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Research Article

A Randomized Controlled Trial Comparing Carbetocin and Oxytocin for the Prevention of Postpartum Hemorrhage in Elective and Emergency Cesarean Deliveries

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ABSTRACT

Background: Postpartum hemorrhage (PPH) remains a leading cause of maternal morbidity worldwide. Oxytocin is the traditional first-line uterotonic, whereas Carbetocin, a longer-acting analogue, may offer superior uterine tone and reduced need for additional interventions.

Objective: To compare the efficacy and safety of Carbetocin versus Oxytocin in preventing PPH in women undergoing cesarean delivery.

Methods: A prospective, randomized, parallel-group trial was conducted in a tertiary care center over 12 months. A total of 240 parturients undergoing cesarean delivery were randomized into two groups: Group C (Carbetocin 100 µg IV single dose) and Group O (Oxytocin 10 IU IV bolus followed by 20 IU infusion). Primary outcome was estimated blood loss (EBL). Secondary outcomes included need for additional uterotonics, incidence of PPH (>1000 mL), hemodynamic changes, and adverse effects.

Results: Mean EBL was significantly lower in Group C (682 ± 210 mL) compared to Group O (815 ± 260 mL) ($p < 0.001$). The need for additional uterotonics was reduced in Group C (8.3%) versus Group O (21.7%) ($p = 0.004$). Incidence of PPH was lower in Group C (5%) compared to Group O (12.5%). Carbetocin caused fewer hemodynamic fluctuations and nausea.

Conclusion: Carbetocin significantly reduced blood loss, need for additional uterotonics, and uterotonic-related adverse events compared with Oxytocin. Carbetocin may be a superior alternative for routine prevention of PPH in cesarean deliveries.

Keywords: Postpartum hemorrhage, Carbetocin, Oxytocin, Cesarean section, Uterotonics, Randomized controlled trial.

INTRODUCTION

Postpartum hemorrhage (PPH) is responsible for nearly one-quarter of maternal deaths worldwide. Cesarean deliveries pose an increased risk due to surgical blood loss and uterine atony.

Oxytocin, the standard uterotonic agent, has a short half-life and requires continuous infusion, which may cause dosing variability and hemodynamic instability.

Carbetocin, a long-acting oxytocin analogue, provides sustained uterine contractions with a single dose and may reduce the need for additional uterotonic agents. Evidence suggests potential superiority of Carbetocin, but results vary across populations and practice settings.

This study aims to compare Carbetocin vs Oxytocin in preventing PPH during cesarean delivery, assessing both efficacy and safety in an Indian tertiary care context.

AIMS AND OBJECTIVES

Primary Objective

To compare total estimated blood loss (EBL) between Carbetocin and Oxytocin groups in cesarean deliveries.

Secondary Objectives

To compare the incidence of PPH (>1000 mL).
To assess the need for additional uterotonics.
To evaluate hemodynamic changes following drug administration.
To document adverse drug reactions.

MATERIALS AND METHODS

Study Design

Prospective randomized controlled trial
Parallel-group, single-blind (outcome assessors blinded)

Study Setting

Department of Obstetrics & Anaesthesiology, VIMS BALLARI
Duration: 12 months

Sample Size Calculation

Based on expected 20% reduction in PPH incidence

$\alpha = 0.05$, power = 80%

Required sample = 120 per group (Total = 240)

Inclusion Criteria

Women aged 18–40 years
Singleton pregnancy
Elective or emergency cesarean delivery
Hemodynamically stable preoperatively

Exclusion Criteria

Coagulopathy
Placenta previa/accreta spectrum
Multiple gestation
Known hypersensitivity to study drugs
Severe anemia (Hb < 7 g/dL)

Randomization

Computer-generated block randomization
Allocation by sealed opaque envelopes

Groups:

Group C: Carbetocin 100 µg IV slow bolus
Group O: Oxytocin 10 IU IV bolus + 20 IU infusion over 4 hours

Outcome Measures

Primary Outcome:
Estimated blood loss (difference in pre/post-operative Hb, gravimetric method, suction volume)

Secondary Outcomes:

Incidence of PPH (>1000 mL)
Hemodynamic parameters (HR, MAP)

Additional uterotonic requirement
Adverse effects (nausea, vomiting, flushing, hypotension)

Statistical Analysis

SPSS version 26
Continuous variables: Mean ± SD, compared using Student's t-test
Categorical variables: Chi-square test
($p > 0.05$).

Primary Outcome: Estimated Blood Loss

Outcome	Group C (Carbetocin)	Group O (Oxytocin)	p-value
Mean EBL (mL)	682 ± 210.	815 ± 260	<0.001

Carbetocin significantly reduced blood loss compared to Oxytocin.

Secondary Outcomes

PPH incidence (>1000 mL):

Group C: 5%

Group O: 12.5% ($p = 0.03$)

Additional uterotonics required:

Group C: 8.3%

Group O: 21.7% ($p = 0.004$)

Hemodynamic Changes

Oxytocin group showed significantly greater declines in MAP and increased heart rate immediately after administration ($p < 0.01$).

Adverse Effects

Nausea/vomiting: Group C (4%), Group O (12%)

$p < 0.05$ considered statistically significant

RESULTS

Baseline Demographics

Both groups were comparable in age, BMI, parity, gestation, and indication for cesarean section

Hypotension requiring vasopressors: Group C (2%), Group O (8%)

DISCUSSION

Postpartum hemorrhage (PPH) continues to be one of the leading contributors to maternal morbidity and mortality worldwide, particularly in low- and middle-income countries. Effective uterotonic administration immediately after delivery is universally recommended as the cornerstone of PPH prevention by the World Health Organization (WHO) (WHO, 2018)[3]. Oxytocin, traditionally regarded as the first-line uterotonic, has well-established efficacy but notable limitations, including a short half-life (4–10 minutes), requirement for continuous infusion, and significant hemodynamic side effects such as hypotension and tachycardia (Dyer et al., 2010)[4].

Carbetocin, a long-acting oxytocin analogue with a half-life nearly 4–10 times longer, offers sustained uterine contraction with a single IV dose. The present randomized controlled trial found that Carbetocin significantly lowered total estimated blood loss compared with Oxytocin, corroborating

findings from previous trials and meta-analyses (Attilakos et al., 2010; Su et al., 2012)[12].

Comparison with Previous Studies

The reduction in mean blood loss in our study (682 mL vs 815 mL) aligns with Attilakos et al. (2010)[1], who demonstrated superior uterine tone and reduced need for additional uterotonics with Carbetocin in cesarean deliveries. Similarly, Boucher et al. (2004)[5] reported that Carbetocin significantly decreased the incidence of uterine atony, highlighting its pharmacological advantage of prolonged receptor activation.

A systematic review by Su et al. (2012)[2] concluded that Carbetocin is more effective than Oxytocin in preventing PPH ≥500 mL and reducing uterotonic use, which is consistent with our observation of lower additional uterotonic requirement (8.3% vs 21.7%). These findings collectively reinforce the growing evidence that Carbetocin provides more stable and sustained uterine contractility.

Hemodynamic Stability

Oxytocin's cardiovascular effects are well documented. Dyer et al. (2010)[4] demonstrated dose-dependent hypotension following rapid Oxytocin bolus administration due to vasodilation and reduced systemic vascular resistance. In our study, the Oxytocin group showed significantly greater fluctuations in mean arterial pressure and heart rate immediately after administration, whereas the Carbetocin group maintained better hemodynamic stability. This offers an important clinical advantage, especially in women with pre-existing cardiac disease, anemia, or hypovolemia.

Incidence of PPH

The observed reduction in PPH (>1000 mL) in the Carbetocin group (5% vs 12.5%) mirrors the findings of Singh et al. (2020)[8] and the SOGC guidelines (2018)[10], both of which recommend Carbetocin as an effective prophylactic uterotonic for cesarean sections. While the absolute incidence of PPH varies geographically due to differences in anemia rates, obstetric risk factors, and surgical technique, the relative superiority of Carbetocin remains consistent across studies.

Need for Additional Uterotonics

Requiring additional uterotonics is a strong indicator of suboptimal uterine contraction. In our study, the Oxytocin group required significantly more rescue agents, a pattern also seen in the multicenter trials analysed by Novikova & Hofmeyr (2015)[9]. Reduced reliance on additional agents not only improves maternal comfort but also decreases potential drug-related side effects such as hypertension (ergometrine) and bronchospasm (prostaglandins).

CONCLUSION

Carbetocin is more effective and safer than Oxytocin in preventing PPH during cesarean deliveries. Routine use of Carbetocin may improve maternal outcomes, particularly in high-risk populations.

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