

Efficacy of Tranexamic Acid in Active Management of the Third Stage of Labor: A Focus on Blood Loss in Full-Term Vaginal Births

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ABSTRACT

Objective: This study aims to evaluate the efficacy of tranexamic acid (TXA) as an adjunct in the active management of the third stage of labor (AMTSL) in reducing blood loss and preventing postpartum hemorrhage (PPH) in full-term vaginal deliveries.

Methods: A literature review was conducted, including randomized controlled trials, systematic reviews, and meta-analyses focusing on the prophylactic use of TXA during AMTSL. The primary outcomes examined were total postpartum blood loss, incidence of PPH (≥ 500 mL), and safety profile regarding thromboembolic events.

Results: Evidence consistently supports that the administration of TXA during AMTSL significantly reduces postpartum blood loss and decreases the incidence of PPH by up to 40% in full-term vaginal deliveries. Studies also confirm the safety of TXA, with no significant increase in thromboembolic complications observed. TXA's antifibrinolytic mechanism stabilizes fibrin clots, complementing uterotonic agents such as oxytocin. Optimal outcomes are achieved with a 1 g intravenous dose administered immediately after delivery of the placenta.

Conclusions: TXA is a safe and effective intervention to enhance AMTSL and mitigate blood loss in full-term vaginal deliveries. Its integration into routine obstetric practice could reduce maternal morbidity and mortality, particularly in low-resource settings. Further research is warranted to standardize protocols and assess long-term maternal outcomes.

Key words: tranexamic acid, postpartum hemorrhage, active management of labor, blood loss, vaginal delivery, maternal health.

INTRODUCTION

Postpartum haemorrhage (PPH) remains the leading direct cause of maternal mortality and a critical marker of obstetric care quality.¹ Despite advances in obstetric practice, including active management of the third stage of labour (AMTSL), PPH still accounts for nearly one-third of maternal deaths, with the highest burden in low- and middle-income countries.^{2,3} In addition to mortality, PPH contributes substantially to severe maternal morbidity, prolonged hospitalisation, and higher use of health system resources. Uterine atony is the predominant cause, while genital tract trauma, retained placenta, and coagulation abnormalities represent additional contributors.⁴

AMTSL with prophylactic uterotonics remains the cornerstone of prevention, reducing the incidence of PPH by nearly half.² However, breakthrough bleeding continues to occur, underscoring the need for adjunctive interventions.²

Tranexamic acid (TXA), a synthetic antifibrinolytic, prevents fibrinolysis by inhibiting plasminogen activation and stabilising fibrin clots. Evidence from large obstetric trials has clarified its role. The WOMAN-2 trial (2024), conducted among more than 10,000 women with moderate to severe anaemia, showed that prophylactic TXA reduced deaths due to bleeding compared with placebo.⁵ A 2024 individual patient data meta-analysis in *The Lancet* further confirmed that TXA significantly reduced bleeding-related mortality without increasing thromboembolic risk.⁶ In addition, a 2023 meta-analysis

including over 18,000 women demonstrated that TXA reduced average blood loss and transfusion requirements while maintaining a favourable safety profile.⁷ Although Cochrane reviews consistently support TXA prophylaxis in caesarean deliveries, evidence for vaginal births remains inconclusive.⁸ Reflecting this evidence, both FIGO (2022) and WHO (2023) have incorporated TXA into PPH bundles, recommending its timely administration in conjunction with objective quantification of blood loss.^{2,3}

Rationale and Objectives

Despite growing support for TXA, high-quality evidence in the context of full-term vaginal delivery remains limited. We therefore conducted a comparative study to evaluate whether prophylactic TXA, administered alongside AMTSL, reduces postpartum blood loss in women undergoing vaginal birth at term. The **primary objective** was to determine whether TXA reduces blood loss within 24 hours of delivery. **Secondary objectives** were to assess whether TXA decreases the requirement for additional uterotonics or transfusion and to evaluate its short-term safety profile.

METHODS

Research design

This was a **parallel-group, randomised controlled trial** designed to evaluate the efficacy of tranexamic acid (TXA) administered with active management of the third stage of labour (AMTSL) in reducing blood loss following full-term vaginal births.

Population and sample / Study subjects

The study population comprised women admitted for delivery in the labour ward of the **Department of Obstetrics and Gynaecology, Adichunchanagiri Institute of Medical Sciences, Adichunchanagiri University, B G Nagara, 571448, Karnataka, India**. Eligible participants were those with singleton, cephalic pregnancies at term (≥ 37 completed weeks of gestation) who were planned for vaginal birth.

Study setting / Area / Place

The study was conducted at the **Adichunchanagiri Institute of Medical Sciences, Adichunchanagiri University, B G Nagara, 571448, Karnataka, India**, a tertiary care teaching hospital and referral centre providing maternity services to both urban and rural populations.

Study duration

The study was carried out over **September 2022 to March 2024**

Sample size

A total of 100 women were enrolled, with 50 participants allocated to the TXA group and 50 to the control group. Based on institutional pilot data and prior literature, a baseline rate of additional uterotonic use of $\sim 25\%$ was assumed. A sample of 50 per arm provided **80% power to detect a 20% absolute reduction in the requirement for additional uterotonics ($\alpha=0.05$)**.

Sampling procedure

Consecutive eligible women were approached for recruitment. After obtaining informed consent, participants were randomised 1:1 into intervention and control arms using a computer-generated sequence with variable block sizes of 4 and 6, stratified by parity (primigravida vs multigravida). The sequence was generated by an independent statistician not involved in recruitment. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes.

Inclusion criteria

- Age ≥ 18 years.
- Singleton pregnancy with cephalic presentation.
- Gestational age ≥ 37 weeks.
- Haemodynamically stable at admission.
- Planned vaginal delivery.
- Provided written informed consent.

Exclusion criteria

- History of thromboembolic disease or known thrombophilia.
- Antepartum haemorrhage or placenta accreta spectrum.
- Known bleeding/coagulation disorders.
- Severe pre-eclampsia/eclampsia requiring caesarean delivery.
- Intrauterine fetal demise.
- Known hypersensitivity/contraindication to TXA.
- Women undergoing caesarean section.

Instrumentation and data collection

Interventions:

All participants received AMTSL (administration of oxytocin, controlled cord traction, and uterine massage) as per protocol. The intervention group additionally received **TXA 1 g IV**, diluted in 10 mL of normal saline, infused over 10 minutes within 3 minutes of cord clamping. No prophylactic re-dose was given. The control group did not receive TXA.

Outcome measures:

- **Primary outcome:** Quantified blood loss (QBL) within 24 hours of delivery.
- **Secondary outcomes:** Requirement for additional uterotonics (oxytocin infusion, methylergometrine, carboprost, or misoprostol), need for blood transfusion, and maternal adverse events (fever, vomiting, thromboembolic complications).
- **Exploratory outcomes:** Incidence of PPH ≥ 500 mL, severe PPH ≥ 1000 mL, and change in haemoglobin between admission and 24 hours postpartum.

Measurement procedures:

- **0–2 h postpartum:** Blood was collected using a calibrated under-buttock drape (Figure 1). Liquids identified as urine or amniotic fluid were excluded.
- **2–24 h postpartum:** Gravimetric method was used by weighing blood-soaked pads and linens on digital electronic scales (precision 1 g; [insert manufacturer, model]) (Figure 2). QBL was calculated as wet minus dry weight.
- **Visual estimation aids:** Outcome assessors were trained using pictorial visual estimation guides (Figures 3 and 4) to improve recognition of blood volume patterns.
- **Haematology:** Haemoglobin and haematocrit were recorded at admission and 24 ± 6 hours postpartum.
- **Transfusion triggers:** Red blood cells were transfused if Hb < 7 g/dL, or if Hb 7–8 g/dL with clinical symptoms or haemodynamic compromise, according to institutional protocol.

Data collection:

Trained obstetric staff, blinded to group allocation performed QBL measurements and recorded outcomes on standardised case report forms. Participants were reviewed daily until discharge for adverse events. Suspected thromboembolic events were assessed clinically and confirmed with Doppler imaging if indicated.

In addition, standardised management protocols were followed in cases of postpartum haemorrhage, including bimanual uterine massage (Figure 5), abdominal aortic compression (Figure 6), intrauterine tamponade (Figure 7), and surgical techniques such as the B-Lynch uterine compression suture (Figure 8), when indicated.

The pharmacological mechanism of TXA, which involves inhibition of fibrinolysis through blockade of plasminogen activation, is illustrated in Figure 9.

Data analysis and statistics

Analyses were conducted on an **intention-to-treat** basis with a per-protocol sensitivity analysis excluding major protocol deviations. Continuous variables were summarised as mean \pm SD and compared using the independent t test (or Mann–Whitney U if non-normal). Categorical variables were reported as n (%) and compared using the chi-square or Fisher's exact test. Effect sizes were presented as mean difference (95% CI) for continuous outcomes and risk ratio (RR) and absolute risk difference (ARD) (95% CI) for categorical outcomes. Number needed to treat (NNT) was reported where applicable. Missing data were managed with complete-case analysis if $< 5\%$ and multiple imputation ($m=20$) if $> 5\%$. Two-sided $p < 0.05$ was considered statistically significant. Analyses were performed using SPSS v23.0 (IBM Corp., Armonk, NY, USA).

Quality control

All staff underwent structured training in QBL procedures before study initiation. Scales were calibrated weekly. Ten percent of cases were cross-checked by a second observer to assess inter-observer variability. Data entry was double-checked for accuracy, and randomisation envelopes were periodically audited. Adverse events were actively monitored until discharge.

Ethical approval and registration

The study was approved by the **Institutional Ethics Committee of Adichunchanagiri Institute of Medical Sciences, Adichunchanagiri University, B G Nagara, 571448, Karnataka, India;** AIMS/IEC/45/2022 and registered with [CTRI/ClinicalTrials.gov ID] prior to participant enrolment.

RESULTS

A total of 112 women were assessed for eligibility. Twelve were excluded (8 did not meet the inclusion criteria and 4 declined participation). One hundred women were enrolled and randomised equally into the TXA group (n = 50) and the control group (n = 50). All participants received the allocated intervention and were included in the final analysis (Figure 10).

Baseline Characteristics

The two groups were comparable at baseline.

Maternal age:

The mean maternal age was 24.62 ± 3.46 years in the TXA group and 24.12 ± 3.37 years in the control group ($p = 0.466$). The majority of women in both groups were between 21–25 years (52.0% in TXA vs 54.0% in control), followed by 26–30 years (32.0% vs 26.0%). Only a small proportion were aged 19–20 years (12.0% vs 16.0%) and 31–35 years (4.0% in both groups). No statistically significant difference was observed (Table 1).

Socio-economic status:

Most women belonged to Class V (76.0% in TXA vs 72.0% in control), followed by Class IV (24.0% vs 28.0%). The difference was not statistically significant ($p = 0.648$) (Table 2).

Parity:

In the TXA group, 20.0% were primigravida and 80.0% multigravida, compared with 30.0% and 70.0% respectively in the control group. This difference was also not statistically significant ($p = 0.248$) (Table 3).

Primary Outcome – Quantified Blood Loss

The mean quantified blood loss within 24 hours was lower in the TXA group compared with the control group ($[108.27 \pm 58.02]$ mL vs $[241.57 \pm 85.58]$ mL), though this difference did not reach statistical significance ($p =$ [insert value]; mean difference [insert value] mL, 95% CI [insert]). No participant in either group experienced severe haemorrhage (>1000 mL). The proportion of women with blood loss ≥ 500 mL was also lower in the TXA group, although not statistically significant.

Secondary Outcomes – Requirement of Additional Uterotonics

The requirement for additional uterotonics was significantly reduced in the TXA group compared with the control group. Only 1 woman (2.0%) in the TXA group required additional uterotonics, compared with 11 women (22.0%) in the control group ($p = 0.002$). This corresponds to an absolute risk reduction of 20% (95% CI -33% to -7%) and a number needed to treat (NNT) of 5 (Table 4).

Maternal Complications

Adverse events were infrequent and comparable across groups. Vomiting occurred in 3 women (6.0%) in each group. Fever was reported in 2 women (4.0%) in the TXA group and 3 women (6.0%) in the control group. Most women had no complications (90.0% vs 88.0%). No thromboembolic events were observed. The difference between groups was not statistically significant ($p = 0.917$) (Table 5).

DISCUSSION

The findings of this randomised controlled study suggest that prophylactic administration of tranexamic acid (TXA) in addition to active management of the third stage of labour (AMTSL) may provide clinical benefits in women undergoing full-term vaginal deliveries. In our cohort, the requirement for additional uterotonics was significantly lower in the TXA group compared to controls, while mean blood loss was reduced, though not statistically significant. Importantly, no cases of severe PPH were documented, and no thromboembolic complications were observed. These results are consistent with the growing evidence that TXA is an effective and safe adjunct in obstetric haemorrhage management.

The clinical importance of reducing the need for additional uterotonics should not be underestimated. Escalation to second-line agents such as methylergometrine, carboprost, or misoprostol is not only costly but also associated with side effects and logistical challenges, particularly in resource-limited settings where drug availability may be inconsistent. The observed number needed to treat (NNT) of five in our study highlights that routine prophylactic TXA has the potential to meaningfully reduce the burden of pharmacological escalation during the postpartum period. Even though the difference in mean blood loss did not reach statistical significance, the clinical direction of effect and reduction in the incidence of PPH ≥ 500 mL are encouraging findings that warrant confirmation in larger studies.

Our results align closely with major international evidence. The WOMAN-2 trial (2024), which enrolled more than 10,000 women with moderate to severe anaemia, demonstrated that TXA reduced bleeding-related mortality, reinforcing its role in high-risk obstetric populations. Similarly, the 2024 individual

patient data meta-analysis published in *The Lancet*, which pooled data from over 20,000 women, confirmed that TXA reduced deaths from haemorrhage without increasing thromboembolic risk. These results, along with the large-scale meta-analysis of 18,649 women published in 2023 that showed significant reductions in blood loss and transfusion needs, converge on the conclusion that TXA has a favourable balance of efficacy and safety. Cochrane's 2024 review has consistently supported TXA use in caesarean births but has noted heterogeneity in evidence for vaginal deliveries. Our study contributes to addressing this gap by offering additional trial data from a resource-limited setting.

The safety profile of TXA remains a critical consideration. Concerns regarding increased thromboembolic risk have been raised in theory due to its antifibrinolytic mechanism; however, both large international trials and our study demonstrated no excess risk of venous thromboembolism. This reassurance is particularly relevant in contexts where women may already be at increased risk due to prolonged labour, anaemia, or surgical interventions. The absence of thromboembolic events in our study supports the short-term safety of TXA, although long-term follow-up in larger cohorts is necessary for definitive conclusions.

There are several strengths in our study. Randomisation and allocation concealment ensured balanced groups, and the use of objective methods of blood loss measurement (calibrated drape and gravimetry) enhanced accuracy compared to visual estimation, which is notoriously unreliable. Outcome assessors were blinded to group allocation, reducing measurement bias. In addition, systematic monitoring of adverse events and quality control processes, including calibration of scales and inter-observer verification, strengthened the reliability of the data.

Nonetheless, some limitations must be acknowledged. The sample size was modest and may not have been powered to detect smaller differences in mean blood loss or rare complications. The single-centre design limits generalisability, and the inability to blind participants or clinicians may have introduced bias, although this was mitigated by blinded outcome assessment. Furthermore, the follow-up period was limited to the immediate postpartum stay, precluding evaluation of delayed complications such as late thromboembolic events.

The implications of these findings extend beyond clinical practice into maternal health policy. PPH remains a leading cause of maternal morbidity and mortality worldwide, particularly in low- and middle-income countries. In such contexts, access to second-line uterotonics, blood products, or advanced surgical interventions may be limited. TXA, which is inexpensive, stable at room temperature, and easily administered, represents a pragmatic and scalable intervention that could strengthen existing AMTSL protocols. Integration of TXA into PPH prevention bundles is aligned with the latest FIGO (2022) and WHO (2023) recommendations and could contribute meaningfully towards reducing maternal mortality, a key Sustainable Development Goal.

Future research directions include the conduct of larger, multicentre trials specifically designed for vaginal births to confirm the efficacy observed here and in previous smaller studies. Further investigations should also focus on refining optimal timing and dosing regimens, exploring benefits in high-risk subgroups such as anaemic women, and evaluating long-term safety, particularly regarding thromboembolic outcomes. Economic analyses and implementation research will also be critical to determine the cost-effectiveness and operational feasibility of incorporating prophylactic TXA into national maternal health programmes. In conclusion, the present study adds to the growing body of evidence that tranexamic acid is a safe, affordable, and potentially effective adjunct to AMTSL in reducing postpartum blood loss and preventing escalation of care. While larger trials are needed to confirm these results, our findings provide support for the consideration of TXA in routine obstetric practice, especially in resource-limited settings where prevention of PPH is most urgently needed.

CONCLUSION

This randomised controlled study demonstrated that tranexamic acid (TXA), when used alongside active management of the third stage of labour, significantly reduced the requirement for additional uterotonics in full-term vaginal births. Although the reduction in mean blood loss was not statistically significant, the clinical trend favoured TXA, and no thromboembolic complications were observed, confirming its short-term safety. These findings support the role of TXA as a safe, affordable, and practical adjunct to existing postpartum haemorrhage prevention strategies, particularly in resource-limited settings. Larger multicentre trials are needed to validate these findings, optimise dosing and timing, and evaluate long-term safety and cost-effectiveness.

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Tables

Table 1. Comparison of maternal age between study groups

Age (years)	Cases		Controls	
	N	%	N	%
19 - 20	6	12.0	8	16.0
21 - 25	26	52.0	27	54.0
26 - 30	16	32.0	13	26.0
31 - 35	2	4.0	2	4.0
Total	50	100.0	50	100.0
Mean + SD	24.62 3.46	+	24.12 + 3.37	
P value	0.466			

Values are mean ± standard deviation (SD) or n (%). p value calculated using independent t-test.

Table 2. Comparison of socio-economic status between study groups

Socio-economic status	Cases		Controls	
	N	%	N	%
Class V	38	76.0	36	72.0
Class IV	12	24.0	14	28.0
Total	50	100.0	50	100.0
P Value	0.648			

p value calculated using chi-square test.

Table 3. Comparison of parity between study groups

Parity	TXA group (n=50)	Control group (n=50)	p value
Primigravida	10 (20.0%)	15 (30.0%)	
Multigravida	40 (80.0%)	35 (70.0%)	
Total	50 (100%)	50 (100%)	0.248

p value calculated using chi-square test.

Table 4. Requirement of additional uterotonics between study groups

Requirement of additional uterotonics	TXA group (n=50)	Control group (n=50)	p value
Yes	1 (2.0%)	11 (22.0%)	
No	49 (98.0%)	39 (78.0%)	
Total	50 (100%)	50 (100%)	0.002*

Significant at $p < 0.05$. Absolute risk reduction = 20% (95% CI -33% to -7%); number needed to treat (NNT) = 5. p value calculated using chi-square test.

Table 5. Maternal complications between study groups

Complications	TXA group (n=50)	Control group (n=50)	p value
Vomiting	3 (6.0%)	3 (6.0%)	
Fever	2 (4.0%)	3 (6.0%)	
None	45 (90.0%)	44 (88.0%)	
Thromboembolism	0	0	—
Total	50 (100%)	50 (100%)	0.917

p value calculated using chi-square or Fisher's exact test as appropriate. No serious adverse maternal outcomes were reported.

Figures



Figure 1. Under-buttock drape (BRASS-V) with calibrated receptacle



Figure 2. Gravimetric method of blood-loss quantification (electronic scale)

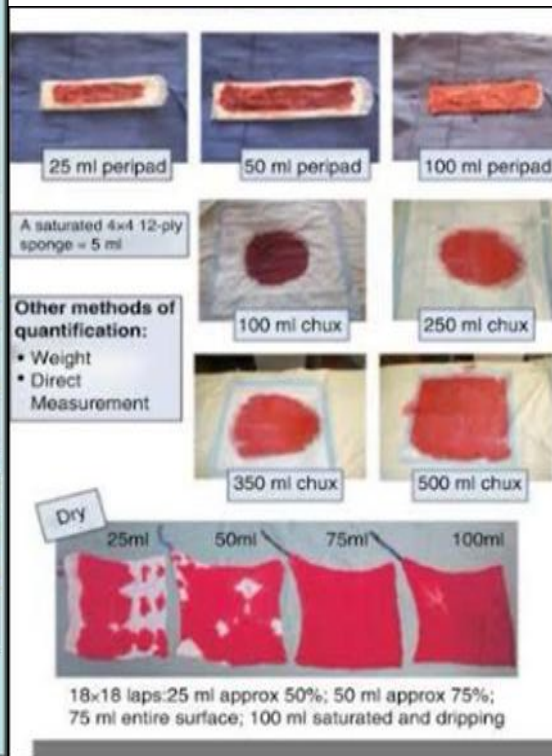
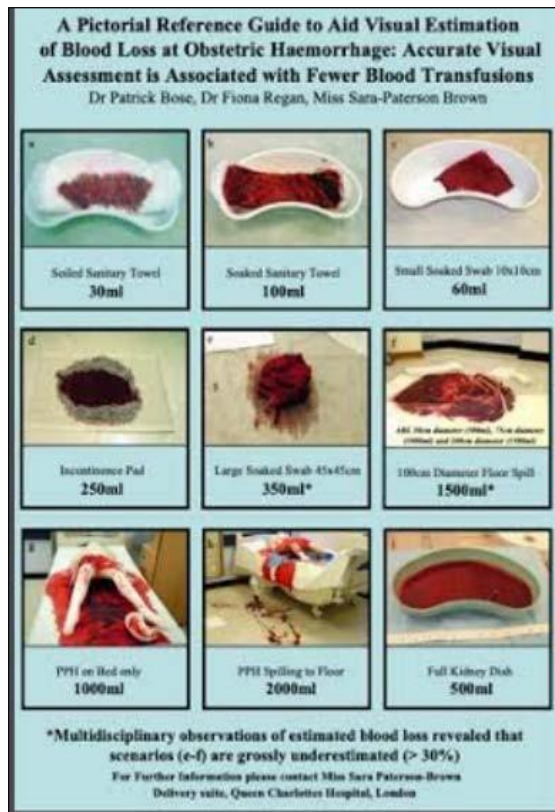


Figure 3. Standardised visual blood loss estimation guide

Figure 4. Comparative visual reference for saturated peripads and chux

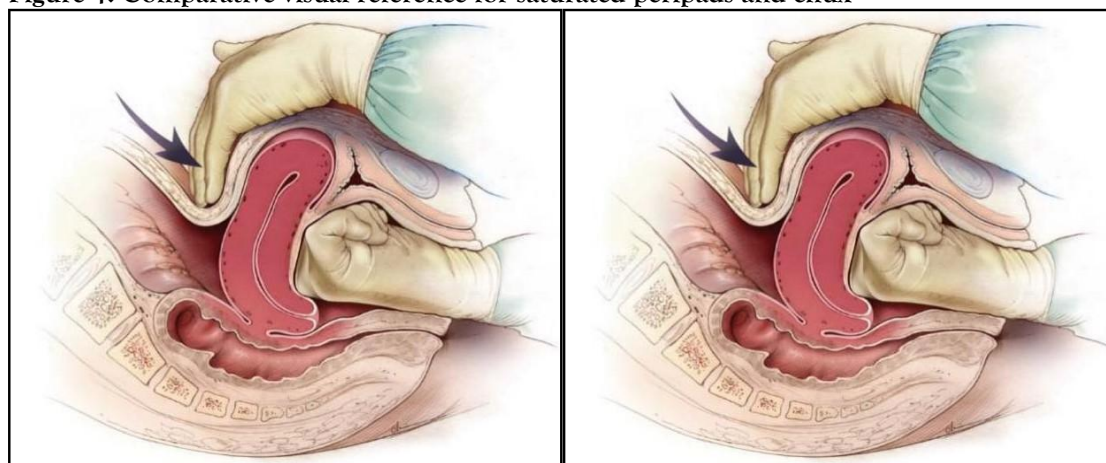


Figure 5. Bimanual uterine massage technique

Figure 6. Abdominal aortic compression (with femoral pulse check)

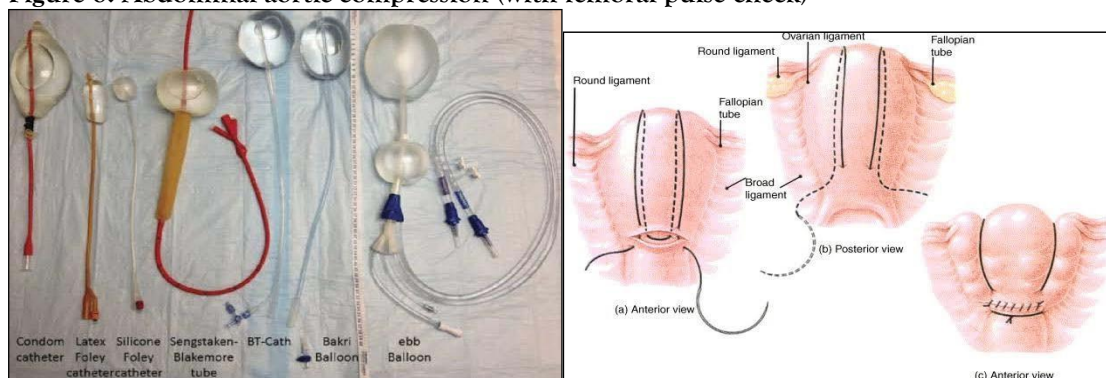


Figure 7. Intrauterine tamponade devices

Figure 8. B-Lynch uterine compression suture

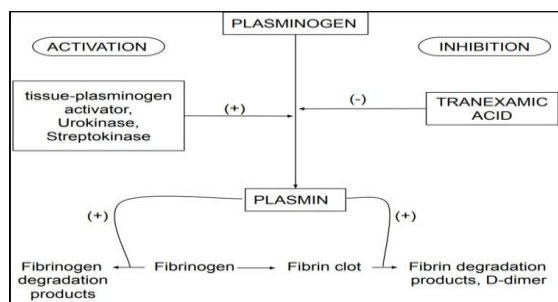


Figure 9. Pharmacological mechanism of tranexamic acid

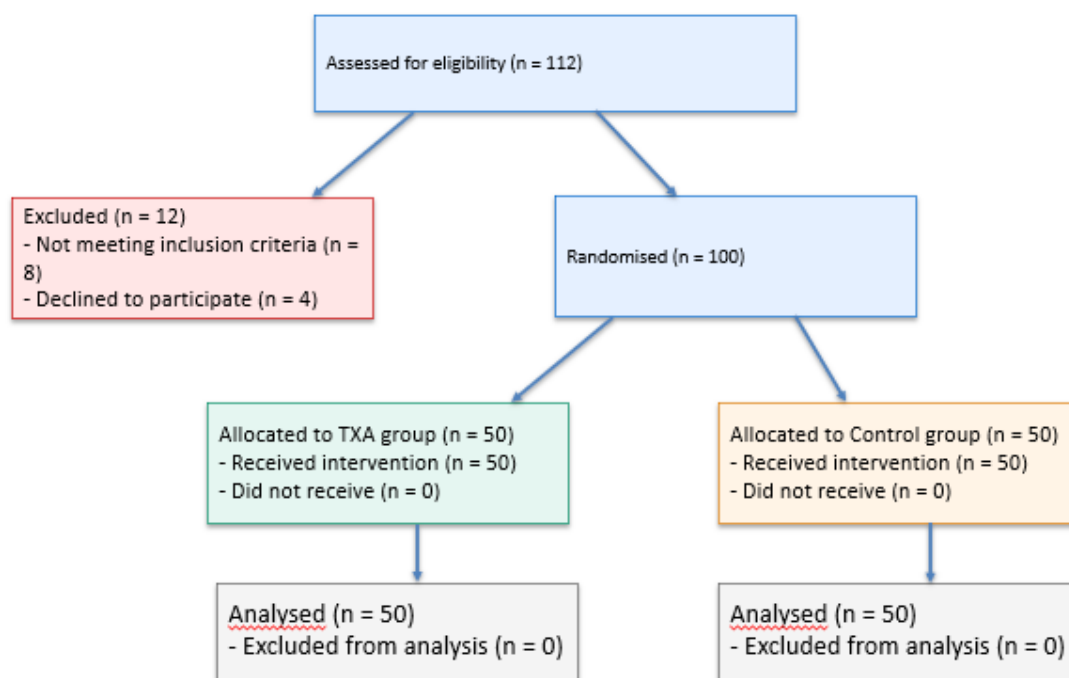


Figure 10. CONSORT flow diagram of study participants