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Dr. Bharadwaj Chandra G
MBBS, Department of Obstetrics
& Gynecology, SVS Medical
College, Mahbubnagar, Telangana,
India

Dr. Bhanurekha S
MBBS, MD, Department of
Obstetrics & Gynecology, SVS
Medical College, Mahbubnagar,
Telangana, India

Dr. Jagatha Satya
MBBS, MS, Department of
Obstetrics & Gynecology, SVS
Medical College, Mahbubnagar,
Telangana, India

Corresponding Author:
Dr. Bharadwaj Chandra G
MBBS, Department of Obstetrics
& Gynecology, SVS Medical
College, Mahbubnagar, Telangana,
India

Efficacy of tranexamic acid in managing postpartum hemorrhage in normal vaginal delivery in a tertiary care hospital

Bharadwaj Chandra G, Bhanurekha S and Jagatha Satya

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Abstract

Background: Postpartum haemorrhage (PPH) is a significant cause of maternal mortality worldwide. Recent studies have shown that the use of tranexamic acid (TXA) in conjunction with Oxytocin has the potential to lead to a substantial reduction in maternal deaths, offering a hopeful prospect for maternal health. However, the frequency of TXA use in India is not well-documented. This study aims to determine whether the prophylactic use of TXA, in addition to Oxytocin, can effectively reduce blood loss during vaginal delivery and improve postpartum care, offering a hopeful prospect for maternal health.

Objective: This research will evaluate the impact of TXA combined with Oxytocin compared to Oxytocin alone, focusing on how varying hemodynamic conditions influence management during the third and fourth stages of vaginal birth. It will examine various parameters, including blood loss, haemoglobin levels, and platelet counts. The goal is to assess whether using TXA reduces the occurrence and severity of postpartum haemorrhage, thereby enhancing maternal health outcomes.

Methodology: This prospective study, uniquely designed to evaluate the impact of TXA combined with Oxytocin compared to Oxytocin alone, was conducted at SVS Medical College and Hospital, a leading institution in maternal health research. The study included a cohort of eighty women planned for vaginal delivery, randomly assigned to two groups: the treatment group received both Oxytocin and TXA. In contrast, the control group received prophylactic Oxytocin following the Active Management of the Third Stage of Labor (AMTSL) guidelines. The study's inclusion and exclusion criteria were meticulously defined, and vital signs, blood indices, haemoglobin levels, platelet counts, and blood loss were meticulously documented and analysed. Statistical analysis was performed using paired T-tests, with significance established at $p < 0.05$.

Results: The results indicate a significant difference in average blood loss between the TXA group (153 ml) and the control group (171 ml), providing convincing evidence of the efficacy of TXA. The TXA group experienced a slightly smaller average decrease in haemoglobin levels (6.25%) compared to the control group (6.64%), both of which were statistically significant ($p < 0.0001$). Haemoglobin and platelet counts increased in both groups, with substantial differences observed in pre- and post-delivery measurements ($p < 0.001$). Adding TXA was associated with reduced blood loss and a less significant drop in haemoglobin levels, indicating a more substantial preventive effect.

Conclusion: The addition of TXA to the prophylactic regimen of Oxytocin during vaginal birth significantly reduces blood loss and stabilises haemoglobin levels. This study suggests that TXA is an effective adjunct for preventing PPH, greatly enhancing maternal safety by reducing the risk of severe postpartum haemorrhage. The study's findings provide compelling evidence for the routine use of TXA alongside Oxytocin in actively managing the third stage of labour, particularly in settings where PPH is prevalent. These findings have significant implications for maternal health practices, offering a sense of reassurance and confidence in the potential of TXA to improve maternal outcomes.

Keywords: Postpartum haemorrhage, tranexamic acid, oxytocin, vaginal delivery, maternal mortality, blood loss management, prophylactic treatment

Introduction

Stages of Labor: There are four stages of labour. The first and second stages involve the onset of actual labour pains and the expulsion of the fetus. The third stage is the separation and expulsion of the placenta, during which approximately 500 ml of blood loss is expected in a healthy woman undergoing vaginal delivery. The fourth stage includes a one-hour observation period post-delivery.

Risks of Vaginal Delivery: Risks associated with vaginal delivery include haemorrhage, which can be atonic or traumatic.

Postpartum Hemorrhage: Primary postpartum haemorrhage (PPH) is defined as cumulative blood loss of ≥ 500 ml following a vaginal delivery or ≥ 1000 ml following cesarean delivery, or any amount of blood loss within 24 hours after birth, as evidenced by a rise in pulse rate and falling blood pressure. Hemorrhage is the leading cause of maternal mortality, accounting for approximately 19.7% of all pregnancy-related deaths worldwide. The rates of maternal death due to PPH are exceptionally high in low- and middle-income countries. Approximately 14 million women worldwide experience PPH each year, resulting in about 70,000 maternal deaths globally. Incidence rates of PPH are reported to be 2% to 4% after vaginal deliveries and 6% after cesarean sections, with uterine atony being the cause in about 50% of cases in India.

Management of PPH: To prevent postpartum haemorrhage, uterotonics such as Oxytocin, methylergometrine, and carbetocin are administered. In addition, antifibrinolytic drugs like tranexamic acid (TXA) and platelet aggregators like ethamsylate can be given alongside routine uterotonics. TXA, an antifibrinolytic drug, works by preventing the breakdown of fibrin, the main protein in a blood clot. This action helps with blood clotting, thereby reducing blood loss.

Objectives

1. To measure the amount of blood loss in correlation with HB, platelets, and blood indices after using Oxytocin to prevent postpartum haemorrhage.
2. To measure the amount of blood loss correlated with HB, platelets, and blood indices after injecting Oxytocin and tranexamic acid.
3. Whether the prophylactic administration of TXA in addition to prophylactic Oxytocin in women with vaginal delivery would decrease the incidence of postpartum haemorrhage.
4. To obtain the demographic data and perform an analysis of it.

Methodology

This study was carried out in SVS Medical College and Hospital, a tertiary care hospital known for its expertise in maternal health, with Patients of the OBG ward who came for vaginal delivery.

Study design

- **Type of study:** A Prospective study
- **Study population:** All women who are coming to SVS hospital and had vaginal delivery.
- **Sample size:** 80

Inclusion criteria

- All Normal delivery patients.
- All primi and multi gravidas.
- Hb > 10gm/dl.
- Singleton pregnancy.
- In patients where the use of Tranexamic acid is not a contraindication.
- Only Oxytocin is used.

Exclusion criteria

- Hb < 10gms/dl

- In patients where the use of tranexamic acid is a contraindication.
- Pregnant women using anticoagulants or anti-platelet medication.
- Pregnant women with bleeding diathesis and abnormal coagulation profile.
- Pregnant women with preexisting renal or hepatic disorders or with comorbidities like preeclampsia, eclampsia, heart diseases, IUGR, anaemia, and GDM.
- Patients with uncontrolled systemic diseases or medical comorbidities.
- Patients are not giving consent.
- Other oxytocics like PGF2 α and methyl ergometrine.

Procedure

The sample size is divided into two groups.

- **Control group:** Injection of Oxytocin
- **Treatment group:** Injection of Oxytocin and tranexamic acid.

Injection of Oxytocin: Just after the birth of the neonate. It is recommended to administer ten units of Oxytocin IM or through slow IV (Active management of third-stage labour)

Injection of tranexamic acid: The treatment begins as soon as possible after the fetus's birth in the third stage. It is recommended to be administered as a consistent dosage of 1 gram in a 10 millilitre (100 mg/mL) IV injection, delivered over 10 minutes. A second dose of 1 gram may be given if bleeding persists after 30 minutes or if bleeding recurs within 24 hours after completing the initial dose. The injection is done slowly to prevent any potential drop in blood pressure. It can be mixed with most infusion solutions, such as electrolytes, carbohydrates, amino acids, and dextran. It can be given through the same IV cannulas used for hydration or uterotonic administration. TXA should not be given to women with specific contraindications, such as an earlier thromboembolic event during pregnancy, a history of coagulopathy, active intravascular clotting, or an established hypersensitivity to TXA.

Confidentiality

Patient details were kept confidential.

Statistical tools

Data entry of all variables was done, and it was statistically analysed. Statistical test – T-test was applied to test before and after mean scores. The test significance was tested at $p < 0.05$ (95% CI). The statistical software SPSS version 23 was used for statistical and data analysis.

Ethical considerations

The institution's ethical committee accepted the study protocol before enrolling patients. Informed consent was obtained from the patient for the study.

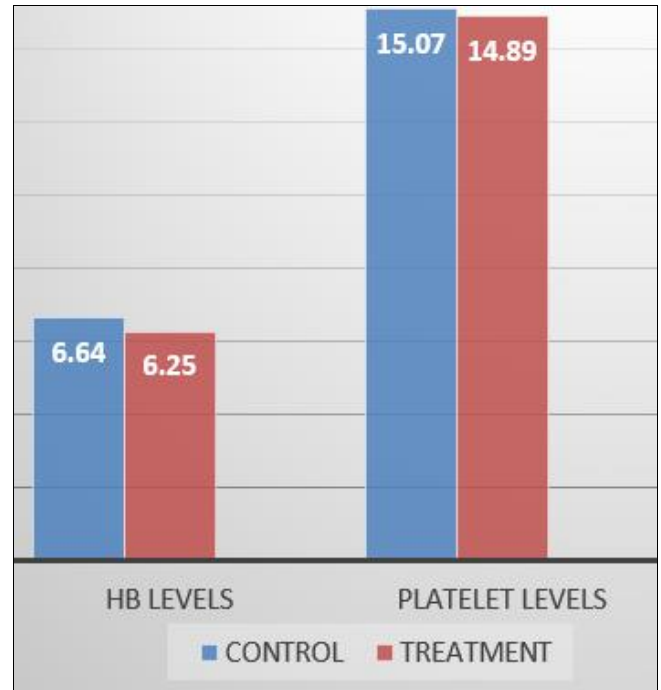
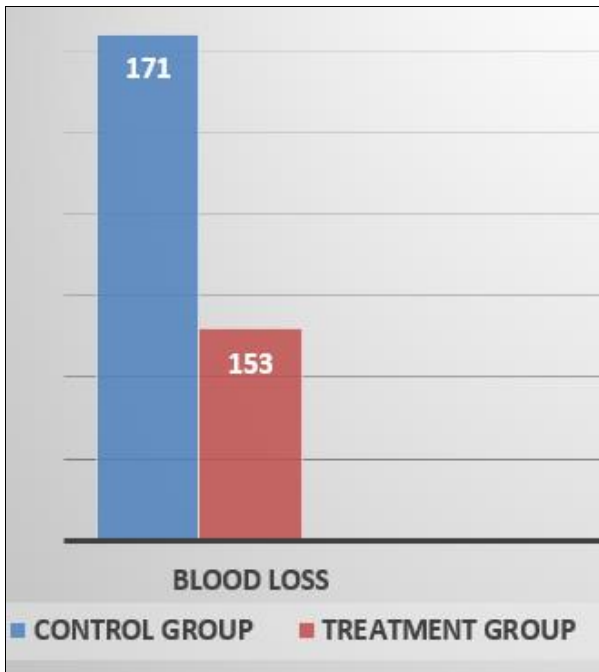
Results and Observation

Blood Loss: All the patients in this study are having blood loss during expected vaginal delivery in the range of 100 ml to 500 ml. The average blood loss in the control group is 171 ml, while in the treatment group, it is 153 ml; both groups have a significant difference.

Haemoglobin Levels: All the patients in this study have an

average decrease in haemoglobin levels ranging from 6.64% to 6.25%. The average fall in haemoglobin in the control group is 6.64%, while in the treatment group, it is 6.25%. For the control group: Pre-hemoglobin and post-hemoglobin with T-test $T=9.92$; $P<0.0001$ (highly significant). For the treatment group: Pre-hemoglobin and post-hemoglobin with T-test $T=6.21$; $P<0.0001$ (highly important).

Platelet Levels: All the patients in this study had an average increase in platelet count ranging from 15.07% to 14.89%. The average increase in platelet count in the control group is 15.07%, while in the treatment group is 14.89%. For the control group: Pre-platelets and post-platelets with T-test $T=7.97$; $P<0.0001$ (highly significant). For the treatment group: Pre-platelets and post-platelets with T-test $T=3.70$; $P<0.001$ (significant).



T-Test of control group

Table 1: Paired sample statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair-1	Pre-Hb	11.66	40	1.007	0.159
	Post-Hb	10.89	40	0.989	0.156
Pair-2	Pre-platelets	1.96	40	0.499	0.079
	Post-platelets	2.23	40	0.526	0.083

Table 2: Paired sample correlations

		N	Correlation	Sig.
Pair-1	Pre-Hb & Post-Hb	40	0.879	0.0001
Pair-2	Pre-platelets & Post-platelets	40	0.914	0.0001

Table 3: Paired samples test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error means	95% Confidence Interval of the Difference				
					lower	upper			
Pair-1	Pre & post- Hb	0.770	0.490	0.078	0.613	0.927	9.928	39	0.000
Pair-2	Pre & post-platelets	-0.270	0.214	0.034	-0.338	-0.201	-7.975	39	0.000

T-Test of treatment group

Table 4: Paired sample statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair-1	Pre-Hb	12.32	40	0.69695	0.11020
	Post-Hb	11.55	40	1.02457	0.16200
Pair-2	Pre-platelets	2.0163	40	0.44818	0.07086
	Post-platelets	2.2877	40	0.56119	0.08873

Table 5: Paired sample correlations

		N	Correlation	Sig.
Pair-1	Pre-Hb & Post-Hb	40	0.645	0.000
Pair-2	Pre-platelets & Post-platelets	40	0.599	0.000

Table 6: Paired sample test

		Paired Differences				t	df	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error mean	95% Confidence Interval of the Difference				
					lower				upper
Pair-1	Pre & post-Hb	0.77000	0.78388	0.12394	0.51930	1.02070	6.213	39	0.000
Pair-2	Pre & post-platelets	-0.27150	0.46290	0.07319	-0.41954	-0.12346	-3.709	39	0.001

Summary

Postpartum haemorrhage (PPH) constitutes a formidable challenge in maternal health, with significant implications for global maternal mortality, particularly in low- and middle-income regions where it accounts for 20% of pregnancy-related deaths. This study investigates the effectiveness of adjunctive tranexamic acid (TXA) administration combined with Oxytocin, aimed at mitigating blood loss during vaginal delivery and thereby enhancing the management of PPH. Conducted at SVS Medical College and Hospital, this prospective study enrolled 80 women undergoing vaginal deliveries. Participants were randomly assigned to receive either prophylactic Oxytocin alone (control group) or a combination of Oxytocin and TXA (treatment group). The inclusion criteria required participants to have haemoglobin levels ≥ 10 g/dL and no contraindications to TXA, while exclusions included severe anaemia and TXA. Results indicated that the addition of TXA to Oxytocin significantly reduced average blood loss (153 ml in the treatment group versus 171 ml in the control group), with a notable decrease in the decline of haemoglobin levels in the TXA group (6.25% compared to 6.64% in the control group). Both groups increased platelet counts, with statistically significant differences observed in pre- and post-delivery measurements. The findings underscore TXA's role in enhancing the efficacy of Oxytocin in reducing postpartum blood loss and stabilising haemoglobin levels. By integrating TXA into standard prophylactic practices, the study provides robust evidence supporting its use in actively managing the third stage of labour, potentially leading to improved maternal outcomes. These results advocate for the broader adoption of TXA in labour management protocols, contributing to global efforts to mitigate PPH and enhance maternal safety. Further research is needed to consolidate these findings and assess their applicability across diverse healthcare settings.

Conclusion

This study demonstrates that adjunctive administration of tranexamic acid (TXA) alongside Oxytocin significantly mitigates blood loss during vaginal delivery, thereby enhancing the efficacy of PPH management. The reduction in average blood loss and stabilisation of haemoglobin levels in the TXA group underscores its valuable role in actively managing the third stage of labour. These results substantiate the integration of TXA into standard prophylactic regimens, presenting a promising advancement in maternal healthcare protocols. Further research is warranted to validate these findings across varied clinical settings, thereby optimising strategies to improve maternal outcomes and combat postpartum haemorrhage effectively.

Conflict of Interest: Not available.

Financial Support: Not available.

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