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Original Research Article

Carbetocin in the prevention of postpartum hemorrhage

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ABSTRACT

Background: Postpartum hemorrhage (PPH) is the most common and a potentially life-threatening complication of childbirth in both vaginal and caesarean deliveries. Carbetocin is a newer analogue of oxytocin with longer half-life and more heat stable. This study was aimed to assess the efficacy of carbetocin in the prevention of postpartum hemorrhage (PPH) in vaginal and caesarean deliveries, at a single tertiary care centre.
Methods: A total of 130 pregnant patients included in the study received a bolus of carbetocin 100 µg i.v./i.m. at the delivery of anterior shoulder. After patients received uterotonic agent (carbetocin), patients were observed for 24 hours. The change in hemodynamic and clinical variables such as drop in hematocrit than one obtained on admission was observed. Clinical signs such as pallor, cold clammy skin, hypotension and tachycardia were also noted. In addition uterine tone after receiving carbetocin was also noted.
Results: There were comparable hemodynamic parameters in terms of heart rate, SBP and DBP in the pre-labor and post-labor. Most of the patients 54.6% (n=71) had contracted uterine tone followed by well-contracted in 35.4% (n=46). There was no significant difference found in terms of hemoglobin concentration and hematocrit in pre-labor and post-labor. 3.1% (n=4) patients experienced PPH. 6.15% (n=8) needed blood transfusion. No adverse effects or complications or maternal mortality was observed in the present study.
Conclusions: This study concludes that using carbetocin in the third stage of labour resulted in decreased incidence of post-partum hemorrhage, decreased blood transfusion as well as decreased use of additional uterotonics.

Keywords: Carbetocin, Lower segment caesarean section, PPH, Uterine tone, Vaginal delivery

INTRODUCTION

Postpartum hemorrhage (PPH) is the most common and a potentially life threatening complication of childbirth in both vaginal and caesarean deliveries.[1] PPH was redefined by the American College of Obstetrics and Gynecology, as a cumulative blood loss more than 1000 ml with signs and symptom of hypovolemia, within 24 hours of delivery, regardless of route of delivery.[2] Postpartum hemorrhage remains one of the major cause of maternal morbidity and mortality especially in developing countries.[3]

There are various potential causes of PPH including uterine atony, genital lacerations, retained placenta, abnormal placentation and coagulation disorders. Among these, uterine atony is the most common primary cause and accounts for approximately 80% of all PPHs.[4] The risk factors of atony include high maternal parity, chorioamnionitis, prolonged use of oxytocin, general anesthesia etc.

As the most common cause of PPH is uterine atony, therefore active management of the third stage of labor is important. After delivery of baby and placenta, immediate hemostasis requires myometrial contractions to cause the occlusion of uterine blood vessels and prevent blood flow from the vascular space into the uterine cavity. Active pharmacological management of the third stage of labor is

an evidence-based intervention, which has shown to reduce the occurrence of PPH by 60% with expectant or physiological management.[5]

The various prophylactic agents used currently are mainly oxytocin and syntometrine, mixture of these combines the rapid onset of oxytocin and sustained uterotonic effect of ergometrine. Although prophylactic use of syntometrine in the third stage of labor is effective in reducing blood loss and PPH, cardiovascular and gastrointestinal side effects such as nausea, vomiting and raised blood pressure are considerably higher mainly due to stimulation of smooth muscle contraction and vasoconstriction by ergometrine.[6] These women are then administered oxytocin which is less effective in the prevention of PPH.

Administration of prostaglandins such as misoprostol and carboprost has been explored for several years. The use of oral or rectal misoprostol for the prevention of postpartum hemorrhage demonstrates lower effect than injectable uterotonic agent following vaginal delivery and is associated with a higher incidence of severe PPH and additional uterotonics[7]. These factors deem misoprostol unsuitable prophylactic agent for the prevention of excessive bleeding. Among the other agents that have been explored for the prevention of PPH, carbetocin appears to be a promising medication.[8]

Carbetocin, which is a long-acting oxytocin analogue, has been widely used in preventing postpartum hemorrhage since 1997, and heat-stable carbetocin has been shown to remain active for more than 36 months at 30 degrees Celsius and 75% relative humidity.[9] Carbetocin has an efficacy and safety profile very similar to oxytocin and, due to its pharmacokinetic characteristics, has a longer uterotonic activity.[10,11] According to the national guidelines, oxytocin is the uterotonic agent of choice in prevention of PPH, however, international guidelines like those from the Royal College of Obstetricians and Gynecologists (RCOG) and The Society of Obstetricians and Gynecologists of Canada (SOGC) already include carbetocin as an alternative, mainly in elective caesarean section.[12,13]

Carbetocin can be administered as a single dose injection in the route of intravenous or intramuscular in one ampoule in 100 ml Normal Saline. In pharmacokinetic studies, intravenous injections of carbetocin produced tetanic contractions within 2 minutes, followed by rhythmic contractions for a further one hour. Intramuscular injection produced titanic contractions within 2 minutes, lasting about 11 minutes, and followed by rhythmic contraction for an additional 2 hours. In comparison with oxytocin, carbetocin produces a prolonged uterine activity when administered postpartum, with respect to both frequency and amplitude of contractions.[14] Carbetocin is well tolerated and the safety profile is similar to that of oxytocin.[15,16]

The present study was aimed to assess the efficacy of carbetocin in the prevention of postpartum hemorrhage (PPH) in vaginal and caesarean deliveries, at a single tertiary care centre.

METHODS

The present study was done in the postgraduate department of obstetrics and gynecology, Lal Ded, Associated Hospital of Government Medical College, Srinagar, Jammu and Kashmir. The institutional medical and ethics committee consent was obtained before collecting the data. This was a prospective, observational study, conducted over a time period of 18 months from January 2023 to July 2024. Informed and written consent was obtained from each case before enrolment in the study.

Inclusion criteria

All high risk pregnancies: (1) polyhydramnios (2) severe anemia (3) prolonged third stage of labor (4) difficult instrumental delivery (5) previous history of PPH (6) accidental hemorrhage (7) fetal macrosomia (weight >4 kg) (8) placenta previa.

Exclusion criteria

Pregnant women allergic to oxytocin, pregnant women allergic to carbetocin, pregnant women with any disease of the liver and kidney, pregnant women with heart disease, pregnant women with epilepsy, pregnant women with migraines, pregnant women with asthma, pregnant women with pre-eclampsia or eclampsia.

Patients who attended the obstetrics and gynecology OPD and subsequently getting admitted in the hospital for delivery fulfilling the inclusion criteria were enrolled in the study after obtaining the written informed consent from the patients/relatives of the patients. Detailed history of each patient was taken which included details of present pregnancy such as if the patient has multiple gestation, fetal macrosomia (weight >4 kg), placenta previa, severe anemia or details of past pregnancy such as history of PPH, medical history such as heart disease, epilepsy, migraines, asthma, any liver or kidney disease. After admission in labour room thorough clinical examination including general physical examination, systemic examination, per abdomen examination and internal pelvic examination was done. Investigations of patients such as routine tests including CBC, LFT, KFT were done. After patients received uterotonic agent (carbetocin) 100 µg i.v./i.m. at the delivery of anterior shoulder, patients were observed for 24 hours. The change in hemodynamic and clinical variables such as drop in hematocrit than one obtained on admission was observed. Clinical signs such as pallor, cold clammy skin, hypotension and tachycardia were also noted.

Statistical analysis

All the collected data was entered in Microsoft excel spreadsheet and exported to data editor of Statistical Package for Social Sciences (SPSS ver. 23). Continuous variables were summarized as mean and standard deviation. Continuous variables with outliers or a non-normal distribution were summarized as percentages. The difference in two means was analyzed using impaired t-test. Two-sided p-values was reported and $p<0.05$ was considered statistically significant.

RESULTS

A total of 130 patients were analyzed in our study. The mean age of patients was 31.15±2.7 years and the mean BMI was 31.60±2.4 kg/m^2. The mean gestational age was 38.70±1.2 weeks. The most common mode of delivery was cesarean section accounting for 79.2% (n=103) as shown in Table 1.

Table 1: Distribution of patients according to mode of delivery.

Mode of delivery	Frequency	Percentage
Vaginal	27	20.8
LSCS	103	79.2
Total	130	100

Table 2: Baseline data distribution.

Variables	Pre-labour	Post-labour
HR	86.04±1.05	88.08±2.61
SBP	111.3±4.2	109.8±2.4
DBP	69.6±2.1	68.9±3.5

The mean pulse was 86.04 beats per minute pre-labor and 88.08 beats per minute post-labor. The mean systolic blood pressure pre-labor was 111.3 mmHg and 109.8 post-labor. The mean diastolic blood pressure was pre-labor 69.6 mmHg and 68.9 post-labor as shown in Table 2.

Table 3. Risk factor distribution.

Risk factor	Frequency	Percentage
PIH	24	18.46
Polyhydramnios	23	17.69
Twin pregnancy	30	23.07
Severe anemia	18	13.84
Prolonged 3rd stage of labor	15	11.53
Difficult instrumental delivery	07	5.38
Previous history of PPH	08	6.15
Fetal macrosomia	19	14.61
Placenta previa	40	30.76
Acute hemorrhage	02	1.53
Total	130	100

The most common underlying risk factor was placenta previa seen in 30.76% (n=40) pregnant women followed by twin pregnancy in 23.07% (n=30) as shown in Table 3. PIH was seen in 18.46% (n=24). Polyhydramnios was seen in 17.69% (n=23). Least common factor seen was acute hemorrhage in 1.53% (n=2).

Table 4: Distribution of patients according to uterine tone.

Uterine Tone	Frequency	Percent
Atonic	13	10.0
Contracted	71	54.6
Well-contracted	46	35.4
Total	130	100

It was observed that after carbetocin administration, most of the patients 54.6% (n=71) had contracted uterine tone followed by well-contracted in 35.4% (n=46) had atonic uterine tone as shown in Table 4.

Table 5: Distribution of patients according to Blood Parameters.

Parameter	Pre-labour	Post-labour	P value
Hb concentration (gm/dl)	11.05±0.5	10.90±0.8	0.07
PCV (%)	32.76±0.5	31.8±0.5	<0.001

The mean pre-labor Hb concentration was 11.05 gm/dl and post-labor Hb concentration was 10.90 gm/dl. The mean pre-labor and post-labor PCV was 32.76% and 31.8% as shown in Table 5.

Table 6: Distribution of patients according to outcome.

Parameters	Frequency	Percentage
PPH	4	3.1
Blood transfusion	8	6.15
Complication	0	0
Mortality	0	0

Table 6. shows that out of 130 patients included in the study, 3.1% (n=4) experienced PPH and 6.15% (n=8) needed blood transfusion. There were no complications or adverse effects seen in the study subjects. There was no mortality seen in this study.

DISCUSSION

Postpartum hemorrhage is a common complication seen both in vaginal and cesarean deliveries. PPH remains the leading cause of maternal mortality exacting huge tolls on economic and human capital particularly in countries with inadequate resources. According to WHO, PPH is the leading cause of maternal mortality worldwide, accounting for 35% of the deaths. 38% of maternal deaths in India can

be attributed to the PPH.[17] With increasing prevalence of PPH, use of systematic and comprehensive maternal hemorrhage protocols by multidisciplinary teams is crucial to successful prevention of PPH. All hospital labor and delivery units should have a comprehensive PPH protocol, and provide trainings to multidisciplinary staff regarding its use.

The present study was a hospital-based prospective observational study aimed to assess the efficacy of carbetocin in prevention of PPH in both vaginal and caesarean deliveries to prevent the morbidity and reduction in blood transfusions. In our study a total of 130 women who underwent vaginal or caesarean delivery were enrolled. All high-risk pregnancies were included in the study. Women allergic to carbetocin were excluded.

In our study, the mean age of patients was 31.15 years. Mean BMI was 31.60 kg/m2 and mean gestational age was 38.70 weeks. Similar findings were reported by; Korb et al in their study had mean age of 32.2 years and gestational age of 38.5 weeks in carbetocin group.[18] Elgarhy et al had mean age of 28.4 years, mean BMI of 26.2 kg/m^2 and gestational age of 38.8 weeks in carbetocin group.[19] Bashir et al had mean gestational age of ≥38 weeks in carbetocin group.[20] Larciprete et al in their study of 102 pregnant women reported the mean age of 37.1 years in carbetocin group and mean gestational age of 38 weeks.[13]

Cesarean section is a recognized risk factor for PPH and cesarean delivery has escalated over the past four decades to 20–30% in most developed countries. In our study, most of the patients underwent cesarean section deliveries, accounted for 79.2% (n=103) while as remaining 20.8% (n=27) had vaginal delivery (Table 2). When compared to other studies from outside countries, the vaginal mode of delivery was significantly higher than cesarean section deliveries. Chen et al[21] and Liu et al[22] both had more of a vaginal mode of deliveries than cesarean.[21,22] Anurag et al also had a total of 220 patients who all underwent vaginal delivery.[23]

In our study, the mean systolic blood pressure (SBP), diastolic blood pressure (BBP) and heart rate (HR) in pre-labour and post-labor period were 111.3 mmHg, 69.6 mmHg, 85.04 and 88.04, 108.8 and 66.9 respectively. The hemodynamic changes were comparable in pre- and post-labour. Bashir et al in her comparative study found carbetocin group had more hemodynamic stability than other used drug.[20] Aziz et al, in a comparative study did not find any significant difference in hemodynamics using carbetocin and misoprostol.[24]

In our study, the most common underlying risk factor was placenta previa which was present in 30.76% (n=40) cases, followed by twin pregnancy in 23.07% (n=30). PIH was seen in 18.46% (n=24). Polyhydramnios was seen in 17.69% (n=23) cases, severe anemia in 13.84% (n=18), fetal macrosomia was seen in 14.62% (n=19), prolonged third stage of labour was observed in 11.53% (n=15). 6.15% (n=8) patients had previous history of PPH, 5.38% (n=7) had difficult instrumental delivery. 1.53% (n=2) experienced acute hemorrhage in perinatal period. Similar findings were reported by; Bashir et al in their study reported twin pregnancy, fetal macrosomia and fetal polyhydramnios as common risk factors.[20] Liu et al in their study had gestational diabetes, hypertension and macrosomia as most common risk factors.[22] Larciprete et al reported placenta previa in 11.8%, fetal macrosomia in 11.8% and twin pregnancy in 21.6% women in carbetocin group.[13] In our study, most of the patients 54.6% (n=71) had contracted uterus, 35.4% (n=36) had well-contracted uterus and 10% (n=13) had atonic uterus. The findings resulted in overall less requirement of additional uterotonic in the third stage of labour. Similar finding were observed in studies by; Bashir et al, Kang et al, Anurag et al and Kalafat et al all have reported less use of uterotonic in carbetocin group than other groups.[20,23,25,26] Dansereau et al described a lower additional uterotonic need for treatment of uterine atony in women who took carbetocin soon after delivery.[27] Borruto et al described a lower rate of additional oxytocic need in women undergoing carbetocin administration during caesarean section.[28] Rath et al also reported the longer action of carbetocin with less use of additional uterotonics.[29] Arif et al in their study concluded that carbetocin demonstrated a longer duration of action when administered a single dose 100 µg intravenously.[30]

In our study, the mean HB pre-partum and post-partum was 11.05 and 10.90 gm/dl. Mean PCV pre-partum and post-partum was 31.76% and 32.65%. There was a not statistically significant difference found in hemoglobin concentration and packed cell volume before and after delivery. The findings were in correspondence to the findings of Anurag et al who had pre- and post-labor mean hemoglobin concentration and mean PVC of 11.60 and 10.26 and 38.68 and 39.01 in carbetocin group, with no significant difference in either group.[23] Elgarhy et al had mean hemoglobin concentration of 10.66 and 9.94, mean PCV of 31.76 and 29.8 in pre-and post-labor in carbetocin group, however the difference was not significant.[19] In contrast, Bashir et al had mean hemoglobin concentration in pre- and post-labor in carbetocin group 12 and 11.1, with no significant difference.[20]

In our study, out of 130 patients, 3.1% (n=4) patients experienced PPH. Blood transfusion was done in 8 patients out of 130. There were no adverse events seen with carbetocin usage or complications or maternal deaths in our study. Maged et al reported 12% patients in carbetocin group who needed blood transfusion.[31] Anurag et al in their study concluded that both carbetocin and oxytocin had comparable safety profile, with no incidence of adverse events seen in either group.[23]

The present study had some limitations both in terms of sample quantity and time duration. We recommend a large group study for further determination of Carbetocin efficacy.

CONCLUSION

Post-partum hemorrhage is the most common threat in the obstetric department and is associated with increased maternal complications and deaths. Prevention of PPH needs a well-handled third stage of labor, where potent and effective pharmacological agents are needed for rescue. Use of oxytocin has been proven to be the most effective tool but a newly formed analogue carbetocin has been shown to be more effective with less use of uterotonic as well. In our study, we conclude that using carbetocin in the third stage of labour resulted in decreased incidence of post-partum hemorrhage, decreased blood transfusion as well as decreased use of additional uterotonics.

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