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A study to evaluate and compare the role of carbetocin along with oxytocin to prevent postpartum hemorrhage in northern India women

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Abstract
Introduction: Postpartum hemorrhage is a common cause of maternal mortality all over the world and its incidence is increasing day by day.
Objective: To compare the efficacy of single dose of 100 µg Intravenous Carbetocin to single dose of 10 Unit Intravenous Oxytocin in reducing incidence and severity of Postpartum Hemorrhage in women at risk.
Material and Methods: This study was conducted in the Department of Obstetrics and Gynecology, ESIC Medical College and Hospital, Faridabad, Haryana (India). A total of 128 women who underwent delivery were enrolled with various risk factors for primary post-partum hemorrhage.
Results: A total of 128 patients enrolled were divided into 64 patients in each group. The mean age of mothers of study group was 28.18+4.25 years and in control group was 29.12±4.19 years. The average gestational age was 37.6 weeks in study group and 38 weeks in control group. Multigravida women was 43(67.19%) in study group and 41(64.06%) in control group. A total of 53.13% cases in study and 56.25% cases in control group underwent LSCS and 45.31% cases in study group and 43.75% cases in control group underwent vaginal delivery. Mean birth weight in study group was 2.53 kg and in control group was 2.69 kg. Mean blood loss in study group was 428.11±336.24ml and in Control group was 587.2±437.15ml. Mean fall in hemoglobin in study group was 0.45±0.32gm/dl and in control group was 0.71±0.37gm/dl i.e. statistically significant. 14.06% of cases in study group and 29.68% of cases in control group needed additional uterotonic other than assigned uterotonics that was statistically significant. Mean urine output in study group was 1217.26±413.34ml and in control group was 1036.28±362.16ml. Significant difference according to additional uterotonic requirement, The mean fall in hemoglobin in the study group was 0.52 ±0.36 gm/dL compared to 0.81±0.47 gm/dL in the control group, indicating a statistically significant difference (p = 0.06). The mean fall in hemoglobin in the study group was 0.52 ±0.36 gm/dL compared to 0.81±0.47 gm/dL in the control group, indicating a statistically significant difference. Greater fall in hemoglobin was observed in the oxytocin group (p = 0.06). Sustained contraction by carbetocin showed maximum number of patient in study group had abdominal pain i.e. 16.89% cases and 14.16% in control group had abdominal pain after giving uterotonic.
Conclusion: The present study concluded that intravenous Carbetocin as compared to intravenous Oxytocin in reducing postpartum blood loss, postpartum anemia, incidence of atonic postpartum haemorrhage found to be effective. Requirement of additional uterotonic, and blood transfusion in high risk pregnancy. Single dose of Carbetocin appears to be more effective than single dose of oxytocin to prevent the Postpartum Haemorrhage, with similar hemodynamic profile and minor antidiuretic effect.

Keywords: Carbetocin, oxytocin, prevention, postpartum hemorrhage

Introduction
Postpartum hemorrhage (PPH) is the most common cause of maternal mortality worldwide and found to be a quarter of maternal deaths throughout the world [1] and its incidence in the developed countries reported to be increasing [2]. Worldwide, postpartum haemorrhage continuously played a significant role in maternal morbidity and mortality mainly due to 'too little being done too late' [2]. In 2014, WHO reported 8% of all maternal deaths due to Postpartum Haemorrhage in developed regions 20% in Eastern Asia, and 32% in northern Africa [1]. In our country, obstetrics haemorrhage found to be the main cause of maternal mortality i.e. 47% of the cases and could be higher in poorer states [3]. When blood loss >500mL within 24 hours of vaginal delivery and 1000mL after caesarean section, it is called primary PPH. It is called minor when 500-1000 mL or major when > 1000 mL [2] blood loss occurred. Major PPH is divided into (i) moderate 1000-2000 mL and (ii) massive >2000mL resulting in changes in the haemodynamic parameters [2]. Secondary PPH is defined as excessive blood loss from

the genital tract from 24 hours following delivery, until 12 weeks post-delivery [2, 4] Common risk factors associated with Postpartum Haemorrhage are Placenta praevia, Abruptio placenta, Multiple pregnancies, Previous Postpartum Haemorrhage, Induced labour, Big Baby>4kg, Prolonged Labour > 12 Hours [2].

Postpartum Haemorrhage is a major complication leading to hypovolaemic shock, multi-organ dysfunction, and maternal death, within two to six hours of delivery [2].

These deaths are preventable with early identification and prompt interventions. The use of uterotonics is key to prevent Postpartum Haemorrhage, which makes it the most important component of active management of 3rd stage of labor [5, 6] Heat-stable carbetocin, an oxytocin analogue, does not require cold-chain transport and storage; it has been shown to maintain stability for 36 months at 30°C and 75% relative humidity [7].

A single bolus dose of 100 microgram has been demonstrated to be at least as effective as a 16-hour continuous infusion of oxytocin in reducing postpartum haemorrhage following delivery[8]. Therefore to advance our understanding of the use of a single dose of injection carbetocin in prevention of postpartum haemorrhage, present study was conducted in the Department of Obstetrics and Gynecology, ESIC Medical College and Hospital, Faridabad, Haryana (India).

Aim and Objectives

To evaluate and compare the role of single dose of 100 microgram IV carbetocin with single dose of 10 Unit IV oxytocin in decreasing the incidence rate and severity of postpartum haemorrhage, requirement of additional uterotonic agent and drop in Haemoglobin level.

Material and Method

The present prospective and comparative study was conducted in the Department of Obstetrics and Gynecology, ESIC Medical College and Hospital, Faridabad, Haryana (India). 128 women underwent delivery were consecutively enrolled, with risk factors for primary post-partum haemorrhage such as multiple pregnancies, one or more previous caesarean sections, presence of placenta previa, history of Postpartum Haemorrhage, fetal macrosomia, polyhydramnios and medical disorders such as HDP, GDM, IHCP. A written informed consent was obtained from all the patients before inclusion into the study.

Inclusion Criteria

The inclusion criteria were multiple pregnancies, one or more previous caesarean sections, HDP including GHTN, preeclampsia, placenta previa, history of Postpartum Haemorrhage, any previous uterine surgery, fetal macrosomia polyhydramnios and medical disorders such as gestational diabetes mellitus etc.

Exclusion Criteria

Women having cardiac problems, deranged renal parameters or liver and epilepsy etc.

Methodology

All patients were well informed after admission about the study. A 2 mL of blood was collected for CBC. All the women were further sub-divided into 64 each i.e. control group (oxytocin) or study group (carbetocin). Immediate after the birth of child but before placental delivery, already prepared syringe of oxytocin or carbetocin was used in both groups of women. Control group women received 10U of oxytocin injection over 1-minute period and similarly, study group women received 100 microgram of carbetocin over 1 minute period. The hemodynamic parameters etc. were monitored before use of assigned drug, 2 hours postpartum, and at 12 hours postpartum and blood loss was measured. Uterine atony was evaluated by manual palpation. 24 hours after delivery, 2 mL of blood was obtained for repeated CBCs. The patient baseline characteristics, pregnancy outcomes, hemodynamic changes, additional uterotonic agent requirement, urine output in 24 hours, various side effects, and pre & post-delivery hemoglobin recorded and analyzed. Primary outcomes of study was need for additional uterotonic agents, drop in haemoglobin level and blood loss. The secondary outcomes of this study were (i) Blood pressure (in mmHg) was monitored at 2 hours, 12 hours (<100/60mmHg considered at hypotension), urine output monitored at 24 hours and uterine tone (standardized as contracted, poorly contracted, Atonic) assessed after delivery by the same duty doctor and (ii) Need of blood transfusion within 24 hours after delivery and adverse effects of both drugs.

Statistical Analysis

At the end of the study, all the data were collected and analysed statistically by using appropriate statistical tests. A p value of <0.05 was considered as significant.

Results

Present study included 128 patients in which 53.12% of cases in study group and 51.56% of cases in control group were between the age group of 21-30 years of age. 46.88% of cases in study group and 48.44% of cases in control group were between the age group of 31-40 years of age. No patient in the age group below 20 years of age and above 40 years of age (p=0.87). No significant difference in mean age of the study group i.e. 29.88±4.71 years and in control group 30.02±4.98 years and no significant difference was seen in mean age between Carbetocin group and oxytocin group (p=0.50 non-significant). No significant difference was also found according to BMI in both groups 12.5% of cases were in the BMI range of 18.5(Kg/m^2) to 24.9(Kg/m^2). 59.3% of cases in study group and 50% of cases in control group were in the BMI range of 24.9-29.9(Kg/m^2). 28.13% of cases in study group and 37.5% of cases in control group were in the BMI range of >30(Kg/m^2). In both groups BMI range of the expected mother was the same i.e. there was no significant difference seen (p=0.97 non-significant).

No significant difference according to Gestational age in which 17.19% of cases in study group and 17.19% of cases in control group were in between 33-37 weeks of gestation. 64% of cases in study group and 65.63% of cases in control group were in between 37-40 weeks of gestation. 18.75% of cases in study group and 17.19% of cases in control group were >40 weeks of gestation. The average gestational age of the patients was 38.6 weeks in study group and 38 weeks in control group with range of 8 weeks (33 to 41 weeks) and maximum patients were between 37 to 40 weeks in both groups (p=0.71 non-significant).

No significant difference according to Parity i.e. 64.06% of cases in control group and 67.19% of cases in study group were second gravida and more. 35.94% of cases in control group and 32.81% of cases in study group were primigravida (p=0.90 non-significant). No significant difference according to history of the previous section i.e. 67.19% of cases in study group and 60.94% of cases in control group had no history of previous cesarean section.

In the present study, 10.95% of cases in study group and 12.59% of cases in control group had over distension of uterus either due

to big size baby or multiple pregnancy or due to polyhydroamnios. 43.71% of cases in study group and 46.88% of cases in control group had history of uterine surgery that included history of previous LSCS, history of Myomectomy, history of D & E. 25% of cases in study group and 26.56% of cases in control group had history of any medical disorder of pregnancy (HDP, GDM, IHCP). 7.81% of cases in study group and 6.26% of cases in control group had H/o of any placental disorder (Low lying Placenta, Abruptio placenta). 29.69% of cases in study group and 39.06% of cases in control group had anaemia. 12.5% of cases in study group and 9.37% of cases in control group had H/O Postpartum Haemorrhage. 1.56% of cases in study group and 3.13% of cases in control group had PROM. In both groups patients allocated randomly. No statically significant difference seen in prevalence of risk factor between both groups (p=0.85). No significant difference according to predelivery haemoglobin i.e. in study group 9.93±1.27gm/dl and in control group 10.10±1.22gm/dl. No statically significant difference seen in the mean of predelivery Haemoglobin in between carbetocin group and oxytocin group patient (p=0.58 non-significant). No significant difference according to Mode of Delivery i.e. 53.13% of cases in study group and 56.25% of cases in control group underwent LSCS. 45.31% of cases in study group and 43.75% of cases in control group underwent vaginal delivery. 1.56% of cases in study group underwent instrumental delivery.

Table 1: Distribution according to Duration of third stage of labor (Minutes)

Duration Of third stage of labor (minutes)					
Study	Min-Max	Median	Mean	±SD	P Value
	2-15	5.0	5.7	3.4	0.03 Significant

Significant difference according to Duration Of 3rd stage of labor (Min.) was observed. Maximum duration of 3rd stage of labor in study group was 15 min. where as in control group was 30 min. Minimum duration in both group was same that was 2 min. In carbetocin group duration of third stage of labor was less with statically significant difference (p=0.03). Significant difference according to Duration Delivery of placenta i.e. 90.6% of cases in study group and 76.56% cases of control group placenta delivered spontaneously and 9.4% of cases in study group and 23.44% of cases in control group manual removal of placenta done. So in Carbetocin group requirement of manual removal of placenta was less and statically significant difference found between carbetocin and oxytocin group. Significant difference according to Additional Uterotonic requirement. 14.06% of cases in study group 29.68% of cases in control group needed additional uterotonic other than assigned uterotonics. So less number of patients in carbetocin group needed additional uterotonics.

No significant difference according to Birth weight (Kg) was observed. There was no significant difference in birth weight in both the groups. Mean birth weight in study group was 2.93±0.54 Kg and in control group was 2.89±0.58 Kg. In both the groups patients assigned randomly

Table 2: Comparative Distribution according to Estimation of blood loss

Study group	Estimation of blood loss				
	Min-Max	Median	Mean	±SD	P value
Study	90-1400	350	488.13	356.94	0.03 Significant
Control	100-1500	550	637.5	427.25	

Significant difference according to Estimation of blood loss was observed. Mean blood loss in study group was 488.13±356.94ml and in control group was 637±427.3ml. Statically significant difference found in estimated blood loss between two groups. In oxytocin group blood loss found to be more than carbetocin group. Maximum number of patient in study group had blood loss under 500ml. Significant difference according to Urine output in 24hrs. Mean urine output in study group was 1247.66±418.84ml and in control group was 1046.88±363.06ml. Statically significant difference found in urine output between two groups. Mean fall in Haemoglobin in study group was 0.52±0.36gm/dl and in control group was 0.81±0.47gm/dl. So there was statically significant difference in fall in Haemoglobin between study group and control group. There was more fall in Haemoglobin in oxytocin group (p=0.06). No significant difference according to Uterine Tone was observed. 81.25% of cases in study group and 68.75% of in control group had well contracted uterus. 10.93% of cases in study group and 6.25% of cases in control group had poorly contracted uterus. 7.81% of cases in study group and 25% of cases in control group had atonic uterus. Hence more number of patients in carbetocin group had well contracted uterus after giving utertonics compared to oxytocin group but statically no significant difference seen (p=0.34 nonsignificant). No significant difference according to Blood transfusion i.e. 6.25% of cases in study group and 10.93% of cases in control group needed blood transfusion. Less number of patient in Carbetocin required blood transfusion but statically non- significant difference seen.

Table 3: Comparative Distribution according to Post-delivery Hypotension

Post-delivery Hypotension	Study Group		Control Group		
	N	%	N	%	P value
At 2 hour	4	6.25	12	18.75	0.04 Significant difference
At 12 hour	8	12.5	12	18.75	0.33 NS

Significant difference according to Post-delivery Hypotension in 1st 2hr. 4 cases in study group and 12 cases in control group had hypotension in 1st2 hrs. i.e. less number of patients in carbetocin group had post-delivery BP less than 100/60mmhg.

Table 4: Comparative Distribution according to adverse effects

Adverse effects	Study Group		Control Group		
	N	%	N	%	P value
Abdominal Pain	11	17.19	9	14.06	0.62 NS
Flushing	2	3.13	4	6.25	0.40 NS
Headache	2	3.13	7	10.94	0.06 NS
Nausea, Vomiting	5	7.81	4	6.25	0.73 NS
Tachycardia	4	6.25	5	7.81	0.73 NS

Non-Significant difference according to adverse effects. In the Carbetocin group more patients had abdominal pain due to sustained uterine contraction but a statically non-significant difference was found. Rest all adverse effects found more in the oxytocin group. However, the statistically non-significant difference in the incidence of adverse effects between the two groups.

Table 5: Comparative Distribution according to Estimation of blood loss

Groups	Mean ±SD	p value
Study group	488.13±356.94	0.03 (Significant)
Control group	637.5±427.3	

A significant difference was observed in the estimation of blood loss. The mean blood loss in the study group was 488.13±356.94 ml, whereas in the control group it was 637±427.3 ml. A statistically significant difference was found in the estimated blood loss between the two groups. In the oxytocin group, blood loss was higher than in the carbetocin group. The maximum number of patients in the study group had blood loss under 500 ml.

Table 6: Distribution according to fall in haemoglobin

Groups	Mean ±SD	p value
Study group	0.52±0.36	<0.001 (Significant)
Control group	0.81±0.47	

The mean fall in hemoglobin in the study group was 0.52 ±0.36 gm/dL compared to 0.81±0.47 gm/dL in the control group, indicating a statistically significant difference. Greater fall in hemoglobin was observed in the oxytocin group (p = 0.06).

No significant difference in uterine tone was observed. In the study group, 52 (81.25%) of cases had a well-contracted uterus, compared to 44 (68.75%) in the control group. Poorly contracted uterus was noted in 7 (10.93%) of the study group and 4 (6.25%) of the control group. An atonic uterus was present in 5 (7.81%) of the study group and 16 (25%) of the control group. Although more patients in the carbetocin group had a well-contracted uterus following uterotonic administration compared to the oxytocin group, the difference was not statistically significant (p = 0.34, non- significant).

No significant difference was observed in adverse effects. In the carbetocin group, more patients experienced abdominal pain due to sustained uterine contraction, but the difference was statistically non-significant. All other adverse effects were found more frequently in the oxytocin group. However, the difference in the overall incidence of adverse effects between the two groups was statistically non-significant.

Table 7: Comparative Distribution according to adverse effects

Adverse effects	Study Group		Control Group		
	N	%	N	%	P value
Abdominal Pain	11	17.19	9	14.06	0.62 NS
Flushing	2	3.13	4	6.25	0.40 NS
Headache	2	3.13	7	10.94	0.06 NS
Nausea, Vomiting	5	7.81	4	6.25	0.73 NS
Tachycardia	4	6.25	5	7.81	0.73 NS

Non-Significant difference according to adverse effects. In the Carbetocin group more patients had abdominal pain due to sustained uterine contraction but a statically non-significant difference was found. Rest all adverse effects found more in the oxytocin group. However the statically non-significant difference in the incidence of adverse effects between the two groups.

Discussion

As per WHO Postpartum Haemorrhage is defined as blood loss of 500ml or more within 24 hours of childbirth, on the other hand, ACOG defined Postpartum Haemorrhage as cumulative loss of greater than and equal to 1000ml accompanied by signs and symptoms of hypovolemia within 24 hours of the birth process regardless of mode of delivery. Postpartum Haemorrhage is one of leading causes of maternal deaths. Uterine atony is most common cause associated with PPH. To prevent PPH in the active management of 3rd stage of labor, routine uterotonics are administered to minimize bleeding and bleeding-related complications as prophylaxis. As per WHO 2018, SOGC (The Society of Obstetricians and Gynaecologists of Canada) 2009, RANZCOG (Royal Australian and New Zealand College of Obstetricians and Gynaecologists) 2017, FIGO (International Federation of Gynecology and Obstetrics) 2022, FCOG (Fellow of Indian Colleges of Obstetricians and Gynecologists) 2015, Carbetocin is recommended for prevention

of Postpartum Haemorrhage. Therefore to advance our understanding of the use of a Single dose of Injection Carbetocin in the Prevention of Postpartum Haemorrhage, we conducted this study at ESIC Medical College and Hospital, Faridabad, Haryana (India).

In the present study average age of patients was 29.88 years in Carbetocin group and 30.02 years in oxytocin group. Most of the patient in age group of 21 to 30 years (53.12%) in Carbetocin group and 51.56% in the oxytocin group. There was non-significant difference in mean age of women in Carbetocin group and oxytocin group in present study as well as other previous studies with $P>0.05$. In present study no significant difference was seen in average gestational age between the two groups. In previous studies also there was no significant difference seen in average gestational of women who participated in the study $P>0.05$.

Most of the patients in present study were multigravida patients 67.19% in the Carbetocin group and 64.06% in the oxytocin group. Primigravida patients 32.81% in the Carbetocin group and 35.94% in the oxytocin group. No significant difference seen in parity of women who participated in the study with $P>0.05$. In present study average BMI in Carbetocin group was 31.83 kg/m^2 and oxytocin group was 30.07 kg/m^2. There was non-significant difference found in BMI of women in Carbetocin group and oxytocin group in present study as well as other previous studies with $P>0.05$. 10.95% of cases in Carbetocin group and 12.59% of cases in oxytocin had overdistension of uterus either due to big size baby or multiple pregnancy or due to polyhydroamnios. 43.71% cases in Carbetocin group and 46.88% cases in oxytocin group had H/o uterine surgery that includes previous LSCS, Myomectomy, D & E. 25% cases in Carbetocin group and 26.56% cases in oxytocin group had history of any medical disorder of pregnancy (HDP, GDM, IHCP). 7.81% cases in Carbetocin group and 6.26% cases in oxytocin group had placental disorder (Low lying Placenta, Abruptio placenta). 29.69% cases in Carbetocin group and 39.06% cases in oxytocin group had anaemia. 12.5% cases in Carbetocin group and 9.37% cases in oxytocin group had postpartum Haemorrhage. 1.56% cases in Carbetocin group and 3.13% cases in oxytocin group had PROM.

In present study average duration of 3rd stage of labor in Carbetocin group was 5.7 min whereas in oxytocin group was 7.078 min which was statically significant ($p<0.05$) but non-significant in study conducted by Amornpetchakul *et al* [9].

In present study 14.06% of cases in Carbetocin group 29.68% of in oxytocin group needed additional uterotonic other than assigned uterotonics. There was significant difference found in need of additional uterotonics in Carbetocin group and oxytocin group in present study as well as in Giovanni Larciprete *et al* [10] and Amornpetchakul *et al* [9] study ($p<0.05$).

In present study average Mean blood loss in Carbetocin group was 488.13ml and in oxytocin group was 637.5ml. There was significant difference found in Mean blood loss of women in Carbetocin group and oxytocin group in present study as well as other previous studies ($p<0.05$).

In present study average mean fall in haemoglobin in carbetocin group was 0.52±0.36gm/dl and in oxytocin group was 0.81±0.47gm/dl. So there was statically significant difference in fall in Haemoglobin between Carbetocin group and oxytocin group in present study as well as previous study. There was more fall in Haemoglobin in oxytocin group. In present study average 6.25% of cases in Carbetocin group and 10.93% of cases in oxytocin group underwent blood transfusion. There was non-significant difference found in need for blood transfusion in Carbetocin group and oxytocin group in present study as well as other previous study $P>0.05$. There was non-significant difference in birth weight in Carbetocin group and oxytocin group in present study and Amornpetchakul *et al* [9] study ($P>0.05$).

The CHAMPION trial (Carbetocin Haemorrhage Prevention) was a major WHO-led study comparing heat-stable carbetocin to oxytocin for preventing postpartum hemorrhage (PPH) after vaginal birth, finding carbetocin non-inferior for preventing significant blood loss (>= 500ml) but not for very severe loss (>= 1000ml) [11].

Limitations

The findings of the study need to be validated by larger studies with multicentric study designs, its effects on females with multiple risk factor and to identify its adverse effects on larger group of population. Also single obstetrician was not involved, as a result uterine tone measurement by the attending physician was subjective and potentially variable due to the palpation method.

Conclusions

The study concluded the effectiveness of intravenous carbetocin compared to intravenous oxytocin for reducing postpartum blood loss, postpartum anemia, incidence of atonic postpartum haemorrhage, requirement of additional uterotonic, blood transfusion in high risk pregnancy. Oxytocin the current standard therapy for prevention of PPH is susceptible for heat degradation in low income group countries. In these countries a safe and heat stable uterotonic carbetocin with half-life of 40min can play an important role in reducing maternal mortality. Single dose of Carbetocin appears to be more effective than single dose of oxytocin to prevent the postpartum haemorrhage, with similar haemodynamic profile and minor antidiuretic effect.

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