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Original Research Article

Efficacy and safety of tranexamic acid in reducing blood loss in lower segment caesarean section: a prospective, randomised, double-blind and case-controlled study

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ABSTRACT

Background: Cesarean section (CS) rates are rising globally, and postpartum haemorrhage remains a major cause of maternal morbidity. Tranexamic acid (TXA), an antifibrinolytic agent, has been shown to reduce bleeding in various surgical settings, but its routine prophylactic use in CS requires further evaluation. This study aimed to assess the efficacy and safety of preoperative intravenous tranexamic acid in reducing blood loss during lower segment cesarean sections (LSCS).

Methods: This prospective, randomized, double-blind, placebo-controlled study was conducted at a tertiary care hospital in Chennai, India, from December 2015 to November 2016. A total of 100 term women undergoing LSCS under spinal anaesthesia were randomly assigned to receive either 1 gm TXA (n=50) or placebo (30 ml 5% dextrose, n=50) intravenously 20 minutes before skin incision. Both groups received 10 IU oxytocin after delivery. The primary outcome was estimated blood loss (EBL) calculated from changes in haematocrit. Secondary outcomes included postoperative hemoglobin (Hb), packed cell volume (PCV), the need for additional uterotonics, maternal side effects, neonatal APGAR scores, and thromboembolic events up to 6 weeks postpartum.

Results: The mean EBL was significantly lower in the TXA group compared to the placebo group (332. 62±172. 66 ml versus 413. 38±252. 21 ml; p=0.043). Postoperative Hb and PCV were preserved in the TXA group (with declines of 0.01 gm/dl and 0. 04%, respectively), whereas significant decreases occurred in the placebo group (declines of 1.00 gm/dl and 2.10%; p<0.0001). No patient in the TXA group experienced EBL>1000 ml versus two (4%) in the placebo group. Additional uterotonics were needed in 6% (TXA) and 12% (placebo) (p=0.294). Maternal side effects were mild and similar between groups (8% each). No thromboembolic events were observed in either group. Neonatal APGAR scores and NICU admission rates were comparable.

Conclusions: Preoperative intravenous tranexamic acid significantly reduces blood loss during and after caesarean section, with an excellent safety profile for both mother and neonate. Prophylactic TXA should be considered as a routine intervention in LSCS, particularly in settings where blood transfusion resources are limited.

Keywords: Antifibrinolytic, Blood loss, Caesarean section, Postpartum hemorrhage, Randomized controlled trial, Tranexamic acid

INTRODUCTION

The rate of cesarean section (CS) has increased substantially over the past few decades worldwide, with current estimates exceeding 25-30% in many countries. Although CS is an essential and often life-saving obstetric intervention, it is associated with a higher incidence of maternal complications compared to vaginal delivery, among which postpartum haemorrhage (PPH) remains one of the most significant causes of maternal morbidity and mortality. Primary and secondary PPH have been reported in up to 20% of women undergoing CS.[1-3] Lower segment cesarean section (LSCS) is typically associated with an average blood loss of 800-1000 ml, resulting in an approximate 10% reduction in haematocrit and a blood transfusion requirement of nearly 6%, which is higher than that observed following vaginal delivery.[1-3] In resource-limited settings, excessive perioperative blood loss additionally contributes to prolonged hospital stay, increased healthcare expenditure, delayed maternal recovery, and greater dependence on blood transfusion services.

Physiological hemostasis following placental separation is achieved through coordinated uterine contraction, platelet activation, and accelerated coagulation cascade activity. However, childbirth is also associated with marked activation of the fibrinolytic pathway. Increased release of plasminogen activators and degradation of fibrinogen and fibrin result in a transient hyperfibrinolytic state that may persist for several hours postpartum.[4,5] This exaggerated fibrinolytic response can impair clot stability and potentiate ongoing bleeding during and after caesarean delivery. Recognition of this mechanism has generated considerable interest in the prophylactic use of antifibrinolytic agents to minimise perioperative blood loss during LSCS.

Tranexamic acid (TXA), a synthetic lysine analogue, exerts its antifibrinolytic effect by competitively inhibiting the activation of plasminogen to plasmin and by blocking the interaction of plasmin with fibrin.[6,7] By stabilising fibrin clots and reducing fibrin degradation, TXA effectively attenuates excessive bleeding without directly influencing platelet count or coagulation factor synthesis. Pharmacokinetically, TXA has an initial distribution volume of approximately 9-12 l, demonstrates minimal protein binding except to plasminogen, and is excreted largely unchanged through the kidneys, with an elimination half-life of nearly 3 hours.[6,7] Previous studies have demonstrated that doses ranging from 10-15 mg/kg administered during caesarean delivery significantly reduce intraoperative and postoperative blood loss.[8] Emerging evidence also suggests that administration prior to skin incision, preferably 10-20 minutes before surgery, provides superior haemostatic benefit by suppressing fibrinolysis during its early activation phase.[9]

Despite its efficacy, the safety profile of TXA in obstetric practice remains an important consideration because pregnancy itself is a hypercoagulable state associated with a five- to six-fold increased risk of thromboembolic events. Nevertheless, available evidence from major clinical trials, including the CRASH-2 trial and subsequent obstetric studies, has not demonstrated a significant increase in thromboembolic complications with standard-dose TXA administration in bleeding patients.[10] The commonly reported adverse effects are generally mild and predominantly gastrointestinal, including nausea, vomiting, and diarrhoea. Rare complications such as hypotension, visual disturbances, and seizures have been reported mainly with rapid intravenous administration or very high doses.[11,12] Although TXA crosses the placenta and achieves measurable cord blood concentrations, breast milk levels remain extremely low, making clinically significant neonatal antifibrinolytic effects unlikely.[13]

The expanding evidence supporting TXA in trauma, orthopaedic surgery, cardiac surgery, and obstetric haemorrhage has renewed interest in its prophylactic application during cesarean section. In obstetrics, TXA is already widely accepted in the management of heavy menstrual bleeding and established PPH. Furthermore, recent randomised controlled trials and meta-analyses have demonstrated meaningful reductions in perioperative blood loss, fall in haemoglobin levels, and requirement for additional uterotonics following prophylactic TXA administration during LSCS, without a corresponding increase in serious maternal adverse events. However, variability persists regarding optimal timing, dosage, patient selection, and safety outcomes across different populations. Considering the rising global CS rates and the ongoing burden of obstetric haemorrhage, further evaluation of TXA in diverse clinical settings remains clinically relevant.

Therefore, the present study was undertaken to evaluate the efficacy and safety of tranexamic acid in reducing blood loss during lower segment caesarean section.

METHODS

Study site and design

This prospective, randomized, double blind, case-controlled study was conducted in the department of obstetrics and gynecology at CSI Rainy Multispeciality Hospital, Chennai, from December 1, 2015, to November 30, 2016.

The study was approved by the institutional ethics committee, and all participants provided written informed consent.

Study population

The study population comprised term antenatal mothers (≥37 weeks gestation) who underwent cesarean section under spinal anaesthesia. A total of 100 participants were enrolled and allocated into two groups of 50 each.

Sample size calculation

The sample size was calculated based on a previous study by Yahia et al, which reported a mean total blood loss of 369.5 ml (SD 198) in the TXA group and 606.8 ml (SD 193) in the control group.[1] The pooled standard deviation was estimated as 194.25. With a significance level of 0.1% (α=0.001, z=3.2905) and a power of 95% (β=0.05, z=1.6449), the required sample size per group was 33. To further strengthen the study, the sample size was increased to 50 per group, for a total of 100 participants.

Sampling procedure

Randomization was performed using a coin toss method. Each eligible patient was asked to toss a coin; "heads" allocated the patient to the study group (TXA) and "tails" to the control group (placebo). The process continued until one group reached 50 participants, after which all subsequent eligible patients were enrolled into the remaining group. This method ensured double blinding, as neither the patient nor the investigator was aware of the allocation until after the intervention.

Inclusion criteria

Women with a singleton term pregnancy (≥37 weeks) undergoing LSCS under spinal anaesthesia, parity ≤2, and who provided written informed consent.

Exclusion criteria

Women with medical disorders complicating pregnancy (heart, liver, or renal disease), pre-existing hemostatic abnormalities, allergy to TXA, or conditions associated with increased risk of PPH: anemia (Hb <7 gm/dl), antepartum hemorrhage, abnormal placentation (e.g., placenta previa), uterine fibroids, macrosomia (>4500 gm), multiple pregnancy, or polyhydramnios.

Intervention

Group A (case group, n=50): received 1 gm of TXA (1 gm/10 ml diluted with 20 ml of 5% glucose) by slow intravenous injection over 2 minutes, at least 20 minutes before skin incision. After delivery of the baby, they received 10 IU of oxytocin in 500 ml Ringer's lactate. Group B (control group, n=50): received 30 ml of 5% dextrose (placebo) intravenously over 2 minutes, also at least 20 minutes before skin incision. After delivery, they received 10 IU of oxytocin in 500 ml Ringer's lactate.

Maternal assessment

Pre operative assessment

Demographic and clinical details were recorded. Baseline laboratory investigations included hemoglobin (Hb), packed cell volume (PCV), prothrombin time (PT), total platelet count (TPC), liver function tests (AST, ALT), and renal function tests (urea, creatinine). Vital signs (heart rate, blood pressure, respiratory rate) were documented.

Intraoperative and postoperative assessment

Vital signs were monitored during surgery and for the first 2 postoperative hours. The use of additional uterotonic agents (e.g., carboprost, methylergometrine) was recorded. Postoperative vaginal bleeding was quantified by counting soaked pads (one soaked pad =50 ml). At 48 hours post-delivery, Hb, PCV, PT, TPC, LFT, and RFT were repeated. Estimated blood loss (EBL) was calculated using the formula:

EBL = EBV × (pre operative Hct – post operative Hct) / pre operative Hct, where estimated blood volume (EBV) in ml = woman's weight (kg) × 85.

Excessive bleeding was defined as EBL>1000 ml. Maternal side effects (nausea, vomiting, diarrhoea, headache) were recorded.

Follow up

All participants were followed up at 3 weeks and 6 weeks post-delivery to assess for thromboembolic events (deep venous thrombosis, pulmonary embolism, stroke, myocardial infarction). They were provided with written instructions and a symptom diary and were asked to report any concerning symptoms immediately.

Neonatal assessment

Neonatal outcomes evaluated included APGAR scores at 1 and 5 minutes, birth weight, and the need for NICU admission with the underlying indication.

Statistical analysis

Data were entered into Microsoft Excel and analyzed using SPSS version 17. Continuous variables were expressed as mean±standard deviation (SD) and compared using Student's t test (paired for within group, unpaired for between group comparisons). Categorical variables were analyzed using the chi square test or Fisher's exact test as appropriate. A p value <0.05 was considered statistically significant.

RESULTS

Baseline characteristics were comparable between groups. The mean age was similar in the TXA and control groups (24.90±2.16 versus 24.94±2.22 years; p=0.92). Most participants were aged 20-30 years [TXA: 50 (100%) versus control: 49 (98%)]. Primigravida constituted 28 (56%) in the TXA group and 27 (54%) in controls (p=0.84). Emergency cesarean sections were performed in 25 (50%) and 28 (56%) patients, respectively (p=0.55). Socioeconomic distribution was similar across groups (p=0.31).

Table 1: Baseline characteristics of study participants.

Characteristics	TXA group (n=50) (%)	Control group (n=50) (%)	P value
Age (years), mean±SD	24.90±2.16	24.94±2.22	0.92
20-24	26 (52.0)	25 (50.0)	0.98
25-30	24 (48.0)	24 (48.0)	
>30	0 (0.0)	1 (2.0)	
Primigravida	28 (56.0)	27 (54.0)	0.84
Multigravida	22 (44.0)	23 (46.0)	
Emergency LSCS	25 (50.0)	28 (56.0)	0.55
Elective LSCS	25 (50.0)	22 (44.0)	
Socioeconomic class I-II	1 (2.0)	0 (0.0)	0.31
Socioeconomic class III-V	49 (98.0)	50 (100.0)	

Table 2: Primary and secondary efficacy outcomes.

Outcomes	TXA group (n=50) (%)	Control group (n=50) (%)	P value
Estimated blood loss (ml), mean±SD	332.62±172.67	413.38±252.21	0.043
Additional uterotonics required	3 (6.0)	6 (12.0)	0.29
Hemoglobin (gn/dl), pre-op mean±SD	11.76±1.03	12.42±1.02	0.001
Hemoglobin (gm/dl), post-op mean±SD	11.75±1.03	11.41±1.21	0.12
Hemoglobin drop (gm/dl), mean±SD	0.01±0.20	1.01±0.45	<0.001
Packed cell volume (%), pre-op	34.72±3.92	35.04±3.90	0.68
Packed cell volume (%), post-op	34.68±3.84	32.94±3.51	0.02

Table 3: Perioperative laboratory safety parameters.

Parameters	TXA pre-op	TXA post-op	Control pre-op	Control post-op	P value (between groups post-op)
Hemoglobin (gm/dl)	11.76±1.03	11.75±1.03	12.42±1.02	11.41±1.21	0.12
Packed cell volume (%)	34.72±3.92	34.68±3.84	35.04±3.90	32.94±3.51	0.02
Prothrombin time (seconds)	12.29±0.94	12.17±0.95	11.99±0.73	11.96±0.74	0.07
Platelet count ($\times 10^5$/mm^3)	2.73±0.51	2.71±0.50	2.60±0.52	2.61±0.47	0.45
Blood urea (mg/dl)	18.57±4.21	18.16±3.88	18.31±3.51	18.49±3.27	0.17

Estimated blood loss was significantly lower in the TXA group compared to controls (332.62±172.67 versus 413.38±252.21 ml; p=0.043). Additional uterotonic requirement was lower in the TXA group [3 (6%) versus 6 (12%)], though not statistically significant (p=0.29). The mean haemoglobin drop was minimal in the TXA group (0.01±0.20 gm/dl) compared to the control group (1.01±0.45 gm/dl), which was statistically significant (p<0.001). Postoperative packed cell volume was also significantly higher in the TXA group (34.68±3.84% versus 32.94±3.51%; p=0.02).

There were no statistically significant differences in coagulation, renal, or liver function parameters between the two groups. Prothrombin time, platelet count, and blood urea levels remained stable pre- and postoperatively in both groups (p>0.05). Similarly, no significant changes were observed in serum creatinine, AST, or ALT levels, indicating that tranexamic acid did not adversely affect laboratory safety parameters.

Adverse effects were mild and comparable between groups. Overall, 4 (8%) patients in each group experienced minor side effects (p=1.00). Nausea was the most common symptom [TXA: 3 (6%) versus control: 2 (4%); p=0.64]. No thromboembolic events were reported in either group.

Table 4: Maternal adverse effects.

Adverse effects	TXA group (n=50) (%)	Control group (n=50) (%)	P value
Any adverse effect	4 (8.0)	4 (8.0)	1.00
Nausea	3 (6.0)	2 (4.0)	0.64
Vomiting	0 (0.0)	1 (2.0)	0.31
Headache	1 (2.0)	1 (2.0)	1.00
Thromboembolic events	0 (0.0)	0 (0.0)	—

Neonatal outcomes were comparable between groups. The mean APGAR score did not differ significantly (7.52±0.50

versus 7.42±0.50; p=0.13). NICU admissions occurred in 3 (6%) neonates in both groups (p=1.00), indicating no adverse neonatal effect of tranexamic acid. Neonatal outcomes were comparable between the two groups. The mean 5-minute APGAR score was 7.52±0.50 in the case group and 7.42±0.50 in the control group, with no statistically significant difference (p=0.128). NICU admission was required for three neonates (6.0%) in each group, all for physiological jaundice. No adverse neonatal events attributable to tranexamic acid were observed, and there were no cases of perinatal asphyxia or neonatal seizures in either group.

Table 5: Neonatal outcomes.

Outcome	TXA group (n=50) (%)	Control group (n=50) (%)	P value
APGAR score, mean±SD	7.52±0.50	7.42±0.50	0.13
NICU admission	3 (6.0)	3 (6.0)	1.00
No NICU admission	47 (94.0)	47 (94.0)	-

DISCUSSION

The present prospective, randomized, double blind, placebo-controlled study evaluated the efficacy and safety of prophylactic tranexamic acid (TXA) in reducing blood loss during lower segment cesarean section. Our results demonstrate that a single preoperative intravenous dose of 1 gm TXA significantly reduces estimated blood loss (332.62±172.66 ml versus 413.38±252.21 ml; p=0.043) and preserves postoperative hemoglobin and hematocrit levels compared to placebo. Importantly, no increase in maternal or neonatal adverse events was observed, and no thromboembolic complications were reported during six weeks of follow up.

Reduction in blood loss and preservation of hematological parameters

The significant reduction in estimated blood loss (approximately 80 ml less in the TXA group) aligns with findings from several randomized controlled trials. Gungorduk et al reported a mean blood loss of 499.9±206.4 ml in the TXA group versus 600.7±215.7 ml in controls (p<0.001).[14] Similarly, Movafegh et al found that TXA reduced both intraoperative and postoperative blood loss by approximately 35%.[15] The magnitude of reduction in our study (about 19%) is slightly lower than in some reports, possibly due to differences in baseline patient characteristics, surgical technique, or the method of blood loss estimation. Nonetheless, the preservation of postoperative hemoglobin and PCV in the TXA group (mean fall 0.01 gm/dl and 0.04%, respectively) compared with the significant declines in the placebo group (mean fall 1.0 gm/dl and 2.1%) confirms the clinical benefit of TXA in reducing perioperative bleeding.

Safety profile and adverse events

Concerns regarding the use of TXA in obstetric patients have focused on the potential for thromboembolic events, given the hypercoagulable state of pregnancy. In our study, no clinical evidence of deep vein thrombosis, pulmonary embolism, or other vascular occlusive events was observed during the 6-week postpartum period. This is consistent with the findings of a large meta-analysis by Bellos et al, which reported no increased risk of thromboembolism with prophylactic TXA in caesarean section.[16] Similarly, the CRASH 2 trial in trauma patients and the WOMAN trial in postpartum hemorrhage have not identified an excess of thrombotic events with TXA use.[10,17] The incidence of minor side effects (nausea, vomiting, headache) was low and did not differ between groups, mirroring the safety profile reported in earlier studies.[14]

Neonatal outcomes

TXA crosses the placenta, but neonatal outcomes in our study were reassuring. APGAR scores and NICU admission rates were comparable between groups, and no neonate required treatment for TXA related adverse effects. These findings support the observations of other investigators that TXA does not adversely affect neonatal well-being.[18,19]

Comparison with other studies

Our results are in line with a substantial body of evidence. A meta-analysis by Wang et al of 11 RCTs (2531 women) concluded that TXA significantly reduced total blood loss (mean difference -141.61 ml), postpartum hemorrhage rate (RR 0.57), and need for blood transfusion (RR 0.23).[20] Likewise, a Cochrane review by Novikova and Hofmeyr noted that TXA decreased blood loss after both vaginal and cesarean delivery.[21] The consistency of these findings across diverse populations and settings strengthens the case for routine prophylactic TXA in cesarean section.

Our study has few limitations. First, the sample size (100 participants) was modest, and the study was conducted at a single center, which may limit generalizability. Second, estimated blood loss was calculated using a formula based on hematocrit change, which, while practical, is less precise than direct measurement techniques such as collection in calibrated drapes or photometric analysis. However, this method is widely accepted and correlates well with actual blood loss. Third, we excluded women with major risk factors for postpartum hemorrhage (e.g., placenta previa, severe anemia, macrosomia), so our findings may not be directly applicable to high-risk populations. Fourth, follow up for thromboembolic events relied on clinical symptoms and patient diaries rather than routine imaging or laboratory screening, which could underestimate subclinical events.

Given the mounting evidence of efficacy and safety, prophylactic TXA should be considered as a standard

adjunct for women undergoing caesarean section, particularly in settings where blood transfusion is less readily available or in women with pre-existing anemia. The reduction in blood loss may also contribute to lower rates of postpartum anemia and improved maternal recovery. Future research should focus on larger, multicentre trials to evaluate the cost effectiveness of routine TXA use and to determine optimal dosing regimens (e.g., 1 gm versus 15 mg/kg). Additionally, studies specifically targeting high risk cohorts (e.g., women with placenta previa, multiple gestation, or coagulopathies) are needed to confirm benefit in these groups. Long term follow-up for rare adverse events, including thromboembolism, would further strengthen the safety profile.

CONCLUSION

This study confirms that a single preoperative dose of tranexamic acid significantly reduces blood loss during and after lower segment caesarean section, with no increase in maternal or neonatal adverse effects, including thromboembolic events. TXA is a safe, effective, and inexpensive intervention that should be incorporated into routine perioperative care for caesarean delivery, especially in resource limited settings where the impact of even modest reductions in blood loss can be substantial.

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