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Comparative Evaluation of Prophylactic Carbetocin versus Oxytocin in Prevention of Postpartum Hemorrhage Following Vaginal Delivery: A Randomized Controlled Trial

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ABSTRACT

To compare the efficacy and safety of prophylactic carbetocin versus oxytocin in the prevention of postpartum hemorrhage (PPH) after normal vaginal delivery. Methods: This was a single-blind randomized controlled trial including 84 women undergoing vaginal delivery. Group A received 100 mcg IV carbetocin; Group B received 10 IU IM plus 10 IU IV oxytocin in 500 ml RL. Primary outcomes included postpartum blood loss and changes in hemoglobin/hematocrit levels. Secondary outcomes included the need for additional uterotonics, blood transfusions, and adverse effects. Results: Mean blood loss was significantly lower in the carbetocin group (197.36 ± 77.63 ml) compared to oxytocin (316.64 ± 107.71 ml, $p=0.04$). Postpartum hemoglobin and hematocrit decline were less significant in the carbetocin group ($p<0.001$). No significant differences were observed in the need for transfusion ($p=0.69$) or adverse effects ($p=0.75$). Conclusion: Carbetocin significantly reduces postpartum blood loss compared to oxytocin, with a comparable safety profile. Its use may be beneficial in resource-limited settings due to its heat stability and single-dose regimen. Keywords: postpartum hemorrhage, carbetocin, oxytocin, vaginal delivery, randomized controlled trial

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INTRODUCTION

Postpartum hemorrhage remains a leading cause of maternal morbidity and mortality globally, accounting for up to 35% of maternal deaths. Active management of the third stage of labor, primarily with uterotonics, is a cornerstone in PPH prevention. While oxytocin is the standard drug, limitations such as cold storage requirements and need for infusion pose challenges, particularly in low-resource settings. Carbetocin, a long-acting heat-stable oxytocin analogue, offers practical advantages, but data on its efficacy in vaginal deliveries remain limited. This study aims to compare the efficacy of carbetocin versus oxytocin in preventing PPH in normal vaginal deliveries.

METHODS

Study Design and Participants

This was a single-center, single-blind, randomized controlled trial conducted at Dr. Moopen's Medical College, Wayanad, India. Eighty-four antenatal women meeting inclusion criteria (primi and second gravida undergoing normal vaginal delivery) were enrolled. Exclusion criteria included cesarean delivery, assisted delivery, hypertensive disorders, and known hypersensitivity to study drugs.

Randomization and Intervention

Participants were randomized into two groups ($n=42$ each):

Group A (Carbetocin): 100 mcg IV over 1 minute post-delivery.

Group B (Oxytocin): 10 IU IM + 10 IU IV in 500 ml RL infusion post-delivery.

Outcomes

Primary outcomes:

- Measured blood loss post-delivery.
- Hemoglobin and hematocrit changes from pre- to post-delivery.

Secondary outcomes:

- Requirement for additional uterotonics and blood transfusions.
- Incidence of adverse events within 24 hours postpartum.

Statistical Analysis

Data were analyzed using SPSS v25.0. Continuous variables were compared using t-tests, categorical variables with chi-square tests. A p-value <0.05 was considered statistically significant.

RESULTS

Both groups were comparable in age (25.6 ± 3.7 vs 25.6 ± 3.6 years), gestational age (38.5 vs 38.4 weeks), and parity. Mean blood loss was significantly lower in the carbetocin group (197.36 ± 77.63 ml vs 316.64 ± 107.71 ml, $p=0.04$). Mean hemoglobin reduction was 0.59 vs 1.03 g/dL ($p<0.05$), and mean hematocrit drop was 2.22 vs 4.95% ($p<0.001$). No significant differences were found in the need for transfusion ($p=0.69$), additional uterotonics ($p=0.66$), or adverse events ($p=0.75$).

DISCUSSION

This study demonstrated that carbetocin results in significantly lower postpartum blood loss and a smaller decline in hemoglobin and hematocrit levels compared to oxytocin in women undergoing normal vaginal delivery. Carbetocin was well tolerated, and no increase in adverse events was observed. Its single-dose use and heat stability support its potential advantage, particularly in low-resource settings.

CONCLUSION

Carbetocin significantly reduces postpartum blood loss compared to oxytocin and has a similar safety profile. Its stability and simplified dosing make it a promising option for PPH prevention, especially in resource-limited environments.

DECLARATIONS

Ethical Approval: Approved by the Institutional Ethics Committee, IEC-SC/DMMC/MAY/2023-22.

Trial Registration: CTRI/2025/03/082455

Conflicts of Interest: None.

Funding: None.