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Original Research Article

TO COMPARE THE EFFICACY AND SAFETY OF SUBLINGUAL MISOPROSTOL 600µG AND INTRAMUSCULAR OXYTOCIN 10 IU IN THE ACTIVE MANAGEMENT OF THIRD STAGE OF LABOUR AT TERTIARY CARE CENTRE- A HOSPITAL BASED OBSERVATIONAL STUDY

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ABSTRACT

Background: Misoprostol has attracted low-income low-resource countries for the active management of the third stage of labour. The objective of this study was to compare the efficacy of sublingual misoprostol and intramuscular oxytocin in the active management of the third stage of labour. **Materials & Methods:** Total three hundred low risk pregnant women at term gestation with spontaneous onset of labour were included in the study and were divided into 2 groups of 250 women each. Group A and Group B patients were given Sublingual 600mcg Misoprostol and Intramuscular 10 IU of Oxytocin, at the time of delivery of anterior shoulder of baby. The main outcome measures with respect to third stage of labour were duration, blood loss by volume, difference in haemoglobin, need for additional oxytocics and side effects. **Results:** Oxytocin group had a slightly reduction in blood loss (p=0.22) when compared to the misoprostol group, but there was no statistical significant difference found. There was no statistically significant difference in the duration of third stage of labour and mean fall in haemoglobin level in two groups (p>0.05). Need for additional oxytocics were more in Misoprostol group (%) as compared to Oxytocin group. **Conclusion:** It is evident from the present study that Sublingual Misoprostol 600mcg can be used as alternative to Intramuscular Oxytocin 10 IU in active management of third stage of labour especially in developing countries, even though side effects are comparatively more with Misoprostol group than oxytocin but they are not life threatening.

INTRODUCTION

Post partum haemorrhage (PPH) is an important cause of maternal morbidity and mortality especially in developing countries where up to 25% of the maternal deaths are attributed to this cause. Although risk factors may increase a woman's chances of developing post-partum haemorrhage, 2/3rd of the cases of PPH occur without any predisposing factors, hence all pregnant women remain at a risk of developing PPH.

World Health Organization recommends the use of uterotonics for the prevention of postpartum hemorrhage (PPH) during the third stage of labor in all types of birth.[1] According to these guidelines, administration of a uterotonic immediately after the birth of the baby is useful in reducing the risk of PPH. Misoprostol, carboprost, and oxytocin are some of the commonly used uterotonics for the management of the third stage of labor. The use of prostaglandins such as misoprostol is popular as it is economical and can be administered orally, sublingually, and through vaginal or rectal routes, whereas oxytocin can be delivered intravenously or intramuscularly. Oxytocin is a hormone that stimulates uterine contractions and prevents PPH and is a recommended standard of care during the third stage of labor for the prevention of PPH.[1]

Active management of third stage of labour is constituted by use of uterotonics immediately after the delivery the of the anterior shoulder, delayed cord clamping and placental delivery by controlled cord traction(optional), Fundal massage(optional), post partum uterine vigilance.[1] The prophylactic use of

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oxytocic's in the third stage of labour has shown to significantly reduce the risk of postpartum haemorrhage by about 40%, implying that for every 22 women who are given such an oxytocic, one postpartum haemorrhage is prevented, so its use is generally advocated in the management of third stage of labour.

Most of the oxytocic's require parenteral administration and oxytocin is one of the most widely used oxytocic. However, the administration and storage of oxytocin may not always be possible in some hospitals or rural communities due to non-availability of sterile needles, syringes or refrigeration equipment. The efficacy of syntometrine is significantly reduced when it is stored in suboptimal environment.

Oral administration of ergometrine has shown to be ineffective in reducing postpartum blood loss.[2] The use of ergometrine is contraindicated in hypertensive cases as ergometrine stimulates vasoconstriction, causes hypertension, and may cause headache, convulsions and even death in pre-eclamptic cases. Misoprostol shown to decrease the mean arterial pressure and systemic vascular resistance, hence may be used as an oxytocic in hypertensive or pre-eclamptic women undergoing vaginal delivery.[3]

Misoprostol is an orally active uterotonic agent; it is a prostaglandin E1 analogue and was first marketed as a drug against NSAID induced gastritis. It is also found to be effective in medical cervical ripening, induction of labour, and first and second trimester termination of pregnancy. After sublingual administration it is absorbed rapidly into the blood stream. It is stable at high temperature and has a long shelf life. WHO has also recently recommended the use of misoprostol for active management of third stage of labour, especially by trained birth attendants in rural areas. The present study is an attempt to evaluate the safety and efficacy of sublingual misoprostol 600µg and intramuscular oxytocin 10 IU in AMTSL.

MATERIALS AND METHODS

A hospital based prospective study done on 300 women in labour in department of gynaecology at Government Medical college, Chhitorgarh, Rajasthan, India during one-year period.

The inclusion criteria were low-risk pregnant women in labor having singleton pregnancy, cephalic presentation, scheduled to undergo vaginal delivery, and willing to participate in the study. The exclusion criteria were women undergoing instrumental delivery, women with a history of uterine surgery, polyhydramnios, cardiac diseases, respiratory diseases, coagulation disorders, and hypertensive disorder with pregnancy, and women with hypersensitivity to the drugs being administered. Women who had traumatic PPH were also excluded.

The cases were divided into two equal groups. Each of the patients was allotted to one of the groups by random sampling method.

Group A: 600 mcg sublingual misoprostol given at the time of delivery of anterior shoulder.

Group B: Inj. Oxytocin 10 IU i.m, given at the time of delivery of anterior shoulder.

Methodology:

An informed consent was obtained from each patient who satisfied the inclusion criteria. Selected patients were registered and underwent a detailed history, general and systemic examination like cardiovascular system, respiratory system, per abdomen and per vaginal examination. Routine investigations sent.

The women were given either Sublingual misoprostol 600mcg or Intramuscular oxytocin 10 IU at the delivery of anterior shoulder of foetus.

The placenta was delivered by controlled cord traction. The duration of third stage of labour was noted in both the groups. The blood loss was measured in both the groups for the 1st hour after the delivery. The blood loss was measured by graduated jar after direct collection in the pan and by gravimetric method. Post partum haemorrhage in the present study is defined as blood loss more than 500ml in 1st hour after delivery. Once the diagnosis of post-partum haemorrhage was made, the patients were managed as per the needs by giving additional oxytocics drugs (injection Methyl ergometrine or injection Prostadin). The maternal Hemoglobin was measured on admission and 24hrs after delivery by Sahli's Hemoglobinometer and the change in haemoglobin percentage was taken as an objective measure of post-partum haemorrhage. The patients were observed for one hour following the delivery for vital signs and bleeding for vagina. The occurrence of side effects like nausea, vomiting, shivering, fever, diarrhoea, hypotension etc within first 24hrs of delivery were recorded. This study was computed by using parametric and non-parametric tests like impaired 't'-test and chi-square test.

RESULTS

Our study showed that Misoprostol group and Oxytocin Group had Mean age of 26.78±3.67 and 27.24±3.21 respectively, value was calculated and p value of 0.410 was obtained. Therefore, No Significant difference found. 102 belonged to "Misoprostol Group" and 104 to "Oxytocin Group" from the parity group Multigravida. Therefore, No Significant difference found P-Value of 0.734 was obtained (table 1).

Duration of 3rd stage of labour in Misoprostol Group and Oxytocin Group was 4.63±1.31 and 4.37±1.28 respectively, which was statistically non-significant (P>0.05) (table 1).

In the present study, distribution of blood loss in the two groups showed mean blood of 186.32 ml in misoprostol group, while in the oxytocin group 178.27 ml which is statistically insignificant.

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Therefore, in our study mean blood loss in third Stage is significantly low (table 2).

Table 1: Different Variables in between groups

		Misoprostol group (N=150)	Oxytocin group (N=150)	P-value
Age (yrs) (Mean±SD)		26.78±3.67	27.24±3.21	>0.05
Parity	**Primi**	48 (32%)	46 (30.66%)	>0.05
	Multi	102 (68%)	104 (69.33%)	
Average duration (mins)		4.63±1.31	4.37±1.28	>0.05

Table 2: Comparison of outcome

Outcome	Misoprostol Group	Oxytocin Group	P value
Mean amount of blood loss (in ml)	186.32 + 53.65	178.27 + 44.29	0.382
Mean amount of fall in haemoglobin level (gm/dl)	0.385+ 0.263	0.357 + 0.227	0.072
Use of Additional Oxytocics	7	3	0.093

DISCUSSION

Post partum haemorrhage is one of the most important cause of maternal deaths throughout the world. Active management of the third stage of labour has reduced its incidence in many countries. The third stage of labour is a crucial period where negligence can turn a previously uneventful pregnancy into a disaster. The role of oxytocics is to stimulate myometrial contraction, the major factor reducing the third stage bleeding.

Recent studies show that there are still wide variations in practice around the world in the management of third stage of labour. Methylergometrine is a conventional oxytocic used extensively but is associated with unpleasant side effects like hypertension. Intramuscular oxytocin used alone has been found effective in preventing postpartum haemorrhage and results in fewer side effects and is recommended by world health organization.

Misoporstol, a synthetic analogue of Prostaglandin E1 has been extensively studied for the prevention of postpartum haemorrhage administered by oral, rectal route, sublingual route. Recent studies shows that it is also effective in prevention and treatment of post-partum haemorrhage. Sublingual route avoids the first pass effect through the liver and can also be given in patients where oral administration is not possible. It is associated with side effects like shivering and fever.

A study done by Shilpa pawar et al (2014)[4], the mean age in misoprostol groups 25.14±6.3 and in oxytocin group was 25.37±4.8 years which was statistically non-significant. This study was compatible with our results.

In the present study, the duration of third stage of labour was compared between 2 groups. It is found that the mean duration of the third stage in the misoprostol group was 4.63 min while in the oxytocin group it was 4.37 min. By applying chi square test and p value of 0.298 is not statistically significant. Shilpa pawar et al (2014)[4] found no statistically significant difference in the mean duration of third stage of labour.

Even the studies that found sublingual misoprostol to be as effective as intramuscular oxytocin documented a significantly higher rate of adverse events in the misoprostol group compared to the oxytocin group.[5,6] Mukta and Sahay reported the mean amount of blood loss to be higher (15.9% higher) in the misoprostol group compared to the oxytocin group, but they did not find this difference to be statistically significant.[5] They also observed that the mean fall in hemoglobin levels was higher in the misoprostol group (0.55 g/dl) than in the oxytocin group (0.48 g/dL) but again did not find it to be statistically significant. In the present study, we observed similar results and found this difference to be statistically significant.

A Cochrane review evaluating the use of prostaglandins for the prevention of PPH, which included data from 72 trials involving 52,678 women, concluded that the use of misoprostol over conventional injectable uterotonics cannot be preferred as part of the management of the third stage of labor, particularly in low-risk women.[7] In the present study, we also found that sublingual misoprostol was significantly less effective in preventing PPH than the conventional uterotonic (intramuscular oxytocin) recommended for the active management of the third stage of labor.

In their study from Nepal, which had a sample size of 120 (60 in each group), Kaudel et al. observed that in few women blood loss was >200 mL in third stage of labor. Four women in the misoprostol group and one woman in the oxytocin group had > 200 mL of blood loss. Average blood loss was higher (118 mL) in the third stage of labor in the oxytocin group compared to the misoprostol group (115.5 mL) and fall in hemoglobin level was higher in the misoprostol group (0.56±0.35 g/dL) compared to the oxytocin group (0.46±0.29 g/dL).[8] There was a significant difference in the side effect profile between the two groups. However, they found misoprostol to be as effective as oxytocin.

Studies from other underdeveloped and developing countries report similar findings[9,10], despite showing the higher amount of blood loss, the need for additional uterotonics, and the adverse effects in the misoprostol group.

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CONCLUSION

Women in low income countries continue to die at alarming rates from preventable postpartum haemorrhage. It is for this reason that the lifesaving potential of sublingual misoprostol must be further explored. Hence sublingual misoprostol can be used in place of intramuscular oxytocin prophylactically during active management of third stage of labour in low risk women for vaginal delivery in areas where the appropriate storage condition for oxytocin injection is not possible. It also has the advantage of easy mode of administration and does not require cold storage and cold chain transportation.

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