Research Article

A Prospective Study to Evaluate the Efficacy of Trenexamic Acid in Addition to Oxytocin for Prevention of Post Partum Hemorrhage

Rini Bachotiya[2], Gayatri Mathuriya[1], Deepmala Chauhan[1], Rini Bachotiya[2]*

Background: One of the most prevalent causes of maternal mortality worldwide is postpartum hemorrhage which can be prevented by early prompt action. Active control of the third stage of labor is one such intervention that is strongly recommended.

Methods: Prospective, randomized, comparative study conducted in Department of Obgyn in MY Hospital, Indore, with comparative groups of 500 each. One group received oxytocin alone and other group received oxytocin and trenexamic acid both.

Results: The mean age in group I was 23.73 ± 3.53 years and in group II it was 23.83 ± 3.34 years, showing a comparable mean age between the two groups. The incidence of anemia was 9.6%, PPH was 6.0% and hemorrhagic shock was 0.6% in group I and in group II it was 8.0, 5.4 and 0.8%, respectively. The incidence of anemia and postpartum hemorrhage was higher in group I in comparison to group II. The mean blood loss in group I was 257.04 ± 139.17 mL, while in group II it was 242.60 ± 120.89 mL, showing a significantly lower blood loss in group II in comparison to the group I shows that trenexamic acid shows decrease and blood loss and anemia and occurance of PPH.

Conclusions: Analysis concluded that tranexamic acid tended to minimize blood loss and the need for blood transfusions during childbirth during caesarean sections and vaginal deliveries and appeared safe and efficient for prevention and control of bleeding during pregnancy.

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Keywords: Trenexamic acid, Post partum hemorrhage, Oxytocin, PPH.

Introduction

A significant cause of maternal mortality and serious maternal complications following conception is postpartum hemorrhage. For all mothers, prophylactic administration of a uterotonic agent shortly after birth is currently prescribed as the only treatment that has been proven to mitigate postpartum hemorrhage rates. Tranexamic acid, an antifibrinolytic agent, decreases the rate of bleeding and death in patients with wounds during elective surgery, without raising the incidence of occlusive vascular events, and is thus prescribed in these cases. Recently, tranexamic acid has been shown to decrease bleeding-related mortality in women with postpartum hemorrhage, especially when the medication was given shortly after delivery.[1] The value of early care was indicated by a meta-analysis of evidence from individual patients, including data from trauma patients and women with postpartum hemorrhage. A decrease of approximately 10% in the value against bleeding-related deaths was correlated with any 15-minute pause in administration and no major advantage was observed when the medication was delivered more than 3 hours after delivery. These results show that tranexamic acid is thought to be an intervention not just for the recovery but also for the prevention of postpartum coagulopathy, but that there is weak evidence to suggest a prophylactic impact on postpartum bleeding.

One of the most prevalent causes of maternal mortality worldwide is postpartum hemorrhage, which accounts for 127,000 deaths annually. PPH is a preventable condition and the progression of this terrible condition can be avoided by early, prompt action. Active control of the Third Stage of Labor is one such intervention that is strongly recommended. In order to avoid PPH, it is the only intervention known.[1]

Analysis concluded that tranexamic acid tended to minimize blood loss and the need for blood transfusions during childbirth during caesarean sections and vaginal

[1]Department of Obstetrics and Gynaecology, MGM Medical College, MYH, Indore, Madhya Pradesh, India.

[2]Department of Obstetrics and Gynaecology, RD Gardi Medical College, Ujjain, Madhya Pradesh, India.

Correspondence to: Rini Bachotiya, Department of Obstetrics and Gynaecology, RD Gardi Medical College, Ujjain, Madhya Pradesh, India. E-mail: dr.rinibachotiya@gmail.com

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deliveries and appeared safe and efficient for prevention and control of bleeding during pregnancy.[2] WHO advises that in addition to routine treatment, early use of intravenous tranexamic acid (within 3 hours of delivery) is indicated for women with clinically confirmed postpartum hemorrhage after vaginal birth or caesarean section.[3]

The use of tranexamic acid did not result in a postpartum hemorrhage rate of at least 500 mL among women with vaginal delivery who received prophylactic oxytocin, which was slightly lower than the placebo rate.[4] Taking into account the benefits of the prophylactic use of tranexamic acid in vaginal delivery women, the present research was conducted to evaluate the potency and effectiveness of tranexamic acid in preventing postpartum hemorrhage after vaginal delivery in terms of reducing postpartum hemorrhage occurrence and reducing maternal mortality.

Aim

To evaluate the efficacy of addition of tranexamic acid to oxytocin in the prevention of postpartum hemorrhage after vaginal delivery

Objectives

- Incidence of postpartum hemorrhage after giving tranexamic acid and its comparison to oxytocin alone group.
- Incidence and comparison of maternal mortality in both the groups.
- Mean blood loss

Methods

Place of Study

Department of Obstetrics & Gynecology, M.Y. Hospital, Indore (M.P.)

Study Design

Prospective, randomized, comparative study.

Sample Size

500 women in each group were enrolled.

Grouping

The women were allocated into two groups of 500 each using computer generated random numbers.

Group 1: Received 10 IU of oxytocin intramuscularly, followed by placebo (10 mL) slow intravenous push in 10 minutes.

Group 2: Received 10 IU of oxytocin intramuscularly, followed by tranexamic acid 1-gm (10 mL) slow intravenous push in 10 minutes

Inclusion Criteria

- All women of age more than 18 years and less than or equal to 40 years admitted in MYH undergoing normal vaginal delivery.
- Not having any prior bleeding disorder.

Exclusion Criteria

All women who are <18 or >40 years of age, has indication for c-section, having any kind of bleeding disorder, on anticoagulant therapy.

Results

Table 1 shows the distribution of women in both the groups in relation to age. The difference was found to be statistically not significant (p = 0.646), showing a comparable mean age between the two groups.Majority of the women were in the age group 21 to 25 years, followed by 26 to 30 years.

Table 2 shows the distribution of women in both the groups according to parity. There was no statistically significant association seen between parity and the groups (p = 0.290), showing a comparable distribution of women according to parity in both the groups.

Table 3 shows the comparison of mean blood loss between the two groups. The mean blood loss in group I was 257.04 ± 139.17 mL, while in group II it was 242.60 ± 120.89 mL. The difference was found to be statistically significant (p = 0.04), showing a significantly lower blood loss in goup II in comparison to the group I.

Table 4 shows the distribution of women in both the groups in relation to adverse events. In group I, 48 (9.6%) women were having anemia, 30 (6.0%) women were having PPH, 5 (1.0%) women had hemorrhagic shock and 442 (88.4%) women were not having any adverse events. In group II, 40 (8.0%) women were having anemia, 27 (5.4%) women were having PPH, 3 (0.6%) women had hemorrhagic shock and 446 (89.2%) women were not having any adverse events. The incidence of anemia was slightly lower in group II in comparison to group I

Discussion

Age

The mean age in group I was 23.73 ± 3.53 years and in group II it was 23.83 ± 3.34 years. The difference was found to be statistically not significant (p = 0.646), showing a comparable mean age between the two groups. Similar study was done by Ducloy-Bouthors *et al*. (2011)[5] and Alavi *et al*. (2018)[6] the mean age was comparable between the two groups.

Table 1: Distribution of women according to age

Age (in years)	*Group 1 (n = 500)*		*Group 2 (n = 500)*	
	No.	*%*	*No.*	*%*
18–20	103	20.6	74	14.8
21–25	278	55.6	317	63.4
26–30	100	20.0	89	17.8
31–35	17	3.4	19	3.8
More than 35	2	0.4	1	0.2
Total	500	100.0	500	100.0
Mean	23.73 ± 3.53		23.83 ± 3.34	
't' value, df	-0.460, df = 998			
p-value	0.646, Not significant			

Table 2: Distribution of women according to parity

Parity	*Group I (n = 500)*		*Group II (n = 500)*	
	No.	*%*	*No.*	*%*
Nullipara	248	49.6	224	44.8
Primipara	161	32.2	181	36.2
Multipara	91	18.2	95	19.0
Total	500	100.0	500	100.0

Table 3: Comparison of mean blood loss

	No.	*Mean ± SD*	*T value*	*p-value*
Group I	500	257.04 ± 139.17	11.752, df = 998	0.04, NS
Group II	500	242.60 ± 120.89		

Table 4: Adverse events

Adverse events	*Group I (n = 500)*		*Group II (n = 500)*	
	No.	*%*	*No.*	*%*
Anemia	48	9.6	40	8.0
PPH	30	6.0	27	5.4
Hemorrhagic shock	5	1.0	3	0.6
None	442	88.4	446	89.2

Parity

In group I, 32.2% women were primipara and 18.2% women were multipara, while in group II 36.2% women were primipara and 19.0% women were multipara. The distribution of women in both the groups was comparable in relation to their parity (p = 0.290).

Blood Loss

The mean blood loss in group I was 257.04 ± 139.17 mL, while in group II it was 242.60 ± 120.89 mL. The difference was found to be statistically significant (p = 0.04), showing a significantly lower blood loss in group II in comparison to the group I.

According to the study done by Abdel-Aleem *et al*. (2013),[7] Saccone *et al*. (2020),[8] Ducloy-Bouthors *et al*. (2011),[5] Novikova *et al*. (2015),[9] Peitsidis *et al*. (2011)[10] and Sentilhes *et al*. (2018)[11] in their study also they found that women in the tranexamic acid group had a lower rate of clinically significant postpartum hemorrhage than those in the placebo group ($p < 0.05$).

Adverse Events

The incidence of anemia was 9.6%, PPH was 6.0% and hemorrhagic shock was 0.6% in group I and in group II it was 8.0, 5.4 and 0.8%, respectively. The incidence of anemia and postpartum hemorrhage was higher in group I in comparison to group II, while incidence of hemorrhagic shock was slightly higher in group II.

A meta-analysis done by Corte *et al*. (2018)[12] had included 14363 women with established PPH after vaginal delivery. They reported that in women who had received tranexamic acid immediately after the diagnosis of PPH had a significantly lower incidence of hysterectomy in comparison to those women who had not received tranexamic acid. Though in our study, we did not compare the incidence of hysterectomy, but considering it as an adverse event, we also found lower incidence of adverse events in the group which received tranexamic acid.

Saccone *et al*. (2020)[8] in their meta-analysis reported that women who had received tranexamic acid after vaginal delivery prophylactically had a significantly lower incidence of primary PPH (8.7 *versus* 11.4%), which is comparable to our study.

Ducloy-Bouthors *et al*. (2011)[5] had included 144 women divided as 72 each into two groups. One group received tranexamic acid and the other was the control group. They reported mild, transient adverse manifestations more often in tranexamic acid group in comparison to the control group (p = 0.03).

Novikova *et al*. (2015)[9] in their study did not report any serious side effects in women who had received tranexamic acid.

Conclusion

PPH is a leading cause of maternal mortality and morbidity worldwide. Clinicians providing intrapartum care must be prepared not only to treat but, if possible, to anticipate and prevent PPH. Evidence is in support of the use of uterotonics for the prevention of postpartum blood loss. Studies have shown support in favour of the use of tranexamic acid for the prevention of postpartum hemorrhage.

The findings of the present study are of the opinion that in any of the medicalfacility setting (either high or low), tranexamic acid should be used prophylactically in women undergoing vaginal delivery to prevent postpartum hemorrhage and its severe complications.

Indian women already deficient in hemoglobin levels and further blood loss is a very high for their life and during pregnancy and delivery this risk increases further. In such conditions, tranexamic acid has proven to be efficacious in improving the maternal outcome.

Funding

The present study was conducted in a state government run hospital. Here all the patients admitted or on OPD basis are provided treatment without any charges. Also no additional test was conducted for the specific requirement of the study. Hence, there was no additional financial burden on the woman and/or her legally acceptable representative. The costs related to the conduct of the study were borne by the investigator.

Conflict of Interest

None was found.

Ethical Approval

The protocol of the present study was presented to the Ethics Committee for review. After obtaining their approval, the study was initiated in the institution. Also prior to the inclusion of any woman into the study, a voluntary written informed consent was obtained from the woman and/or her legally acceptable representative. This consent was in addition to the consents that are obtained routinely for the management of the condition.

References

1. Kumar N. Postpartum Hemorrhage; a Major Killer of Woman: Review of Current Scenario. Obstet Gynecol Int J 2016;4(4):1-7. DOI: 10.15406/ogij.2016.04.00116.
2. Peitsidis P, Kadir RA. Antifibrinolytic therapy with tranexamic acid in pregnancy and postpartum. Expert Opin Pharmacother. 2011 Mar;12(4):503-16.
3. WHO recommendation on tranexamic acid for the treatment of postpartum hemorrhage. Available from: https://extranet.who.int/rhl/topics/preconception-pregnancychildbirth-and-postpartum-care/postpartum-care/whorecommendation-tranexamic-acid-treatment-postpartum-haemorrhage.Accessed on 29.03.2019.
4. Sentilhes L, Winer N, Azria E, Sénat MV, Le Ray C, Vardon D, et al. Tranexamic Acid for the Prevention of Blood Loss after Vaginal Delivery. N Engl J Med. 2018 Aug 23;379(8):731-42.
5. Ducloy-Bouthors AS, Jude B, Duhamel A, Broisin F, Huissoud C, Keita-Meyer H, Mandelbrot L, Tillouche N, Fontaine S, Le Goueff F, Depret-Mosser S, Vallet B; EXADELI Study Group, Susen S. Highdose tranexamic acid reduces blood loss in postpartum hemorrhage. Crit Care. 2011;15(2):R117.
6. Alavi Z, Atiqpour F, Zare S, Nasiri Z. Effect of tranexamic acid on postpartum vaginal hemorrhage in Sharieti Hospital of Bandar Abbas in 2014- 2015. Journal of Research in Medical and Dental Science. 2018;6(3):452-8.
7. Abdel-Aleem H, Alhusaini TK, Abdel-Aleem MA, Menoufy M, Gülmezoglu AM. Effectiveness of tranexamic acid on blood loss in patients undergoing elective cesarean section: randomized clinical trial. J Matern Fetal Neonatal Med. 2013 Nov;26(17):1705-9.
8. Saccone G, Della Corte L, D'Alessandro P, Ardino B, Carbone L, Raffone A, Guida M, Locci M, Zullo F, Berghella V. Prophylactic use of tranexamic acid after vaginal delivery reduces the risk of primary postpartum hemorrhage. J Matern Fetal Neonatal Med. 2020 Oct;33(19):3368-76.
9. Novikova N, Hofmeyr GJ. Tranexamic acid for preventing postpartum hemorrhage. Cochrane Database Syst Rev. 2010 Jul 7;(7):CD007872.
10. Peitsidis P, Kadir RA. Antifibrinolytic therapy with tranexamic acid in pregnancy and postpartum. Expert Opin Pharmacother. 2011 Mar;12(4):503-16.
11. Sentilhes L, Winer N, Azria E, Senat MV, Ray CL, Vardon D, et al. Tranexamic acid for the prevention of blood loss after vaginal delivery. N Engl J Med 2018; 379:731-42.
12. Corte LD, Saccone G, Locci M, Carbone L, Raffone A, Giampaolino P, et al. Tranexamic acid for treatment of primary postpartum hemorrhage after vaginal delivery: a systematic review and metaanalysis of randomized controlled trials, The Journal of Maternal-Fetal & Neonatal Medicine. 2020;33(5):869-74.