

EXPLORATORY STUDY EXAMINES POTENTIAL ROLE OF ORAL TRANEXAMIC ACID USED WITH SUBLINGUAL MISOPROSTOL TO TREAT EXCESSIVE BLEEDING AFTER CHILDBIRTH

Excessive bleeding after childbirth – postpartum hemorrhage (PPH) – is a complication that can occur without warning and can quickly lead to death. Timely treatment strategies are urgently needed wherever women deliver. While uterotonic drugs (e.g. oxytocin and misoprostol) are important in controlling bleeding due to uterine atony, some women will not respond to them, and some, including those who experience trauma-related PPH, will need additional treatment.

Tranexamic acid (TXA) is a blood clot stabilizer used routinely for reduction of blood loss in surgery and trauma. It has shown promise in reducing the risk of death from postpartum bleeding due to any cause when given intravenously within three hours of delivery, and is recommended in clinical guidelines ([WHO 2017](#)). The route and time-dependent administration make TXA out of reach for most women who experience PPH in settings where intravenous (IV) administration is not feasible and transfer within three hours is unlikely.

TXA is widely available in tablet form at low cost and is stable at room temperature, creating a potential opportunity for its use as part of a PPH management package in lower level health facilities and home births. However, there is no evidence for the use of alternative routes of TXA administration.

Research Summary

To assess the potential benefit of offering two oral medications (misoprostol 800 mcg sublingual and TXA 1950 mg oral) together as a first-line treatment for PPH following vaginal birth, Gynuity Health Projects and partners conducted a small exploratory study in secondary and tertiary hospitals in Vietnam and Senegal to document efficacy, safety, and acceptability. Two hundred and sixty women diagnosed with PPH were randomly assigned to receive sublingual misoprostol and either oral TXA or placebo. Providers measured blood loss for two hours after administration of the medicines and recorded suspected cause of PPH, blood loss, additional interventions, and side effects.

Main Findings

- Baseline characteristics were comparable between the two study groups, as was the level of blood loss (700ml median) when treatment was administered.
- Uterine atony (failure of the uterus to contract) was a suspected reason for PPH in 90% of women in both groups; perineal lacerations were a cause in approximately 20% of women.
- There were no statistical differences detected in any clinical outcome measures – active bleeding was controlled with the study medicine alone (i.e. no additional interventions) for 59% of women in both groups, which was the primary outcome for this study.
- Recourse to additional interventions was very common and limits generalizability of findings especially at lower levels of care where there may be fewer available additional interventions.
- Side effects did not differ between groups and overall were acceptable to women.
- There were no maternal deaths among women diagnosed and treated for PPH.

Conclusions and Implications

- This small exploratory study did not show that the addition of oral TXA confers an advantage over use of misoprostol alone for treatment of PPH.
- It is likely that prompt access to additional interventions, including suturing and blood transfusions, contributed to good outcomes for women in this study.
- The need remains for simple options and alternatives to IV therapy for the management of PPH at lower level facilities and home births.
- Research on other TXA formulations, including oral regimens or a single-use injectable, warrants further consideration.
- Uterotonic medicines continue to be the first response to excessive bleeding after delivery, which is largely due to uterine atony. Access to these drugs must remain a focus of program and policy efforts.