Original Article

Effectiveness of Prophylactic Intravenous Tranexamic Acid in Preventing Postpartum Hemorrhage After Vaginal Delivery: A Quasi-Experimental Study

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Abstract

Objective: To evaluate the effectiveness of prophylactic TXA in reducing PPH among women undergoing vaginal delivery
Methodology: This prospective non-randomized clinical trial included 192 women undergoing vaginal delivery from Sir Ganga Ram Hospital, Lahore, from March 2023 to February 2024. Inclusion criteria were age 18-40 years, gestational amenorrhea >37weeks, parity ≤3, polyhydramnios, induced labour, and previous history of PPH Women in TXA group (n=96) received intravenous TXA 100 mg/mL, and women in SOC group (n=96) received only standard of care (SOC). Gravimetric method was used to estimate blood loss. Independent sample t-test employed to compare blood loss between groups.
Results: Baseline means of age (30.34 ± 8.51 vs. 30.10 ± 7.53 years, p-value 0.822), and BMI (26.01 ± 3.74 vs. 25.80 ± 3.33 Kg/m2, p-value 0.757) were comparable between the two study groups. The proportions of age categories (p-value 0.826), BMI classes (p-value 0.626) and parity (p-value 0.688) were also similar in both groups PPH immediately after delivery of placenta (323.59 ± 49.91 vs. 424.88 ± 41.28 ml; p-value <0.001), and up to 6-hours (70.14±6.54 ml vs. 104.68±8.53 ml; p-value <0.001) in TXA group was significantly lesser than SOC group. Requirement of blood transfusion (3.1% vs. 10.4%; p-value 0.04) in TXA group was significantly lower than SOC group. However, allergic reactions (8.3% vs. 0.0%; p-value 0.007) were only observed in TXA group. Other side effects including nausea/ vomiting (7.3% vs. 2.1%; p-value 0.169), and diarrhoea (6.3% vs. 1.0%; p-value 0.118) were also higher in TXA group, but the difference remained statistically insignificant.
Conclusion: Prophylactic intravenous administration of tranexamic acid significantly reduced postpartum blood loss both immediately after placental delivery and within the first six hours following vaginal delivery.
Keywords: Tranexamic Acid, Postpartum Hemorrhage, Pregnancy, Blood Loss, Placenta.

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Introduction

Postpartum hemorrhage (PPH) remains a major maternal health concern worldwide, including in Pakistan, where it accounts for 89% of deaths due to obstetric hemorrhage.[1] The World Health Organization (WHO) defines PPH as blood loss ≥ 500 mL within 24 hours after childbirth.[2] Uterine atony accounts for nearly 70% of postpartum hemorrhage cases.[3] Antenatal factors include advanced maternal age, multiparity and anaemia. Intrapartum factors include induced labour, obstructed labour, and surgical delivery.[4] PPH can also occur in women with low-risk pregnancies and no identifiable risk factors. Therefore, preventive measures should be implemented for all women, regardless of their risk profile.[5]

Tranexamic acid (TXA), a synthetic compound derived from the amino acid lysine, functions by impeding the

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process of fibrinolysis through the obstruction of the lysine binding sites present on plasminogen. TXA is employed as a therapeutic intervention to mitigate blood loss and reduce the need for blood transfusions in the treatment of various gynaecological ailments.[6] Several studies have evaluated the efficacy and safety of TXA in reducing the risk of PPH in both vaginal and cesarean deliveries. A study comparing TXA with a placebo reported that women who received TXA experienced less blood loss than those in the placebo group, suggesting a beneficial role for TXA in preventing PPH in vaginal deliveries.[7] Another study similarly demonstrated reduced estimated blood loss among women treated with TXA compared to a placebo in vaginal deliveries.[8] In Pakistan, only a few studies have recently evaluated the efficacy of TXA, but these mostly focused on cesarean deliveries,[9,10] or compared high versus low doses of TXA.[10]

Although these studies show the effectiveness of intravenous TXA in preventing PPH,[7-10] there is considerable variability across the literature Differences are noted in terms of study populations such as vaginal deliveries[7,8] or cesarean deliveries,[9,10] TXA dosage at 15 mg/kg versus 10 mg/kg,[10] and PPH assessment times which ranged between 30 minutes and 24 hours.[7-10]

These differences make direct comparisons between studies difficult. There is a notable gap in research involving our local population, where prophylactic TXA is still not routinely used during vaginal deliveries in standard clinical practice. Most local studies have assessed TXA in cesarean sections, but its role in vaginal delivery remains less explored locally. Therefore, the present study evaluated the effectiveness of a 100 mg/mL intravenous TXA dose in reducing blood loss among women undergoing vaginal delivery to provide local evidence for its use.

Methodology

This prospective non-randomized clinical trial was conducted in the Obstetrics and Gynecology unit at Sir Ganga Ram Hospital, Lahore, from 6th March 2023 to 28th February 2024. The study received ethical approval (No.09-Synopsis/FJ/ERC dated 3rd March 2023) from the Ethics Review Committee (ERC) of Fatima Jinnah Medical University, Lahore. All volunteer participants provided informed consent.

All women undergoing vaginal delivery were enrolled from emergency department of Obstetrics and Gynecology by using non-probability consecutive sampling method. Other inclusion criteria were age 18-40 years, gestational amenorrhea >37weeks, parity ≤3, polyhydramnios, induced labour, and previous history of PPH. Exclusion criteria were uterine atony, trauma, tissue retention, coagulopathy, surgical history or history of hypersensitivity reaction to TXA. The sample size was estimated using mean blood loss in TXA group (250.10 ± 133.54) and placebo group (334.2 ± 141.78),[7] with 99% CI, 90% power of test, and 20% drop out rate.

A total of 192 women were non-randomly allocated into two study groups: the TXA group and the SOC group. Women in the TXA group (n = 96) received intravenous dose of tranexamic acid 100 mg/mL (1 g in 10 mL) at the time of skin incision, administered at a rate of 1 mL per minute over 10 minutes, in accordance with the WHO guidelines for PPH.[11] In contrast, women in the SOC group (n = 96) received only the standard of care (SOC). All women were delivered after active management of third stage of labour in both groups.

Demographic details including age (years), gestational age (weeks), parity and body mass index (BMI) were noted on a research proforma. Blood loss was estimated twice: first, immediately after the delivery of the placenta, and second, up to six hours postpartum. Initially, blood collected in an emesis basin was transferred into a calibrated measuring jar to determine the exact volume. In addition, the weights of dry and wet pads were measured using an electronic weighing scale. Then, all women were monitored up to six hours after delivery.

During this follow up period, the weight of all absorbents including pads, epi balls, and sheets were measured. The gravimetric method was used to estimate blood loss, where the difference in weight between dry and wet materials was converted to milliliters (1 gram = 1 ml).[11] Moreover, number of blood transfusions required and any adverse events including allergic reactions, nausea, vomiting, and diarrhea were recorded.

Data were analyzed using Statistical Package for Social Sciences (SPSS) version 25.0. Continuous variables including age, gestational age, BMI, and blood loss reported using mean and standard deviation. Categorical variables including age groups, BMI categories, parity, blood transfusion requirements and adverse events reported using frequency (percentage). Blood loss, both immediate and up to six hours postpartum, was compared between the groups using independent sample t-test. The value of $P \leq 0.05$ was taken statistically significant.

Results

Table I shows that baseline characteristics including age, gestational age, parity and BMI were comparable between the two study groups.

PPH immediately after placental delivery (323.59 ± 49.91 vs. 424.88 ± 41.28 ml; p-value <0.001), and up to 6-hours (70.14±6.54 ml vs. 104.68±8.53 ml; p-value <0.001) was significantly less in TXA group than SOC group. Requirement of blood transfusion (3.1% vs. 10.4%; p-value 0.04) was also significantly less in TXA group than SOC group. However, allergic reactions (8.3% vs. 0.0%; p-value 0.007) were only observed in TXA group compared to SOC group. Other side effects including nausea, vomiting and diarrhoea were also higher in TXA group, but the difference remained statistically insignificant. (Table II)

Postpartum blood loss immediate and up to 6-hours were stratified for age and BMI. TXA group showed significantly less blood loss for all age and BMI sub-groups compared to SOC group (all p-values <0.001). (Table III)

Discussion

PPH may lead to anaemia, need for blood transfusion and potentially life-threatening complications.[12] Recent studies suggest that prophylactic TXA can improve maternal outcomes and lower healthcare costs by effectively decreasing blood loss among women at higher risk of PPH after vaginal delivery.[13,14] The results

Table I: Baseline characteristics of study groups.

		TXA (n=96)	SOC (n=96)	p-value
Age (years)		29.47±6.17	29.02±6.79	0.633
	18-30 years	57 (59.4%)	53 (55.2%)	0.559
	31-40 years	39 (40.6%)	43 (44.8%)	
Gestational age (weeks)		37.99±0.86	38.07±0.94	0.524
Parity	Primiparous	12 (12.5%)	13 (13.5%)	0.830
	Multiparous	84 (84.5%)	83 (86.5%)	
BMI (kg/m^2)		26.44±3.27	26.26±3.35	0.710
	Normal weight	27 (28.1%)	29 (30.2%)	0.902
	Overweight	61 (63.5%)	58 (60.4%)	
	Obese	08 (8.3%)	09 (9.4%)	

TXA: Tranexamic acid, SOC: Standard of care, BMI: Body mass index

Table II: Effectiveness and safety profile of tranexamic acid versus standard of care group.

		TXA (n=96)	SOC (n=96)	p-value
PPH	Immediately	323.59 ± 49.91	424.88 ± 41.28	<0.001
	Up to 6 hours	70.14 ± 6.54	104.68 ± 8.53	<0.001
Blood transfusion	Yes	03 (3.1%)	10 (10.4%)	0.040
	No	93 (96.9%)	86 (89.6%)	
Allergic reactions	Yes	08 (8.3%)	0 (0.0%)	0.007
	No	88 (91.7%)	96 (100.0%)	
Nausea/ vomiting	Yes	07 (7.3%)	02 (2.1%)	0.169
	No	89 (92.7%)	94 (97.9%)	
Diarrhea	Yes	6 (6.3%)	01 (1.0%)	0.118
	No	9 (93.8%)	95 (99.0%)	

TXA: Tranexamic acid, SOC: Standard of care, PPH: Postpartum hemorrhage

Table III: Postpartum hemorrhage in tranexamic acid versus standard of care group after stratification.

		TXA (n=96)	SOC (n=96)	p-value
Immediately after placental delivery				
Age (years)	18-30	321.46 ± 53.57	425.02 ± 13.45	<0.001
	31-40	326.72 ± 44.51	424.70 ± 15.40	<0.001
BMI (kg/m^2)	Normal weight	317.67 ± 52.28	426.90 ± 14.54	<0.001
	Overweight	326.16 ± 49.39	423.33 ± 14.45	<0.001
	Obese	324.00 ± 50.69	428.33 ± 12.22	<0.001
Up to 6-hours				
Age (years)	18-30	69.74 ± 7.00	104.13 ± 7.88	<0.001
	31-40	70.72 ± 5.83	105.35 ± 9.31	<0.001
BMI (kg/m^2)	Normal weight	68.11 ± 6.86	103.66 ± 8.39	<0.001
	Overweight	70.98 ± 6.42	104.60 ± 8.59	<0.001
	Obese	70.50 ± 5.55	108.44 ± 8.44	<0.001

TXA: Tranexamic acid, SOC: Standard of care, BMI: Body mass index

showed that intravenous administration of TXA significantly reduced the hemorrhage, both immediate after placental expulsion and within the first six hours postpartum. These findings are in agreement with previous studies,[15-17] which have similarly demonstrated the effectiveness of TXA in reducing PPH. This consistent evidence across different clinical settings and populations supports the potential of TXA as a valued intervention for the management of PPH and its associated complications.

When compared to placebo, Igboke and co-workers observed significantly lower blood loss in Nigerian women receiving TXA (174.87 ± 119.83 vs. 341.07 ± 67.97 mL; p < 0.001).[8] Similar results were reported by Hinchigeri and colleagues in Indian women (250.10 ± 133.54 vs. 334.2 ± 141.78 mL; p < 0.001),[7] and by Hasan et al. in Iraqi women (284.4 ± 105 vs. 354.5 ± 97.9 mL; p < 0.001).[18] Even in RCT studies where TXA was compared to no intervention, the outcomes remained constant. Farhadifar et al. found significantly reduced blood loss in Iranian women (300 ± 97 vs. 573 ± 166 mL; p 0.001),[19] and Nambiar et al. reported similar outcomes in Indian women (245 ± 42.19 vs. 327 ± 44.96 mL; p < 0.001).[20] The present study also supports this trend, showing a significant reduction in blood loss in the TXA group compared to the SOC group (323.59 ± 49.91 vs. 424.88 ± 41.28 mL; p < 0.001). However, the volume of blood loss observed in this study was notably higher than in studies comparing TXA to placebo, and more comparable to those comparing TXA to no intervention. This consistent direction of effect across all studies reinforces the efficacy of TXA in minimizing postpartum blood loss.

Unlike previous studies that focused on blood loss after vaginal delivery, two Pakistani studies evaluated TXA use during cesarean section and reported similar reduction in blood loss. In first study, Kafayat et al. observed significant decrease in blood loss after administration of TXA (711.78 ± 20.89 vs. 866.92 ± 39.23 mL; p < 0.001).[9] In second study, Malik et al. compared two different doses of TXA in anemic women and noted less blood loss with the higher dose (15 mg/kg). Although difference was not statistically significant (491.36 ± 74.57 vs. 521.89 ± 56.48 mL; p 0.079), but it supports the effectiveness of TXA use across modes of delivery.[10] In addition, blood transfusion requirement was significantly less in the TXA group compared to the SOC group (3.1% vs. 10.4%; p 0.040), which indicates a beneficial effect of TXA in reducing transfusion requirements in the present study. In contrast, Sentilhes et al. found no difference between groups with similar need for blood transfusion (0.9% vs. 0.9%; p 0.88).[12]

Regarding safety profile, the present study demonstrated a higher incidence of minor adverse effects in the TXA group that included allergic reactions (8.3% vs. 0.0%; p 0.007), nausea and vomiting (7.3% vs. 2.1%; p 0.169), and diarrhea (6.3% vs. 1.0%; p 0.118). Similarly, Farhadifar et al. reported a significantly higher rate of allergic reactions in the TXA group (50.0% vs. 0.0%; p < 0.05),[19] whereas Sentilhes et al. noted higher incidence of nausea and vomiting.[12] Despite these mild side effects, the overall safety profile of TXA remained favorable and support TXA use in preventing PPH in women undergoing vaginal delivery.

The present study had certain limitations. Its design may introduce selection bias, which can limit the strength of causal implications. Because of a single-center setting, these results may not be generalizable to a larger population. The short-term follow-up period restricted the ability to evaluate long-term maternal outcomes and adverse events.

Conclusion

Prophylactic intravenous administration of TXA significantly reduced blood loss both immediately after placental delivery and within the first six hours following vaginal delivery. These results support the potential role of TXA in minimizing PPH and its complications among women at higher risk of blood loss. However, TXA use should be balanced against higher incidence of minor adverse effects.

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