

Original Research Article

COMPARATIVE STUDY ON CARBETOCIN VS OXYTOCIN FOR PREVENTION OF POSTPARTUM HEMORRHAGE IN CAESAREAN SECTION OF HIGH RISK PREGNANCIES

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ABSTRACT

Background: Postpartum haemorrhage (PPH), is the leading direct cause of maternal mortality globally, responsible for about a quarter of all maternal deaths. The most important component to prevent PPH is the use of uterotonic like oxytocin, carbetocin and misoprostol during active management of the third stage of labor (AMTSL). The aim of this study was to compare the efficacy of Injection carbetocin and oxytocin in the prevention of post-partum haemorrhage during caesarean section in high-risk pregnancy cases.

Materials and Methods: A hospital based prospective comparative study was done at the Department of Obstetrics & Gynaecology at Shaheed Hassan Khan Mewati Government Medical College, Nuh, Haryana over the study period of 1 year to compare the efficacy of Injection carbetocin and oxytocin in the prevention of post-partum haemorrhage during caesarean section in 100 high-risk pregnancy cases (50 in each group). Primary Outcome Measures were assessed by estimating the amount of intra-operative blood loss, incidence of Post-partum haemorrhage, need of additional uterotonic during first 24 hours after Carbetocin or oxytocin administration. Secondary Outcome Measures were assessed by evaluating the fall in Haemoglobin levels (preoperative and 24 hours postoperative), adverse effects of carbetocin and oxytocin.

Results: Baseline characteristics including age, parity, and gestational age were comparable without any statistical significant difference between the carbetocin and oxytocin study groups, providing a balanced foundation for evaluating drug efficacy. Mean blood loss was significantly less in cases managed by Carbetocin as compared to Oxytocin group (455.6 vs 790.5 ml). Compared to Carbetocin, Oxytocin managed cases exhibited a higher incidence of atonic postpartum haemorrhage (10% vs 24%). The requirement for additional uterotonic drugs occurred in 24 % of cases managed with Oxytocin, compared to only 10% of cases managed with Carbetocin. Decrease in mean hemoglobin levels post-delivery was significantly more in cases managed by Oxytocin as compared to Carbetocin (0.84gm% vs 0.48 gm%). The mean preoperative heart rate and the mean heart rate during follow-up were comparable between both the study groups, without statistically significant difference (p=0.84). The mean preoperative systolic and diastolic blood pressures and those measured during follow up were comparable between the two study groups, with no statistically significant differences observed. (p=0.51). The incidence of headache was 38 % in the Oxytocin group versus 18 % in the Carbetocin group, while nausea and/or vomiting occurred in 12 % cases in Oxytocin group and 10 % cases in

Carbetocin group. This indicates that both drugs have comparable safety profiles.

Conclusion: This study demonstrates that carbetocin is more effective than oxytocin in preventing postpartum haemorrhage (PPH), as it significantly reduces blood loss and the need for additional uterotonics, while maintaining a comparable safety profile. Carbetocin holds the advantages of stability at room temperature and prolonged duration of action, which make it a valuable alternative particularly in low-resource settings where refrigeration is limited. A single 100 µg IV dose of carbetocin administered after delivery is sufficient to maintain adequate uterine contraction, effectively preventing uterine atony and excessive bleeding, with efficacy comparable to several hours of oxytocin infusion and a similar haemodynamic profile. Carbetocin presents a viable alternative to conventional uterotonic agents, such as oxytocin, for the prevention of postpartum haemorrhage following caesarean sections in high-risk women. However, further studies are needed to assess the cost-effectiveness of carbetocin as a uterotonic agent in order to support its broader implementation.

Keywords: Oxytocin, Carbetocin, Postpartum hemorrhage (PPH).

INTRODUCTION

Globally 14 million women suffer from postpartum haemorrhage each year, leading to approximately 70,000 maternal deaths worldwide.^[1]

Developing countries like India, have a high maternal mortality rate (97 deaths per 10,000 live births from 2018 to 2020), out of which PPH alone attributed to 38% of maternal deaths.^[2,3]

The Sustainable Development Goal 3 Target 3.1 aims to reduce the Maternal Mortality Rate to less than 70 per 100 000 live births by 2030.^[4]

Considering uterine atony as the most common cause of hemorrhagic blood loss during delivery. It is recommended to systematically use uterotonic drugs immediately after delivering the newborn for prevention of PPH.^[5]

World Health Organization (WHO) recommended uterotonic drug- Oxytocin, is one of the most widely used drugs for preventing and treating PPH. However, Oxytocin is heat-sensitive and must be stored at 2–8 degrees Celsius, which is difficult to maintain in many low- and middle-income countries (LMICs) like India because of their insufficient cold chain capacity.^[6]

As a result, studies have shown that much of the oxytocin available in LMIC markets like India either does not meet drug quality standards or is stored improperly.^[7,8,9]

A new drug, HeatStable Carbetocin (HSC), has been shown to prevent PPH effectively.^[10,11,12]

Unlike oxytocin, HSC is stable at 30 degrees Celsius, which is advantageous in areas without adequate cold chain capacity.^[10]

This drug is new to the market and has been registered recently in India, and injectable HSC (100 µg/mL) was added to the WHO's Model List of Essential Medicines in 2021.^[13]

At the same time, WHO has recommended HSC in contexts where the quality of oxytocin cannot be guaranteed.^[6]

Thus, in the absence of oxytocin or when its quality cannot be assured, heat-stable carbetocin (HSC) has been recommended for PPH prevention in the 2018 WHO recommendations.^[14]

The main indication for which carbetocin has been proposed is cesarean delivery as it is associated with a higher prevalence of severe PPH and requires invasive second-line therapies three times more often than vaginal deliveries do.^[15]

HSC is a long-acting uterotonic that has been shown to be non-inferior to oxytocin and may be more effective for some outcomes in the prevention of PPH without an increase in side effects.^[16,17]

However taking into account the high cost of injection carbetocin, there is need for further research, so this study was carried out to evaluate the efficacy and safety of cabetocin and oxytocin for the prevention of PPH in caesarean sections of high-risk pregnancies.

MATERIALS AND METHODS

This hospital based Prospective comparative study was conducted at the Department of Obstetrics & Gynaecology at Shaheed Hassan Khan Mewati Government Medical College, Nuh, Haryana over the study period of 1 year from July 2022 to July 2023 after taking approval from Institutional ethical committee.

Inclusion criteria: Pregnant women with the risk factors for primary post-partum haemorrhage such as multiple pregnancy, previous history of caesarean section, presence of Placenta Previa, past history of PPH in previous pregnancy, fetal Macrosomia, Obstructed labour, Pregnancy with moderate and severe anaemia, Failure of induction, fetal malformations associated with Polyhydramnios-who underwent caesarean section at our institute.

Exclusion criteria: HELLP syndrome, Eclampsia, Coagulation disorders, history of classical uterine incision, Past or present medical history of Cardiac, Renal or Liver diseases, Epilepsy, history of

hypersensitivity reaction to Carbetocin (according to the Br National Formulary).^[18]

After taking the written informed consent, all pregnant women fulfilling the inclusion and exclusion criteria and undergoing caesarean section were taken up in Carbetocin group (study group A) in the first month followed by Oxytocin group (study group B) in the next month and so on till desired sample size of 100 (50 in each group) is reached. On admission, the enrolled patients were subjected to complete history, examination, routine laboratory investigations and data was collected as per predesigned structured data collecting proforma. After giving regional anaesthesia, eligible patients were positioned in recumbent position and for continuous blood pressure measurement a limb cuff was applied. Women in the carbetocin group (group A) received bolus dose 100 µg diluted in 10 ml normal saline and administered IV slowly (over 30-60 seconds) at the delivery of anterior shoulder. Women in the oxytocin group (group B) received 20 IU of oxytocin in 500 ml of 0.9% NaCl solution as IV infusion (150mL/hour) at the delivery of anterior shoulder of baby. To evaluate the hemodynamic effects between carbetocin and oxytocin we considered the drop in blood pressure, by comparing the BP immediately after anesthesia before skin incision followed by BP measurement at 1 minute, 3 minutes and 5 minutes after drug (carbetocin or

oxytocin as per group) administration. BP was recorded at 2 hours, 12 hours and 24 hours after completion of caesarean section.

Primary Outcome Measures assessed were: The amount of intra-operative blood loss (visual estimation, number of used swabs, sponges and the amount of aspirated blood in suction jar), Incidence of Post-partum haemorrhage (PPH during caesarean section is defined as blood loss of 1000 ml or more), Need of additional uterotonics during first 24 hours after Carbetocin or Oxytocin administration, Uterine tone after uterotonic drugs (standardized as Very good, Good, Sufficient, Atony), uterine position (with respect to the umbilical point, UP).

Secondary Outcome Measures assessed were: The fall in Haemoglobin levels (preoperative and 24 hours postoperative), adverse effects of carbetocin and oxytocin (nausea, vomiting, flushing, headache).

Statistical Analysis: All the data was noted down in a pre-designed study proforma. Qualitative data was represented in the form of frequency and percentage. Association between qualitative variables was assessed by Chi-Square test. Quantitative data was represented using Mean \pm SD. A p-value < 0.05 was taken as level of significance.

RESULTS

Table 1: Mean age comparison among study groups

Study Group	N	Mean	SD	p-value
Carbetocin (A)	50	25.06	4.47	0.801
Oxytocin (B)	50	25.28	4.23	

Mean age of the study subjects in both the study groups have no statistically significant difference (p=0.801).

A total of 46% cases were primi-gravida while 54% were multi-gravida with no significant difference between the study groups (p= 1.0)

Table 2: Mean gestational age comparison among study groups

Variables	Study Group	N	Mean	SD	P-value
Gestation Age (weeks)	Carbetocin (A)	50	38.06	2.19	0.17
	Oxytocin (B)	50	37.20	3.79	

Mean Gestational age at admission was 38.06 weeks and 37.20 weeks in Carbetocin group and Oxytocin group respectively. The Carbetocin and Oxytocin

study groups showed no significant differences in Age, Parity, Gestational age, providing a balanced foundation for evaluating drug efficacy.

Table 3: Comparison of Mean blood loss among study groups

Variable	Study Group	N	Mean	SD	p-value
Blood Loss (ml)	Carbetocin	50	455.60	383.13	<0.01
	Oxytocin	50	790.50	664.05	

Mean blood loss was significantly less in cases managed by Carbetocin as compared to Oxytocin group (455.6 vs 790.5 ml).

Table 4: Distribution of study groups as per development of Atonic Post-partum haemorrhage

PPH	Group		Total
	Carbetocin	Oxytocin	
No	45	38	83
	90.0%	76.0%	83.0%
Yes	5	12	17
	10.0%	24.0%	17.0%
Total	50	50	100
	100.0%	100.0%	100.0%

p- value - 0.06

Compared to Carbetocin, Oxytocin managed cases exhibited a higher incidence of atonic postpartum hemorrhage (10% vs 24%).

The requirement for additional uterotonic drugs occurred in 24 % of cases managed with Oxytocin, compared to only 10% of cases managed with Carbetocin.

Table 5: Comparison of Mean Pre and post operative Hemoglobin and mean change in Hemoglobin levels

Hemoglobin (gm%)	Study Group	N	Mean	SD	P-value
Pre-op	Carbetocin (A)	50	8.64	0.86	0.201
	Oxytocin (B)	50	8.86	0.83	
Post-op	Carbetocin(A)	50	8.16	1.00	0.542
	Oxytocin (B)	50	8.02	1.22	
Change in Hb (gm)	Carbetocin (A)	50	0.48	0.40	<0.01
	Oxytocin (B)	50	0.84	0.70	

Mean pre-op Hemoglobin levels were comparable between the two study groups (8.64 vs 8.86 gm%; p-0.201). Decrease in mean hemoglobin levels post-delivery was significantly more in the cases managed by Oxytocin as compared to Carbetocin (0.84gm% vs 0.48 gm%; p<0.01).

The mean preoperative heart rate and the mean heart rate during follow-up were comparable between both

the study groups, without statistically significant difference (p-0.84). The mean preoperative systolic and diastolic blood pressures and those measured during follow up were comparable between the two study groups, with no statistically significant difference. (p-0.51).

Table 6: Distribution of study groups as per Adverse Drug Reactions

ADRs	Group		Total
	Carbetocin	Oxytocin	
Headache	9	19	28
	18.0%	38.0%	28.0%
Nausea/ Vomiting	5	6	11
	10.0%	12.0%	11.0%
None	36	25	61
	72.0%	50.0%	61.0%
Total	50	50	100
	100.0%	100.0%	100.0%

p- value - 0.33

The incidence of headache was 38 % in the Oxytocin group versus 18 % in the Carbetocin group, while nausea and/or vomiting occurred in 12 % and 10 % of cases, respectively; no statistically significant

differences in adverse reactions were observed between the study groups (p-0.33). This indicates that both the drugs have comparable safety profiles.

DISCUSSION

Postpartum hemorrhage (PPH) is a leading cause of maternal mortality worldwide, highlighting the critical need for effective, accessible, and safe interventions across various healthcare settings.^[19,20] Active management of the third stage of labor plays a crucial role in preventing postpartum hemorrhage (PPH), with uterotonic agents alone capable of reducing the risk by up to 60%.^[21] The present study was done to evaluate the efficacy and safety of

carbetocin and oxytocin for the prevention of PPH in caesarean sections of high risk pregnancies. Baseline characteristics including age, parity and gestational age in our study were comparable without any statistical significant difference between the carbetocin and oxytocin study groups, providing a balanced foundation for evaluating drug efficacy. In our study, the mean age of the study subjects among the carbetocin group was 25.06 and among oxytocin group was 25.28, this finding is in close agreement with the study conducted by A Laxmi et.al, 2024.^[22] which showed that the mean age of the study subjects

was 24.7 ± 3.1 among the carbetocin group and 25.2 ± 3.9 among oxytocin group. Demetz J et.al.,2013.^[23] also showed that mean age of study subjects in carbetocin group were 26.5 years and 26.7 years among the oxytocin group which is similar to our study.

In our study Mean blood loss was significantly less in cases managed by Carbetocin as compared to Oxytocin group (455.6 vs 790.5 ml). Our results align with the studies done by Chen CY et.al, 2016.^[24] Mohamed Maged A et.al,2017.^[25] Chen YT et.al,2018.^[26] in the general population, showing that Carbetocin is associated with reduced blood loss compared to Oxytocin.

Compared to Carbetocin, Oxytocin managed cases exhibited a higher incidence of atonic postpartum hemorrhage (10% vs 24%) in our study. This finding is in close agreement with the study done by Kumar k et.al, 2024.^[27] in which it was observed that the incidence of atonic PPH was lower in the carbetocin group (10%) compared to the oxytocin group (18%), with statistical significance ($p=0.03$). Su et al., in the 2007 Cochrane review on Oxytocin agonists for preventing postpartum haemorrhage and the 2012 Cochrane review on Carbetocin for preventing postpartum haemorrhage, concluded that carbetocin is more effective than oxytocin in preventing postpartum haemorrhage (PPH) in women undergoing caesarean section. However, they noted that the available data and evidence were still insufficient.^[28,29,30,31,32,33]

In our study the requirement for additional uterotonic drugs occurred in 24 % of cases managed with Oxytocin, compared to only 10% of cases managed with Carbetocin. This finding is also in close alignment with the study done by Porreco R et.al, 2010,^[34] which indicated that fewer patients in the carbetocin group (12%) required supplementary uterotonics compared to those in the oxytocin group (24%). A similar study conducted by Rosminiet al. 2024,^[35] also reported that carbetocin's effects lasted longer than those of oxytocin, resulting in reduced rates of additional uterotonic use and more effective maintenance of uterine tone during the critical postpartum period. Attilakos et.al, 2010.^[30] also demonstrated that a significantly higher number of women in the oxytocin group required additional oxytocics compared to those in the carbetocin group. Giovanni l et.al, 2013.^[36] found a complete absence of additional uterotonic need after caesarean section in women at high risk for PPH who received carbetocin. Danzereau et al. were the first to report a reduced need for additional uterotonics to treat uterine atony in women who received carbetocin shortly after delivery.^[37]

In our study it was observed that decrease in mean hemoglobin levels post-delivery was significantly more in cases managed by Oxytocin as compared to Carbetocin (0.84gm% vs 0.48 gm%). This finding is in contrast to the observations of the study done by Kumari et.al, which reported that the pre-operative

and post operative hemoglobin showed no significant difference between both the groups.^[38]

In our study the mean preoperative heart rate and the mean heart rate during follow-up were comparable between both the study groups, without statistically significant difference ($p=0.84$). However, previous studies done by Sweeney G et.al, 1990^[39] and Van Dongen PWJet.al, 1998.^[40] have shown that carbetocin could induce maternal tachycardia and facial flushing.

The mean preoperative systolic and diastolic blood pressures and those measured during follow up were comparable between the two study groups, with no statistically significant differences observed ($p=0.51$) in our study. This indicates that both drugs have comparable safety profiles. Another study by N Kabir et al, 2019.^[41] showed, the mean preoperative systolic BP of patients were 108 ± 8.6 mm of Hg and diastolic BP were 71 ± 5.4 mm of Hg in carbetocin group and mean systolic BP were 105 ± 7.2 mm of Hg and diastolic BP were 70 ± 6.2 mm of Hg in oxytocin group which were almost similar. In contrast to these findings, Moertl MG et.al, 2011.^[42] reported that patients treated with oxytocin has a more pronounced hypotension and haemodynamic rebound than patients treated with carbetocin, with comparable effects on the cardiovascular system. These results indicate that carbetocin appears to possess an acceptable haemodynamic safety profile.

In our study the incidence of headache was 38 % in the Oxytocin group versus 18 % in the Carbetocin group. This finding is in alignment with the study done by Robabeh et.al which reported that the headache was more common in oxytocin group.^[43] In our study nausea and/or vomiting occurred in 12 % cases in Oxytocin group and 10 % cases in Carbetocin group. This finding diverges from the results observed by Rath W. which reported that the risk of headache and nausea were similar in women who received Carbetocin or oxytocin.^[44]

CONCLUSION

A single intravenous injection of carbetocin has been shown to be more effective than a continuous oxytocin infusion in preventing postpartum hemorrhage (PPH), while maintaining a similar safety profile. Heat-stable carbetocin offers a significant advantage in low-resource settings, where maintaining refrigeration and cold-chain logistics is challenging, due to its room temperature stability and prolonged duration of action. In the settings with reliable cold chain infrastructure, oxytocin remains a cost-effective and highly efficacious option for preventing postpartum haemorrhage, supported by a robust evidence base. Conversely, in remote or underserved areas where refrigeration is difficult to maintain, heat-stable carbetocin offers notable logistical advantages, despite its higher per-dose cost. These trade-offs should be carefully considered by policymakers and healthcare providers. Although

oxytocin remains a reliable and cost-effective option under optimal conditions, the stability and simplified storage requirements of carbetocin make it particularly well-suited for enhancing maternal healthcare delivery in resource-limited or challenging settings. Despite its benefits, the high cost of carbetocin remains a significant barrier, raising concerns about its cost-effectiveness and the feasibility of widespread implementation. Further studies are needed to assess the cost-effectiveness of carbetocin as a uterotonic agent in order to support its broader implementation.

Confidentiality of the data was maintained.

No conflict of interest.

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