



Effects of Carbetocin and Oxytocin on Haemodynamic among Women with Post-Partum Hemorrhage after Caesarean Section: A Single Blind Parallel Arm Randomized Controlled Trial



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Abstract

Background: Management of haemodynamic among women with post-partum hemorrhage after caesarean section. **Objective:** The purpose of the present study was to compare the effect of carbetocin and oxytocin on haemodynamic among women with post-partum hemorrhage after caesarean section. **Methodology:** This randomized controlled trial was conducted in the Department of Obstetrics and Gynaecology at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh from July 2015 to December 2015 for a period of six months. Pregnant women diagnosed on the standard criteria admitted in BSMMU, Dhaka, Bangladesh were selected as study population by consecutive type of sampling. Randomization was performed according to computer generated simple random sampling method. An Uterotonic was an agent used to induce contraction or greater tonicity of the uterus. Then the patients were monitored pre-operatively and post-operatively. All the information was recorded in data collection sheet. Main outcome variables were estimated blood loss. **Results:** A total number of 96 pregnant women were recruited for this study of which 48 cases were enrolled in group I and the rest of 48 cases were enrolled in group II. The mean age with SD of the group I and group II were 24.4±4.7 years and 24.7±3.7 years ($p=0.729$). Before administration of drug, mean systolic blood pressure was found 115.6±5.8 mmHg in group I and 114.8±7.8 mmHg in group II. At 24 hours after caesarean section, mean systolic blood pressure was found 116.9±5.8 mmHg in group I and 113.9±8.8 mmHg in group II ($p>0.05$). Before administration of drug, mean diastolic blood pressure was found 75.8±7.9 mmHg in group I and 76.9±9.9 mmHg in group II. At 24 hours after caesarean section, mean diastolic blood pressure was found 76.7±6.6 mmHg in group I and 76.1±7.2 mmHg in group II ($p>0.05$). Before administration of drug, mean maternal blood loss was found 376.4±110.4 ml in group I and 439.4±199.9 ml in group II. At 24 hours after caesarean section, mean maternal blood loss was found 468.2±121.9 ml in group I and 532.6±243.0 ml in group II ($p>0.05$). **Conclusion:** In conclusion the systolic blood pressure, diastolic blood pressure and blood loss are not significantly varied in group I and II. [*Journal of National Institute of Neurosciences Bangladesh, July 2023;9(2):141-146*]

Keywords: Carbetocin; oxytocin; haemodynamic; caesarean section; post-partum hemorrhage

Introduction

The administration of uterotonic drugs widely prevents the post-partum hemorrhage and it significantly decreases the incidence of post-partum hemorrhage¹. Therefore, it is the main point of active management. Oxytocin (10 IU) is administered intramuscularly and is the preferred medication for the prevention of low risk vaginal and caesarean deliveries². Oxytocin is relatively

safe when used at recommended doses, and side effects are uncommon³. The hemodynamic effects of an oxytocin bolus consist of systemic vasodilatation, with hypotension, tachycardia, and an increase in cardiac output and pulmonary artery pressure, resulting in brief hypotension and tachycardia in a dose dependent manner⁴⁻⁵. It is an effective drug for the control of post-partum hemorrhage, but the disadvantage is its short

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half-life of 4 to 10 minutes, regularly requiring a continuous intravenous infusion or repeated intramuscular injections⁶.

Endogenous and synthetic oxytocin has a half-life of approximately 3.5 minutes⁷. Carbetocin, in comparison, has a much longer half-life ranging from 85 to 100 minutes⁸. The bioavailable dose is around 80%. The elimination half-life following intravenous administration is around 40 minutes⁹. Conventional uterotonics like oxytocin has used for preventing post-partum hemorrhage but it has some limitations like shorter half-life, less contraction time and more side effects like fluid overload, convulsion, arrhythmia and pulmonary edema¹⁰. Carbetocin is a synthetic analogue of oxytocin with a long half-life approximately 4 to 10 times longer than oxytocin. Moreover, carbetocin significantly reduces the need for additional uterotonic agents or uterine massage to prevent excessive bleeding compared to oxytocin¹¹.

By using this promising uterotonic, it can be prevented severe blood loss and it will help to reduce maternal morbidity and mortality¹². As this type of study is not common in the perspective of Bangladesh, the present study will be conducted in tertiary level hospital to find out the best drug for the prevention of postpartum haemorrhage after caesarean section. By proper prevention of post-partum hemorrhage maternal morbidity and mortality can be reduced and we can be one step forward to ensure safe motherhood. Keeping the above context in mind the aims of the present study was to compare the hemodynamic effects, adverse effects of carbetocin and oxytocin and the additional uterotonic needed in caesarean section for the control of postpartum haemorrhage.

Methodology

Study Settings and Population: This randomized controlled trial was conducted in the Department of Obstetrics and Gynaecology at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh from July 2015 to December 2015 for a period of six months. Pregnant women diagnosed on the standard criteria admitted in BSMMU, Dhaka, Bangladesh were selected as study population by consecutive type of sampling. Patient with risk factors for primary post-partum haemorrhage such as multiple pregnancy, one or more previous caesarean section, presence of uterine fibroids, previous myomectomy, presence of placenta previa, past history of post-partum hemorrhage, fetal macrosomia and fetal malformations associated with polyhydramnios were included in this

study. Presence of hypertension, eclampsia, cardiac, renal or liver diseases, epilepsy, general anaesthesia, as well as women with history of hypersensitivity to Carbetocin according to the British National Formulary or patients unwilling to give consent for this study were excluded from this study.

Randomization and Blinding: Randomization was performed according to computer generated simple random sampling method. Single binding was performed without knowing the drugs to the participants.

Study Procedure: Postpartum haemorrhage was defined as any amount of bleeding from or into the genital tract following birth of the baby up to the end of puerperium, which adversely affects the general condition of the patient evidenced by rise in pulse rate and falling blood pressure, is called postpartum haemorrhage. An Uterotonic was an agent used to induce contraction or greater tonicity of the uterus. Detail history was taken by structured questionnaire. At first the pregnant women were selected according to inclusion and exclusion criteria. Then detailed informed written consent was taken from each patient. The drug that was introduced during caesarean section was allocated by coin tossing.

Follow up and Outcomes Measures: Then the patients were monitored per operatively and post operatively. All the information was recorded in data collection sheet. Main outcome variables were Estimated blood loss (Visual estimation, number of used mops, amount of aspirated blood), difference between preoperative and post-operative haemoglobin level, vital sign during and after operation, Uterine tone, Incidence of blood transfusion and Adverse effects like nausea, vomiting, headache and so on.

Statistical Analysis: Statistical analyses were carried out by using the Statistical Package for Social Sciences version 20.0 for Windows (SPSS Inc., Chicago, Illinois, USA). The mean values were calculated for continuous variables. The quantitative observations were indicated by frequencies and percentages. Chi-Square test with Yates correction was used to analyze the categorical variables, shown with cross tabulation. Student t-test was used for continuous variables. P values <0.05 was considered as statistically significant.

Ethical implications: Ethical clearance was obtained from Institutional Review Board of BSMMU. Written informed consent was obtained from the patient or from her legal guardian. Patient confidentiality was strictly maintained. No name, address or contact details of the patient was divulged.

Results

A total number of 96 pregnant women were recruited for this study of which 48 cases were enrolled in group I and the rest of 48 case were enrolled in group II. The mean age with SD of the group I and group II were 24.4±4.7 years and 24.7±3.7 years. The difference between the mean age of group I and group II were not statistically significant (Table 1).

Table 1: Distribution of the study patients by demographic variable (n=96)

Age Group	Group I	Group II	P value
≤20 Years	13(27.1%)	9(18.8%)	
21 to 30 Years	31(64.6%)	35(72.9%)	
More than 30 Years	4(8.3%)	4(8.3%)	
Total	48(100.0%)	48(100.0%)	
Mean±SD	24.4±4.7	24.7±3.7	0.729
Range (min, max)	19, 39	19, 33	

Before administration of drug, mean systolic blood pressure was found 115.6±5.8 mmHg in group I and 114.8±7.8 mmHg in group II. At 1 minute after caesarean section, mean systolic blood pressure was found 102.5±6.7 mmHg in group I and 101.7±7.1 mmHg in group II. At 30 minutes after caesarean section, mean systolic blood pressure was found 105.9±7.4 mmHg in group I and 107.8±9.9 mmHg in group II. At 12 hours after caesarean section, mean systolic blood pressure was found 116.2±5.9 mmHg in group I and 114.4±8.2 mmHg in group II. At 24 hours after caesarean section, mean systolic blood pressure was found 116.9±5.8 mmHg in group I and 113.9±8.8 mmHg in group II. The mean difference were not statistically significant (p>0.05) between two groups (Table 2).

Table 2: Systolic Blood Pressure in Different Follow Up (Mean ±SD)

Systolic Blood Pressure (mmHg)	Group I	Group II	P value
Before admission of drug	115.6±5.8	114.8±7.8	0.570
Range (min, max)	100, 130	100, 128	
At 1 minute after caesarean section	102.5±6.7	101.7±7.1	0.572
Range (min, max)	85, 115	90, 112	
At 30 minutes after caesarean section	105.9±7.4	107.8±9.9	0.289
Range (min, max)	90, 115	90, 120	
At 12 hrs after caesarean section	116.2±5.9	114.4±9.2	0.257
Range (min, max)	95, 120	90, 120	
At 24 hrs after caesarean section	116.9±5.8	113.9±8.8	0.052
Range (min, max)	100, 130	90, 130	

ns= not significant; P value reached from unpaired t-test

Before administration of drug, mean diastolic blood pressure was found 75.8±7.9 mmHg in group I and 76.9±9.9 mmHg in group II. At 1 minute after caesarean section, mean diastolic blood pressure was found 67.1±7.6 mmHg in group I and 67.9±7.9 mmHg in group II. At 30 minutes after caesarean section, mean diastolic blood pressure was found 75.4±9.1 mmHg in group I and 73.1±9.9 mmHg in group II. At 12 hrs after caesarean section, mean diastolic blood pressure was found 74.1±8.0 mmHg in group I and 72.7±8.2 mmHg in group II. At 24 hours after caesarean section, mean diastolic blood pressure was found 76.7±6.6 mmHg in group I and 76.1±7.2 mmHg in group II. The mean difference was not statistically significant (p>0.05) between two groups (Table 3).

Table 3: Diastolic Blood Pressure in Different Follow-Up (Mean±SD)

Diastolic Blood Pressure (mmHg)	Group I	Group II	P value
Before admission of drug	75.8±7.9	76.9±9.9	0.549
Range (min, max)	60, 85	60, 90	
At 1 minute after caesarean section	67.1±7.6	67.9±7.9	0.614
Range (min, max)	55, 85	60, 90	
At 30 minutes after caesarean section	75.4±9.1	73.1±9.9	0.239
Range (min, max)	60, 85	60, 90	
At 12 hrs after caesarean section	74.1±8.0	72.7±8.2	0.399
Range (min, max)	60, 85	60, 90	
At 24 hrs after caesarean section	76.7±6.6	76.1±7.2	0.259
Range (min, max)	60, 90	60, 90	

ns= not significant; P value reached from unpaired t-test

Before administration of drug, mean maternal blood loss was found 376.4±110.4 ml in group I and 439.4±199.9 ml in group II. At 30 minutes after caesarean section, mean maternal blood loss was found

Table 4: Maternal Blood Loss in Different Follow Up (Mean ±SD)

Maternal Blood Loss (ml)	Group I	Group II	P value
Before administration of drug	376.4±110.4	439.4±199.9	0.059
Range (min, max)	260, 660	310, 890	
At 30 minutes after caesarean section	397.2±114.3	470.1±240.1	0.060
Range (min, max)	280, 710	340, 1020	
At 12 hours after caesarean section	432.2±125.1	510.1±254.1	0.060
Range (min, max)	300, 790	350, 1190	
At 24 hours after caesarean section	468.2±121.9	532.6±243.0	0.104
Range (min, max)	290, 810	380, 1200	

ns= not significant; P value reached from unpaired t-test

397.2±114.3 ml in group I and 470.1±240.1 ml in group II. At 12 hours after caesarean section, mean maternal blood loss was found 432.2±125.1 ml in group I and 510.1±254.1 ml in group II. At 24 hours after caesarean section, mean maternal blood loss was found 468.2±121.9 ml in group I and 532.6±243.0 ml in group II. The mean difference was not statistically significant between two groups ($p>0.05$) (Table 4).

Discussion

This randomized controlled trial study was carried out with an aim to compare the haemodynamic effects of carbetocin and oxytocin and to compare the adverse effects like nausea, vomiting, headache of these two drugs as well as to compare the need of additional uterotonic drugs for the control of post-partum hemorrhage. A total of 96 patients admitted in Gynaecology and Obstetrics department of Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh for delivery between July to December 2015 were included in this study. Among them 48 cases treated with Carbetocin was considered as group I and rest 48 treated with Oxytocin was considered as group II. Patient with risk factors for primary post-partum haemorrhage such as: multiple pregnancy, one or more previous caesarean section, presence of uterine fibroids, previous myomectomy, presence of placenta previa, past history of post-partum hemorrhage, fetal macrosomia and fetal malformations associated with polyhydramnios were enrolled in this study. Presence of hypertension, eclampsia, cardiac, renal or liver diseases, epilepsy, general anaesthesia, as well as women with history of hypersensitivity to Carbetocin according to the Br National Formulary and patients unwilling to give consent were excluded from the study. The present study findings were discussed and compared with previously published relevant studies.

In this present study it was observed mean age was found 24.4±4.7 years in group I and 24.7±3.7 years in group II. The mean marital age was found 4.4±4.0 years in group I and 4.1±3.9 years in group II. The difference was not statistically significant ($p>0.05$) between two groups. Reyes et al.²⁰ found the mean age was 26.52±9.12 years in Carbetocin group and 26.78±8.39 years in Oxytocin group. The difference was not statistically significant ($p>0.05$) between two groups, which is closely resembled with the present study. On the other hand, Al Anwar et al¹¹ had observed the mean age was 33.0±4.6 years in carbetocin group

and 33.3±4.6 years in oxytocin group. Similarly, Magann et al¹² observed at baseline, there was no significant difference between carbetocin and oxytocin in terms of mean age, where mean was 30 years and 31 years respectively. The higher mean age may be due to geographical variations, racial, ethnic differences, genetic causes, different lifestyle and increased life expectancy may have significant influence in their study patients⁹.

In this study it was observed that before administration of drug, mean systolic blood pressure was found 115.6±5.8 mmHg in group I and 114.8±7.8 mmHg in group II. At 1 minute after caesarean section, mean systolic blood pressure was found 102.5±6.7 mmHg in group I and 101.7±7.1 mmHg in group II. At 30 minutes after caesarean section, mean systolic blood pressure was found 105.9±7.4 mmHg in group I and 107.8±9.9 mmHg in group II. At 12 hours after caesarean section, mean systolic blood pressure was found 116.2±5.9 mmHg in group I and 114.4±8.2 mmHg in group II. At 24 hours after caesarean section, mean systolic blood pressure was found 116.9±5.8 mmHg in group I and 113.9±8.8 mmHg in group II. The mean difference was not statistically significant between two groups ($p>0.05$).

In this present study it was observed that before administration of drug, mean diastolic blood pressure was found 75.8±7.9 mmHg in group I and 76.9±9.9 mmHg in group II. At 1 minute after caesarean section, mean diastolic blood pressure was found 67.1±7.6 mmHg in group I and 67.9±7.9 mmHg in group II. At 30 minutes after caesarean section, mean diastolic blood pressure was found 75.4±9.1 mmHg in group I and 73.1±9.9 mmHg in group II. At 12 hours after caesarean section, mean diastolic blood pressure was found 74.1±8.0 mmHg in group I and 72.7±8.2 mmHg in group II. At 24 hours after caesarean section, mean diastolic blood pressure was found 76.7±6.6 mmHg in group I and 76.1±7.2 mmHg in group II. The mean difference was not statistically significant ($p>0.05$) between two groups. Magann et al¹² found systolic and diastolic BP were not significantly different immediate post intervention between the two groups, immediate post-operative and while recovering between group were also not significant. Butwick et al¹³ obtained that systolic blood pressure was lower in the oxytocin group at the 5th minute after administration, at uterine closure time, at 12 hours postoperatively. Al Anwar et al¹¹ showed there were significant changes with time for each of systolic blood pressure and diastolic blood

pressure respectively but no significant main effect of group, which are similar with the current study.

In this current study it was observed that before administration of drug; mean maternal blood loss was found 376.4 ± 110.4 mL in group I and 439.4 ± 199.9 mL in group II. At 30 minutes after caesarean section, mean maternal blood loss was found 397.2 ± 114.3 mL in group I and 470.1 ± 240.1 mL in group II. At 12 hours after caesarean section, mean maternal blood loss was found 432.2 ± 125.1 mL in group I and 510.1 ± 254.1 mL in group II. At 24 hours after caesarean section, mean maternal blood loss was found 468.2 ± 121.9 mL in group I and 532.6 ± 243.0 mL in group II. Maternal blood loss was lower in group I but the mean difference was not statistically significant ($p > 0.05$) between two groups. Patel and Radeos¹⁴ showed the proportion of subjects with blood loss [500 ml (carbetocin 28.8%, oxytocin 26.9%) and [1,000 ml (carbetocin 7.8%, oxytocin 8.4%) was also comparable for both groups. In another study Butwick et al¹³ reported that there was no significant difference in the amount of estimated blood loss and in the incidence of primary post-partum haemorrhage (>1000 mL) in both groups. In fact, the investigators did not demonstrate any difference in the amount of blood loss after caesarean section and in the drop of haemoglobin level within 2 hours and 24 hours, but we showed in the oxytocin group a significant need (23.5%) of additional uterotonic agents. Patel and Radeos¹⁴ study showed that carbetocin could induce maternal tachycardia and facial flushing, but none in our carbetocin subgroup had these adverse events.

Conclusion

In conclusion before administration of drug, at 1 minute after caesarean section, at 30 minutes after caesarean section, at 12 hours after caesarean section and at 24 hours after caesarean section the mean difference of systolic blood pressure in group I and in group II is varied. This mean difference is not statistically significant between two groups. Again, at 1 minute, at 30 minutes, at 12 hours and at 24 hours, the mean difference of diastolic blood pressure in group I and in group II is varied. This mean difference is not statistically significant between two groups. Further large scale study should be carried out.

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Contribution to authors: Choudhury FH, Ahmed S, Tanzin ST conceived and designed the study, analyzed the data, interpreted the results, and wrote up the draft manuscript. Rahman S, Fatema N, Khatun K involved in the manuscript review and editing. All authors read and approved the final manuscript.

Data Availability

Any inquiries regarding supporting data availability of this study should be directed to the corresponding author and are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate

Ethical approval for the study was obtained from the Institutional Review Board. As this was a prospective study the written informed consent was obtained from all study participants. All methods were performed in accordance with the relevant guidelines and regulations.

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