### LABOUR INDUCTION WITH INTRAVAGINAL MISOPROSTOL VERSUS OXYTOCIN IN TERM PREMATURE RUPTURE OF MEMBRANES

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**ABSTRACT:** Labour Induction with intravaginal Misoprostol versus Oxytocin in Term Premature Rupture of Membranes. **OBJECTIVES:** To compare the safety and efficacy of misoprostol with oxytocin for labour induction in women with premature rupture of membranes beyond 36 weeks gestation. **METHODS:** 65 subjects with rupture of membranes without labour were assigned to receive. vaginally administered misoprostol 50 ug, every 4 hrs. and another 65 subjects with rupture of membranes at term received intravenous oxytocin infusion and we compared the duration of labour, intrapartum complications, mode of delivery and the maternal and neonatal outcomes in the two groups. **RESULTS:** Results of the 130 subjects studied, 65 received misoprostol and 65 oxytocin infusion. The average interval, from start of induction vaginal delivery was significantly shorter (660 minutes) in the misoprostol group than the oxytocin group (1105 min). Oxytocin administration was necessary in 13 (20%) subjects receiving misoprostol. There was increased incidence of tachysystole in misorpostol group 22 (33.8%) compared to the oxytocin group 9 (13.8%) No significant difference was found in the mode of delivery neonatal and maternal outcomes in the two groups. **CONCLUSION:** Vaginal administration of misorpostol is safe and effective alternative to oxytocin infusion for labour induction in women with premature rupture of membranes at term.

KEYWORDS: Labour, induction, prom, misoprostol, prostaglandins.

**INTRODUCTION:** Premature rupture of membranes (PROM) beyond 36 weeks of gestation and before the onset of labour occurs in approximately 10% of pregnancies. Clinical management of this condition remains controversial. Traditionally, induction of labour is undertaken to prevent chorioamnionitis and neonatal sepsis. Labour induction with intravenous oxytocin in gravidas at term with PROM, especially those with unfavourable cervices, is associated with an increased incidence of failed induction and an increased cesarean rate. Therefore, an optimal agent would have the dual capacity of cervical ripening and labour induction.

Five published studies found that a synthetic analogue of PGE, (Misoprostol) ripens the cervix and induces labour in patients with unfavourable services.

The objective of this study is to compare the safety and efficacy of misoprostol with oxytocin for labour induction in women with term premature rupture of membranes.

**MATERIALS & METHODS:** From February, 2012 to July 2012 all women with spontaneous rupture of membranes beyond 36 weeks gestation at Ekopa Hospital, Karad were evaluated for selection to the study.

#### Patients were recruited if they satisfied the following Criteria.

1. Gestational age of 37-42 weeks.

- 2. Singleton pregnancy.
- 3. Spontaneous rupture of membranes.
- 4. Woman not in labour on admission.
- 5. Normal fetus with a reactive non-stress test on admission.
- 6. No contra indication to labour/ vaginal delivery. Those assigned to the misoprostol group received. 50 mg intravaginally in the posterior fornix and was repeated every 4 hrs. Until adequate labour was achieved to a maximum total dose of 600 mg.

Women assigned to the oxytocin group, it was administered as an intravenous infusion 2.50 of oxytocin was added to 500 ml of Ringer lactate and started at admission, increasing by 4 drops every half an hour.

Induction with either misoprostol or oxytocin was started a minimum of 6 hrs after the spontaneous rupture of membranes in the absence of uterine contractions.

The primary outcome measure was the occurrence of vaginal delivery within 24 hrs from start of induction, defined as a successful induction.

#### **RESULTS:**

Particulars	Misoprostol (n-65)	Oxytocin (n-65)
Age	23.7	23.1
Initial Bishop score	5.7	6.1
Gestation at ROM (WK)	38.8	38.8
Percentage of Primigravidas	76%	73%
Table 1: Demographic Characteristics		

(Rate is presented as mean)

Particulars	Misoprostol	Oxytocin	P<0.04)
Interval from start to	660	1105	S
delivery (min) mean	(380-1100)	(780-1520)	3
Vaginal delivery within 12 hrs.	25 (43%)	15 (23%)	S
Vaginal delivery within 24 hrs.	55 (84.6%)	38 (58.4%)	S
Need for oxytocin (misoprostol group)	13 (20%)	-	
Maximum rate of oxytocin	3.75 mIU/min	11.25 mIU/min	S
Table 2: Labor Characteristics			

S-Significant, NS-Not Significant.

Particulars	Misoprostol	Oxytocin	P>0.04)
Spontaneous Vaginal	49 (75.3%)	51 (78.46)	NS
Instrumental	7 (10.7%)	8 (12.3%)	NS
Cesarean Delivery	9 (13.8%)	8 (12.3%)	NS
Table 3: Mode of Delivery			

Particulars	Misoprostol	Oxytocin	P<0.04)
Fetal distress	13 (20%)	15 (23%)	NS
Postpartum Haemorrhage	7 (1.5%)	9 (13.8%)	NS
Tachysystole	nysystole 22 (33.8%) 9 (6.1%)		
Hyperstimulation Syndrome5 (7.6%)4 (6.1%)NS			
Table 4: Intrapartum Complications			

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Particulars	Misoprostol	Oxtocin
Birth wt (kg)	2.5 kg	2.560 Kg
	(1.8 – 3.2 kg)	(1.8 – 3.3 kg)
Apgar Score <7 1min	8 (12.3%)	7 (10.6%)
5 min	1 (1.5%)	0
Admission to NICU	7 (10.6%)	10 (13.8%)
Chorioamnionitis	2 (3.7%)	3 (4.6%)
Table 5: Neonatal & Material Out come		

**RESULTS:** Patients in the misoprostol and oxytocin group were similar with respect to maternal age parity, initial Bishop's score and gestational age (table1) labour characteristics in the two groups are compared in the Table 2. The mean interval from start of induction to delivery was significantly shorter in the misoprostol group. A significantly lower mean maximum rate of oxytocin was administered to women in the misoprostol group 84.6% patients in the misoprostol group delivered within 24hors from start of induction where as 58.4% in the oxytocin group .There was no significant difference in the mode of delivery between the two groups. (Table 3) (Table 4) Observations regarding neonatal and maternal outcomes were also compared (Table5) and no significant difference was seen in the two groups.

**DISCUSSION**: The safety and efficacy of prostaglandins for cervical ripening and labour induction in patients with PROM at term have been the subject of several clinical trials. Although several randomised trials<sup>(1-7)</sup> reporting the utility of PGE1 for labour induction included patients with PROM at term numbers have been insufficient to draw conclusion regarding women with this indication for induction This study demonstrates that misoprostol significantly reduces the interval from induction of labour to delivery without increasing rates of fetal distress or cesarean delivery. And subjects in the misoprostol group less frequently required oxytocin augmentation.

A concern in the use of misoprostol for induction of labour is tachysystole 3,6 It appears that the incidence of uterine tachysystole is dose related as indicated by an incidence of 17% with the 25mg dose<sup>(8)</sup> 37% with 50mg<sup>(6)</sup> and 72% with 100mg dose. In the studies of Wing at al<sup>(6,8)</sup> Sanches Ramos & colleagues<sup>(3)</sup> Ralph.; L.K etal<sup>(9)</sup> and ours, the relatively high incidence of tachysystole did not result in low Apgar score, increase in cesarean rate or admission to the NICU. On the basis of these preliminary findings misopostol appears to be a safe and effective alternative to oxytocin infusion for labour induction in women with premature rupture of membranes at term.

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We believe that studies are required to further evaluate the optional misoprostol dose, dose interval and total number of doses administered additionally, long-term neonatal follow up is needed.

Inducing labour when the cervix is ripe is not difficult but complications increase significantly when the cervix is not ripe. There is a plethora of techniques available for induction of labour. However prostaglandins remain the single most effective means of achieving cervical ripening and inducing labour.<sup>(10-14)</sup> PGE 2 is registered in many countries for labour induction. However it is expensive and sensitive to temperature changes and needs to be kept under refrigeration Oxtocin again needs cold chain maintenance and intravenous access Misoprostl (PGE1) analogue) has several potential advantages. It is stable at room temperature relatively inexpensive and can be given by several routes. (Oral, vaginal, sublingual and buckle)These properties make misprostol an ideal agent for induction of labour.

In Cochrane Database of systematic Reviews 2010. There were 25 trials with 3074 participants. Vaginal misoprostol appeared to be more effective than oxytocin for the induction of labour (10 trials averages RR for failure to achieve vaginal delivery within 24 hours 0.65, 95% (10.47-0.96) Two trials that had used less than 50ug misoprostol showed no reduction in failure to achieve vaginal delivery within 24 hours Twenty-five studies showed a reduction in caesarean section risk with the use of misoprostol (Average RR 0.76,95%GI 0.60-0.96) However, uterine hyperstimulation without fetal heart rate changes was more in women who had received misoprostol (15 trial, RR2.24,95% (11.82-2.77) The incidence of vaginal instrumental delivery was lower in the mioprostol group (13 trials, RR 0.74,95% (10.56-0.99). There were no differences between vaginal misoprostol and oxytocin in terms of prenatal or maternal adverse outcomes.

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