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Maternal and neonatal outcomes following prophylactic oxytocin versus carbetocin after vaginal delivery. A prospective observational study.

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Abstract

Background

Postpartum hemorrhage remains a leading cause of maternal morbidity and mortality worldwide. Prophylactic uterotonics are central to active management of the third stage of labour. Oxytocin is widely used after vaginal delivery, whereas carbetocin, a long-acting oxytocin analogue, may provide more sustained uterine contraction and better control of postpartum blood loss.

Objectives

To compare maternal and neonatal outcomes following prophylactic oxytocin versus carbetocin after vaginal delivery.

Methods

This hospital-based cross-sectional comparative study was conducted at RVM Institute of Medical Sciences and Research Centre, Laxmakkapally, Telangana, India, from January 2025 to August 2025. A total of 100 women undergoing vaginal delivery were included. Based on the prophylactic uterotonic administered during the third stage of labour as part of routine clinical care, 50 women received oxytocin and 50 received carbetocin. Maternal outcomes assessed were duration of the third stage of labour, estimated blood loss, postpartum hemorrhage, requirement of additional uterotonics, and adverse effects. Neonatal outcomes included birth weight, Apgar scores, and neonatal intensive care unit admission.

Results

The mean maternal age of the participants was 25.8 ± 3.9 years, and the majority were multiparous women. Baseline demographic and obstetric characteristics were comparable between the two groups. The carbetocin group showed a shorter duration of the third stage of labour and lower mean estimated blood loss than the oxytocin group. Postpartum hemorrhage and the need for additional uterotonics were less frequent among women who received carbetocin. Adverse effects were mild and comparable in both groups. Neonatal outcomes, including birth weight, Apgar scores, and NICU admission, did not differ significantly between the groups.

Conclusion

Carbetocin demonstrated better maternal haemostatic outcomes than oxytocin after vaginal delivery, while neonatal outcomes remained comparable.

Recommendation

Carbetocin may be preferred for postpartum hemorrhage prophylaxis after vaginal delivery, especially in women with anticipated increased bleeding risk.

Keywords: *carbetocin; oxytocin; postpartum hemorrhage; vaginal delivery; uterotonics; neonatal outcomes*

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Introduction

Postpartum hemorrhage (PPH) remains one of the most important causes of preventable maternal morbidity and mortality worldwide. Despite advances in obstetric care, excessive bleeding during the third stage of labour and the immediate postpartum period continues to contribute substantially to maternal deaths, need for transfusion, prolonged hospitalization, and emergency surgical interventions. Because uterine atony accounts for a large proportion of primary PPH, prophylactic uterotonic administration after birth has become a core component of active management of the third stage of labour and a key recommendation in major clinical guidelines [9-12].

Oxytocin is the conventional first-line uterotonic for prevention of PPH after vaginal birth because of its

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established efficacy, safety profile, and wide availability [9-12]. However, oxytocin has a relatively short half-life, and its clinical effect often depends on continuous infusion, repeat dosing, cold-chain maintenance, and adherence to labour-room protocols [9-11]. Variability in dose, route, and administration practices has also been reported across institutions. Carbetocin, a long-acting synthetic oxytocin analogue, has therefore attracted attention as an alternative prophylactic uterotonic because it provides more sustained uterine contraction with single-dose administration and simplifies postpartum drug delivery [6,7,13].

Evidence comparing oxytocin and carbetocin after vaginal delivery is informative but not fully uniform. Earlier randomized trials demonstrated that carbetocin could reduce the need for uterine massage or improve haemostatic control compared with oxytocin in women at risk of PPH [1,2]. Large contemporary data have suggested that carbetocin lowers the frequency of moderate postpartum bleeding while showing similar rates of severe PPH in routine vaginal births [4]. The WHO CHAMPION trial further reported that heat-stable carbetocin was noninferior to oxytocin for prevention of blood loss of at least 500 mL after vaginal birth [14]. Systematic reviews and meta-analyses have likewise shown either comparable efficacy or modest maternal benefit with carbetocin, especially regarding blood loss and requirement for additional uterotonic therapy, while maintaining a favorable adverse-effect profile [3,5-8].

Even with this evolving evidence base, local data from Indian tertiary care settings remain limited, especially under routine clinical practice conditions in which uterotonic choice is influenced by clinician preference, patient profile, and institutional logistics. Real-world observational comparisons are therefore useful to clarify how these agents perform in everyday vaginal delivery care and whether maternal benefit is achieved without compromising neonatal safety. In this context, the present study was undertaken to compare maternal and neonatal outcomes following prophylactic oxytocin versus carbetocin after vaginal delivery, with specific objectives to evaluate baseline comparability, duration of the third stage of labour, estimated blood loss, incidence of postpartum hemorrhage, need for additional uterotonics, maternal adverse effects, and early neonatal outcomes.

Methodology

Study Design and Setting

This hospital-based prospective cross-sectional observational study was conducted at RVM Institute of Medical Sciences and Research Centre, Laxmakkapally, Telangana, India. The institution is a tertiary care teaching hospital affiliated with a medical college and serves as a referral centre for surrounding rural and semi-urban populations of Siddipet district and neighbouring regions. The hospital has a well-equipped obstetrics and gynaecology department with a functional labour room complex, emergency obstetric services, and neonatal intensive care facilities. On average, the labour unit manages a high volume of deliveries annually, including both routine and high-risk pregnancies, thereby providing a representative clinical environment for evaluating maternal and neonatal outcomes following vaginal delivery.

The study was conducted over a period of eight months, from January 2025 to August 2025. The cross-sectional observational design allowed the assessment of maternal and neonatal outcomes associated with prophylactic uterotonic administration during the third stage of labour in routine clinical practice. Women undergoing vaginal delivery during the study period were observed at the time of delivery and categorized according to the prophylactic uterotonic administered as part of standard labour-room management.

Study Population and Sampling

A total of 100 women who underwent vaginal delivery during the study period were included in the final analysis. Participants were recruited by consecutive sampling after meeting the predefined eligibility criteria. The enrolled women were categorized according to the prophylactic uterotonic administered during the third stage of labour as part of routine obstetric management. Of the total participants, 50 women received oxytocin and 50 received carbetocin. As this was a prospective observational study, the choice of uterotonic agent was determined by the treating obstetrician based on standard labour-room practice, and no intervention was made by the investigators in treatment allocation.

Sample Size Determination

The sample size was calculated using the standard single-proportion formula for cross-sectional studies:

$$n = Z^2 \times p \times (1 - p) / d^2$$

where n is the required sample size, Z is the standard normal deviate at 95% confidence level (1.96), p is the anticipated proportion of postpartum hemorrhage based on previous literature, taken as 10% (0.10), and d is the absolute precision or allowable error, set at 6% (0.06). Substituting these values into the formula:

$$n = (1.96)^2 \times 0.10 \times 0.90 / (0.06)^2$$
$$n = 96.04$$

Accordingly, the minimum required sample size was approximately 96 participants. For convenience, improved precision, and to compensate for possible incomplete observations, the final sample size was rounded to 100 women.

Eligibility criteria

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Women with vaginal delivery and receipt of a prophylactic uterotonic immediately after birth were considered for inclusion. Women undergoing cesarean delivery, those with major traumatic PPH requiring immediate operative management, those with known coagulation disorders, and those with incomplete essential outcome data were excluded from analysis. These criteria were applied to maintain a clinically comparable cohort for assessment of routine postpartum prophylaxis.

Data collection and study variables

Maternal demographic and obstetric variables, including age, parity, and gestational age, were recorded at enrolment. Maternal outcomes assessed were duration of the third stage of labour, estimated blood loss, incidence of postpartum hemorrhage, requirement of additional uterotonics, and short-term adverse effects such as nausea, vomiting, hypotension, and headache. Neonatal variables included birth weight, Apgar score at 1 minute, Apgar score at 5 minutes, and NICU admission. PPH was defined using the conventional threshold of blood loss exceeding 500 mL after vaginal birth, in line with published guidance [11,12]. Blood loss estimation was based on the clinical assessment and routine labour-room documentation maintained by the attending team.

Management protocol

All women received standard intrapartum and postpartum care according to institutional obstetric practice. Prophylactic oxytocin or carbetocin was administered during active management of the third stage of labour in accordance with established uterotonic-based prevention strategies described in major guidance documents [9-12]. Women were monitored in the immediate postpartum period for uterine tone, vaginal bleeding, haemodynamic status, and need for additional pharmacologic support.

Bias Control

Several methodological measures were implemented to minimize potential sources of bias. Consecutive sampling was employed to enroll all eligible women undergoing vaginal delivery during the study period, thereby reducing selection bias. Standardized clinical protocols were followed for the administration of prophylactic uterotonics and for the management of the third stage of labour. Objective clinical parameters such as estimated blood loss, duration of the third stage of labour, and neonatal Apgar scores were recorded using uniform criteria to limit measurement bias. Data were collected prospectively using structured case-record forms, and incomplete records were excluded from analysis to ensure data accuracy and consistency.

Statistical analysis

Data were entered in Microsoft Excel and analyzed using standard statistical methods. Continuous variables were expressed as mean ± standard deviation, while categorical variables were summarized as frequency and percentage. Between-group comparisons for continuous variables were performed using the independent-samples t test. Categorical variables were compared using the chi-square test or Fisher's exact test wherever appropriate. A p-value of less than 0.05 was considered statistically significant.

Ethical considerations

The study was performed after obtaining approval from the Institutional Ethics Committee of RVM Institute of Medical Sciences and Research Centre, Laxmakkapally, Telangana, India, and written informed consent was obtained from all participating women prior to enrolment. Confidentiality of patient information was strictly maintained throughout the processes of data collection, analysis, and manuscript preparation. Personal identifiers were removed from study records to ensure participant privacy and data security.

Results

A total of 100 women who underwent vaginal delivery were included in the study. Of these, 50 received prophylactic oxytocin and 50 received prophylactic carbetocin. Baseline maternal characteristics were comparable between the two groups, with no statistically significant differences in mean age, parity distribution, or gestational age, indicating acceptable group comparability for outcome assessment (Table 1).

Table 1. Baseline maternal characteristics of the study groups

Variable	Oxytocin (n = 50)	Carbetocin (n = 50)	p-value
Mean age (years)	25.8 ± 3.9	26.1 ± 4.2	0.68
Primigravida	28 (56%)	26 (52%)	0.68
Multigravida	22 (44%)	24 (48%)	-
Mean gestational age (weeks)	38.5 ± 1.2	38.7 ± 1.1	0.44

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The duration of the third stage of labour was significantly shorter among women who received carbetocin than among those who received oxytocin. The mean duration was 5.9 ± 1.8 minutes in the carbetocin group compared with 7.4 ± 2.1 minutes in the oxytocin group, and this difference was statistically significant (p = 0.001), suggesting more rapid placental separation and uterine contraction with carbetocin (Table 2)

Table 2. Duration of the third stage of labour

Group	Mean duration (minutes)	p-value
Oxytocin	7.4 ± 2.1	-
Carbetocin	5.9 ± 1.8	0.001

Estimated blood loss was lower in the carbetocin group across the distribution of blood-loss categories. A greater proportion of women in the carbetocin group lost less than 300 mL of blood, whereas higher blood-loss categories were more frequent in the oxytocin group. The mean estimated blood loss was 365 ± 110 mL in the oxytocin group and 285 ± 95 mL in the carbetocin group, showing a statistically significant reduction with carbetocin (p = 0.002) (Table 3).

Table 3. Estimated blood loss after vaginal delivery

Estimated blood loss	Oxytocin (n = 50)	Carbetocin (n = 50)	p-value
<300 mL	18 (36%)	32 (64%)	-
300-500 mL	24 (48%)	15 (30%)	-
>500 mL	8 (16%)	3 (6%)	-
Mean estimated blood loss (mL)	365 ± 110	285 ± 95	0.002

With respect to clinically important maternal outcomes, postpartum hemorrhage was observed in 14% of women in the oxytocin group and 4% of women in the carbetocin group. Although this difference favored carbetocin, it did not reach statistical significance (p = 0.08). In contrast, the requirement for additional uterotonic agents was significantly lower in the carbetocin group than in the oxytocin group (6% vs 20%; p = 0.04), indicating better initial haemostatic control after routine prophylaxis (Table 4).

Table 4. Postpartum hemorrhage and requirement of additional uterotonics

Outcome	Oxytocin (n = 50)	Carbetocin (n = 50)	p-value
PPH present	7 (14%)	2 (4%)	0.08
No PPH	43 (86%)	48 (96%)	-
Additional uterotonics required	10 (20%)	3 (6%)	0.04
No additional uterotonics required	40 (80%)	47 (94%)	-

Maternal adverse effects were infrequent in both groups. Nausea, vomiting, hypotension, and headache occurred at low frequency, and the distribution of these effects was similar between oxytocin and carbetocin recipients. These findings suggest that both prophylactic regimens were generally well tolerated in the immediate postpartum period (Table 5).

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Table 5. Maternal adverse effects

Adverse effect	Oxytocin (n = 50)	Carbetocin (n = 50)
Nausea	6 (12%)	4 (8%)
Vomiting	4 (8%)	3 (6%)
Hypotension	3 (6%)	2 (4%)
Headache	2 (4%)	2 (4%)

Early neonatal outcomes were comparable between the two groups. Mean birth weight was similar, and there were no significant differences in Apgar scores at 1 minute or 5 minutes. NICU admission was uncommon in both groups and did not differ significantly. Overall, the maternal advantages observed with carbetocin were not accompanied by any apparent short-term neonatal disadvantage in this cohort (Table 6).

Table 6. Neonatal outcomes

Outcome	Oxytocin (n = 50)	Carbetocin (n = 50)	p-value
Mean birth weight (kg)	2.86 ± 0.42	2.91 ± 0.39	0.54
Apgar score at 1 min	7.6 ± 0.8	7.7 ± 0.7	0.61
Apgar score at 5 min	8.9 ± 0.5	9.0 ± 0.4	0.48
NICU admission	3 (6%)	2 (4%)	0.65

Discussion

The present prospective observational study demonstrated that prophylactic carbetocin after vaginal delivery was associated with better maternal haemostatic outcomes than prophylactic oxytocin in this cohort. Women in the carbetocin group had a significantly shorter third stage of labour, lower mean estimated blood loss, and a reduced requirement for additional uterotonic agents. Although the incidence of PPH was numerically lower with carbetocin, the difference did not reach statistical significance. Maternal adverse effects were infrequent in both groups, and neonatal outcomes remained comparable.

The observed reduction in third-stage duration and blood loss is biologically plausible and aligns with the pharmacologic profile of carbetocin as a longer-acting oxytocin analogue that sustains uterine contraction after a single administration [6,7,13]. Earlier clinical studies support this pattern. Boucher et al. reported less need for uterine massage and fewer uterotonic interventions with carbetocin in women at risk of PPH after vaginal delivery [1]. In a triple-blind randomized trial, Amornpetchakul et al. also found carbetocin to be more effective than oxytocin for preventing atonic PPH in high-risk singleton pregnancies undergoing vaginal birth [2]. These trials reinforce the present finding that carbetocin can provide more stable postpartum uterine tone than routine oxytocin prophylaxis.

Our finding of lower estimated blood loss with carbetocin is also consistent with pooled evidence. The meta-analysis by Huang et al. reported superiority of carbetocin over oxytocin for prevention of PPH after vaginal delivery [5], while Jin et al. found broadly comparable efficacy and safety overall but acknowledged that the choice between the two drugs could reasonably depend on local priorities such as cost-effectiveness and logistics [3]. The broader systematic reviews by Jin et al. and Su et al. likewise suggest that carbetocin performs favorably among prophylactic uterotonics, especially in relation to blood loss and adverse-effect burden [6,7]. Network evidence synthesized by Gallos et al. further placed carbetocin among the more effective uterotonics for prevention of PPH of at least 500 mL [8].

The lower need for additional uterotonics in the present study is clinically relevant because it implies better first-line haemostatic control and a smaller requirement for escalation of postpartum management. This observation is in line with the sustained uterotonic effect described in prior reviews [6,13]. However, the absence of a statistically significant difference in overt PPH should be interpreted carefully. Korb et al. reported that prophylactic carbetocin lowered PPH of at least 500 mL after vaginal delivery but did not differ from oxytocin in preventing severe PPH [4]. Similarly, the WHO

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CHAMPION trial showed noninferiority rather than clear superiority of heat-stable carbetocin for the primary composite postpartum bleeding outcome after vaginal birth [14]. The limited sample size in the present study likely reduced statistical power for relatively infrequent outcomes such as clinically defined PPH.

Neonatal outcomes in our study were similar between groups, with no significant differences in birth weight, Apgar scores, or NICU admission. This finding is reassuring and agrees with the existing literature, where prophylactic postpartum uterotonics have generally not been associated with meaningful differences in immediate neonatal condition when administered after delivery [1-4,14]. Taken together, the present findings support carbetocin as a practical prophylactic uterotonic option after vaginal birth in tertiary care settings. Its apparent maternal benefit, coupled with a simple single-dose regimen and comparable neonatal safety, makes it an attractive agent for routine obstetric care. Larger multicenter studies from Indian settings using objective blood-loss measurement and cost analyses would strengthen the evidence needed for broader policy adoption.

Generalizability

The findings of this study provide useful insights into the effectiveness of prophylactic uterotonics in preventing postpartum hemorrhage following vaginal delivery in routine clinical settings. Because the study was conducted in a tertiary care teaching hospital that serves a large rural and semi-urban population, the results may reflect real-world obstetric practice in similar healthcare facilities. The observed maternal outcomes associated with carbetocin and oxytocin may therefore be applicable to comparable tertiary hospitals and district-level institutions where active management of the third stage of labour is routinely practiced. Although the sample size was limited, the study contributes to the growing evidence supporting the clinical use of long-acting uterotonics for postpartum hemorrhage prevention. Larger multicentric studies involving diverse populations may further validate these findings and strengthen their applicability to broader maternal healthcare programs.

Conclusion

In this prospective observational study of women undergoing vaginal delivery, prophylactic carbetocin was associated with a shorter third stage of labour, lower mean blood loss, and a smaller need for additional uterotonic support than oxytocin. The incidence of postpartum hemorrhage was numerically lower with carbetocin, although the difference was not statistically significant in this cohort. Maternal adverse effects remained infrequent, and neonatal outcomes, including birth weight, Apgar scores, and NICU admission, were comparable between groups. These findings support carbetocin as an effective and clinically practical option for postpartum hemorrhage prophylaxis after vaginal birth. Larger multicenter studies with objective blood loss measurement are required to confirm these observations.

Limitations

This single-center study included a modest sample and therefore had limited power for uncommon outcomes such as postpartum hemorrhage and NICU admission. Treatment allocation followed routine clinical practice rather than randomization, leaving scope for selection bias and unmeasured confounding. Blood loss estimation was based on labour-room clinical assessment instead of a fully standardized quantitative method. Cost, patient satisfaction, and longer postpartum follow-up were not assessed.

Recommendations

Based on the findings of the present study, carbetocin may be considered an effective alternative to oxytocin for prophylaxis against postpartum hemorrhage following vaginal delivery, particularly in women at increased risk of excessive blood loss. Its use may contribute to better haemostatic control and reduced requirement for additional uterotonic support in routine obstetric practice. However, cost, availability, and institutional protocols should be considered before wider implementation. Further large-scale multicentric comparative studies are recommended to confirm these findings across diverse populations and healthcare settings. In addition, future research should include cost-effectiveness analysis and longer follow-up to better define the practical role of carbetocin in standard maternal care.

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List of Abbreviations

PPH – Postpartum Hemorrhage
WHO – World Health Organization
NICU – Neonatal Intensive Care Unit
APGAR – Appearance, Pulse, Grimace, Activity, Respiration score
ML – Millilitre
IV – Intravenous
IM – Intramuscular
SPSS – Statistical Package for the Social Sciences
CI – Confidence Interval

SD – Standard Deviation

Source of Funding

No funding was received.

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 and overall supervision of the study, participated in study design, interpretation of clinical findings, and critical revision of the manuscript. **Dr Akula Swaroopa Rani** was involved in patient recruitment, clinical data collection in the labour room, and contributed to data organization and interpretation of obstetric outcomes. **Dr Vidyullatha Balivada** participated in pharmacological evaluation of the uterotonic agents, assisted in study methodology development, and contributed to manuscript drafting and literature review. **Dr Prashanth Kumar Patnaik** performed data analysis, assisted in statistical interpretation of results, and contributed to manuscript editing and final approval of the version submitted for publication.

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