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Comparative Clinical Study for Uterotonic Drugs Used in Reducing Postpartum Haemorrhage for Risky Patients in Caesarean Section

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ABSTRACT

Background: Obstetric hemorrhage is the most prevalent cause of maternal death. Uterine atony accounts for around 80% of postpartum hemorrhage (PPH) cases.

Objectives: This study aimed to compare between oxytocin and carbetocin in the prevention of PPH in Caesarean section (CS).

Methods: This prospective observational study was carried out on 100 female participants with risk factors of PPH delivered by CS at the Obstetrics and Gynecology Department, Menoufia University Hospitals. They were divided into 2 groups: **Group 1** that included 50 pregnant women who received 100 mcg/ml of carbetocin and **group 2** that included 50 pregnant women who received 10 IU of oxytocin infusion (8ml/m over one hour). All participants were subjected to full medical history and full clinical examination. Vital signs, intraoperative blood loss estimation, routine investigations (CBC, ABO, Rh, RBS, Coagulation profile, S. creatinine & urinalysis and LFT), and obstetric US were done for all females.

Results: Overall 100 participants that were recruited, there was no significant difference regarding demographic data. Group 2 (oxytocin) had significantly lower hemoglobin levels and hematocrit l2 hours & 24 hours postoperatively. Group 1 had better uterine contractions than group 2. There were 17 cases in group 2 that needed additional uterotonic drugs with a p-value <0.001. There were 6 cases in group 2 that developed PPH and 4 of them needed blood transfusion.

Conclusion: A single intravenous injection of carbetocin (100 mcg) was more effective than a continuous intravenous infusion of oxytocin (10 IU) for maintaining uterine tone and prevention of PPH.

Keywords: CS, Carbetocin, Oxytocin, PPH, Third stage.

INTRODUCTION

Blood loss within the first 24 hours following birth that is greater than 500 mL following vaginal delivery and more than 1000 mL following cesarean section is known as primary PPH. An estimated 25% of the approximately 500,000 women who pass away from this potentially avoidable cause each year so as a result of hemorrhaging after childbirth. It accounts for 25% of fatalities annually and is the primary cause of maternal mortality worldwide [1].

PPH can cause the mother to have a number of issues, including severe anemia, the requirement for blood transfusions and the associated risks, coagulopathy, Sheehan's syndrome (pituitary infarction), and damage to organs from shock and hypotension. The Perinatal Database's International Classification of Disease (ICD) codes—ICD-9 and ICD-10—are the basis for PPH diagnosis [2].

Active treatment of the third stage of labor lowers the risk of PPH compared to expectant care, according to the Society of Obstetricians and Gynecologists of Canada's (SOGC) practical recommendations on PPH, and it should be made available to and recommended for all women [3].

The primary goal of active care is the use of uterotonic medicines, which greatly reduce the incidence of PPH and largely prevent it. The recommended drug to prevent PPH in Cesarean births is oxytocin (10 IU) [4]. While oxytocin is the most commonly used uterotonic agent, there are alternative medications on the market, and they are not entirely obvious. These medication are the best for preventive usage [4]. To avoid PPH and lessen the need for therapeutic uterotonics, an intravenous bolus of 100 μg of carbetocin delivered over a minute can be used in place of a continuous oxytocin infusion during an elective Cesarean surgery [3]. First reported in 1987, carbetocin is a synthetic oxytocin analogue with a lengthy half-life. When administered intravenously at an ideal dosage of 100 μg, it causes uterine contractions in less than two minutes, and its half-life is 40 minutes, approximately 4–10 longer than that of oxytocin [5].

In terms of increasing uterine tone and lowering the risk of PPH during an elective Cesarean surgery, a single dosage of carbetocin has been proposed to function as a 16-hour intravenous oxytocin infusion [6]. This study aimed to compare oxytocin and carbetocin in the prevention of PPH in high-risk patients during CS.

PATIENTS AND METHODS

This was a prospective observational study that was conducted at Menuofia University Hospital including women who underwent Cesarean section from January 2022 to April 2023. All participants were randomly divided into: Group 1 (Carbetocin group) and group 2 (Oxytocin group) according to a random allocation sequence developed via a random number table in a statistical textbook and was distributed

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through sequenced opaque closed envelopes, where each envelope contained a single assignment: Group 1 included 50 women who received 100 µg (100 mcg/ml) carbetocin (Babal, Ferring pharmaceuticals) diluted in 10 ml normal saline 0.9% as an IV bolus over one minute after delivery of the anterior shoulder during Caesarean section. Group 2 included 50 women who received continuous intravenous of 10 IU of oxytocin (oxytocin, MINAPHARM) diluted in 500 ml of 0.9% normal saline by 8 ml/minute over 1 hour.

Inclusion criteria: Pregnant women with risk factors for primary PPH such as grand multipara, multiple pregnancies, polyhydramnios, fetal macrosomia, prolonged and/or obstructed labor, presence of uterine fibroid and history of PPH.

Exclusion criteria: Pregnant women with placenta previa and accreta, abruptio placenta, bleeding disorders and women who have previously had carbetocin hypersensitivity under the British National Formulary.

Methods: Each patient received thorough history taking, a general examination, an abdominal examination, a vaginal examination, and laboratory investigations including CBC, Rh typing, coagulation profile (prothrombin time, partial thromboplastin time, and INR), liver function tests, and serum creatinine. An ultrasound scan was used to determine gestational age by doing a trans-abdominal scan. Evaluation of all potential PPH risk factors.

All patients had spinal anesthesia. After application of this anesthesia, subjects were connected to monitor for continuous blood pressure measurement. The drop in blood pressure following the spinal procedure, 1 minute, 3 minutes, and 5 minutes after drug administration were recorded by the anesthetic team, at the time of uterine repair and term of Cesarean procedure, 2 hours, 12 hours, and 24 hours after CS, was taken into consideration for the evaluation of the hemodynamic effects between carbetocin and oxytocin. Prior to Cesarean sections and 24 hours after delivery, the hematocrit value and hemoglobin concentration were recorded.

For every group, the variations between the pre- and post- CS values were computed. The uterine tone and size were measured by palpating the fundus and anterior wall. One may suspect uterine atony if they have a swampy uterus, severe vaginal bleeding, or growing uterine size. Each group population's requirement for extra uterotonic medication was recorded and totaled. PPH incidence was recorded and totaled. Additionally, blood loss was measured just after the Cesarean, with a blood loss of more than 1000 milliliters being considered a hemorrhage. The surgeon evaluated the amount of blood lost using the standard method (visual estimates: Little blood clots = 50–100 ml & big blood clots = 350–400 ml) [7].

Palpating the fundus and anterior wall allowed for the measurement of the uterine tone and size. If a person experiences heavy vaginal bleeding or a swollen uterus, or both, they may be suspects of uterine atony. The amount of additional uterotonic medicine required for each group was noted and summed. The incidence of PPH was noted and added up. The surgeon calculated the amount of blood lost [8]. We weighed the towels soaked with blood and calculated the volume of blood as follows: Volume of blood = weight of soaked towels- weight of dry towels).

Study drug administration: During CS, 10 IU of oxytocin diluted in 500 ml saline was administered by intravenous infusion (8 ml/minute over 1 hour), and the research medicine (carbetocin 100 µg) was delivered slowly (over 30–60 seconds) intravenously. It has been demonstrated that the gradual infusion lessens the potentially hazardous hemodynamic effects of carbetocin and oxytocin.

Ethical consideration: Menoufia University Faculty of Medicine's Ethics Committee accepted the study procedure. Prior to the commencement of the trial, all participants provided written permission. All participants received an explanation of the research's procedures, and they all had the option to withdraw from the study at any moment without giving a reason. The Helsinki Declaration was adhered to at every stage of the investigation.

Statistical analysis

SPSS version 26.0 was used to analyze the data. The qualitative data was evaluated with Fisher's exact test and the X^2-test, and it was expressed as a number and percentage. The Shapiro-Wilks test was used to check the normalcy of quantitative data, assuming that $P > 0.05$ indicated normalcy. The quantitative data was characterized by mean ± SD, and range, as determined by the Student's "t" test and Fisher exact test if the data were regularly distributed, otherwise it was determined by the Mann-Whitney U test and the Kruskall-Wallis test. P-value ≤ 0.05 was deemed significant.

RESULTS

There was no significant difference between both groups regarding age, parity, indications of CS, Weight, height, gestational age at delivery, and birth weight (Table 1).

Table (1): Comparison between the two studied groups regarding their demographic data

Variables	Group 1 (Carbetocin) (n=50)		Group 2 (Oxytocin) (n=50)		Test of significance	p-value
	No	%	No	%		
Age						
<30 years	26	52	29	58	χ^2=0.346	0.546
>30 years	24	48	21	42		
Parity						
PG	13	26	12	24	χ^2=0.244	0.993
G1	3	6	4	8		
G2	18	36	19	38		
G4	15	30	14	28		
G5	1	2	1	2		
Indications for CS						
Emergency	5	10	9	18	χ^2=5.228	0.664
Fibroid	5	10	4	8		
Macrosomia	9	18	12	24		
Obstructed labor	1	2	1	2		
Polyhydramnios	6	12	4	8		
PPH	6	12	7	14		
Prolonged labor	3	6	0	0		
Twins	15	30	13	26		
Weight (kg)						
Mean ± SD	78.90 ± 9.46		77.76 ± 9.71		t=0.549	0.554
Range	60-90		60-90			
Height (Cm)						
Mean ± SD	164.84 ± 2.38		164.70 ± 2.44		t=0.291	0.772
Range	161-168		161-168			
Gestational age						
Mean ± SD	37.3 ±0.78		37.84 ± 0.77		t=5.426	0.72
Range	37-38		37-39			
Birthweight (gm)						
Mean ± SD	3270 ± 760.19		3216.9 ± 775.28		t=0.346	0.730
Range	2025-4500		2050-4500			

Group 2 had significantly lower hemoglobin levels and lower hematocrit 2 hours & 24 hours postoperatively (Table 2).

Table (2): Comparison between the two studied groups regarding their hemoglobin and hematocrit level at different intervals

Variables	Group 1 (Carbetocin) (n=50) Mean ± SD	Group 2 (Oxytocin) (n=50) Mean ± SD	Student t-test	p-value
Hemoglobin preoperative	11.39 ±0.74	11.16 ±0.89	1.144	0.256
2 hours postoperative	11.09 ±0.71	10.62 ±0.85	3.031	**0.003***
24 hours postoperative	10.82 ±0.71	9.66 ±1.25	5.699	**<0.001***
Hematocrit preoperative	35.12 ±0.43	34.77 ±0.81	1.864	0.065
2 hours postoperative	34.85 ±0.44	32.43 ±2.69	5.984	**<0.001***
24 hours postoperative	34.60 ±0.43	30.50 ±3.01	9.052	**<0.001***

There was a significant difference between both groups regarding the usage of additional uterotonic drugs as 17 cases in group 2 needed additional uterotonic drug (p value < 0.001) (Table 3).

Table (3): Comparison between the two studied groups regarding usage of additional uterotonic drugs

Usage of additional uterotonic drugs	Group 1 (Carbetocin) (n=50)		Group 2 (Oxytocin) (n=50)	
	No	%	No	%
Yes	0	0	17	34
No	50	100	33	66
Test of significance	X2=49.254			
p-value	**<0.001***			

There was a significant difference between both groups regarding uterine contractions as group 1 had better uterine contractions 1 and 2 hours after delivery than group 2 (p-value <0.001 and 0.011 respectively), and after 12 hours both groups had 100 % contracted uterus (Table 4).

Table (4): Comparison between the two studied groups regarding uterine contractility

Uterine contractility	Group 1 (Carbetocin) (n=50)		Group 2 (Oxytocin) (n=50)		X^2 test	p-value
	No	%	No	%		
1 hour after delivery						
Contracted	50	100	33	66	49.25	**<0.001***
Non	0	0	17	34		
2 hours after delivery						
Contracted	50	100	44	88	6.383	**0.011***
Non	0	0	6	12		
12 hours after delivery						
Contracted	50	100	50	100	-	-
Non	0	0	0	0		

There was a significant difference between both groups regarding the development of PPH as there were 6 cases in group 2 that had PPH after 2 hours of CS. Also, there was a significant difference between both groups regarding the need for blood transfusion as 4 cases in group 2 needed blood transfusion (p value 0.027). There was a significant difference between both groups regarding the number of soaked pads post-operatively as group 2 had more soaked pads than group 1 with a p-value of 0.003. However, there was no significant difference between both groups regarding estimated intraoperative blood loss **(Table 5).**

Table (5): Comparison between the two studied groups regarding blood transfusion, estimated intraoperative blood loss, occurrence of PPH and number of soaked pads

Variables	Group 1 (n=50)		Group 2 (n=50)		Test of significance	p-value
	No	%	No	%		
PPH					FE=6.4	**0.021***
Yes	0	0	6	12		
No	50	100	44	88		
Blood transfusion					FE= 6.383	**0.027***
Yes	0	0	4	8		
No	50	100	46	92		
Estimated intraoperative blood loss					t=0.034	0.973
Mean ± SD	645.70 ±31.23		753.30 ±30.90			
Range	600-700		700-800			
Number of soaked pads post-operative					U=2.963	**0.003***
Mean ± SD	1.66 ±0.48		2.40 ±1.46			
Range	1-2		1-6			

DISCUSSION

This was an observational comparative study between uterotonic drugs in the prevention of PPH in CS. According to the results of the current study, there was no discernible variation in demographic information between the two groups. This is in line with the findings of the research by **Mannaerts *et al.*** [9], which showed that 68 women with comparable demographic features were enrolled and randomly assigned to one of the two therapy groups. Also, this was documented with other previous studies [10].

Our study found that group 2 who received oxytocin had significantly lower hemoglobin levels 2 hours & 24 hours postoperatively. Also had significantly lower hematocrit than group 1 at 2 hours & 24 hours postoperatively. This is in line with the findings of **Taheripanah *et al.*** [11], which showed that oxytocin group had considerably larger mean hemoglobin drop, hematocrit, and bleeding volume than the carbetocin group. This is also in line with the findings of **Ibrahim *et al.*** [10] who found that the oxytocin group had lower post-operative hemoglobin and hematocrit than the carbetocin group. Unlike **Mannaerts *et al.*** [9], who reported that although the oxytocin group had slightly higher mean hemoglobin, the difference in hematocrit was not statistically significant.

Regarding preoperative SBP, we found that there was no discernible difference between the two groups, after spinal anesthesia, after uterotonics administration, and all postoperative intervals. This is in line with the research by **Ahmed *et al.*** [12], which discovered that there was no statistically significant variation in systolic blood pressure between the groups before surgery and throughout the whole recovery period. This is also supported by a research by **Mannaerts *et al.*** [9], which indicated that there was no discernible change in SBP upon administration or after six minutes or longer. After three minutes, the mean systolic blood pressure reduction for carbetocin was 14.4 mmHg (95% CI 9.5–19.3), and for oxytocin, it was 8.6 mmHg (95% CI 4.8–12.4). In contrast to the study by **Kansouh and El Naggar** [13] who found that two hours after CS, the oxytocin group's female participants had substantially greater SBP and DBP than the carbetocin group.

Also, we found that in terms of DBP in preoperative patients, there was no discernible difference between the two groups, after spinal anesthesia, after uterotonics by 1 minute, 3 minutes, at uterine repair, at the end of CS, 2 hours, 12 and 24 hours after CS, but, group 2's DBP significantly decreased following the delivery of uterotonics for five minutes. Unlike **Kansouh and El Naggar** [13] who discovered that after two hours of CS, the diastolic blood pressure of the women in the oxytocin group was greater. According to **Bashir and Sabha's study** [14], oxytocin and carbetocin both have hypotensive effects on hemodynamics. The oxytocin group showed reduced systolic blood pressure and diastolic blood pressure at uterine closure time and the fifth minute following injection. Additionally, diastolic blood pressure was shown to be statistically significant to be lower in the oxytocin group at the 3 and 5 minute administration time as well as 12 and 24 hours postoperatively, according to the study by **Abdelhamid *et al.*** [15].

Our study found that there was a notable distinction between the two groups with respect to the usage of additional uterotonic drugs as 17 cases in group 2 needed additional oxytocin dose and /or other uterotonic drugs (Methyl ergometrine & misoprostol). This is in line with a research by **Abdelhamid *et al.*** [15], which found that the oxytocin group had a highly significant demand for more uterotonic drugs. This is also supported by **Bashir and Sabha** [14], who discovered that group A did not get any extra uterotonics. Of the patients in the oxytocin group, 46% required extra uterotonics. This is also supported by the findings of **Borruto *et al.*** [16] who discovered that in contrast to five of the women (9.6%) getting an IV oxytocin infusion, two of the women (3.8%) receiving carbetocin needed extra uterotonics for clinical purposes. As opposed to **Yesmin *et al.*'s study** [17], which found that the oxytocin group had a much higher demand for extra uterotonic medications than the other group, but this difference was not yet statistically significant.

According to our research, there were notable differences between the two groups with relation to uterine contractions as group 1 had better uterine contractions 1 and 2 hours after delivery than group 2 (p value wax <0.001 and 0.011 respectively), and after 12 hours both groups had 100 % contracted uterus. This is consistent with **Taheripanah *et al.*** [11] who found that the oxytocin group required several times more uterine massage than the carbetocin group, and their mean uterine height (as measured in various ways) was considerably greater ($P < 0.05$). Also **Ahmed *et al.*** [12] found that the carbetocin group had better uterine contractility than oxytocin group. In contrast, **Abdelhamid *et al.*** [15] discovered that there was no statistically significant change in uterine contractility between the two medications. Additionally, **Bashir and Sabha** [14] discovered that uterine tone increased earlier in the oxytocin group—in less than 30 seconds—while it took with the carbetocin group 60 seconds to have an increase in uterine tone. But in the group that received carbetocin, the tone persisted.

We also found that there was a notable distinction between the two groups with respect to the development of PPH as there were 6 cases in group 2 had PPH after 2 hours of CS, and 4 cases of them needed blood transfusion. Additionally, there was no discernible difference in the predicted intraoperative blood loss between the two groups. According to **Borruto *et al.*** [16], the mean blood loss following the injection of carbetocin was 30 ml lower than that following the administration of oxytocin. With carbetocin, the proportion of patients experiencing a 500 ml blood loss was higher (81 vs. 55%). This is also supported by **Yesmin *et al.*** [17], who discovered that group I (the carbetocin group) lost 70–

100 ml less blood than the other group, despite the fact that the difference in blood loss between the two groups was not statistically significant. In contrast to **Ben Tareef *et al.* [18]** found that in both groups, the estimated or computed blood loss during Caesarean births was the same. When comparing the carbetocin group to the oxytocin group, the incidence of PPH was greater (10.3% vs. 6.6%). Two women (0.3%) in the oxytocin group and nine (1.4%) in the carbetocin group required blood transfusions. Also, **Abdelfath *et al.* [19]** found that the estimated blood loss during vaginal birth differed between the two medications in a way that was statistically significant and favored the carbetocin group. There was no significant difference between the two groups regarding the requirement for blood transfusion, however there was a statistically significant difference for the PPH between the two medications in favor of the Carbetocin group.

Strength of study: Randomization in our study had basic benefits as follows: It removes selection bias, levels out the groups concerning several known and unknown confounding or prognostic factors, and provides the foundation for statistical testing, including an assumption-based free statistical test of treatment equality.

Limitation of study: Small sample size of the study group. This is a unicenter study, multicenter study may strengthen our results.

CONCLUSION

From our study we concluded that for maintaining adequate uterine tone, minimizing blood loss, avoiding the need for additional uterotonic drugs and blood transfusions, and reducing the incidence of PPH, a single intravenous injection of carbetocin (100 mcg) appeared to be more effective than a continuous intravenous infusion of oxytocin (10 IU). It also had a similar safety profile and causes only minor side effects in the third stage and the first 24 hours following delivery. But, carbetocin had a higher cost than Oxytocin.

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