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Original Research Article

Effect of prophylactic tranexamic acid in normal vaginal delivery

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ABSTRACT

Background: Use of tranexamic acid (TXA) in combination with uterotonics in management of postpartum haemorrhage is quite established, but its use for prophylaxis is still uncommon, specifically post normal delivery. Shock index (SI) (heart rate divided by systolic blood pressure) and delta shock index (DSI) i.e., difference of SI before and after an event are being recognized as tools for hemodynamic status evaluation and bedside assessment for individual respectively. The present study compared the combined effect of TXA and oxytocin uterotonic on postpartum blood loss as evaluated by shock index (SI) and delta shock index (DSI) in low-risk pregnancies.
Methods: 230 subjects divided equally, underwent randomised control trial with combination of Injection TXA and oxytocin versus oxytocin alone immediately post-delivery and impact evaluated using SI, DSI, postpartum haemoglobin (HB) and haematocrit (HCT) at admission and one hour postpartum, followed for six weeks for any complications.
Results: Prophylactic use of TXA in terms of SI values, HB and HCT revealed significant improvement, in both preterm and term pregnancies with either spontaneous or induced labours. DSI with a sensitivity of 69.6% and specificity of 67% with a simple plus or minus notation gave a satisfactory idea of shift of stability and instability of hemodynamic status of an individual as an indirect predictor of blood loss with a cut-off between -0.0682 to +0.1182. 6 weeks postpartum follow up was uneventful.
Conclusions: The study depicted benefit and safety profile of prophylactic use of TXA in low-risk pregnancies, significant for developing countries with high incidence of anaemia during pregnancy and advocates incorporation of SI and DSI as markers of haemodynamic status in partograph.

Keywords: Postpartum haemorrhage, Pregnancy, Shock, Tranexamic acid

INTRODUCTION

At the international level, maternal mortality and morbidity are significant health markers. Amongst causes of maternal mortality and morbidity, postpartum haemorrhage (PPH) is a leading catastrophe. Recent definitions emphasize symptoms like air hunger or/and syncope, confusion, restlessness, diaphoresis, palpitations, weakness, light-headedness, and symptoms of hypovolemia (such as low oxygen saturation, oliguria, tachycardia, hypotension).

Prophylactic use of uterotonics is an established protocol for active management of 3rd phase of labour to augment uterine tone. World Health Organisation (WHO), as well as various international groups, have recommended oxytocin as the choice of drug for this purpose.[1] TXA ("tranexamic acid") is a strong antifibrinolytic agent that uses its impact by inhibiting plasminogen molecules from bindings sites to lysine.[2] Consequently, it inhibits clot breakdown or fibrinolysis and reduces bleeding. When the placenta splits from the uterine wall during delivery, a series of haemostatic and physiologic variations take place to decrease bleeding, such as increased platelet activity,

strong myometrial contractions, as well as a vast release of coagulant factors; but fibrinolytic activity also rises at the same time. While oxytocin administration improves the 1st process, TXA administration counters the latter and is thus expected to facilitate the haemostatic mechanism.

The change in hemodynamic status is not always reflected by the amount of blood loss. Thus, the best criteria for evaluation will be the ones that can effectuate the hemodynamic status of an individual.

The SI, a bedside evaluation described as heart rate divided by SBP was revealed to have a better co-relation of hemodynamic status, intervention, and follow-up for the non-pregnant population.[3] But, physiological changes in various systems during pregnancy and reversal of events altering the circulatory system soon after delivery precludes the application of SI values of non-pregnant on parturient. Le Bas et al recently found that the normal value for the SI is greater during pregnancy than in the non-pregnant adult population due to an increase in PR (pulse rate) and a drop in SBP. SI>1 was found to be correlated with a rise in the chance of needing a blood transfusion after PPH. With scant literature available on SI in obstetrical populations some critical values have emerged for inference of requirements of blood transfusions, intensive care unit (ICU) services and severe morbidity and mortality, etc.[4]

A recent study focused on the DSI which is the variation between SI before and after an event as a better tool for individual assessment and management. Treating SI≤1.1 as normal in peripartum, a retrospective study in PPH conferred the superiority of SI and DSI in blood transfusion, predicting PPH, and the requirement for a surgical intervention taking. The study quoted that SI≥1.412 and SI≥1.143 were strong initial and "critical" levels. When potential confounders were taken into account, both SI and DSI remained sensitive and specific, though DSI was the overall strongest classifier.[5]

Since DSI is a simple, reproducible and economically viable tool for determining blood loss establishing a cut-off for DSI is very important in predicting outcomes in Indian pregnant women with a very high prevalence of anaemia.

The present study compared the impact of TXA in addition to oxytocin on postpartum blood loss as evaluated by SI and DSI in low-risk pregnancies.

METHODS

In this prospective randomized control, a comparative analysis was carried out in the "department of obstetrics and gynecology" at a tertiary care institute after approval from the Institutional Ethics Committee. All pregnant women fulfilling the inclusion norms were registered in the research.

Study design

It was a prospective randomized control, comparative study between two groups of 115 patients each.

Sample size

Optimum sample size was calculated on the basis of 1.8% blood loss of more than equal to 500 ml in experimental group using routine oxytocin in combination with TXA and 6.8% in control group with routine oxytocin alone. Level of significance was assumed to be 5% and power of test to be 80%. The optimum sample to be covered in present RCT came out to be 230 which was divided in two groups taking 115 study subjects in each group.

Patients were recruited to two randomized groups with computerized generated tables and the allotment of cases was performed using sealed opaque envelopes: group A: these subjects were given only routine 10 IU intramuscular (IM) oxytocin during the intrapartum period. Group B: these subjects received 1 gm slow intravenous (i.v.) infusion of TXA in 200 ml normal saline in addition to i.m. oxytocin given to group A subjects.

Inclusion criteria

All low-risk pregnancies with singleton pregnancies were admitted to the labour ward of GMCH Sector 32, Chandigarh for normal vaginal delivery.

Exclusion criteria

Personal and family history of venous (pulmonary embolism or/and deep vein thrombosis) or arterial (stroke, myocardial infarction, angina pectoris) thrombosis. Medical disorders that affect bleeding: like blood, liver, cardiovascular, and renal disorders, epilepsy, sickle cell, autoimmune diseases, etc. Use of drugs affecting bleeding or clotting times like aspirin, heparin, warfarin, antipsychotic and antidepressants, NSAIDs, etc. High-risk pregnancies- multiple pregnancies, placental abruption, minor degrees of placenta previa, eclampsia, HELLP syndrome, intrauterine fetal death, chorioamnionitis, macrosomia, polyhydramnios, etc. Intrapartum complications like rupture uterus, retailed placenta, tears, and trauma.

At admission all demographic and personal information was documented on a proforma and informed approval was taken. Subjects were examined for PR, SBP, and other general physical examinations. SI was calculated for all subjects as PR/SBP. All subjects were sampled for complete blood count including haematocrit (HCT) at admission and one-hour post-partum.

Records of any additional intervention required for management of blood loss were also maintained like concomitant use of number and doses of other uterotonic

agents, blood and blood products, tamponade, or other measures, etc.

The fourth stage of labour was observed as recommended routinely and obstetric SI was calculated for the subjects after one hour of delivery.

DSI value was also calculated for all subjects, after one hour of delivery.

All subjects were followed for six weeks post-delivery for any thromboembolic events.

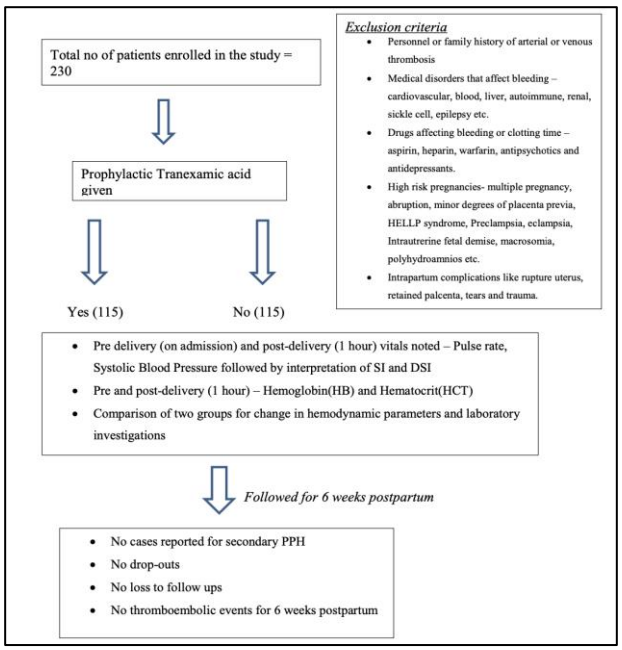

Figure 1: Consort diagram.

Statistical analysis

Continuous data were given as mean±SD and range or median and interquartile range, as appropriate. Normality of quantitative data were checked by measures of Kolmogorov Smirnov tests of normality. For skewed data (our data was skewed for all variables except for POG) comparisons for two groups (tranexamic acid given/not given) were made by Mann-Whitney test. For normally distributed data (POG) Student t-test was applied to compare two groups. Change for shock index, SBP, pulse rate were calculated by subtracting value of each subject T_0-T_1 i.e. time 1 – time 0, percentage changes were calculated; then its mean /medians were calculated for the two groups. Mann-Whitney U test was carried out to compare the two groups. For time related variables i.e. two timings of same variable were compared by Wilcoxon Signed rank test. Categorical variables were reported as counts and percentages. Group comparisons were made with the Chi-Square test or Fisher's exact test. Receiver operating characteristic (ROC) curves were obtained to find maximal cut-off values of shock index 2 and delta shock index for (tranexamic acid given/not given). The ROC curve is a plot of sensitivity versus 1-specificity for maximal cut-off values. Spearman correlation coefficient were calculated to see relation of the variables with change in shock index. All statistical tests were two-sided and performed at a significance level of α=0.05. Analysis was conducted using IBM SPSS statistics (version 22.0).

RESULTS

This prospective comparative study was conducted between January 2019 to February 2020 in the department of obstetrics and gynaecology, of a tertiary care hospital. Out of 230 subjects enrolled in the study,70 subjects were <37 weeks (30.4%) and 160 subjects were ≥37 weeks (69.6%). Most of the subjects were primigravida (73.5%) and multigravida with previous non-viable pregnancies or abortions (26.5%). 112 patients were into spontaneous labour (SOL) and 118 patients were induced (IOL) for maternal or fetal indications.

When comparing the PR of two groups, the data was skewed. 50% of subjects from both groups had PR within the normal range on admission and post-delivery irrespective of administration of TXA. But the median difference between the two PR (difference in control group = -6, cases = +6) was statistically substantial ($p<0.05$). The median change in SBP (cases- 6 mmHg versus controls- 10 mmHg) was not found to be significant ($p>0.05$).

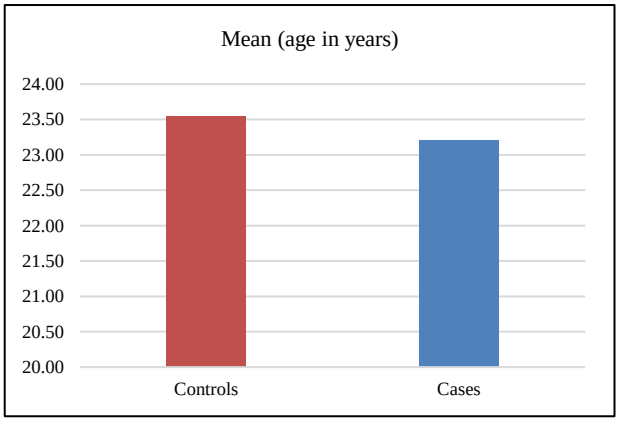

Figure 2: Mean age (in years)- cases versus controls.

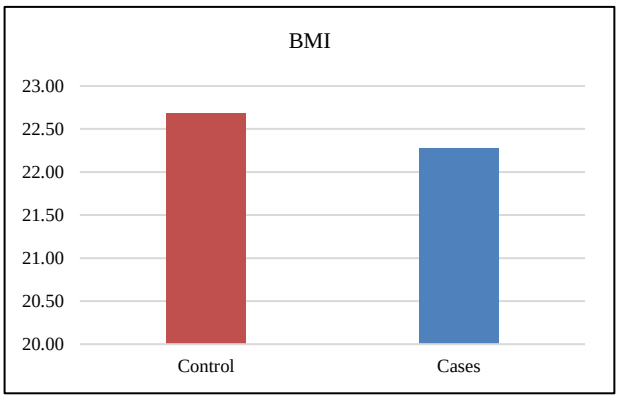

Figure 3: Mean BMI amongst cases and controls.

Table 1: Comparison of SI between cases and controls.

TXA		N	Mean	Std. deviation	Minimum	Maximum	Percentiles		
							25th	50th (median)	75th
Yes	SI 1	115	0.8406	0.09414	0.65	1.20	0.7719	0.8308	0.8909
	SI 2	115	0.8179	0.12055	0.54	1.10	0.7273	0.8182	0.9000
No	SI 1	115	0.8184	0.09880	0.58	1.05	0.7455	0.8182	0.8654
	SI 2	115	0.9073	0.15274	0.54	1.20	0.8000	0.9000	1.020

Table 2: Comparison of DSI between cases and controls.

TXA		N	Mean	Std. deviation	Minimum	Maximum	Percentiles		
							25th	50th (median)	75th
Yes	DSI	115	+0.0227	0.13346	-0.30	0.42	-0.0682	0.0182	0.1182
No	DSI	115	-0.0888	0.15572	-0.49	0.30	-0.1867	-0.0909	0.0364

The median SI, pre-, and post-delivery for the TXA group were 0.8308 and 0.8182 with a statistically insignificant (p>0.05) drop in SI. In comparison, in the control group, a statistically substantial rise in SI (0.8182 and 0.9000) was noticed (p<0.001) signifying a shift towards deranged hemodynamics (Table 1).

When comparing the changes in SI with or without the use of TXA, though statistically insignificant, a small role of TXA in improving the value of SI was observed.

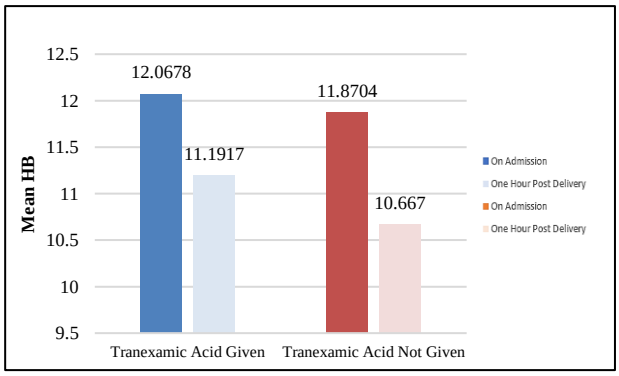

Figure 4: Comparison of HB between cases and controls.

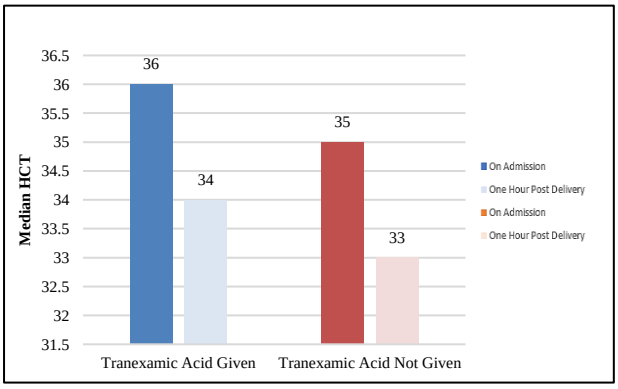

Figure 5: Comparison of HCT between cases and controls.

The mean HB pre-delivery and one-hour post-delivery in the cases group were 12.0678 and 11.1917 respectively, while in controls they were 11.8704 and 10.6670 respectively. The post-delivery HCT values for 50 percent of patients in the cases group remained in the normal range (interquartile range- 32-36%) with a median change of 2% whereas there was a drop below 30% in HCT in the placebo group (interquartile range- 29-36%) with a median change of 3% (p<0.05%) (Figures 4 and 5).

The values of SI were unable to prove the statistical significance in the improvement of hemodynamics. So, a better predictor i.e., DSI was introduced. Although it is the same value as we have discussed earlier, a change in SI, a single value easily gives an idea about the shift in hemodynamics. The plus sign implies more stable hemodynamics and provides a better tool for the prediction of the risk of blood loss. A range of -0.682 to +0.1182 gives a significant predictive value for the risk of blood loss in 50% population (Table 2).

The sensitivity of the DSI was 69.6% and specificity was 67% at a value greater than or equal to -0.0385. Similarly, the sensitivity of SI 2 was 65.2% and specificity was 66.7% at a value greater than or equal to 0.8618.

None had secondary PPH or thromboembolic events due to a single dose of TXA till 6 weeks post-partum.

DISCUSSION

Although the occurrence of PPH changes based on the definition and standards employed, the intention of the treating clinicians is to preferably prevent PPH and reduce blood loss. Since uterine atony is largely presumed to be the cause of PPH, most drugs utilized to prevent and treat PPH are uterotonics with a process of action that promote uterine contraction. Though, the pathophysiology of severe PPH also involves coagulopathy and needs corrective measures. TXA has lately been more widely utilized to treat PPH due to its antifibrinolytic effects.

A large multicentric randomized, double-blinded, placebo-controlled trial- TRAAP and TRAAP2 calculated the incidence of PPH in normal vaginal deliveries and caesarean deliveries respectively. It was observed that TXA was related to a reduced incidence of PPH than placebo with no increased risk of serious adverse events such as thrombotic problems within 3 months after delivery.[6]

The current study was conducted to explore the use of TXA as a prophylactic drug in normal vaginal deliveries.

Yang and colleagues in their study showed that when comparing a single dose of 1 gm versus 0.5 gm, the occurrence of PPH was observed to be lower in the group receiving the larger dose.[7] Hence the dose of use in the present study was kept as 1 gm of TXA. Since oxytocin is the standard drug used for active management of 3rd phase of labour in the present study the benefit of the same was extended to subjects of both the groups. However, in the study group, 1 gm TXA slow IV was added to the routine dose of oxytocin.

A randomized double-blinded control trial evaluated the importance of the timing of treatment. The study reported that every 15 minutes delay in administration was linked with a 10% decrease in the protection against bleeding-related mortality, and no substantial benefit was reported when the medicine was provided more than 3 hours after birth. Women in the TXA group (8.1%) had a lower incidence of clinically significant PPH as determined by the provider than those in the placebo group (9.8%). Amongst secondary outcomes, no significant difference was noted between the two. The occurrence of thromboembolic events in the three months after delivery was 0.1% and 0.2% for the TXA group and the placebo respectively.[8] The study suggests that used as a therapy for PPH, TXA must be administered as soon as feasible after the onset of bleeding.

Overall, amongst 230 women enrolled in our study limited to normal vaginal delivery, the half that received TXA showed better hemodynamics in comparison to the other half that did not receive TXA.

The parameters of the study i.e., PR and SBP were recorded at admission and one-hour post-delivery. The median change in SBP (cases- 6 mmHg versus controls- 10 mmHg) was not found to be significant ($p>0.05$). For PR, the median increase of 6 bpm was noted in the control group in comparison to a median decrease of 6 bpm in the intervention group and was highly significant ($p<0.05$) as a predictor of instability of hemodynamics.

These findings were comparable to an Indian analysis by Roy et al, where the effectiveness of parenteral TXA in lowering blood loss in normal labour was compared with the quantity of blood loss in patients who got a placebo in the 3rd phase of labour. In that research, the mean raise in PR was 1.40 bpm in the study group as well as 5.60 bpm in the control group ($p<0.001$), and the mean fall in SBP was 1.40 mmHg in the study group along with 3.30 mmHg in the control group ($p<0.001$).[9] However the study does not specify the dose used.

Although the current study, PR showed a substantial drop in postpartum in the intervention group, PR alone cannot be considered a good indicator for the prediction of blood loss or hemodynamic instability as there are many factors that affect PR in post-partum some of which include the physiological decline of PR in post-partum or increase due to fever, anxiety or pain.

The mean variation in HB in the placebo group was 1.2035 in comparison to 0.8762 in those who received TXA ($p<0.05$) while the median changes in HCT were 3% (IQR- 2-4.2%) and 2% (IQR- 1-3%) in controls and cases respectively ($p<0.05$). In comparison, Roy et al reported the mean drop in HB as 0.20 gm% in the study group and 0.70 gm% in the control group, and the mean drop in HCT as 0.40% in the study group as well as 1.20% in the control group ($p<0.001$).[9]

Since HB and HCT are not a good measure of acute blood loss and the incidence of PPH is maximum up to the fourth phase we estimated HB and HCT after the fourth phase of labour. Since SI is a parameter for the stability of hemodynamics the same was also calculated for all subjects.

The median SI post-delivery were 0.8182 (IQR- 0.7273-0.9) and 0.9 (IQR- 0.8-1.02) for cases and controls respectively. Although there was a statistically insignificant change in the value of SI post-delivery in the intervention group, a significant increase in the same was reported in the control group implying the role of the drug in maintaining the values of SI within the normal range.

Nathan et al also used SI as a predictor of PPH and proposed a value of SI≥0.9 for detecting women needing urgent high-level care.[10]

However, to the best of our knowledge, this is the 1st research of the kind evaluating the influence of prophylactic TXA usage in an otherwise normal delivery with SI as the parameter of haemodynamic.

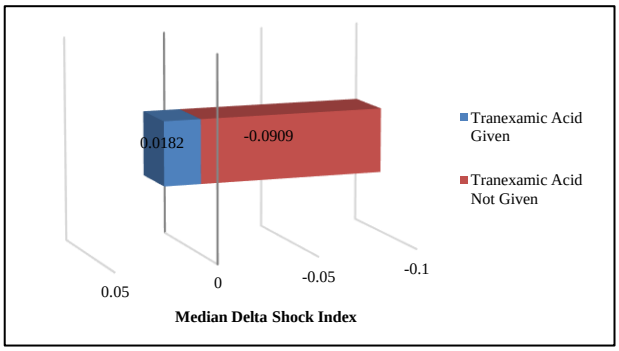

Figure 6: Delta shock index in cases and controls.

DSI (SI 1 minus SI 2) which is a change in SI at admission and one-hour post-delivery, the group receiving TXA had a median DSI of +0.0182 while the control group had a mean DSI of -0.0909 (Figure 6).

The negative sign with the value of DSI signifies a change in SI value towards the right i.e. increasing but with deteriorated hemodynamic. Similarly, the + sign indicates left shift with more stable hemodynamic and decreased blood loss and hence also decreased chances of PPH.

In the present study sensitivities and specificities of DSI were compared with SI 2. With the sensitivity and specificity of DSI being 69.6% and 67% respectively at a value of more than equal to -0.0385 and the sensitivity and specificity of SI 2 being 65.2% and 66.7% respectively at a value of more than equal to 0.8618 to predict hemodynamic changes, the study suggests DSI as a better tool than even SI for assessing the haemodynamic status of an individual.

Therefore, a single value of DSI indirectly predicts the level of blood loss. The range for DSI for the 50% population in our study was observed between -0.618 to +0.1182. The more the negative value, the more is the risk of blood loss.

One of the most dreaded complications of TXA is thrombosis and to evaluate the same, the cases were followed for 6 weeks postpartum. None of the cases reported thromboembolic events with a single dose of TXA. The findings were comparable to a work by Alam et al where minor side impacts were more prevalent in those who got TXA (OR, 2.51; 95% CI, 1.69-3.74; $p<0.00001$) without a higher risk of venous thromboembolism and no variation in the length of hospital stay related with TXA use.[11]

Strength of the study

Since this was a prospective randomized control, a comparative study between two groups, it shares strengths of accuracy and quality of data collection, and follow-up of subjects enrolled in the study. Moreover, this study used a large sample size (n=230) and enrolled patients over a long study period (1 year). Furthermore, the patient dropout rate was zero and none of the patients were lost to follow up.

Also, this study uses hemodynamic parameters such as SI and DSI for the prediction of PPH replacing the outdated methods of calculation of blood loss which were unreliable.

To the best of our knowledge, this is the 1st research assessing the prophylactic usage of TXA in terms of SI and DSI.

This study has some limitations. Though planned well while evaluating results it was felt that certain changes would have improved the quality of the study still further, which can be planned as another study.

The present study excluded the high-risk population which was factually more prone to PPH and the inclusion of the same as a 3rd group could have resulted in a better understanding of SI and DSI to need for and type of interventions required. Also, the effects of TXA on low-risk versus high-risk populations could have been compared. The study did not include the data on any tendency of excessive bleeding after the first hour since the maximum incidence of primary PPH occurs within the first few hours, but the tendency to bleed could have been studied after four hours again as the effect for TXA is expected to pass away after three hours or so. Probably including cases of PPH too would give a better prediction of the value of SI and DSI for the kind of intervention required. The study did not include the amount of blood loss as a factor to weigh the hemodynamic variables as it was neither practical nor accurate as reflected by literature. But doing so could have reflected the appropriate values at which a certain amount of blood loss highlights a change in hemodynamic stability. In our study, we could have also focussed on the dosage and timing of administration of TXA, multi-dosage versus single dose to study any benefits of giving it after 3 hours postpartum.

CONCLUSION

Postpartum haemorrhage is the leading cause of maternal morbidity and mortality. Treatment of PPH relies primarily on uterotonics, but TXA which is an antifibrinolytic agent and hence a different mode of action stands already proven to reduce the blood loss in operative delivery as well as in normal vaginal delivery both therapeutically as well prophylactically. This use may be of greater benefit in high-risk pregnancies prone for PPH but even in low-risk pregnancy it has a definite role as apparent from lower risk of PPH in the present study. Further the study confirms that in the study group using TXA for prophylaxis definitely has better haemoglobin preservation compared to those where TXA is not used. This is significant in developing countries with anaemia as a common phenomenon in women. Above all SI and DSI seem to be near perfect markers to assess the impact of blood loss on hemodynamic and should be incorporated in partographs. The drug comes with minor side effects like nausea, vomiting, dizziness to very rare major side effect of thromboembolism, however no such side-effects were observed with single dose of 1 gram of TXA. Thus, TXA is a safe drug for prophylactic use with other uterotonics to effectively reduce the blood loss and should be propagated for both low and high-risk pregnancies. TXA can be used as an adjunct to improve hemodynamics and prevent blood loss.

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Ethical approval: This research was performed on ethical standards for biomedical study on the human subject as outlined in the "Declaration of Helsinki" and by CEHER ("Central Ethics Committee on Human Research") of ICMR, New Delhi

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