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Role of 600mcg Sublingual Misoprostol in Active Management of Third Stage Of Labour. Comparitive Study with Oxytocin 10 Iu I.M.

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Abstract: *This is a hospital based prospective randomized study conducted at department of Obstetrics and Gynaecology , Guntur, Andhra Pradesh.*
Objective: *Postpartum hemorrhage is one of the leading causes of maternal mortality.Our study aims to evaluate and compare the effectiveness of sublingual misoprostol (600mcg) versus intramuscular oxytocin (10 IU) in prevention of postpartum hemorrhage.*
Conclusion: *Misoprostol is as effective as intramuscular Oxytocin(10IU). Misoprostol has advantage of ease of administration by unskilled health personnel. Side effects of this drug are also not severe and it can be used safely in third stage of labour for prevention of atonic postpartum hemorrhage.*
Keywords: *Misoprostol , Oxytocin , Post partum hemorrhage , Sublingual route , Active management of third stage of labour.*

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I. Introduction

Pregnancy and child birth involves significant health risks , even to women with no pre-existing health problems. Post partum hemorrhage is the most common cause of obstetrical hemorrhage. Atonic postpartum hemorrhage accounts for a mortality rate of 1,40,000 per year, or one maternal death for every four minutes worldwide and is the most common preventable cause [1]. As per SRS 2010-12 reports , Indian Maternal mortality rate is 178 per one lack live births while that of Andhra Pradesh is 110 per one lack live births [2]. Uterine atony accounts for 80% of cases of postpartum hemorrhage [3-4]. Majority of these deaths are due to problems of third stage of labour and occur within four hours of delivery[5,6] . Post partum hemorrhage is defined as any amount of bleeding from or in to genital tract following birth of baby within 24hrs of delivery. Active management of third stage of labour which includes early cord clamping, controlled cord traction for placental delivery and intramuscular uterotonic therapy is an effective measure to prevent postpartum hemorrhage. Active management of third stage of labour has shown to reduce the blood loss by as much as 66% in comparison to expectant management [7].Oxytocin is unstable at high ambient temperature, need refrigeration for storage and transport, need clean syringe and trained person for administration. It is expensive, has certain limitations and unpleasant side effects. FIGO recommends active management of third stage of labour for all parturients to reduce the postpartum hemorrhage and its related consequences[8].Where maternal mortality is high and resources are limited, the introduction of low cost, evidence based practices to prevent and manage postpartum hemorrhage can improve maternal and infant survival. Thus, there is a need for an effective uterotonic drug that can be administered orally and which does not require special storage condition.

Misoprostol, a synthetic prostaglandin E1 analogue, which causes the uterus to contract and thus reduce postpartum bleeding. Misoprostol has a range of potential benefits including ease of administration (oral and rectal or sublingual), rapidly absorbed, low cost and does not require any specific condition for the storage and transport, has a shelf-life of several years and thus is a suitable uterotonic agent for use in prophylactic management of third stage of labour especially in developing countries like ours. The present study is an attempt to assess the effect of sublingual misoprostol on third stage of labour in comparison with standard oxytocin regimen[9].

II. Aim of the study

Postpartum hemorrhage is the most common cause of obstetrical hemorrhage and leading cause of maternal death. Our study aims to compare sublingual misoprostol (600mcg) and oxytocin 10 IU intramuscular in the active management of third stage of labour ; to study the blood loss in both groups ; to study the side effects of both drug regimens.

III. Materials And Methodology

This randomized study was done to compare the efficacy of sublingual misoprostol with intramuscular oxytocin in the management of third stage of labour in low risk vaginal deliveries. This study was conducted in the Department of Obstetrics and Gynaecology at Guntur General Hospital , Guntur, during the period of

Inclusion criteria: Singleton pregnancy with live fetus with cephalic presentation ; pregnancy of more than 28 weeks ; spontaneous onset of labour ; delivering vaginally.

Exclusion criteria: Grand multipara-more than 5 ; chorioamnionitis ; hydromnios ; antepartum hemorrhage ; pre eclampsia and eclampsia ; history of previous post partum hemorrhage ; previous cesarean section ; instrumental deliveries ; coagulation abnormalities ; severe anemia in pregnancy with Hb % less than 6 gm% ; cardiac diseases and diabetes ; intrauterine death.

IV. Methodology

After a detailed history, general and obstetric examination and routine investigations, patients who fulfilled the selection criteria were assigned randomly to two groups**:**

Group 1- Misoprostol group(100) cases . 3 tablets misoprostol 200µg each was given sublingually after cord clamping and cutting .

Group2-- Oxytocin group(100) cases . Injection oxytocin 10IU intramuscular after cord clamping and cutting.

V. Discussion

A total of 200 cases were studied with 100 cases in each group. In the third stage of labour, 500ml of isotonic fluid(Ringer Lactate) was started in two groups, and immediately after delivery of baby, the cord was clamped and cut. The women were asked to keep misoprostol sublingually 600µg or injection of oxytocin 10IU was given intramuscularly. 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 first hour after delivery. Blood loss was measured by graduated jar after direct collection in the pan and by gravimetric method. Postpartum hemorrhage the present study is defined as less than 500ml in first hour after delivery. Once the diagnosis of postpartum hemorrhage was made, the patients were managed as per the needs by giving additional oxytocic 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 hemoglobin percentage was taken as an objective measure of postpartum hemorrhage. Patients were observed for one hour following delivery for vital signs and bleeding per vagina. The occurrence of side effects like nausea, vomiting, shivering, fever, diarrhea, hypotension, etc. within first 24hrs of delivery was recorded. This study was computed by using parametric and non - parametric tests like impaired 't'-test and chi-square test.

A total of 200 patients undergoing spontaneous vaginal delivery, who fulfilled the selection criteria were randomly assigned to two groups .**Group-1** (100 cases), who received sublingual misoprostol 600µg after cord clamping and cutting. **Group**-2 (100 cases), who received intramuscular oxytocin 10IU after cord clamping and cutting. The results of both the groups were then compared. The demographic characteristics of both the groups were comparable in relation to age , parity and period of gestation. Therefore, the present study was undertaken to evaluate the efficacy of sublingual misoprostol in the active management of third stage of labour and compare it with injection oxytocin used intramuscularly in low risk women. Prophylactic administration of uterotonics to reduce blood loss from atonic postpartum hemorrhage in the active management of third stage of labour is rising significantly day by day universally. Misoprostol use in Active management of third stage of labour is increasing enormously, especially in poor resource settings with limited facilities for oxytocin storage and minimal skilled health care personnel for administration of medication.

VI. Results

Table 1: Distribution of cases according to parity

Parity	Misoprostol group	Oxytocin group
PRIMI	49	51
MULTI	51	49
TOTAL	100	100

The distribution of patients according to parity was similar in both groups.Almost equal number of cases of primi and multi gravidae were included in the study.

Table 2: Duration of third stage of labour (min)

Duration	Misoprostol group	Oxytocin group
<4	58	44
4-5	20	38
5-7	13	13

>8	09	05
Total	100	100

Duration of third stage of labour was less than 5 minutes in maximum number of patients in both the groups. There were only few cases with third stage of labour more than 8 minutes.

Table3: Distribution of blood loss in both groups (ml)

Blood loss(ml)	Misoprostol group	Oxytocin group
<100	10	11
101-200	53	46
201-300	26	27
301-400	08	12
401-500	01	02
>500	02	02
Total	100	100

In both the groups blood loss in most of the cases was upto 200ml.Both the groups have equal number of cases with blood loss more than 500ml.

Table 4 : Distribution of hemoglobin levels before delivery in both groups

Pre delivery hemoglobin (g/dl)	Misoprostol group (n=100)	Oxytocin (n=100)
8.1-9	10	12
9.1-10	59	42
10.1-11	19	29
11.1-12	05	11
>12	07	06
Total	100	100

In both the study groups most of the cases pre delivery hemoglobin levels are in between 9-11 g/dl.

Table 5: Mean hemoglobin levels difference in study groups

	Pre delivery mean hemoglobin	Post delivery mean hemoglobin	Mean difference
Misoprostol	10.20	9.3	0.9
Oxytocin	10.30	9.5	0.8

There was a mean difference of 0.9 and 0.8 between the pre delivery and post ddelivery hemoglobin levels noted in the Misoprostol and oxytocin groups respectively.These particular differences were not statistically significant [chi-square value=0.001 , P=0.48].

Table 6: Post partum complications in both groups

Complications	Misoprostol group (n=100)	Oxytocin group (n=100)
Post partum hemorrhage	2	2
Retained placenta	--	--

There were equal number of cases of postpartum hemorrhage in both the groups . There was no case of retained placenta noted in either of group.

Table 7: Additional oxytocics given in both the groups

Additional oxytocics	Misoprostol group (n=100)	Oxytocin group (n=100)
Injection Methergin and prostadin	2	2
Total	2	2

There are only 2 cases in each group with occurrence of postpartum hemorrhage with blood loss >500ml which required additional oxytocics like methyl ergometrine and prostadin to control blood loss. Number of cases who received additional oxytocics were 2 in each group.

Table 8: Side effects in both groups

Side effects	Misoprostol group	Oxytocin group
Shivering	12	2
Pyrexia	4	2
Vomitings	1	1
Pain abdomen	0	0
Diarrhea	0	0

Shivering and pyrexia were most common side effects noted in misoprostol group

Table 8: Comparison of mean blood loss between both groups

Authors(years)	Amount of blood loss	
	Misoprostol group	Oxytocin group
Rojaria et al (2013)	210	223
Chaudari et al(2012)	153	146
Present study	217.9	233.45

In the present study average blood loss in the Misoprostol group was approximately 217.9ml whereas oxytocin group parturients had a bloodloss of 233.45 ml. The mean blood loss in misoprostol group was more compared to oxytocin group. But the difference between two groups was not statistically significant. The result of the present study was in accordance with the above studies. In Rajaria et al mean blood loss in misoprostol group is 210 ml and 223 ml in oxytocin group. In Chaudari et al the mean blood loss in misoprostol group is 153ml and 143ml in oxytocin group respectively.

Table 9: Cases received additional oxytocics

Authors(years)	Additional oxytocics	
	Misoprostol group	Oxytocin group
Mukta mani et al(2013)	22	16
Chaudari et al(2012)	6	5
Present study	2	2

In the present study additional oxytocics were used in 2% of cases in each group. Additional oxytocics were administered only when blood loss was >500ml or postpartum hemorrhage was diagnosed..The mean blood loss in misoprostol group was more compared to oxytocin group. But the difference between two groups was not statistically significant. In Mukta mani et al study 22% cases in misoprostol group and 16% cases in oxytocin group developed postpartum hemorrhage and given oxytocics.

Table 10: Side effects of drugs

Author(years)	Shivering		Pyrexia		Vomiting	
	Misoprostol group	Oxytocin group	Misoprostol group	Oxytocin group	Misoprostol group	Oxytocin group
Atukunda et al(2014)	56	26	9.3	2.1	24	15
Mukta mani et al(2013)	50	8	6	2	4	2
Chaudari et al(2012)	12	3	5	2	2	1
Present study	12	2	4	2	1	1

Shivering and pyrexia were the most common side effect noted in misoprostol group.

VII. Conclusion

This study was done to assess the efficacy of oral misoprostol in the active management of third stage of labour in comparison with intramuscular oxytocin and also to assess the side effects of drugs. 200 women of low risk category were randomly selected wit 100 women in each group. The results of the misoprostol group(100 patients) were compared with oxytocin group(100 patients).. We found that both sublingual misoprostol and intramuscular oxytocin were equally effective in the management of third stage of labour.

Administration of sublingual misoprostol in the active management of third stage of labour in patients is as effective as intramuscular oxytocin in terms of reduction of postpartum hemorrhage. Side effects like shivering and pyrexia are more common with misoprostol , but not severe enough to discontinue use of drug for active management of third stage of labour. Misoprostol is safe to use in the third stage of labour for prevention of atonic postpartum hemorrhage .Sublingual administration of misoprostol offers the advantage administration by unskilled health personnel and making it an important medication in underserved regions. No requirement of refrigeration for storage of misoprostol when compared to intramuscular oxytocin adds to its potential use in poor resource settings.

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