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Intravenous Tranexamic Acid in Lower Segment Caesarean Section: A Randomized Controlled Trial on Blood Loss

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Abstract

Introduction: With the rising global incidence of Caesarean sections (CS), managing perioperative blood loss has become a critical concern. Tranexamic acid (TXA), an antifibrinolytic agent, has demonstrated efficacy in reducing blood loss in various surgical procedures. This study evaluates the prophylactic role of TXA in reducing intraoperative and early postoperative blood loss during lower segment Caesarean section (LSCS).

Material and Methods: A single-blind randomized controlled trial was conducted over 18 months at a tertiary care hospital in North India. Seventy term pregnant women undergoing elective or emergency LSCS were randomized into two groups. Group I received 1g intravenous TXA 30 minutes before skin incision, while Group II underwent standard management without TXA. Blood loss was measured intraoperatively and up to two hours postoperatively using both visual and objective methods. Hematocrit levels were assessed preoperatively and on postoperative Day 2. Data were analyzed using SPSS v20, with $p<0.05$ considered statistically significant.

Results: Group I showed significantly lower intraoperative (306.03 ± 121.21 mL vs. 482.29 ± 162.41 mL) and total blood loss (355.46 ± 122.68 mL vs. 536.86 ± 162.89 mL) compared to Group II ($p<0.001$). The mean hematocrit drop was also lower in the TXA group (3.08% vs. 4.35%, $p<0.001$). No patient required blood transfusion or additional uterotonics.

Conclusion: Prophylactic intravenous TXA significantly reduces perioperative blood loss and hematocrit decline during LSCS, supporting its safe and effective use in obstetric surgery.

Keywords: Tranexamic acid, Caesarean section, Blood loss, Hematocrit, Randomized controlled trial

Introduction

Globally, more than 18 million Caesarean section (CS) deliveries are performed each year, representing approximately 19.1% of all births. [1] This marks a substantial increase from the global CS rate of 7% reported in 1990, with projections suggesting a rise to 29% by 2030.[2] Both developed and developing nations are experiencing high CS rates, currently estimated at 27.2% and 20.9%, respectively, with Asia reporting the highest annual increase at 6.4%.[3] In India, the proportion of CS deliveries has escalated significantly—from 3% in 1992–93 to 21.5% in 2019–21—highlighting a marked upward trend.[4]

Tranexamic acid (TXA), a synthetic antifibrinolytic agent structurally related to lysine, acts by reversibly inhibiting the activation of plasminogen to plasmin, thereby preventing the degradation of fibrin clots and reducing hemorrhage. While TXA has been widely utilized in various surgical disciplines such as hepatic transplantation, orthopedic surgery, and transurethral prostate resection, its prophylactic role in obstetric practice—particularly in the prevention of postpartum hemorrhage (PPH)—remains underexplored.[5] Although current evidence supports the therapeutic efficacy of TXA in the management of established PPH, limited data exist regarding its effectiveness when administered prophylactically during lower segment Caesarean section (LSCS).[6]

The present study aims to evaluate the efficacy and safety of intravenous TXA administered within 30 minutes prior to LSCS in reducing intraoperative and immediate postpartum blood loss, thereby potentially improving maternal outcomes.

Materials and Methods

This single-blind, randomized, controlled trial was conducted in the Department of Obstetrics and Gynaecology at the tertiary care center in North India over a period of 18 months, from September 2022 to March 2024. The study was initiated following approval from the Institutional Ethics Committee (IEC approval number to be inserted) and was

conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines. Written informed consent was obtained from all participants prior to enrolment.

A total of 70 pregnant women scheduled to undergo elective or emergency lower segment Caesarean section (LSCS) were recruited based on predefined inclusion and exclusion criteria. Inclusion criteria comprised women aged 18–40 years with singleton term pregnancies (≥37 weeks gestation) undergoing LSCS for standard obstetric indications. Exclusion criteria included known coagulopathies, antepartum hemorrhage, thromboembolic disorders, pre-existing cardiovascular or renal disease, hypersensitivity to tranexamic acid, and refusal to consent. Participants were randomized into two equal groups (n = 35 per group) using computer-generated block randomization (block size of 4) with a 1:1 allocation ratio. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes. The trial was single-blind, with participants unaware of their group assignment, although the surgical and anesthetic teams were aware due to the nature of the intervention.

Group I (intervention group) received 1 gram of tranexamic acid diluted in 100 mL of normal saline, administered intravenously over 10 minutes, 30 minutes prior to skin incision. Group II (control group) received no tranexamic acid but underwent the standard operative protocol. Both groups received routine preoperative medications, including intravenous ceftriaxone-sulbactam (1.5 g), metoclopramide (10 mg), and pantoprazole (40 mg), administered approximately 30 minutes before the procedure. All Caesarean sections were performed under spinal anesthesia by experienced obstetric surgeons using a standardized surgical technique. Active management of the third stage of labor (AMTSL) was ensured in all cases, with the administration of 10 IU of intravenous oxytocin immediately after delivery to the neonate. Intraoperative blood loss was measured using both objective and visual estimation methods. Objective quantification involved weighing surgical mops and drapes before and after use and measuring the volume of blood in suction containers, subtracting the amount of amniotic fluid and irrigation fluid. Postoperative blood loss was assessed using gravimetric analysis of vaginal pads over the first 2 hours following surgery.

Maternal vital signs (pulse rate, blood pressure, oxygen saturation, and temperature) were closely monitored intraoperatively and for two hours postoperatively. Hematocrit levels were measured preoperatively (within 24 hours before surgery) and on postoperative Day 2 to assess any significant drop, serving as an indirect marker of blood loss. Data were entered and analyzed using IBM SPSS Statistics for Windows, Version 20.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD) and compared using independent t-tests or paired t-tests, as appropriate. Categorical variables were presented as frequencies and percentages and analyzed using the chi-square test or Fisher's exact test. A p-value of ≤0.05 was considered statistically significant.

Results

Table no 1: Distribution of patients according to preoperative and postoperative mean hematocrit difference in both groups

Mean Hematocrit (in %)	Group I			Group II		
	n	Mean	SD	n	Mean	SD
Pre operative	35	35.634%	3.491	35	35.397%	3.152
Post operative	35	32.551%	3.493	35	31.043%	3.195
Mean difference	3.083			4.354		
p value	< 0.001			< 0.001		

Group I demonstrated a preoperative mean hematocrit (HCT) level of 35.63%, which declined to 32.55% postoperatively, reflecting a mean reduction of 3.08%. In contrast, Group II exhibited a preoperative mean HCT of 35.40%, which decreased to 31.04% postoperatively, corresponding to a mean reduction of 4.35%. The difference in mean hematocrit reduction between the two groups was statistically significant ($p < 0.001$), indicating a greater decline in HCT values among participants who did not receive tranexamic acid. These findings suggest that prophylactic administration of tranexamic acid was associated with reduced perioperative hematocrit loss in women undergoing lower segment Caesarean section.

Table no 2: Distribution of patients according to Total Blood Loss estimated by visual assessment

Total Blood Loss (in ml)	Group					
	Group-I		Group-II		Total	
	n	%	n	%	N	%
<500	31	88.6%	13	37.1%	44	62.9%
500-1000	4	11.4%	22	62.9%	26	37.1%
>1000	0	0.0%	0	0.0%	0	0.0%
Total	35	100.0%	35	100.0%	70	100.0%
Mean	355.46 ±122.68		536.86 ± 162.89		446.16 ± 169.81	
p-value <0.001, chi square 19.825						

In Group I (tranexamic acid group), the majority of patients (88.6%) experienced intraoperative blood loss of less than 500 mL. Conversely, in Group II (control group), a substantial proportion (62.9%) recorded blood loss in the range of 500–1000 mL. Notably, no patients in either group had blood loss exceeding 1000 mL.

The mean estimated blood loss in Group I was 355.46 ± 122.68 mL, compared to 536.86 ± 162.89 mL in Group II. The difference in blood loss between the two groups was statistically significant, as evidenced by a chi-square value of 19.825 and a p-value of 0.0001. Importantly, none of the participants in either group required the administration of additional uterotonic agents or hemostatic drugs to manage intraoperative or immediate postoperative bleeding.

Table no 3: Distribution of patients according to mean blood loss (intraop and post operative till 2 hrs post op) estimated by visual assessment

Blood Loss by visual assessment (in ml)	Group						t- value	p-value
	Group-I			Group-II				
	n	Mean	SD	n	Mean	SD		
Intra OP	35	306.03	121.21	35	482.29	162.41	5.145	.0001**
Post OP (up to 2 hrs)	35	49.43	19.70	35	48.57	18.49	.188	.852
Total	35	355.46	122.68	35	536.86	162.89	5.263	.0001**

The mean intraoperative blood loss was significantly lower in Group I (tranexamic acid group), measuring 306.03 ± 121.21 mL, compared to 482.29 ± 162.41 mL in Group II (control group). This difference was statistically significant ($t = 5.145$, $p < 0.0001$). However, postoperative blood loss measured up to two hours post-surgery did not differ significantly between the groups. Group I had a mean postoperative blood loss of 49.43 ± 19.70 mL, while Group II recorded 48.57 ± 18.49 mL ($t = 0.188$, $p = 0.852$). When intraoperative and postoperative losses were combined, total blood loss was significantly reduced in Group I, with a mean of 355.46 ± 122.68 mL, compared to 536.86 ± 162.89 mL in Group II ($t = 5.263$, $p < 0.0001$). These findings underscore the efficacy of prophylactic intravenous tranexamic acid in reducing overall blood loss associated with lower segment Caesarean section.

Table no 4: Distribution of patients according to objective assessment of blood loss

Total Blood Loss (in ml)	GROUP I		Group II		TOTAL	
	n	%	n	%	n	%
<500	21	60.0%	11	31.4%	32	45.7%
500-1000	14	40.0%	24	69.6%	35	50.0%
>1000	0	0.0%	0	0.0%	0	0
Total	35	100.0%	35	100.0%	70	100.0%
MEAN	452.649 ± 188.403		644.227 ± 225.571			
P value	.0001**					

In Group I (tranexamic acid group), 60.0% of patients experienced total blood loss of less than 500 mL, while the remaining 40.0% had blood loss ranging from 500 to 1000 mL. In contrast, only 31.4% of patients in Group II (control group) had blood loss below 500 mL, whereas 68.6% experienced blood loss between 500 and 1000 mL.

The mean total blood loss was significantly lower in Group I at 453.65 ± 188.40 mL, compared to 644.23 ± 225.57 mL in Group II, yielding a mean difference of 190.58 mL. This substantial difference reinforces the efficacy of prophylactic tranexamic acid in reducing perioperative blood loss during lower segment Caesarean section. Notably, no patient in either group had blood loss exceeding 1000 mL. Furthermore, no participants required the use of additional hemostatic agents or blood transfusion, indicating satisfactory bleeding control in both groups without the need for escalated medical intervention.

Discussion

Perioperative Hematocrit Levels and Blood Loss

Hematocrit (HCT) values are an indirect yet clinically significant measure of perioperative blood loss, especially in the setting of obstetric surgery, such as the lower segment of the Caesarean section (LSCS). In this randomized trial in progress, a considerable postoperative reduction in HCT values was observed in both groups of study; however, the reduction was much smaller in the tranexamic acid (TXA) group (from 35.63 ± 3.49% to 32.55 ± 3.49%) compared to the control group (from 35.40 ± 3.15% to 31.04 ± 3.19%). Such a variation indicates that TXA prophylactic administration reduces perioperative blood loss considerably. The results of the current study are in line with existing studies. Farahat et al. (2019)[7] had previously reported the same protective effect of TXA on hematocrit levels with a lesser drop in the TXA group (33.0 ± 3.7% to 31.8 ± 1.5%) compared to the control group (32.9 ± 1.6% to 29.1 ± 1.0%). Similarly, Oseni et al. (2021)[8] observed a significantly lower reduction in HCT in patients administered TXA. Such similarity among various studies supports the hypothesis that TXA plays a role in stabilizing fibrin matrices and avoiding capillary leakage during surgery, thus allowing red cell mass maintenance.

Intraoperative and Postoperative Blood Loss

The intraoperative blood loss in the TXA group was significantly less (mean: 306.03 ± 121.21 mL) compared with the non-TXA group (mean: 482.29 ± 162.41 mL), reflecting a strong hemostatic effect of TXA intraoperatively. Postoperative blood loss within the first two hours, however, was not significantly different between the groups, implying that TXA's major effect is intraoperative and not extended into the early postoperative period. This is consistent with evidence from Malathi et al. (2016)[9], who observed less intraoperative blood loss in the TXA group (375 ± 69 mL vs. 410 ± 79.9 mL). Likewise, Agarwal et al. (2021)[10] observed a statistically significant decrease in intraoperative loss (517.12 ± 72.07 mL vs. 735 ± 109.95 mL). The difference in absolute values of blood loss in these and our studies may be due to technique. While our study used visual estimation—a subjective but standard approach—others used gravimetric or suction measurements, which are more objective and may provide lower or more uniform values. Mathumitha et al. (2023)[11] utilized a combined method of gauze weighing and suction collection and reported overall intraoperative losses to be less. Yet, the trend of less bleeding in the TXA group was uniform and supported the effectiveness of the drug regardless of the assessment method.

Total Blood Loss: Visual and Objective Comparisons

When overall blood loss is brought into account, the TXA group had significantly lower mean blood loss (355.46 ± 122.68 mL) than the non-TXA group (536.86 ± 162.89 mL). Visual estimation per se is a source of observer variability and underestimation, and yet the divergence between the two groups recorded is still clinically meaningful and statistically significant. Gravimetric and mathematical models previously (Farahat et al., 2019)[7] have documented even larger absolute differences, adding weight to the hypothesis that TXA makes an important contribution toward hemostasis in LSCS. For example, Agarwal et al. (2021)[10] showed a decrease in mean blood loss from 850.74 ± 119.49 mL in the non-TXA group to 582 ± 73.25 mL in the TXA group, gravimetrically measured. Similarly, Lakshmi et al. (2016)[12], Roy et al. (2018)[13], and Bhagyajyoti et al. (2022)[14] showed comparable decreases in blood loss due to TXA in different populations and clinical contexts.

Methodological Issues: Visual Inspection vs. Objective Analysis

A significant finding in our research was the visual underestimation of total blood loss, a limitation that has been well-documented in the literature. Hancock et al. (2015)[15] and Thurer et al. (2017)[16] pointed out that visual estimation of blood loss often underestimates true blood loss, which may delay the identification and treatment of postpartum hemorrhage (PPH). Objective methods, including gauze weighing, suction measurement, spectrophotometric measurement, and algorithmic mathematical models (which use hematocrit differentials and body weight), are more accurate and reproducible.

While taking longer, they enhance clinical decision-making and can be invaluable in resource-limited or high-risk surgical settings. The persistent underestimation in visual evaluation, as shown in our findings, emphasizes the necessity of integrating objective measures of quantifying blood loss into routine obstetric care, particularly when evaluating the efficacy of pharmacologic interventions such as TXA. This would improve accuracy in clinical studies while simultaneously improving maternal safety through the elimination of delays in interventions.

Conclusion

The present randomized controlled trial demonstrates that prophylactic administration of intravenous tranexamic acid prior to lower segment cesarean section significantly reduces intraoperative and total perioperative blood loss, with a corresponding attenuation in the decline of hematocrit levels, thereby highlighting its efficacy as a blood-conserving strategy in obstetric surgery. The strengths of this study include its randomized design, standardized timing of drug administration, and comparative evaluation using both visual and objective assessment techniques. However, limitations such as reliance on visual estimation for intraoperative blood loss, potential observer bias, and the absence of long-term maternal or neonatal outcome data may restrict the generalizability of findings. Future multicentric studies with larger sample sizes and standardized gravimetric or photometric blood loss measurement methods are warranted to further validate the clinical utility and safety profile of tranexamic acid in diverse obstetric populations.

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References

1. Kambo I, Bedi N, Dhillon BS, Saxena NC. A critical appraisal of cesarean section rates at teaching hospitals in India. Int J Gynaecol Obstet. 2002;79:151-8.
2. Betran AP, Ye J, Moller AB, Souza JP, Zhang J. Trends and projections of caesarean section rates: global and regional estimates. BMJ Glob Health.2021;6:e005671.
3. Roy A, Paul P, Chouhan P, Rahaman M, Kapasia N. Geographical variability and factors associated with caesarean section delivery in India:a comparative assessment of Bihar and Tamil Nadu. BMC Public Health. 2021;21:1715.
4. Kwawukume E. Caesarean section in developing countries. Best Pract Res Clin Obstet Gynaecol. 2001;15:165-78.
5. Gai MY, Wu LF, Su QF, Tatsumoto K. Clinical observation of blood loss reduced by Tranexamic acid during and after caesarean section: a multicentre randomized trial. Eur J Obstet Gynecol Reprod Biol. 2004;112:154-7.
6. Astedt B. Clinical pharmacology of tranexamic acid. Scand J Gastroenterol. 1987;137:22-5.
7. Farahat MA. Role of intravenous tranexamic acid on cesarean blood loss: a prospective randomized study. J Women's Health. 2019;8:226-30.
8. Oseni RO, Zakari M, Adamou N, Umar UA. Effectiveness of preoperative tranexamic acid in reducing blood loss during caesarean section at Aminu Kano Teaching Hospital, Kano: a randomized controlled trial. Pan Afr Med J. 2021;39(1).
9. Malathi P, Anupama D, Habitha P. Effect of injection Tranexamic acid on perioperative blood loss during Cesarean section. Int Arch Integr Med. 2016;3:280-9.
10. Agarwal N, Lahiri A. Determining the role of prophylactic tranexamic acid in reducing blood loss during and after lower segment caesarean section.J Adv Med Med Res. 2021:153.
11. Mathumitha K, Gopalan U. Role of prophylactic use of tranexamic acid in reducing blood loss during caesarean section in a tertiary care hospital. Indian J Obstet Gynecol Res. 2023;10:126-30.
12. Lakshmi SD, Abraham R. Role of prophylactic tranexamic acid in reducing blood loss during elective caesarean section: a randomized controlled study. J Clin Diagn Res. 2016;10:QC17.
13. Roy I, Chakraborty S, Mukhopadhya S. Role of intravenous tranexamic acid on cesarean blood loss: A prospective randomized study. Trop J Obstet Gynaecol. 2018;35:49-53.
14. Bhagyajyoti, Usharani N, Pratibha A. Role of prophylactic tranexamic acid in reducing blood loss during and after the lower segment caesarean section: a randomized clinical trail. J Cardiovasc Dis Res. 2022;30:43-47.
15. Hancock A, Weeks AD, Lavender DT. Is accurate and reliable blood loss estimation the 'crucial step' in early detection of postpartum haemorrhage: an integrative review of the literature. BMC Pregnancy Childbirth. 2015;15:1-9.
16. Thurer RL, Castro JM, Javidroozi M, Burton K, Bernal NP. Accurate measurement of intraoperative blood loss improves prediction of postoperative hemoglobin levels. J Anesth Clin Res. 2017;8:1-7