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**Original Article**

# Clinical profile, treatment response, and safety of tranexamic acid in postpartum hemorrhage. A cross-sectional observational study.

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## Abstract

### Background
Postpartum hemorrhage (PPH) remains a major cause of maternal morbidity and mortality, and tranexamic acid (TXA) has emerged as an important adjunct in its management. Real-world evidence from tertiary care hospitals remains valuable for evaluating short-term treatment response and safety.

### Objectives
To assess the clinical profile, treatment response, and short-term safety outcomes among women with PPH receiving TXA in a tertiary care teaching hospital.

### Methods
This hospital-based observational study included 100 women with clinically diagnosed PPH who received TXA as part of standard management at RVM Institute of Medical Sciences and Research Centre, Telangana, India, from February 2025 to September 2025. Demographic, obstetric, etiological, therapeutic, and outcome-related variables were recorded and analyzed using descriptive statistics.

### Results
Most women were aged 21-30 years, multiparous, and delivered vaginally. Uterine atony was the commonest cause of PPH. TXA was administered within 1 hour of diagnosis in 64% of women. Estimated blood loss remained below 1000 mL in 68% after treatment. Additional uterotonics and blood transfusion were required in 32% and 28%, respectively. Hemorrhage was controlled with medical management alone in 78%, whereas 20% required surgical intervention and 3% underwent hysterectomy. Recovery without major complication occurred in 86% of women; ICU admission was required in 11%, and maternal mortality was 2%. Adverse effects were infrequent, with nausea or vomiting in 6%, transient hypotension in 3%, and no thromboembolic events observed.

### Conclusion
In this observational cohort, TXA used as part of multimodal PPH management was associated with favorable hemorrhage control and a low short-term adverse-event burden. These findings support its continued integration into tertiary care obstetric hemorrhage protocols.

### Recommendation
Early administration of tranexamic acid should be encouraged in postpartum haemorrhage management to reduce blood loss, complications, and improve maternal outcomes.

**Keywords:** postpartum hemorrhage; tranexamic acid; maternal outcomes; uterine atony; obstetric hemorrhage; tertiary care hospital
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## Introduction

Postpartum hemorrhage (PPH) remains one of the most serious obstetric emergencies and continues to contribute substantially to maternal morbidity and mortality worldwide [1-4]. Although advances in obstetric care, blood transfusion services, and critical care support have improved survival in many settings, the burden of severe bleeding after childbirth remains considerable, especially in resource-constrained

health systems [1,3,4]. PPH is not only associated with maternal death, but also with shock, coagulopathy, the need for transfusion, emergency surgery, prolonged hospitalization, intensive care admission, and loss of reproductive potential in women who require hysterectomy [2-4].

The clinical diagnosis of PPH has evolved from a simple blood-loss threshold to a broader assessment that includes cumulative blood loss and its hemodynamic consequences [4]. In practical obstetric care, timely recognition remains challenging because visual estimation frequently underestimates blood loss, and progression from apparently moderate bleeding to life-threatening hemorrhage can be rapid [1,3,4]. Uterine atony is consistently reported as the leading cause of PPH, followed by retained placental tissue, genital tract trauma, placental abnormalities, and coagulation disorders [2,3]. Because many women who develop severe hemorrhage do not have all classical risk factors, clinicians must maintain a high index of suspicion and act promptly when bleeding is recognized [2,3].

Standard management of PPH relies on a coordinated bundle of care that includes uterine massage, uterotonic agents, correction of reversible causes, fluid resuscitation, blood component therapy when needed, and timely escalation to surgical or critical care interventions [4-6]. Tranexamic acid (TXA), an antifibrinolytic agent that inhibits plasminogen activation and stabilizes formed clots, has gained an important role as an adjunctive therapy in this treatment pathway [5,6]. Updated international guidance recommends early intravenous TXA for women with clinically diagnosed PPH, ideally as soon as possible after bleeding onset, because the therapeutic effect is greatest when treatment is not delayed [5,9]. The WOMAN trial provided robust evidence that early TXA reduces death due to bleeding without increasing thromboembolic complications, and subsequent reviews have reinforced its favorable safety profile in obstetric use [7-9,12,14]. At the same time, prophylactic studies in vaginal and cesarean delivery have shown context-dependent benefits, emphasizing that treatment outcomes should also be interpreted in relation to case mix, timing, and co-interventions [10-14].

Despite increasing acceptance of TXA in obstetric practice, data from routine tertiary care settings in India describing patient profile, timing of administration, response to treatment, need for escalation, and short-term adverse effects remain limited. Hospital-based observational data are useful because they reflect actual bedside practice and can complement trial findings by documenting real-world maternal outcomes. Therefore, the present study was undertaken to evaluate the safety and effectiveness indicators of TXA in women with PPH managed at a tertiary care teaching hospital. The specific objectives were to describe the demographic and obstetric profile of women receiving TXA, identify the etiological pattern of PPH, assess treatment response and maternal outcomes following TXA administration, and document short-term adverse effects associated with its use.

## Methodology

### Study design and setting.

This hospital-based observational study was conducted in the Department of Obstetrics and Gynecology at the RVM Institute of Medical Sciences and Research Centre, Laxmakkapally, located in Mulugu Mandal of Siddipet District, Telangana, India. The institute is a tertiary care teaching hospital affiliated with a medical college and serves as an important referral centre for surrounding rural and semi-urban populations. The hospital provides comprehensive multidisciplinary healthcare services including obstetrics and gynaecology, general medicine, surgery, paediatrics, anaesthesiology, orthopaedics, and other allied specialties.The study was carried out over eight months, from February 2025 to September 2025. The study aimed to describe the clinical characteristics, treatment response, and short-term safety outcomes among women with postpartum hemorrhage who received tranexamic acid during routine obstetric care.

### Participants

The study included women who developed clinically diagnosed postpartum hemorrhage after vaginal delivery or cesarean section and received tranexamic acid as part of standard management during the study period. PPH was identified on the basis of cumulative postpartum blood loss with clinical assessment of ongoing bleeding and hemodynamic status, in line with contemporary obstetric definitions and treatment principles [4-6]. Women with secondary postpartum hemorrhage occurring beyond 24 hours after delivery, women who did not receive tranexamic acid, and records lacking essential outcome details were not considered for final analysis. A total of 100 eligible women constituted the study sample.

### Management protocol

All women were managed according to the institution's postpartum hemorrhage protocol. Initial care included rapid clinical assessment, uterine massage where indicated, administration of uterotonic agents, intravenous fluids, identification of the underlying cause of bleeding, and blood component support when required. Tranexamic acid was administered intravenously by the treating obstetric team as an adjunct to routine care, consistent with contemporary guideline recommendations for early use in PPH [5,6]. Decisions regarding additional uterotonics, blood transfusion, surgical procedures, ICU transfer, and ongoing monitoring were made by the treating team according to the severity of hemorrhage and clinical response.

## Data collection

Data were collected from labor room records, cesarean section registers, inpatient case sheets, operative notes, ICU records, and blood bank documentation using a structured proforma. The variables recorded included age, parity, gestational age at delivery, mode of delivery, primary cause of postpartum hemorrhage, timing of TXA administration after diagnosis, estimated blood loss category, need for additional uterotonics, blood transfusion requirement, achievement of hemorrhage control with medical management, requirement for surgical intervention, hysterectomy, ICU admission, maternal death, and immediate adverse effects attributable to TXA.

**Outcome measures and statistical analysis.** The principal effectiveness indicators were hemorrhage control with medical management alone, requirement for escalation to surgical intervention, hysterectomy rate, and transfusion requirement. Safety was assessed from documented adverse effects such as nausea, vomiting, transient hypotension, and clinically evident thromboembolic events during hospital stay. The collected data were compiled and analyzed using descriptive statistics. Continuous data were summarized as appropriate, while categorical variables were presented as frequencies and percentages. Because the study was observational and lacked a comparison arm, the analysis remained primarily descriptive.

## Ethical considerations.

The study was undertaken in accordance with institutional ethical standards and the principles of the Declaration of Helsinki. Ethical approval was obtained from the Institutional Ethics Committee of RVM Institute of Medical Sciences and Research Centre, Laxmakkapally, Mulugu Mandal, Siddipet District, Telangana, India. Patient confidentiality was maintained during data collection and analysis by de-identifying all records. The institutional ethics approval number can be inserted by the authors at the time of journal submission, if required by the target journal.

## Results

A total of 100 women with postpartum hemorrhage who received tranexamic acid as part of routine management were included in the analysis. Most participants were between 21 and 30 years of age, with the 21-25 year group accounting for 30.0% and the 26-30 year group accounting for 26.0%. Multiparous women constituted 62.0% of the study population, and 62.0% of hemorrhagic events followed vaginal delivery. Most deliveries occurred at term, with 74.0% of women delivering between 37 and 40 weeks of gestation (Table 1).

**Table 1. Baseline demographic and obstetric characteristics of the study participants (N = 100)**

| Variable | Category | n | % |
|---|---|---|---|
| Age group (years) | ≤20 | 12 | 12.0 |
| | 21-25 | 30 | 30.0 |
| | 26-30 | 26 | 26.0 |
| | 31-35 | 24 | 24.0 |
| | >35 | 8 | 8.0 |
| Parity | Primiparous | 38 | 38.0 |
| | Multiparous | 62 | 62.0 |
| Mode of delivery | Vaginal delivery | 62 | 62.0 |
| | Cesarean section | 38 | 38.0 |
| Gestational age at delivery | <37 weeks | 14 | 14.0 |
| | 37-40 weeks | 74 | 74.0 |
| | >40 weeks | 12 | 12.0 |

The etiological profile of PPH showed that uterine atony was the leading cause, observed in 60.0% of women. Retained placental tissue and genital tract trauma accounted for 15.0% and 13.0% of cases, respectively, while placenta previa/accreta and coagulation disorders were less frequent. Tranexamic acid was administered within 1 hour of diagnosis in 64.0% of women, whereas 36.0% received it between 1 and 3 hours. In 68.0% of women, the estimated blood loss category after treatment remained below 1000 mL, while 22.0% had blood loss between 1000 and 1500 mL and 10.0% had blood loss exceeding 1500 mL (Table 2).

**Table 2. Clinical profile and etiology of postpartum hemorrhage among study participants (N = 100)**

| Variable | Category | n | % |
|---|---|---|---|
| Primary cause of PPH | Uterine atony | 60 | 60.0 |
| | Retained placental tissue | 15 | 15.0 |
| | Genital tract trauma | 13 | 13.0 |
| | Placenta previa/accreta | 7 | 7.0 |
| | Coagulation disorder | 5 | 5.0 |
| Time of TXA administration after diagnosis of PPH | Within 1 hour | 64 | 64.0 |
| | 1-3 hours | 36 | 36.0 |
| Estimated blood loss | <1000 mL | 68 | 68.0 |
| | 1000-1500 mL | 22 | 22.0 |
| | >1500 mL | 10 | 10.0 |

Assessment of treatment response demonstrated that additional uterotonics were required in 32.0% of women and blood transfusion in 28.0%. Hemorrhage control with medical management alone was achieved in 78.0% of women. However, 20.0% required escalation to surgical intervention. Among all participants, B-Lynch suturing was performed in 9.0%, uterine artery ligation in 8.0%, and hysterectomy in 3.0% (Table 3).

**Table 3. Treatment response and effectiveness outcomes following tranexamic acid administration (N = 100)**

| Variable | Category | n | % |
|---|---|---|---|
| Additional uterotonics required | Yes | 32 | 32.0 |
| | No | 68 | 68.0 |
| Blood transfusion required | Yes | 28 | 28.0 |
| | No | 72 | 72.0 |
| Hemorrhage control achieved with medical management | Yes | 78 | 78.0 |
| | No | 22 | 22.0 |
| Surgical intervention required | Yes | 20 | 20.0 |
| | No | 80 | 80.0 |
| Type of surgical intervention* | B-Lynch suture | 9 | 9.0 |
| | Uterine artery ligation | 8 | 8.0 |
| | Hysterectomy | 3 | 3.0 |

** Percentages for surgical interventions are shown out of the total study population.*

Maternal outcomes were favorable in the majority of cases. Recovery without major complication was documented in 86.0% of women, while 12.0% recovered after surgical management. Maternal death occurred in 2.0% of cases. Adverse effects attributable to tranexamic acid were uncommon and generally mild. Nausea or vomiting was recorded in 6.0%, transient hypotension in 3.0%, and no thromboembolic events were documented during the hospital stay. ICU admission was required in 11.0% of women (Table 4). Overall, the findings indicate that tranexamic acid, when used as part of multimodal PPH management, was associated with favorable short-term hemorrhage control and a low immediate adverse-event burden.

**Table 4. Maternal outcomes and adverse effects associated with tranexamic acid use (N = 100)**

| Variable | Category | n | % |
|---|---|---|---|
| Final maternal outcome | Recovered without major complication | 86 | 86.0 |
| | Recovered after surgical management | 12 | 12.0 |
| | Maternal death | 2 | 2.0 |
| Adverse effects of TXA | Nausea/vomiting | 6 | 6.0 |
| | Transient hypotension | 3 | 3.0 |
| | Thromboembolic events | 0 | 0.0 |
| | No adverse effects observed | 91 | 91.0 |
| ICU admission | Yes | 11 | 11.0 |
| | **No** | **89** | **89.0** |

## Discussion

The present hospital-based observational study describes the short-term maternal outcomes of 100 women with postpartum hemorrhage who received tranexamic acid in a tertiary care teaching hospital. The findings show that most women were young, multiparous, and delivered vaginally, with uterine atony as the dominant etiology. These patterns are consistent with the established epidemiology of PPH, in which uterine atony remains the most common underlying cause and a major driver of severe maternal morbidity across settings [2-4]. The predominance of vaginal deliveries in the present cohort should not be interpreted as a lower risk with cesarean delivery; rather, it reflects the case profile encountered in routine institutional practice over the study period.

An important observation in this study was that tranexamic acid was administered within 1 hour of PPH diagnosis in nearly two-thirds of women. This is clinically relevant because international guidance emphasizes that TXA should be given as early as possible once PPH is diagnosed, and evidence from the WOMAN trial demonstrated greater benefit when treatment is initiated within 3 hours of birth [5,8,9]. Early administration in the present series was accompanied by hemorrhage control with medical management alone in 78.0% of women, while only one-fifth required surgical escalation. In a real-world setting where TXA is used alongside uterotonics, resuscitation, and cause-directed obstetric interventions, these findings support the practical value of integrating TXA early into PPH bundles of care [5,6,8].

The need for additional uterotonics in 32.0% and blood transfusion in 28.0% of women indicates that TXA was not used as a stand-alone therapy, but rather as part of multimodal hemorrhage management. This reflects contemporary obstetric practice and accords with consensus recommendations that pharmacologic, hemostatic, and surgical approaches must be coordinated according to severity and etiology [5,6]. The low hysterectomy rate of 3.0% in the present study is noteworthy, although it should be interpreted cautiously because the observational design does not permit direct attribution of this outcome solely to TXA. Nevertheless, the overall pattern of high medical control and limited need for definitive ablative surgery is clinically encouraging.

The short-term safety profile in this cohort was favorable. Only mild adverse effects such as nausea, vomiting, and transient hypotension were documented, and no thromboembolic events were observed during hospitalization. This finding is in line with the WOMAN trial and subsequent systematic reviews, which did not demonstrate a meaningful increase in thromboembolic

complications with obstetric TXA use [8,9,12,14]. Recent broader evidence, including the WOMAN-2 trial and contemporary meta-analytic data, has further refined understanding of TXA across treatment and prevention contexts, while also showing that benefit varies by indication, timing, and baseline risk [10-14]. Taken together, the present findings add tertiary care observational evidence from India and support the continued use of TXA as an adjunctive component of timely, protocol-based management for postpartum hemorrhage.

## Generalizability

The findings of this study provide useful clinical insights into the management of postpartum hemorrhage using tranexamic acid in a tertiary care hospital setting. Since the study population included women receiving routine obstetric care in a teaching hospital that caters to both rural and semi-urban communities, the results may reasonably reflect clinical practices in similar tertiary care centres in developing regions. However, as the study was conducted in a single institution and utilized a cross-sectional observational design, caution should be exercised when extrapolating the findings to all healthcare settings. Variations in patient demographics, availability of emergency obstetric services, blood bank facilities, and institutional treatment protocols may influence treatment outcomes. Therefore, larger multicentre studies involving diverse populations would be valuable to further validate and generalize these observations.

## Conclusion

In this hospital-based observational study, tranexamic acid appeared to be a useful adjunct in the management of postpartum hemorrhage in a tertiary care setting. Most women achieved hemorrhage control without major surgical intervention, while the requirements for hysterectomy, ICU admission, and maternal death remained limited relative to the severity of the condition. The adverse-effect profile was reassuring, with only minor immediate reactions and no documented thromboembolic events during hospitalization.

## Limitations

This study was conducted at a single tertiary care center and used an observational design without a control group, which limits causal inference regarding tranexamic acid effectiveness. The sample size was modest, follow-up was confined to the in-hospital period, and confounding from concurrent uterotonics, transfusion practices, and surgical interventions was unavoidable. Detailed laboratory severity markers and long-term thromboembolic surveillance were not available.

## Recommendations

Early administration of tranexamic acid should be considered as an important component of standard management protocols for postpartum hemorrhage, particularly in tertiary care and referral hospitals. Strengthening early recognition of postpartum hemorrhage and prompt pharmacological intervention may help reduce maternal morbidity and prevent severe complications associated with excessive obstetric blood loss. Future research involving larger populations and multicentric designs is recommended to further evaluate long-term outcomes and optimize treatment guidelines.

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## List of Abbreviations

PPH – Postpartum Hemorrhage
TXA – Tranexamic Acid
WHO – World Health Organization
IV – Intravenous
Hb – Hemoglobin
BP – Blood Pressure
HR – Heart Rate
ICU – Intensive Care Unit
LSCS – Lower Segment Caesarean Section
RVMIMSRC – RVM Institute of Medical Sciences and Research Centre

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## Conflict of Interest

The authors declare no conflict of interest.

## Data Availability

Data Available on request

## Author contributions

Dr Manjula D contributed to the conceptualization of the study, study design, supervision of patient recruitment, clinical data collection, and overall coordination of the research work. She also participated in interpretation of the clinical findings and review of the manuscript.

Dr Akula Swaroopa Rani was involved in study planning, patient evaluation, data acquisition from obstetric cases, and contributed to drafting and critical revision of the manuscript for important intellectual content.

Dr Vidyullatha Balivada contributed to pharmacological evaluation, interpretation of drug-related safety parameters, literature review, and assisted in the preparation and editing of the manuscript.

Dr Prashanth Kumar Patnaik participated in data analysis, interpretation of results, methodological guidance related to pharmacological aspects of tranexamic acid therapy, and critical revision of the final manuscript.

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