ORIGINAL ARTICLE

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Effect of tranexamic acid use on hemoglobin levels in postpartum women immediately after vaginal delivery, randomized clinical trial

Efecto del uso del ácido tranexámico en los valores de hemoglobina en puérperas inmediatas en el posparto vaginal, ensayo clínico aleatorizado

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ABSTRACT

Objective: To compare prepartum and postpartum hemoglobin values in anemic pregnant women who were administered tranexamic acid with those who did not receive this medication. Methods: This is a controlled clinical trial conducted at the Honorio Delgado Hospital in Arequipa, at 2335 meters above sea level. Two groups of 30 pregnant women were randomly selected. The experimental group received tranexamic acid at a dose of 1 g diluted in 10 cc immediately after cord clamping, and the control group did not receive tranexamic acid. Hemoglobin levels were determined in both groups before delivery and 4 to 6 hours after delivery. The chi-square test, Student's t-test, or Mann-Whitney test was used depending on the normality of the numerical data. Results: The pregnant women were similar in age and parity ($p > 0.05$). Hemoglobin values were similar before delivery, with an average value of 9.90 ± 0.99 g/dL in the experimental group and 9.97 ± 0.88 g/dL in the control group ($p > 0.05$). After delivery, a significantly lower value was found in the control group (8.42 ± 1.26 g/dL) than in the experimental group (9.06 ± 1.22 g/dL; $p < 0.05$). In the group receiving tranexamic acid, there was a decrease of 0.84 ± 0.64 g/dL in hemoglobin, while in the control group the decrease was significantly greater (1.55 ± 0.96 g/dL; $p < 0.05$). Conclusion: In the group of anemic pregnant women who received tranexamic acid, a smaller decrease in postpartum hemoglobin values was observed.

Keywords: tranexamic acid, pregnant women, anemia, hemoglobin, prepartum, postpartum hemoglobin.

RESUMEN

Objetivo: Comparar los valores de hemoglobina preparto y posparto en gestantes anémicas a las cuales se administró ácido tranexámico con las que no recibieron esta medicación. Métodos: Es un ensayo clínico controlado en Hospital Honorio Delgado de Arequipa, a 2335 msnm. Se seleccionó al azar dos grupos de 30 gestantes, el grupo experimental recibió ácido tranexámico a dosis de 1 g diluido en 10cc inmediatamente después del pinzamiento del cordón y el grupo control sin ácido tranexámico. En ambos se determinó el nivel de hemoglobina antes del parto y 4 a 6 horas después del parto. Se utilizó la prueba chi cuadrado, t de Student o prueba de Mann Whitney según la normalidad de los datos numéricos. Resultados: Las gestantes fueron semejantes en edad y paridad ($p > 0,05$). Los valores de hemoglobina fueron similares antes del parto, con un valor promedio de 9,90 ± 0.99 g/dL en el grupo experimental y 9,97 ± 0,88 g/dL en el grupo control ($p > 0,05$). Luego del parto, se encontró un valor significativamente más bajo en el grupo control (8,42 ± 1,26 g/dL) que en el grupo experimental (9,06 ± 1,22 g/dL; $p < 0.05$). En el grupo con ácido tranexámico se produjo un descenso de 0,84± 0,64 g/dL de hemoglobina, mientras que en el grupo control el descenso fue significativamente mayor (1,55± 0,96 g/dL; $p < 0.05$). Conclusión: En el grupo de gestantes anémicas que recibieron ácido tranexámico se observó que la caída de los valores de hemoglobina posparto fue menor.

Palabras clave: ácido tranexámico, gestantes, anemia, hemoglobina, preparto, hemoglobina posparto.

Introduction

Maternal and perinatal mortality constitutes a key indicator of social inequality, as it reflects disparities in access to education, social support, adequate nutrition, and timely, high-quality medical care among women in vulnerable populations[1]. Hemorrhage-related maternal deaths occur in 23.9% of cases during the antepartum period, 15.5% intrapartum, and 60.6% in the immediate postpartum period. Even in the absence of fatal outcomes, severe maternal complications are frequently observed. In 2015, the prevalence of anemia among pregnant women in Peru was 24.2%, with higher rates reported in rural areas (30.5%) and in the highland regions (30.7%). The city of Arequipa is included among districts with a high prevalence of anemia, exceeding the national average and reaching levels comparable to those reported by the Ministry of Health (MINSA), ranging between 28% and 30%[2–4].

The volume of blood loss and the severity of maternal compromise are largely determined by the woman's pre-existing clinical condition, including nutritional status, baseline hemoglobin concentration, the presence of comorbidities, and the rate at which hemorrhage develops. Iron deficiency anemia in pregnant women with hemoglobin levels below 9 g/dL has been associated with an increased prevalence of postpartum hemorrhage in developing countries[3,4]. In this context, the World Health Organization (WHO, 2024) recommends the use of a continuous hemoglobin adjustment formula based on altitude, rather than categorical altitude ranges. This correction is applied beginning at 1,000 meters above sea level and increases progressively with altitude according to the following equation: corrected hemoglobin = measured hemoglobin − [0.002 × (altitude in meters − 1,000)]. For the city of Arequipa, located at 2,335 meters above sea level, the adjustment corresponds to 0.27 g/dL; therefore, hemoglobin cut-off values should be determined using the corrected hemoglobin value (measured hemoglobin − 0.27 g/dL)[5].

Tranexamic acid (TXA) is an antifibrinolytic agent whose immediate use after delivery can help reduce postpartum bleeding in anemic patients[5, 6]. A systematic review and meta-analysis involving a total of 3,308 women found that tranexamic acid significantly reduced the estimated amount of blood loss after vaginal delivery[7]; and prophylactic administration of tranexamic acid is also effective among women undergoing cesarean section to reduce postpartum blood loss and limit the drop in hemoglobin[8, 9].

The objective of the present study was to assess the effect of tranexamic acid on postpartum blood loss as measured by changes in hemoglobin levels in anemic pregnant women, and to compare prepartum and postpartum hemoglobin values between women who received tranexamic acid and those who did not.

Materials and methods

Study design and location

A randomized, controlled, prospective clinical trial was conducted in the Obstetrics Department of the Honorio Delgado Espinoza Regional Hospital in the city of Arequipa, Peru (altitude: 2,335 m above sea level). Data collection took place between April and November 2022.

Population and sample

The study population consisted of anemic pregnant women who attended the hospital for full-term eutocic delivery (37–42 weeks).

Sixty participants were selected and randomly assigned in a 1:1 ratio to two groups:

- Experimental group (n = 30): received tranexamic acid (TXA).
- Control group (n = 30): did not receive TXA.

The sample size was determined considering an expected difference of 0.6 g/dL in the mean postpartum hemoglobin drop, a 95% confidence level, and 80% statistical power, resulting in 30 pregnant women per group.

Inclusion and exclusion criteria

Inclusion criteria:

- Vaginal delivery of a single full-term baby (37–42 weeks).
- Diagnosis of mild or moderate anemia with altitude-corrected hemoglobin below 11 g/dL, according to WHO 2024 criteria.

- Signed informed consent.

Exclusion criteria:

- Maternal age less than 18 or greater than 35 years.
- Multiparous or grand multiparous women.
- Uterine height > 35 cm.
- History or risk of coagulopathies.
- Known allergy to tranexamic acid or its excipients.
- Maternal obesity (BMI ≥ 30 kg/m²).
- Postpartum hemorrhage before clamping of the umbilical cord.
- Transfusion of blood products prior to postpartum hemoglobin control.

Interventions

In both groups, delivery was induced with oxytocin (10 IU intramuscularly) immediately after fetal expulsion and an intravenous infusion of oxytocin with 20 IU in 1 L of 5% dextrose for 12 hours.

Patients in the experimental group received a single dose of 1 g of tranexamic acid (10 mL, 100 mg/mL) intravenously at a slow rate (1 mL/min) immediately after clamping of the umbilical cord.

No cases of uterine atony or adverse reactions attributable to the drug were recorded.

Variables and measurement

The primary variable was the change in hemoglobin between the prepartum and postpartum values (4 to 6 hours after delivery).

- Prepartum hemoglobin (Hb_1): measured within 12 hours prior to delivery.
- Postpartum hemoglobin (Hb_2): measured between 4 and 6 hours after delivery.

Hemoglobin was determined using the cyanomethemoglobin method in the hospital laboratory, using validated automated analyzers.

Procedures

Random assignment was performed in order of entry into the study, using a predefined list of computer-generated random numbers. Pregnant women with odd numbers were assigned to the experimental group and those with even numbers to the control group.

Tranexamic acid was administered by trained obstetric staff following a standardized protocol.

Statistical analysis

The data were analyzed using SPSS version 24.0. Measures of central tendency and dispersion (mean, standard deviation) were applied for numerical variables, and frequencies and percentages for categorical variables.

Comparisons between independent groups were performed using Student's t-test (or Mann–Whitney U test if the distribution was not normal). Categorical variables were compared using the χ^2 test. Statistical significance was considered at $p < 0.05$.

Results

Table 1 presents the distribution of participants according to age, parity, and educational level. Regarding age, women who received tranexamic acid (TXA) were predominantly represented in the 20–24 and 25–29 year age groups, whereas in the control group the 25–29 year group was the most frequent, followed by the 20–24 year group. No statistically significant differences were observed between the groups ($p > 0.05$). With respect to parity, primiparity was more prevalent in the experimental group, while nulliparity predominated in the control group; however, these differences did not reach statistical significance ($p > 0.05$). Concerning educational level, 76% of participants in the experimental group had completed secondary education, 16% had technical training, and 6% had higher education. In the control group, 70% had completed secondary education, 20% had technical education, and 10% had higher education. No statistically significant differences were identified between the groups for educational attainment ($p > 0.05$).

Table 1: Distribution of women by age, parity, and level of education.

	With TXA (n = 30)		Without TXA (n = 30)		
	No.	%	No.	%	*p*-value
Age					
< 20 y	5	16.67	3	10.00	
20-24 y	10	33.33	11	36.67	0.82*
25-29 y	10	33.33	12	40.00	
30-35 y	5	16.67	4	13.33	
Parity					
Nulliparous	12	40.00	16	53.33	0.30**
Primipara	18	60.00	14	46.67	
Degree of instruction					
Secondary	23	76.67	21	70.00	0.55*
Technical	5	16.67	6	20.00	
Higher	2	6.66	3	10.00	

TXA: Tranexamic Acid
**U of Mann Whitney*
U of Mann Whitney Chi-square*

Table 2 shows that the severity of prepartum anemia was similar between the two groups (p=1.00). However, in the postpartum period, mild anemia was found in 60% of women in the TXA group and moderate to severe anemia in 40%, while in the control group, mild anemia was observed in 30%, moderate anemia in 50%, and severe anemia in 20% of patients (p=0.025).

In Table 3, we can see that in the prepartum period, the mean hemoglobin in the TXA group was 9.90 g/dL and in the control group it was 9.97 g/dL, with no statistical difference (p=0.03) between these groups, which means that these groups are comparable. However, in the postpartum period, hemoglobin in the experimental group was 9.06 g/dL and in the control group it was 8.42 g/dL, this difference being statistically significant (p=0.03).

Table 2: Distribution of women according to severity of anemia.

	With TXA (n = 30)		Without TXA (n = 30)		
	No.	%	No.	%	*p*-value
Prepartum anemia					
Mild	24	80.00	24	80.00	1.00
Moderate	6	20.00	6	20.00	
Postpartum anemia					
Mild	18	60.00	9	30.00	0.025
Moderate	9	30.00	15	50.00	
Severe	3	10.00	6	20.00	

θ2 = 0.00 Chi square
U = 589 Mann-Whitney U

Table 3: Comparison of pre- and post-partum hemoglobin values between the TXA and non-TXA groups

	With TXA (n=30) g/dl	Without TXA (n=30)g/dl	*p*-value
Prenatal			
Arithmetic mean	9.90	9.97	0.98*
Median	10.10	10.05	
D. Standard	0.99	0.88	
Variance	0.97	0.77	
Minimum value	7.60	8.00	
Maximum value	10.90	10.90	
Postpartum			
Arithmetic mean	9.06	8.42	0.03*
Median	9.20	8.55	
D. Standard	1.22	1.26	
Variance	1.49	1.60	
Minimum value	6.00	6.10	
Maximum value	10.90	10.60	

TXA: Tranexamic Acid
** Mann Whitney's U*

Table 4 shows the variation in hemoglobin values before and after delivery in each individual patient, which was analyzed using the paired Student's t-test. We found that the pre-delivery and post-delivery mean values in the TXA group were 9.0 g/dL and 9.06 g/dL, meaning that hemoglobin decreased by 0.84 g/dL, which is a highly significant difference (p=0.001), while in the group without ATX, the average hemoglobin values were 9.97 g/dL before delivery and 8.42 g/dL after delivery, with a decrease of 1.55 g; a statistically significant difference (p=0.001).

Table 4: Paired comparison of hemoglobin values before and after delivery in patients with and without TXA.

	Pre-delivery	Postpartum	*p*-value
With TXA			
Arithmetic mean	9.90	9.06	0.001 *
Median	10.10	9.20	
D. Standard	0.99	1.22	
Variance	0.97	1.49	
minimum value	7.60	6.00	
Maximum value	10.90	10.90	
Without TXA			
Arithmetic mean	9.97	8.42	0.001 *
Median	10.05	8.55	
D. Standard	0.88	1.26	
Variance	0.77	1.60	
minimum value	8.00	6.10	
Maximum value	10.90	10.60	

** paired t*

Discussion and comments

This randomized clinical trial demonstrated that the prophylactic administration of 1 g of tranexamic acid (TXA) immediately following umbilical cord clamping significantly attenuated the decline in hemoglobin levels during the immediate postpartum period. Women who received TXA exhibited a mean hemoglobin reduction of 0.84 g/dL, compared with a reduction of 1.55 g/dL in the control group ($p < 0.05$), in addition to a lower proportion of cases of moderate and severe anemia. These findings support the efficacy of TXA in the prevention of postpartum hemorrhage among anemic pregnant women managed at an altitude of 2,335 meters above sea level, a setting in which hematological physiology is altered by hypobaric conditions[3,4].

Furthermore, studies conducted in Cusco (3,400 m) and Puno (3,820 m) have reported prevalences of gestational anemia ranging from 27% to 35%, despite higher absolute hemoglobin concentrations[10]. This observation is consistent with the findings of Gonzales[4], who identified an increased risk of intrauterine growth restriction and maternal morbidity among pregnant women residing at high altitude. Collectively, these results underscore the importance of adjusting diagnostic and therapeutic parameters to account for altitude-related physiological adaptations[10].

The results of this study are consistent with those of the WOMAN Trial[6], which demonstrated a significant reduction in mortality from bleeding (1.5% vs. 1.9%; $p = 0.045$) with early administration of TXA, without an increase in thromboembolism. Similarly, Sentilhes et al.[11] observed in a multicenter trial involving more than 3,800 women who had vaginal deliveries a mean decrease in hemoglobin of 0.77 g/dL with TXA versus 0.79 g/dL with placebo, confirming its efficacy in limiting blood loss. In our study, conducted in a high-altitude population with pre-existing anemia, the effect was comparable, although with lower initial hemoglobin values (9.9 g/dL), reflecting the particular hematological characteristics of pregnant women living above 2,000 m above sea level.

The age distribution was similar to that described in the international WOMAN trial[6], where the highest frequency of pregnant women was in the 26-33 age group (46%) and in the 16-25 age group (34%), as these age groups account for the highest proportion of births. Nualart[12] included patients over 16 years of age and reported that the administration of tranexamic acid within the first three hours reduced maternal deaths from hemorrhage by one-third.

Patients were distributed according to parity in order to homogenize the participants and make the study groups comparable. The proportion of nulliparous women in the TXA group was 40% and in the control group was 53%, This proportion is similar to that found in the study by Sentilhes[9], which included 52% of primiparous women in the TXA group and 53% in the control group. This was done to avoid possible bias due to multiparity, which could increase the risk of postpartum hemorrhage. When assessing the severity of anemia (Table 2), it was determined that this was identical for both groups (p=1.00), which supports the homogeneity of the study groups, making them comparable. In the literature reviewed, no studies were found that took into account the assessment of the degrees of anemia in pregnant women. Most studies evaluated blood loss expressed in terms of bleeding volume, clinical assessment of blood volume, physical changes in the patient, state of consciousness, etc.

With regard to the classification of postpartum anemia after the intervention (Table 2), in addition to mild and moderate anemia, a new group of patients with severe anemia was added. It is also interesting to note that in the group of participants who did not receive TXA, cases of severe anemia (20%) were twice as high as in those who did receive it (10%). Likewise, a higher percentage of cases with moderate anemia (50%) were found compared to the study group (30%), and mild anemia was twice as high (60%) in the TXA group compared to the control group (30%). The differences described were significant ($p<0.05$), with favorable results observed in the group receiving tranexamic acid.

The average hemoglobin level of participants before delivery (Table 3) was 9.90 g/dL in the group of women who received TXA and 9.97 g/dL in the control group, with a difference of 0.07 g/dL in favor of those who did not receive TXA. When applying the U test (since the distribution was non-normal, being asymmetrical in the group

with tranexamic acid and potentially normal in the group without the drug), it was found that both groups were similar, and there was no statistically significant difference. Dawoud[13] included women with hemoglobin of 11.17 g/dL who underwent cesarean section in the TXA group and found a decrease in hemoglobin of 0.78 g/dL with TXA compared to 1.32 g/dL in the control group ($p < 0.001$), a result very similar to that observed in our study.

The intragroup decrease in postpartum hemoglobin in the TXA group was 0.84 g/dL, while in the control group it was 1.55 g/dL (Table 3), a statistically significant difference, which is similar to that described by Sentilhes[11], who reported a decrease of 0.77 g/dL in the study group (1,921 women) compared to 0.79 in the control group (1,946 women). In other words, the administration of TXA was effective in reducing postpartum hemorrhage.

In Table 4, we observe the average decrease in hemoglobin in each patient in both groups after the intervention, obtaining prepartum values of 9.90 g/dL and then 9.06 g/dL in the group that received TXA. and prepartum values of 9.97 g/dL reaching 8.42 g/dL in the control group, with a difference of 0.64 g/dL in favor of the group that received TXA (paired t-test of p=0.03). Dawoud[10] reported a prepartum hemoglobin of 11.17 g/dL and a postpartum value of 10.39 g/dL in the TXA group, with a decrease of 0.78 g/dL, while in the control group, prepartum hemoglobin was 11.21 g/dL and postpartum hemoglobin was 9.89 g/dL, a decrease of 1.32 g/dL (p<0.001).

In 2017, in the WOMAN trial[6], the results obtained were clinically relevant because mortality from bleeding was significantly reduced in women who received TXA, with 1.5% dying in the group that received TXA vs. 1.9% in the placebo group (p=0.045). García de la Torre[14] quantified the volume of bleeding in pregnant women with HELLP syndrome, observing that the mean amount of bleeding in the treated group was 328 ml vs. 388 ml in the control group, with a 16.5% increase in bleeding in the control group.

Shakur[15] determined that TXA administered intravenously reduces mortality due to bleeding in women with primary PPH, regardless of mode of delivery, and without increasing the risk of thromboembolic events. Taken together with reliable evidence of the effect of TXA in trauma patients, the evidence suggests that TXA is effective if administered as early as possible.

Goulart[16] and Camelo[17] found that the use of tranexamic acid reduced hemorrhagic mortality in vaginal deliveries and cesarean sections; as a result, they observed a 33% reduction in laparotomies to control bleeding after delivery. Ortuanya[18] demonstrated that prophylactic administration of tranexamic acid significantly reduces postpartum blood loss, improves postpartum hemoglobin, reduces the need for additional uterotonics, and prevents postpartum hemorrhage after cesarean section in pregnant women at high risk of postpartum hemorrhage. He proposes its routine use during cesarean section in high-risk women.

Yang et al.[19] analyzed a total of 21 studies, nine randomized clinical trials, and 12 cohort studies, involving 1,896 patients who received prophylactic TXA and 1,909 patients who received placebo or no treatment. Compared with the control group, preoperative intravenous prophylactic administration of TXA significantly reduced intraoperative blood loss 2 hours after delivery and reduced the decrease in hemoglobin, but did not significantly affect blood loss 6 hours after delivery (p = 0.05).

Prophylactic TXA treatment may reduce the incidence of postpartum hemorrhage and reduce the need for blood transfusion. It is suggested that prophylactic intravenous TXA administration be considered as the standard of care in low-risk cesarean deliveries[20]. Tranexamic acid may also decrease the need for additional uterotonic agents[21].

The concordance between international evidence and the results obtained in our high-altitude setting reinforces the efficacy of TXA as a safe, economical, and easily applicable prophylactic intervention, even in environments where hematological physiology differs from sea level. In this cohort, the proportion of severe anemia was 10% in the ATX group compared to 20% in the control group, which is clinically relevant in a setting where maternal anemia affects 25–30% of women of childbearing age according to reports from MINSA (2024) and WHO[5].

These findings indicate that the prophylactic administration of tranexamic acid (TXA) could be considered for routine incorporation into the active management of the third stage of labor in high-altitude healthcare settings, thereby contributing to a reduction in postpartum anemia and supporting the attainment of national goals aimed at decreasing maternal morbidity in Peru.

Among the principal limitations of this study are its single-center, single-blind design, which may introduce selection and measurement biases, as well as the relatively small sample size (n = 60), limiting the generalizability of the findings. Additionally, hemoglobin measurements may have been affected by hydration status or technical variability in laboratory procedures. Nevertheless, the baseline comparability between study groups, the use of randomization, and the standardized implementation of the intervention protocol enhance the internal validity of the study and support its relevance as preliminary evidence in high-altitude populations.

Conclusion

This study demonstrates that the prophylactic administration of tranexamic acid immediately following vaginal delivery significantly mitigates the decline in hemoglobin levels among anemic postpartum women managed in a high-altitude setting.

These findings have important clinical implications for the prevention of postpartum anemia and for reducing maternal morbidity associated with obstetric hemorrhage, which continues to represent one of the leading causes of maternal mortality in Peru and across Latin America.

The incorporation of TXA into active delivery management in Andean regions could represent a cost-effective and safe measure to improve maternal outcomes.

Multicenter trials with larger sample sizes and longitudinal follow-up are recommended to evaluate the efficacy of TXA at different altitudes and levels of anemia severity, as well as its economic and programmatic impact within national maternal health programs.

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