

Evaluating the efficacy of carbetocin versus oxytocin for preventing intraoperative blood loss, early postpartum hemorrhage, and maintaining a favorable hemodynamic profile in lower segment cesarean section: A prospective observational study



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Submission: 18-12-2024

Revision: 05-01-2024

Publication: 01-02-2025

ABSTRACT

Background: Postpartum hemorrhage (PPH) remains a significant concern in obstetric practice, contributing substantially to maternal morbidity and mortality worldwide. Uterine atony, characterized by inadequate uterine muscle tone, constitutes approximately 70% of PPH cases. The initial step in medical management involves the use of uterotonic agents such as oxytocin, ergot alkaloids, and prostaglandins. However, their use is compounded by the accompanying side effects, hence the need for uterotonic agents with relatively better pharmacokinetic and pharmacodynamic profile continues. Carbetocin may require less additional uterotonic administration to manage blood loss compared to oxytocin alone. Carbetocin has a significantly longer half-life than oxytocin, potentially leading to more sustained uterine contractions and reduced blood loss. **Aims and Objectives:** The aim of this study was to compare the efficacy of carbetocin versus oxytocin in preventing intraoperative blood loss and their individual impact on hemodynamics. **Materials and Methods:** A total of 360 patients were enrolled for the study, sample size was calculated using Cochran's formula considering 95% confidence level, and 0.5 variability of proportions and a precision of 5%, with 180 patients in each group, using simple randomization technique, the patients in either group received their assigned drugs during lower segment cesarean section (LSCS). Both the groups were assessed in terms of hemodynamic profile, intraoperative blood loss, need for additional uterotonic agents, and blood transfusion. **Results:** On comparing the data between carbetocin group and oxytocin group, the carbetocin group had less incidence of hypotension and tachycardia ($P < 0.001$), less intraoperative blood loss (Group C: Group O, mean \pm SD mL; 328.7 ± 72.59 : 435.9 ± 99.08 [$P < 0.001$]), and minimal use of additional uterotonic agents ($P < 0.001$); however, the requirement of blood transfusion was comparable between the two groups ($P = 0.157$). **Conclusions:** Carbetocin is an effective alternative to conventionally used oxytocin in LSCS.

Key words: Lower-segment caesarean section; Oxytocin; Carbetocin; Postpartum hemorrhage; Obstetric hemorrhage

Access this article online

Website:

<https://ajmsjournal.info/index.php/AJMS/index>

DOI: 10.71152/ajms.v16i2.4365

E-ISSN: 2091-0576

P-ISSN: 2467-9100

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INTRODUCTION

Postpartum hemorrhage (PPH) remains a significant concern in obstetric practice, contributing substantially to maternal morbidity and mortality worldwide. Its incidence renders it a leading cause of maternal mortality and morbidity, a concern particularly pronounced in regions where access to emergency obstetric care is constrained by limited resources.¹ Globally, it is the leading cause of maternal deaths and is responsible for 25% of maternal deaths annually.^{2,3} PPH is a critical obstetric emergency, affecting 1–10% of all deliveries.^{4,5} Severe PPH, which occurs in approximately 1–2% of deliveries, is a leading cause of maternal mortality and morbidity worldwide.^{6,7}

PPH is a multifactorial condition with various etiological factors and risk factors contributing to its occurrence. Understanding these factors is crucial for effective prevention, early detection, and management of PPH. The most prevalent causes of PPH by far are the uterine atony, characterized by inadequate uterine muscle tone, it constitutes approximately 70% of PPH cases. The treatment and management of PPH is centered on resuscitating the patient while promptly identifying and addressing the underlying cause.⁸ Medical management options include the use of uterotonic agents, uterine tamponade, pelvic artery embolization, and surgical intervention.⁹

The initial step in medical management involves the use of uterotonic agents on identification of uterine atony. While oxytocin is routinely administered during delivery as a preventive measure, additional uterotonic medications may be administered concurrently along with bimanual uterine massage as an initial response to hemorrhage. Uterotonic agents encompass a range of medications including oxytocin, ergot alkaloids, and prostaglandins. Oxytocin is a vital uterotonic agent used in the prevention and management of PPH. Immediately following delivery, oxytocin is routinely administered as part of active management of the third stage of labor to facilitate placental delivery and stimulate uterine contractions. By enhancing uterine muscle contractility, oxytocin helps expel the placenta, compress uterine blood vessels, and reduce the risk of excessive bleeding.¹⁰ Overall, oxytocin stands as a cornerstone in the management of PPH due to its potent uterotonic properties and cost effectiveness. However, its use is not without potential adverse effects. These may include complications such as uterine rupture, fetal asphyxia, and water intoxication to mention a few.

Carbetocin, a synthetic long-lasting oxytocin agonistic analog with an extended half-life, presents promising advantages over oxytocin.¹¹ Its prolonged uterine activity offers theoretical benefits over oxytocin, its natural

counterpart. Indicated for the prevention of PPH resulting from uterine atony following delivery, whether through cesarean section under epidural or spinal anesthesia, or vaginal delivery, carbetocin plays a crucial role in obstetric care.¹² The side-effect profile of carbetocin has been found to be comparable to that of oxytocin, with no significant differences noted.¹³ The comparison between carbetocin and oxytocin in preventing PPH during cesarean section involves evaluating not only their efficacy in reducing blood loss but also their respective hemodynamic effects intraoperatively. Hemodynamic stability during CS is crucial for maternal safety, particularly in women with comorbidities or obstetric complications. This study was aimed to compare the intraoperative hemodynamic profile of the two drugs along with their safety and efficacy with respect to prevention of excessive intraoperative blood loss and early PPH during cesarean section.

Aims and objectives

The aim of this study was to compare the efficacy of carbetocin versus oxytocin in preventing intraoperative blood loss and their individual impact on hemodynamics.

MATERIALS AND METHODS

This prospective and comparative study was conducted in the Department of Anesthesiology at SKIMS, Srinagar, which is a tertiary care hospital in North India. The study was conducted over a period of 2 years, from October 2022 to September 2024. The study included 360 term pregnant patients scheduled for caesarean section. Written informed consent was obtained from the participants and the study was conducted after obtaining ethical clearance from the Institutional Ethics Committee: IEC/SKIMS Protocol #271/2022.

The sample size calculation was done using Cochran's formula ($n = z^2 pq/e^2$) considering 95% confidence level, and 0.5 variability of proportions, a precision of 5%, and a non-response of 10%. The study subjects were divided equally into two groups of 180 patients each using simple randomization technique.

Inclusion criteria

The inclusion criteria were as follows; full-term pregnant patients of age >20 years, American Society of Anesthesiologists (ASA) class II and III, who were at a higher risk for PPH were enrolled in the study.

Exclusion criteria

The exclusion criteria were as follows; patients refusing to consent, ASA class \geq IV, patients with known allergy to either of the medication, and patients with antepartum hemorrhage were excluded from the study.

The study subjects were randomly allocated to either of the two groups using computer generated random allocation numbers. Group O (patients receiving Oxytocin): The patients in this group received, 30 IU of oxytocin in 500 mL of normal saline IV (150 mL/hour) at the delivery of the anterior shoulder. Group C (patients receiving Carbetocin): Were given an infusion of 100 µg carbetocin in 100 mL normal saline IV at the delivery of the anterior shoulder.

Hemodynamic effects, such as blood pressure (BP) and heart rate (HR), were monitored at 1-min, 5-min, and 15-min intervals after the drug administration. We noted intraoperative blood loss, need for additional uterotonic agents, and blood transfusion.

The recorded data were compiled and entered in a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). Continuous variables were expressed as Mean±SD and categorical variables were summarized as frequencies and percentages. Graphically, the data were presented by bar and line diagrams. The Shapiro–Wilk test was applied to test the normality of data. Student’s independent t-test or Mann–Whitney U-test, whichever feasible, was employed for comparing continuous variables. Chi-square test or Fisher’s exact test, whichever appropriate, was applied for comparing categorical variables. P<0.05 was considered statistically significant.

RESULTS

As shown in Table 1, the baseline characteristics of the patients were comparable between the two groups.

Table 2 depicts that, the Intraoperative HR varied significantly between the groups, with group O having a higher average intraoperative HR compared to group C (P<0.001).

As shown in Table 3, the mean arterial pressure (MAP) demonstrated a continuous downward trend in Group O showing a greater propensity for intraoperative hypotension as compared to Group C (P<0.001).

Table 4 shows that, the average intraoperative oxygen saturation (SpO₂) was comparable between the two

groups, demonstrating that oxytocin and carbetocin had no prominent effects on respiratory parameters.

Table 5 depicts that both oxytocin and carbetocin had significant impact in preventing uterine atony, but carbetocin has a better pharmacological profile as carbetocin group had minimal blood loss, minimal requirement for additional uterotonics, lesser drop in hemoglobin (Hb) levels, and consequently lower requirement of blood transfusions, although on comparison, the need for transfusion was statistically non-significant (P=0.157).

DISCUSSION

Carbetocin and oxytocin are pivotal in obstetric care for their ability to induce uterine contraction, thereby mitigating the risk of excessive bleeding post-delivery. This prospective and observational study was aimed to establish which of these agents not only provides superior efficacy in controlling hemorrhage but also ensures optimal hemodynamic stability during surgical interventions.

The present study involved 360 high-risk PPH patients who were randomly assigned into two groups of 180 each using random computer generation. Group O received oxytocin, while Group C was administered carbetocin. The study’s age distribution data revealed that the majority of patients in both groups fell within the 25–29 years age range. The mean ages of the groups were closely aligned, with Group C averaging 25.9±3.89 years and Group O averaging 26.4±3.94 years (P=0.3021). Similar observations were found by Uthpala and Gracelyn,¹⁴ and Jannu et al.,¹⁵ in their respective studies.

The parity distribution analysis between Group C (carbetocin) and Group O (oxytocin) revealed marginal differences that were statistically non-significant (P=0.607). These findings align with the studies conducted by Banu et al.,¹⁶ and Ijaya et al.¹⁷

The analysis of gestational age at delivery for the two study groups in the present study revealed no statistically significant differences. In Group C, the mean gestational age was 37.91±0.845 weeks in Group O, the mean gestational age was 38.13±0.907 weeks (P=0.174). Patil

Table 1: Patient characteristics

Parameter	Group C	Group O	P-value
Age (Mean±SD years)	25.9±3.89	26.4±3.94	0.302
Parity (n/p ₁ /p ₂ /≥p ₃)*	13.3/29.4/45.6/11.7	16.1/27.8/43.3/12.8	0.607
Gestational age (mean±SD weeks)	37.91±0.84	38.13±0.90	0.174
Pre-operative Hb (Mean±SD mg/dL)	10.39±0.75	10.48±0.81	0.308

*n=nullipara, p₁=para 1, p₂=para 2, p₃=para 3, Hb: Hemoglobin

Table 2: Mean intraoperative heart rate

Heart rate (beats/min) in two groups at various intervals of time					
Time interval	Group C		Group O		P-value
	Mean	SD	Mean	SD	
Pre-operative	83.53	9.83	81.53	7.99	0.135
0 min	85.35	9.29	84.68	7.24	0.448
5 min	84.08	7.99	89.12	7.08	<0.001
15 min	87.87	7.44	94.31	6.64	<0.001
30 min	89.57	6.82	97.61	5.67	<0.001
45 min	90.08	6.71	95.11	5.75	<0.001
60 min	87.37	7.54	89.47	6.78	0.158
75 min	84.12	7.30	85.24	7.69	0.256
Post-operative	82.60	6.97	83.41	6.45	0.353

Statistically Significant Difference (P<0.05)

Table 3: Intraoperative mean arterial pressure

Time interval	Group C		Group O		P-value
	Mean	SD	Mean	SD	
Pre-operative	90.25	5.26	89.44	5.44	0.149
0 min	85.8	4.05	85.2	5.21	0.224
5 min	84.69	3.02	78.46	3.86	<0.001
15 min	80.89	3.12	73.29	3.44	<0.001
30 min	78.4	2.49	67.79	3.24	<0.001
45 min	77.47	2.14	72.42	2.51	<0.001
60 min	80.5	4.51	78.33	3.89	0.093
75 min	83.64	4.43	82.03	3.25	0.137
Post-operative	86.87	3.9	85.91	4.72	0.218

Statistically Significant Difference (P<0.05)

Table 4: Intraoperative oxygen saturation

Oxygen saturation (%) in two groups at various intervals of time					
Time interval	Group C		Group O		P-value
	Mean	SD	Mean	SD	
Pre-operative	98.07	0.557	97.95	0.945	0.143
0 min	99.04	0.804	99.03	0.822	0.846
5 min	98.91	0.767	99.02	0.787	0.176
15 min	99.03	0.871	98.95	0.779	0.339
30 min	99.10	0.819	99.04	0.787	0.471
45 min	98.93	0.809	98.89	0.787	0.644
60 min	98.97	0.801	99.06	0.844	0.337
75 min	99.06	0.810	99.13	0.815	0.364
Post-operative	98.13	0.677	98.20	0.805	0.372

Table 5: Intraoperative variables

Parameter	Group C	Group O	P-value
Uterine atony (%)	Nil	Nil	-
Amount of blood loss (range in mL)	318.10-339.30	421.40-450.30	<0.001
Additional uterotonic used in subjects (%)	3.9	20.6	<0.001
Drop in Hb (Mean±SD gm/dL)	0.78±0.908	1.31±0.771	<0.001
Need for transfusion in subjects (%)	0.6	3.9	0.157

Hb: Hemoglobin

et al.,¹⁸ and Algharib et al.,¹⁹ reported a similar observation with regard to distribution of gestational age between the two groups. The comparable baseline age distribution, parity distribution, and gestational age between the groups ensures that any observed differences in outcomes are likely attributable to the specific interventions rather than demographic or baseline health factors.

We observed a favorable hemodynamic profile with carbetocin, although both interventions led to significant increases in HR and reductions in MAP. However, it was noted that Group C had less occurrence of tachycardia affecting 3.3% of participants compared to 13.3% of patients in O group developing tachycardia, and Group O exhibiting consistently higher HRs throughout the procedure (P<0.001). The MAP was significantly lower in Group O at multiple intervals (P<0.001). Notably, there were no significant differences in SpO₂ levels between the groups across all time intervals, suggesting that neither carbetocin nor oxytocin significantly influenced SpO₂ in our study. These findings underscore oxytocin's profound impact on cardiovascular parameters during the post-operative phase following cesarean section, aligning with current literature on its hemodynamic effects. Our study results showed a superior hemodynamic profile of carbetocin over oxytocin in terms of effects on HR and mean BP changes following administration of these drugs. These results are consistent with the studies conducted by Jannu et al.,¹⁵ and Bahr et al.,²⁰ who reported a lesser decrease in MAP with carbetocin, their study also found that carbetocin did not produce significant changes in HR responses, whereas oxytocin significantly increased HR compared to carbetocin (P<0.0001), corroborating our results.

Uterine atony is recognized as the predominant cause of PPH, contributing to approximately 80% of cases (Esseissah et al.²¹ In the present study, no cases of significant uterine atony leading to PPH were reported in either group. The fact that neither group experienced this complication suggests several potential reasons. First, the use of effective uterotonic agents such as carbetocin and oxytocin likely played a pivotal role in maintaining uterine tone post-delivery. Second, meticulous clinical management and proactive perioperative monitoring may have contributed in preventing uterine atony. In addition, the absence of reported cases could be attributed to the study's rigorous inclusion criteria and the vigilant oversight provided by skilled healthcare professionals. This finding highlights the efficacy of contemporary obstetric practices in mitigating serious complications associated with postpartum uterine dysfunction.

In the present study, there was a statistically significant difference in the need for additional uterotonics between

Group C (carbetocin) and Group O (oxytocin). Specifically, a lower proportion of participants in Group C required additional uterotonics (3.9%) compared to Group O (20.6%). This finding suggests that carbetocin may be more effective than oxytocin in preventing significant uterine atony that requires additional intervention to control bleeding. This outcome aligns with existing literature that discusses the varying effectiveness of different uterotonic agents in managing PPH. Kang et al.²² and Attilakos et al.,²³ observed a reduced requirement of additional uterotonic agents in the carbetocin group compared to oxytocin. In addition, Dansereau et al., concluded that carbetocin resulted in fewer instances of requiring further uterotonic agents compared to oxytocin.²⁴ This advantage may be attributed to carbetocin's prolonged action and enhanced uterine contractility, which contributes to better clinical outcomes and healthcare resource utilization in obstetric practice.

The assessment of uterotonic effectiveness often hinges on evaluating Hb decline rates as a key indicator of bleeding severity. Our study population had no significant difference in pre-operative baseline Hb levels between the groups (carbetocin group, mean Hb=10.39±0.758) and oxytocin group, mean Hb=10.48±0.819 [P>0.05]), similar to studies conducted by Kang et al.,²² and Arunshankar et al.²⁵ An analysis of post-operative Hb levels revealed that, Group C, had a mean post-operative Hb level of 9.61±0.898 g/dL (reflecting a drop of 0.78 g/dL from pre-operative values). In contrast, Group O exhibited a lower mean post-operative Hb level of 9.17±0.684 g/dL (a decline of 1.31 g/dL from pre-operative levels) (P<0.0001). These findings correlate with the observations of recent literature. Arunshankar et al., observed a Hb decline of 0.76 g/dL in the carbetocin group compared to 1.03 g/dL in the oxytocin group.²⁵ Similarly, Gürsoy et al., reported a significantly lower drop of Hb levels in patients receiving carbetocin compared to oxytocin (P=0.044).²⁶ However, it is noteworthy that few studies did not observe a statistically significant difference in Hb decline between oxytocin and carbetocin groups, suggesting variability in findings across different clinical settings and patient populations.^{27,28} Carbetocin's pharmacological profile, characterized by its prolonged effect and enhanced ability to maintain uterine tone, is instrumental in minimizing Hb decline, thereby offering a superior alternative in the management of PPH. However, discrepancies may arise from variations in study design, population demographics, dosing protocols, and clinical practices, highlighting the need for a contextual understanding when interpreting these results.

In the present study, we observed that there was a significant difference in the amount of blood loss

during cesarean section between the two groups. In Group C, the mean blood loss was 328.7±72.59 mL. In contrast, Group O had a higher mean blood loss of 435.9 mL±99.08 mL (P<0.001). This suggests that carbetocin administration during cesarean section significantly reduces the amount of blood loss compared to oxytocin. These results are consistent with multitude of studies. Patil et al., documented substantial blood loss in both groups, with a mean blood loss of 377.68±98.57 mL in the oxytocin group and 345.34±80.54 mL in the carbetocin group, highlighting reduced blood loss with carbetocin.¹⁸ Ortiz et al., reported a mean blood loss of 366 mL in the carbetocin group and 400 mL in the oxytocin group, reinforcing the efficacy of carbetocin.²⁹ In addition, studies of Maged et al.,³⁰ Elsafty et al.,³¹ and Ashraf et al.,³² further consolidate the carbetocin's favorable pharmacological properties that enhance uterine contraction and reduce the risk of PPH.

In our study, the need for blood transfusion differed between Group C and Group O, with only 1 participant (0.6%) in the carbetocin group requiring transfusion compared to seven participants (3.9%) in the oxytocin group. However, this difference was not statistically significant (P=0.157). This result is consistent with the findings of Attilakos et al., who observed lower transfusion rates in carbetocin group, reinforcing our findings of insignificant differences.²³ In addition, Patil et al., reported a lower incidence of transfusion in the carbetocin group compared to the oxytocin group, though the difference was not statistically significant.¹⁸ El Behery et al., and Ashraf F et al., similarly noted trends where fewer patients required transfusion in the carbetocin group compared to the oxytocin group, and like our study, they reported non-significant differences in their respective studies.^{32,33} In contrast, Uy et al., (2013) did not find significant differences in transfusion requirements or the occurrence of severe anemia between the groups studied, differing from our results.³⁴ These variations across studies highlight the complexity of factors influencing transfusion needs and suggest that while carbetocin may offer a potential advantage in reducing transfusion rates, more extensive and diverse studies are necessary to confirm these findings definitively.

Limitations of the study

1. The specific patient populations studied may limit the generalizability of 13 the results to other settings or population with different characteristics.
2. Other factors that influence PPH and hemodynamic effects, such as Patients characteristics, surgical factors and concurrent medications might not be fully controlled or accounted for.

CONCLUSIONS

Carbetocin group exhibited a relatively better hemodynamic profile and was superior to oxytocin in preventing uterine atony and excessive blood loss as well as decreasing the need for additional uterotonic agents and blood transfusion in caesarean section surgeries. Hence, carbetocin is a safe and effective alternative to conventionally used oxytocin for lower-segment cesarean section; however, further studies are warranted.

ACKNOWLEDGMENT

We are highly grateful to every patient for their valuable consent and time for participating in this study, without their cooperation this study would not have been possible, we also thank our senior and junior faculty members and colleagues for their suggestions and support.

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Source of Support: Nil, **Conflicts of Interest:** None declared.