Original Research

A Prospective Study To Compare The Efficacy Of Carbetocin With Oxytocin In Prophylaxis Of Post Partum Hemorrhage In Vaginal Deliveries

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ABSTRACT

Background:In this prospective study we compared the efficacy of carbetocin with oxytocin in prevention of uterine atony after normal vaginal delivery along with need of other uterotonics, fall in hemoglobin,side effects and amount of blood loss in both the groups

Material and methods: Patients were divided into 2 groups randomly by envelope method into Group A and Group B. During the study Group A women received carbetocin 100 µg I/M as a single dose and Group B women received 10 IU of oxytocin im immediately after delivery. The primary outcome was measured by the amount of blood loss immediately after delivery.

Results: In this study, mean age in group C and O was 28.4±3.3 years and 28.1±3.4 years respectively. This difference was not found to be statistically significant.In our study, mean duration of 3rd stage in group C and O was 19.9±4.4 min and 20.9±3.7 min respectively. This difference was not found to be statistically significant.In our study, no statistically significant difference was found in any adverse effect and wascomparable in both the groups.In our study, out of the 75 participants in group C, 3 had primary PPH and out of the 75 participants in group O, 11 had primary PPH. This difference was found to be statistically significant.In our study, mean blood loss in group C and O was 443.3± 38.8 ml and 467.9±46.9 ml respectively. This difference was found to be statistically significant.

Conclusion: Our study showed superior results in favor of carbetocin compared to oxytocin. In this study a statistically significant less blood transfusion, less blood loss, less requirement of additional uterotonic and less primary PPH was found in group carbetocin compared to oxytocin group.So, according to the current study, Carbetocin is an effective new drug compared to Oxytocin for prevention of postpartum hemorrhage in vaginal delivery.

Keywords: postpartum haemorrhage, carbetocin, mortality

INTRODUCTION

Postpartum hemorrhage is a common complication that occurs after 2-4% of vaginal deliveries and 6% of caesarean procedures. According to the World Health Organization, it is the largest cause of maternal mortality globally, accounting for 35% of all deaths.[1] Postpartum hemorrhage is responsible for 38% of maternal mortality in India.[2]

Post-partum hemorrhage (PPH) is defined as any blood loss >500 ml following vaginal delivery and >1000 ml after cesarean section.[3] Definitions vary in various parts of world and are often based on inaccurate estimates of blood loss.[4-5] It can also be defined as fall in hematocrit>10%.[6]

PPH is often classified as

1. **Primary:** Bleeding from or into the genital tract occurring within 24 hours of delivery and is more common form of PPH
2. **Secondary:** Defined as bleeding from or into the genital tract after 24 hours and up to six weeks post-partum.[7]

PPH is a significant contributor to severe maternal morbidity and long-term disability as well as to a number of other severe maternal conditions generally associated with more substantial blood loss, including shock and organ dysfunction.[5]Uterine atony is the most common cause of PPH, but genital tract trauma (i.e. vaginal or cervical lacerations), uterine rupture, retained placental tissue, or maternal coagulation disorders may also result in PPH. Although the majority of women who experience PPH have no identifiable clinical or historical risk factors, grand multiparity and multiple gestation are associated with an increased risk of bleeding after birth. PPH may be aggravated by pre-existing anaemia and, in such instances, the loss of only a small volume of blood may result in adverse clinical outcome.[8]

In this prospective study we compared the efficacy of carbetocin with oxytocin in prevention of uterine atony after normal vaginal delivery along with need of other uterotonics, fall in hemoglobin,side effects and amount of blood loss in both the groups.

MATERIAL AND METHODS

The study was conducted in Department of Obstetrics and Gynaecology, Deen Dayal Upadhyay Hospital, New Delhi. It was a prospective randomised comparative study conducted from May 2022 till May 2023. All eligible patients who fulfill the inclusion criteria were recruited for the study. After an informed written consent, a detailed history and examination was done.Patients will be divided into 2 groups randomly by envelope method into Group A and Group B. During the study Group A women were received carbetocin 100 µg I/M as a single dose and Group B women were received 10 IU of oxytocin im immediately after delivery. The primary outcome was measured by the amount of blood loss immediately after delivery.Quantitative estimation of blood loss was done by gravimetric analysis ie by weighing the soaked mops. Here mops were weighed pre and post delivery and the difference calculated.Difference in gms was converted to ml using the conversion(“x” gms=” x” ml).The amount of blood collected in delivery basins and plastic bags were measured by measuring container. Electronic weighing machines were used for all weighing purposes.The secondary outcomes were measured by change in vitals, need for additional uterotonics drug, additional blood transfusion as well as adverse effects immediately after delivery. Uterine tone was evaluated by palpation and administration of additional uterotonics as per the decision of the investigator.Data analysis was done using licensed SPSS software version 21.0 (Chicago, Illinois).

RESULTS

Group C: Patients received carbetocin
Group O: Patients received oxytocin

Table 1: Age distribution of study participants:

Group	Mean	SD	Median	Minimum	Maximum	p-value
C	28.39	3.328	28.00	19	38	0.562
O	28.07	3.410	28.00	19	38	
Total	28.23	3.362	28.00	19	38	

In this study, mean age in group C and O was 28.4±3.3 years and 28.1±3.4 years respectively. This difference was not found to be statistically significant.

Table 2: Comparison of average duration (in min) of 3rd stage between both groups:

Group	Mean	SD	Median	Minimum	Maximum	p-value
C	19.87	4.425	20.00	10	25	0.113
O	20.93	3.739	20.00	15	25	
Total	20.40	4.117	20.00	10	25	

In our study, mean duration of 3rd stage in group C and O was 19.9±4.4 min and 20.9±3.7 min respectively. This difference was not found to be statistically significant.

Table 3: Comparison of different adverse effect between both groups

Adverse effect		Group				p-value
		C		O		
		Count	%	Count	%	
Nausea	no	73	97.3%	71	94.7%	0.405
	Yes	2	2.7%	4	5.3%	
Vomiting	no	74	98.7%	73	97.3%	0.560
	Yes	1	1.3%	2	2.7%	
abdominal pain	no	74	98.7%	72	96.0%	0.311
	Yes	1	1.3%	3	4.0%	
Fever	no	74	98.7%	73	97.3%	0.557
	yes	1	1.3%	2	2.7%	
Headache	no	74	98.7%	72	96.0%	0.311

	yes	1	1.3%	3	4.0%	

In our study, no statistically significant difference was found in any adverse effect and wascomparable in both the groups.

Table 4: Comparison of primary PPH between both groups:

Primary PPH	C		O		p-value
	Count	%	Count	%	
No	72	96.0%	64	85.3%	0.025
Yes	3	4.0%	11	14.7%	
Total	75	100.0%	75	100.0%	

In our study, out of the 75 participants in group C, 3 had primary PPH and out of the 75 participants in group O, 11 had primary PPH. This difference was found to be statistically significant.

Table 5: Comparison of average blood loss between both groups:

Group	Mean	SD	Median	Minimum	Maximum	p-value
C	443.33	38.776	450.00	340	620	0.001
O	467.87	46.913	460.00	400	630	
Total	455.60	44.623	460.00	340	630	

In our study, mean blood loss in group C and O was 443.3± 38.8 ml and 467.9±46.9 ml respectively. This difference was found to be statistically significant.

DISCUSSION

Current study was randomized controlled study conducted in Department of Obstetrics and gynaecology, Deen Dayal Upadhyay Hospital, New Delhi. This study aimed to compare the efficacy of Carbetocin with Oxytocin in prophylaxis of Post Partum Hemorrhage in vaginal deliveries. A total 150 participants were included in the study and randomized into 2 groups. Group C patients received carbetocin 100µg I/M as a single dose and group O patients received 10 IU of oxytocin IM immediately after delivery.

AGE: In our study, mean age in group C and O was 28.4±3.3 years and 28.1±3.4 years respectively and out of the 75 participants in group C, maximum 42 (56%) belonged to 26-30 years followed by 22 (29.3%) in age of >30 years. Out of the 75 participants in group O maximum 42 (56%) belonged to 26-30 years followed by 19 (25.3%) in age of >30 years. This difference was not found to be statistically significant.

A similar study was done by Ashraf F et al[9] and total 94 woman delivered by vaginal delivery were included and randomized into 2 groups and Mean age of study population were 23.9 ± 3.2 in carbetocin group and 23.3 ± 3.2 in oxytocin group.

Similar to our results, Ai W et al[10] performed a prospective double-blind randomized controlled trial with severe preeclampsia for prevention of PPH where the mean age of study patient in carbetocin group were 26.5 years and 26.7 years in oxytocin group.

Nahaeret al[11] also did a randomized study and found similar age in both groups. In this study mean age of study patients were 25.2 years in carbetocin group and 24.9 years in oxytocin group.

Comparison of efficacy between both group:

Our study showed a superior results in favour of carbetocin compare to oxytocin. In this study a statistically significant less blood transfusion, blood loss, requirement of additional uterotonic and primary PPH was found in group carbetocin compared to oxytocin group.

In the present study, no statistically significant difference was found in uterine tone, requirement of fundal massage, any adverse effect and was comparable in both the groups.

In our study, out of the 75 participants in group C, 4 (5.3%) required blood transfusion, 4 (5.3%) required additional uterotonic and 3 (4%) had primary PPH and out of the 75 participants in group O, 9 (12%) required blood transfusion, 15 (20%) required additional uterotonic and 11 (14.7%) had primary PPH. These differences were found to be statistically significant.

In our study, mean blood loss in group C and O was 443.3± 38.8 ml and 467.9±46.9 ml respectively. This difference was found to be statistically significant.Manal M. E Behery et al[12] showed that none of women in carbetocin group required blood transfusion, while 15.5% in oxytocin group required blood transfusion. Study by Ashraf et al[9], none of patients in carbetocin group needed blood transfusion but in oxytocin group blood transfusion were required by 10.6% patients. Manal M. E Behery et al[12] showed that none of the patient in carbetocin group required additional uterotonics while as high as 71.5% of women in oxytocin group needed additional oxytocin to ensure adequate uterine contraction for long period. Samimi M et al[13] investigated carbetocin versus oxytocin for the prevention of postpartum hemorrhage following vaginal delivery among high risk women and found that fundal massage was required by 10% patients in carbetocin group and 83% patients in oxytocin group. In this study none of patients of carbetocin group required additional uterotonic but in oxytocin group additional uterotonics were required

for 10.6% patients. Ahmed Mohamed Magedet al[14] also showed the occurrence of PPH were 4% in carbetocin group and 16% in oxytocin group. In this study, occurrence of PPH in oxytocin group was 8% patients but in carbetocin group none of patients had developed PPH.Carbatocin was shown to have less postpartum blood loss, lower incidence of atonic PPH (0.3% vs. 6.3%), and lower requirement for additional uterotonic medicines (9.1%) than oxytocin in the research by Amornpetchakul and colleagues.[15]Anurag A et al[16] also revealed that Uterine tone, vaginal bleeding, changes in Hb and PCV, and the occurrence of side events were utilized to assess the efficacy and safety of both medicines. Carbetocin was statistically equivalent to oxytocin in avoiding uterine atony and thus PPH, with comparable duration of uterotonic activity and less need for further uterotonic medications.Huang X et al[17] conducted a meta-analysis to examine the efficacy of carbetocin and oxytocin in the prevention of PPH in vaginal delivery women. The proportion of women who needed additional uterotonics was lower in the carbetocin group than in the oxytocin group. However in contrast to our study, the proportion of women requiring blood transfusion did not differ significantly between the carbetocin and oxytocin groups.

CONCLUSION

Our study showed a superior results in favour of carbetocin compared to oxytocin. In this study a statistically significant less blood transfusion, less blood loss, less requirement of additional uterotonic and less primary PPH was found in group carbetocin compared to oxytocin group.So according to the current study, Carbetocin is an effective new drug compared to Oxytocin for prevention of postpartum hemorrhage in vaginal delivery.

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