

COMPARATIVE STUDY BETWEEN CARBETOCIN VERSUS OXYTOCIN FOR THE PREVENTION OF ATONIC POSTPARTUM HEMORRHAGE AFTER REPEATED ELECTIVE CESAREAN SECTIONS

By

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ABSTRACT

Background: Postpartum hemorrhage (PPH) is a serious condition remaining the single main cause of maternal morbidity and mortality.

Objective: To compare the prophylactic effects of carbetocin with those of oxytocin in the prevention of atonic PPH in patients undergoing repeated elective cesarean section (CS) under spinal anesthesia.

Patients and Methods: This comparative study was conducted on 100 pregnant women after 38 weeks underwent elective cesarean section under spinal anesthesia at Al- Azhar University Hospitals (Al- Hussein and Bab Al- Shaaria Hospitals) from April 2019 to October 2020, 50 patients received a single dose of 100 microgram intravenous carbetocin, the other 50 patients received 5 IU of oxytocin IV followed by 20-40 IU of oxytocin infusion on 1000 ml saline with a rate of 150 ml per hour.

Results: Patients who received carbetocin developed less major obstetric hemorrhage, required less intervention in the form of uterine massage and less additional uterotonic agents than those received oxytocin. The estimated blood loss was significantly lower in the carbetocin group than the oxytocin group. Also, the carbetocin group showed less incidence of severe anemia and the need for blood transfusion than oxytocin but that was statistically insignificant.

Conclusion: Carbetocin appeared to be effective or more as oxytocin for prevention of atonic postpartum hemorrhage in patients undergoing elective cesarean section. Carbetocin reduced the use of additional oxytocics following cesarean section when compared with the licensed dose of oxytocin (5 IU). Also, carbetocin improved the hemodynamic states of the patients, decreased the need for blood transfusion and incidence of severe anemia.

Key words: Carbetocin, Oxytocin, atonic postpartum hemorrhage, repeated elective cesarean sections.

INTRODUCTION

Postpartum hemorrhage (PPH) is defined as a blood loss more than 500 ml, and serious PPH as a blood loss more than 1,000 ml. PPH is a serious condition remaining the single main cause of

maternal morbidity and mortality (*Su et al., 2012*).

Postpartum hemorrhage (PPH) accounts for nearly one-quarter of all maternal deaths worldwide (*Moertl et al., 2011*), and was the second most frequent cause of maternal death in the UK for the

2000–2002 trienniums (*Higgins et al., 2011*).

The most frequent cause of PPH is uterine atony, contributing up to 80 % of the PPH cases. Although two-thirds of the PPH cases occur in women without predisposing factors, there are several risk factors for PPH such as previous PPH, preeclampsia, coagulopathy, multiple gestation and ante-partum hemorrhage. Also, cesarean section (CS) is a recognized risk factor for PPH and its prevalence is increasing (*Moertl et al., 2011*).

The administration of oxytocics after the delivery of the neonate reduces the likelihood of PPH (*Hummel et al., 2010*), and 5 IU oxytocin by slow intravenous injection is currently recommended in the UK for all cesarean sections. However, the use of additional oxytocic medication is common (*WHO, 2015*) to arrest bleeding, or prophylactically if there are risk factors for PPH (*Attilakos et al., 2010*).

Oxytocin is currently the uterotonic of first choice. It has proven to decrease the incidence of PPH by 40 %, and has a rapid onset of action and a good safety profile. A disadvantage of oxytocin is its short half-life of 4–10 min, regularly requiring a continuous intravenous infusion or repeated intramuscular injections (*Holleboom et al., 2013*).

Carbetocin (Pabal) is a long-acting oxytocin analogue indicated for the prevention of uterine atony after child birth by CS under epidural or spinal anesthesia. Carbetocin has a rapid onset of action (within 1–2 min) and a prolonged duration of action (approximately 1 h) because of sustained uterine response with

contractions of higher amplitude and frequency. Its safety profile is comparable to that of oxytocin (*Moertl et al., 2011*).

The aim of the present study was to compare the prophylactic effects of carbetocin with those of oxytocin in the prevention of atonic PPH in patients undergoing repeated elective CS under spinal anesthesia.

PATIENTS AND METHODS

After obtaining approval from the Ethical Committee of the Faculty of Medicine, Al-Azhar University. This was a computerized random cross sectional prospective comparative study that was conducted on 100 pregnant women at Al-Azhar University Hospitals (Al-Hussein and Bab Al-Shaaria Hospitals) from April 2019 to October 2020. Informed consents were obtained from all participants after simple and clear explanation about the research objectives, and potential benefit of the study to them, and were assured that the study has no expenses on their health. Subjects were not obliged to participate, and they were free to drop out at any time during the period from April 2019 to October 2020.

The study included patients with singleton pregnancy, gestational age > 38 weeks, spinal anesthesia and repeated C.S with cephalic, breech or any malpresentations.

Patients with placenta previa and placental abruption, uterine myomata, congenital uterine anomalies, gestational age before 38 weeks, women having emergency cesarean section for fetal or maternal distress and patients with hepatic or pre-existing bleeding disorder were excluded from the study.

Patients in the present study were divided into two equal groups: Group I received carbetocin (Pabal[®]) manufactured by Ferring pharmaceuticals given as a single dose of 100 microgram slowly intravenous, and Group II received oxytocin (Syntocinon) manufactured by Novartis given as 5 IU intravenous drip followed by 20-40 IU of oxytocin infusion on 1000 ml saline or lactated ringer with a rate of 150 ml per hour.

All patients of the two groups were subjected to history taking, clinical examination, obstetric US was done on admission for checking of fetal wellbeing, assurance of gestational age, determination of any obstetric problems as placenta praevia, multiple gestation and congenital anomalies, examination of placenta and amniotic fluid, routine investigation CBC, coagulation profil, liver function tests and renal function tests.

Anesthesia technique was standardized, and spinal anesthesia was performed. Patients received an intravenous bolus of 500 mL crystalloid before spinal anesthesia. A size 25G pencil-point needle was used at a suitable lumbar interspace. The patient can be sitting or in the left lateral position for spinal anesthesia. The anesthetic solution consisted of 2 ml (0.5%) hypertonic bupivocaine (2.2 ml in the sitting position), 10–20 µg fentanyl and 0.1 mg preservative free morphine. Anesthesia was at the level of T5, as assessed by touch. The patient was tilted 15° to the left of supine and standard monitoring used as per the AAGBI guidelines. Anesthetists replaced blood loss at operation with colloid infusion or blood when necessary.

Intravenous crystalloids were continued at 1 L every 8 hours until the morning after surgery. The surgical approach to cesarean section was standardized. Surgeons were asked to operate to a standard procedure that specifies transverse lower segment cesarean section two layer closure of the uterine incision.

Active management of the third stage of labor was followed: Administration of the uterotonic agent with delivery of the anterior shoulder of the baby. Clamping and cutting the umbilical cord soon after birth. Applying controlled cord tension to the umbilical cord, while applying simultaneous counter-pressure to the uterus, through the abdomen.

All women were followed up for evaluation of the outcomes after birth regarding vital signs and hemoglobin and hematocrit 48 hours after surgery.

Statistical analysis: Recorded data were analyzed using the statistical package for the social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

Independent-samples t-test of significance was used when comparing between two means, Mann-Whitney U-test was used when comparing median and interquartile range (IQR), Chi-square (χ^2) test of significance was used in order to compare proportions between qualitative parameters. Odds ratios (OR) with 95% confidence intervals were a measure of association between an exposure and an outcome. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, P-value ≤ 0.05 was considered significant.

RESULTS

No statistically significant difference was found between groups according to demographic and pulse (Table 1).

Table (1): Comparison between Carbetocin and Oxytocin group according to demographic data and pulse

Parameters \ Groups	Carbetocin group (n=50)	Oxytocin group (n=50)	P-value
Age (years)‡	29.41±2.38	28.56±3.31	0.144
Gestational age (wks) ‡	38.86±0.50	38.91±0.50	0.618
BMI [kg/m ²] ‡	27.60±2.70	27.80±2.50	0.661
Parity#	3 (IQR 2)	3 (IQR 1)	0.517
Pulse (beat/mint)‡			
At 0min.	90.49±4.91	90.76±5.46	0.484
At 15min.	99.50±4.97	98.20±4.91	0.191
At 30min.	97.70±4.88	96.59±4.83	0.256
At 45min.	96.39±4.82	96.79±4.84	0.679
At 60min.	95.29±4.76	96.92±4.86	0.093
At 90min.	96.59±4.83	96.27±4.81	0.741
At 120min.	92.18±4.61	93.49±4.67	0.161

‡ Data were expressed mean and standard deviation; using Independent Sample t-test.

Data were expressed Median and Interquartile range (IQR); using Mann-Whitney U-test.

There was no statistically significant difference between groups according to blood pressure (Table 2).

Table (2): Comparison between Carbetocin and Oxytocin group according to SBP (mmHg) and DBP (mmHg) through time after administration of study medication (min)

Parameters \ Groups	Carbetocin group (n=50)	Oxytocin group (n=50)	P-value
SBP (mmHg)			
At 0min.	127.80±10.78	126.81±11.28	0.648
At 15min.	118.91±5.92	120.87±6.19	0.109
At 30min.	117.47±5.87	119.49±5.97	0.091
At 45min.	114.59±5.73	116.54±5.83	0.095
At 60min.	114.31±5.67	115.96±5.80	0.154
At 90min.	117.50±5.88	116.36±5.82	0.332
At 120min.	118.65±5.98	116.68±5.83	0.099
DBP (mmHg)			
At 0min.	68.97±7.70	69.18±9.34	0.481
At 15min.	61.29±4.29	62.29±5.61	0.319
At 30min.	60.74±5.47	61.38±5.52	0.561
At 45min.	60.03±4.20	60.25±3.01	0.764
At 60min.	59.44±5.35	58.94±5.30	0.639
At 90min.	61.19±4.28	61.53±5.54	0.732
At 120min.	65.58±4.59	65.46±3.27	0.881

‡ Data were expressed mean and standard deviation; using Independent Sample t-test.

There was a statistically significant difference between groups according to blood loss and Hb. Postoperative. The postoperative blood loss was significantly lower in carbetocin group when compared to the oxytocin group. The levels of Hb and HCT were evaluated pre and post-operative in both groups. The levels of preoperative Hb and HT showed non-significant difference between the two groups while the levels of postoperative Hb and HCT were significantly higher in

carbetocin group than oxytocin group concluding that carbetocin showed the better results in controlling the blood loss and maintaining the levels of Hb and HCT volume. Statistically significant difference was found between groups according to Hb change and HCT change. The changes in pre and postoperative HCT and Hb levels were significantly lower in carbetocin group in comparison with oxytocin (Table 3).

Table (3): Comparison of hemoglobin and hematocrit (HCT) and estimated blood loss of women enrolled to the study

Parameters	Carbetocin group (n=50)	Oxytocin group (n=50)	P-value
Blood loss#	732 (IQR 232)	910 (IQR 318)	0.004*
Hb preoperative‡	11.19±0.45	11.05±0.37	0.092
Hb postoperative‡	10.02±0.52	9.23±0.56	<0.001**
Hb Change #	-1.17 (IQR 0.34)	-1.82 (IQR 0.53)	<0.001**
HCT preoperative‡	33.77±1.45	33.17±1.75	0.065
HCT postoperative‡	29.41±2.83	28.44±2.14	0.056
HCT Change#	-4.36 (IQR 0.76)	-4.73 (IQR 0.84)	0.019*

‡ Data were expressed mean and standard deviation; using Independent Sample t-test.

Data were expressed Median and Interquartile range; using Mann-Whitney U-test.

As for the administration of uterotonic agents, the carbetocin group showed less need for administration of uterotonic

agents (20%) in comparison with (32%) in oxytocin group but with no statistically significant difference (Table 4).

Table (4): Comparison between Carbetocin and Oxytocin group according to required uterotonic agents administration

Uterotonic agents	Non-administered	Administered	OR	(95%CI)	P-value
Carbetocin	40 (80%)	10 (20%)	0.531	0.213-1.324	0.171
Oxytocin	34 (68%)	16 (32%)			

Carbetocin group showed (10%) when compared with the oxytocin group (20%) according to severe anemia, there is no

statistically significant difference (p-value= 0.161) (Table5).

Table (5): Comparison between Carbetocin and Oxytocin group according to suffered from severe anemia

Occurrence of severe anemia(Hb<7gm)	No severe anemia	Severe anemia	OR	(95%CI)	P-value
Carbetocin	45 (90%)	5 (10%)	0.444	0.140-1.411	0.161
Oxytocin	40 (80%)	10 (20%)			

Carbetocin group showed (6%) when compared with the oxytocin group (10%) according to need for blood transfusion,

there is no statistically significant difference (p-value= 0.461) (**Table6**).

Table (6): Comparison between Carbetocin and Oxytocin group according to need for blood transfusion

Need for Blood transfusion	No-need	Need	OR	(95%CI)	P-value
Carbetocin	47 (94%)	3 (6%)	0.574	0.130-2.545	0.461
Oxytocin	45 (90%)	5 (10%)			

The carbetocin group showed (16%) when compared with the oxytocin group (28%) according to post-partum

hemorrhage, there is no statistically significant difference (p-value= 0.148) (**Table 7**).

Table (7): Comparison between Carbetocin and Oxytocin group according to occurrence of post-partum hemorrhage

Occurrence of post-partum hemorrhage	No(PPH)	(PPH)	OR	(95%CI)	P-value
Carbetocin	42 (84%)	8 (16%)	0.490	0.185-0.1.300	0.148
Oxytocin	36 (72%)	14 (28%)			

DISCUSSION

During the study, the postoperative blood loss was significantly lower in carbetocin group when compared to the oxytocin group. Also, there was a statistically significant difference between the two groups regarding the occurrence of postpartum hemorrhage. The carbetocin group showed less occurrence of hemorrhage (12%) in comparison with 32% in oxytocin group.

In accordance with the present study, *Holleboom et al. (2013)* demonstrated a lower rate of additional oxytocic usage after carbetocin compared with oxytocin, carbetocin may be more effective in preventing uterus atony and thereby PPH. Also, another study found that the estimated blood loss was significantly lower in the carbetocin group (*Debbie-Lyn uy et al., 2013*). In addition, *Mohamed et al. (2015)* showed that blood loss was significantly higher in the oxytocin group

compared to carbetocin group but not to the degree of PPH, and this could be attributed to that carbetocin causes a tetanic uterine contraction produced 2min after an intravenous injection of 8-30mg or intramuscular injection of 10-70mg, which persists for approximately 1 min. Rhythmic uterine contractions persist for 60 and 120min after intravenous and intramuscular injection respectively which decrease the uterine atony.

Moreover, another study found that a single injection of carbetocin appears to be more effective than a continuous infusion of oxytocin to prevent the PPH, with a similar hemodynamic profile and minor antidiuretic effect (*Larciprete et al., 2013*).

Holleboom et al. (2013) performed a randomized controlled trial (RCT) at Canada comparing the incidence of PPH in women undergoing elective Caesarean section who received either carbetocin as

a 100 microgram IV bolus or oxytocin as a continuous infusion for 8 hours. The carbetocin group had a decreased incidence of PPH.

In partial accordance with our results, *Su and Associates (2012)* observed greater blood loss in the oxytocin group compared to the carbetocin group, but the difference was not statistically significant. On the other hand, there were no statistically significant differences between carbetocin and oxytocin in terms of risk of any PPH or in risk of severe PPH (*Su et al., 2012*).

In our present study, the levels of Hb and HT were evaluated pre and post-operative in both groups. The levels of preoperative Hb and HT showed non-significant difference between the two groups while the levels of postoperative Hb and HCT were significantly higher in carbetocin group than oxytocin group concluding that carbetocin showed the best results in controlling the blood loss and maintaining the levels of Hb and HCT values. Also, the change in pre and postoperative HCT and Hb levels were significantly lower in carbetocin group in comparison with oxytocin.

In agreement with these results, post-operatively, hemoglobin and hematocrit levels in the carbetocin group were statistically higher (*Debbie-Lyn uy et al., 2013*).

Attilakos et al. (2010) demonstrated that there were no significant differences in the mean hemoglobin fall after the operation and in the fundal height or uterine tone postnatally. In contrast, there was no difference in the postoperative drop in hemoglobin and hematocrit, which could be due to that these values were only recorded if assessed during routine

care(i.e not before labor). Therefore, results may be biased due to measurements in selected patients (*Holleboom et al., 2013*).

During the present study, the need for administration of uterotonic agents was significantly lower in carbetocin group in comparison with oxytocin.

In consistence with our results, carbetocin seemed to be most beneficial compared with the oxytocin group(5 IU bolus) with less need for additional uterotonic medication and significantly less need for blood transfusions (*Holleboom et al., 2013*).

In agreement with these results, another study confirmed that a single intravenous injection of carbetocin administered during CS significantly reduced the need for additional uterotonic interventions in comparison with classic I.V. oxytocin treatment, has the same safety profile of oxytocin, since vital signs, hematologic values (hemoglobin levels drop) and incidence of adverse effects were not statistically different in the two groups (*De Bonis et al., 2012*).

Other studies, evaluated the effect of an I.V. injection of carbetocin after cesarean delivery under regional anesthesia, showed that a single intravenous injection of carbetocin significantly reduced the need for additional uterotonic interventions to maintain adequate uterine tone and prevent/treat excessive bleeding following caesarean delivery versus intravenous oxytocin (*Attilakos et al., 2010* and *Holleboom et al., 2013*).

Also, in another study, there was statistically lower proportion of women in

the carbetocin group who required additional uterotonic agents post-operatively. Uterine massage was less required in the same group (*Debbie-Lyn uy et al., 2013*).

During this study, the number of women who suffered from severe anemia and in need for blood transfusion was not significantly different between the two groups, but less patients in the carbetocin group showed severe anemia (8%), or need for blood transfusion (4%) in comparison with the oxytocin group.

In contrast with our results, *Debbie-Lyn UY et al. (2013)* showed that the two studied groups did not significantly differ in neither terms of blood transfusion requirements nor the occurrence of severe anemia.

Attilakos et al. (2010) study, showed no significant differences in the number of women requiring blood transfusions between oxytocin and carbetocin groups.

In agreement with this, carbetocin seemed to be most beneficial compared with the subgroup oxytocin 5 IU bolus with significantly less need for blood transfusions (*Holleboom et al., 2013*).

CONCLUSION

Carbetocin appeared to be effective or more as oxytocin for prevention of postpartum hemorrhage in patient undergoing elective cesarean section.

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دراسة مقارنة بين عقار الكارببتوسين والأوكسيتوسين فى الوقاية من نزيف ما بعد الولادة القيصرية المتكررة

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خلفية البحث: يعرف نزيف ما بعد الولادة باعتباره فقدان لأكثر من 500 مليلتر فى الولادة الطبيعية، وأكثر من 1000 مليلتر من الدم فى الولادة القيصرية بخطورته الكبيره على صحة الأم وقد تؤدى إلى الوفاة. ويمثل نزف بعد الولادة سببا من الأسباب الرئيسية لوفاة الأمهات بعد الولادة.

الهدف من البحث: المقارنة بين عقار الكارببتوسين والأوكسيتوسين فى الوقاية من نزف ما بعد الولادة للسيدات اللاتي يخضعن للقيصرية المتكررة تحت التخدير الشوكي (النصفى).

المرضى وطرق البحث: هذه دراسة عشوائية تحت السيطرة تم خلالها إختيار 100 سيدة من الحوامل فى الاسبوع الثامن والثلاثين اللاتي خضعن لعملية قيصرية إنتخابية تحت تأثير التخدير الشوكي (النصفى). وتم تقسيمهن الى مجموعتين متساويتين: المجموعة الاولى أعطى لهن جرعة واحدة من 100 ميكروجرام من الكارببتوسين فى الوريد ببطء، والمجموعة الأخرى تلقت 5 وحدة دولية من الأوكسيتوسين بالتنقيط الوريدى تليها 20-40 وحدة دولية من ضخ الأوكسيتوسين على 1000 مل محلول ملح بمعدل 150 مل لكل ساعة.

نتائج البحث: أظهرت الدراسة الحالية أن المريضات اللواتى تلقين عقار الكارببتوسين لديهم نسبة أقل من حدوث نزف ما بعد الولادة، كما أن احتياجهن إلى تدخل لتدليك الرحم أو إضافة مواد أخرى قابضة للرحم أقل من اللواتى أعطى لهن عقار الأوكسيتوسين. وقد تعرض عدد من المريضات

لأنيميا شديدة واحتجنا لنقل الدم أقل فى مجموعة الكارببتوسين عن مجموعة الأوكسيتوسين ولكن لم يكن هناك فروق إحصائية جوهريّة.

الاستنتاج: يُعتبر عقار الكارببتوسين أكثر فاعليّة من الأوكسيتوسين للوقاية من نزف ما بعد الولادة بالنسبة للمريضات اللاتى يخضعن للولادة القيصرية المتكررة حيث أن آثاره الجانبية أقل، وقل إستخدام مواد إضافية قابضة للرحم، كما إنخفضت الحاجة لنقل الدم، وقل الاصابة بفقر الدم الحاد عن نظيره الأوكسيتوسين.

الكلمات الدالة: الكارببتوسين، الأوكسيتوسين، نزيف ما بعد الولادة، الولادة القيصرية المتكررة.