

## ORAL MISOPROSTOL V/S INTRAVAGINAL DINOPROSTONE GEL IN PREMATURE RUPTURE OF MEMBRANES AT TERM: COMPARATIVE STUDY

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### ABSTRACT

**Objective:** To compare the efficacy and safety of oral misoprostol and intravaginal dinoprostone gel for induction of labour in premature rupture of membranes at term gestation. **Methods:** One hundred woman with premature rupture of membrane at term fulfilling inclusion criteria for the study, were consented to participate in this study. 50 cases were included in misoprostol group and a 75 microgm misoprostol tablet (3/4 of 100microgm tablet) was given orally. Another 50 cases were included in dinoprostone gel group, instilled in posterior fornix of vagina. Two groups were compared with respect to mode of delivery, labour characteristics, neonatal and maternal outcome. **Results:** The mean induction to active phase of labour duration was significantly shorter in misoprostol (3.23±1.34hrs) as compared to PGE2 gel (3.93±1.74 hrs, p<0.05). The mean interval from induction to delivery was also significantly shorter in misoprostol group [(5.41±1.2 hrs) v/s (6.37±1.66 hrs)p<0.001]. Tachysystole and hyperstimulation observed more in PGE2 gel 8 % and 6% as compared to 6% and 2% in misoprostol group. There was no difference in regard to rate of cesarean delivery. Apgar score at 1 and at 5 minutes, NICU admission, maternal and neonatal outcome had no significant difference in both group. **Conclusions:** oral misoprostol is more effective and as safe as intravaginal dinoprostone gel for induction of labor in premature rupture of membrane at term.

**Keywords:** premature rupture of membrane at term, oral misoprostol, intravaginal dinoprostone gel, induction of labor.

### INTRODUCTION:

Premature rupture of membranes (PROM) is one of the most confusing and controversial obstetric dilemma. It is defined as spontaneous rupture of membranes with release of amniotic fluid with a latent period before the onset of labor. Rupture before 37 completed weeks of gestation is known as preterm PROM. When it occurs after 37 completed weeks it is called term PROM. The latent period is the time interval between the rupture of membranes to the onset of labour. The average incidence of PROM is 10% and it varies from 2-18% (1). Out of these 10%,

60-80% of cases are term PROM (2). About 80% of women at term will go into spontaneous labour within 24 hrs. and 10-25% will have a latent period of >24 hrs. If the latent period is >24 hrs. the chances of infection increases. Therefore the management of such patient is induction of labor (3). Prostaglandin E1 (misoprostol) and PGE2 (dinoprostone) are effective in inducing labor in PROM at term. several studies have demonstrated the use of vaginal and oral prostaglandin in women at term PROM .

This study was undertaken to compare these two prostaglandin for their safety and efficacy for induction of labor.

## METHOD

This prospective study was conducted on 100 pregnant women with premature rupture of membranes at term (37 or more completed weeks) in department of obstetrics and Gynaecology, SMS medical college, jaipur.

Rupture of membrane was diagnosed by clinical history of passage of liquor, by per speculum examination, by palpation through cervical canal, by fern test. Inclusion criteria for recruitment under study were singleton gestation; cephalic presentation; gestation age  $\geq 37$  weeks; reassuring fetal heart rate; patient not in active labour with PROM; no contraindication for vaginal delivery. Women were excluded if they had bishop score  $\leq 7/13$ ; chorioamnionitis, antepartum hemorrhage, IUGR, multifetal gestation, proteinuric hypertension, meconium stained liquor, parity  $> 5$ , contraindication to prostaglandin use.

Women were assigned randomly to receive misoprostol or dinoprostone gel. Women in misoprostol group received 75 microgm of misoprostol orally every 4 hrly till bishop score improves or active labour sets in. Women in PGE<sub>2</sub> gel group received application of PGE<sub>2</sub> gel 0.5 mg in posterior fornix of vagina in dorsal position. Movement restricted for 30 minutes after instillation, same dose repeated after 6 hrs if bishop score did not improve. Baseline bishop score, uterine activity and fetal heart sound of all subjects analysed at the time of admission in labor ward. Labor augmented with oxytocin if uterine contraction were not strong enough, although had reached in active phase of labor. Monitoring of labor patients done with electronic fetal monitoring and for abnormal uterine contractions.

Various outcome noted as interval between induction to active phase of labor, induction to delivery, number of doses used for induction, maternal outcome as occurrence of chorioamnionitis (maternal fever, fetal and maternal tachycardia, uterine

tenderness, leucocytosis), endometritis (maternal fever, uterine tenderness, foul smelling lochia), perineal trauma, mode of delivery, neonatal outcome as Apgar score at 1 and 5 minutes, NICU admission, birth asphyxia, meconium aspiration syndrome.

## RESULTS

There was no statistically significant difference between women in misoprostol and PGE<sub>2</sub> gel with respect to age, parity, previous history of PROM, duration of rupture of membranes to admission, baseline bishop score (table 1).

Significant relationship was noted in two groups for labour characteristic i.e. interval between induction to active phase of labour, induction to full dilatation, induction to delivery interval. Labour augmented with oxytocin in 44% of misoprostol and 58% in PGE<sub>2</sub> gel group. Misoprostol was repeated in 2<sup>nd</sup> dose in 8% of patients after 4 hours (no further dose required). PGE<sub>2</sub> gel repeated in 12% patient after 6 hours. Cesarean section rate was not statistically different in two groups. All cesarean sections in both groups were done for arrest of second stage of labour. None of the cesareans done for hyperstimulation or fetal distress (table 2).

Hyperstimulation, tachysystole, hypertonus was seen more in PGE<sub>2</sub> gel group but was not significant statistically. None of the patients had chorioamnionitis, endometritis, uterine rupture in both groups. 4 patients had cervical tear and traumatic PPH in both groups (table 3).

Incidence of apgar score  $< 7/10$  at 1 and 5 minutes, meconium passage and NICU admission was nearly similar in both groups. None of the neonates had birth asphyxia, and meconium aspiration syndrome. (table 4).

Negative correlation between bishop score and various parameters seen. This was statistically significant in both groups. (table 5).

## DISCUSSION

Our study was conducted to compare efficacy and safety of oral misoprostol and intravaginal PGE<sub>2</sub> gel for induction of labour in PROM at term. 75 microgm

of misoprostol used orally every 4 hrly and maximum of 5 doses are used . johan MG crane et al 2003(4) used similar dose and dose schedule. PGE<sub>2</sub> gel instilled 0.5 mg in posterior fornix and repeated after 6 hours if needed. Same doses were used by chaudhuri snehamay et al 2006(5). 63% of woman in our study were nulliparous. While Johan MG crane et al (4) chaudhuri snehamay et al, 2006(5), frohn WE et al 2002(6) had greater number of nulliparous in their study.

Interval between induction to delivery was shorter in misoprostol group (5.41±1.22 hrs) as compared to PGE<sub>2</sub> gel group (6.37±1.66 hrs). wing D A jones et al 1995(7) also observed significant difference in two groups. In our study 88% of patients in PGE<sub>2</sub> gel group required single dose for induction , chaudhuri snehamay et al 2006(5) reported similar findings in their study ( 91%).

Maximum number of patients had spontaneous vaginal delivery: only 4% of woman in each group had cesarean delivery. while in the study of frohn WE et al 2002(6), 19% of patients in misoprostol and 25% in PGE<sub>2</sub> gel group required cesarean section. Tachysystole, hyperstimulation, hypertonus observed more in PGE<sub>2</sub> gel group as compared to misoprostol group .This was not statistically significant (8%,6%,2%,v/s 6%,2%,2%) (p>0.05). This was in contrast to study of frohn WE et al 2002(6) which reported higher incidence of abnormal uterine contraction with misoprostol.

None of the patients in present study had chorioamnionitis and endometritis while in other studies, chaudhuri snehamay et al 2006(5), 1.8% had chorioamnionitis in PGE<sub>2</sub> gel group, frohn WE et al 2002(6) reported 6% in misoprostol and 9% PGE<sub>2</sub> gel group but in study of Kimberly D butt et al 1999(8), none of the patient had chorioamnionitis and endometritis.

In present study 22% of neonate in misoprostol and 20% in PGE<sub>2</sub> gel group had apgar score <7/10 at 1 minute. Frohn WE et al 2002(6) observed apgar score >6/10 at 1 minute in 78% of misoprostol group and 89% cases of PGE<sub>2</sub> gel group. NICU admission was

not significantly different in both groups, similar finding reported by frohn WE et al 2006(6).

## CONCLUSION

Oral misoprostol is more effective and as safe as intravaginal dinoprostone gel for induction of labour in premature of rupture of membrane at term.

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**Table 1: Demographic and clinical characteristics**

| Characteristics   | misoprostol group (n=50)              | dinoprostone gel group (n=50) |
|---|---------------------------------------|-------------------------------|
| Age (in year )  | 24.28±3.12                            | 22.90±4.46                    |
| <b>Parity</b>   |                                       |                               |
| Primipara   | 30(60)                                | 33(66)                        |
| Multipara   | 20(40)                                | 17(34)                        |
| History of PROM in previous pregnancy                       | 5(10)                                 | 3(6)                          |
| duration between rupture of membrane and admission (in hrs) | 5.14±1.96*                            | 4.42±2.13*#                   |
| baseline bishop score                                       | 4.08±1.45                             | 4.18±1.4*#                    |
| *mean ± SD  | # P value is not significant (p>0.05) |                               |

**Table 2 : labour characteristics**

| Characteristics                             | Misoprostol Group (n=50) | dinoprostone gel Group (n=50) | p value |
|---|--------------------------|-------------------------------|---------|
| Induction to active phase Of labour         | 3.23±1.34 hrs.           | 3.93±1.74 hrs.                | <0.05   |
| Induction to full dilatation                | 4.96±1.20hrs.            | 5.87±1.68 hrs.                | <0.01   |
| Induction to delivery                       | 5.41±1.22 hrs.           | 6.37±1.66 hrs.                | <0.001  |
| Oxytocin augmentation Required              | 22 (44)                  | 29(58)                        |         |
| <b>Dosage used</b>                          |                          |                               |         |
| 1   | 46(92)                   | 44(88)                        |         |
| 2 or >2                                     | 4(8)                     | 6(12)                         |         |
| <b>Mode of delivery</b>                     |                          |                               |         |
| Spontaneous                                 | 48(96)                   | 48(96)                        | >0.05   |
| Vaginal delivery                            | 2(4)                     | 2(4)                          |         |
| Cesarean section                            |                          |                               |         |
| Indication for cesarean                     | 2(100)                   | 2(100)                        |         |
| Section (arrest of second Stage of labour ) |                          |                               |         |

**Table 3 : maternal outcome**

| <b>Outcome</b>                          | <b>Misoprostol Group<br/>(n=50)</b> | <b>dinoprostol gel Group<br/>(n=50)</b> | <b>p value</b> |
|---|-------------------------------------|---|----------------|
| <b>Abnormal uterine<br/>Contraction</b> |                                     |   |                |
| <b>Tachysystole</b>                     | 3(6)                                | 4(8)                                    | >0.05          |
| <b>Hyperstimulation</b>                 | 1(2)                                |   | >0.05          |
| <b>Hypertonus</b>                       | 1(2)                                | 1(2)                                    | >0.05          |
| <b>Perineal trauma</b>                  |                                     |   |                |
| <b>3<sup>rd</sup> degree</b>            | 0                                   | 0                                       |                |
| <b>4<sup>th</sup> degree</b>            | 0                                   | 0                                       |                |
| <b>Cervical tear</b>                    | 2(4)                                | 2(4)                                    |                |
| <b>PPH</b>                              | 2(4)                                | 2(4)                                    |                |
| <b>Uterine rupture</b>                  | 0                                   | 0                                       |                |
| <b>Chorioamnionitis</b>                 | 0                                   | 0                                       |                |
| <b>Endometritis</b>                     | 0                                   | 0                                       |                |

**Table 4: Neonatal outcome**

| <b>Outcome</b>                      | <b>misoprostol group<br/>(n=50)</b> | <b>dinoprostone gel group<br/>(n=50)</b> |
|-------------------------------------|-------------------------------------|--|
| <b>Apgar score &lt;7/10</b>         |                                     |  |
| <b>1 minute</b>                     | 11 (22)                             | 10(20)                                   |
| <b>5 minute</b>                     | 3(6)                                | 3(6)                                     |
| <b>Meconium passage</b>             | 3(6)                                | 3(6)                                     |
| <b>Birth asphyxia</b>               | 0                                   | 0  |
| <b>NICU Admission</b>               | 4(8)                                | 3(6)                                     |
| <b>Meconium aspiration syndrome</b> | 0                                   | 0  |

**Table 5: correlation between bishop score and various parameters**

| Correlation   | misoprotol group |       |              | dinoprostone gel group |       |              |
|---|------------------|-------|--------------|------------------------|-------|--------------|
|   | (n=50)           |       |              | (n=50)                 |       |              |
|   | r-value          | P     | Significance | r-value                | p     | Significance |
| <b>Bishop score v/s induction to active phase of labour</b> | -0.725           | <0.01 | Sig          | -0.397                 | <0.05 | Sig          |
| <b>Bishop score v/s induction to full dilation</b>          | -0.673           | <0.01 | Sig          | -0.386                 | <0.05 | Sig          |
| <b>Bishop score v/s induction to delivery</b>               | -0.683           | <0.01 | Sig          | -0.342                 | <0.05 | Sig          |