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"A Comparative Study of Efficacy of Carbetocin and Oxytocin in Preventing Postpartum Hemorrhage in Lower Section Cesarean Section"

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ABSTRACT

BACKGROUND: Postpartum haemorrhage is one of the leading cause of maternal mortality and an important cause for serious morbidity in the developing and developed world. **AIM:** To compare efficacy of oxytocin and carbetocin in terms of intraoperative blood loss in cesarean section, additional uterotonic needed, side effects of both drugs and cost analysis. **METHODOLOGY:** This study was conducted to compare the efficacy of carbetocin and oxytocin in preventing postpartum hemorrhage in patients undergoing lower segment caesarean section and to study their side effects. A total number of 200 low risk singleton near term pregnant mothers, who had lower segment caesarean section were studied. Out of these, 100 patients received Inj carbetocin 100 mcg intravenously and 100 patients receives Inj oxytocin 10 IU intramuscularly after the delivery of anterior shoulder of the baby in lower segment caesarean section. **RESULTS:** It was found that intraoperative estimated blood loss, need for uterine massage, additional uterotonics and incidence of primary PPH was more among the group receiving oxytocin than carbetocin. Postoperative hemoglobin, HCT after 48 hours of caesarean section were affected drastically in oxytocin group along with need for postoperative blood transfusion in oxytocin group. **CONCLUSION:** Carbetocin appeared to be effective or more as oxytocin for prevention of atonic postpartum hemorrhage in patients undergoing elective cesarean section.

KEYWORDS: Carbetocin, Oxytocin, postpartum hemorrhage.

I. INTRODUCTION

The traditional definition of PPH is a bleed of 500 mL or more in vaginal deliveries and in excess of 1000 mL in abdominal deliveries, as quoted by the WHO, the American College of Obstetricians and Gynecologists (ACOG) and the International Federation of Gynaecology and Obstetrics (FIGO). Hemorraghe during first 24 hours after delivery is termed 'early' or 'primary' PPH, whereas 'late' or 'secondary' PPH occurs more than 24 hours after, but within 6-12 weeks of delivery.

Endogenous oxytocin is synthesized in the supraoptic and paraventricular nuclei of the hypothalamus, the axons of which terminate in the posterior pituitary gland. Oxytocin is rapidly eliminated by both the kidney and liver with a plasma half-life of approximately 1 to 6 minutes. Endogenous oxytocin production and secretion is controlled by a positive feedback mechanism in which the initial release of oxytocin stimulates actions, such as contractions, leading to cervical dilation and these actions amplify oxytocin release from the pituitary, referred to as the Ferguson reflex. The oxytocin receptor is a G-protein coupled receptor, and oxytocin binding and receptor activation triggers intracellular calcium mobilization and smooth muscle contraction.

Carbetocin is a long-acting structural analogue of naturally-occurring human oxytocin, with a half-life of approximately 40 minutes. To create carbetocin, several modifications were made to the oxytocin molecule, specifically the amino group (NH2) in cysteine has been replaced with a hydrogen atom, the disulphide bond has been changed to a thio-ether bond (CH2S), and the hydroxyl group (OH) of tyrosine has been substituted by methyl ether group. The carbetocin molecule is therefore more resistant to aminopeptidase and disulphidase cleavage. Together, these alterations reduce the chance of enzymatic degradation and prolong the half-life of the peptide (8 times longer) thus extending its pharmacological action.

Carbetocin has been recommended by the SOGC as the first line therapy for preventing uterine atony in women undergoing elective caesarean section. The Danish society of Obstetrics and Gynaecology recommends carbetocin for PPH prevention as an alternative to oxytocin in high risk women (twins, multipara, previous PPH and coagulation disorders) for caesarean sections and vaginal deliveries. Clinical guidelines from the National Centre for Health Technology Excellence in Mexico and the Queensland Maternity and Neonatal Clinical Guidelines Program also affirm

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that carbetocin is an effective therapy for preventing uterine atony and can be used or considered for use instead of continuous infusion of oxytocin in women delivering by elective caesarean section. A Cochrane review in 2012 found that carbetocin reduced the use of additional uterotonics and uterine massage, when compared with oxytocin. In 2018, a meta-analysis involving seven trials showed that carbetocin was effective in reducing the use of additional uterotonics, as well as in reducing postpartum haemorrhage and transfusion, when used during Caesarean section.

II. AIMS AND OBJECTIVES

The aim of the present study is to compare the efficacy of carbetocin and oxytocin in preventing PPH in lower section caesarean section.

The objective is to compare efficacy of oxytocin and carbetocin in terms of the following:

- To study intraoperative blood loss in cesarean section.
- To study additional uterotonic needed in caesarean section.
- To study side effects of both drugs
- To study cost analysis.

III. MATERIALS AND METHODS

This interventional prospective study was conducted on 200 pregnant women undergoing lower section caesarean section in the Department of Obstetrics and Gynecology, at Tertiary Care center & Teaching hospital of South Gujarat, from January 2023 to June 2024. The study was approved by the institutional ethics committee, and all patients provided written informed consent for participation. The study was conducted for period of 18 months.

The inclusion criteria was women with Near-Term pregnancy undergoing lower segment cesarean section upto 3rd gravida. The patients with Cardiac diseases, Renal diseases, Liver diseases, Epilepsy, Hypertension, Preeclampsia, Pre-existing bleeding disorder, Multiple pregnancy, Hypersensitivity to carbetocin and oxytocin, General anesthesia to be given were excluded from the study.

Patients in the present study were divided into two equal groups: Group I - 100 patients received Inj. Carbetocin 100 mcg Intravenously and Group II -100 patients received Inj. Oxytocin 10 IU Intramuscularly. The patients selected randomly were subjected to history taking, clinical examination, routine ANC investigations and ANC ultrasonography and were taken for lower section caesarean section under spinal anesthesia. Surgeons were asked to operate to a standard procedure that specifies transverse lower segment caesarean section. Active management of third stage of labor was done: administration of uterotonic agent with the delivery of the anterior shoulder of the baby. Delayed clamping and cutting of the umbilical cord after the birth. Applying controlled cord traction to the umbilical cord while applying simultaneously counter pressure to the uterus, through the abdomen. Even after this, desirable uterine contraction not felt then additional uterotonics were given (Inj. Carboprost 250 mcg intramuscularly). Intraoperatively, 10*10 cm^2 mops were used. When one 10*10 cm^2 mop was fully soaked, blood loss was estimated to be 100 ML. All women were followed up for the evaluation of outcomes after birth regarding vital signs after surgery and hemoglobin and hematocrit after 48 hours of surgery.

The data collection included age, parity, gestational age, routine investigations on entry into the study and outcome was observed on the basis of number of mops used, estimated blood loss in mL was calculated, uterine massage given intraoperatively, additional uterotonics to be given, any side effects, blood transfusion given, has postpartum hemorrhage occurred and postoperative investigations after 48 hours.

Statistical analysis: Recorded data were analysed using the statistical package for the social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Independent-samples t-test of significance was used when comparing between two means, Chi-square (x^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.

IV. RESULTS

In the following study population, no statistically significant difference was found between groups according to demographic data (**Table 1**). The mean age of study participants in the present study was 22.6 + 4.7 years.

International Journal Dental and Medical Sciences Research
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Table 1: Comparison between Carbetocin and Oxytocin group according to demographic data.

No	Variable	CARBETOCIN (N = 100)	OXYTOCIN (N =100)	P value
A	**AGE (YEARS)**			
	≤ 20	8	4	0.20
	21-25	43	60	
	26-30	41	31	
	31-35	7	4	
	>35	1	1	
B	**GESTATIONAL AGE(WEEKS)**			
	36-37 weeks	7	11	0.193
	37-40 weeks	66	63	
	>40 weeks	10	19	
	Not known	17	7	
C	**PARITY**			
	Primi	30	31	0.747
	Second	33	35	
	Third	37	34	

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. The changes in pre and postoperative HCT and Hb levels were significantly lower in carbetocin group in comparison with oxytocin **(Table 2).**

Table 2: Comparison of hemoglobin and hematocrit (HCT) and estimated blood loss of women enrolled to the study.

No	Variable	CARBETOCIN (N = 100)	OXYTOCIN (N =100)	P value
A	Hb preoperative (g/dl)	10.6 ± 2.1	10.2 ± 2.8	0.708
B	Hb postoperative (g/dl)	11.3 ± 4.7	9.2 ± 3.4	0.011
C	HCT preoperative (%)	53.6 ± 9.1	54.1 ± 11.8	0.147
D	HCT postoperative (%)	56.1 ± 14.3	52.2 ± 21.4	0.000
E	Estimated blood loss (ml)	286.9 ± 97.4	401.8 ± 88.6	0.000

As shown in the following **Table 3,** the need for uterine massage after administration of uterotonics was more in oxytocin group. It is evident from the **Table 3** that there is statistically significant difference among the groups in case of additional uterotonics (inj carboprost) given, administration of blood transfusion and incidence of PPH and their need and incidence are comparatively less in case of carbetocin group.

Table 3: Comparison of Uterine Massage, additional uterotonics, blood transfusion given and incidence of primary PPH among study participants in both groups.

No	Variable	CARBETOCIN (N = 100)	OXYTOCIN (N =100)	P value
A	**UTERINE MASSAGE GIVEN**			
	Yes	29	49	0.007
	No	71	51	
B	**ADDITIONAL UTEROTONICS GIVEN**			
	Yes	7	33	0.000

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	No	93	67	
C	**BLOOD TRANSFUSION GIVEN**			
	yes	4	12	0.033
	No	96	88	
D	**INCIDENCE OF PRIMARY PPH**			
	Yes	0	6	0.014
	No	100	94	

V. DISSCUSION

Mean age of women undergoing LSCS in carbetocin and oxytocin group was found to be 22.6 ± 4.7 years. In present study, majority of the patients belonged to the age group of 21-25 years in both the groups. Comparable results were seen in study conducted by **Arunshankar R et al** and **Mohamed E. Ahmed et al.**

The mean gestational age in carbetocin group was found to be 38.23 ± 2.86 weeks and that in oxytocin group were found to be 38.34 ± 3.65 weeks but there was no statistical significance observed among the distribution of gestational age in both groups. Similar results were observed in one of the studies conducted by **Mohamed E. Ahmed et al.**

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. Similar results were seen in studies of **Arunshankar R et al** and **Mohamed E. Ahmed et al.** However, **Attilakos et al. (2010)** demonstrated that there were no significant differences in the mean hemoglobin fall after the operation.

During the study, the postoperative blood loss was significantly lower in carbetocin group when compared to the oxytocin group. Similar results were observed in a study conducted by **Mohamed E. Ahmed et al** and **Korb et al.** On the other hand, in the study conducted by **Attilakos et al,** the results were found to be statistically insignificant.

There is statistically significant association as more patients in oxytocin group required uterine massage showing less efficacy of oxytocin compared to that of carbetocin. These results were comparable with the study by **Boucher et al 2004** and **Borruto et al.**

In consistence with our results, carbetocin seemed to be most beneficial compared with the oxytocin group with less need for additional uterotonic medication and significantly less need for blood transfusion. Similar results were observed with additional uterotonics in studies conducted by **Attilakos et al, Boucher et al 2004** and **Borruto et al.**

There was a statistically significant difference between the two groups regarding the occurrence of postpartum hemorrhage. The carbetocin group showed less occurrence of hemorrhage (0%) in comparison with 6% in oxytocin group. This suggests that carbetocin is longer acting than oxytocin and more efficacious in preventing PPH. This is comparable to a study conducted by **Korb et al.**

VI. CONCLUSION

Carbetocin shows several advantages in women undergoing caesarean section as compared with oxytocin: it significantly reduces the need for additional uterotonics and uterine massage, the time to further uterotonic treatments (when needed) is significantly increased, it is associated with more women experiencing blood loss <500 mL. In addition, carbetocin is now available as a new formulation which is stable at room temperature and is in a more convenient vial presentation. This eliminates the cold-chain considerations involved in therapy with oxytocin.

In conclusion, carbetocin is an effective option for the prevention of PPH and provides the above-described improvements over oxytocin.

VII. LIMITATION OF THE STUDY

The sample size in current study was small and it was conducted in one centre. If study would have been conducted with a larger sample size and in multiple centres, the result of the study would be more reliable and generalised. Since, the patients with pre-eclampsia, eclampsia, multiple pregnancy, pregnant females with known case of cardiac disorder, renal disease were excluded in current study, the overall effect of the drugs cannot be studied thoroughly. The observation in the current study are based on interventional and prospective observational studies. These are subject to biases and confounding factor that may have influenced the results.

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