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Original Research Article

Carbetocin versus Oxytocin in Active Management of Third Stage of Labour

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Abstract

Background: One of the leading causes of maternal morbidity and mortality is still postpartum hemorrhage (PPH). The incidence of PPH is significantly reduced by active management of the third stage of labor (AMTSL) with uterotonic drugs. The most common uterotonic, oxytocin, may require repeated doses due to its brief duration of effect. A single dose of carbetocin, a long-acting oxytocin mimic, provides prolonged uterine contraction.

Methods: An interventional clinical trial was conducted in the Department of Obstetrics and Gynaecology, PMCH, Patna, Bihar from September 2022 to April 2024 for comparison of heat stable carbetocin versus oxytocin in an attempt to determine the more efficacious drug for active management of third stage of labour. A total of 200 pregnant women were divided into 2 groups, Group A {Carbetocin group} with 50 cases of vaginal deliveries and 50 cases of caesarean section who were given IV bolus of 100 µg of Carbetocin and Group B {Oxytocin group} with 50 cases of vaginal deliveries and 50 cases of caesarean section who were administered 10 IU of Oxytocin IM. Comparison was done regarding the efficacy of both drugs in prevention of blood loss on the basis of estimated amount of blood loss, tonicity, time taken to achieve good tone, hemoglobin levels before and after delivery, Reduction in hemoglobin levels, occurrence of PPH, need of other uterotonic agents and need of blood transfusion.

Results: Mean blood loss in the 1st 24 hours postpartum was significantly lower in the carbetocin group compared to the oxytocin group (485.5±299.02 ml versus 514.5±350.49 ml; p=0.581). Comparison of estimated amount of blood loss between Carbetocin and Oxytocin group {Vaginal delivery} was (296±173.45 ml versus 321±221.33 ml; p=0.564). Comparison of estimated amount of blood loss between Carbetocin and Oxytocin group {Caesarean section} was (669±282.1 ml versus 708±350.42 ml; p=0.739).

Conclusion: Therefore, it can be concluded that Injection Carbetocin has the potential to become the drug of choice for active management of third stage of labour. It is more efficient than oxytocin in maintaining uterine tone in less time which is a crucial component in active management of third stage of labour.

Keywords: Carbetocin, Oxytocin, Postpartum hemorrhage, Third stage of labor, Uterotonics.

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Introduction

Postpartum haemorrhage is one of the most dreaded complications of pregnancy and child birth. Although there have been many recent advancements in the field, still PPH is the leading cause of maternal mortality and morbidity. According to WHO [1] each year, about 14 million women experience.

PPH resulting in about 70,000 maternal deaths globally. In India 45,000 maternal deaths take place annually and 20- 60% are due to postpartum haemorrhage. [2] India has recently achieved its Sustainable Development Goal of less than 100 maternal mortality ratio, standing at 97 per 100000 live births in 2020 yet the leading cause of maternal

death continues to be the same.[3]

In Bihar, the Maternal Mortality Ratio is as high as 118 and falls in the category of very high maternal mortality.[4] Postpartum haemorrhage is defined by WHO as blood loss of more than 500 ml in vaginal delivery and more than 1000 ml in caesarean section, that occurs in the first 24hrs after delivery (WHO, 2012).[5] PPH occurs in the third stage of labour making it the most crucial stage. Third stage of labour is the time between the delivery of the baby and the expulsion of the placenta.

Active management of third stage of labour is (AMTSL) is a prophylactic and effective intervention to prevent PPH. It facilitates smooth placental expulsion and effective contraction of uterus.

The components of active management of Third stage of labour are as follows (WHO, 2012)[5]:

1. Administration of uterotonic agents immediately after delivery of the baby
2. Controlled cord traction
3. Uterine Palpation every 10 mins after delivery

Delayed cord clamping is also recommended

The most important component of active management of third stage of labour is administration of uterotonic agents. Several uterotonic agents are available now a days which have proved to be effective in preventing PPH. WHO (2018) recommends Oxytocin as the first line agent for active management. The uterotonics currently available are oxytocin, carbetocin, methylergometrine, misoprostol, carboprost etc. Although, Oxytocin has always been the conventional and most preferred drug to be used in third stage of labour but the oxytocin quality and supply has been an issue. WHO recommends a high-quality oxytocin which has been kept in cold chain and is not exposed to heat for longer periods, otherwise its potency is reduced. WHO also emphasises on a continuous supply of oxytocin which is a challenge in some parts of the world. (WHO,2018)[6]

Carbetocin, a long-acting analogue of oxytocin has been emerging out to be much a better drug option than oxytocin as the drug is heat stable and more potent.[7]

Materials and Methods

The Interventional Trial was conducted on patients from Emergency Obstetrics Unit in the Department of Obstetrics and Gynecology in Patna Medical College and Hospital, Patna, Bihar from September 2022 to April 2024.

Total 200 cases (100 cases of vaginal delivery and 100 cases of caesarean section) were included in this study. The sample size was calculated on 95% Confidence interval (Z score- 1.96) with margin of error as 6.9%.

Case: Cases is selected on the basis of inclusion and exclusion criteria i.e. pregnant women with hypersensitivity to carbetocin or oxytocin, epilepsy and migraine, cardiovascular diseases, hepatic and renal impairment and asthma were excluded in this study.

Control: The control group includes all the women who are administered Injection Oxytocin for active management of third stage of labour.

Ethical clearance: Ethical clearance was obtained from the college ethical committee.

Consent: Informed consent was taken from the study groups.

Proforma: The proforma was filled with the details like name of the patient, age, registration number, gestational age, parity, complete history of the patient was obtained and detailed clinical examination was done. All basic investigations were taken.

Methods

Women are divided in two groups

Group A {Carbetocin group}: 50 cases of vaginal deliveries and 50 cases of caesarean section who were given IV bolus of 100 ug of Carbetocin.

Group B {Oxytocin group}: 50 cases of vaginal deliveries and 50 cases of caesarean section who were administered 10 IU of Oxytocin IM

Comparison was done regarding the efficacy of both drugs in prevention of blood loss on the basis of

a. Estimated amount of blood loss
b. Tonicity
c. Time taken to achieve good tone
d. Hemoglobin levels before and after vaginal delivery and c section
e. Reduction in hemoglobin levels
f. Occurrence of PPH
g. Need of other uterotonic agents
h. Need of blood transfusion

Study Procedure and methodology: After an informed consent, a total of 200 pregnant women in which 100 pregnant women who had a vaginal delivery and the other 100 who had a Caesarean Section were selected randomly to administer the drugs. A Complete history, clinical examination and investigations including hemoglobin levels were done. Patient's vitals were monitored throughout the intrapartum and postpartum period.

Group A {Carbetocin group} had 50 cases of vaginal deliveries and 50 cases of caesarean section who were given IV bolus of 100 ug of Carbetocin

and Group B {Oxytocin group} consisted of 50 cases of vaginal deliveries and 50 cases of caesarean section who were administered 10 IU of Oxytocin IM. Both the drugs were administered in the active management of third stage of labour that is immediately after the delivery of the baby. Immediately after giving the drug uterine tone was measured via palpatory method and marked as i) Very good ii) Good iii) Atonic. Palpation was done at 1 minute after delivery then every 5 minutes to check a good tone. A good tone is the one achieved in 2 to 5 minutes. Therefore, we also noted down the time taken by each drug to obtain a good tone.

The estimated blood loss was calculated through visual estimation based on number of pads and swabs soaked in vaginal delivery and amount of blood aspirated during Caesarean section in the suction canister and surgical swabs. The presentation of the Categorical variables was done in the form of number and percentage (%). On the other hand, the quantitative data were presented as the means ± SD and as median with 25th and 75th percentiles (interquartile range). The data normality was checked by using Shapiro-Wilk test. The cases in which the data was not normal, we used non parametric tests. The following statistical tests were applied for the results:

1. The comparison of the variables which were quantitative and not normally distributed in nature were analyzed using Mann-Whitney Test and variables which were quantitative and normally distributed in nature were analyzed using independent t test.
2. The comparison of the variables which were qualitative in nature were analyzed using Chi-Square test. If any cell had an expected value of less than 5 then Fisher's exact test was used.
3. The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, version. 25.0.

For statistical significance, p value of less than 0.05 was considered statistically significant.

Results

Group A {Carbetocin group}: 50 cases of vaginal deliveries and 50 cases of caesarean section who were given IV bolus of 100 µg of Carbetocin.

Group B {Oxytocin group}: 50 cases of vaginal deliveries and 50 cases of caesarean section who were administered 20 IU of Oxytocin (10IU IM and 10 IU IV infusion).

Table 1: Comparison of different types of variables between Carbetocin and Oxytocin group (Vaginal delivery)

	Carbetocin group (n=50)	Oxytocin Group (n=50)	Total	P value
Estimated amount of blood loss (mL)				
Mean±SD	296± 173.45	321±221.33	308.5±198.23	0.564§
Median(25th - 75thpercentile)	275(200-350)	300(150-400)	300(187.5-400)	
Range	100-900	50-1000	50-1000	
§Mann Whitney test				
Uterine tone				
Very good	26(52%)	14(28%)	40(40%)	0.045*
Good	22(44%)	31(62%)	53(53%)	
Atony	2(4%)	5 (10%)	7(7%)	
Total	50(100%)	50(100%)	100(100%)	
*Fisher's exact test				
Time to achieve tone (minutes)				
Mean±SD	2.94±1.63	5.56±2.64	4.25±2.55	<.0001§
Median(25th - 75thpercentile)	2.5(2-4)	5(4-6)	4(2-5)	
Range	1-10	2-15	1-15	
§Mann Whitney test				
Hemoglobinslevels (g/dL)				
Hemoglobins levels before delivery (g/dL)				
Mean±SD	10.17±1.43	10.05±1.07	10.11±1.26	0.636‡
Median(25th - 75thpercentile)	10(9-11)	10(9-11)	10(9-11)	
Range	7-13	8-12	7-13	
Hemoglobins levels after delivery (g/dL)				
Mean±SD	9.47±1.5	9.4±1.4	9.43±1.44	0.826‡
Median(25th - 75thpercentile)	9.9(8.5-10.75)	9(8.5-10)	9.65(8.5-10)	
Range	6-12	7-12	6-12	
‡Independent t test				

Decrease in hemoglobin (g/dL)				
Mean±SD	0.7±0.58	0.65±0.62	0.68±0.6	0.629§
Median (25th -75thpercentile)	1(0-1)	0.75(0-1)	1(0-1)	
Range	0-2	0-2	0-2	
§Mann Whitney test				
PPH				
No	45(90%)	41(82%)	86(86%)	0.249†
Yes	5 (10%)	9 (18%)	14(14%)	
Total	50(100%)	50(100%)	100(100%)	
†Chi-square test				
Need of other uterotonic drug				
No	40(80%)	28(56%)	68(68%)	0.01†
Yes	10(20%)	22(44%)	32(32%)	
Total	50(100%)	50(100%)	100(100%)	
†Chi-square test				
Need of blood transfusion				
No	47(94%)	41(82%)	88(88%)	0.121*
Yes	3(6%)	9 (18%)	12(12%)	
Total	50(100%)	50(100%)	100(100%)	
***Fisher's exact test**				

Table 2: Comparison of different types of variables between Carbetocin and Oxytocin group (Caesarean section)

	Carbetocin group (n=50)	Oxytocin Group (n=50)	Total	P value
Estimated amount of blood loss (mL)				
Mean±SD	669±282.1	708± 350.42	688.5±317.09	0.739§
Median (25th - 75th percentile)	675(500-800)	650(500-800)	675(500-800)	
Range	300-1800	150-2000	150-2000	
§Mann Whitney test				
Uterine tone				
Very good	23(46%)	15(30%)	38(38%)	0.191*
Good	22(44%)	31(62%)	53(53%)	
Atony	5 (10%)	4(8%)	9(9%)	
Total	50(100%)	50(100%)	100(100%)	
***Fisher's exact test**				
Time to achieve tone (minutes)				
Mean±SD	4.34±4.64	6.32±5.06	5.33±4.93	0.0002§
Median(25th – 75thpercentile)	3(2-4)	5(4-7.75)	4(2-6)	
Range	1-25	1-30	1-30	
§Mann Whitney test				
Hemoglobinslevels (g/dL)				
Hemoglobins levels before delivery (g/dL)				
Mean±SD	10.41±1.03	10.24±0.89	10.32±0.96	0.378‡
Median (25th - 75th percentile)	10.5(10-11)	10(10-11)	10(10-11)	
Range	8-12	8-12	8-12	
Hemoglobins levels after delivery (g/dL)				
Mean±SD	9.41±1.26	9.11±1.17	9.26±1.21	0.213‡
Median(25th - 75thpercentile)	9.5(8.5-10)	9(8.5-10)	9(8.5-10)	
Range	7-12	6-11.5	6-12	
‡Independent t test				
Decrease in hemoglobin (g/dL)				
Mean±SD	1± 0.58	1.13±0.71	1.06±0.65	0.515§
Median(25th -75thpercentile)	1(1-1.15)	1(1-1.5)	1(1-1.5)	
Range	0-2	0-4	0-4	
§Mann Whitney test				
PPH				
No	47(94%)	42(84%)	89(89%)	

Yes	3(6%)	8 (16%)	11(11%)	0.2*
Total	50(100%)	50(100%)	100(100%)	
*Fisher's exact test				
Need of other uterotonic drug				
No	39(78%)	33(66%)	72(72%)	
Yes	11(22%)	17(34%)	28(28%)	0.181†
Total	50(100%)	50(100%)	100(100%)	
†Chi-square test				
Need of blood transfusion				
No	44(88%)	44(88%)	88(88%)	
Yes	6 (12%)	6 (12%)	12(12%)	1†
Total	50(100%)	50(100%)	100(100%)	
†Chi-square test				

Table 3: Comparison of different type's variables between Carbetocin and Oxytocin group

	Carbetocin Group (n=100)	Oxytocin Group (n=100)	Total	P value
Estimated amount of Blood loss (mL)				
Mean±SD	482.5±299.02	514.5±350.49	498.5±325.35	
Median (25^{th} -75^{th}percentile)	400(287.5-700)	450(300-712.5)	400(300-700)	0.581§
Range	100-1800	50-2000	50-2000	
§Mann Whitney test				
Uterine tone				
Very good	49(49%)	29(29%)	78(39%)	
Good	44(44%)	62(62%)	106(53%)	0.015†
Atony	7(7%)	9(9%)	16 (8%)	
Total	100(100%)	100(100%)	200(100%)	
†Chi-square-test				
Time to achieve tone (minutes)				
Mean±SD	3.64±3.53	5.94±4.03	4.79±3.95	
Median(25^{th} -75^{th}percentile)	3(2-4)	5(4-7)	4(2-5)	<.0001§
Range	1-25	1-30	1-30	
§Mann Whitney test				
Hemoglobinslevels (g/dL)				
Hemoglobins levels before delivery (g/dL)				
Mean±SD	10.29±1.24	10.14±0.99	10.22±1.12	
Median (25^{th} -75^{th}percentile)	10(9-11)	10(9.5-11)	10(9.5-11)	0.362‡
Range	7-13	8-12	7-13	
Hemoglobins levels after delivery (g/dL)				
Mean±SD	9.44±1.37	9.26±1.29	9.35±1.33	
Median(25^{th} -75^{th}percentile)	9.5(8.5-10.125)	9(8.5-10)	9(8.5-10)	0.33‡
Range	6-12	6-12	6-12	
‡Independent t-test				
Decrease in hemoglobin (g/dL)				
Mean±SD	0.85±0.59	0.89±0.71	0.87±0.65	
Median(25^{th} - 75^{th}percentile)	1(0.5-1)	1(0.2-1)	1(0.425-1)	0.872§
Range	0-2	0-4	0-4	
§Mann Whitney test				
PPH				
No	92(92%)	83(83%)	175(87.50%)	
Yes	8(8%)	17(17%)	25(12.50%)	0.054†
Total	100(100%)	100(100%)	200(100%)	
†Chi-square test				
Need of other uterotonic drug				
No	79(79%)	61(61%)	140(70%)	
Yes	21(21%)	39(39%)	60(30%)	0.005†
Total	100(100%)	100(100%)	200(100%)	

†**Chi-square test**				
Need of blood transfusion				
No	91(91%)	85(85%)	176(88%)	0.192†
Yes	9(9%)	15(15%)	24(12%)	
Total	100(100%)	100(100%)	200(100%)	
†**Chi-square test**				

Discussion

Of the 200-study population, the age of the participants varied across the study, there were a total of 28 (14%) patients in the age group of 18 to 20 years, 162 (81%) were in the group of 21 to 30 years making it the group of largest number of participants, and only 10 patients (5% of total) were present in the 31-to-40-year age group. The data rightfully signifies the distribution of age in real life scenario as the common reproductive age group is 21 to 30 years of age.

The study has an established divide of parity in two groups. Groups being Primigravida and multi gravida. Out of 200, 80 (40%) were primigravidae and 120 (60%) were multigravida.

Uterine tone was classified in three categories as Very Good, Good and atony where a 'very good tone' was most desirable and atony was almost threatening. In the case of vaginal deliveries, Compared to Oxytocin, Carbetocin had significantly higher proportion of patients with uterine tone classified as very good (52%: Carbetocin vs. 28%: Oxytocin). Conversely, proportion of patients with uterine tone classified as good was significantly lower in Carbetocin compared to Oxytocin (Good: 44% vs. 62%). Atony was significantly low in carbetocin group compared with oxytocin (4% vs. 10%) which is contrary to the several studies but in correspondence of the study conducted by Larciprete et al, 2013.[8]

Amongst Caesarean section parturients, Carbetocin had comparable distribution of uterine tone with 46% in Carbetocin group achieving very good tone.

In vaginal delivery, Carbetocin had significantly lower median time to achieve good or adequate tone with 2.5 (2-4) minutes being the average whereas the time taken is 5 (46) minutes in Oxytocin group.

Similarly in Caesarean section scenarios, Carbetocin showed significantly lower median time to achieve good tone,3 (2-4) minutes in Carbetocin group vs. 5 (4-7.75) minutes in Oxytocin group. This comparison shows carbetocin to be superior in maintaining better tonicity in less time, similar results were also found in studies of Boucher et al in 1998[9] and Suya Kang et al in 2021[10] but studies by Khushbu Bashi and Madieha Sabha in 2023 [11] have failed to show the same. The mean estimated blood loss overall in Carbetocin group was 482.5±299.02 ml whereas, In oxytocin group the mean was 514.5±350.49 ml. Carbetocin had comparable median estimated amount of blood loss, with 400 (287.5-700) ml in Carbetocin group vs. 450 (300-712.5) ml in Oxytocin group, showing no significant difference between them. However the studies of Ibrahim et al[12] had significant reduction in blood loss.

Across the 100 vaginal deliveries, the patient had estimated blood loss of 296±173.45 ml in Carbetocin group and 321±221.33 ml in the oxytocin group.

100 pts who went through Caesarean section, the blood loss had a mean of 669+/- 282 ml in carbetocin group and 708+/- 350.42 ml in oxytocin group. It can be said that there is a slight but insignificant difference in estimated blood loss in both groups, making both drugs equivalent performers in AMTSL which is in correspondence to the study of Suya Kang et al in 2021.

Hemoglobin levels before and after vaginal delivery, No significant difference was observed in hemoglobin levels between Carbetocin and Oxytocin groups. Hemoglobin levels before delivery were comparable, as were hemoglobin levels after delivery. Mean before delivery values in Carbetocin group were 10.17±1.43 g/dL, and after delivery, it was 9.47±1.5 g/dL. In Oxytocin group, mean hemoglobin levels before delivery were 10.05±1.07 g/dL, and after delivery, it was 9.4±1.4 g/dL, with no significant difference between them.

Similarly, Hemoglobin levels before and after Caesarean section were comparable. Mean hemoglobin levels before delivery in Carbetocin group was 10.41 ± 1.03 g/dL, and after delivery, it was 9.41 ± 1.26 g/dL. In Oxytocin group, mean hemoglobin levels before delivery were 10.24 ± 0.89 g/dL, and after delivery, it was 9.11 ± 1.17 g/dL, with no significant difference between them. This result is in accordance the results given by NuguelisRazali et al in 2016 where they stated that there was difference in blood loss.

Decrease in haemoglobin levels were noted after 24 hours of delivery and compared to the Haemoglobin levels before the delivery, no significant decrease was observed in haemoglobin levels between Carbetocin and Oxytocin groups in Haemoglobin levels before and after delivery.

Compared to Oxytocin {Vaginal delivery}, Carbetocin had comparable median decrease in haemoglobin, with value of 1 (0-1) g/dL in Carbetocin group vs. 0.75 (0-1) g/dL in Oxytocin group, showing no significant difference between them. Compared to Oxytocin {Caesarean section}, Carbetocin had comparable median decrease in haemoglobin, with value of 1 (1-1.15) g/dL in Carbetocin group vs. 1 (11.5) g/dL in Oxytocin group, showing no significant difference between them. After ruling out traumatic PPH as the cause of PPH, An overall 25 cases PPH was noted despite of uterotonic use. Compared to Oxytocin, Carbetocin had comparable distribution of PPH with 8% in Carbetocin group and 17% in oxytocin group.

In Vaginal delivery patients, out of 50 who were give inj. carbetocin, 5 (10%) had PPH whereas 9 (18%) had PPH in 50 who were given inj. oxytocin. Carbetocin seems to be slightly better than oxytocin in preventing PPH. This result is in uniformity to the CHAMPION TRIAL, 2018 where the drug is said to be an equal of the conventional drug oxytocin.

In Caesarean section, PPH occurred in 3 (6%) of 50 who were given injection Carbetocin and in 8 (16%) of 50 who were injection Oxytocin.

Overall proportion of patients who required other uterotonic drugs was significantly lower in Carbetocin compared to Oxytocin (21% vs. 39%) but such results were not comprehended by Ahmad Ben Tareef, 2022 in a similar study.[13] 10 (20%) out of 50 in carbetocin group needed other uterotonic agents whereas 22 (44%) out of 50 in oxytocin were given other uterotonic agents making a significant difference in the need of other uterotonic agent in both groups. The other uterotonic drugs used were Injection Methergine, Tablet Misoprostol and Injection Carboprost respectively

In 100 C section cases, other uterotonic agents were used in a total of 28 patients. Compared to Oxytocin, Carbetocin had comparable distribution of need for other uterotonic drugs [Carbetocin vs. Oxytocin, (22% versus 34%). 11 (22%) in Carbetocin group and 17 (34%) in oxytocin group needed other uterotonic agents, making Carbetocin more potent as a single uterotonic agent. The results are in solidarity of the studies conducted by NuguelisRazali et al in 2015 and Hian Yan Voon et al. in 2018 where it was stated that with carbetocin the need of other uterotonic is reduced. [14,15] Need of Blood Transfusion: Overall, a total of 9 in Carbetocin group and a total of 15 in oxytocin went through blood transfusions. In Vaginal delivery, Carbetocin had comparable distribution of need for blood transfusion (Carbetocin vs. Oxytocin 6% vs. 18%).

In Caesarean section, Carbetocin had identical distribution of need for blood transfusion (Carbetocin vs. Oxytocin, 12% versus 12%). This is contrary to the studies of Ahmad Ben Tareef et al, 2021 which concluded that blood transfusions were more common in carbetocin. The results here also do not comply with that of Hian Yan Voon et al. (2018) which said that there was significant reduction in transfusion rates.

Conclusion

Several inferences could be drawn in this comparative study based on different parameters.

Unopposed superiority of the drug Carbetocin could not be established. However, the drug comes out to be a promising drug as single uterotonic agent as the need of a second uterotonic is very minimal in the cases of both vaginal delivery and C section. Therefore, it can be concluded that Injection Carbetocin has the potential to become the drug of choice for active management of third stage of labour. It is more efficient than oxytocin in maintaining uterine tonicity in less time which is a crucial component in active management of third stage of labour. It also does not need any other uterotonic drug and can be used as a single agent in settings where a bundle of drugs is not available. Cost effectiveness and accessibility of the drug remains a major issue but can surely be resolved with further advancements in uterotonic drugs in near future.

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