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Original Article

A Comparative Study on Oxytocin Versus Carbetocin in Prevention of Primary Postpartum Haemorrhage After Childbirth

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Abstract

Background: Postpartum haemorrhage (PPH) remains a leading cause of maternal morbidity and mortality worldwide. Effective prophylactic uterotonic agents are essential for preventing primary PPH after childbirth. The study aims to compare the effectiveness and safety of oxytocin versus Carbetocin in preventing primary PPH following both vaginal and caesarean deliveries in a tertiary care setting in Eastern India.

Methodology: This prospective, open-label, randomized controlled superiority trial was conducted over 18 months (October 2022-March 2024) at B.R. Singh Hospital, Kolkata. One hundred and twenty pregnant women aged 18-35 years with singleton pregnancies ≥37 weeks undergoing normal vaginal delivery or caesarean section were randomized into two groups. The Oxytocin group (n=60) received 10 IU intravenously with a maintenance dose, while the Carbetocin group (n=60) received 100µg intravenously without a maintenance dose. Primary outcomes included total blood loss and incidence of PPH. Secondary outcomes included uterine atony and additional uterotonic requirements, hemodynamic changes, change in hemoglobin levels, and maternal side effects.

Results: Carbetocin significantly reduced total blood loss in both delivery modes ($p<0.001$). PPH incidence was lower with Carbetocin (17.9% vs 29.6% in caesarean delivery; 9.4% vs 27.3% in vaginal delivery). Post-delivery haemoglobin levels were significantly higher, and haemoglobin drop was significantly lower in the Carbetocin group. Uterine atony occurred less frequently with Carbetocin (23.3% vs 43.3%, $p<0.05$). Carbetocin caused minimal hemodynamic changes compared to the significant hypotensive effects of oxytocin.

Conclusion: Carbetocin is superior to oxytocin in preventing primary PPH, offering better efficacy and safety profile through reduced complications.

Keywords: Postpartum haemorrhage, Oxytocin, Carbetocin, uterotonic agents, caesarean section, vaginal delivery, uterine atony, maternal safety

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Introduction

Postpartum haemorrhage (PPH) remains a leading cause of maternal mortality globally, accounting for approximately 27% of maternal deaths according to the World Health Organization [1,2]. In India, PPH contributes to 38% of maternal mortality cases, making it a critical public health concern [3]. Primary PPH, defined as blood loss exceeding 500 mL after vaginal delivery (VD) or 1000 mL after caesarean section within 24 hours of delivery, primarily results from uterine atony due to inadequate uterine contractions following childbirth [4].

The current gold standard for PPH prevention is oxytocin (10 IU intravenously/intramuscularly) as part of active management of the third stage of labour, which has reduced PPH incidence by approximately 50% [5]. However, the short half-life of oxytocin (4-10 minutes) necessitates continuous infusion or repeated injections, and its heat-sensitivity compromises efficacy in resource-limited settings lacking cold-chain storage [6].

Carbetocin, a long-acting synthetic oxytocin analogue with a 40-minute half-life and superior heat-stability, has emerged as a potential alternative [7]. While some studies suggest that prophylactic administration of Carbetocin may be a good alternative to oxytocin to prevent post-partum haemorrhage [8-10], others have concluded that Carbetocin was superior to oxytocin for the prevention of PPH or the use of additional uterotonic agents [11,12]. A meta-analysis has reported that Carbetocin was as effective and safe as oxytocin for the prevention of postpartum haemorrhage in women undergoing VD [13]. However, there is a dearth of adequate studies comparing the effectiveness of these two uterotonic agents for the control of PPH in the Indian pregnant population undergoing delivery by either means – VD or caesarean delivery.

While studies suggest comparable efficacy between these agents [8-13], most existing research is from high-income countries with limited evidence from the Indian subcontinent. Regional data is essential for formulating context-appropriate national guidelines and ensuring generalizability of findings to our population. Therefore, this study was conducted to compare the effectiveness and safety of oxytocin versus Carbetocin in preventing primary PPH following both vaginal and caesarean deliveries in a tertiary care setting in Eastern India.

Material and Methods

Study design and setting This prospective, open-label randomized controlled superiority trial was conducted at the Department of Obstetrics and Gynaecology, B. R. Singh Hospital and Centre for Medical Education and Research, Kolkata, over an 18-month period from October 2022 to March 2024. The study received ethical approval from the Institutional Ethics Committee (IEC) of B. R. Singh Hospital and Centre for Medical Education and Research, Kolkata. The study protocol obtained ethical approval from the Institutional Ethics Committee of the concerned institution and was subsequently registered with the Clinical Trials Registry of India (CTRI/2022/06/002145; Date: 12/06/2022). The observations of the study were reported in compliance with the CONSORT guidelines.

Study population The study population comprised antenatal mothers aged 18-35 years with singleton pregnancy at ≥37 weeks of gestation, without any evidence of fetal distress on admission, undergoing either normal VD or lower segment caesarean section (LSCS) at term pregnancy. Women were excluded if they had any of the following: multiple pregnancy, grand multiparity (≥5 previous deliveries), intrauterine fetal death, vaginal delivery complicated by episiotomy or perineal tears, pre-existing medical conditions (cardiac disease, renal disease, hypertension), severe anemia, known bleeding or coagulation disorders, or required emergency obstetric intervention.

Sample size, randomization, and blinding. Sample size was calculated using the standard formula for superiority trials. Based on a previous study by Kabir et al. [8], with a reported PPH incidence of 0% in the Carbetocin group and 12.8% in the Oxytocin group, 95% confidence level ($Z_{1-\alpha/2} = 1.96$), and 80% power ($Z_{\beta} = 0.84$), the minimum estimated sample size was 108 participants (54 per group). For convenience, 120 patients were recruited, with 60 participants in each group.

All patients screened as eligible were invited to participate in the study. Recruitment of participants was initiated after explaining the procedure and obtaining informed consent from the patients. The recruited study participants were randomized in a 1:1 ratio into either of the study groups using a computer-generated random allocation sequence. The computer-generated random allocation sequence was prepared prior to study initiation by an independent statistician who was not involved in patient recruitment or clinical care. The sequence was concealed using sequentially numbered, opaque, sealed envelopes (SNOSE). At the time of enrollment, after obtaining informed consent, the recruiting physician opened the next consecutive envelope to reveal the group assignment. This ensured that the allocation sequence remained concealed from the investigators during the recruitment process, thereby preventing selection bias. Recruitment was continued till there were 60 study participants in each of the study groups (Figure 1).

Study groups Participants assigned to the **Oxytocin group** were given an injection of oxytocin 10 IU in an intravenous fluid after delivery of the anterior shoulder for both VD and LSCS, followed by a maintenance dose of 10 IU in intravenous fluid over four hours for both delivery modes. Participants allotted to the **Carbetocin group** were administered an injection of Carbetocin 100µg dissolved in 10ml normal saline as slow intravenous administration after delivery of the anterior shoulder for both VD and LSCS, with no maintenance dose.

Outcome measures: The primary outcome measure was the total blood loss and incidence of PPH in both study groups. Secondary outcome measures included incidence of uterine atony and use of additional uterotonic agents; hemodynamic changes (blood pressure); change in haemoglobin levels (pre-delivery vs. 24 hours post-delivery); and maternal adverse effects.

Data collection and study procedure: Demographic details, obstetric history, and haemoglobin levels estimated at the time of admission for delivery were noted from medical records. Study participants received either oxytocin or carbetocin during delivery (vaginal or cesarean section) according to their assigned group as per the study protocol. Systolic and diastolic blood pressures were measured immediately before and 5 minutes after drug administration. The total volume of blood lost during vaginal delivery and caesarean delivery was measured using the following method:

- In case of vaginal delivery, a calibrated blood collecting drape was placed under the gluteal region and tied anteriorly over the abdomen and thighs. The collected blood after the separation of the placenta was measured after 1 hour. In caeserean delivery, after the separation of the placenta, blood was collected into the suction container, and the soaked mops were weighed. Each patient, after delivery, was given standard-sized sanitary napkins (standard weight of one dressing is 25gm) during the 24 hours post-delivery hospital stay.
- During vaginal delivery, the total volume of blood lost within 24 hours was estimated by the calculation: (weight of the soaked dressing after removal - weight before application)/1.06 + volume collected in the calibrated drape. In caesarean section, the total volume of blood lost within 24 hours was estimated by the calculation: (weight of the soaked mops and sanitary napkins – weight of such before application)/1.06 + volume of blood in the suction container. Note: The density of blood is 1.06.

Uterine tone was assessed by fundal palpation at regular intervals: every 15 minutes for the first hour post-delivery, hourly for the next 6 hours, and then every 6 hours for the remaining 24-hour observation period

after transfer from the operating theatre or labour room. The objective criteria for administering additional uterotonics included:

1. Uterine atony detected on palpation (soft, boggy uterus above the umbilicus)
2. Postpartum haemorrhage is defined as blood loss >500 mL (vaginal delivery) or >1000 mL (caesarean section), measured using calibrated drapes/collection bags and the gravimetric method.
3. Persistent lochia rubra with clots despite uterine massage
4. Hemodynamic instability (tachycardia, hypotension) suggestive of ongoing blood loss

The decision to administer additional uterotonics was made by the attending obstetrician based on these predefined clinical and quantitative parameters, ensuring standardized and objective assessment across both study groups.

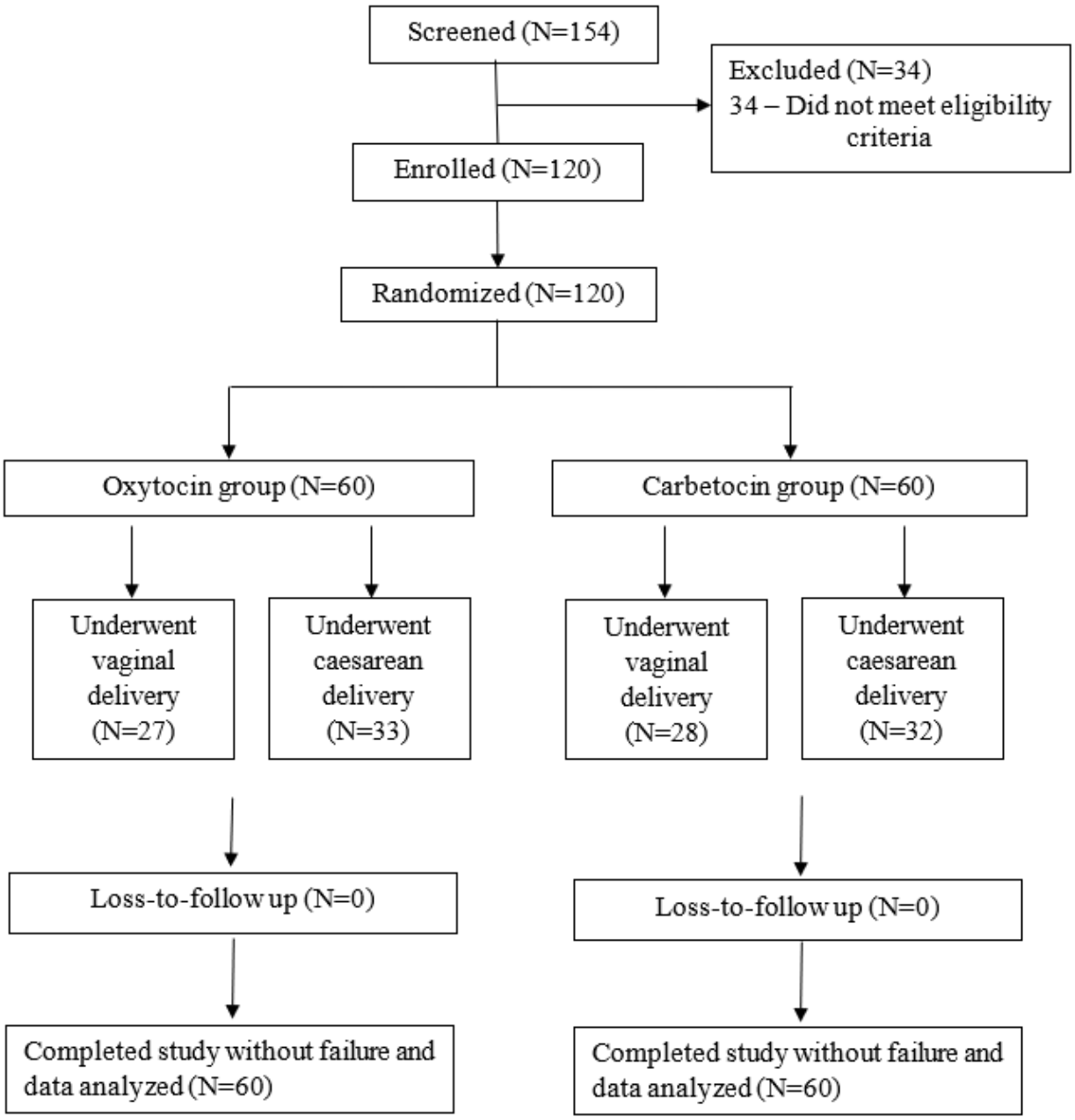
Post-delivery haemoglobin level was documented at 24 hours. Maternal side effects were recorded based on patient self-reporting during the 24-hour postpartum observation period. Participants were specifically asked about any discomfort or symptoms they experienced, and all reported complaints were documented. All procedures were performed according to standard guidelines. All details were recorded in a predesigned proforma.

Statistical analysis: Data were analyzed using SPSS version 23.0. Continuous variables were expressed as mean ± standard deviation, and categorical variables as frequencies and percentages. The normality of continuous variables was assessed using the Shapiro-Wilk test. Where the data did not follow a normal distribution, non-parametric tests (Mann-Whitney U test) were employed for comparison between groups; for normally distributed variables, an independent samples t-test was used. Categorical variables were compared using the Chi-square test or Fisher's exact test, as appropriate. All analyses were conducted on a per-protocol basis, with participants analyzed according to their original group as per the protocol, with no exclusions. A value of $p<0.05$ was considered statistically significant.

Results

A total of 154 pregnant women were screened for eligibility during the study period. Of these, 34 women were excluded as they did not meet the inclusion criteria. The remaining 120 eligible participants were enrolled and randomized in a 1:1 ratio into two groups: Oxytocin group (n=60) and Carbetocin group (n=60). In the Oxytocin group, 27 women underwent vaginal delivery and 33 underwent cesarean section, while in the Carbetocin group, 28 had vaginal delivery and 32 had cesarean delivery. There was no loss to follow-up in either group, and all 120 randomized participants completed the study protocol and were included in the final analysis (Figure 1).

Figure 1: CONSORT flow diagram



The baseline demographic and clinical characteristics of the study participants are presented in Table 1. The mean ± SD age was 26.4 ± 3.1 years in the Oxytocin group and 25.9 ± 2.7 years in the Carbetocin group, which was comparable statistically (p=0.877). Also, study participants were comparable in terms of parity, gestational age, and mode of delivery (p>0.05) (Table 1).

Table 1: Baseline characteristics of the participants in both the study groups (N=120)

Characteristics	Categories	Oxytocin group (N=60)	Carbetocin group (N=60)	p-value#
Age (years)	--	26.4 ± 3.1	25.9 ± 2.7	0.877
Parity	Nulliparous	21 (35.0)	19 (31.7)	0.384
	Primiparous	38 (63.3)	37 (61.6)	
	Multiparous	1 (1.7)	4 (6.7)	
Gestational age	37-37+6	11 (18.3)	12 (20.0)	0.859
	38-38+6	28 (46.7)	25 (41.7)	
	39-39+6	21 (35.0)	23 (38.3)	
Mode of delivery	VD	27 (45.0)	28 (46.7)	0.855
	LSCS	33 (55.0)	32 (53.3)	

p-value based on Mann-Whitney U test

While systolic blood pressure (SBP) and diastolic blood pressure (DBP) prior to administration of study drugs were comparable in both groups, there was a drop in blood pressure, and SBP and DBP recordings after 5 minutes of drug administration were significantly different in the two study groups ($p<0.001$). However, on pre-post analysis, it was found that a decline in SBP and DBP values at 5 minutes after oxytocin administration was statistically significant compared to the initial corresponding values ($p<0.001$); while the difference was not statistically significant after administration of carbetocin ($p=0.120$) (Table 2).

Table 2: Comparison of SBP and DBP before and after 5 minutes of administration of study drug (N=120)

Characteristics	Oxytocin group (N=60)	Carbetocin group (N=60)	p-value#
SBP before drug administration	126.9 ± 3.9	124.3 ± 3.6	0.964
SBP after 5 minutes of drug administration	112.7 ± 4.2	120.3 ± 3.8	<0.001*
Pre-post analysis (**p-value**^)	<0.001*	0.061	
DBP before drug administration	76.9 ± 2.9	77.2 ± 3.1	0.635

DBP after 5 minutes of drug administration	69.4 ± 2.8	75.3 ± 2.6	<0.001*
Pre-post analysis (**p-value**^)	<0.001*	0.120	

p-value based on Mann-Whitney U test

^ p-value based on paired T test

* p<0.05 was considered statistically significant

The mean total blood loss during LSCS was significantly higher in the Oxytocin group compared to the Carbetocin group (p<0.001). Similar results were observed in the VD group (Table 3).

Table 3: Blood loss according to mode of delivery in both the study groups (N=120)

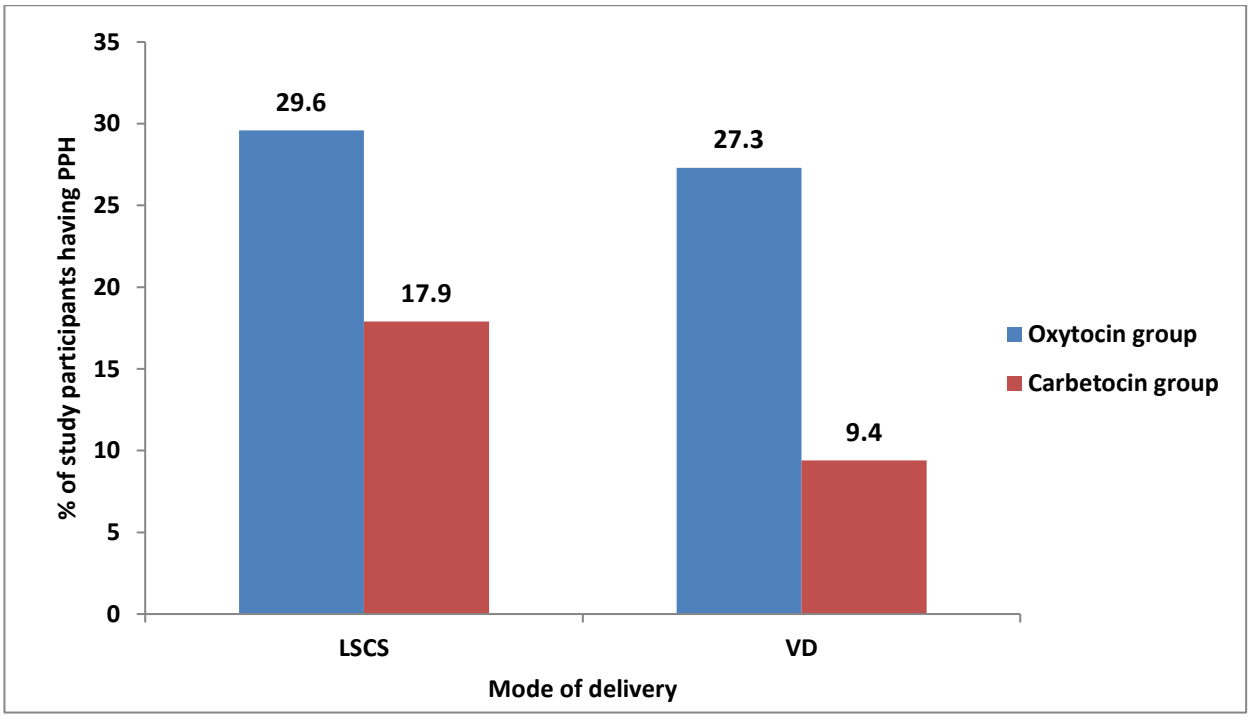
Characteristics	**Oxytocin group (N=60)**	**Carbetocin group (N=60)**	**p-value#**
LSCS (n=55)			
Blood loss during LSCS (from placenta delivery to end of LSCS) (ml)	573.7 ± 178.5	434.6 ± 154.7	<0.001*
Blood loss after LSCS (till 24 hours post-partum) (ml)	115.1 ± 60.7	64.3 ± 36.5	0.042*
Total blood loss during and after LSCS (ml)	688.8 ± 219.8	498.9 ± 177.5	<0.001*
VD (n=65)			
Blood loss during VD (from placental separation to 1 hour post-delivery) (ml)	294.8 ± 77.3	195.9 ± 50.2	0.031*
Blood loss after VD (from 1 hour till 24 hours post-delivery) (ml)	113.6 ± 52.8	63.8 ± 38.8	0.045*
Total blood loss during and after VD (ml)	408.1 ± 129.2	261.6 ± 73.1	<0.001*

p-value based on Mann Whitney U test

* p<0.05 was considered statistically significant

Among patients undergoing LSCS, the incidence of PPH was 29.6% in the Oxytocin group (8/60) and 17.9% in the Carbetocin group (5/60). Among those having vaginal delivery, the incidence of PPH was 27.3% in the Oxytocin group (9/60) and 9.4% in the Carbetocin group (3/60). The incidence of PPH in LSCS and VD was statistically comparable in both the study groups (p>0.05) (Figure 2).

Figure 2: Incidence of PPH according to mode of delivery in both the study groups (N=120)



The mean pre-delivery Hb levels were comparable between patients in the Oxytocin group and the Carbetocin group (p>0.05). However, the mean Hb level 24 hours post-delivery was significantly lower among those in the Oxytocin group as compared to the Carbetocin group (9.1±1.1 vs 10.2±1.2 in patients undergoing LSCS and p=0.003; 9.5±1.3 vs 10.5±1.6 in patients having VD and p=0.004) (Table 4).

Table 4: Comparison of change in haemoglobin and total urine output 24 hours post-delivery according to mode of delivery in both the study groups (N=120)

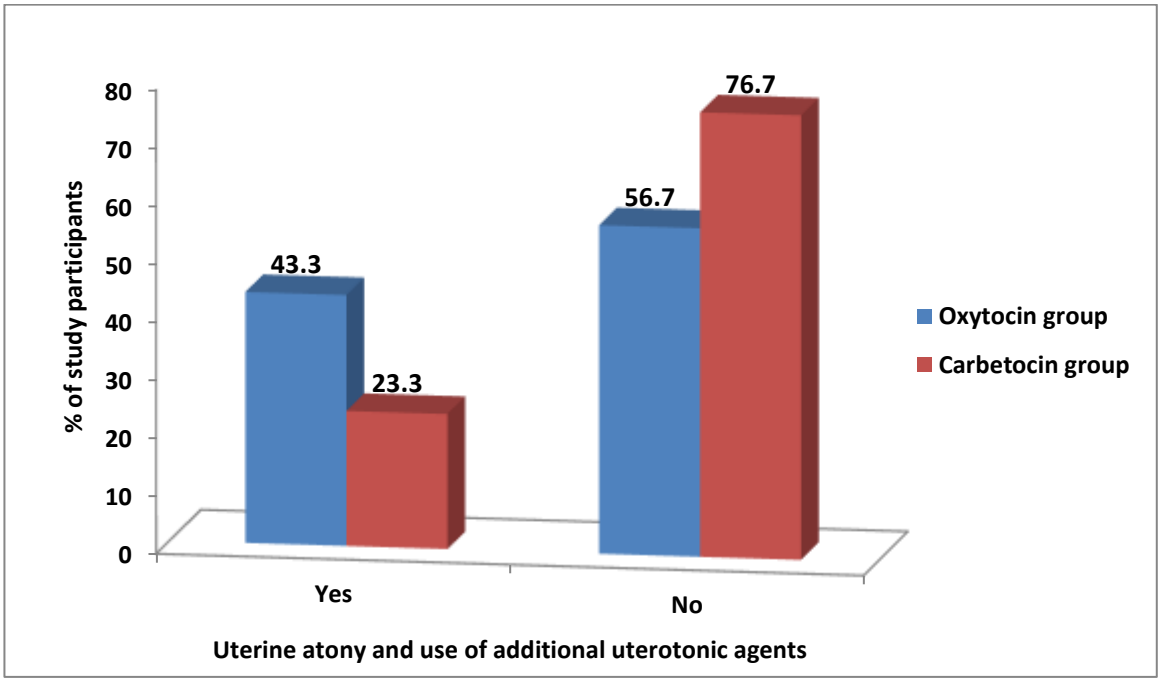
Characteristics	Oxytocin group (N=60)	Carbetocin group (N=60)	p-value#
LSCS (n=55)			
Pre-delivery Hb (g/dl)	11.2 ± 1.5	11.4 ± 1.6	0.893
24 hours post-delivery Hb (g/dl)	9.1 ± 1.1	10.2 ± 1.2	0.003*
Drop in Hb (g/dl)	2.1 ± 0.8	1.2 ± 0.6	<0.001*
VD (n=65)			
Pre-delivery Hb (g/dl)	11.3 ± 1.6	11.6 ± 1.4	0.799
24 hours post-delivery Hb (g/dl)	9.5 ± 1.3	10.5 ± 1.6	0.004*
Drop in Hb (g/dl)	1.8 ± 0.6	1.1 ± 0.4	<0.001*

p-value based on Mann-Whitney U test

* p<0.05 was considered statistically significant

The proportion of patients with uterine atony was significantly higher in the Oxytocin group (26/60, 43.3%) when compared to the corresponding figure in the Carbetocin group (14/60, 23.3%). Use of additional uterotonic agents was warranted in those having uterine atony, and their proportions corroborated with that of the incidence of uterine atony in the respective study groups (Figure 3).

Figure 3: Incidence of uterine atony and use of additional uterotonic agents in both the study groups (N=120)



The various reported side effects were headache (5/60, 8.3%), vomiting (4/60, 6.7%), and flushing (8/60, 13.3%) in the Oxytocin group and headache (4/60, 6.7%) and vomiting (5/60, 8.3%) in the Carbetocin group. Overall, the incidence of maternal side effects was 28.3% in the Oxytocin group (17/60) and 15% in the Carbetocin group (9/60). However, differences in the proportion of side effects in the two groups were statistically comparable (p=0.076).

Discussion

The present study demonstrated several important findings regarding the comparative effectiveness of carbetocin versus oxytocin in preventing primary PPH following both vaginal and caesarean deliveries. The baseline demographic characteristics of our study population, including maternal age, parity, and gestational age, were comparable between the two groups, ensuring the validity of our comparative analysis. This homogeneity in baseline parameters is crucial for eliminating confounding variables that could influence the study outcomes.

One of the most significant findings of our study was the better hemodynamic stability observed with carbetocin compared to oxytocin. While both groups had comparable blood pressure readings prior to drug administration, oxytocin caused a statistically significant decline in both systolic and diastolic blood pressure at 5 minutes post-administration, whereas carbetocin did not produce any significant hemodynamic changes. This finding aligns with recent evidence suggesting that carbetocin provides better cardiovascular stability compared to oxytocin [14]. Studies have consistently demonstrated that oxytocin

causes significant dose-dependent circulatory effects, including decreases in systemic vascular resistance and arterial blood pressure, while carbetocin shows minimal hemodynamic effects [15,16].

Analysis of blood loss in our study revealed that carbetocin was significantly more effective than oxytocin in reducing total blood loss during both caesarean sections and vaginal deliveries. The mean total blood loss during caesarean delivery was significantly lower in the Carbetocin group compared to the Oxytocin group, which is consistent with multiple meta-analyses demonstrating the superior efficacy of carbetocin in preventing postpartum haemorrhage [17]. Recent systematic reviews have confirmed that carbetocin is effective in reducing postpartum haemorrhage and the need for blood transfusion when used during caesarean deliveries [18]. Similarly, for vaginal deliveries, our findings support the conclusion that carbetocin provides better control of haemorrhage, although some meta-analyses have shown no significant difference between carbetocin and oxytocin in blood loss ≥500 ml in women undergoing vaginal delivery [19].

The incidence of primary postpartum haemorrhage in our study showed interesting patterns across delivery modes. Among patients undergoing caesarean section, the PPH incidence was 29.6% in the Oxytocin group compared to 17.9% in the Carbetocin group, while for vaginal deliveries, it was 27.3% versus 9.4%, respectively. Although these differences did not reach statistical significance, the consistent trend toward lower PPH rates with carbetocin across both delivery modes suggests a clinically meaningful benefit. Large-scale studies have reported similar PPH rates between the two drugs, but the clinical significance of even modest reductions in haemorrhage rates cannot be understated, given the potential for severe maternal morbidity [4].

The evaluation of pre- and post-delivery haemoglobin provided compelling evidence for the improved efficacy of carbetocin. While pre-delivery haemoglobin levels were comparable between groups, the post-delivery haemoglobin levels were significantly higher in the Carbetocin group for both delivery modes. More importantly, the mean drop in haemoglobin was significantly lower with carbetocin (1.2±0.6 g/dL for caesarean and 1.1±0.4 g/dL for vaginal delivery) compared to oxytocin (2.1±0.8 g/dL and 1.8±0.6 g/dL, respectively). This finding directly correlates with the reduced blood loss observed with carbetocin and has important implications for maternal recovery and the need for blood transfusion. The preservation of maternal haemoglobin levels is particularly crucial in populations with high baseline anaemia prevalence, as is common in many developing countries, including India [20].

The assessment of uterine atony revealed that carbetocin was significantly more effective in maintaining adequate uterine contractility. The proportion of patients with uterine atony was significantly lower in the Carbetocin group (23.3%) compared to the Oxytocin group (43.3%). Consequently, the need for additional uterotonic agents was also reduced in the Carbetocin group. This finding is consistent with the pharmacological properties of carbetocin, which has a prolonged duration of action compared to that of oxytocin, thereby avoiding the need for repeated injections to treat uterine atony [17]. The sustained uterotonic effect of carbetocin is particularly valuable in busy obstetric units where continuous monitoring and repeated drug administration may be challenging.

Regarding maternal side effects, our study found a numerically lower incidence of adverse effects with carbetocin (15%) compared to oxytocin (28.3%), although this difference did not reach statistical significance. The side effect profile included headache, vomiting, and flushing in both groups, with flushing being more prominent in the Oxytocin group. Kabir et al. [8] reported no major adverse effects in either of the drug groups, with a comparable profile of adverse effects comprising nausea, vomiting, abdominal pain, and headache. Widmer et al. [11] stated low and comparable incidence of vomiting, chest pain, flushing, and abdominal pain as adverse effects between the two drug groups. Anurag et al. [3] reported no incidence of adverse effects in either group within the first 24 hours post administration.

The clinical implications of our findings are significant, particularly in the context of resource-limited settings where postpartum haemorrhage remains a major cause of maternal mortality. The better efficacy of carbetocin in reducing blood loss, maintaining hemodynamic stability, and providing sustained uterine contraction makes it an attractive alternative to oxytocin. However, the issue of cost-effectiveness warrants careful consideration that needs to be balanced against its clinical benefits [13]. While our study demonstrates superior clinical efficacy of carbetocin, we did not conduct a formal cost-effectiveness analysis comparing the two agents. Such an analysis would need to account for not only the direct drug acquisition costs but also indirect costs related to PPH management, including additional uterotonic agents, blood transfusions, prolonged hospital stay, intensive care requirements, and potential surgical interventions. Updated meta-analyses combining results from multiple randomized trials have found that carbetocin is associated with a reduction of PPH compared with oxytocin, supporting the findings of our study [21].

Limitations of the study: Several limitations should be acknowledged in interpreting the findings of this study. Firstly, our research exclusively enrolled low-risk patients with singleton term pregnancies, which may limit the generalizability of our findings to high-risk obstetric populations. Secondly, the economic implications of carbetocin use present a significant consideration for healthcare systems, particularly in resource-limited settings. Carbetocin is substantially more expensive than oxytocin in the Indian healthcare context, and our study did not include a comprehensive cost-effectiveness analysis. Thirdly, the single-centre design of our study may limit the external validity of our findings. Fourthly, the nature of our intervention precluded complete blinding of the clinical operators, as the administration protocols and physical characteristics of the medications differed between groups. This limitation introduces the potential for operator bias in data collection and clinical decision-making, particularly regarding subjective assessments such as uterine tone evaluation and the decision to administer additional uterotonic agents. Moreover, blood loss measurement using the gravimetric method, while standard practice, may be subject to measurement error and inter-observer variability, potentially affecting the accuracy of our primary outcome assessment. Lastly, the assessment of maternal adverse effects was based on patient self-reporting without a validated symptom assessment tool, which may introduce reporting bias and could have influenced the frequency and severity of documented side effects. Future studies should consider strategies to minimize operator bias, such as standardized protocols for outcome assessment and independent evaluation by blinded investigators where feasible.

Conclusion

This comparative study demonstrates that carbetocin is superior to oxytocin in preventing primary PPH after childbirth. Carbetocin significantly reduced total blood loss during both caesarean sections and vaginal deliveries, with a lower incidence of PPH and better haemoglobin levels post-delivery, with significantly less haemoglobin drop. Additionally, carbetocin caused less hemodynamic instability, with no significant blood pressure changes compared to the notable hypotensive effects of oxytocin. The incidence of uterine atony and subsequent need for additional uterotonic agents was significantly lower with carbetocin. These findings suggest carbetocin as a more effective and safer alternative to oxytocin for preventing primary postpartum haemorrhage.

Author contributions: All authors were affiliated with the study hospital throughout the research period and participated actively in data curation, collation, and analytical processes.

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