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# Comparison of Efficacy of Carbetocin and Oxytocin in Prevention of Postpartum Hemorrhage Following Normal Vaginal Delivery

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## Abstract

**Background:** Postpartum hemorrhage (PPH) remains a leading cause of maternal mortality globally, with uterine atony being its most frequent etiology. Although oxytocin is the first-line agent for prophylaxis, its short half-life limits its utility. Carbetocin, a long-acting oxytocin analog, offers potential advantages.

**Objective:** To compare the efficacy and safety of carbetocin versus oxytocin in preventing PPH among women undergoing normal vaginal delivery.

**Methods:** A double-blinded randomized controlled trial was conducted at BRD Medical College, Gorakhpur, from November 2022 to October 2023. A total of 209 women aged 20–35 years with singleton term pregnancies undergoing uncomplicated vaginal deliveries were randomly assigned to receive either 100 mcg IV carbetocin (n=102) or 10 IU IM oxytocin (n=107) during active management of the third stage of labor. Primary outcomes included blood loss, uterine tone, need for additional interventions, and hemoglobin deficit. Secondary outcomes assessed were hospital stay >3 days and ICU admissions.

**Results:** Mean blood loss was significantly lower in the carbetocin group (289.84 ± 100.3 mL) compared to the oxytocin group (384 ± 211.5 mL; $p<0.001$). Carbetocin group showed significantly reduced need for blood transfusion (6.9% vs 16.8%; $p=0.027$), uterine massage (5.9% vs 28.0%; $p<0.001$), and balloon tamponade (1.0% vs 11.2%; $p=0.003$). Hemoglobin deficit was lower in the carbetocin group (0.396 vs 0.524 g/dL; $p<0.001$), and fewer patients required extended hospital stay ($p=0.002$).

**Conclusion:** Carbetocin was significantly more effective than oxytocin in reducing blood loss, minimizing the need for further uterotonics and interventions, and shortening hospital stay following normal vaginal delivery. These findings support the use of carbetocin as a superior alternative to oxytocin in routine PPH prophylaxis.

**Keywords:** Postpartum hemorrhage, maternal mortality, Oxytocin, Carbetocin

## Introduction

The traditional definition of Postpartum Haemorrhage, based on blood loss thresholds, has evolved to encompass broader criteria of a cumulative blood loss of 1000 mL or more of blood loss associated with signs or symptoms of hypovolemia during any mode of delivery. Within 24 hours after giving birth, primary PPH takes place, although secondary PPH can develop up to 12 weeks later. As summed up by the four "T's" (tone, trauma, tissue, and thrombin), the causes necessitate immediate attention. Inter professional management is used, with a focus on source control, fluid replacement, and precise blood loss evaluation.[1]

Postpartum Haemorrhage is a life-threatening obstetric emergency seen following 2-4 % following vaginal deliveries and 6% of cesarean sections.[2] It is one of the major causes of maternal mortality, accounting for nearly one quarter (35%) of all maternal deaths worldwide as per WHO.[2] 38% of maternal mortality in India can be attributed to PPH. Maternal Mortality in India in 2020 is 99 per lakh live births.[3]

Uterine atony is the most common cause of PPH.[4]

PPH-induced morbidity and mortality can be prevented with early diagnosis and Active Management of Third Stage of Labor (AMTSL).[2]

Administration of uterotonic agents is an essential component of AMTSL, as this prophylactic strategy has decreased the incidence of PPH by nearly half[5]. Oxytocin is the drug of choice for the prevention of PPH [6]. Oxytocin stimulates uterine contraction by binding directly to oxytocin receptors and increasing the intracellular calcium concentration within uterine smooth muscle[7]. Constant intravenous infusion of oxytocin is advised in standard postpartum therapy due to its short half-life (4–10 min) & length of activity. Common side effects of oxytocin include decreased blood pressure, nausea, vomiting, cardiac arrhythmia, pulmonary edema, water intoxication, and seizure [5,7]. To minimize these effects, slow intravenous injection or infusion is recommended, as opposed to rapid bolus intravenous injection [5,7].

A synthetic oxytocin agonist, carbetocin, has a half life of 40 mins, which is longer than that of oxytocin. It starts two minutes after intravenous and intramuscular injection and lasts for one to two hours. Flushing, lowered blood pressure, headache, tachycardia, stomach pain, and bitter tongue are some of the adverse effects. Although side effects are similar to those of oxytocin, the majority of studies do not disclose any significant adverse events following administration. [5,7,8,9,10]

The effectiveness of carbetocin in standard obstetric practice is well known, and recent clinical trials of the drug for PPH prophylaxis have been concentrated on cesarean deliveries. A recent Cochrane review has reported that carbetocin is more effective than oxytocin for reducing the need for additional uterotonic drugs following cesarean delivery and the need for uterine massage following both cesarean and vaginal delivery [9]. The Society of Obste tricians and Gynaecologists of Canada (SOGC; 2009) rec ommends carbetocin as a

first-line drug for the prevention of PPH after elective cesarean delivery and after normal vaginal delivery in pregnant woman with one risk factor for PPH [10].

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**Material and methods**

The randomized Controlled Study included all antenatal women between 20-35 years of age undergoing uncomplicated normal vaginal deliveries in Nehru Hospital, Obstetrics and Gynaecology BRD Medical College Gorakhpur. The research ran from November 1, 2022, to October 31, 2023, for more than a year. The Helsinki Declaration and Good Clinical Practices (GCP) were followed in the conduct of this investigation. This research includes term pregnant women with no risk factors who give birth naturally and without complications.

Patients and their family members who remain as birth companions are briefed on the purpose of the research, its advantages, and its disadvantages. Patients who expressed interest in participating in the experiment provided written informed permission in the regional language (Hindi) in the format specified before any study-related procedures were carried out. In illiterate patients, the left thumb impression was taken after the study was thoroughly explained to the birth partner, who acts as an unbiased witness.

A study was conducted with a sample size of 94 patients in each group, selected based on specific eligibility criteria. The insertion criteria required patients to be in 20 & 35 yrs old, have a singleton pregnancy, be at term (37–42 weeks of gestation), undergo vaginal delivery, and provide informed consent. Exclusion criteria included contraindications for Oxytocin and Carbetocin, age below 18 years, gestation period less than 35 weeks or beyond 42 weeks, known coagulation disorders, cesarean section, hypertensive disorders like eclampsia and pre-eclampsia, prior classical uterine incision or myomectomy, and various medical conditions such as epilepsy, fetal macrosomia, gestational diabetes mellitus (GDM), polyhydramnios, prolonged labor, fibroids, antepartum hemorrhage, anemia (Hb <8gm), asthma, cardiovascular, hepatic, and renal diseases. Additionally, instrumental vaginal delivery, placental insertion anomalies, multiple pregnancies, malpresentations, and associated medical or surgical disorders were considered exclusion factors. The study followed a structured methodology to ensure a well-defined participant group for accurate and reliable results.

**Study procedure**

During active labor, patients were closely monitored for vital signs and fetal heart rate. Upon entering the 2nd stage, 3rd stage of labor was actively managed. Patients in control group received 10 units of intramuscular oxytocin, while those in the intervention group were

given 100 mcg of carbetocin. Placental delivery was conducted using controlled cord traction, and uterine tone was assessed at multiple intervals post-delivery to classify contractions. Cases of atonic postpartum hemorrhage (PPH) were identified based on poor uterine tone and bleeding. Vital signs were recorded post-delivery and regularly monitored. Primary outcomes included uterine tone, "blood loss, and the need for additional" interventions such as uterotonic agents, blood transfusions, balloon tamponade, devascularization procedures, compression sutures, or peripartum hysterectomy. Secondary outcomes included hospital stays exceeding three days and ICU admissions. Hemoglobin and hematocrit levels were measured before labor and within 12–24 hours post-delivery using a standard automated method, and estimated blood loss was calculated based on pre- and post-delivery hematocrit values.

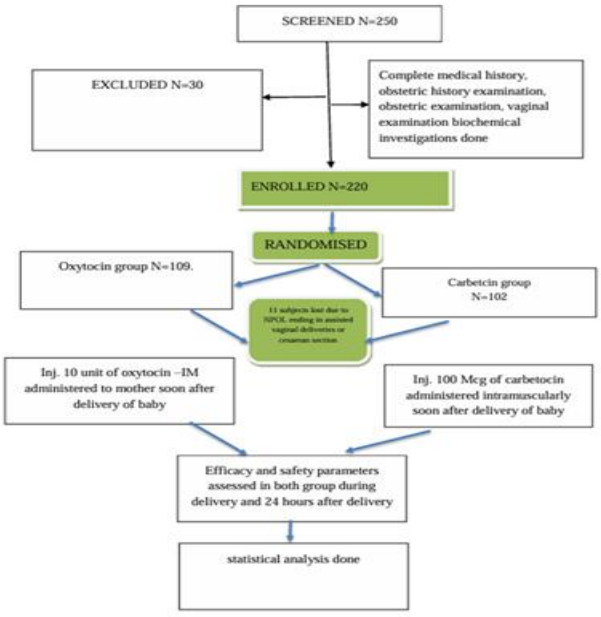


Figure 1: Flow diagram of the study protocol

**Statistical analysis**

Microsoft Excel sheet program was used for data entry, while SPSS-20 software was used for code analysis. P value of less than 0.05 was deemed statistically significant.

**Results**

The entire of 209 participants were involved in the analysis, with 102 receiving Carbetocin and 107 receiving Oxytocin. Baseline characteristics between groups were statistically comparable. Key outcome variables including blood loss, uterine tone, intervention requirements, and hemoglobin drop were analyzed in the study.

Table 1:- Distribution and association of sociodemographic and obstetric profile.

| Sr. no | Particulars | | Carbetocin N= 102 n (%)/Mean (SD) | Oxytocin N= 107 n (%)/Mean (SD) | P -value |
|---|---|---|---|---|---|
| 1 | Age (Years) | | 25.07 (3.5) | 24.62 (3.1) | 0.321* |
| 2 | Weight (Kg) | | 58.82 (4.8) | 59.66 (5.2) | 0.819* |
| 3 | Gestational Age (weeks) | | 38.59 (1.3) | 38.65 (1.2) | 0.703* |
| 4 | Socioeconomic status | Upper Lower | 30 (29.4%) | 34 (31.8%) | 0.711# |
| | | Lower | 72 (70.6%) | 73 (68.2%) | |
| 5 | Parity | Primigravida | 49 (48.0%) | 56 (52.3%) | 0.896# |
| | | G2 | 28 (27.5%) | 29 (27.1%) | |
| | | G3 | 14 (13.7%) | 13 (12.1%) | |
| | | >G3 | 11 (10.8%) | 9 (8,4%) | |

*-unpaired t- Test, #- Chi-Square Test

Table 1 presents the distribution and association of sociodemographic and obstetric profiles between two groups receiving different medications, Carbetocin (N=102) and Oxytocin (N=107). Participants receiving Carbetocin had a mean age of 25.07 years (SD=3.5), slightly higher than Oxytocin recipients at 24.62 years (SD=3.1), but the difference was not significant (p=0.321). Weight was also similar, with Carbetocin at 58.82 kg (SD=4.8) and Oxytocin at 59.66 kg (SD=5.2) (p=0.819). Gestational age showed no significant difference either, with Carbetocin at 38.59 weeks (SD=1.3) and Oxytocin at 38.65 weeks (SD=1.2) (p=0.703).

Table 2: Distribution and association between the effective blood loss and the use of uterotonics

| Blood Loss (millilitres (ml)) | Carbetocin N=102 Mean (SD) | Oxytocin N=107 Mean (SD) | P value (t-test) |
|---|---|---|---|
| Effective Blood loss | 289.84 (100.3) | 384 (211.5) | <0.001 |

Table 2 compares effective blood loss between participants receiving Carbetocin and Oxytocin. “The mean blood loss for the Carbetocin group” (N=102) was 289.84 ml (SD=100.3), while for the Oxytocin group (N=107), it was higher at 384 ml (SD=211.5). This difference was “statistically significant, with a p-value of”

Table 3: Distribution and association of Hemoglobin, and the blood transfusion

| Sr. no | | Carbetocin N= 102 | Oxytocin N= 107 | P value |
|---|---|---|---|---|
| Blood Transfusion | Yes | 7 (6.9%) | 18 (16.8%) | 0.027 |
| | No | 95 (93.1%) | 89 (83.2%) | |
| Hb Deficit | | 0.396 (0.141) | 0.524 (0.31) | <0.001 |

The table 3 presents a comparison of blood transfusion rates and hemoglobin (Hb) deficit between participants receiving Carbetocin and Oxytocin. Blood transfusion was required in 6.9% (7 out of 102) of the Carbetocin group, compared to 16.8% (18 out of 107) in the Oxytocin group, a statistically significant difference (p=0.027). Additionally, the mean Hb deficit was lower in the Carbetocin group (0.396 g/dL, SD=0.141) than in the Oxytocin group (0.524 g/dL, SD=0.31), with a highly significant p-value of

Table 4: Additional Interventions and Complications

| Sr. No | | Carbetocin N= 102 | Oxytocin N= 107 | P value |
|---|---|---|---|---|
| Uterine Massage | Yes | 6 (5.9%) | 30 (28.0%) | <0.001 |
| | No | 96 (94.1%) | 77 (72.0%) | |
| Balloon Tamponade | Yes | 1 (1.0%) | 12 (11.2%) | 0.003 |
| | No | 101 (99.0%) | 95 (88.8%) | |

The table compares the need for uterine massage and balloon tamponade between participants receiving Carbetocin and Oxytocin. Uterine massage was significantly less frequent in the Carbetocin group, with only 5.9% (6 out of 102) requiring it, compared to 28.0% (30 out of 107) in the Oxytocin group (p <0.001). Similarly, balloon tamponade was required in just 1.0% (1 out of 102) of Carbetocin recipients, whereas 11.2%

(12 out of 107) of Oxytocin recipients needed it, showing a statistically significant difference (p=0.003). These findings suggest that Carbetocin was associated with a lower need for additional uterine interventions.

Table 5: Association between the duration of stay in the hospital and the use of uterotonics

| Sr. no | | Carbetocin N= 102 | Oxytocin N= 107 | P value |
|---|---|---|---|---|
| Hospital Stay >3 days | Yes | 1 (1.0%) | 13 (12.1%) | 0.002 |
| | No | 101 (99.0%) | 94 (87.9%) | |

The table 5 presents a comparison of the need for balloon tamponade between Carbetocin and Oxytocin recipients. Only 1.0% (1 out of 102) of those receiving Carbetocin required the procedure, while a significantly higher 11.2% (12 out of 107) of Oxytocin recipients needed it. This difference was statistically significant (p=0.003), indicating that Carbetocin was associated with a reduced requirement for balloon tamponade, suggesting better uterine control and decreased postpartum complications.

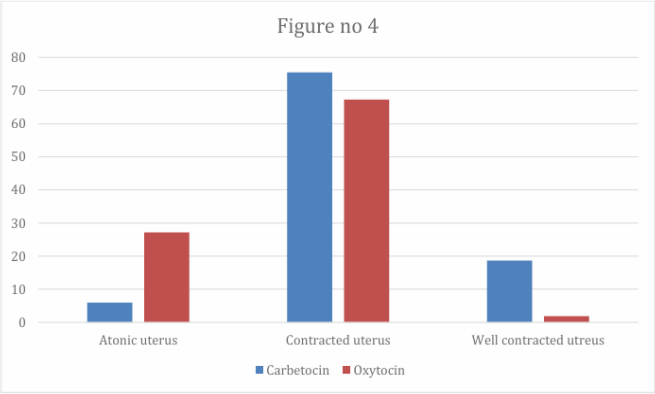


Figure 1: Distribution of Uterine Tone

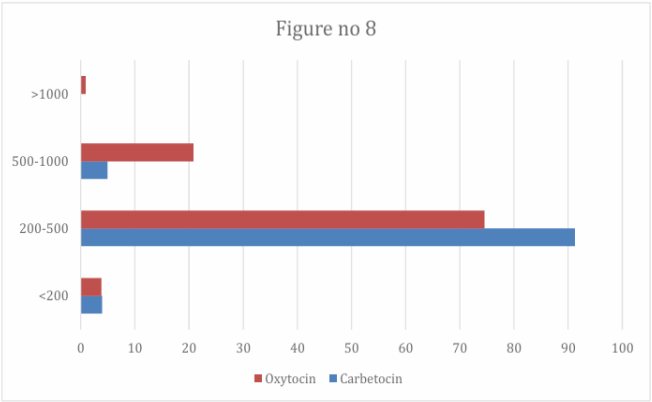


Figure 2: Effective Blood Loss Categories

**Discussion**

The present study, carried out at "the Department of Obstetrics and Gynaecology, Baba Raghav Das Medical College in Gorakhpur, Uttar Pradesh," sought to investigate & compare the effectiveness of carbetocin injection vs oxytocin injection in preventing postpartum hemorrhage. Employing a double-blinded randomized control trial design with a sample size of 209, the research followed rigorous ethical standards and obtained proper consent from participants.

In terms of participant demographics, the mean maternal age in the carbetocin group was 25.07 (SD=3.5), while in the oxytocin group, it was 24.62 (SD=3.1), and the statistical analysis revealed an insignificant difference (p=0.321).Similar age distributions were observed in studies by Widmer M et al (2018) [13] and Esseissah S A et al (2022). [14] However, it's worth noting that Gursoy et al (2021) reported a higher mean maternal age in both the oxytocin and carbetocin groups compared to the current study. [15]

Regarding gestational age, "there was no statistically significant difference between the carbetocin" group (38.59 weeks, SD=1.3) and the oxytocin group (38.65 weeks, SD=1.2), indicating an equal distribution. This aligns with findings from Widmer M et al (2018) and Gursoy et al (2021). Primigravida constituted 48.0% in the carbetocin group and 52.3% in the oxytocin group, mirroring the results of Gursoy et al (2021). [13, 15]

"Significant differences were observed in the incidence of" atonic uterus (5.9% in carbetocin, 27.1% in oxytocin; p value <0.001), necessitating uterine massage (5.9% in carbetocin, 28.0% in oxytocin; p value <0.001). Similar findings were reported by Anurag A et al (2022) while studies by Widmer M et al (2018), Esseissah S A et al (2022), Gursoy et al (2021) and Boucher et al (2004) showed insignificant differences in the use of additional uterotonics. [16,13,15,17]

The need for blood transfusion was 6.9% in the carbetocin group and 16.8% in the oxytocin group, with a statistically significant difference (p=0.027), aligning with the findings of Nida et al (2023). [18] However, Srinivas et al. (2023) reported comparable blood transfusion between the two groups. [19] The postpartum hemoglobin deficit was significantly higher in the oxytocin group (p value <0.001), aligning with the findings of Esseissah S A et al (2022). However, Gursoy et al (2021), Anurag et al (2022), and Boucher et al (2004) reported no significant differences. [14-17]

Overall, the present study had shown the significant alteration between the carbetocin & oxytocin in aspect of uterine tone, requirement of uterine massage, additional uterotonic use, blood transfusion, hemoglobin deficit, postpartum hematocrit, effective blood loss with postpartum hemmorhage, and mean duration of hospital stay, which were significantly lesser on carbetocin side as compared to the oxytocin.

**Conclusion**

This comprehensive study conducted at "the Department of Obstetrics and Gynaecology, Baba Raghav Das Medical College, Gorakhpur, Uttar Pradesh," has offered insightful information on the relative efficacy of oxytocin and carbetocin in halting postpartum bleeding.

Crucially, the study found that the two groups' results regarding the need for blood transfusions, further uterotonics, and uterine massage differed significantly. Furthermore, the study reported a significantly lower rate of blood transfusions in the carbetocin group, emphasizing potential advantages in managing postpartum hemorrhage with carbetocin.

The study also noted a higher hemoglobin deficit in the oxytocin group, suggesting potential differences in the impact of the two medications on post-delivery hemoglobin levels. Carbetocin is reported to be more effective than oxytocin in preventing PPH, blood loss after birth, the need for extra uterotonic medicines, hemoglobin level deviations, and blood transfusions. It also has a longer duration of action.

These results contribute to the ongoing discourse in maternal healthcare and provide clinicians with valuable information to guide evidence-based decisions in managing postpartum hemorrhage.

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