p<0.01$).[18]

In our study, there were no significant differences in maternal complications between groups. Vomiting occurred in 7% vs. 6% and fever in 5% vs. 6% of patients in the study and control groups. Thromboembolic events were not observed. Apgar scores remained similar between groups, with 96% vs. 94% scoring ≥8 at 10 min, confirming TXA's safety during delivery, which aligns with the studies by Al-dardery et al. and Abu-Zaid et al., concludes that TXA significantly decreases mean blood loss and the incidence of PPH compared to placebo and TXA use led to increased rates of nausea and vomiting, these side effects were generally well-tolerated with

ISSN (O): 2687-5365; ISSN (P): 2753-6556

no risk of thromboembolic events was observed with TXA use.[19,20]

CONCLUSION

This study concludes that the prophylactic administration of tranexamic acid via the intravenous route effectively reduces blood loss following vaginal delivery without causing significant complications. Its use has been shown to significantly reduce blood loss during and after normal vaginal delivery (NVD). The administration of tranexamic acid was not associated with adverse drug reactions such as diarrhoea or thrombosis. Foetal outcomes, as assessed by the Apgar scores, were not adversely affected, although a significant increase in nausea and vomiting was observed. Overall, tranexamic acid can be safely used in individuals undergoing NVD.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556