ABSTRACT

INTRODUCTION: Postpartum hemorrhage (PPH) accounts for at least 150,000 maternal deaths worldwide each year. Several investigators have evaluated misoprostol for preventing PPH, drawn by its low cost, stability at room temperature, and ease of use.

OBJECTIVE: To assess the efficacy and safety of misoprostol for prevention of PPH by evaluating relevant published trials using evidence-based methodology.

METHODS: USP, a not-for-profit organization recognized by the U.S. Congress for setting standards of drug quality, develops authoritative standards, and developing evidence-based drug and therapeutic information

RESULTS: Misoprostol reduced postpartum blood loss. Side effects were mild, including gastrointestinal disturbances, shivering, and pyrexia.

CONCLUSIONS: The USP Expert Committee concluded that misoprostol is safe and effective in preventing PPH and considered this indication as an accepted off-label use. They recommended it as an alternative agent especially where oxytocin and other uterotonic drugs are not available. The single dose is 400 to 600 micrograms orally or rectally immediately following delivery of the child. Based on this consensus, the USP DI® monograph and review on misoprostol have been revised to include this off-label use.

The USP Expert Committee

Concluded that misoprostol is safe and effective in preventing PPH

Recommended misoprostol as an alternative agent in preventing PPH, especially in situations where oxytocin and other uterotonic drugs are not available

Considered prevention of PPH as accepted off-label use for misoprostol in the USP DI

Recommended a single dose of 400 to 600 micrograms orally or rectally immediately following delivery of the child to prevent PPH

Implications for Developing Countries

In developing countries where there is a high incidence of severe anemia during pregnancy, even a relatively small reduction in postpartum blood loss could be clinically relevant

Misoprostol is a promising alternative for prophylactic use in PPH because of its stability, low cost, safety, tablet form, availability, and ease of administration

Selected Bibliography


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