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Research Article

A Comparative Study to Assess the Efficacy and Safety of Oxytocin, Misoprostol and Carboprost In Active Management of Third Stage of Labour at A Tertiary Care Hospital

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Abstract
Background: Third stage of labour is the most perilous for woman because of the risk of postpartum haemorrhage (PPH) and the primary cause being uterine atony. Active management of the third stage of labour is a well-established protocol.
Objectives: To assess the efficacy and safety of oxytocin, misoprostol and carboprost in active management of third stage of labour.
Methods: One hundred and eighty pregnant women with term gestation were recruited and randomised into three groups. Group A received intravenous infusion of 10U of oxytocin in 500ml normal saline, Group B received 600µg of Misoprostol per rectally and Group C received 125µg of Carboprost intramuscularly at the delivery of anterior shoulder of the baby. Primary outcomes were duration of third stage, amount of blood loss and incidence of PPH.
Results: Misoprostol and carboprost were associated with shorter durations of the third stage of labor (5.16 ± 1.85 and 5.25 ± 1.73 minutes, respectively) compared with oxytocin (6.43 ± 2.6 minutes). Blood loss was also significantly lower in the carboprost group (157.41 ± 49.43 ml) than in the misoprostol (183.25 ± 51.93 ml) and oxytocin (206.16 ± 56.81 ml) groups. Additionally, the carboprost group required the fewest additional uterotonic agents and experienced the smallest decreases in hemoglobin and hematocrit levels.
Conclusion: This study highlights the superior uterotonic profile of carboprost 125µg compared to other agents studied. Prophylactic carboprost may therefore be a valuable alternative for the active management of the third stage of labor.

Keywords: Active management of third stage of labour; Oxytocin; Misoprostol; Carboprost

INTRODUCTION

The third stage of labour is the time from the birth of the baby to the delivery of the placenta and membranes. [1] This period is perilous for woman because of the risk of postpartum haemorrhage (PPH). The World Health Organization (WHO) defines PPH when blood loss after birth exceeds 500 ml in the first 24 hours. [2] Though healthy women can easily cope with this amount of blood loss, for women of low-income countries who may be malnourished and anaemic it can cause considerable morbidity and mortality. Postpartum haemorrhage complicates approximately 4% of vaginal deliveries and accounts for 25% of maternal deaths worldwide, making it a major public health concern.[3]

"Uterine atony, the leading cause of postpartum hemorrhage (PPH) as defined by

the WHO, accounts for 75% of all cases.[4] While risk factors for severe hemorrhage and adverse maternal outcomes have been identified, PPH often occurs unexpectedly, even in the absence of recognized clinical or historical risk factors.[5] Therefore, the cornerstone of PPH management is prevention, followed by effective treatment should prevention fail.

Active management of the third stage of labor (AMTSL) is a proven strategy for significantly reducing the incidence of postpartum hemorrhage (PPH),[6,7] decreasing blood loss by 20% and shortening the third stage by 50%.[8] As defined by FIGO and WHO, AMTSL comprises uterotonic administration, controlled cord traction, and uterine massage. Routine uterotonic use during the third stage is a crucial intervention for PPH prevention. While the choice of uterotonic depends on clinical judgment, drug availability, and a balance of benefits and side effects, the optimal agent remains a subject of ongoing investigation.[2]

Oxytocin, administered prophylactically or after placental delivery, reduces postpartum hemorrhage (PPH) by 40%.[9] Its efficacy is comparable to ergot alkaloids or prostaglandins, but with fewer side effects, making it the preferred agent for PPH prevention.[10,11,12]

Misoprostol, a PGE1 analogue, offers several advantages for resource-limited settings. Its multi-year shelf life and temperature stability eliminate specialized storage requirements, and its low cost makes it a viable option for active management of the third stage of labor (AMTSL).[13] Carboprost, a 15-methyl analogue of PGF2-alpha, is effective in managing severe PPH caused by uterine atony unresponsive to conventional treatments, including cases where oxytocin has failed.[14]

While the WHO recommends intravenous oxytocin as first-line treatment for PPH prevention, this recommendation is based on only moderate-quality evidence.[2] Recommendations for ergometrine or prostaglandins are supported by even weaker evidence. Consequently, there is a clear need to identify the most effective agent for PPH prevention. This study aimed to evaluate the efficacy and safety of oxytocin, misoprostol, and carboprost in the active management of the third stage of labor.

METHODOLOGY

It is a Prospective, open label, comparative study, was conducted in the labour wards of Vani Vilas hospital attached to Bangalore Medical College and Research Institute. After obtained clearance and approval from the institutional ethics committee, one hundred and eighty women with singleton pregnancy with > 37 weeks of gestation, anticipated vaginal delivery with longitudinal lie, who were willing to give written and informed consent, included in the study. one hundred and eighty study subjects were divided into three groups of sixty each. The study drug was administered at the birth of anterior shoulder of the baby. Group A received intravenous oxytocin 10 IU in 500ml of normal saline. Group B received misoprostol 600 µg per rectal. Group C received carboprost 125 µg intramuscularly. The patients who were excluded are, Gestational age < 37 weeks and > 41 weeks, History of hypersensitivity to any of the active ingredients of the preparations that will be used and Women with any of the conditions like Previous PPH, previous caesarean section, Grand multipara, Anaemia, Prolonged labour, Twin pregnancy, Eclampsia, Pre-eclampsia, Antepartum haemorrhage and Hydramnios. Socio-demographic data and clinical examination – general, systemic and obstetric was recorded using case record form. Efficacy was assessed by both primary and secondary outcome. Primary Outcome was measured by the Duration of third stage of labour, the Amount of blood loss during the third stage, and incidence of postpartum hemorrhage. Blood loss was estimated using calibrated Brass V obstetric drape. Secondary Outcome was measured by the number of patients requiring additional doses and alternative uterotonics, Number of patients requiring blood transfusions, Number of patients requiring hysterectomy, Number of patients shifted to ICU, and Percentage decrease in haemoglobin and hemotocrit concentration after 24 hrs postpartum from baseline depends on Lab investigations. Safety - Adverse drug reactions was assessed using WHO causality assessment scale.

RESULTS

Table 1: Maternal age distribution in the study groups

Age group (years)	Oxytocin	Misoprostol	Carboprost

	(n = 60)	(n = 60)	(n = 60)
≤ 20	22 (36.7%)	11 (18.3%)	24 (40%)
21- 25	27 (45%)	35 (58.3%)	23 (38.3%)
26 – 30	10 (16.6%)	12 (20%)	11 (18.3%)
>30	01 (1.6%)	02 (3.3%)	02 (3.3%)
Mean age ± SD	22.83 ± 3.50	23.5 ± 3.44	22.53 ± 3.71
Range	18 – 33	18 – 32	18 – 32

Chi square test: $X^2 = 8.38$, $p = 0.21$
Table 1 demonstrates that the maternal age group distribution of participants in all three treatment groups were well-matched at baseline.

p-value <0.05 is considered statistically significant.
Data was analyzed using a chi-square test

Table 2: Baseline Characteristics

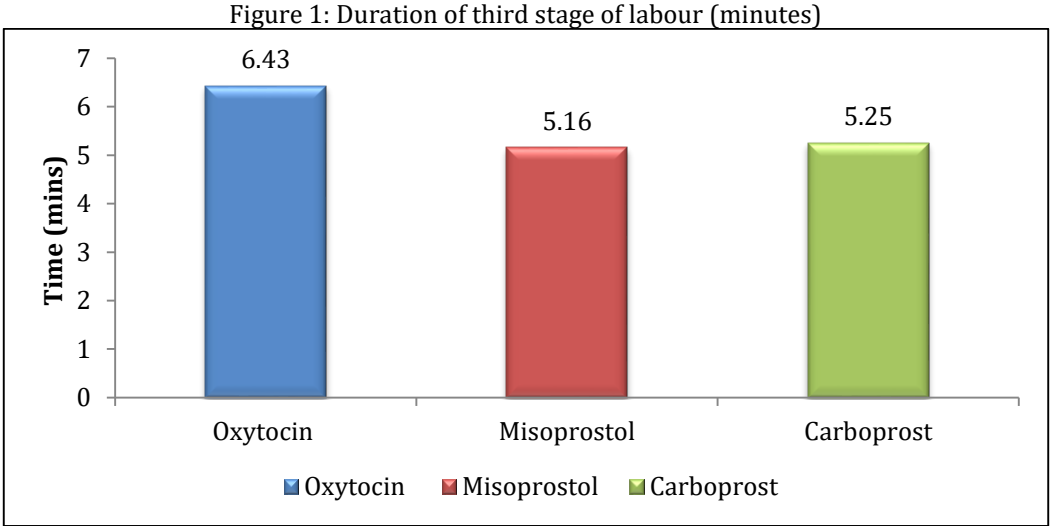
S.no	Baseline characteristics		Oxytocin	Misoprostol	Carboprost	p-value
1.	Parity	Primi	36 (60%)	28 (47%)	38 (63%)	0.14
		Multi	24 (40%)	32 (53%)	22 (37%)	
2.	Gestational age in weeks	37-38 weeks	15 (25%)	13 (21.7%)	17(28.3%)	0.93
		>38weeks	45(75%)	47(78.3%)	43(71.6%)	
3.	Mode of labor	Spontaneous	43 (71.7%)	44 (73.3%)	18 (30%)	0.92
		Induced	17 (28.3%)	16 (26.7%)	42 (70%)	
4.	Requirement of episiotomy	Required	54 (90%)	42 (70%)	53 (88.3%)	0.06
		Not required	06 (10%)	18 (30%)	07 (11.7%)	

Table 2 demonstrates that the baseline characteristics of participants in all three treatment groups were well-matched at baseline.

p-value <0.05 is considered statistically significant.
Data was analyzed using a chi-square test.

Efficacy Parameters
Primary outcome

Figure 1: Duration of third stage of labour (minutes)



F = 6.83, **p = 0.0013*** , Data Analysed using one way ANOVA

Post HOC Tukeys Test –* p < 0.01 between oxytocin and misoprostol

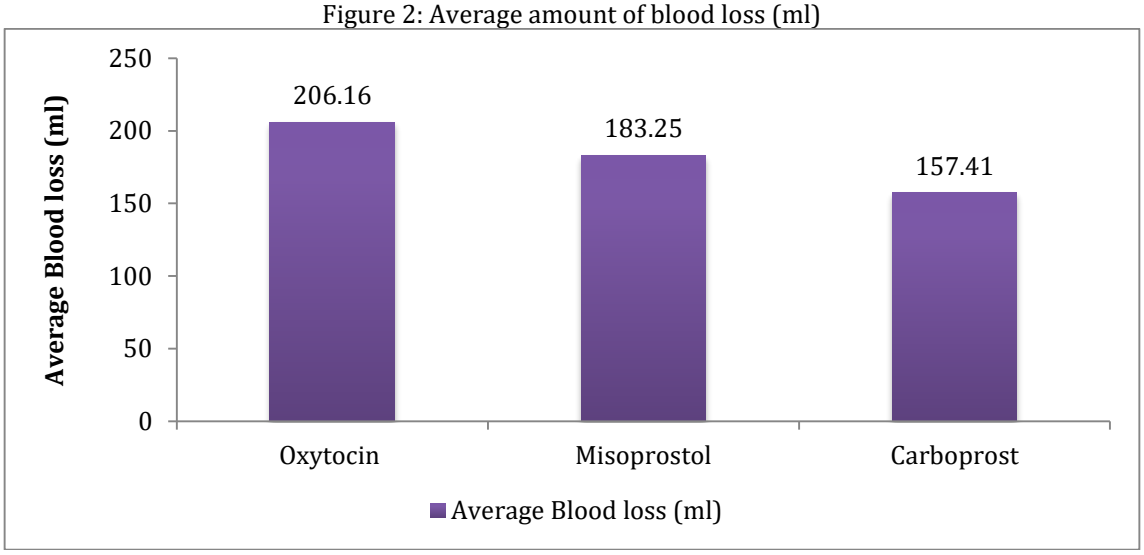
** p < 0.01 between oxytocin and carboprost

The average duration of third stage of labour in oxytocin group was 6.43 ± 2.6 minutes, Misoprostol 5.16 ± 1.85 minutes in misoprostol and 5.25 ± 1.73 minutes in carboprost group.

The average duration of third stage of labour in misoprostol group was significantly reduced as compared to oxytocin group (p < 0.01). The average duration of third stage of labour in carboprost group was significantly reduced as compared to oxytocin group (p < 0.01).

There was no significant difference in average duration of third stage of labour between misoprostol and carboprost group.

Figure 2: Average amount of blood loss (ml)



F = 12.79, **p = 0.0001***, Data Analysed using one way ANOVA

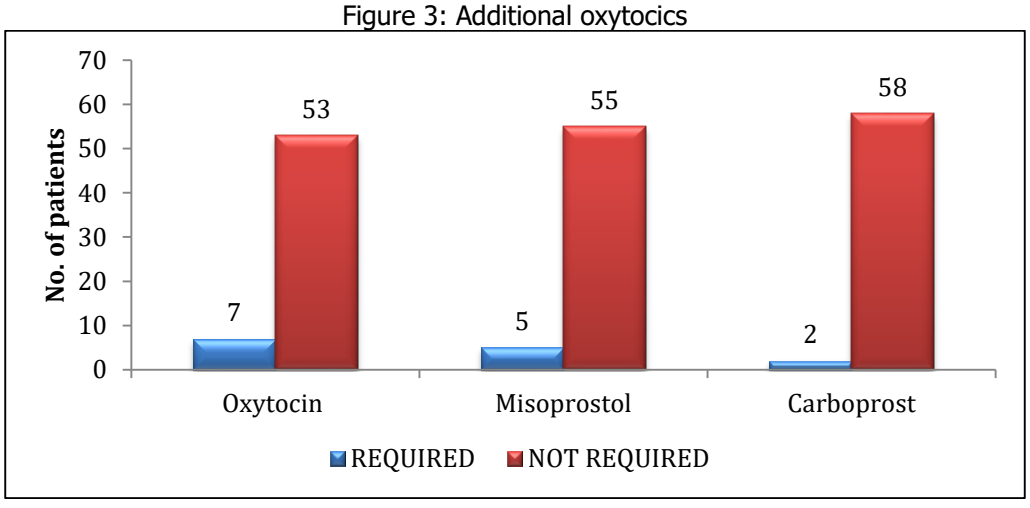
Post HOC Tukeys Test –* p < 0.05 between oxytocin and misoprostol

** p < 0.01 between oxytocin and carboprost

# p < 0.05 between misoprostol and oxytocin

The average amount of blood loss was more in oxytocin group – 206.16 ± 56.81 ml, 183.25 ± 51.93ml in misoprostol and least in carboprost 157.41 ± 49.43 ml. There was statistically significant difference between the three groups.

Figure 3: Additional oxytocics



In Oxytocin group, 7 partuitants required additional oxytocic,5 patients and 2 patients in misoprostol and carboprost required additional oxytocic.

The difference in usage of additional oxytocic was not statistically significant.

Table 3: Haemoglobin changes in Study Groups

GROUP	PRE-PARTUM Hb%	POST-PARTUM Hb%	Drop in Hb%
Oxytocin	10.9 ± 1.3	9.9 ± 1.3	1 ± 0.1
Misoprostol	11.3 ±1.1	10.5 ± 1.2	0.8 ± 0.1
Carboprost	11.2 ± 1.3	10.7 ± 1.3	0.6 ± 0.1

t test - change in Hb% within group was significant in all the groups **(p < 0.05)**
One way ANOVA – drop in Hb% between the group was also significant
Post HOC Tukeys Test – p < 0.01 in oxytocin vs misoprostol, oxytocin vs carboprost & misoprostol vs carboprost

There was reduction of post-partum haemoglobin in all the groups. The difference was 1gm/dl, 0.8gm/dl and 0.6gm/dl in oxytocin, misoprostol and carboprost group respectively.
Intergroup comparison showed that reduction in Hb% between groups was significant.

Figure 4: Haemoglobin changes in Study Groups

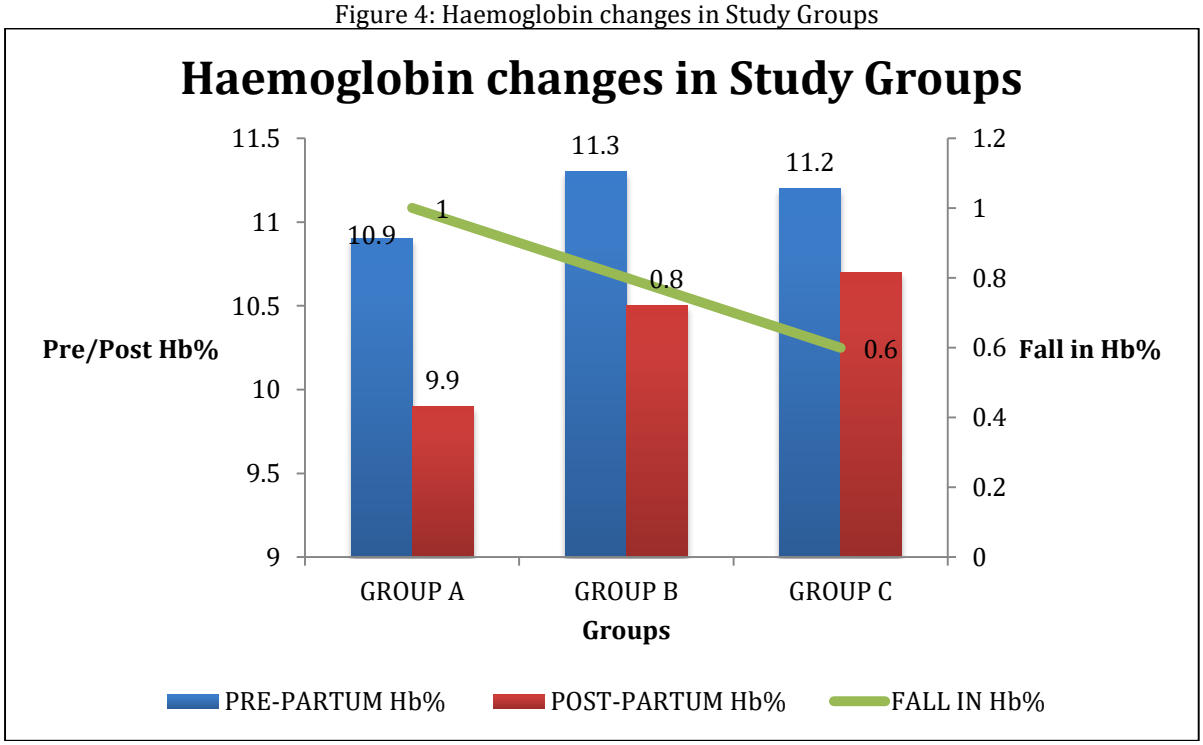


Table 4: Haematocrit changes in Study Groups

GROUP	PRE-PARTUM HCT%	POST-PARTUM HCT%	DROP IN HCT%
Oxytocin	33 ± 3	30.1 ± 3.6	2.9 ± 1.2
Misoprostol	34.1 ± 3	32.1 ± 3.3	2 ± 1
Carboprost	33.9 ± 3	32.3 ± 3.5	1.6 ± 1*

t test - change in HCT% within group was significant in all the groups **(p < 0.05)**

One way ANOVA – drop in HCT% between the group was also significant
Post HOC Tukeys Test – $p < 0.01$ in oxytocin vs misoprostol,
oxytocin vs carboprost
*non significant in misoprostol vs carboprost

There was reduction of post partum haematocrit in all the groups. The difference was 2.9%, 2 % and 1.6 % in oxytocin, misoprostol and carboprost group respectively.

Figure 5: Haematocrit changes in Study Groups

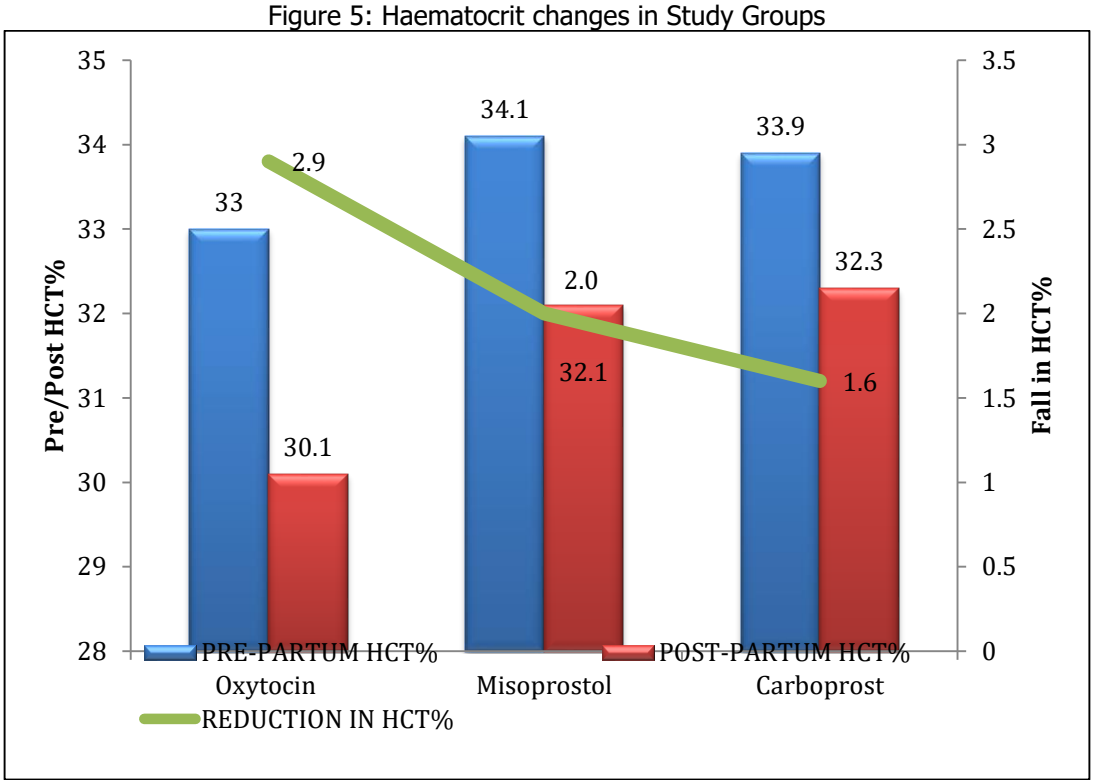


Table 5: Adverse effects in the study groups

ADVERSE EFFECTS	OXYTOCIN (n=60)	MISOPROSTOL (n=60)	CARBOPROST (n=60)
NAUSEA	1	0	1
VOMITING	0	1	1
PYREXIA	1	5	3
SHIVERING	0	9	0
DIARRHEA	0	1	2
ABDOMINAL CRAMPS	0	4	0

DISCUSSION

Postpartum hemorrhage (PPH) is a major contributor to maternal mortality globally, responsible for approximately 25% of all such deaths. PPH can be classified as atonic (originating from the placental implantation site), traumatic (resulting from injury to the genital tract), or a combination of both. Reported incidence rates range considerably, from 3% to 15% of all deliveries. Of those affected, roughly 20% experience severe PPH, posing a life-threatening risk to the mother.[15]
Active management of the third stage of labour (AMTSL) has become a cornerstone of

modern obstetrics, demonstrably reducing both the incidence of PPH and the morbidity associated with uterine atony. Compared to expectant management, AMTSL is associated with decreased blood loss, lower transfusion rates, a shorter third stage, and a reduced risk of postpartum anemia. The core principle of AMTSL involves stimulating robust uterine contractions shortly after delivery of the anterior shoulder through the administration of a parenteral oxytocic agent. This promotes both timely placental separation and effective sustained uterine contraction post-separation.[16,17] Despite widespread recognition of its importance, management of the third stage of labour exhibits significant global variations. Furthermore, an optimal oxytocic regimen, specifically regarding drug type and route of administration, remains undefined. This lack of consensus prompted the present study.

Maternal Age: In this study, the largest proportion of participants (47%) were aged 21-25 years (Table 1), consistent with findings reported by Supe et al.[13] This contrasts slightly with the mean maternal age of 25 years observed by Gohil et al.[18] This difference likely reflects the typical age range of peak reproductive activity.

Parity: Table 2 shows that the majority of the pregnant women in this study were primigravid (57%), with 43% being multigravid. This distribution aligns with the findings of Ramappa et al.[19] However, it contrasts with the results reported by Vaid et al.[20] and Walley et al.[21.] In multiparous women, factors such as anemia, inadequate uterine retraction, and a history of adherent placenta may contribute to the risk of PPH.

Period of gestation: More than half of the study partuitants were between 38 - 39 weeks of gestation as seen in Table 2. This gestational age distribution differs from that reported by Supe et al.[13]

Induction of labour: In our study the onset of labour was spontaneous in 71.1% and induced in 28.3% which was alike the study done by Gohil et al. [18]

Episiotomy: Episiotomy was performed across all study groups in this research, is often associated with underestimation of blood loss, which can increase the risk of postpartum hemorrhage.[22] The presence of multiple bleeding sites, even if individually considered within a physiological range, cumulatively elevates the risk of PPH. This highlights the importance of restrictive episiotomy policies during vaginal birth.

Duration of third stage of labour:

The mean duration of the first and second stages of labor was similar across all three study groups. However, the third stage was significantly shorter in the misoprostol (5.17 minutes) and carboprost (5.25 minutes) groups compared to the oxytocin group (6.43 minutes). These findings are consistent with previous research. Sunil Kumar et al.[23] reported a significantly shorter third stage with carboprost (6.05 minutes) compared to oxytocin (7.02 minutes). Our results contrast with those of Ramappa et al.[19] who found no significant difference between carboprost (3.73 minutes) and oral misoprostol (4.07 minutes). Carboprost is a potent uterotonic agent that plays a physiological role in both fetal delivery and postpartum hemorrhage control. It exhibits a dose-dependent effect, increasing uterine tone, contraction frequency, and contraction intensity. A study by Lamba et al.[24] conducted in North India, reported a third-stage duration of 4.32 minutes using a higher carboprost dose of 250µg. None of the study subjects in our study had prolonged third stage of labour or retained placenta.

Blood loss

The extent of blood loss during placental separation and delivery is determined by the speed of placental detachment, the effectiveness of uterine contraction around the placental bed and blood vessels, and the efficiency of placental expulsion. Uterotonic agents induce strong uterine contractions, compressing the myometrial arteries and arresting hemorrhage from the placental separation site. In this study, statistically significant differences were observed in mean blood loss: 206.16 ml in the oxytocin group, 183.25 ml in the misoprostol group, and 157.41 ml in the carboprost group. The carboprost group exhibited the lowest blood loss, a statistically significant finding consistent with the results of Pandey et al.[25] and Lamba et al.[24] when compared to misoprostol and oxytocin, respectively. Intramuscular carboprost administration in healthy postpartum women effectively enhances uterine contractility while simultaneously inducing vasoconstriction.

In this study, the majority of women in all three groups experienced blood loss of up to 200 ml, with no instances of blood loss exceeding 500 ml, and therefore no cases of

PPH as defined by that threshold. Among those experiencing blood loss between 200 and 300 ml, the oxytocin group had the highest number, followed by the misoprostol group, and then the carboprost group. Given the high prevalence of anemia among childbearing women in India, minimizing blood loss is crucial for reducing the risk of postpartum anemia, infection, and subsequent morbidity.

This study analysed several secondary outcomes following childbirth, including the need for additional uterotonic medications, blood transfusions, hysterectomy, intensive care unit (ICU) admission, and the percentage decrease in hemoglobin and hematocrit levels 24 hours postpartum. No patients in this study required blood transfusions, hysterectomy, or ICU admission. Fourteen partutients required additional uterotonics to control bleeding. The requirement for additional uterotonics alongside the primary medication suggests an increased risk of postpartum hemorrhage. Our findings indicate that patients receiving carboprost required fewer additional uterotonics compared to the other two groups studied. None of the patients in the study groups required blood transfusion or surgical intervention.

This study found that side effects were most prevalent in the misoprostol group, specifically where 15% of partutients experienced shivering, a side effect not observed in the other two groups. However, this shivering was self-limiting, resolving within 10-15 minutes in all cases. In the carboprost group, side effects included nausea (1.6%), vomiting (1.6%), diarrhea (3.3%), and fever (5%). The oxytocin group exhibited the fewest side effects, with only 1.6% of patients experiencing nausea and 1.6% reporting fever.

This study's strengths included the randomized study design and the objective measurement of blood loss using the Brass V drape method, along with the assessment of hematocrit concentration as recommended by American College of Obstetricians and Gynecologists.

This study has some limitations. The lack of blinding could have introduced bias. Furthermore, the necessary administration of additional oxytocics in some cases may have masked the true extent of blood loss and decrease in hemoglobin concentration. The single-center design also limits the generalizability of the findings. A larger, multicenter trial, including high-risk pregnancies, is needed to definitively establish the equivalence of these three uterotonic agents.

CONCLUSION

In conclusion, this study suggests that carboprost 125µg demonstrates a superior uterotonic profile compared to the other medications studied. Its prophylactic use may be considered as an alternative approach in the active management of the third stage of labor.

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Conflict of Interest: Nil

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