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Original Research Article

Carbetocin versus oxytocin in the prevention of postpartum hemorrhage in cesarean section: a prospective randomised comparative study

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ABSTRACT

Background: Postpartum hemorrhage is the leading cause of maternal mortality. The prevention of PPH can be best done by active management of the third stage of labour. Oxytocin is currently the uterotonic of choice. The study compared the efficacy of Carbetocin 100 µg intravenous bolus and oxytocin 10 IU intravenous infusion over 2 hours by measuring total blood loss, the need for additional uterotonic agents, and the need for blood transfusion. It is important to evaluate the efficacy of Carbetocin compared to oxytocin in low-income countries, especially where patient affordability is a major concern.
Methods: A prospective randomised comparative single-blinded study was conducted in the department of obstetrics and gynecology, Kurji Holy Family Hospital, Patna, Bihar. 100 patients undergoing elective cesarean section fitting in the inclusion criteria were randomly allocated by a sealed envelope system to either case study group A receiving Carbetocin 100 µg intravenous and control study group B receiving oxytocin 10 IU intravenous infusion. Three specific outcomes were measured: total blood loss, additional uterotonic use and the need for blood transfusion.
Results: In this study, Carbetocin was found to significantly reduce total blood loss in comparison to oxytocin ($p<0.0001$), the use of additional uterotonics was significantly less in the Carbetocin group ($p=0.023$), the need for blood transfusion was less in Carbetocin group but not significantly ($p=0.538$).
Conclusions: Carbetocin has better efficacy in comparison to oxytocin in reducing total blood loss, hence preventing PPH. The need for additional uterotonic agents is less with Carbetocin use. The need for blood transfusion was also less with Carbetocin use but needs larger studies to be proved. Carbetocin may be cost-effective.

Keywords: Cesarean section, Carbetocin, Oxytocin, Postpartum hemorrhage, Uterotonics

INTRODUCTION

Postpartum haemorrhage (PPH) is the leading cause of maternal deaths worldwide.[1] It continues to receive the attention of researchers in the medical community.

World Health Organization (WHO) defines PPH as blood loss of 500 ml or more following a vaginal delivery or 1000 mL or more following a cesarean section within 24 hours after birth.[1] PPH is the consequence of several different factors, such as uterine atony, retained placental tissue, genital tract trauma and coagulation dysfunction (the 4 T's mnemonic tone, tissue, trauma and thrombin). Most cases of PPH are caused by uterine atony.[1] Globally, PPH affects around 6-10% of all deliveries, contributing to 70,000 maternal deaths annually, which accounts for 20% of all maternal deaths worldwide.[2] In India, the incidence of PPH is notably higher compared to the global average. In 2016, Ramdurga et al reported in their study that in India, PPH is responsible for nearly 40% of all maternal

deaths.[3] The incidence of PPH is reported as 2 to 4% after vaginal delivery and 6% after cesarean section.[4]

PPH is life-threatening but preventable. It mostly occurs during the third stage of labour and active management of the third stage of labour (AMTSL) helps prevent PPH. AMTSL, as recommended by WHO, is oxytocin 10 I.U. intramuscular (IM) after the delivery of the baby, controlled cord traction by trained birth attendants.[5] AMTSL has proven to reduce the rate of severe PPH by 60-70%.[6] Oxytocin is currently the uterotonics of choice.[5] Oxytocin has a rapid onset of action and a good safety profile. However, oxytocin must be stored and transported at 2-8°C to maintain its effectiveness. In many countries, especially with limited resource settings and unreliable electricity, lack of temperature-controlled storage capacity, and a lack of cold chain facilities, oxytocin effectiveness is often compromised at the point of care. Another disadvantage of oxytocin is its short half-life of 4 to 10 minutes, regularly requiring a continuous intravenous infusion.[7] Carbetocin is a long-acting oxytocin analogue indicated for the prevention of uterine atony after childbirth. There are two forms of Carbetocin: heat-stable Carbetocin and non-heat-stable Carbetocin.[8] Both forms are equally effective in preventing PPH. However, the newer heat-stable version offers a logistical advantage without compromising on efficacy but may be more expensive. It is heat-stable and does not require cold-chain transport and storage. It maintains its stability over 36 months at 30°C and 75% relative humidity. Carbetocin has a rapid onset of action (within 1 to 2 minutes) and a prolonged duration of action (approximately one hour). Its safety profile is comparable with that of oxytocin. Carbetocin has a much longer half-life of 85-100 minutes.[9] The WHO conducted a large Carbetocin haemorrhage prevention (CHAMPION) Trial, which concluded that Carbetocin is non-inferior to oxytocin in the prevention of PPH.[10]

WHO's recommendations on uterotonics, 2018 recommend heat-stable Carbetocin for the prevention of PPH after all births in settings where oxytocin is unavailable, or its quality cannot be guaranteed and where its cost is comparable to other effective uterotonics.[11]

Reduction in re-treatment, staffing requirements, transfusion and potential medication errors from faulty cold-chain maintenance mitigate the higher index cost of Carbetocin. Studying the efficacy of this drug in the prevention of PPH is important in India, a developing nation where the affordability of patients is a major concern.

In this backdrop, the study was conducted to compare Carbetocin versus oxytocin for the prevention of postpartum haemorrhage during elective cesarean among Indian pregnant women. Considering that oxytocin has been vital in reducing PPH worldwide, our study was done to determine the real-world efficacy of Carbetocin. This study was conducted in one of the low-resource states in India to explore the effectiveness of Carbetocin in reducing the PPH in elective cesarean section. The use of Carbetocin has not been popular in our state. Understanding its effectiveness can improve maternal care in a region where healthcare resources may be limited and can potentially lead to changes that can benefit women across the state to combat the mortality and morbidity due to PPH. To our knowledge, there are no studies on Carbetocin in our state to date. This study may serve as a foundation for further regional studies where maternal health is a key concern.

Aims and objectives

To compare the efficacy of Carbetocin 100 µg intravenous (i.v.) with that of oxytocin 10 IU infusion in elective cesarean section in the prevention of PPH. Three specific outcomes: total blood loss, use of additional uterotonics, and need for blood transfusion were recorded.

METHODS

Study design and participants

A prospective randomised controlled trial was conducted in the department of obstetrics and gynecology, Kurji Holy Family Hospital, Patna, Bihar, over 11 months. All primigravida and multigravida with singleton pregnancy more than 37 weeks gestational age admitted for elective cesarean section were included in the study. Patients with a history of PPH were not excluded from the study. Patients with multiple pregnancy, polyhydramnios, pregnancy-induced hypertension, macrosomia, pregnancy with maternal medical diseases including liver, brain, heart, kidney and coagulation disorders, placenta previa, placenta accreta, pregnancy with myoma and patients not willing to participate were excluded from the study.

Sample size calculation

The study of Franco Borruto et al observed that the percentage of patients with blood loss ≤500 ml was greater with Carbetocin as compared to Oxytocin (81% versus 55%).[12] Taking these values as a reference, the minimum required sample size with 80% power of study and 5% level of significance is 47 patients in each study group. To reduce the margin of error, the total sample size taken was 100 (50 patients per group).

The formula used was:

$$N \geq \{[pc*(1-pc)+pe*(1-pe)]*(Z_{\alpha} +Z_{\beta})^2\}/(pc-pe)^2$$

With,

Pc=percentage of patients with blood loss ≤500 ml in Carbetocin;

Pe=percentage of patients with blood loss ≤500 ml in oxytocin;

Where, Z_α is the value of Z at a two-sided error of 5%, and Z_β is the value of Z at a power of 80%.

Calculations

$n \geq \{[0.81*(1-0.81)+0.55*(1-0.55)]*(1.96+0.84)^2\}/(0.81-0.55)^2$

$\geq 46.55 \approx 47$ (approximately).

So, the sample size in the study was taken as 50 in each group. Hence, the total sample size was 100 patients.

Data collection and methodology

A total of 100 women were enrolled in the study. These patients were divided into two groups: case study group A received Carbetocin 100 µg i.v. bolus over 1 minute, and control group B received oxytocin 10 IU i.v. infusion over 2 hours.

Each group consisted of 50 patients and was allocated by block randomisation with a sealed envelope system. In this technique, patients were randomised in a series of blocks of ten.

In this, we prepared 10 randomly generated treatment allocations within sealed opaque envelopes, assigning A and B in 5 envelopes each, where A represents the Carbetocin group and B represents the oxytocin group.

Once a patient gave consent to enter the trial, an envelope was picked up by the patient.

The patient was not aware which group had been allocated to her as the envelopes were sealed and opaque, making the study single-blinded.

The patients underwent a cesarean section under spinal anaesthesia as per the standard protocols of our department. The patient was given the uterotonic based on the group to which it belonged after the delivery of the baby once the umbilical cord was clamped. Delayed cord clamping is the standard protocol of our institution.[1] All the sponges used during surgery were weighed before and after the surgery. Using the gravimetric method, blood loss was calculated. We used the WHO definition for PPH, which is blood loss exceeding 500 ml following vaginal delivery and 1,000 ml following cesarean delivery.[1] Two suction bottles were used, one for amniotic fluid and the other for blood. Weight of the pads used 2 hours postoperatively were weighed.

Intra-operative (in ml) = (weight of used sponges during – the weight of dry sponges before the surgery) + volume of blood sucked in the suction bottle.

2 hours postpartum blood loss (ml) = weight of pad used after completion of cesarean section up to 2 hours postpartum was separately weighed.

Total blood loss (ml) = intraoperative blood loss (ml) + 2 hours postpartum blood loss.

Gravimetric method: every gram of weight equivocal to 1 ml of blood loss. It was assumed that weight is only due to the blood and not environmental water or debris.

Total blood loss was calculated as intraoperative and 2 hours postoperative. The use of additional uterotonics intraoperative was noted. The need for blood transfusion 48 hours postoperative was noted.

Statistical analysis

Categorical variables were presented in number and %, and continuous variables were presented as mean±SD and median. Normality of data tested by Kolmogorov-Smirnov test. If the normality was rejected, then a non-parametric test was used.

Statistical test was applied as follows-

Quantitative variables were compared using an unpaired t-test/Mann-Whitney test (when the data sets were not normally distributed) between the two groups.

Qualitative variables were compared using the chi-square test/Fisher exact test.

A p value of <0.05 was considered statistically significant. The data was entered in an MS Excel spreadsheet, and analysis was done using the Statistical Package for Social Sciences (SPSS) version 21.0.

RESULTS

The baseline characteristics like age, parity, body mass index (BMI) and indication for elective cesarean section are summarised in (Tables 1-4). Distribution of age (years) was comparable between groups A and B (20-30 years- 66% versus 70% respectively, 31-40 years- 34% versus 30% respectively) (p value=0.668). The mean±SD of age (years) in group A was 28.28±4.47, and in group B was 27.6±4.58 with no significant difference between them (p value =0.455) (Table 1).

Distribution of body mass index (BMI) (kg/m^2) was comparable between groups A and B [18.5 to 24.99 kg/m^2 (normal BMI)- 0% versus 2% respectively, 25 to 29.99 kg/m^2 (overweight)- 76% versus 62% respectively, ≥30 kg/m^2 (obese)- 24% versus 36% respectively] (p value=0.194) (Table 2). The mean±SD of body mass index (kg/m^2) in group A was 29.23±1.45, and in group B was 29.36±2.34 (p=0.753) (Table 2).

Distribution of parity (P) was comparable between groups A and B (P0- 38% versus 36% respectively, P1- 46% versus 44% respectively, ≥P2- 16% versus 20% respectively) (p value =0.873) (Table 3).

Table 1: Comparison of age (years) between groups A and B.

Age (years)	A (n=50)	B (n=50)	Total	P value
20-30	33 (66%)	35 (70%)	68 (68%)	0.668†
31-40	17 (34%)	15 (30%)	32 (32%)	
Mean±SD	28.28±4.47	27.6±4.58	27.94±4.52	
Median (25^{th}-75^{th} percentile)	27 (25.25-31.75)	28(23.25-31)	27(24.75-31)	0.455‡
Range	20-38	21-40	20-40	

‡ Independent t-test, † Chi-square test.

Table 2: Comparison of body mass index (BMI) between groups A and B.

BMI (kg/m^2)	A(n=50)	B(n=50)	Total	P value
18.5 to 24.99 (normal BMI)	0 (0%)	1 (2%)	1 (1%)	
25 to 29.9 9 (overweight)	38 (76%)	31 (62%)	69 (69%)	0.194*
≥30 (obese)	12 (24%)	18 (36%)	30 (30%)	
Mean±SD	29.23±1.45	29.36±2.34	29.29±1.94	
Median (25^{th}-75^{th} percentile)	29.14(28.298-29.952)	29.01(27.445-30.731)	29.14 (28.03-30.366)	0.753‡
Range	26.67-32.89	24.6-36.16	24.6-36.16	

‡ Independent t-test, * Fisher's exact test.

Table 3: Comparison of obstetric history between groups A and B.

Obstetric history	A (n=50) (%)	B (n=50) (%)	Total (%)	P value
Parity(P)				
P0	19 (38)	18 (36)	37 (37)	
P1	23 (46)	22 (44)	45 (45)	0.873†
≥P2	8 (16)	10 (20)	18 (18)	

† Chi-square test.

Table 4: Comparison of indication of cesarean section (CS) between groups A and B.

Indication of CS	A (n=50) (%)	B (n=50) (%)	Total (%)	P value
Breech	6 (12)	5 (10)	11 (11)	
Cephalopelvic disproportion	3 (6)	1 (2)	4 (4)	
Failed IOL*	7 (14)	8 (16)	15 (15)	
IUGR	3 (6)	1 (2)	4 (4)	
Maternal wish	4 (8)	3 (6)	7 (7)	0.924*
Previous 1 CS	19 (38)	20 (40)	39 (39)	
Previous 2 CS	7 (14)	10 (20)	17 (17)	
Previous myomectomy	1 (2)	1 (2)	2 (2)	
Transverse lie	0 (0)	1 (2)	1 (1)	
Total	50 (100)	50 (100)	100 (100)	

*Fisher's exact test.

Distribution of indication of cesarean was comparable between groups A and B (breech- 12% versus 10% respectively, CPD- 6% versus 2% respectively, failed IOL- 14% versus 16% respectively, IUGR- 6% versus 2% respectively, maternal wish- 8% versus 6% respectively, previous 1 CS- 38% versus 40% respectively, previous 2 CS- 14% versus 20% respectively, previous myomectomy- 2% versus 2% respectively, transverse lie- 0% versus 2% respectively) (p value =0.924) (Table 4).

Carbetocin use reduced blood loss from placental delivery to end of cesarean section compared to oxytocin group (339.8±130.24 ml versus 470.4±156.84 ml respectively) (p<0.0001) as well as 2 hours postpartum (in case group 55.88±22.13 ml compared to control group 72.2±26.9 ml) (p<0.0001) (Table 5). Total blood loss was also significantly lower in the Carbetocin group compared to oxytocin (p<0.0001) (Table 5). The Carbetocin group had a lower number of PPH cases, 4%, as compared to the oxytocin group, 6% (Table 5). Additional uterotonics were statistically less in the Carbetocin group (16%) compared to the oxytocin group (36%) (p=0.023) (Table 6).

Table 5: Comparison of blood loss (ml) between groups A and B.

Blood loss	A (n=50)	B (n=50)	Total	P value
Total blood loss (ml)				
Mean±SD	395.68±147.93	470.4±156.84	433.04±156.26	
Median (25th-75th percentile)	360 (340-390)	440 (410-470)	400 (360-460)	<0.0001§
Range	310-1140	360-1150	310-1150	
Blood loss from placental delivery till uterus closure (ml)				
Mean±SD	339.8±130.24	398.2±135.37	369±135.37	
Median (25th-75th percentile)	310 (292.5-340)	380 (342.5-387.5)	340 (300-380)	<0.0001§
Range	250-1000	300-950	250-1000	
Blood loss 2 hours post cesarean section (ml)				
Mean±SD	55.88±22.13	72.2±26.9	64.04±25.84	
Median (25th-75th percentile)	50 (40-60)	80 (60-80)	60 (40-80)	0.0002§
Range	40-140	40-200	40-200	
PPH cases reported in the samples (≥1000 ml)	2 (4%)	3 (6%)	5 (5%)	-

§ Mann Whitney test, * Fisher's exact test, PPH- Postpartum hemorrhage.

Table 6: Comparison of use of additional uterotonics between groups A and B.

Use of additional uterotonics	A (n=50) (%)	B (n=50) (%)	Total (%)	P value
No	42 (84)	32 (64)	74 (74)	
Yes	8 (16)	18 (36)	26 (26)	0.023†
Total	50 (100)	50 (100)	100 (100)	

†Chi-square test.

Table 7: Comparison of need for blood transfusion between groups A and B.

Need for blood transfusion	A (n=50) (%)	B (n=50) (%)	Total (%)	P value
No	45 (90)	43 (86)	88 (88)	
Yes	5 (10)	7 (14)	12 (12)	0.538†
Total	50 (100)	50 (100)	100 (100)	

†Chi-square test.

No surgical methods or tamponades were used to control the PPH. 5 patients in the Carbetocin group and 7 in the oxytocin group required blood transfusion (p=0.538) (Table 7). No massive transfusion was required in either group.

DISCUSSION

Carbetocin is a long-acting, synthetic analogue of oxytocin that does not require cold-chain transport and storage. The half-life of Carbetocin is 4-10-fold longer than oxytocin and can be administered as a single dose injection either intravenously or intramuscularly rather than as an infusion over several hours, as is the case with oxytocin.[7] Carbetocin is being investigated by several trials for its effectiveness in preventing PPH in cesarean section and vaginal delivery. This study aims to evaluate the efficacy of Carbetocin in comparison to oxytocin for the prevention of PPH in elective cesarean section. Our findings demonstrate that Carbetocin is more effective in reducing total blood loss and the need for additional uterotonics, with fewer cases of PPH observed in the Carbetocin group. The need for blood transfusion was less in the Carbetocin group.

Baseline characteristics

The possible confounding factors like age, BMI, parity and indication of cesarean section were comparable in both groups. Stratifying participants by key demographic and clinical factors like age, BMI, and parity ensures that different subgroups are equally represented in both treatment and control groups. This helps in enhancing the external validity of findings. Diverse representation improves generalizability. To minimise the variation due to other factors, we included only cases of elective cesarean section with no significant difference in the indications of cesarean section in both groups.

Reduction in blood loss

Carbetocin significantly reduced the total blood loss during elective cesarean section in patients at low risk for PPH as compared to oxytocin. The finding is similar to other studies. Ibrahim et al, showed that blood loss was

significantly more in oxytocin than in Carbetocin group 679.5±200.25 versus 424.75±182.59 respectively (p<0.001).[14] Meta-analysis of RCT in the cesarean section comparing oxytocin and Carbetocin for the prevention of PPH by Voon et al showed a significant reduction in the rates of PPH (p=0.009) when Carbetocin was used rather than oxytocin.[15] Carbetocin's prolonged duration of action likely contributes to its superior ability to control blood loss compared to oxytocin, which has a much shorter half-life and requires continuous infusion. Although the difference in PPH cases between the two groups was small (4% in the Carbetocin group versus 6% in the oxytocin group), it reinforces the overall trend of reduced blood loss with Carbetocin.

Need for additional uterotonics

One of the most notable findings of our study was the reduced need for additional uterotonics in the Carbetocin group. Only 16% of patients in this group required additional uterotonics, compared to 36% in the oxytocin group. Similar results are shown in several studies. Al Zubaidi et al study showed that Carbetocin was superior to oxytocin by 12% in reducing the need for additional uterotonics.[16] Attilakos et al study reported a higher need for additional oxytocics in the oxytocin group compared with Carbetocin group (45.5% versus 33.5% respectively) (RR 0.74, 95% CI 0.57-0.95).[17] The reduction in the need for additional uterotonic suggests better uterine contraction, lowering the risk of bleeding. The use of additional uterotonic was at the discretion of the surgeon. It was most often carboprost followed by misoprostol. Methergin was used in very few cases. None of the cases required tamponades or surgical interventions related to PPH. Uterine atony may result in PPH and requires intensified monitoring and prolonged observation time in the recovery room with increased use of medical staff time. Therefore, the use of additional uterotonics is an important surrogate measure of financial savings.

Blood transfusion

Blood transfusion requirement was less in the Carbetocin group as compared to the oxytocin group, but not statistically significant. Our results are consistent with studies of Maged et al, which showed that the Carbetocin group had less blood transfusion requirement than the oxytocin group (12% versus 18%) but not statistically significant (p=0.401).[18] The blood transfusion requirement intraoperatively till 48 hours was noted. A total of 12 patients required blood transfusion, of which 5 of them were in the Carbetocin group and 7 in the oxytocin group. This suggests that, while both drugs are effective in preventing severe haemorrhage, Carbetocin may offer a slight advantage in reducing the need for transfusions in some cases.

The main limitations of this study were a small cohort including only elective cesarean section, blood loss was measured only after placental delivery and skin, muscle and uterine incision blood loss was not considered. Blood absorbed over the drape sheet was not considered. The use of additional uterotonic agents per-operatively was subjective to the surgeon.

CONCLUSION

Given Carbetocin's longer duration of action and its stability in higher temperatures, it presents a practical advantage in resource-limited settings. Our findings support the use of Carbetocin as a viable alternative to oxytocin. Further studies focusing on cost-effectiveness and long-term outcomes are needed.

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