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Comparative study of effectiveness of Sublingual Misoprostol (600mcg) versus Intramuscular Oxytocin (10U) in AMTSL(Active Management of Third Stage of Labour)

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Abstract:
Objective: *To compare the effectiveness of sublingual misoprostol(600µg)versus Intramuscular Oxytocin(10IU) in the active management of 3rd stage of labour and to study the blood loss and side effects in both the groups.*
Materials& Methods: *This study was conducted in the Department of Obstetrics& Gynaecology at Government General Hospital, Guntur during the period of March 2016 to August 2017 in low risk vaginal deliveries adhering to certain inclusion and exclusion criteria .A total of 200 cases were studied with 100cases in each group. Group-I were given 3 tablets of misoprostol200µg each and Group-II were given inj.Oxytocin 10IU intramuscular after cord clamping and cutting. Data regarding age, parity, amount of blood loss, predelivery and postdelivery Hb levels, need for additional oxytocics, side effects, postpartum complications were taken and analysed.*
Results: *The average blood loss was 217.9ml in misoprostol group compared to 233.45ml in oxytocin group. The fall in haemoglobin percentage was 0.9g/dl and 0.8g/dl respectively. The difference in observation of both groups was statistically not significant(p>0.05).The incidence of PPH was 2% in both the groups. The need for additional oxytocics was also 2% in both the groups. Shivering and pyrexia were the commonest side effects noted in misoprostol group.*
Conclusion: *Both sublingual misoprostol and intramuscular oxytocin were equally effective in the active management of 3rd stage of labour.*
Keywords: *AMTSL ,misoprostol, oxytocin.*

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I. INTRODUCTION

Pregnancy and child birth involves significant health risks even to women with no pre-existing health problem.PPH is the most common cause of obstetrical haemorrhage. Atonic post partum haemorrhage(PPH) accounts for a mortality rate of 1,40,000 per year or one maternal death for every four minutes world wide and is the most common preventable cause.(1)As per SRS 2010-12 reports, Indian MMR is 178per one lakh live births while that of Andhra Pradesh is 110 per one lakh live births.(2)Uterine atony accounts for 80% of cases of PPH(3-4).Majority of these deaths are due to problems of third stage of labour and occur within 4hrs of delivery(5,6).Catastrophic nature of PPH accounts for the higher maternal morbidity and mortality rates in developing countries like India.PPH is defined as any amount of bleeding from or into genital tract following birth of baby within 24hrs of delivery that deteriorates -the maternal condition Active management of the third stage of labour(AMTSL) which includes early cord clamping, controlled cord traction for placental delivery and intramuscular uterotonic therapy is an effective measure to prevent PPH. 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). These uerotonic agents stimulate uterine contractions which cause compression of the maternal blood vessels at the placental site after delivery of the placenta and controls bleeding. 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 AMTSL for all parturients to reduce the post partum haemorrhage and its related consequences(8).

Hence current oxytocic drugs are far from ideal, particularily for routine use in developing countries, where 76% of deliveries takes place at home, far from the hospitals or medical facilities and are supervised solely by trained birth attendants. Where maternal mortality is high and resources are limited, the introduction of low cost evidence based practices to prevent and manage post partum haemorrhage can improve maternal and fetal survival. Thus there is a need for effective uterotonic drug that can be administered orally and which does not require special storage condition. Misoprostol, a synthetic prostaglandin E1analogue, which causes the uterus to contract and thus can reduce the post partum bleeding. Misoprostol has a range of potential benefits

including ease of administration(oral, rectal or sublingual),rapidly absorbable ,low cost and doesnot require any specific condition for storage, transport, has a shelf-life of several years and thus is a suitable uterotonic agent for use in the prophylactic management of third stage of labour especially in developing countries like ours.
Present study is an attempt to assess the effect of sublingual Misoprostol on third stage of labour in comparison with standard oxytocin regimen.

II.MATERIALS AND METHODOLOGY

This randomised study was done to compare the efficacy of sublingual Misoporostol with the intramuscular oxytocin in the management of third stage of labour in low risk vaginal deliveries. This study was conducted in Dept of Obstetrics& Gynaecology at Government General Hospital, Guntur during the period March 2016 to August 2017.

Inclusion criteria:
a) Singleton pregnancy with live fetus with cephalic presentation
b) pregnancy of more than 28wks of gestation.
c) spontaneous onset of labour
d) delivering vaginally

Exclusion criteria:
- Grand multipara-more than 5
- Chorioamnionitis
- Hydramnios
- Antepartum haemorrhage
- Pre-eclampsia-eclampsia
- History of previous PPH
- Previous Caesarean section
- Instrumental delivery
- Coagulation abnormalities
- Severe anemia in pregnancy with Hb less than 6gm
- Cardiac diseases and diabetes
- Intra uterine death

Methodology:
After a detailed history, general and obstetrical examination and routine investigation, patients who fulfilled the selection criteria were assigned randomly to two groups.
Group-I
Misoprostol group(100cases)
3tablets of Misoprostol 200mcg each was given sublingually after cord clamping and cutting.
Group-II
Oxytocin group(100cases)
Injection Oxytocin 10IU intramuscular after cord clamping and cutting.

A total of 200cases were studied with 100cases in each group. In the third stage of labour 500ml of isotonic fluid (RL) was started in both the groups and immediately after the delivery of the baby, the cord was clamped and cut. The women were asked to keep Misoprostol 600mcg sublingually or Inj.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 bloodloss was measured in both the groups for the 1^{st} 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 1^{st} 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.

III. OBSERVATION AND RESULTS

Table:1 Distribution of cases according to age(years)

Age(in yrs)	Misoprostol group	Oxytocin group
<20	25	34
21-25	57	49
26-30	14	15
>30	04	02
Total	100	100

Maximum of women were between 21-25years in both groups.

Table:2 Duration of 3rd stage of labour(min)

Duration (min)	Misoprostol group	Oxytocin group
<4	58	44
4-5	20	38
5-7	13	13
>8	09	05
Total	100	100

Duration of labour of 3rd stage was less than 5min in maximum number of patients in both the groups.

Table:3 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 the present study,53% women in Misoprostol group and 46% women in oxytocin group had blood loss between 100to 200ml. 26%in Misoprostol group and 27%in oxytocin group had blood loss between 200-300ml. 2% of cases in each group had blood loss more than 500ml and required additional oxytocics. Both groups have equal number of cases with blood loss more than 500ml.

Table:4 Distribution of Haemoglobin levels before delivery in both groups.

Pre delivery Haemoglobin (g/dl)	Misoprostol group	Oxytocin group
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 predelivery haemoglobin levels are in between 9-11g/dl.

Table:5 Distribution of haemoglobin levels after delivery in both groups.

Post delivery haemoglobin(g/dl)	Misoprostol group	Oxytocin group
8-9	47	38
9.1-10	40	45
10.1-11	12	13
11.1-13	01	04
Total	100	100

In both groups, most of the cases postdelivery Hb levels were in between 8-10g/dl.

Table:6 Post partum Complications in both the groups

Complications	Misoprostol group	Oxytocin group
Postpartum haemorrhage	2	2
Retained placenta	-	-

There were equal number of cases of post partum haemorrhage in both groups.There was no case of retained placenta noted in either of group.

Table:7 Additional Oxytocics given in both groups

Additional oxytocics	Misoprostol group (n=100)	Oxytocic group (n=100)
Inj.methergin and Prostadin	2	2
Total	2	2

There are only 2cases in each group with occurrence of PPH with blood loss>500ml which required additional oxytocics like methyl ergometrine and prostadin to control the blood loss.

Table:8 Side effects in both groups

Side effects	Misoprostol group	Oxytocin group
Shivering	12	2
Pyrexia	4	2
Vomiting	1	1
Pain abdomen	0	0
Diarrhoea	0	0

In the present study, shivering was observed in 12% of cases in Misoprostol group and 2% of cases in oxytocin group.4%of cases in Misoprostol and 2% of cases in Oxytocin group had pyrexia.1% of cases in each group had vomiting. Shivering and prexia were the most common side effects noted in Misoprostol group.

IV. DISCUSSION

In developing countries, the risk of dying from PPH is 1in 1000deliveries.The incidence of PPH varies from 4to6% of all deliveries 75 to 90% of cases PPH is due to atonicity of uterus. More than half of deaths from post partum haemorrhage occur within the first 24hrs of delivery. Of these 88% occur within 4hours of delivery. Active management of 3rd stage of labour by routine use of oxytocic drugs has been estimated to reduce PPH by 40%. Current oxytocic drugs are far from ideal particularly for routine use in developing countries, where simple route of administration, stable and inexpensive drugs are needed because many deliveries take place far from hospitals or medical facilities and are supervised solely by birth attendants. Misoprostol is a PGE_1 analogue, which has been shown to have myometrial stimulating properly. It can be administrated orally and is rapidly absorbed, stable at room temperature, has low cost and can be used by birthattendants. Its use in 3rd stage of labour was suggested by many studies . The present study was conducted in the Department of Obstetrics & Gynaecology, Guntur Medical College, Guntur. A total of 200 patients undergoing spontaneous vaginal delivery, who fulfilled the selection criteria were randomly assigned to two groups. Group -I(100cases) who received sublingual misoprostol 600µg after cord clamping and cutting.

Group-II(100cases) 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 3rd 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 PPH in the active management of third stage of labour is rising significantly day by day universally. Misoprostol use in AMTSL is increasing enormously, especially in poor resource settings with limited facilities for oxytocin storage and minimal skilled health care personnel for administration of medication. In the present study, the average blood loss was 217.9ml in Misoprostol group compared to 233.45ml in oxytocin group. The fall in haemoglobin percentage as 0.9g/dl in Misoprostol group compared to 0.8g/dl in oxytocin group. The difference in observation of both groups was statistically not significant($p>0.05$).The incidence of postpartum haemorrhage was 2% in both the groups. There was no case of retained placenta in either of the groups. The need for additional oxytocics was also 2% in both the groups as they were given only when the blood loss is more than 500ml.Shivering and pyrexia were the commonest side effects noted in Misoprostol group. We found that both sublingual misoprostol and intramuscular oxytocin were equally effective in the management of 3rd stage of labour.

V.CONCLUSION

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 PPH. Side effects like shivering and pyrexia are more common with misoprostol but not severe enough to discontinue the use of the drug for AMTSL. Misoprostol is safe to use in the third stage of labour for prevention of atonic PPH. Sublingual route of administration of misoprostol offers the advantage of administration by unskilled health personnel and making it an important medication in the underserved regions to prevent atonic PPH. No requirement of refrigeration for storage of misoprostol when compared to intramuscular oxytocin adds to its potential use in poor settings.

Further randomized controlled trials involving larger study populations are needed to assess the safety profile and effectiveness of sublingual misoprostol over intramuscular oxytocin in prevention of atonic postpartum haemorrhage.

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