**ORIGINAL ARTICLE**

# Comparison of Oral Misoprostol with $Pge_2$ Gel for Induction of Labour in Prom at Term with Unfavourable Bishop Score

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## ABSTRACT

**Background:** Prelabour rupture of membranes (PROM) is defined as rupture of fetal membranes before onset of labour at term. It occurs in 5-10% of pregnancies and 60% PROM occurring at term. Five percent of patient deliver within 5 hours of membrane rupture while 95% take 28 hours.
**Aim:** To compare the mean duration of induction to delivery time with oral misoprostol and $PGE_2$ gel for induction of labour in PROM with poor bishop score at term.
**Methods:** 100 pregnant women who fulfilled the inclusion criteria were selected for this study. This randomized controlled trial was conducted from January 2011 to June 2011, at Gynae Unit-I, Sir Ganga Ram Hospital Lahore. Patients having previous history of uterine surgery, palpable uterine contractions, and Any contraindication to vaginal delivery e.g. placenta previa on USG were excluded from this study. Patients were randomly allocated to group A (50 patients) and group B (50 patients) by lottery method. Patients in group A were induced with oral misoprostol 50µg 4 hours apart upto maximum of 3 doses and patients in group B were induced with 0.5mg PGE2 gel 6 hours apart upto maximum of 2 doses.
**Results:** The mean age of the patients in group A was 26.0±3.8 years and in group B was 25.7±3.9 years The mean gestational age in group A was 38.8±1.1 weeks and in group B was 38.9±1.2 weeks. The mean induction to delivery time in group A was 620.0±115.7 minutes and in group B was 930.0±206.9 minutes. In group A, 41(82%) patients delivered by vaginal delivery and 9(18%) patients by caesarean section and in group B, 40(80%) patients delivered by vaginal delivery and 10(20%) patients by caesarean section.
**Conclusion:** It is concluded from this study that there is less mean duration of induction to delivery time in patients induced with oral misoprostol as compared to vaginal PGE2 gel in pregnant females presenting with PROM and poor bishop score at term.
**Key words:** PROM, oral misoprostol, $PGE_2$ gel, induction to delivery interval, mode of delivery

## INTRODUCTION

Prelabour rupture of membranes (PROM) is defined as rupture of fetal membranes before onset of labour at term. It occurs in 5-10% of pregnancies and 60% PROM occurring at term[1,2].

Five percent of patients deliver within 5 hours of membrane rupture while 95% take 28 hours.[3] As interval between rupture membranes and delivery increases. It increases risk of fetomaternal infection, cord prolapse, cord compression and placental abruption which subsequently increases maternal and fetal morbidity, caesarean rate and hospital stay[4,5]. So induction of labour is preferred shortly after membranes ruptures in term pregnancy[3,4].

More recently different prostaglandins have been used for induction of labour in PROM because prostaglandins have dual capacity of both ripening cervix and initiate uterine contractions[1,5,6].

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Prostaglandins are unsaturated carboxylic acids derived from arachidonic acid act via various prostanoid receptors which belongs to plasma membrane G-protein linked seven transmembrane spanning proteins[7,8]. So prostaglandins act by three mechanisms (1) it soften cervix by altering extracellular ground substance (2) increases activity of smooth muscles of cervix and uterus by Gxi (inhibitory G protein) to inhibit adenylcyclase or activate phospholipase C increasing intramyometrial calcium causing contraction (3) increases gap junctions formation for coordinated uterine contraction[6,8].

Side effect associated with prostaglandins use is uterine hyperstimulation, fetal heart rate changes and uterine rupture[9]. Misoprostol a synthetic analogue of PGE1 is an effective agent for cervical ripening and induction of labour in viable pregnancies[6]. It is cheep, heat stable and easy to store[2,10]. In comparison PGE2 gel also ripens unfavourable cervix but is costly unstable at room temperature and causes risk of ascending infection.[11] Use of oral misoprostol can cause approximately 5 hours reduction in induction to

delivery interval and decrease caesarean rate.6 In addition oral misoprostol in PROM patients reduces the risk of fetomaternal sepsis and given better efficacy as vaginally administered drug can partly flow out with draining fluid.

In a study, 61 patients with PROM and poor bishop were taken. 31 patients induced with oral misoprostol and 30 with PGE2 gel. Patients induced with oral misoprostol had shorter induction to delivery interval 615±282 minutes verses 1070±339 minutes. 27 of 31(87.1%) in the misoprostol group and 25 of 30 women (83.3%) in PGE2 group had a normal vaginal delivery[11].

The rationale of my study is to compare mean induction to delivery time with oral misoprostol and vaginal PGE2 gel for induction of labour in PROM with poor bishop score at term to reduce fetomaternal morbidity and financial burden on health services by reducing the duration of hospital stay and operative deliveries by knowing better cost effect treatment.

## MATERIAL AND METHODS

This randomized controlled trial was conducted on 100 pregnant women from January 2011 to June 2011, at Gynae Unit-I, Sir Ganga Ram Hospital Lahore. The gestational age of 37 weeks upto 41 weeks, and age 20 to 35 years were included. Patients having previous history of uterine surgery, palpable uterine contractions, and any contraindication to vaginal delivery e.g. placenta previa on USG were excluded. Patients were randomly allocated to group A (50 patients) and group B (50 patients) by lottery method. Patients in group A were induced with oral misoprostol 50µg 4 hours apart upto maximum of 3 doses and patients in group B were induced with 0.5mg PGE2 gel 6 hours apart upto maximum of 2 doses. These patients were observed for time interval between induction to delivery.

These patients were observed for time interval between induction and delivery. Other variables as mode of delivery were also noted. Data was entered into SPSS version 16 and analyzed. All the quantitative variables like age, gestational age and duration of induction to delivery interval were described by calculating mean and standard deviation. Frequency and percentage was calculated for mode of delivery. Paired 't' test was used for comparison of mean duration of induction to delivery interval between the groups. P value $\leq 0.05$ was taken as significant.

## RESULTS

The mean age of the patients in group A was 26.0±3.8 years and in group B was 25.7±3.9 years. The mean gestational age in group A was 38.8±1.1 weeks and in group B was 38.9±1.2 weeks. The mean induction to delivery time in group A was 620.0±115.7 minutes and in group B was 930.0±206.9 minutes. In group A, 41(82%) patients delivered by vaginal delivery and 9(18%) patients by caesarean section and in group B, 40 (80%) patients delivered by vaginal delivery and 10 (20%) patients by caesarean section.

Table 1: Distribution of patients by age (n=100)

| Age ( years) | Group A | Group B |
|---|---|---|
| 20-25 | 25(50%) | 32(32%) |
| 26-30 | 20(40%) | 59(59%) |
| 31-35 | 5(10%) | 9(9%) |
| Mean±SD | 26.0±3.8 | 25.7±3.9 |

Table 2: Distribution by induction to delivery time

| Induction to delivery time (Minutes) | Group A | Group B |
|---|---|---|
| Upto 500 | 11(22%) | 0 |
| 501-700 | 25(50%) | 6(12%) |
| 701-900 | 13(26%) | 18(36%) |
| 901-1100 | 1(2%) | 18(36%) |
| 1101-1300 | 0 | 9(18%) |
| Mean±SD | 620.0±115.7 | 930.0±206.9 |

P value 0.001

Table 3: Distribution of patients by mode of delivery

| Mode of delivery | Group A | Group B |
|---|---|---|
| Vaginal delivery | 41(82%) | 40(80%) |
| Caesarean section | 9(18%) | 10(20%) |
| Total | 50(100%) | 50(100%) |

P = 0.8

## DISCUSSION

The management of prelabour rupture of membranes at term is still a matter of debate, and varies from centre to centre. While active induction of labour soon after prelabour rupture of membranes has resulted in a lower risk of maternal and fetal sepsis in some studies[12], it has also been associated with a higher caesarean section rate in others.[13,14] The largest randomised controlled trial on prelabour rupture of membranes to date[15] found that active labour induction with oxytocin or vaginal prostaglandin $E_2$ ($PGE_2$) gel, and expectant treatment resulted in similar rates of caesarean sections and neonatal infections, although the risk of maternal infection was lower with oxytocin induction. This

reduction in maternal infections was not seen with vaginal $PGE_2$, and was probably due to a greater number of vaginal examinations in this group. Women with active management had shorter prelabour rupture of membranes to delivery intervals as compared with the expectant group and tended to prefer active management.

Misoprostol, a PGE1 analogue has been used effectively both orally and vaginally for labour induction with prelabour rupture of membranes[16,17,18,19]. The advantage of misoprostol orally, with particular reference to prelabour rupture of membranes, might be that repeated vaginal examinations could be avoided thus resulting in less risk of sepsis for mother and baby. Oral $PGE_2$ preparations have been tried in other studies, and although found to be effective for labour induction, have been associated with significant gastrointestinal side effects, with quoted incidences of 10–50%.[20] They are therefore not used routinely. The risk of hyperstimulation with misoprostol seems to be related both to the dosage and route of administration. With oral preparations at doses of 100 mg or less, this risk is small[16,17,18,19].

Misoprostol a synthetic analogue of PGE1 is an effective agent for cervical ripening and induction of labour in viable pregnancies.[6] It is cheep, heat stable and easy to storne.[2,10] In comparison PGE2 gel also ripens unfavourable cervix but is costly unstable at room temperature and causes risk of ascending infection[11]. Use of oral misoprostol can cause approximately 5 hours reduction in induction to delivery interval and decrease caesarean rate.[6] In addition oral misoprostol in PROM patients reduces the risk of fetomaternal sepsis and given better efficacy as vaginally administered drug can partly flow out with draining fluid.

In our study the mean age of the patients was n group A was 26.0±3.8 years and in group B ws 25.7±3.9 years. As compared with the study of Nyende et al[21] the mean age of the patients in oral misoprostol group was 24.7±5.6 years, which is comparable with our study.

In our study the mean gestational age in group A was 38.8±1.1 weeks and in group B was 38.9±1.2 weeks. As compared with the study of Shetty et al[22] the mean gestational age of the patients in oral misoprostol group was 39 weeks, which is comparable with our study.

In our study the mean induction to delivery time in group A was 620.0±115.7 minutes and in group B was 930.0±206.9 minutes. As compared with the study of Nagpal et al[11] the mean induction to delivery time in oral misoprostol group was 615 minutes and in PGE2 gel was 1070 minutes, which is comparable with our study.

In another study conducted by Chang et al[23] the mean induction to delivery time in oral misoprostol group was 480±172 minutes and in PGE2 group the mean induction to delivery interval was 657±436 minutes. While in our study the mean induction to delivery time in group A was 620.0±115.7 minutes and in group B was 930.0±206.9 minutes, which is comparable with the above study.

According to the study of Levo et al[24] the mean induction to delivery time in oral misoprostol group was 822±348 minutes and in placebo group the mean induction to delivery time was 1218±4.8 minutes.

In our study in group A, 82% patients delivered by vaginal delivery and 18% patients by caesarean section and in group B, 80% patients delivered by vaginal delivery and 20% patients by caesarean section. As compared with the study of Shetty et al[22] in oral misoprostol group 83.3% women delivered vaginally and 16.7% by caesarean section and in PGE2 gel group 83.8% women delivered vaginally and 16.2% by caesarean section, which is comparable with our study.

On the above discussion, it is concluded that there is less mean duration of induction to delivery time in patients induced with oral misoprostol as compared to vaginal $PGE_2$ gel in pregnant females presenting with PROM and poor bishop score at term.

## CONCLUSION

It is concluded from this study that there is less mean duration of induction to delivery time in patients induced with oral misoprostol as compared to vaginal PGE2 gel in pregnant females presenting with PROM and poor bishop score at term.

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