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AN OBSERVATIONAL ANALYTICAL STUDY ON COMPARISON OF HEMODYNAMIC EFFECTS OF CARBETOCIN AND OXYTOCIN IN PATIENT UNDERGOING ELECTIVE LOWER SEGMENT CAESAREAN SECTION UNDER SPINAL ANAESTHESIA.

Anaesthesiology

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ABSTRACT

Background and Aims: Postpartum haemorrhage (PPH) is a leading cause of maternal mortality, primarily due to uterine atony. Prophylactic uterotonics are a cornerstone of PPH prevention. While oxytocin is the first-line agent, it is frequently associated with significant hemodynamic instability. Carbetocin, a long acting synthetic oxytocin analogue, may offer comparable efficacy with improved hemodynamic stability. This study compared the hemodynamic effects, uterotonic efficacy, need for additional uterotonics, blood loss, and side effect profiles of carbetocin versus oxytocin in patients undergoing elective caesarean section under spinal anaesthesia. **Materials and Methods:** In this observational analytical study, 70 patients scheduled for elective caesarean section under spinal anaesthesia were randomly allocated into two groups (n=35 each). One group received a single intravenous dose of carbetocin, while the other received oxytocin. Hemodynamic parameters, including systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR), were recorded at regular intervals. The need for additional uterotonics, estimated postoperative blood loss, and incidence of adverse effects were assessed. **Results:** The carbetocin group exhibited significantly greater hemodynamic stability, with a lower incidence of hypotension compared to the oxytocin group, most notably at the 10-minute mark (p=0.031). Uterotonic efficacy, as assessed by initial uterine contraction, was comparable between groups. However, the requirement for additional uterotonic agents was significantly lower in the carbetocin group (5.7%) than in the oxytocin group (31.4%). Postoperative blood loss and the overall profile of side effects were similar between the two groups. **Conclusions:** Carbetocin provides superior hemodynamic stability compared to oxytocin, with equivalent uterotonic efficacy and a comparable safety profile. The significantly reduced need for rescue uterotonics further supports carbetocin as a preferable prophylactic agent in patients undergoing caesarean section under spinal anaesthesia.

KEYWORDS

Carbetocin, Oxytocin, Haemodynamic Stability, Caesarean Section, Spinal Anaesthesia, Postpartum Haemorrhage.

INTRODUCTION

Postpartum haemorrhage (PPH) remains the leading cause of maternal mortality worldwide,1 with uterine atony identified as its most common cause.2 Active management of the third stage of labour, including the administration of prophylactic uterotonics, is a standard practice to mitigate this risk. This is critical, as the massive bleeding associated with PPH can be detrimental and significantly impact maternal outcomes.3 The various uterotonics available differ in their effects on uterine tone, maternal hemodynamics, and associated adverse effects. For the anaesthesiologist managing patients during caesarean section, a thorough understanding of these drugs is essential. This includes their indications, contraindications, clinical effectiveness, and hemodynamic impacts. This knowledge is crucial for maintaining vigilance, enabling the prompt detection and management of any adverse effects, and ultimately improving patient safety and outcomes. Oxytocin is the first-line uterotonic agent administered following delivery. While its use has successfully reduced the incidence of PPH, the frequent need for additional uterotonics to sustain adequate uterine tone remains a clinical challenge. This may be attributed to oxytocin's heat-labile nature and the potential failure to maintain a consistent cold chain in realworld settings, thereby compromising its efficacy compared to ideal conditions. A further disadvantage is its short halflife, which necessitates administration as a continuous intravenous infusion. Oxytocin is also associated with dosedependent side effects, including nausea, vomiting, hypotension, tachycardia, and arrhythmias. While these effects may be manageable in low-risk patients, they can be clinically significant and potentially life-threatening in highrisk parturients. Carbetocin, a newer uterotonic, is a heat-stable, longacting synthetic analogue of oxytocin.4 It is administered as a single intravenous bolus, eliminating the need for a continuous infusion.5 Numerous clinical trials have demonstrated that the uterotonic efficacy of carbetocin is comparable or superior to that of oxytocin, largely due to its prolonged half-life. A key additional benefit is its potential to reduce the requirement for rescue uterotonics. However, data regarding the specific impact of carbetocin on maternal hemodynamics remain limited. Therefore, this study was designed with the primary objective of comparing the effects of carbetocin versus oxytocin on maternal hemodynamics. Secondary objectives include the assessment of uterine tonicity and the profile of associated side effects.

METHODOLOGY

This observational analytical study was conducted in the tertiary care teaching center in Maharashtra, India. The study protocol was approved by the Institutional Research Committee and the Institutional Ethics Committee. The study was conducted in accordance with the approved protocol and applicable regulatory requirements. Written informed consent was obtained from all participants after a detailed explanation of the study's risks and benefits using a patient information sheet. Confidentiality was maintained, and all participants received standard care. The study enrolled women aged 18–35 years with ASA physical status II, who were undergoing elective lower segment caesarean section (LSCS) under spinal anaesthesia with term singleton pregnancies. Exclusion criteria comprised patient refusal, ASA III or IV status,contraindications to spinal anaesthesia, pregnancy-related complications (e.g., pre-eclampsia, gestational diabetes), preexisting systemic diseases (e.g., cardiovascular, renal, or thyroid disorders), and obstetric complications such as placenta previa, placental abruption, multiple gestation, or spinal abnormalities. The sample size was calculated based on heart rate (HR) differences reported by Moertl et al.6 with HR values of 12.98 ± 2.53 bpm for oxytocin and 14.20 ± 2.45 bpm for carbetocin. Using the standard OpenEpi Software, 35 participants were enrolled in each group. Upon arrival in the preoperative area, participants were randomized into two groups: Group O (Oxytocin)

and Group C (Carbetocin) using a closed-envelope technique. Both the participants and the attending clinicians were blinded to the group assignment. In the operating room, an 18-gauge intravenous cannula was secured. Baseline hemodynamic parameters (blood pressure, ECG, and pulse oximetry) were recorded after attaching routine monitors. All patients were preloaded with 15 ml/kg of Ringer's lactate solution. Spinal anaesthesia was administered in the sitting position at the L3-L4 or L4-L5 interspace using a 25G Quincke needle, with 2 ml of 0.5% hyperbaric bupivacaine and 25 µg fentanyl. Patients in Group O (Oxytocin) received a 5 IU intravenous bolus diluted in 9 ml of normal saline to a total volume of 10 ml, administered over one minute. This was followed by a continuous infusion of 15 IU oxytocin in 500 ml of Ringer's lactate, running at 100 ml/hr. Patients in Group C (Carbetocin) received a 100 µg intravenous bolus, similarly diluted in 9 ml of normal saline to a 10 ml total volume and administered over one minute. This was followed by an infusion of 2 ml of plain Ringer's lactate in 500 ml of Ringer's lactate at 100 ml/hr, serving as a placebo-equivalent infusion to maintain blinding. Hemodynamic parameters, including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP), were recorded immediately before drug administration (baseline) and at 1-, 2-, and 5-minutes post-administration, then every 5 minutes until surgery concluded. Uterine tone was assessed by the operating surgeon via manual palpation at 2, 5, and 10 minutes after study drug administration. The need for additional uterotonics was determined at the surgeon's discretion. Intra-operative side effects such as vomiting, headache, and flushing were monitored. Hypotension, defined as a systolic blood pressure <90 mmHg or a >20%decrease from baseline, was treated with a 6 mg IV bolus of mephentermine, and the total dose required was recorded. Data were analysed using Microsoft Excel and SPSS version 21. Descriptive statistics (mean, median) were used for numerical variables, and frequency distributions were used for categorical data. The Chi-square test and Fisher's exact test were employed to assess associations between categorical variables. A p-value of less than 0.05 was considered statistically significant. 3.

RESULTS

A total number of 70 participants were enrolled and randomized into two groups of 35: Group O (Oxytocin) and Group C (Carbetocin) (Figure 1).

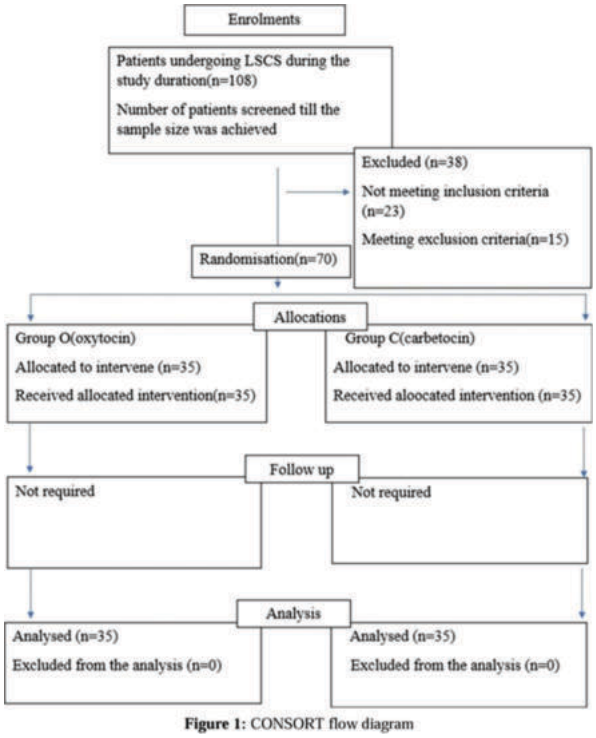

Figure 1: CONSORT flow diagram

The demographic profiles of the two groups were comparable, with no statistically significant differences in mean age or period of gestation. The primary indication for surgery was a Lower Segment Cesarean Section (LSCS) on request, which accounted for 83% of cases in Group O (Oxytocin) and 94% in Group C (Carbetocin). The mean and Standard Deviation (SD) of heart rate and SBP in both groups were analyzed using an unpaired t-test. No significant differences were found between Group O and Group C at any time point. The analysis between mean and SD of DBP in both groups was done using an unpaired t-test (Table 1).

Table 1: Comparison of diastolic blood pressure between oxytocin and carbetocin group

Diastolic BP	Group O			Group C			Unpaired t-test p value
	N	Mean	SD	N	Mean	SD	
Baseline	35	76.5	8.6	35	79.1	12.8	0.322
Immediately Before the study drug	35	70.0	10.4	35	71.2	9.7	0.612
1 min after completion	35	63.3	11.6	35	60.5	9.6	0.275
2 mins after completion	35	65.5	7.8	35	66.1	9.8	0.789
5 mins after completion	35	63.1	8.5	35	65.3	9.6	0.319
10 mins after completion	35	59.1	9.0	35	63.9	9.1	0.031
15 mins after completion	35	59.1	10.3	33	60.6	9.7	0.549
20 mins after completion	33	58.5	10.7	30	63.1	9.9	0.084
25 mins after completion	30	62.2	10.5	22	64.5	9.2	0.417
30 mins after completion	28	64.4	9.8	18	65.9	7.7	0.597
35 mins after completion	22	67.8	9.0	14	67.5	9.7	0.921
40 mins after completion	15	72.1	9.9	10	70.3	6.5	0.626
45 mins after completion	11	69.3	3.8	6	75.3	9.8	0.083
50 mins after completion	8	70.4	5.3	3	74.3	5.7	0.309
55 mins after completion	5	74.0	6.5	1	67.0	NA	0.382
60 mins after completion	5	74.6	9.7	0	NA	NA	NA

Table 2: Comparison of mean arterial pressure between oxytocin and carbetocin group

MAP	Group O			Group C			Unpaired t test p value
	N	Mean	SD	N	Mean	SD	
Baseline	35	91.7	10.4	35	90.8	11.7	0.739
Immediately before the study drug	35	82.6	11.2	35	85.1	8.6	0.285
1 min after completion	35	77.5	12.0	35	75.0	10.2	0.349
2 mins after completion	35	79.8	8.3	35	80.2	9.7	0.854
5 mins after completion	35	77.2	8.5	35	79.4	8.9	0.294
10 mins after completion	35	73.3	8.8	35	77.6	8.9	0.046
15 mins after completion	35	73.9	10.1	33	75.7	9.5	0.443
20 mins after completion	33	73.4	9.9	30	77.5	9.4	0.102
25 mins after completion	30	76.5	10.5	22	79.2	9.5	0.341
30 mins after completion	28	78.0	8.9	18	79.4	8.3	0.609
35 mins after completion	22	81.3	9.0	14	79.9	10.7	0.663
40 mins after completion	15	84.5	8.2	10	85.1	8.1	0.851
45 mins after completion	11	82.6	4.4	6	87.2	11.1	0.243
50 mins after completion	8	85.3	6.3	3	88.3	6.5	0.490
55 mins after completion	5	89.0	7.7	1	81.0	NA	0.396
60 mins after completion	5	89.2	11.2	0	NA	NA	NA

A significant difference was noted at 10 minutes intraoperatively, with Group O having a lower DBP than Group C (p = 0.031). This indicates that Group O experienced more significant hypotension compared to Group C during the early intraoperative period. No significant differences were found at other intraoperative time points.

Table 3: Comparison of additional uterine tonics requirement intraoperatively and postoperatively between oxytocin and carbetocin group

Additional Uterine Tonics		Group O		Group C		p value (Fisher exact test)
		N	%	N	%	
Intraoperatively	Yes	11	31.4%	2	5.7%	0.012
	No	24	68.6%	33	94.3%	
Postoperatively	Yes	2	5.7%	0	0.0%	0.493
	No	33	94.3%	35	100.0%	

Table 4: Comparison of side effects between study groups

Parameter Side Effects, n (%)	Group O (Oxytocin) (n=35)	Group C (Carbetocin) (n=35)	p-value (Fisherexact test)
Nausea	0 (0.0%)	3 (8.6%)	0.239
Headache	3 (8.6%)	0 (0.0%)	0.239

The mean and SD of MAP in both groups were analyzed using an unpaired t-test (Table 2). Significant differences were observed intraoperatively at 10 minutes, with Group O showing lower MAP than Group C (p = 0.046). This highlights that Group O experienced significant hypotension during the early intraoperative period compared to Group C. No significant differences were found at other time points. The assessment of uterotonic efficacy showed that both drugs produced rapid uterine contractions. In the oxytocin group, the majority of patients (27/35) achieved adequate contraction within 2 minutes, with six and one patient achieving it at 5 and 10 minutes, respectively. In the carbetocin group, 32 patients achieved adequate contraction within 2 minutes, and three at 5 minutes. However, the requirement for additional uterotonics differed significantly between the groups. Intraoperatively, 31.4% of patients in Group O required additional uterotonics, compared to only 5.7% in Group C (p=0.012). Postoperatively, 5.7% of patients in the oxytocin group required additional uterotonics, while none in the carbetocin group did, though this difference was not statistically significant (p=0.493). (Table 3)There was no statistically significant difference in pre- and postoperative haemoglobin levels, indicating comparable blood loss between the two groups. The incidence of side effects was also similar (Table 4). Nausea was reported by 8.6% (3/35) of patients in the carbetocin group and by none in the oxytocin group (p=0.239). Conversely, headache was reported by 8.6% (3/35) of patients in the oxytocin group and by none in the carbetocin group (p=0.239).

DISCUSSION

This observational analytical study recruited 70 participants, randomized into 35 patients each in an oxytocin group (Group O) and a carbetocin group (Group C). The primary objective was to compare the effects of these agents on maternal hemodynamics during elective caesarean section under spinal anaesthesia. Secondary objectives included comparing the requirement for additional uterotonics, estimating postoperative blood loss, and profiling associated side

effects. The study groups were comparable at baseline, with no statistically significant differences in socio-demographic parameters such as mean age and period of gestation. The most common indication for surgery in both cohorts was maternal request, accounting for 82.9% and 94.3% of cases in Group O and Group C, respectively, reflecting a prominent trend toward elective caesarean delivery in our study population. Analysis of hemodynamic parameters revealed that heart rate and systolic blood pressure followed similar trends in both groups, with no statistically significant differences observed at any time point. Both drugs caused an initial tachycardia that subsequently stabilized. This finding is partially consistent with the work of Moertl et al., who also reported an initial heart rate increase in both groups, followed by a return to baseline in the carbetocin group and a slight, non-significant rebound bradycardia in the oxytocin group.6 The key hemodynamic finding of our study pertained to blood pressure stability. A significant difference was observed in diastolic blood pressure at the 10-minute mark, where Group O exhibited significantly lower values than Group C (p=0.031). This pattern was mirrored in the mean arterial pressure (MAP), with a statistically significant difference at the same 10-minute interval (p=0.046). This indicates that patients receiving oxytocin experienced more pronounced hypotension in the early intraoperative period. This transient hypotension, however, was effectively managed with vasopressor intervention. Our hemodynamic findings are consistent with existing literature. A study by Moertl et al. concluded that "patients administered oxytocin experienced more significant hypotension and hemodynamic rebound compared to those given carbetocin",6 which aligns with our observation of superior blood pressure stability in the carbetocin group. The statistically significant differences in DBP and MAP at the 10-minute mark in our study underscore this point. Similarly, Mannaerts et al. reported that oxytocin, even at lower doses, induced a hypotensive effect comparable to carbetocin, though patients typically stabilized thereafter.7 The hemodynamic stability offered by carbetocin is further supported by Reyes et al., who found it effective in preventing postpartum bleeding in women with severe preeclampsia while maintaining stable hemodynamics.8 This profile suggests carbetocin may be the preferred agent in high-risk populations, such as those with cardiac disease or pre-eclampsia, where transient compromise uteroplacental perfusion. hypotension could Regarding uterotonic efficacy, our data indicates that while both drugs achieved adequate uterine tone within the first 5 minutes, a noticeable difference emerged at the 10 minute mark, with the oxytocin group showing more variability. This is reflected in the significantly higher need for additional intraoperative uterotonics in the oxytocin group (31.4%) compared to the carbetocin group (5.7%). This finding is strongly supported by multiple studies. A metaanalysis by Voon et al. found that carbetocin reduced the need for additional uterotonics compared to oxytocin.10 The reduced need for rescue uterotonics with carbetocin is a consistent finding, further supported by the work of Holleboom et al.11 Tse et al.,12 and Jin et al.,13 reinforcing its potential for superior efficacy in preventing uterine atony. In contrast to its superior performance in reducing additional uterotonic requirements, our study found no statistically significant difference in postoperative blood loss, as measured by changes in haemoglobin levels. This finding is consistent with the results reported by Mannaerts et al., who also observed no clinically significant difference in haemoglobin drop or need for blood transfusion.7 However, this contrasts with a study by Amornpetchakul et al., which reported that carbetocin reduced postpartum blood loss and the incidence of atonic PPH.14 The side effect profiles of both drugs in our study were comparable, with no statistically significant differences in the incidence of nausea or headache. This finding is in partial accordance with Mannaerts et al., who noted a nonsignificant trend toward less nausea and vomiting with carbetocin.7 These safety data support the conclusion of Jin et al., who stated that carbetocin is associated with a similarly low incidence of adverse effects as oxytocin.13 This study also had several limitations that should be considered when interpreting the results. Firstly, as an observational study, it can demonstrate association but cannot definitively establish causality. The sample size, while adequate for our primary hemodynamic outcomes, may be insufficient to detect statistically significant differences in rarer side effects or smaller variations in blood loss. The assessment of uterine tone, reliant on surgeon palpation, introduces a degree of subjectivity, though this reflects standard clinical practice. Finally, the study was conducted at a single center with a specific patient population, which may limit the generalizability of the findings to other settings or populations with different risk profiles.

CONCLUSIONS

In patients undergoing caesarean section under spinal anaesthesia, carbetocin provides superior hemodynamic stability and significantly reduces the need for additional uterotonics compared to oxytocin. With equivalent uterotonic efficacy, comparable blood loss, and a similar side effect profile, carbetocin is a safe and effective alternative for postpartum haemorrhage prophylaxis.

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