

## Oral Misoprostol Vs. Intravenous Oxytocin for Augmentation of Labour Induction in Primigravidae Women with Artificial Rupture of Membrane at Term

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### Abstract

*Context:* The complications of prolonged labour are well recognized and the caesarean section has been used in liberally. Although prolonged labour continues to be a constant problem due to weak uterine contractions or poor cervical dilatation. The problem can be overcome with the use of oxytocic drugs. *Aims:* To ensure the efficacy, adverse effects, safety, and foeto-maternal outcome of the Artificial Rupture of Membrane (ARM) and oral misoprostol with ARM and oxytocin infusion for augmentation. *Settings and Design:* This prospective study was conducted in the labour room of NRS Medical College and Hospital Kolkata and included 100 primigravidae women carrying singleton pregnancy at term with spontaneous onset of labour. *Methods and Material:* Patients aged between 18 to 28 years, Primigravidae between 37 to 42 weeks of gestational age, Live singleton pregnancy, Cephalic presentation, Spontaneous onset of, Cervical dilatation of 4 cm or more, Inadequate uterine contractions less than three per ten minutes, reassuring foetal heart rate and giving informed consent were included in the study. Each of the agents was applied to every alternate case. Augmentation was done by oral misoprostol 25 mcg at 4-hour interval to maximum of 3

doses (misoprostol group, n=50) Oxytocin infusion was started at the minimum dose of 2mIU/min in Ringer lactate solution, adjusting the dose every 15 minutes till the desired uterine contractions are achieved, with a maximum dose of 5mIU/min at the rate of 15 to 20 drops per minute (oxytocin group, n=50). *Statistical analysis used:* Data were expressed as a percentage and mean  $\pm$  SD. Student's t-test was used to check the significance of the difference between two parameters in parametric data. Chi-square test was used to analyse the significance of the difference between the frequency distribution of the data. *Results:* The study showed that in both the groups (misoprostol and oxytocin), the majority of the participants belong to the age group of 20-30years. The mean duration of delivery was 5.2 hour and 5.5 hours in misoprostol and oxytocin groups respectively. Prolonged was the major indication for LSCS in both the groups. *Conclusion:* Both the agents i.e. oral misoprostol and intravenous oxytocin shortens the duration of effectively and are effective for augmentation of and the need for LSCS was almost similar in both the groups.

**Keywords:** Oxytocin; Misoprostol; ARM.

### Introduction

Maternal mortality remains high between 500.1 and 1000 deaths for 100,000 live births in developing countries. Among survivors, morbidity is significantly high due to complications like sepsis, postpartum haemorrhage, ruptured uterus and urinary fistula. Prolonged labour continues to be a major problem, it can be overcome with the use of oxytocic drugs [1,2,3,4].

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Traditionally there are surgical and medical methods of augmentation of labour. For medical method oxytocin is used for many years. It is the age old procedure to augment labour using intravenous oxytocin. Prostaglandin is a newer drug and can be used as a cervical gel, vaginal tablet or oral route. The oral route is convenient to the patient as well as to doctor. Misoprostol is not well practiced but its efficacy is to be considered about as an alternative to oxytocin [5,6].

Various complications may arise during the course of labour. Prolonged and obstructed labour can cause considerable maternal and fetal morbidity and mortality, especially in the developing world due to sepsis, rupture of the uterus and postpartum hemorrhage. In India incidence of obstructed labour is about 1 to 5% depending upon the availability of health and transport facilities and it contributes to about 10% of maternal deaths [7]. In the developed world, cesarean section rates for dystocia or difficult labour are on the rise and contribute to at least one-third of the overall cesarean section rates. Repeat section after primary cesarean section accounting for another third. Cesarean section leads to increased maternal mortality and morbidity, especially when performed as an emergency procedure (the risk increases to 9 fold) [8,7,9,10].

On the above perspective, this is stressed upon that, the need for augmentation of labour is evident. A thorough comparison between the standard agents like oxytocin and newer agents like PGE1 (misoprostol) has become necessary. It is also considered that efficacy of PGE1 (misoprostol) present a field relatively unexplored [11,12,13,14]. So, the present study will reveal the pros and cons of oxytocin infusion and oral misoprostol in terms of, efficacy, safety, ease of application, availability and possible adverse fetomaternal effects.

## Methods

### *Study Design and Setting*

This prospective study was conducted among 100 primigravidae women carrying singleton pregnancy at term with spontaneous onset of labour in the labour room of NRS Medical College and Hospital, Kolkata during May 2011 to April 2012.

### *Human Participants and Inclusion Criteria*

Patients aged between 18 to 28 years, Primigravidae between 37 to 42 weeks of gestational age, Live singleton pregnancy, Cephalic presentation,

Spontaneous onset of labour, Cervical dilatation of 4 cm or more, Inadequate uterine contractions less than three per 10 minutes, reassuring foetal heart rate and giving informed consent were included in the study. Patients with PROM, Multiple pregnancies, Polyhydramnios, Non-cephalic presentation, Probable CPD, suspected IUGR, scarred uterus, uterine perforation and medical diseases like heart disease, bronchial asthma etc. were excluded from our study.

### *Ethical Consideration*

The institutional ethics committee of NRS Medical College and Hospital, Kolkata approved this study protocol. Informed written consent was obtained from all study participants. They were counseled thoroughly prior to giving consent. A thorough general, systemic and obstetrical examination was done.

### *Data Collection and Sampling Technique*

Assigning of the cases was done by simple random sampling. Each of the agents was applied to every alternate case, likewise 50 cases were allocated in the misoprostol group and another 50 cases were allocated in the oxytocin group.

Augmentation of labour: oral misoprostol 25 mcg at 4-hour interval to maximum of 3 doses was used in misoprostol group, while in oxytocin group intravenous oxytocin infusion was started at the minimum dose of 2mIU/min in Ringer lactate solution, adjusting the dose every 15 minutes till the desired uterine contractions was achieved, with a maximum dose of 5mIU/min at the rate of 15 to 20 drops per minute.

The patients were observed during this process of augmentation for fetal bradycardia or tachycardia, Tachysystole, hypercontraction, and color of the liquor. All the different parameters were noted on the partograph. Per vaginal examination was repeated every 4 hours and non-progress of labour was declared when there was minimal or no change in cervicography, as evidenced by flattening of the curve. In any case of confirmed fetal distress or in cases of confirmed non progress in the first stage of labour termination of pregnancy was done by cesarean section.

### *Statistical Analysis*

The data analysis was done with the help of SPSS 22. Descriptive statistics was used and the data was expressed as a percentage and mean  $\pm$  SD. Student's

t-test was used to check the significance of the difference between two parameters in parametric data. Chi-square test was used to analyse the significance of the difference between the frequency distribution of the data. A *P*-value <0.05 was considered as statistically significant.

## Results

The present study was conducted in the labour room of NRS Medical College and Hospital Kolkata and included N=100 primigravidae women carrying singleton pregnancy at term with spontaneous onset of labour.

The findings of our study showed that in both the groups (misoprostol and oxytocin), the majority of the participants belong to the age group of 20-30 years (n=37, 74% and n=38, 76% respectively). The age distribution of the participants in these two groups was almost similar (Table 1). no statistical significance was observed [ $\chi^2=3.778$ ; *p*=0.638].

It is noted that need for analgesia was found to be almost similar among the participants used

**Table 1:** Distribution of participants to each of the two agent groups in regards to the age

Age distribution	Misoprostol n (n%)	Oxytocin n (n%)	$\chi^2$	<i>P</i> -value
<20	12(24)	10(20)	3.778	0.638
20-30	37(74)	38(76)		
>30	1(2)	2(4)		

**Table 2:** Need for analgesia in both the groups

Need for analgesia	Misoprostol	Oxytocin
Analgesia required	37	35
Percentage (%)	74	70

**Table 3:** The average time interval from the application of the agent to the delivery

Duration of delivery	Misoprostol Group	Oxytocin Group	t	$\chi^2$	<i>P</i> -value
Mean duration of delivery	5.2 hours	5.5 hours	0.604	-	0.126
Delivery within 5 hours (n)	34	7	-	0.649	0.045*
Delivery after 5 hours (n)	16	43	-	1.773	0.006*

**Table 4:** Modes of delivery and Indications of LSCS in both the groups

Mode of delivery	Misoprostol	Oxytocin	
Modes of delivery	LSCS	7(14%)	7(14%)
	Forceps delivery	3(6%)	2(4%)
	Normal vaginal delivery	40(80%)	41(82%)
Indications of LSCS	Foetal distress	1	0
	Prolonged labour	2	2

misoprostol (74%) and oxytocin (70%) and this is represented in Table 2.

The mean duration of delivery was 5.2 hour and 5.5 hours in misoprostol and oxytocin groups respectively. So, the average time interval from augmentation to delivery was a little shorter in the misoprostol group. Significantly higher number of participants in Misoprostol Group had delivery within 5 hours than Oxytocin Group [ $\chi^2=0.649$ ; *p*=0.045\*]. While Significantly higher number of participants in Oxytocin Group had delivery after 5 hours than in Misoprostol Group [ $\chi^2=1.773$ ; *p*=0.006\*]. So in Misoprostol Group the participants had earlier delivery than Oxytocin Group (Table 3).

In the misoprostol group, the incidence of LSCS was 14%, the incidence of forceps delivery was 6% and the incidence of normal vaginal delivery was 80%. In the oxytocin group, the incidence of LSCS was 14%, the incidence of forceps delivery was 4% and the incidence of normal vaginal delivery was 82%. Prolonged labour was the major indication for LSCS in both the groups (Table 4).

## Discussion

Prolonged labour due to weak uterine contractions or poor cervical dilatation is a major complication during labour and the problem can be overcome with the use of oxytocic drugs [1].

Our study shows that the mean duration from application of the agent to the delivery was 5.3±0.2 hours. The time interval from augmentation to delivery was a little longer in the intravenous oxytocin group. A similar study by Ho, Cheng & Li (2010)[15] found out that the median interval of

augmentation to delivery was 5.22 hours in the misoprostol group and 5.20 hours in the oxytocin group. A study by Villano, Lo, Alexander, McIntire & Leveno (2011)[16] found no difference in the augmentation delivery interval between the oral misoprostol and intravenous oxytocin groups. They concluded that the Prolonged labour is a major risk factor and increases maternal and child mortality and morbidity the oral misoprostol is an effective agent for labour augmentation.

The incidence of lower segment cesarean section was highest in both the groups followed by forceps delivery and the percentage of various modes of delivery was almost similar in both the groups. Similar results were found in studies done by Ho et al. (2010) and Villano et al. (2011) [15,16].

The major disadvantage of the oxytocin injection was that it needed storage in the refrigerator and had to be brought out shortly before administration otherwise its efficacy would get lost. But misoprostol tablets did not require cold chain for maintenance of its efficacy. Moreover, the administration of the misoprostol tablet was easier as it had just to be given orally. On the other hand, oxytocin infusion needed ringer's solution for dilution infusion set and intravenous channel for its administration. So its administration posed little difficulty.

### Summary and Conclusion

Patients in the active phase of labour with poor uterine contraction and slow dilatation of the cervix, both the agents i.e. oral misoprostol and intravenous oxytocin shortens the duration of labour effectively and are effective for augmentation of labour. Need for LSCS was almost similar in both the groups. Moreover, it was easier to administer oral misoprostol as compares to intravenous oxytocin, but this context is of little concern. Oxytocin is an old drug for labour augmentation but this study reveals that due to its easy availability and ease of application oral misoprostol has a slight edge over intravenous oxytocin. It was not a double-blind study and it was the limitation of the study, in future it can be overcome.

### Conflict of Interest

The authors declare no conflicts of interest in this work.

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