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Original Research Article

Effect of intravenous tranexamic acid in reducing blood loss during and after caesarean section: a quasi-experimental study in RIMS, Manipur

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ABSTRACT

Background: PPH is the most common cause of maternal death worldwide. Risk factors for PPH include grand multiparity and multiple gestation. However, PPH may occur in women without identifiable clinical or historical risk factors. It is therefore recommended that active management of the third stage of labour be offered to all women during childbirth, whenever a skilled provider is assisting with the delivery. The aim of our study is to determine the efficacy of tranexamic acid in decreasing blood loss in elective LSCS.
Materials: A quasi experimental study was done in 312 pregnant women undergoing elective LSCS in the Department of Obstetrics and Gynaecology, at a tertiary health teaching centre RIMS, Imphal, Manipur from September 2019 to November 2021. Ethical clearance was obtained from Research ethics Board to carry out the study. Data were entered in IBM SPSS version 21 software for Windows.
Results: The total of 312 pregnant women were included in the study. Most of the pregnant women were in the age group of 27 years. In our study, there was a significant decrease in intraoperative and postoperative blood loss in women receiving tranexamic acid. There was significant fall in post-operative haemoglobin in control group as compared to study group. Also, women who received tranexamic acid did not develop any significant complications.
Conclusions: Tranexamic acid can be used safely as a prophylaxis to reduce blood loss during caesarean section.

Keywords: Blood loss, Caesarean section, Haemoglobin, Tranexamic acid

INTRODUCTION

PPH is generally defined as blood loss greater than or equal to 500 ml within 24 hours after birth, while severe PPH is blood loss greater than or equal to 1000 ml within 24 hours. PPH is the most common cause of maternal death worldwide. Most cases of morbidity and mortality due to PPH occur in the first 24 hours following delivery and these are regarded as primary PPH whereas any abnormal or excessive bleeding from the birth canal occurring between 24 hours and 12 weeks postnatally is regarded as secondary PPH.[1] Risk factors for PPH include grand multiparity and multiple gestation. However, PPH may occur in women without identifiable clinical or historical risk factors. It is therefore recommended that active management of the third stage of labour be offered to all women during childbirth, whenever a skilled provider is assisting with the delivery.[2] The incidence of PPH is greatest in low/middle-income nations, particularly in subSaharan Africa where it can be larger than 30%.[3-5] The worldwide incidence of PPH is estimated to be between 6% and 11% with substantial regional variability.[4,5] For nearly 30 years, the international healthcare community has considered the ideal rate for caesarean sections to be between 10% and 15%. This was based on the following statement by a panel of reproductive health experts at a meeting organized by the World Health Organization (WHO) in 1985 in Fortaleza, Brazil: "There is no justification for any region to have a rate higher than 10-15%".[3] The panel's conclusion was drawn from a review of the limited data available at the time, mainly from northern European countries that demonstrated good

maternal and perinatal outcomes with that rate of caesarean sections.[2] TXA is a synthetic derivative of lysine high affinity for lysine binding sites on plasminogen to block plasmin from binding and degradation linked fibrin. TA may enhance the effectiveness of endogenous hemostatic mechanism.[6-8] Early use of intravenous TXA (as early as possible after clinical diagnosis of PPH, and only within 3 hours of birth) in addition to standard care is recommended for women with clinically diagnosed PPH following vaginal birth or caesarean section. The goals of the WHO 2017 recommendation on TXA for PPH treatment are to improve the quality of care for women with PPH and prevent maternal deaths due to PPH. Successful introduction of TXA as part of a standard PPH treatment package will require action on many fronts and engagement of multiple stakeholders across system levels, including policy makers, national and subnational ministry of health managers, professional societies, facility managers, facility health care workers, community leaders, health agents, and women and families. There are considerations for country stakeholders incorporating the WHO 2017 TXA PPH treatment recommendation into national policy and country programmes.[9]

METHODS

A quasi-experimental study was done in 312 pregnant women undergoing elective LSCS in the Department of Obstetrics and Gynaecology, at a tertiary health teaching centre RIMS, Imphal, Manipur from September 2019 to November 2021. Women with uncomplicated singleton pregnancy with gestational age after 37 completed weeks, Primigravida and multigravida up to third parity with 1 or 2 previous caesarean sections were included in the study. Those suffering from medical diseases, thromboembolic disease, abnormal placenta, severe preeclampsia, multiple pregnancies (multipara), macrosomia, polyhydramnios, anaemia, abnormal coagulation tests, allergy to the TXA were excluded from the study. 312 subjects of elective Caesarean cases fulfilling the inclusion were included in the study, in which 156 subject for group A and the rest 156 for control or group B. Every alternate or odd number of the subjects was given intravenous tranexamic acid at the dose of 10 mg/kg twenty minutes before spinal anaesthesia, as group A. The rest numbers did not receive intravenous tranexamic acid. Both groups received 10 units of oxytocin intramuscular soon after delivery of baby. The primary outcome was to estimate the bloss loss. Blood loss was measured by weighing pads, mops, drapes before and after surgery and blood in the suction container after surgery. Two separate suction containers were used to avoid mixing of blood and amniotic fluid. Total blood loss was calculated as the difference in the weight of the pads, mops and drapes before and after surgery and the sum of the amount of blood in the suction container. The difference between the pre- operative and post-operative haemoglobin was compared. The pre-operative, intra-operative and post-operative vitals were also compared. Statistical analysis was done using IBM SPSS version 21.0 for Windows. Descriptive statistics like mean, standard deviation, and percentages were used. Analytical statistics like Chi-Square Test, t-test were used for seeing association. In our study, there was a significant decrease in intraoperative and postoperative blood loss in women receiving tranexamic acid. There was significant fall in post-operative haemoglobin in control group as compared to study group. Also, women who received tranexamic acid did not develop any significant complications. Consent was obtained from the participating individuals. A unique code number was given but no name was mentioned to maintain confidentiality.

RESULTS

The study was done in the Obstetrics and Gynaecology department of RIMS, Imphal. 312 pregnant women were included in the study, of which 156 were study and 156 as control group. Mean age of the study group was 27.7 years and 26.2 years for control group. Most of the respondents were Hindu 154 (49.3%), followed by Muslim 99 (31.7%) and Christian 59 (18.9%).

Table 1: Distribution of respondents by age.

Age group (years)	Study N (%)	Control N (%)	P value
20-24	24 (15.4)	21 (13.4)	0.273
25-29	106 (68)	106 (67.9)	
30-34	23 (14.7)	29 (18.5)	
≥35	3 (1.9)	0 (0)	
Mean±SD	27.7 (2.64)	26.2 (2.72)	

Table 2: Distribution of respondents by religion.

Religion	Study N (%)	Control N (%)	P value
Hindu	68 (44.2)	86 (55.8)	0.098
Christian	35 (59.3)	24 (40.7)	
Muslim	53 (53.5)	46 (46.5)	

Majority of the respondents were parity 1, 129 (41.3%), followed by primigravida 117 (37.5%), and parity 2 50 (16.02%). Only16 (5.12%) were parity 3. The most common indication for LSCS was CPD 87 (55.6%), followed by malpresentation 79 (50.6%), previous caesarean section 76 (48.7%) and maternal request 7 0(45%). The study showed that tranexamic acid significantly reduced bleeding from the time of placental delivery to abdominal wound closure in LSCS with blood loss of 377.8±41.2 ml in tranexamic acid group compared to blood loss of 422.8±36 ml in the control group that was statistically significant (p=0.00). The blood loss from abdominal wound closure to 2 hours post-delivery in TXA group and control group was 73.8±15ml and 118.07±21.3 ml respectively and the difference was also statistically significant (p=0.00). Thus, the mean total blood loss was 457.22±42.0 ml and 536.54±57.5ml in TXA and the control group respectively. The result was found to be highly significant (p=0.00).

Table 3: Distribution of respondents by parity.

Parity	Study N (%)	Control N (%)	P value
P0	59 (37.8)	58 (37.2)	0.437
P1	68 (43.5)	61 (39.1)	
P2	24 (15.3)	26 (16.6)	
P3	5 (3.2)	11 (7.1)	

Table 4: Distribution of respondents by indication.

Indication	Study N (%)	Control N (%)	P value
CPD	41 (26.2)	46 (29.4)	0.93
Maternal request	36 (23)	34 (22)	
Malpresentation	40 (25.6)	39 (25)	
Post CS	39 (25)	37 (23.7)	

There was significant fall in post-operative haemoglobin in control group (1.28±0.37) as compared to study group (0.82±0.19).

The mean duration of LSCS in study group was 41.47±2.9 min and that in control group 50.26±5.8 min. In our study there was also significant increase in pulse rate in both the groups (p=0.00).

HR during placental delivery, 1 hour and 2 hour post-delivery in the study and control group was increased significantly (79.52±6.59 ml and 79.71±2.61 ml). Side effect profile of tranexamic acid such as nausea, vomiting and diarrhoea was similar in both groups. In the current study, there is no significant difference between APGAR score of the baby at 1 min and 5 min following delivery (p=0.7). None of the babies required NICU admission.

Table 5: Distribution of respondents by amount of blood loss.

Amount of blood loss (ml)	Study Mean±SD	Control Mean±SD	Mean difference	95% Confidence Interval	P value
Placental delivery to wound closure	377.8±41.2	422.8±36.1	-45.01	(-53.6, -36.4)	0.00
Wound closure to 2hour	73.8±15.3	118.07±21.3	-44.27	(-48.4, -40.2)	0.00
Total blood loss	457.22±42.0	536.54±57.5	-79.32	(-90.55, -68.10)	0.00

Table 6: Distribution of respondents by fall in Hb level.

Variable	Study Mean±SD	Control Mean±SD	Mean difference	95% CI	P value
Fall in Hb (g/dl)	0.816±0.19	1.289±0.37	-47.29	(-0.54, -0.40)	0.00

Table 7: Distribution of respondents by duration of LSCS.

Variable	Study, Mean ±SD	Control , Mean ±SD	P value
Duration of CS in minutes	41.47±2.9	50.26±5.8	0.00

Table 8: Distribution of respondents by complications.

Complications	Study, N (%)	Control , N (%)	P value
Yes	52 (33.3)	53 (33.97)	0.90
No	104 (66.6)	103 (66.02)	
Nausea	23 (14.74)	28 (17.94)	
Vomiting	18 (11.53)	17 (10.8)	
Diarrhoea	9 (5.76)	6 (3.84)	
Nausea, vomiting and diarrhoea	2	3	
PPH	0	0	
TE	0	0	

DISCUSSION

Tranexamic acid acts by competitively blocking the lysine binding sites on plasminogen, thereby, prevents the lysis of the formed clot. Its onset of action is 5-15 minutes with duration of action of 3 hours. Tranexamic acid binds more avidly with to the plasminogen molecule than amino-caproic acid. It is used to treat or prevent excessive blood loss from major trauma, postpartum bleeding, surgery, tooth removal, epitaxis and heavy menstrual bleeding. After delivery of the baby, there is transient activation of fibrinolytic cascade for 6-10 hours.[31] So the efficacy of antifibrinolytic agent such as tranexamic acid is being evaluated for the prevention of PPH. It was first made in 1962 by Japanese researchers Shosuke and Utako Okomoto. It is on the World Health Organisation's List of

Essential medicines. It belongs to pregnancy category B and is taken orally, injection or topical.

Table 9: Distribution of respondents by APGAR score of baby.

APGAR score		Study N (%)	Control N (%)	P value
1 minute	8	7 (4.48)	8 (5.12)	0.7
	9	149 (95.5)	148 (94.8)	
5 minutes	8	7 (4.48)	84 (5.12)	0.7
	9	149 (95.5)	148 (94.8)	

The study showed that tranexamic acid significantly reduced bleeding from the time of delivery to abdominal wound closure in LSCS with blood loss of 377.8±41.2 ml in tranexamic acid (TXA) group compared to blood loss of 422.8±36.1ml in the control group. The reduction in blood loss was statistically significant (p value=0.00). The blood loss from abdominal wound closure to 2 hours post-delivery in TXA group and control group were 73.8±15.3ml and 118.07±21.3 ml respectively and the difference was statistically significant (p value= 0.00). Thus, the mean total blood loss was 457.22±42.0 ml and 536.54±57.5 ml in the TXA group and the control group, respectively. The result was found to be statistically significant (p value= 0.00). These results were comparable with a study done by Gai et al with total blood loss in CS of 351.57±148.20ml in the TXA group and 439.36±191.48ml in the control group (p=0.002).[31] The blood loss from end of CS to 2 hours post-delivery of 42.75±40.45ml in the TXA group versus 73.98±77.09ml in the control group (p=0.001) was also comparable. Similar results were observed by Mayur et al with the total blood loss in CS from placental delivery to 2 hours post-delivery of 372.71 in the TXA group, versus 469.70 ml in the control group (p=0.003).[17-41] The quantity of blood loss from end of LSCS to 2 hours post-delivery was 75.51ml in the TXA group versus 133.03 ml in the control group, but the reduction in the blood loss was significant (p=0.001).[42-44] Movafegh et al performed their study with intravenous administration of 10 mg/kg of tranexamic acid 20 min before skin incision at caesarean delivery.[45] Mean blood loss was significantly less in the tranexamic acid group compared with the control group for both intra-operative bleeding (262.5±39.6 vs. 404.7±94.4 ml) and post-operative 48hrs bleeding (67.1±6.5 vs. 141.0±33.9ml; p<0.001), respectively. Oxytocin administration was also lesser in the study group (this was not recorded in this study group). Similar results were also observed by Xu et al with total blood loss in CS from placental delivery to 2 hours post-delivery of 379.2±160.1 ml in the TXA group vs. 441.7±189.5 ml in the control group (p=0.02).[12] Blood loss in the period between the end of CS and 2 hours post-delivery of 46.6±42.7 ml in the TXA group vs. 84.7±80.2 ml in the control group (p<0.01) was also comparable. These results were consistent with the study done by Malathi et al with blood loss from placental delivery to end of LSCS of 375±69 ml in TXA group vs. 410±79.9ml in the control group.[22] It also reduced the quantity of blood loss from end of LSCS to 2 hour postpartum which was 52±30 ml in TXA group vs. 131±42 in the control group (p=0.006) which is statistically significant. Abdel et al randomized 740 subjects.[23] The mean blood loss was 241.6ml in the TXA group vs. 510 ml in the control group. Similar results were observed with study conducted by Jayaprakash Sahu et al.[48]. They compared the effect of TXA in 100 subjects and the mean blood loss was 436.5±118.07ml in the study group in comparison to 616.5±153.34ml in the control group (p<0.05) was also comparable. Mirghafourvand et al conducted a double-blind randomized controlled trial on 120 women with a singleton pregnancy.[38] The total blood loss [519 (320) vs. 659 (402) ml, P=0.036] was significantly lower in the TXA group compared to the control group. Sekhavat et al conducted a prospective randomized study on 90 primipara mothers which showed that tranexamic acid significantly reduced blood loss from end of CS to 2-hour post-partum; 28.02±5.53 ml blood loss in the tranexamic group vs. 37.12±8.97 ml in the control group (p=0.000).[21] These results were comparable to our study although they studied only primipara, whereas our study had multipara also. According to a study conducted by Sahid et al tranexamic acid significantly reduced the quantity of blood loss from placental delivery to the end of LSCS which was 356.44±143.2 ml in the TXA group versus 710.22±216.72 ml in the placebo group (p<0.001).[10] However the quantity of blood loss from the end of LSCS to 2 hours postpartum which was 35.68±23.29ml in the TXA group versus 43.63±28.04 ml in the placebo group (p=0.188), was not significant. In our study post operative hemoglobin was higher in TXA group than control group and the finding is significant. There was significant lesser fall in hemoglobin in the TXA group post operatively (p=0.00). Goswami et al formed three groups- 2 study groups (10 mg/kg vs. 15 mg/kg dose) and 1 control.[36] There was a significant difference between pre and post-operative haemoglobin. Ray I et al[29] conducted a prospective, randomized, placebo-controlled, open-label study. The difference between preoperative and post-operative Hb was significantly less in the study group than the control group, 0.26±0.22 versus 0.99±0.48 g% (p<0.001) which is comparable with our study. Similar results were observed by Halder et al with fall in haemoglobin in the TXA group of 1.214g/dl in comparison to 1.7256g/dl in the control group that was statistically significant (p<0.0001).[34] Wang et al conducted a meta-analysis of 11 RCTs to evaluate efficacy of tranexamic acid and showed there was significant difference in mean blood loss, difference in haemoglobin and the need for blood transfusion between the groups. In our study duration of CS was shorter by 8.5 minutes in the TXA group when compared to that of control group and the finding was statistically significant (p=0.00).[13] This had not been documented in any other studies. The shorter duration of CS was probably due to better field of vision for the surgeon by the use of tranexamic acid.

In our study there was also significant increase in pulse rate in both the groups (p=0.00). HR during placental

delivery, 1 hour and 2 hour post-delivery in the study and control group was increased significantly (79.52±6.59 ml and 79.71±2.61 ml), (85.37±3.95 and 83.07±4.2), (82.21±3.30 and 80.96±3.11) respectively (p=0.00). Similarly, in a study conducted by Ray et al there was also significant increase in pulse rate, mean 84/min in the study group versus 92/min in the control group (p=0.000).[46,47] Other parameters such as systolic blood pressure, diastolic blood pressure and respiratory rate did not have any significant difference in the two groups. Side effect profile of tranexamic acid such as nausea, vomiting and diarrhoea was similar in both groups. These results were similar to previous studies. The incidence of thrombosis during pregnancy and puerperium is 5-6 times higher than in the general population. When the antifibrinolytic drug, tranexamic acid is administered, the increased risk of thrombosis should be considered during c-section and postpartum period. In our study, none of the mothers developed thrombosis. In a 51 similar study, Mayur et al did not demonstrated the increase in the risk of thrombosis among 100 patients. In study conducted by Shahid A and Khan while determining the effectiveness of tranexamic acid (TXA) in reducing blood loss during and after caesarean section (CS), the increased in the risk of thrombosis was not reported.[10] Similarly, in Dunn C et al review on the use of tranexamic acid in surgery, increased risk of thrombosis were not observed in any of the patients.[46] Similar studies by Senturk et al in 660 patients, the incidence of thromboembolic events were not increased.[38] In the current study, there is no significant difference between APGAR score of the baby at 1 min and 5 min following delivery (p=0.7). None of the babies required NICU admission. The similar result was found in a study conducted by Gai et al.[31] Thus tranexamic acid has no effect on the APGAR score of the baby.

CONCLUSION

Administration of intravenous tranexamic acid 20 minutes before spinal anaesthesia significantly reduces the amount of blood loss during and after caesarean section. It is not associated with side effects and or complications like thrombosis. Also, it doesn't not have adverse neonatal outcome and can safely be used during CS and postpartum period.

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