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A RANDOMIZED CONTROL STUDY OF SUBLINGUAL MISOPROSTOL VERSUS INTRAMUSCULAR OXYTOCIN FOR ACTIVE MANAGEMENT OF THIRD STAGE OF LABOUR

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ABSTRACT

Objectives: The mean blood loss with sublingual misoprostol was 152.88±61.44ml, average To compare sublingual misoprostol 400 mcg with intramuscular oxytocin 10 IU, in the active management of third stage of labour.
Methods: The study was conducted in Dept of OBG, KIMS Hospital and Research centre for a period of 2 years. 200 women with singleton pregnancy were divided into two groups (100). Group 1- 400 mcg misoprostol sublingually, Group 2- 10 IU of intramuscular oxytocin, was given. Duration of third stage of labour, blood loss, change in Hemoglobin following delivery and the side effects of the drugs were assessed.
Results: Duration of third stage of labour was 5.85±1.85min, fall in Hemoglobin was 0.54±0.23gm/dl .With I.m Oxytocin, it is 190.75±63.95ml, 7.27±2.19min and 0.73±0.28gm/dl respectively (P<0.001**).
Conclusion: Sublingual misoprostol was effective in active management of third stage of labour and can be used in rural areas with low resource settings.

INTRODUCTION

Post partum hemorrhage (PPH), defined as blood loss of >=500 ml after vaginal delivery, is the most common complication of the third stage of labour and is the leading cause of maternal death worldwide accounting for 3.9% (Chan, 2001). In developing countries where nearly half of pregnant women are anemic, even a small reduction in postpartum blood loss can reduce maternal mortality and morbidity. WHO suggests active management of third stage of labour as a means to prevent PPH. The prophylactic use of oxytocics in the third stage of labor has shown to significantly reduce the risk of postpartum haemorrhage by about 40%, and its use is generally advocated in the management of third stage of labour. Oxytocin, Misoprostol and Ergometrine are the commonly used oxytocics (Bellad, 2012). Oxytocin remains an efficient and time-tested uterotonic, but has a shorter half life, needs parenteral administration and cold storage. The administration and storage of oxytocin may not always be possible in some hospitals or rural communities due to the non-availability of continuous power supply, refrigeration equipment, sterile needles and syringes. Moreover the efficacy of oxytocin has been shown to be significantly reduced when it is stored in suboptimal environment. Misoprostol is a synthetic PGE1 analogue, demonstrated to be effective in both prevention and treatment of PPH due to its uterotonic effects. It is being given via oral, sublingual, per rectal and per vaginal route for the purpose of controlling blood loss post delivery. It is stable at high temperature and has a long shelf life. With its ease of administration and storage, there has been increasing evaluation and promotion of misoprostol, especially in developing countries. Unlike ergometrine, Misoprostol has shown to decrease the mean arterial pressure and systemic vascular resistance, hence may be used as an oxytocic in hypertensive or pre-eclamptic women for control of PPH (Chan, 2001).

However the side effects like fever and shivering are more common with misoprostol. Active management of third stage is constituted by early uterotonic therapy with the delivery of the anterior shoulder, early cord clamping and placental delivery by controlled cord traction, following signs of placental separation (Williams, 2009). WHO has recently recommended the use of misoprostol for active management of third stage of labor, especially by trained birth attendants in rural areas. The present study is an attempt to evaluate the safety and efficacy of oral misoprostol versus intramuscularly administered oxytocin, in the active management of third stage of labor.

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Aims and Objectives

The aim of the study was to compare sublingual misoprostol (400 micrograms) and intramuscular oxytocin (10 units) in active management of third stage of labor.

The objectives of our study were

- To assess and compare the amount of blood loss between the study groups.
- To assess and compare the drop in hemoglobin levels.
- To assess the safety of both the drugs.

MATERIAL AND METHODS

The present study was done on the patients admitted in department of obstetrics and gynecology, KIMS Hospital and Research Centre, Bangalore, for a period of 2 years ((November 2013 – October 2015). Two hundred women were included in the study after taking written and informed consent.

Inclusion criteria

- Singleton pregnancy
- More than 28 weeks gestational age.
- Cephalic presentation
- Hb >= 8 gms/dl
- Normal vaginal delivery.

Exclusion criteria

- Patients with hypersensitivity to the drugs under study and respiratory diseases (asthma), Polyhydramnios, Past history of PPH, Grand multipara, Instrumental deliveries.
- Patients were evaluated by history, clinical examination and relevant investigations.
- After delivery of baby (within 1 min of Cord clamping and cutting)

Group 1: (100) received sublingual misoprostol 400 micrograms.
Group 2: (100) received intramuscular oxytocin 10 units.

The amount of blood loss during third stage and immediate post partum period was measured using BRASS-V drape placed under buttocks of patient after delivery and by calculating the difference in the weight of gauze pads and swabs used for delivery. Blood loss was measured for 1 hr after delivery. The duration of third stage of labor, any third stage complications, amount of blood loss, retained placenta and any need for additional oxytocics was noted. Patient's vitals were monitored for 6 hrs after delivery (hrly), any side effects such as fever, nausea, vomiting, diarrhoea, shivering etc., were noted and treated. Blood sample was obtained for hemoglobin estimation at the time of admission and 48hrs after delivery, and the difference noted.

Statistical Analysis

The data was recorded and assessment was done by software SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1. Student t test (two tailed, dependent) has been used to find the significance of study parameters on continuous scale within each group. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

Ethical Issues

Ethical clearance was taken and there was no extra expenditure. There was no funding or monetary benefits involved.

RESULTS

Present study included 200 cases with low risk term pregnancy, who came for delivery. Samples are age matched with P=0.370 and comparable parity wise (P= 0.887).

Table 1. Distribution of cases according to age

Age in years	Misoprostol		Oxytocin	
	No	%	No	%
<20	3	3.0	4	4.0
20-30	95	95.0	93	93.0
31-40	2	2.0	3	3.0
Total	100	100.0	100	100.0
Mean ± SD	23.94±2.80		24.30±2.87	

Table 2. Distribution of cases according to parity

Parity	Misoprostol		Oxytocin	
	No	%	No	%
Primi	55	55	56	56
Multi	45	45	44	44
Total	100	100.0	100	100.0

The duration of 3rd stage (minutes) was 5.85±1.85 in misoprostol group and 7.27±2.19 in oxytocin group (P value <0.001, which is significant). The average amount of blood loss (ml) was 152.88±61.44 ml in misoprostol and 190.75±63.95 in oxytocin group (P value <0.001). Fall in Haemoglobin % (gm/dl) was 0.54±0.23 in misoprostol and 0.73±0.28 in oxytocin groups respectively (P <0.001).

Table 3. Distribution of cases according to outcome of the study

	Misoprostol	Oxytocin	P value
Duration of 3rd stage	5.85±1.85	7.27±2.19	<0.001**
Amount of Blood Loss (ml)	152.88±61.44	190.75±63.95	<0.001**
Fall in Haemoglobin % (gm/dl)	0.54±0.23	0.73±0.28	<0.001**

Table 4. Use of additional oxytocics in both the groups

Use of additional oxytocics	Misoprostol (n=100)		Oxytocin (n=100)	
	No	%	No	%
Nil	89	89.0	81	81.0
Yes	11	11.0	19	19.0
• Erg	6	6.0	17	17.0
• Prost	3	3.0	2	2.0
• Oxy	2	2.0	0	0.0

The use of additional oxytocics was 11% in misoprostol group and 19% in oxytocin group and the P value was >0.05 , which is not significant. The side effects were more in the misoprostol group i.e., 26% and less in oxytocin group i.e.,12%. The P value of the same is 0.012** which is <0.05

and hence significant. Among the side effects majority had shivering in the misoprostol group.

Table 5. Side effects in both the groups

Side Effects	Misoprostol (n=100)		Oxytocin (n=100)	
	No	%	No	%
Nil	74	74.0	88	88.0
Yes	26	26.0	12	12.0
• Fever	8	8.0	6	6.0
• Shivering	10	10.0	3	3.0
• Nausea	4	4.0	2	2.0
• Vomiting	3	3.0	1	1.0
• Diarrhoea	1	1.0	0	0.0

DISCUSSION

The present study showed sublingual misoprostol shortens the duration of third stage of labour and decreases the amount of blood loss but it is associated with more side effects, while intramuscular oxytocin is a little less effective in preventing blood loss, but it has fewer serious side effects. In a similar study by MB Bellad *et al.* (2011), the mean age in both the groups was 23 years and 22.8 years respectively, which was statistically non-significant. In the present study, the mean age in misoprostol group was 23.94±2.80 years (Table 1) and in oxytocin group was 24.30±2.87 (Table 1). The difference in age group is not statistically significant. In both the groups, majority of the women belong to the age group 20-30 years, i.e., 95% in misoprostol group and 93% in oxytocin group. In the present study; distribution of blood loss in the two groups (Table-3) showed mean blood of 152.88±61.44 ml in misoprostol group, while in the oxytocin group it was 190.75±63.95 ml.

On calculation, P<0.001, which is statistically significant i.e., sublingual misoprostol results in significantly lesser amount of blood loss when compared to intramuscular oxytocin. This result was consistent with the study by MB Bellad et al.[2] The comparison of Hb changes (Table 3) following delivery in both the groups is statistically significant with an average fall of 0.54±0.23 gm/dl in misoprostol group and 0.73±0.28 gm/dl in oxytocin group and p<0.001. This shows that sublingual misoprostol results in significantly lesser reduction in Hb when compared to intramuscular oxytocin. This was consistent with the similar study done by Rajoria Lata et al[4]. In the present study, incidence of side effects like shivering (10%) and fever (8%) were more in misoprostol group as compared to oxytocin group. Hence according to our study, side effects are more with sublingual misoprostol than intramuscular oxytocin, with a P value of 0.012* which is moderately significant. This was consistent with the studies conducted by Rajoria Lata et al and Savita Rani Singhal et al (Vimala, 2006). In a study conducted by Z.Alfirevic et al (2010), it was noted that the side effects and their severity with misoprostol were dose dependant. In the present study, hence lower dose (400 mcg) has been used.

Conclusion

The results showed that in misoprostol group there was

- Significantly reduced blood loss,
- Reduction in duration of third stage of labor,
- Significantly less fall in Hb levels after delivery.

Our study showed that Misoprostol was very effective in preventing PPH. In India, major population belongs to rural areas and more than half the deliveries are in rural set ups. PPH is one of the leading cause of maternal mortality and morbidity in our country. In rural areas where there is scarcity of man power, interrupted power supply, misoprostol is ideal drug because of ease of administration and storage and is cost effective. Oxytocin though safe and effective, requires cold chain and skill for administration. hence Misoprostol can be recommended for reducing the blood loss in third stage.

Conflict of Interest: The authors have no conflicts of interest.

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