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Intra-umbilical vein injection of carbetocin versus oxytocin in the management of retained placenta

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ABSTRACT

Introduction: Retained placenta can be defined as lack of expulsion of the placenta within 30 min of delivery of the infant. It is a significant cause of maternal mortality and morbidity throughout the developing world.
Aim of the work: The aim of this study was to compare the efficacy of intra-umbilical vein injection of carbetocin versus oxytocin in the management of retained placenta.
Patients and methods: A total of 200 women were included in this study. They were divided into two groups; each 100 women. The first group received intra-umbilical vein injection of 1 mL carbetocin (containing 100 μg carbetocin) diluted in 20 mL normal saline 0.9% and the second group received intra-umbilical vein injection of 20 IU oxytocin diluted in 20 mL normal saline 0.9%.
Results: Total blood loss (ml) and duration of the third stage of labor (minutes) were significantly lower in carbetocin group when compared to oxytocin group. Postoperative Hb concentration (g/dl) was significantly higher in carbetocin group. Also there was a highly significant difference between both groups as regard change in Hb concentration (g/dl) with less change in the carbetocin group. The need for additional uterotonic drugs following placental delivery and the occurrence of postpartum hemorrhage and the need for blood transfusion were significantly lower in the carbetocin group.
Conclusion: Intra-umbilical carbetocin is more effective than intra-umbilical oytocin as a method for management of retained placenta. Intra-umbilical carbetocin seems to have more acceptable hemodynamic safety profile when compared to intra-umbilical oxytocin in the management of retained placenta.

Introduction

The incidence of retained placenta (RP) varies greatly around the world, affecting between 0.1 and 3.3%of vaginal deliveries depending on the population studied [1]. There is no consensus on the length of the third stage, after which the placenta should be called 'retained' after vaginal delivery. The choice of timing is a balance between the risk of post-partum hemorrhage (PPH), the likelihood of spontaneous delivery and the knowledge from cesarean section (CS) studies that the manual removal itself can cause hemorrhage [2,3].

There is no evidence that, in an uncomplicated delivery without bleeding, interventions to accelerate delivery of the placenta before the traditional 30 to 45 min will reduce the risk of PPH [4]. However, another study showed that postpartum hemorrhage risk increases significantly when the third stage of labor duration is 20 min or more, suggesting that the definition of a prolonged third stage of labor being 30 min or more may be outdated [5]. The most common treatment for a RP is manual removal, which requires an operating theatre, surgeon, and anesthetist. When these facilities are unavailable, the mortality rate can reach as high as 10% [1].

The role of systemic oxytocics in the management of RP is controversial. It has been suggested that RP is associated with retroplacental contractile abnormalities. To overcome this contractile failure, oxytocics have been injected through the umbilical vein for direct delivery to the retroplacental myometrium. This modality of treatment may be further improved if more effective delivery of oxytocics to the myometrium can be achieved [6–8].

Although oxytocin is the most widely accepted uterotonic agent, other drugs are available; however, which agent is ideal for RP has yet to be clearly identified. Carbetocin is a synthetic long-acting oxytocin analogue. It has a half-life of 40 min (approximately 4–10 times longer than oxytocin), and uterine contractions occur in less than 2 min after

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i.v. administration of the optimal dosage of 100 μg [9]. Single dose of intramuscular carbetocin 100 μg may be more effective as compared to a single intramuscular dose of syntometrine in reducing postpartum blood loss with a smaller drop in hemoglobin levels and less adverse effects [10]. A recently published report revealed that carbetocin should be used instead of continuous oxytocin infusion in elective cesarean deliveries for PPH prevention and to decrease the need for therapeutic uterotonics [11].

The aim of this study was to compare the efficacy of intra-umbilical vein injection of carbetocin versus oxytocin in the management of retained placenta.

Patients and methods

This comparative prospective double blind randomized clinical trial was conducted in Obstetrics and Gynecology Department, Faculty of Medicine, Zagazig University Hospitals from October 2014 to October 2018. Inclusion criteria were pregnant women beyond 34 weeks of gestation with a singleton living fetus, vertex presentation, delivered vaginally spontaneously without the need for episiotomy with failure of placental delivery (retained non separated placenta) after 30 min of intravenous injection of 10 IU of oxytocin and 0.2 mg of methylergometrine (uterotonics were immediately injected after delivery of the anterior shoulder of the baby) and in the presence of an intact umbilical cord. After delivery of the baby the cord was clamped and cut and the clamp was left in position.

The exclusion criteria were maternal hypovolemic (hemorrhagic) shock, history of previous uterine scar, previous history of postpartum hemorrhage, antepartum hemorrhage in the current pregnancy, prolonged labor, intrauterine fetal death, precipitate labor, multifetal gestation, increased amniotic fluid volume, intrauterine infection, forceps or vacuum delivery, any medical disorders with pregnancy (e.g., cardiac disease, liver disease), cervical, vaginal, vulvar or perineal tears detected after placental delivery, pregnant women who received anticoagulant therapy, or those with low platelets count or coagulopathy, and women who received regional anesthesia.

After diagnosing the patient as a case of retained placenta, the urinary bladder was evacuated using a sterile metal catheter and controlled cord traction was performed again and a container was placed under the woman's buttocks for collection of blood. With failure of placental delivery again by this simple procedure, women were equally randomized into two groups to receive either intra-umbilical vein injection of carbetocin or oxytocin. Randomization of patients was done using a computerized program.

An informed written consent was obtained from all patients. An approval was obtained from the ethical committee of Zagazig University Hospitals before starting the study. The first group received intra-umbilical vein injection of 1 mL carbetocin (containing 100 μg carbetocin) (Pabal, Ferring GmbH) diluted in 20 mL normal saline 0.9%. The second group received intra-umbilical vein injection of 20 IU oxytocin (Syntocynon, Novartis) diluted in 20 mL normal saline 0.9%. Both drugs were prepared by a nurse and given to the operator without any information about the type of drug. Also all patients were blinded about the used drug (double blind study). Also, all evaluators were blinded about groups during the whole time of collecting data and midwifes estimating blood loss at 2 h postpartum were also blinded. In both groups the injection was done by inserting a size 10 gauge nasogastric tube into the umbilical vein after removal of the clamp and advancing it to the placental insertion site of the cord. When resistance was met at this point, the nasogastric tube is then retracted by 3–4 cm to ensure the tip is not in a placental branch and to allow for any divisions of the vein prior to its insertion into the placenta to receive the uterotonic. The uterotonic solution is then injected and the cord is clamped with the tube in place. This method resulted in complete filling of the placental bed capillaries. Within 30 to 45 min after administration of the uterotonic, or in the case of clinical signs of placental separation, an attempt to deliver the placenta gently was made. If the final attempt to deliver the placenta (45 min after medication administration) failed, manual removal of the placenta was performed in the operation theatre under general anesthesia. If not removed completely, adherent placentas were removed piecemeal.

Standard management of the third stage of labor was continued, including blood transfusion and uterotonic agents if needed for continued bleeding. The primary outcome was the amount of blood loss in the third and fourth stage of labor (2 h following placental delivery). The volume of blood loss was measured by estimating the volume of blood present in the container in ml from the point of diagnosis of retained placenta to 2 h after delivery of the placenta.

Secondary assessment included the duration of the third stage of labor in minutes, postpartum Hb concentration (g/dl) measured 6 h after delivery, change in the hemoglobin concentration which was the difference between Hb on admission and 6 h after delivery (g/dl), the percentage of spontaneously expelled placenta following intra-umbilical injection of the ecbolic drug, the percentage of still retained placenta following intra-umbilical injection of the ecbolic drug (removed manually completely or adherent placenta which needed piecemeal removal and uterine curettage), the need for additional uterotonic drugs (200 μg intravenous methylergometrine or 20 international units oxytocin infusion in 500 mL ringer lactate or 800 misoprostol rectally, or all) following complete placental delivery, the incidence of postpartum hemorrhage (loss of more than 500 cc of blood), the need for blood transfusion (the need for blood transfusion was judged by the attending consultant and guided mainly by the observation of excessive blood loss associated with slight reduction in the previously normal blood pressure and the occurrence of tachycardia) and side effects at the time of injection (anaphylactic reactions, hypotension, and cardiac arrhythmias).

Statistical analysis

The results are presented as the means and standard deviations (± SD) for numerical variables and as numbers and percentages for categorical variables. Statistical significance for differences was analyzed using the independent sample *t*-test, Wilcoxon rank–sum (Mann–Whitney) test, and $\chi 2$-test, when appropriate. The statistical analyses were performed using SPSS version 20.0 with power 80% and confidence interval 95%. Statistical significance was accepted for P-values < 0.05.

Results

During the study period, 227 women were eligible for inclusion in our study. Of these, seven women had severe atonic PPH necessitating immediate manual removal of the placenta after delivery of the baby and 20 patients experienced cervical, vaginal, vulvar and perineal tears following delivery of the baby (traumatic PPH). Those patients were excluded from the final analysis. So, a total of 200 women were finally recruited into the study. 100 women were in the carbetocin group, and 100 women were in the oxytocin group.

The demographic and obstetric data of the study groups were comparable and presented in Table 1. The results for the main and secondary outcomes are presented in Table 2. Total blood loss (ml) was significantly lower in carbetocin group (P value 0.04) when compared to oxytocin group. Duration of the third stage of labor (minutes) was significantly lower in carbetocin group (P value 0.03). Postoperative Hb concentration (g/dl) was significantly higher in carbetocin group (P value 0.03). Also there was a highly significant difference (P value 0.0001) between both groups as regard change in Hb concentration (g/dl) 6 h after delivery with less change in the carbetocin group.

Spontaneous expulsion of the placenta following intra-umbilical injection of the ecbolic drug was significantly higher in the carbetocin group when compared to the oxytocin group (P value 0.036). In the

Table 1
Patients' clinical characteristics and demographic data.

Characteristics	Intra-umbilical carbetocin (N:100)	Intra-umbilical oxytocin (N:100)	P- value
Age (years)	25.4 ± 4.7	26.6 ± 4.6	0.0696
BMI (kg/m^2)	27.2 ± 2.6	26.9 ± 2.9	0.4421
Parity	2.5 ± 1.8	2.8 ± 1.7	0.2271
Induction/augmentation of labor	52 (47.7%)	57 (52.7%)	0.455
Gestational age (weeks)	37.8 ± 3.3	38.1 ± 2.8	0.4890
Neonatal birth weight (gm)	3765 ± 330	3822 ± 299	0.2020
Preoperative Hb concentration (g/dl)	11.34 ± 0.45	11.24 ± 0.33	0.07
History of retained placenta	3 (2.8%)	2 (1.9%)	0.658

carbetocin group 9 placenta were removed manually completely and in 2 cases the placenta was adherent and needed piece meal removal and endometrial curettage, however in the oxytocin group 17 placenta were removed manually completely and in 5 cases the placenta was adherent and needed piece meal removal and endometrial curettage, The need for additional uterotonic drugs following complete placental delivery (in the carbetocin group, only 18 cases needed additional uterotonics and 82 did not need any additional uterotonics. However, in the oxytocin group, 69 cases needed additional uterotonics and 31 did not need any additional uterotonics) was significantly lower in the carbetocin group (P value 0.033). Also the occurrence of postpartum hemorrhage (P value 0.045) and the need for blood transfusion (in the carbetocin group, blood transfusion was needed in one case in which the placenta was removed piecemeal. In the oxytocin group, blood transfusion was needed in 7 cases {in the five cases in which the placenta was removed piecemeal and two cases of manually removed placenta}) (P value 0.03) was significantly lower in the carbetocin group. There were no recorded important side effects in either group.

Discussion

To our best knowledge, this is the first study comparing the use of intra-umbilical carbetocin and intra-umbilical oxytocin for the management of RP. Carbetocin (1-deamino-1-carba-2- tyrosine (O-methyl)-oxytocin) is a synthetic oxytocin analogue that binds to the same oxytocin receptors in the myometrium with an affinity similar to that of oxytocin [12]. Its main advantage over oxytocin is a four-fold longer uterotonic activity, a fact which precludes the necessity of a continuous infusion. Intavenous or intramuscular injection of carbetocin associated with a number of side effects as abdominal pain, nausea, flushing, feeling of warmth, headache, tremors, pruritus, shortness of breath, vomiting, metalic taste, back pain, sweating and dizziness [13]. So, our study advocated the use of intra-umblical carbetocin injection to gain its benefit and minimize its side effects if used intravenously or intramuscularly.

In our study we chose to use 20 IU of oxytocin diluted in 20 Ml normal saline 0.9%. In the studies to date, the choice of dose has largely been empirical. Previous studies have primarily used a dose of 10–20 IU oxytocin, although doses of up to 100 IU have also been reported. The need for manual removal can be reduced by 20% with the use of 30 IU oxytocin injected through the umbilical vein [1].

The mechanism of action of intra-umbilical oxytocin is based on a dual effect, that is, the separation of the placenta from its bed by the total volume injected as well as the strong uterine contractions. None of the studies recorded any clinically significant adverse effects, such as pelvic pain, from strong uterine contractions or PPH [14].

Carbetocin has a rapid onset of action (within 1–2 min) and a prolonged duration of action (approximately 1 h) because of the sustained uterine response with contractions of higher amplitude and frequency. A recent study showed that patients undergoing CS who received oxytocin had more pronounced hypotension and hemodynamic rebound than patients treated with carbetocin, with comparable effects on the cardiovascular system [15].

In a study by Elfayomy, an i.v. bolus of 100-μg carbetocin was equivalent to umbilical vein injection of 50 IU oxytocin in reducing the need for manual removal of the placenta during uncomplicated labor and delivery. Carbetocin seems to have an acceptable hemodynamic safety profile and can be used as an alternative choice to conventional oxytocic agents in the management of retained placenta [16].

Postoperative Hb concentration was significantly higher (P value 0.03) in carbetocin group (10.98 + 2.74 g/dl) when compared to the oxytocin group (10.11 + 2.94 g/dl). This difference between the two groups is very small although significant so, it might be clinically irrelevant. This can be explained by that we measured the postoperative Hb concentration only once, 6 h after delivery and the major change in the Hb concentration after delivery may need more time to be clinically relevant between the two groups (at least 24 h).

As regard the need for additional uterotonic drugs following complete placental delivery: in the carbetocin group, only 18 cases needed additional uterotonics and 82 did not need any additional uterotonics. However, in the oxytocin group, 69 cases needed additional uterotonics and 31 did not need any additional uterotonics. This can be explained by that the locally used carbetocin has more powerful and sustained uterotonic effects when compared with the locally administered oxytocin.

In our study the beneficial effects of carbetocin when compared to oxytocin as regard the previously mentioned parameters is due to that the carbetocin contractions are of sustained higher amplitude and frequency and therefore higher uterine performance. This uterotonic effect of carbetocin could last for 3 h [17].

The clinical importance of intra-umbilical injection of carbetocin over oxytocin is that its association with more spontaneously expelled placentae, less need for manual removal of the placenta, less need for additional uterotonic drugs following complete placental delivery, less incidence of postpartum hemorrhage and less need for blood transfusion.

Conclusion: Intra-umbilical carbetocin is more effective than intra-umbilical oytocin as a method for management of retained placenta. Intra-umbilical carbetocin seems to have more acceptable hemodynamic safety profile when compared to intra-umbilical oxytocin in the management of retained placenta.

Hypothesis tested: intra-umbilical injection of carbetocin is better than intra-umbilical injection of oxytocin in the management of retained placenta.

Limitations: The major limitation in our study is lack of prior research studies on the topic. To our knowledge, this the first study which used the intra-umbilical injection of carbetocin in management of retained placenta. Another limitation was that we measured the Hb level only once six hours after delivery of the baby which was clinically irrelevant. Actually our findings cannot be generalized as we need further studies in this field using larger sample size to prove or disprove our results.

The strength of the study: The active and easy identification of the cases through the use of our reliable sources. No negative side-effects were reported in either group as the drugs were given locally in the umbilical cord vein to reach only the placental bed and act only on the

Table 2
Outcome data for the two study groups.

Variables	Intra-umbilical carbetocin (Mean ± SD) No 100	Intra-umbilical oxytocin (Mean ± SD) No 100	P- value	
Total blood loss (ml)	435 ± 290	533 ± 385	0.04*	
Duration of the third stage of labor (minutes)	57.7 ± 9.2	60.9 ± 11.8	0.03*	
Postpartum Hb concentration (g/dl)	10.98 ± 2.74	10.11 ± 2.94	0.03*	
Change in Hb concentration (g/dl)	0.23 ± 0.05	0.78 ± 0.22	0.0001#	
Variables	Intra-umbilical carbetocin No 100 (%)	Intra-umbilical oxytocin No 100 (%)	P- value	Risk assessment
– Spontaneous expulsion of the placenta following intra-umbilical injection of the ecbolic drug	89	78	0.036*	**1–95% CI** (1.1–3.4) **2-ARR** = 11% **3-RR** = 0.5 (Intra-umbilical carbetocin is protective against persistence of retained placenta by 50%)
– Still retained placenta following intra-umbilical injection of the ecbolic drug	11	22		**4-NNT** = 9 patients We should give 9 patients Intra-umbilical carbetocin in order to get one patient protected against persistence of retained placenta
– Manual removal of the placenta completely	9	17		0.76
– Adherent placenta, piecemeal removal	2	5		
Need for additional uterotonic drugs following complete placental delivery:				**1–95% CI** (1.5–2.5) **2-ARR** = 51%
Yes	18	69	0.033*	**3-RR** = 0.26 (Intra-umbilical carbetocin is protective against the need for additional uterotonic drugs following complete placental delivery by 26%
No	82	31		**4-NNT** = 1.96 patients (We should give 1 to 2 patients Intra-umbilical carbetocin in order to get one patient protected against the need for additional uterotonic drugs following complete placental delivery (highly effective)
**Postpartum hemorrhage:				**1–95% CI (2.1–7.6)**
Yes	3	10		**2-ARR** = 7%
No	97	90	0.045*	**3-RR** = 0.3 (Intra-umbilical carbetocin is protective against postpartum hemorrhage by 30%) **4-NNT** = 14.3 (14–15) patients We should give 14 to15 patients Intra-umbilical carbetocin in order to get one patient protected against postpartum hemorrhage
Blood transfusion:				**1–95% CI** (1.9–9.1)
Yes	1	7	0.03*	**2-ARR** = 6%
No	99	93		**3-RR** = 0.14 (Intra-umbilical carbetocin is protective against blood transfusion by 14%) **4-NNT** = 16.7 (16–17) patients We should give 16 to 17 patients Intra-umbilical carbetocin in order to get one patient protected against blood transfusion

CI; Confidence Interval – **ARR**; Absolute Risk Reduction – **RR**; Relative Risk – **NNT**; The Number Needed to Treat.
* Statistically significant difference (p-value < 0.05).
** Postpartum hemorrhage was diagnosed with the loss of 500 mL of blood or more following a vaginal birth.
# Statistically highly significant difference (p-value < 0.001).

myometrium without reaching the systemic circulation. Also the large sample size during the four years of the study added more strength to our research.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent

An informed written consent was obtained from all participants. An approval was obtained from Institutional Review Board of Zagazig University Hospitals.

Authors' contribution

All authors were included in conception and design of study, acquisition of data, analysis and/or interpretation of data, drafting the manuscript and revising the manuscript critically for important intellectual content.

Declaration of Competing Interest

There are no conflicts of interest.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.srhc.2019.05.002.

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