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Research Article

Bundled Postpartum Haemorrhage Care with Tranexamic Acid, Uterotonics, And Uterine Balloon: A One-Year Observational Study from A Tertiary Care Hospital in West Bengal in Eastern India

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ABSTRACT

Abstract

Background: Postpartum haemorrhage (PPH) remains the leading cause of maternal mortality worldwide. Timely initiation of antifibrinolytic, pharmacologic, and mechanical interventions is essential to reduce morbidity and prevent radical surgery.
Objective: To evaluate the effectiveness of a bundled PPH management protocol combining early tranexamic acid (TXA), uterotonics, and uterine balloon tamponade in a tertiary hospital in Eastern India.
Methods: A prospective observational study was conducted at Gouridevi Institute of Medical Sciences & Hospital, West Bengal, over one year. One hundred consecutive women with primary PPH were managed using a care bundle comprising early intravenous TXA, uterotonics, and balloon tamponade when indicated. Outcomes included successful haemorrhage control without surgery (primary), total blood loss, transfusion requirement, morbidity, and mortality. Subgroup analyses compared outcomes by TXA timing (≤30 vs >30 minutes) and bundle completeness.
Results: Successful control without surgery was achieved in 86% of women, with 4% requiring hysterectomy. Median total blood loss was 737 mL (IQR 563–910), and 37% required transfusion. Early TXA administration was associated with lower blood loss (668 vs 796 mL, $p = 0.028$) and a trend toward higher success rates (91.7% vs 77.5%, $p = 0.088$). Complete bundle adherence was associated with higher success compared with incomplete care (90.9% vs 80.0%, $p = 0.203$). There was one case of shock and one ICU admission; no maternal deaths occurred.
Conclusion: A bundled PPH protocol incorporating early TXA, uterotonics, and balloon tamponade achieved high success rates and reduced the need for surgical intervention. Early TXA was associated with lower blood loss, underscoring the importance of timely antifibrinolytic therapy as part of stepwise bundled management.

Keywords*: postpartum haemorrhage, tranexamic acid, uterotonics, balloon tamponade, maternal outcomes.*

INTRODUCTION

Postpartum haemorrhage (PPH) remains the leading direct cause of maternal mortality worldwide, accounting for approximately one-quarter of maternal deaths, with the greatest burden in low- and middle-income countries. Despite advances in obstetric care, fragmented management and delays in initiating treatment continue to drive preventable maternal morbidity and mortality. Increasingly, a bundled approach that combines pharmacologic, mechanical, and antifibrinolytic interventions has been advocated as a strategy to improve survival.

Evidence from case-based reports suggests that combined interventions may offer synergistic benefits. Kinugasa et al. (2015) described successful control of severe PPH using uterine balloon tamponade in combination with topical tranexamic acid, demonstrating the effectiveness of integrating medical and mechanical strategies [1]. However, as Antoun (2021) emphasized, although multiple treatment options are available—including uterotonics, tranexamic acid, and mechanical devices—implementation in practice often occurs in isolation rather than as part of a coordinated bundle [2].

Additional support for integrated strategies comes from interventional studies. Shady reported that temporary uterine packing combined with topical tranexamic acid during haemorrhagic caesarean delivery reduced blood loss compared with standard management, highlighting the adjunctive role of antifibrinolytics in surgical contexts [3]. Provider perspectives also underscore the value of stepwise bundled care. In a meta-synthesis, Finlayson et al. (2021) found that healthcare workers viewed uterine balloon tamponade as safe and feasible, especially when incorporated into structured PPH protocols [4]. Hofmeyr (2023) similarly highlighted the role of novel and improvised bundled interventions, particularly in resource-limited settings [5]. Complementing these findings, Makwe and Okunade (2024) described conservative management pathways where escalation from uterotonics to balloon tamponade forms a rational and effective continuum [6].

Against this background, the present study was undertaken at Gouridevi Institute of Medical Sciences & Hospital, West Bengal. The objective was to evaluate the outcomes of a bundled approach to PPH care—comprising early administration of tranexamic acid, timely uterotonics, and uterine balloon tamponade—over a one-year period in 100 women presenting with postpartum haemorrhage.

METHODS

Study Design and Setting

This was a prospective observational study conducted over a one-year period in the Department of Obstetrics and Gynaecology at Gouridevi Institute of Medical Sciences & Hospital, West Bengal, India, a tertiary care referral centre serving both rural and semi-urban populations.

Inclusion and Exclusion Criteria

Women were eligible if they developed primary postpartum haemorrhage (PPH), defined as estimated blood loss ≥500 mL after vaginal delivery or ≥1000 mL after caesarean delivery, occurring within 24 hours of birth.
Exclusion criteria were:

1. Secondary PPH (after 24 hours of delivery).
2. Known coagulation disorders (e.g., haemophilia, thrombocytopenia).
3. Severe medical comorbidities contraindicating uterotonics or tranexamic acid.
4. Incomplete or missing clinical records.

Intervention (PPH Care Bundle)

All eligible women received a standardized PPH care bundle comprising:

1. Early Tranexamic Acid (TXA): 1 g intravenously within 30 minutes of diagnosis, repeatable after 30 minutes if bleeding persisted.
2. Uterotonics: Oxytocin as first-line, followed by misoprostol or carboprost if required.
3. Uterine Balloon Tamponade (UBT): Bakri or condom catheter balloon used when pharmacologic measures failed.

Supportive measures (IV fluids, blood transfusion, surgical interventions) were provided as needed.

Outcome Measures

- **Primary outcome:** Successful control of haemorrhage without surgical intervention (compression sutures, artery ligation, hysterectomy).
- **Secondary outcomes:** Total blood loss, transfusion requirements, maternal morbidity (shock, ICU admission), and maternal mortality.

Data Collection

Data were collected prospectively at predefined time points by the attending obstetric team using a standardized proforma:

- At diagnosis of PPH: Maternal demographic and obstetric details (age, parity, gestational age, mode of delivery), estimated baseline blood loss, and hemodynamic status (blood pressure, pulse rate).
- Immediately after intervention initiation: Time of tranexamic acid administration, type and timing of uterotonic given, and timing of uterine balloon tamponade insertion (if used).

- At 1 hour post-intervention: Ongoing blood loss, hemodynamic parameters, and need for additional interventions (repeat uterotonics, repeat TXA, balloon adjustment).
- At 6 hours post-intervention: Cumulative blood loss, transfusion requirement, and maternal vital status.
- At 24 hours post-intervention: Final outcome of haemorrhage control (success vs surgical intervention), maternal morbidity (shock, ICU admission), and survival.

All entries were cross-verified by the senior resident on duty for completeness and accuracy.

Statistical Analysis

Continuous variables were summarized as means ± SD or medians (IQR). Categorical variables were expressed as counts and percentages. Mann–Whitney U was used for continuous data, Chi-square or Fisher's exact test for categorical data. Effect sizes were reported as relative risk (RR) with 95% confidence intervals (CI). $p < 0.05$ was considered statistically significant. All data was analysed using SPSS version 26.

RESULTS

1.Study Population

A total of 100 women with primary postpartum haemorrhage (PPH) were included in the study. The mean maternal age was 27.0 ± 5.4 years, and the median parity was 1 (IQR 0–2). The majority delivered vaginally (70%), while 30% underwent caesarean section. The median baseline blood loss at diagnosis of PPH was 643 mL (IQR 519–777). Baseline characteristics are summarized in Table 1.

Table 1. Baseline characteristics of women with postpartum haemorrhage (n = 100)

Characteristic	Value
Age, years (mean ± SD)	27.0 ± 5.4
Parity, median (IQR)	1 (0–2)
Mode of delivery – Vaginal	70 (70%)
Mode of delivery – Caesarean	30 (30%)
Baseline blood loss, mL (median, IQR)	643 (519–777)

Abbreviations: SD = standard deviation; IQR = interquartile range.

2.Interventions

All women received tranexamic acid (TXA) and uterotonics as part of the postpartum haemorrhage (PPH) bundle. The median time to TXA administration was 28 minutes (IQR 21–35), and 60% of women received TXA within 30 minutes of diagnosis. Oxytocin was administered in all cases, while additional uterotonics such as misoprostol and carboprost were used in 62% and 30% of cases, respectively. Uterine balloon tamponade was required in one-third of women (33%), most commonly using a condom catheter balloon. Overall, the complete bundle (early TXA, uterotonics, and balloon when indicated) was achieved in 55% of cases. Intervention details are shown in Table 2.

Table 2. Interventions received by women with postpartum haemorrhage (n = 100)

Intervention	Value
TXA time, min (median, IQR)	28 (21–35)
Early TXA (≤30 min), n (%)	60 (60%)
Oxytocin use, n (%)	100 (100%)
Misoprostol use, n (%)	62 (62%)
Carboprost use, n (%)	30 (30%)
Balloon tamponade use, n (%)	33 (33%)
Bundle complete*, n (%)	55 (55%)

Bundle complete = receipt of early TXA (≤30 min), uterotonics, and balloon tamponade if required.

3.Primary Outcome – Control of Haemorrhage without Surgery

Overall, successful control of haemorrhage without the need for surgical intervention was achieved in 86% of women. Compression sutures were required in 7% and hysterectomy in 4%.

When stratified by timing of tranexamic acid (TXA), women who received early TXA (≤30 minutes) had higher rates of successful control compared with those receiving delayed TXA (>30 minutes) (91.7% vs 77.5%, $p = 0.088$). Median blood loss was also significantly lower in the early TXA group (668 mL vs 796 mL, $p = 0.028$).

Similarly, success rates were higher among those who received the complete PPH bundle compared with those with incomplete bundle adherence (90.9% vs 80.0%, $p = 0.203$). Details are summarized in **Table 3**.

Table 3. Primary outcomes and subgroup analyses (n = 100)

Outcome / Comparison	Value
Success without surgery, n (%)	86 (86%)
Compression sutures, n (%)	7 (7%)
Hysterectomy, n (%)	4 (4%)
Subgroup analyses	
Success – Early TXA (≤30 min)	55/60 (91.7%)
Success – Delayed TXA (>30 min)	31/40 (77.5%)
p (success vs TXA timing)	0.088
Median blood loss – Early TXA	668 mL
Median blood loss – Delayed TXA	796 mL
p (blood loss vs TXA timing)	0.028
Success – Complete bundle	50/55 (90.9%)
Success – Incomplete bundle	36/45 (80.0%)
p (success vs bundle completion)	0.203

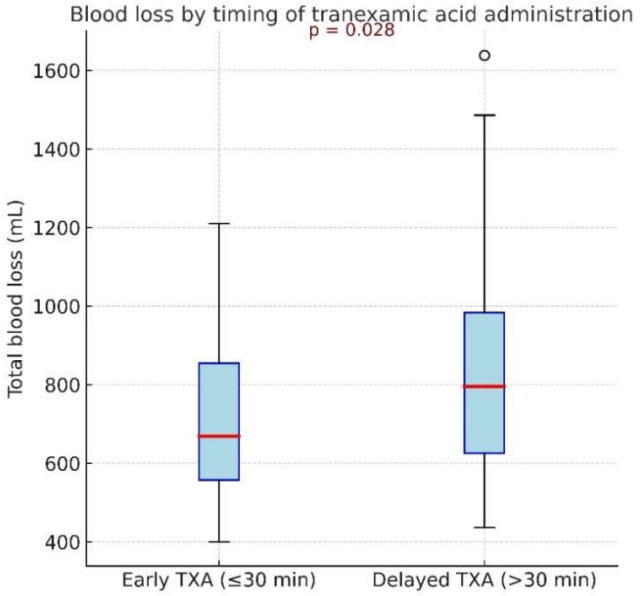

Figure 1. Boxplot comparing total blood loss between women receiving early TXA (≤30 min) and delayed TXA (>30 min). Blood loss was significantly lower in the early TXA group ($p = 0.028$)

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4.Secondary Outcomes

The median total blood loss in the study population was 737 mL (IQR 563–910). Blood transfusion was required in 37% of women, with a median of 0 units (IQR 0–1). One woman (1%) developed shock and one woman (1%) required intensive care unit (ICU) admission. No maternal deaths were recorded during the study period. Secondary outcomes are summarized in Table 4.

Table 4. Secondary outcomes among women with postpartum haemorrhage (n = 100)

Outcome	Value
Total blood loss, mL (median, IQR)	737 (563–910)
Any transfusion, n (%)	37 (37%)
Transfusion units, median (IQR)	0 (0–1)
Shock, n (%)	1 (1%)
ICU admission, n (%)	1 (1%)
Maternal mortality, n (%)	0 (0%)

Abbreviations: IQR = interquartile range; ICU = intensive care unit.

5.Subgroup Analyses

Subgroup analyses were conducted to evaluate whether the timing of tranexamic acid (TXA) administration and completion of the postpartum haemorrhage (PPH) care bundle influenced outcomes.

Women who received early TXA (≤30 minutes) had higher rates of haemorrhage control compared with those who received TXA after 30 minutes (91.7% vs 77.5%), although this difference did not reach statistical significance (p = 0.088). However, median blood loss was significantly lower in the early TXA group (668 mL vs 796 mL, p = 0.028).

Similarly, women who received the complete bundle had higher rates of success compared with those receiving incomplete bundle care (90.9% vs 80.0%, p = 0.203). These results are summarized in Table 5.and visually shown in figure2

Table 5. Association of intervention timing and bundle completion with outcomes

Comparison	Group A	Group B	p-value
Success without surgery (%)	Early TXA (≤30 min): 91.7%	Delayed TXA (>30 min): 77.5%	0.088
Blood loss, mL (median)	Early TXA: 668	Delayed TXA: 796	0.028
Success without surgery (%)	Complete bundle: 90.9%	Incomplete bundle: 80.0%	0.203

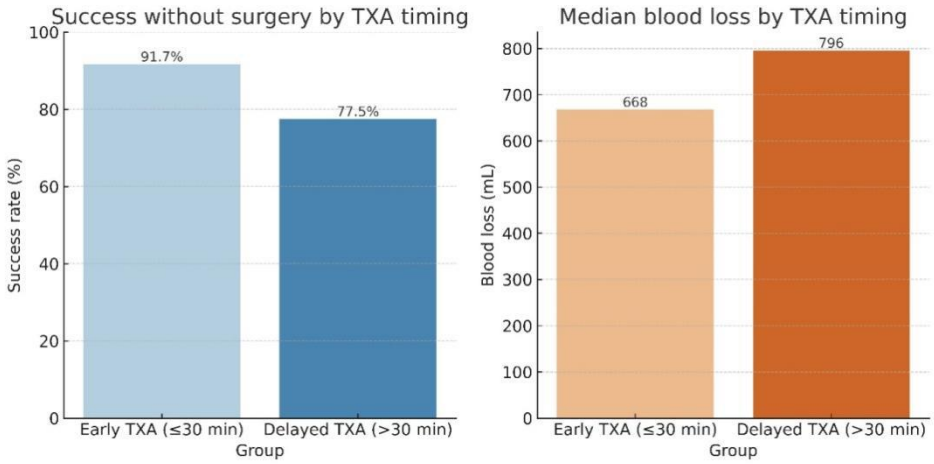

Figure 2. Subgroup analyses by timing of TXA administration. *Panel A:* Success without surgery was higher among women receiving early TXA (≤30 min), though not statistically significant (p = 0.088). *Panel B:* Median blood loss was significantly lower with early TXA compared to delayed TXA (p = 0.028).

DISCUSSION

In this prospective observational study, implementation of a bundled approach to postpartum haemorrhage (PPH) management—comprising early tranexamic acid (TXA), uterotonics, and uterine balloon tamponade—achieved successful haemorrhage control without surgery in 86% of cases, with only 4% requiring hysterectomy. These findings are broadly consistent with recent literature emphasizing conservative, fertility-preserving strategies for PPH. Overton et al. (2024) noted that intrauterine devices and tamponade methods, when used early, can avert progression to hysterectomy in the majority of women [7].

Our results also align with those reported in European simulation studies, where bundled conservative treatments—including uterotonics, TXA, and balloon tamponade—demonstrated high success rates in real-world emergencies [8]. Liu et al. (2023), in their review of refractory PPH, highlighted that stepwise conservative interventions could reduce the need for invasive procedures by up to 70%, provided interventions are implemented promptly [9]. Our study supports this time-sensitive principle, as early TXA administration (≤30 minutes) was associated with lower median blood loss (668 vs 796 mL, p = 0.028) and a trend toward higher success (91.7% vs 77.5%, p = 0.088).

Classic obstetric teaching underscores this escalation model. Leighton and Chandraharan (2021) described a structured algorithm where medical therapy is followed by mechanical tamponade before resorting to surgical intervention [10]. Patel (2024) similarly emphasized that maternal outcomes can be enhanced through effective and timely bundle-based management, particularly in resource-constrained tertiary hospitals [11]. Our observed hysterectomy rate of 4% is at the lower end of published ranges (5–10%), suggesting that early bundled care can avert radical surgery in most cases.

International guidelines also support balloon tamponade as part of bundle-based management. The WHO recommends uterine balloon tamponade for uncontrolled PPH, particularly where surgical expertise is limited [12]. Our 33% utilization rate of balloon tamponade is consistent with this guidance and with Günaydın (2022), who stressed that balloon tamponade is a pivotal component of stepwise management [13]. Systematic reviews have also confirmed its safety and feasibility; Olajumoke and Tolulope reported pooled success rates above 85% across diverse settings [14]. Our findings—86% overall success without surgery—mirror this benchmark.

Recent innovations have further optimized balloon use. Hassim et al. (2024) described uterine balloon volume shifts using a free-flow system, which improved haemostatic control in refractory cases [15]. While our study used standard Bakri or condom-catheter balloons, future adaptation of such methods could enhance bundle efficacy. Karakaya (2025) also outlined advanced intraoperative strategies, underscoring that balloon tamponade remains a cornerstone even during caesarean haemorrhage [16].

Our findings of reduced blood loss and transfusion rates with early TXA resonate with recent reports from Asia. Liu et al. (2024) highlighted that early identification and conservative treatment in cases of lower uterine segment PPH after vaginal delivery significantly reduced transfusion requirements and invasive procedures [17]. In our cohort, transfusion was required in 37% of women, which is comparable to rates of 30–40% reported in similar tertiary care settings, again suggesting external validity.

Taken together, our findings demonstrate that bundled PPH management achieves high rates of bleeding control while minimizing the need for hysterectomy, in line with contemporary global evidence [7–17]. Differences in absolute success rates across studies may reflect variations in case mix (primary vs secondary PPH), timing of interventions, balloon availability, and institutional capacity for rapid transfusion support.

Strengths and Limitations

This study has several strengths. It represents one of the few real-world evaluations of a postpartum haemorrhage (PPH) care bundle in a tertiary hospital in Eastern India, demonstrating the feasibility and effectiveness of integrating tranexamic acid, uterotonics, and balloon tamponade into routine practice. Data collection at predefined time points ensured systematic documentation of intervention timing, blood loss, and outcomes, enhancing the reliability of findings. Furthermore, by including all consecutive cases of primary PPH over one year, the study minimized selection bias and reflected the typical spectrum of cases encountered in a busy labour ward.

However, certain limitations must be acknowledged. The single-centre observational design limits generalizability, and the relatively modest sample size (n = 100) reduced statistical power to detect significant differences in subgroup analyses. While success rates and blood loss were systematically recorded, objective measurement of blood loss can be challenging, and underestimation cannot be excluded. Additionally, although balloon tamponade was available, device type and insertion techniques varied between providers, potentially introducing heterogeneity. Finally, as an observational study, unmeasured confounding factors—such as delays in blood product availability or provider experience—may have influenced outcomes.

CONCLUSION

Implementation of a bundled postpartum haemorrhage (PPH) care protocol combining early tranexamic acid, timely uterotonics, and uterine balloon tamponade achieved high rates of haemorrhage control and a low hysterectomy rate in a tertiary hospital in Eastern India. Early administration of tranexamic acid was associated with reduced blood loss and a trend toward improved outcomes. These findings support the integration of bundled, stepwise management into routine obstetric practice and highlight its potential to improve maternal outcomes in resource-limited settings.

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