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Comparative efficacy of carbetocin versus oxytocin in preventing postpartum haemorrhage after vaginal delivery and caesarean section

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Abstract
Objective: To evaluate the efficacy of carbetocin versus oxytocin for prevention of postpartum haemorrhage in women undergoing vaginal delivery and caesarean section at a tertiary care hospital in North India.
Methods: This institution-based analytical comparative study with prospective design divided 174 randomly selected mothers with full-term singleton pregnancies admitted in KNMH in order to undergo delivery, into 2 groups. Group A was given a bolus dose of 100 mcg of carbetocin via IV after the delivery of the baby. Group B was given 20 IU oxytocin, 10 IU via IM and 10 IU in 500 ml of NaCL solution via IV route. Primary outcome were amount of blood lost during delivery (ml) and Drop of mean serum haemoglobin levels at 48 hours after delivery (gm%). p-value of <0.05 was considered to be statistically significant.
Results: Oxytocin group had a statistically significant higher quantity of blood loss (583.2+/- 118.8 ml) as compared to carbetocin group (539+/-142.6 ml) (p-value- 0.031) and a higher drop of mean Haemoglobin level at 48 hours as compared to carbetocin group (p-value-<0.001)
Conclusion: Carbetocin was found to be a better drug than oxytocin in preventing postpartum haemorrhage among North Indian mothers delivering via either vaginal delivery or caesarean.

Keywords: Carbetocin, oxytocin, postpartum haemorrhage, vaginal delivery, caesarean section uterotonic agents

Introduction

Despite the significant advancements made in the fields of obstetrics in the last few decades, maternal mortality continues to be unacceptably high in India [1]. Majority of the maternal deaths in India are preventable, occurring from causes that can be effectively managed if identified early or prophylactically treated with appropriate interventions [2]. Among them, post-partum hemorrhage (PPH) is arguably the most important [3]. Postpartum Hemorrhage can be defined as blood loss of more than 500ml after a vaginal delivery or more than 1000ml after a caesarean delivery [4]. PPH is associated with nearly one- fourth of all maternal deaths globally and uterine atony is the most common cause of PPH [5]. In India, it has been estimated that more than a third of all maternal deaths are caused by PPH [6].

Of the four major mechanisms implicated in the development of hemorrhage in the immediate postpartum period, (also known as the four Ts i.e., Tone, Trauma, Tissue and Thrombin) the lack of uterine tone after the delivery is the most common cause of PPH [7]. Uterine atony accounts for approximately 70-80% of cases of the condition [8]. In these cases, pharmacological agents that stimulate uterine contractions, known as uterotonics, play a pivotal role in preventing PPH. A number of different uterotonics have been developed in the last few decades. Of them, oxytocin and its analogues like carbetocin are the most commonly used uterotonics [9].

Oxytocin is the primary endogenous, nine amino acid peptide hormone that stimulates uterine contraction during labor. It is synthetized primarily in the hypothalamus and secreted from the posterior pituitary gland [10]. Oxytocin acts on the uterine smooth muscle receptors to stimulate myometrial contraction directly and indirectly by inducing the formation of prostaglandins by the decidua [11]. The primary disadvantages of using oxytocin are the requirements of prolonged IV infusions due to shorter half-life, antidiuretic effects leading to an increased risk of hyponatremia, and large doses/ bolus of oxytocin is associated with adverse effects like hypotension, nausea, vomiting, arrythmias and severe water intoxication with convulsions [12].

Carbetocin is a long-acting synthetic octapeptide analogue of oxytocin having an agonist action at the oxytocin receptor. The structural difference from oxytocin makes carbetocin more stable and thus avoids early decomposition by disulfidase, aminopeptidase and oxidoreductase enzymes [13]. Compared to oxytocin, has several proposed advantages, such as a longer half-life of around 40 minutes, incidence of sustained contraction within 2 to 3 mins of administering the drug, and a lower requirement for stringent storage mechanisms [14].

The current pharmacological policy for the prevention of PPH in most labor suites of India is oxytocin. Most hospitals use either use 5-10 IU oxytocin IM or a continuous infusion of the agent as a prophylactic measure to prevent PPH [15, 16]. While carbetocin has been adopted in some healthcare institutions, it has yet to be included in the PPH management protocols of the majority of hospitals in the country. The present study aimed to compare the two agents in their efficacy in the management of atonic PPH in a cohort of women delivering by Lower Segment Cesarean Section at a tertiary care hospital of Uttar Pradesh, India.

Material and Methods

This institution-based analytical comparative study with a prospective design was conducted at the Department of Obstetrics and Gynaecology of the Kamala Nehru Memorial Hospital, Prayagraj, Uttar Pradesh for 12 months, from June 2022 to June of 2023 on 174 mothers with full-term singleton pregnancies admitted in order to undergo delivery, after approval from the institutional ethical committee. Mothers fulfilling the inclusion criteria were randomly recruited to the carbetocin and oxytocin group. For each mother recruited into the study group, 1 matched control mothers were recruited for the control group, matched with the mothers of the carbetocin group with respect to their age (±2 years) and gestational age (±1 completed week). Study group were given a bolus dose of 100 mcg of carbetocin via IV after the delivery of the baby. Control group were given 20 IU oxytocin, 10 IU via IM and 10 IU in 500 ml of NaCL solution via IV route. . The blood loss following delivery was estimated via visual estimation, number of used swabs and pads, and the amount of aspirated blood in case of LSCS delivery. The fall in the haemoglobin level was measured by estimating haemoglobin of the mothers before the delivery and at 48 hours of the delivery. The systolic and diastolic blood pressure, uterine position, and uterine tone of the mothers of the two study groups were monitored and compared at 2 hours, 12 hours, and 24 hours of delivery. Primary outcomes were Amount of blood lost during delivery (ml) and Drop of mean serum haemoglobin levels at 48 hours after delivery (gm%). Secondary outcomes-Hemodynamic stability (systolic and diastolic blood pressure at baseline 2, 12, and 24 hours of delivery), Uterine tone at delivery, and at 2, 12, and 24 hours of delivery, Uterine position at delivery, and at 2, 12, and 24 hours of delivery, Additional uterotonics and Blood transfusion required. The collected data were checked for consistency, completeness and entered into Microsoft Excel (MS-EXCEL, Microsoft Corp.) data sheet. analyzed with the statistical program Statistical Package for the Social Sciences (IBM SPSS, version 22). Data were organized and presented using the principles of descriptive and inferential statistics. The data were categorized and expressed in proportions. The continuous data were expressed as mean ± SD. The data were graphically presented in the form of tables, vertical bars, horizontal bar, pie diagram. Where analytical statistics were performed, a p-value of <0.05 was considered to be statistically significant for the purpose of the study. For analytical statistics, Chi-square test was used for categorical data and student's t-test was used for continuous data.

Results

The maternal demographic characteristics of the two study groups were broadly comparable, indicating successful randomization and matching. The mean maternal age and gestational age were similar between the carbetocin and oxytocin groups, with no statistically significant differences (p = 0.666 and p = 0.122, respectively). Likewise, the distribution of comorbidities such as gestational diabetes mellitus, hypertensive disorders of pregnancy, and previous lower-segment cesarean section did not differ significantly between groups. (Table 1)

Obstetric risk factors were also evenly distributed across both groups. The majority of women in each cohort had no identifiable additional obstetric risk conditions (83.9% in the carbetocin group vs. 73.6% in the oxytocin group). Other conditions such as bad obstetric history, cephalopelvic disproportion, fetal distress, cord around the neck, oligohydramnios, polyhydramnios, and placenta previa occurred in small numbers and showed no statistically significant differences. (Table 2)

Analysis of primary maternal outcomes demonstrated clear clinical advantages for carbetocin. The mean estimated blood loss was significantly lower among women administered carbetocin (539.8±142.6 ml) compared to those who received oxytocin (583.2±118.8 ml), with the difference reaching statistical significance (p = 0.031). Correspondingly, the decline in hemoglobin levels over 48 hours was significantly smaller in the carbetocin group. Although baseline hemoglobin was comparable between groups, women receiving oxytocin experienced a greater mean drop by 48 hours postpartum (p<0.001). (Table 3)

Hemodynamic trends showed notable differences between groups, particularly in early postpartum systolic blood pressure. At the 2-hour measurement, systolic blood pressure was significantly lower among women in the oxytocin group (110.8±5.5 mmHg) compared with those given carbetocin (118.2±77.9 mmHg), suggesting greater stability with carbetocin (p<0.001). Diastolic pressures showed no statistically significant differences at any time point. (Table 3)

The assessment of uterine contractility and involution further highlighted the superiority of carbetocin. Reduced uterine tone at delivery was significantly more frequent among women receiving oxytocin (17.2%) than in the carbetocin group (8%) (p = 0.048). Differences in uterine position continued to diverge across subsequent time points. At 2 hours postpartum, a markedly higher proportion of carbetocin recipients demonstrated more favorable uterine descent compared to their oxytocin counterparts (p<0.001). Similar trends persisted at 12 and 24 hours, each showing statistically significant superiority of carbetocin in promoting timely uterine involution (p<0.001 and p = 0.004, respectively). (Table 3)

Secondary outcome measures also favored carbetocin. Requirements for additional uterotonic agents were substantially lower in the carbetocin cohort (6.8%) compared to the oxytocin group (23%), a difference that was highly significant (p = 0.003). Furthermore, blood transfusions were required far less frequently among women administered carbetocin (5.7%) than those given oxytocin (21.8%) (p = 0.002). (Table 3)

Discussion

In the present study, two of the most popular uterotonic agents currently in use in the labor suites across India, i.e., oxytocin and

carbetocin were evaluated to assess their effectiveness in the prevention of postpartum hemorrhage among women undergoing either spontaneous vaginal delivery or caesarean section delivery at a tertiary care hospital of North India. In the present study, it was observed that most of the mothers belonged to the 26-30 years age group, with the mean age of the carbetocin group mothers being 26.4±3.1 years and that of the oxytocin group mothers being 26.2±3.0 years. Since the mothers of both the study groups were matched as per age (±2 years), the difference between the two study groups was not observed to be statistically significant on analysis. Since only term singleton pregnancies were considered for the present study, the mean gestational age of the mothers in the present study was observed to be 37.9±0.8 weeks for the carbetocin group and 38.1±0.9 weeks for the oxytocin group. Regarding the booking status, it was seen that the proportion of mothers having <4 antenatal checkup (ANC) visits during their pregnancy was 23% and 18.4% in the carbetocin and oxytocin groups respectively. Proper antenatal care is crucial for the health of both the mother as well as the fetus in any pregnancy and has been shown to increase the risk of PPH [17]. Timely and adequate antenatal care has been shown to be associated with a significantly reduced incidence of a number of maternal complications, which includes postpartum hemorrhage [18].

Research on the topic of postpartum hemorrhage have reported that there are several antenatal and intra-natal factors that are associated with an increased risk of mothers developing the condition during their pregnancy. Several important risk factors that have been identified include the presence of pre-pregnancy and intranatal chronic diseases such as hypertension and diabetes mellitus, previous history of lower segment cesarean section delivery, bad obstetric history with previous abortions, cephalopelvic disproportion, fetal distress, and placental disorders [19, 20]. The present study evaluated the presence of these high-risk factors among the mothers recruited in the two study groups and ascertained the differences between them. It was seen among the mothers of both the carbetocin and oxytocin groups, the most commonly encountered comorbidity was the presence of hypertensive disorders of pregnancy (28.7% in carbetocin group vs 34.5% in oxytocin group, p-value 0.415). The second most common risk factor for PPH found to be prevalent among the mothers interviewed as a part of the present study was the positive history of previous cesarean section delivery. These finding mimics the overall trend of rising incidence of cesarean section among delivering mothers which has been observed in both the developed as well as the developing countries in the recent years [21]. The findings of the present study with respect to the presence of risk factors in the mothers are similar to those reported by other researchers on the topic. Similar to the present study, Chen et al., Holleboom, and Larciprete also reported that bad gestational diabetes, bad obstetric history, and oligohydramnios were the most common risk factors present in the women receiving either carbetocin or oxytocin [22, 23, 24].

The incidence of postpartum hemorrhage in the mothers as well as the efficacy of the two drugs in preventing the condition were measured in the present study in two major ways, the first being by measurement of the total blood lost during the period of delivery. It was observed that in the mothers who received carbetocin, the average amount of blood loss during the entire process of delivery was 539.8±142.6 ml, while for the mothers in the oxytocin group, this was 583.2±118.8 ml respectively. This difference between the two study groups with respect to the average amount of blood lost during pregnancy was also found to be statistically significant. The findings observed in the current study are similar to those reported elsewhere. Matthijsse et al. also reported that women receiving carbetocin were significantly less likely than those receiving oxytocin with regards to the precipitation of a PPH event [25]. Significantly lower incidence of massive blood loss events in carbetocin group mothers as compared to their oxytocin counterparts has also been reported by Kabir et al. in their study [26]. On the other hand, studies such as those conducted by Chen et al., Widmer et al., and Vernekar et al., reported no statistically significant differences between the two drugs with respect to the total amount of blood lost during the delivery event [27, 28, 22] This discrepancy in the findings can be explained by the fact that in these studies, not only the population were different, but the manner of measurement of blood loss was also different, with most of the studies measuring PPH events as proportions rather than measuring the total mount of blood lost during and immediately following the delivery.

The second major way that the present study measured the development of PPH among the two groups of women was by measuring the difference in the mean serum hemoglobin values of the mothers in the two study groups at 48 hours of delivery as compared to the baseline. It was observed that similar to the total amount of measured blood lost during delivery, the fall of the mean hemoglobin in 48 hours after the delivery was significantly lower in the carbetocin group as compared to the oxytocin group (10.5±0.8 g/dl versus 9.7±1.1 g/dl, p-value <0.001). Similar findings have been reported by Maged et al., in their study, who also noted a significantly higher mean hemoglobin levels in the carbetocin group mothers as compared to the oxytocin group mothers 24 hours after delivery.[14] Voon et al., Chen et al., Kabir et al., and Matthijsse et al., also reported findings similar to that of the present study [29, 22, 25, 26]

When the hemodynamic characteristics of the study participants were measured, it was observed that women in the carbetocin group had a much more consistent systolic and diastolic pressures at 2 hours, 12 hours, and 24 hours following delivery as compared to the mothers in the oxytocin group. On the other hand, those mothers receiving oxytocin had an overall lower systolic and diastolic blood pressures as compared to carbetocin group mothers, and the difference was found to be statistically significant at the 2-hours observation mark. In their study, Larciprete et al., also found that while both the drugs showed hypotensive effect, blood pressure was reduced to a greater extent in the oxytocin group mothers as compared to the carbetocin group mothers [24]. Mannaerts et al., also reported similar findings, with their study finding that oxytocin use was observed with a greater reduction of blood pressure parameters following delivery as compared to carbetocin, a finding that was also observed to be the case in the present study [30].

It was observed in the present study that the use of oxytocin was associated with a significantly higher incidence of reduced uterine tone at delivery as compared to those mothers who were administered carbetocin. Furthermore, it was also seen that in those mothers who were administered carbetocin, the uterus returned to the pre-delivery position as a pelvic organ statistically significantly more quickly as compared to those mothers in whom oxytocin was used. These observations provide evidence towards the better efficacy and effectiveness of the former drug in comparison to the latter. Carbetocin, being a uterotonic agent with much longer half-life than oxytocin has been shown to lead to sustained uterine contraction for a longer duration of time as compared to the oxytocin. This leads to improved uterine tone and quicker return to its pre-delivery

position following the delivery, an assertion which was substantiated by the observations made in the present study. El Behery et al., and Larciprete et al. also reported similar observations [31, 24].

Additional uterotonics was required in only 6.8% of the mothers administered with carbetocin as compared to 23% of mothers who had been administered with oxytocin. A statistically significant difference was also observed with regards to the requirement of blood transfusion in the participants (p-value 0.002). In their systematic review and meta-analysis, Jin et al., also found that the use of carbetocin was associated with a significantly lower requirement of additional uterotonics as compared to using oxytocin [32]. Voon et al., Chen et al., and Kabir et al., also reported similar findings [22, 26, 29]. A lower requirement of additional uterotonics can be attributed to the longer half-life and the stability of the carbetocin as compared to oxytocin, and the lower requirement of blood transfusion is a testament to its effectiveness in preventing postpartum blood loss among delivering mothers.

Conclusion

The findings of the present study provide further evidence to the assertion that carbetocin is a better drug than oxytocin in preventing postpartum hemorrhage among North Indian mothers delivering via either NVD or LSCS. Carbetocin was also found to be more hemodynamically stable than oxytocin, associated with faster and better uterine contractility, and a lower requirement for additional uterotonics and blood transfusion in the postpartum period.

Compliance with Ethical Standards

Conflict of interest- Dr. Garima Mahendra & Dr. Shubha Pande declare that they have no conflict of interest.

Ethical Approval- Institutional ethical clearance was take. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institution and with the 1964. Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent- Informed consent was obtained from all individual participants included in the study.

Tables and Figures

Table 1: Maternal Characteritics

Characteritics	Carbetocin (n. %)	Oxytocin (n, %)	p value
Maternal age (mean +/- SD)	26.4+/-3.1	26.2+/-3.0	0.666
Gestational age (mean+/-SD)	37.9+/- 0.8	38.1+/-0.9	0.122
Gestational Diabetes Mellitus	19(21.8)	17(19.5)	0.708
Hypertensive disorder of Pregnancy	25(28.7)	30(34.5)	0.415
Previous LSCS	16(18.4)	22(25.3)	0.271

Table 2: Other Obstetric risk factors

Other obstetric risk factors	Carbetocin group (n, %)	Oxytocin group (n, %)	p-value
None	73 (83.9)	64 (73.6)	0.550
Bad obstetric history	5 (5.7)	9 (10.3)	
Cephalopelvic disproportion	1 (1.1)	0 (0.0)	
Fetal distress	2 (2.2)	1 (1.1)	
Loop of cord	1 (1.1)	3 (3.4)	
Oligohydramnios	3 (3.4)	4 (4.6)	
Polyhydramnios	1 (1.1)	3 (3.4)	
Placenta previa	1 (1.1)	3 (3.4)	
Total	87 (100)	87 (100)	

Table 3: Maternal Outcomes

Characteritics	Carbetocin (n. %)	Oxytocin (n, %)	p-value
Mode of Delivery 1 Spontaneous Vaginal Delivery 2 LSCS	 38(43.7) 49(56.3)	 37(42.5) 50(57.5)	0.878
Blood Loss (mean +/-SD)	539.8+/-142.6	583.2+/-118.8	0.031
Drop in Hb Level (gm/dl) At baseline At 48hours	 11.3+/-1.2 10.5+/-0.8	 11.6+/-1.1 9.7+/-1.1	0.085 <0.001
Systolic BP (mmHg) At baseline 2 hours 12 hours 24 hours	 120.8+/-12.7 118.2+/-77.9 120.8+/-11.4 121.2+/-10.3	 121.4+/-12.5 110.8+/-5.5 121.9+/-5.3 123.3+/-7.2	0.675 <0.001 0.381 0.121
Diastolic BP (mmHg) At baseline 2 hours 12 hours 24 hours	 78.8+/-7.8 76.7+/-6.1 79.3+/-6.6 77.8+/-7.7	 78.9+/-10.2 75.2+/-8.4 78.3+/-6.4 77.9+/-4.4	0.944 0.169 0.318 0.934
Reduced uterine tone at 0 hours	7(8)	15(17.2)	0.048
Uterine Position at Delivery 1 finger	29(33.3) 17(19.5)	30(34.5) 12(13.8)	0.587

2 finger At umbilicus	41(47.2)	45(51.7)	
Uterine position at 2 hours 1 finger 2 finger At umbilicus	10(11.5) 7(8) 70(80.5)	30(34.5) 12(13.8) 45(51.7)	<0.001
Uterine position at 12 hours 1 finger at umbilicus 1 finger below umbilicus	7(8) 10(11.5) 70(80.5)	8(9.2) 34(39.1) 45(51.7)	<0.001
Uterine position at 24 hours at umbilicus 1 finger below umbilicus 2 finger below umbilicus	1(1.1) 81(93.2) 5(5.7)	2(2.3) 85(97.7) 0	0.004
Additional Uterotonics requirement	6(6.8)	20(23)	0.003
Blood transfusion requirement	5(5.7)	19(21.8)	0.002

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