Arch Gynecol Obstet
DOI 10.1007/s00404-015-3911-y

MATERNAL-FETAL MEDICINE

Carbetocin versus oxytocin in the management of atonic post partum haemorrhage (PPH) after vaginal delivery: a randomised controlled trial

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Received: 28 May 2015 / Accepted: 9 October 2015

Abstract

Objective The objective of this study is to compare the effectiveness and safety of carbetocin vs. oxytocin in the management of atonic post partum haemorrhage (PPH) after vaginal delivery.

Methods A prospective randomised study was conducted in which 100 pregnant women were randomised into 2 equal groups: group 1 received Carbetocin 100 µgm (Pabal® Ferring, UK) and group 2 received oxytocin 5 IU (Syntocinon®, Novartis, Switzerland).

Results The amount of blood loss and the need for other uterotonics were significantly lower in the carbetocin group (811 ± 389.17 vs. 1010 ± 525.66 and 10/50 vs. 21/50). There was no significant difference between the carbetocin and oxytocin groups regarding occurrence of major PPH (6 vs. 11), the need for blood transfusion (6 vs. 9), the difference between blood haemoglobin levels before delivery and 24 h after delivery (0.6 ± 0.28 vs. 0.56 ± 0.25), respectively. There was no significant difference between the 2 study groups regarding both systolic and diastolic blood pressure measured immediately after the drug administration and at 30 and 60 min later. Regarding the drugs side effects, there was no significant difference between the 2 groups in the occurrence of nausea, vomiting, tachycardia, flushing, dizziness, headache, shivering, metallic taste, dyspnea, palpitations and itching.

Conclusions Carbetocin is a better alternative to oxytocin in management of atonic PPH with non-significant hemodynamic changes or side effects .

Keywords Carbetocin · Oxytocin · Atonic postpartum haemorrhage · Vaginal delivery

Introduction

Primary postpartum haemorrhage (PPH) is defined as blood loss of ≥500 ml within 24 h after vaginal delivery or ≥1000 ml following caesarean section [1]. It is associated with considerable morbidity and is a leading cause of maternal mortality worldwide [1, 2].

Of the estimated 287,000 maternal deaths worldwide, 85 % occur in low- and middle-income countries [3]. The rate of PPH has increased in recent years in many high income countries, including the United States, Canada, Australia, Norway and Ireland [4–10]. In particular, PPH due to uterine atony has contributed to this rise, although the reasons for this remain unclear [6, 10, 11].

The incidence of postpartum haemorrhage has been reported to be to be 3.9 % in women delivered vaginally [12].

The first cause of haemorrhage at the time of delivery is uterine atony; therefore there is general agreement that active management of the third stage of labour is recommended [13–15].

Oxytocin is the most widely used uterotonic agent [16], but has a half-life of only 4–10 min [17], that is why it is better administered as a continuous intravenous infusion to achieve sustained uterotonic activity [18].

Trial Registration Number NCT02304055.

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Carbetocin is a synthetic long-acting oxytocin agonistic analogue with prolonged half-life prolonging its pharmacological effects [19]. Its prolonged uterine activity may theoretically offer advantages over oxytocin in the management of the third stage of labour. The side-effect profile of carbetocin was not found to be different from that of Oxytocin [20], but may prove to be advantageous when compared to Syntometrine [21].

The aim of this study was to compare the effectiveness and safety of carbetocin vs. oxytocin in the management of atonic PPH after vaginal delivery.

Materials and methods

This study was a prospective double-blind randomised study. It was conducted on 100 pregnant women attending the labour wards in Kasr Al Ainy and Beni Suef maternity hospitals from May 2013 to December 2014.

The study was approved by local ethics committee. All women attending the labour ward were approached, the nature of the study and expected values were explained and women were invited to participate in the study in case they develop PPH. Only women signing informed consents were included in the study. All participants had PPH defined as vaginal bleeding >500 ml after vaginal delivery and uterine atony confirmed by abdominal palpation. The exclusion criteria were gestational age <37 weeks, genital tract trauma, coagulation defect, women with hypertension, preeclampsia, cardiac, renal or liver diseases, epilepsy and known hypersensitivity to carbetocin or oxytocin.

100 women with atonic PPH were randomly divided into 2 equal groups using computer generated random numbers. An independent person generated the allocation sequence, both drugs were coded and packed before recruitment and kept in the labour ward. Neither the patients nor the medical personnel knew the nature of the drugs before the end of the study when the codes were broken. Allocation was concealed using sequentially numbered opaque sealed envelopes containing the drug codes. Each woman was assigned an order and received the drug which code was present in the envelope corresponding to her number. Once atonic PPH developed, two 14-gauge cannulas were inserted and a crystalloid intravenous (IV) infusion was started, oxygen concentration of 10 l/min was administered via face mask. The fundus was rubbed, a Foley's catheter was inserted and a fluid balance chart was recorded. Pulse and blood pressure were recorded every 15 min; venepuncture was done for cross matching 4 units of blood, full blood count, coagulation screen and urea and electrolytes assessment. Ultrasound scan and exploration of the genital tract were done to exclude retained products of conception and genital tract trauma.

Group 1 received Carbetocin 100 µgm (Pabal® Ferring, UK) and group 2 received oxytocin 5 IU (Syntocinon®, Novartis, Switzerland). The allocated drug was diluted in 10 ml saline and given slowly i.v. by an independent registrar.

The uterine tone and amount of bleeding were assessed and the need for further uterotonic agents and blood transfusion was determined 2 min after giving the drug. Blood loss was estimated through weighing the swabs and using pictorial charts. Blood haemoglobin was assessed 24 h after delivery.

If bleeding was not controlled after giving the drug the following measures were taken, respectively: oxytocin (Syntocinon®, Novartis, Switzerland) infusion 40 IU in 500 ml of lactated ringer's solution 125 ml/h, Misoprostol (Cytotec® Pfizer, New York, USA) 1000 µg rectally, insertion of an intrauterine Bakri balloon, laparotomy and B lynch stitch, bilateral uterine artery ligation, bilateral internal iliac artery ligation and hysterectomy.

We recorded possible complications like nausea, vomiting, tachycardia, flushing, dizziness, headache, shivering, metallic taste, dyspnea, palpitation and itching.

Statistics

Data were statistically described in terms of mean ± standard deviation (±SD), or frequencies (number of cases) and percentages when appropriate. Comparison of numerical variables between the study groups was done using independent t test. For comparing categorical data, Chi-square (χ^2) test was performed. Exact test was used instead when the expected frequency is <5. p values < 0.05 were considered statistically significant. All statistical calculations were done using computer program SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) release 15 for Microsoft Windows.

Results

The flow of patients in the study is shown in Fig. 1. The 100 patients were classified into 2 groups: Group 1 included 50 patients who received carbetocin and group 2 included 50 patients who received oxytocin. There was no significant difference between the 2 study groups regarding age, gravidity, parity, body mass index, gestational age and neonatal birth weight (Table 1).

There was no significant difference between the groups regarding the duration of 1st, 2nd and 3rd stages of labour (Table 1). Risk factors for atonic and traumatic postpartum haemorrhage were not significantly different between the groups (Table 2). The amount of blood loss and the need for other uterotonics were significantly lower in the carbetocin group (Table 3, Fig. 2). There was no significant

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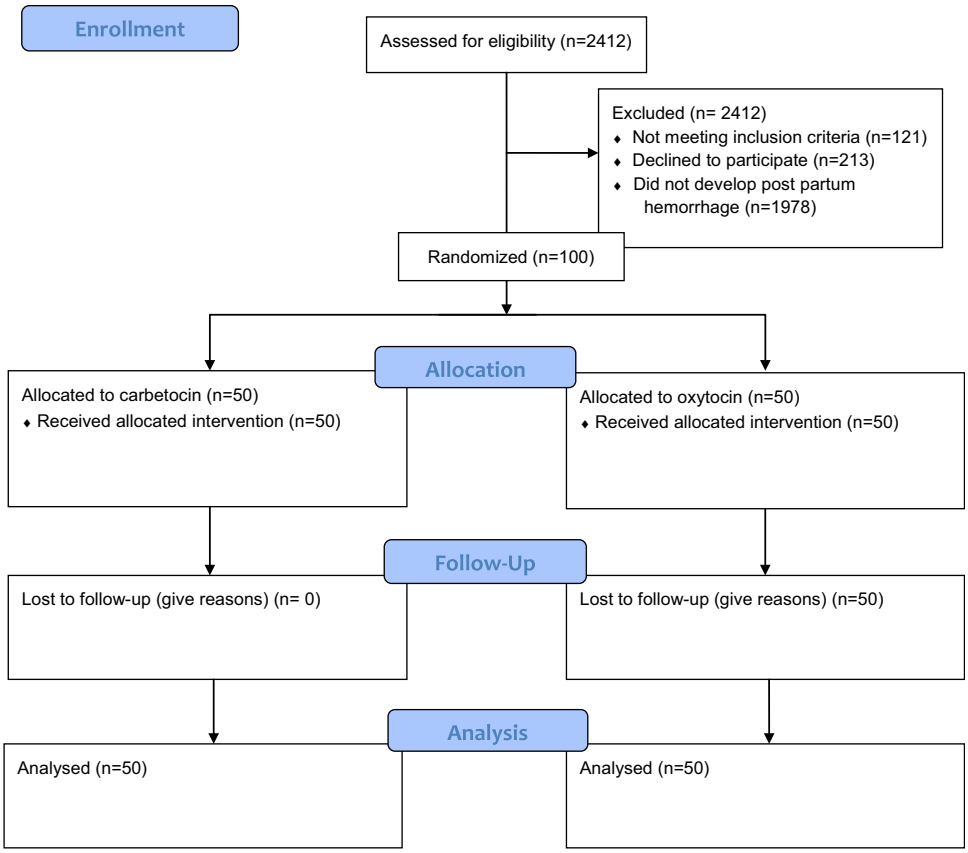

Fig. 1 Consort flow diagram of the study

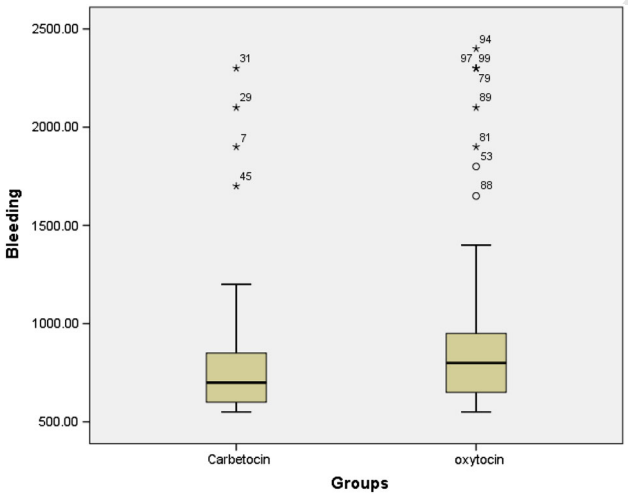

Fig. 2 Amount of bleeding in the groups

difference between the 2 study groups regarding occurrence of major PPH, the need for blood transfusion, the difference between blood haemoglobin levels before delivery and 24 h after delivery (Table 3).

There was no significant difference between the 2 study groups regarding the systolic and diastolic blood pressure measurements immediately after the drug administration and at 30 and 60 min later (Table 4). Regarding the drugs side effects, there was no significant difference between the 2 groups regarding the occurrence of nausea, vomiting, tachycardia, flushing, dizziness, headache, shivering, metallic taste, dyspnea, palpitations and itching (Table 5).

Table 6 presents different measures needed to control the bleeding after failure of carbetocin and oxytocin. One patient in the oxytocin group had uterine artery ligation but bleeding was not controlled and internal iliac artery ligation was needed. There were no mortalities and hysterectomy was not needed in any patient.

Discussion

To the best of our knowledge, this is the first study to compare carbetocin effectiveness, safety and hemodynamic effects with oxytocin in the management, rather than prevention, of atonic PPH.

Our results have shown that when compared to oxytocin, carbetocin has significantly decreased postpartum blood loss and lower need for other uterotonics in women with atonic PPH without significant side effects or hemodynamic changes. But there was no significant difference between both drugs in the mean fall of haemoglobin before and after delivery.

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Table 1 Baseline characteristics of the groups

	Carbetocin ($n = 50$)	Oxytocin ($n = 50$)	p value
Age (years)	30.02 ± 6.02	29.26 ± 5.84	0.523
Gravidity	1.02 ± 0.82	0.96 ± 0.75	0.704
Parity	0.66 ± 0.65	0.58 ± 0.0.78	0.582
BMI (kg/m^2)	25.1 ± 3.71	25.32 ± 3.31	0.755
Gestationa age (weeks)	39.86 ± 0.85	40.06 ± 0.93	0.274
Duration of first stage (h)	10.78 ± 1.91	10.82 ± 2.06	0.92
Duration of second stage (mins)	91.72 ± 16.12	93.66 ± 15.23	0.538
Duration of third stage (mins)	3.84 ± 3.4	4.08 ± 3.34	0.723
Neonatal birth weight (g)	3176 ± 376.64	3182 ± 35.25	0.935

Data are presented as means and standard deviations

BMI body mass index

Table 2 Risk factors for postpartum haemorrhage

		Carbetocin ($n = 50$)	Oxytocin ($n = 50$)	p value
Number of atonic PPH risk factors	No atonic PPH risk factors	23 (46 %)	21 (42 %)	0.687
	1 atonic PPH risk factor	21 (42 %)	20 (40 %)	0.839
	2 atonic PPH risk factors	6 (12 %)	9 (18 %)	0.401
Risk factors for atonic PPH[a]	History of PPH	1 (2 %)	3 (6 %)	0.617
	Anaemia	13 (26 %)	18 (36 %)	0.28
	Foetal macrosomia (>4000 gm)	3 (6 %0	2 (4 %)	1
	Prolonged labour(>12 h)	12 (24 %)	14 (28 %)	0.82
	Twin pregnancy	2 (4 %)	2 (4 %)	1
	APH	3 (6 %)	3 (6 %)	1
Risk factors for traumatic PPH[a]	Episiotomy	22 (44 %)	30 (60 %)	0.109
	Lacerations	3 (6 %)	4 (8 %)	1

PPH postpartum haemorrhage

[a] Data are presented as frequencies and percentages

Table 3 Bleeding and Hb results of the groups

	Carbetocin	Oxytocin	p value
Amount of bleeding (ml)	811 ± 389.17	1010 ± 525.66	0.034
Need for other uterotonics[a]	10 (20 %)	21 (42 %)	0.017
Major PPH (>1000 ml)[a]	6 (12 %)	11 (22 %)	0.183
Need for blood transfusion[a]	6 (12 %)	9 (18 %)	0.401
Hb before delivery (g/dl)	11.45 ± 1.45	11.27 ± 1.43	0.55
Hb 24 h after delivery(g/dl)	10.85 ± 1.51	10.71 ± 1.5	0.645
Hb difference	0.6 ± 0.28	0.56 ± 0.25	0.529

Data are presented as means and standard deviations

[a] Data are presented as numbers and percents

This can be explained by the known longer half-life of Carbetocin effecting more uterine response, in terms of frequency and amplitude of uterine contractions [19].

Our results agreed with those of Samimi et al. who randomised 200 women undergoing vaginal delivery to receive either carbetocin or Syntometrine to prevent PPH. They found that the need for additional uterotonics was significantly lower in carbetocin group. They concluded that carbetocin is more effective than syntometrine in the prevention of PPH [22].

Our results have also agreed with those of Maged et al. who randomised 200 women delivering vaginally with at

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Table 4 Blood pressure measurements in the groups

		Carbetocin	Oxytocin	*p* value
Systolic blood pressure (mmHg)	Immediately after drug administration	109.72 ± 6.18	110.14 ± 6.72	0.746
	30 min after drug administration	104.68 ± 6.49	105.1 ± 7.55	0.766
	60 min after drug administration	106.86 ± 6.17	107.58 ± 6.49	0.571
Diastolic blood pressure (mmHg)	Immediately after drug administration	72.4 ± 6.57	72.26 ± 6.83	0.917
	30 min after drug administration	68.88 ± 6.03	69.42 ± 6.93	0.679
	60 min after drug administration	70.6 ± 5.68	71.32 ± 6.98	0.573

Data are presented as mean ± SD

Table 5 Drug side effects

	Carbetocin ($n = 50$)	Oxytocin (50)	*p* value
Nausea	2 (4 %)	1 (2 %)	0.495
Vomiting	1 (2 %)	0	1
Tachycardia (h >100 b/min)	19 (38 %)	22 (44 %)	0.542
Flushing	1 (2 %)	0	1
Dizziness	2 (4 %)	1 (2 %)	1
Headache	1 (2 %)	0	1
Shivering	1 (2 %)	1 (2 %)	1
Metallic taste	1 (2 %)	0	1
Dyspnea	0	1 (2 %)	1
Palpitations	2 (4 %)	0	1
Itching	0	1 (2 %)	1

Data are presented as number and percent

Table 6 Measures needed to control the bleeding after failure of carbetocin and oxytocin

	Carbetocin ($n = 10$)	Oxytocin ($n = 21$)
Oxytocin infusion	3 (30 %)	7 (33.3 %)
Misoprostol	5 (50 %)	9 (42.9 %)
Bakri balloon	1 (10 %)	2 (9.5 %)
B lynch stitch	1	2 (9.5 %)
Internal iliac artery ligation	0	1 (4.8 %)
Hysterectomy	0	0

No mortalities and no need for hysterectomy

least 2 risk factors of atonic PPH to receive 100 µg IM of carbetocin or 5 IU IM of oxytocin. They found that the amount of bleeding, occurrence of PPH and need for other uterotonics were significantly lower in carbetocin group. They concluded that Carbetocin is a better alternative to traditional oxytocin in prevention of PPH in women with at least 2 factors of PPH with minimal hemodynamic changes and side effects [23].

Boucher et al. randomised 160 women undergoing vaginal delivery with at least one risk factor for PPH to receive either carbetocin 100 µgm IM or oxytocin 10 IU iv oxytocin infusion over 2 h. The need for uterine massage and other uterotonics was significantly lower in the carbetocin group, these results agreed with ours [24].

Attilakos et al. randomised 377 women undergoing caesarean sections to receive either IV carbetocin 100 µg or IV oxytocin 5 IU after the delivery of the baby. The carbetocin group needed significantly less uterotonic drugs, which agrees with our findings [20].

Boucher et al. [24] and Attilakos et al. [20] have found no significant difference in the amount of bleeding between the groups which is different from our findings. Samimi et al. [22] and Maged et al. [23] have found that the mean fall of haemoglobin before and after delivery was lower in the carbetocin group, but our results have not shown this difference. This discrepancy in results may be attributed to the difference in the studied populations; we studied women with atonic PPH but Boucher et al., Samimi et al.,

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Attilakos et al. and Maged et al. were studying women at risk of developing PPH.

We did not find a significant difference between the 2 groups in the systolic and diastolic blood pressure measurements immediately after the drug administration, 30 and 60 min later.

Our results agreed with those of Moertl et al. who studied 56 women undergoing elective caesarean section after spinal anaesthesia. They measured hemodynamic parameters taken for 500 s upon administration of a slow intravenous bolus of 100 μg of carbetocin or 5 IU of oxytocin to prevent PPH. They found a non-significant difference in the hemodynamic effects of both drugs [25].

However, our results disagreed with those of Samimi et al. who found that the systolic BP measurements at 0, 30 and 60 min after delivery were significantly higher in the syntometrine group [22]. In addition to the difference in the studied populations, the difference between our results and those of Samimi et al. may be attributed to the physiological hemodynamic effects in response to PPH and the hemodynamic effect of crystalloid infusions in our study. Moreover, any difference in the drugs hemodynamic effects in our study may have been masked by the additional given uterotonic drugs including the prophylactic dose of ergometrine and blood transfusion.

In our study, there was no significant difference between the 2 groups regarding the occurrence of nausea, vomiting, tachycardia, flushing, dizziness, headache, shivering, metallic taste, dyspnea, palpitations and itching. These results agree with those of Maged et al. [23], Moertl et al. 2011 [25] and Attilakos et al. [20] who found no significant difference in the side effects between carbetocin and oxytocin apart from significant tachycardia in the oxytocin group reported by Maged et al.

The main strength of this study is being the first of its kind to compare the roles of carbetocin and oxytocin in the management, rather than prevention, of atonic PPH. The main weakness of the study was the sample size which was not large enough to detect a significant difference between the groups in the development of major haemorrhage and reducing the need for blood transfusion. Further studies with larger sizes are needed to detect these differences; data from this study can be used to adequately power these studies.

We concluded that carbetocin is a better alternative to oxytocin in the management of atonic postpartum haemorrhage after vaginal delivery as it decreases postpartum blood loss and need for additional oxytocics without significant side effects or hemodynamic changes. Further studies with larger sample sizes are needed.

Compliance with ethical standards

Conflict of interest All authors declare no conflict of interests. This research did not receive any specific grant from any funding agency in the public, commercial or not-for-profit sector.

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