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**ORIGINAL ARTICLE**

# Comparison of Conventional Treatment of Prom (Pre Labor Rupture of Membranes) with Active Treatment in Term Patients

FARAH KHAN[1], NIGHAT ALI SHAH[2], SHABANA KANWAL[3], NUSRAT SHAH[4], FALAK NAZ[5], UROOJ NAZ[6]
[1]*Senior Instructor Gynaecology and Obstetrics, Sindh Reproductive and Genetic Health Centre, Jinnah Sindh Medical University Karachi Pakistan*
[2]*Associate Professor Gynaecology and Obstetrics, Sindh Reproductive and Genetic Health Centre, Jinnah Sindh Medical University Karachi Pakistan*
[3]*Consultant Gynaecology and Obstetrics, Koohi Goth Hospital for Women Karachi Pakistan*
[4]*Pro Vice Chancellor, Dow University of Health Sciences Karachi*
[5]*Consultant Gynaecology and Obstetrics, Lady Duffren Hospital Karachi*
[6]*Assistant Professor Gynaecology and Obstetrics, Dow University of Health Sciences Karachi*
*Corresponding author: Farah Khan, Email: dr.farahfahad@gmail.com*

## ABSTRACT

**Objectives:** To compare outcome of conventional treatment of Pre labor rupture of membranes (PROM) with active treatment in term patients.

**Place and Duration:** This study was Conducted in Family Medics Infertility and Maternity Centre Karachi from March 2022 till June 2022.

**Materials & Methods:** We conducted a randomized control trial on 74 registered patients who presented to the labor room with term pregnancy and with the ruptured membranes at thirty-seven weeks or more gestation verified from the last normal menstrual period or a dating scan. Two groups were randomized as either spontaneous labor or active management by Prostin.37 patients presented in Prelabour rupture of membranes were examined as per departmental policy and left for spontaneous labor and 37 women were actively managed by inserting Prostin in the posterior fornix.

**Main Outcomes Measured:** The outcome of interest was intervention vs .non intervention regarding timespan between PROM and initiation of labour in respective groups. Secondary outcome included patients who did not respond to either conventional measures or active treatment and required caesarian section.

**Results:** The time duration between rupture membrane and initiation of labour was less in intervention group as compared to conservative group (6.40hrs vs. 5.03hrs).The rates with respect to normal delivery or caesarian section were same in test and control groups (27 pts. vs. 25 pts.). There was no statistically significant difference regarding complication in both the arms in study. (P-value=0.967)

**Conclusion:** The results of our study showed that there are no differences in outcomes of conservative management of PROM with that of active management. However, patients managed actively in intervention group delivered earlier as matched with patients with spontaneous management.

**Keywords:** Term pregnancy, PROM, Spontaneous vaginal delivery, Emergency Cesarean section. The Registration number of the study specified by the university is JSMU/IRB/2022/-601.

## INTRODUCTION

Pre labor rupture of membranes (PROM) is defined as women who present with leaking and rupture membranes after 36 completed weeks [(1)]. PROM is seen in approximately l0% of all pregnancies [(2)]. These women usually come in labour room with watery leakage which may be associated with mild show or feeling of discomfort in pelvic region, not associated with labour pains[(3)]. This condition can lead to infection mother and fetus,also in rare cases placental separation and fetal compromise [(3)]. Research shows that almost three quarters of women with this presentation will go in labour within 24 hours [(4)]. Much work has been done on this very relevant issue but still there are grey areas regarding the best possible management [(5)] [(6)]. However, active management with uterine contraction stimulant like syntocinon is known to have a higher rate of failed induction possibly due to an underlying deficiency of prostaglandin production or prostanoid synthesis [(7)]. This hypothesis is supported by a recent Cochrane review that tested prostaglandin with syntocinon for stimulation of labour, and found a more favorable cervix after using prostaglandin as compared to oxytocin alone (70% versus 21%, RR 3.33,95% CI l.6l to 6.89) [(8)]. Stimulation of labor after rupture membranes can cause decrease in time to labour and delivery (11.6 versus l7 hours; P<0.001) [(9)]. Further research has shown that reduced time interval to delivery decreases complications in mother and baby especially infections and sepsis, at the same time it does not increase operative delivery [(10)]. Neonatal shift to ICU is also decreased with active management [(10)]. Literature shows induction of labor with PGE2 as compared to conservative treatment result in decreased operative delivery and of lower rate of forceps or vacuum delivery among women [(11)]. Systematic Reviews support early intervention as compared to wait and see approach as less time to delivery shows statistically significant reduction in sepsis, and ICU admissions for both mother and neonate.[(12)]

Hence our study is comparative study which analyses two groups of women with prelabour rupture membranes at 37 plus weeks. To see the mode of delivery, time interval between initiation of labour and delivery with either wait and see policy or intervention with prostaglandins. The better ofthe two treatment form will be used in future in women with PROM in our practice.

**Objectives:** To evaluate the best practice in term rupture membrane patients either wait and see (do nothing) or intervene by prostaglandins.

## MATERIALS AND METHODS

**Study Design:** Randomized control trial.

**Settng:** A private hospital of community where PI works as an independent consultant.

**Duration of Study:** Data was collected over 4 month's period. Initiation of data collection was started after the IRB approval from March 2022 till June 2022.

**Sample Size:** This included 74womenwho met inclusion criteria were selected and further divided in 37 patientsin each group using software and number of patients coming in the setup with PROM.

**Sampling Technique:** Non probability purposive sampling.

**Sample Selection:** Inclusion criteria included the registered women who presented to the labor room with term pregnancy, with the ruptured membranes at 37 weeks or more gestation verified from the last normal menstrual period or a dating scan:

**Inclusion Criteria:**

- Single fetus in cephalic presentation.
- Not in labor by confirming absence ofuterine contractions.
- Normal heart rate and reactive tracing on cardiotocograph.
- No meconium staining of liquor.
- Has no contraindication for normal vaginal delivery like previous two or more cesarean sections or a classic cesarean

section, previous extensive trans fundal surgeries, placenta previa and active genital tract infection

**Exclusion Criteria:**

- Mother developed intrapartum fever.
- Increased maternal heart rate.
- VBAC (vaginal birth after Cesarean section).
- Presence of Co-morbid (Diabetes-mellitus, Hypertension, IUGR, history Ante partum hemorrhage).
- Refuse to participate.

**Data Collection Procedure & Sources of Information:** After IRB approval, patients presenting to the labour room were included in the study. Pertinent history along with general and abdominal examination was reviewed in the labor room. Uterine contractility if any was noted and those having contraction were excluded. Leaking of fluid was confirmed by detection of amniotic pool and confirmation by using a dipstick confirming alkaline pH. Digital examination was avoided. A fetal heart rate tracing was performed to evaluate fetal wellbeing. After diagnosis of PROM, some basic laboratory workup including blood counts, urine tests and vaginal swab for culture and sensitivity were sent. Thereafter the women were assigned to spontaneous or wait and see group or intervention group through simple random selection. Written consent was pre requisite.Principal Investigator then requested women to select one card and hence assigned to the group of treatment or no treatment as per their selection. The patients were induced immediately by insertion of Prostin or left for spontaneous labour. Maternal pulse, temperature and blood pressures monitored uniformly in both groups every 4 hourly throughout this time. Labour was monitored through graphical representation of partogram as per protocol by a senior assigned midwife. Prophylactic antibiotics (Intravenous Ampicillin and flagyl) were given to both groups. Outcome variables like time of rupture membrane, admission in delivery suite, and insertion of Prostin were noted.Initiation of labour pains of increasing intensity and frequency and birthing time were documented. The mode of delivery was decided on the trend of labor progression and indication for C-section for both groups was uncontrolled hyper stimulation, Chorioamnionitis, fetal distress and non-progress of labor. Women under wait and see policy were kept under observation for 12 hours.Continuous cardiotocogram was performed after initiation of uterine contractions. Labour was monitored vigilantly. If vaginal delivery didn't occur in the 12 hour bracket, then the no intervention group of women were categorized to unsuccessful conservative treatment and intervention was done as per obstetric need and discussion with patient.

**Data Analysis:** Primary outcome was to compare the mode of delivery in both the groups.SPSS version 19 was utilized for data evaluation. Categorical variables including mode of delivery was summarized through descriptive statistics and Frequency and percentages were calculated.The difference between two groups was computed by using Chi-square test. Means and standard deviations were calculated for age of the patient. P-value of less than0.05 was considered significant.

## RESULTS

In the six-month study period, 74 women were enrolled, out of these 37 women were admitted for active management and 37-experienced conservative treatment. As shown in Table-I mean age of women presenting with spontaneous labor or for active induction was comparable (27.38 yrs. vs. 27.08 yrs.).It was observed that parturient in spontaneous labor took longer time to deliver as compared to patients whose labor was induced by immediate insertion of Prostin. (6.40 hrs. vs. 5.03 hrs.). P-value was calculated to be 0.032.The outcomes were similar with respect to mode of delivery (27 pts. vs. 25 pts.) in spontaneous group and immediate group respectively. The rates of chorioamnionitis were comparable in two groups.(p value= 0.967).It was noted that women having spontaneous management were more likely to have cesarean section due to non-progress of labor (62.5% vs. 33.3 %) as compared to patient having induction of labor. It was also noted that women having immediate induction of labor were more likely to have cesarean section due to fetal distress (37.5 % vs. 66.7%) as compared to patients having spontaneous management of labor.

Table 1: Comparison of Characteristics of women undergoing spontaneous Management and Immediate induction of labor.

| | Spontaneous group | (n=37) | Induction group | (n=37) | P- value |
|---|---|---|---|---|---|
| Factor | Mean | Std. Deviation | Mean | Std. Deviation | |
| Age | 27.38 | 4.355 | 27.08 | 4.265 | 0.768 |
| Parity | .46 | .730 | .57 | .959 | 0.587 |
| Gestational age | 38.16 | .928 | 38.32 | 1.002 | 0.472 |
| Duration of labor | 6:40 | 3:21 | 5:03 | 2:56 | 0.032 |
| Chorioamnionitis | 1.9714 | .16903 | 1.9697 | .17408 | 0.967 |

Table 2: Cross-Tabulation for Mode of Delivery and methods of treatment.

| Mode of delivery | Spontaneous Group | Induction Group | Total |
|---|---|---|---|
| Spontaneous Vaginal Delivery n, (%) | 27 (73.0%) | 25(67.6%) | 52(70.3%) |
| Forceps Vaginal Delivery n, (%) | 0 (0.00%) | 2(5.4%) | 2(2.7%) |
| Vacuum Vaginal Delivery n, (%) | 2(5.4%) | 1(2.7%) | 3(4.1%) |
| Cesarean Section n, (%) | 8(21.6%) | 9(24.3%) | 17(23.0%) |
| Total | 37(100%) | 37(100%) | 74(100%) |

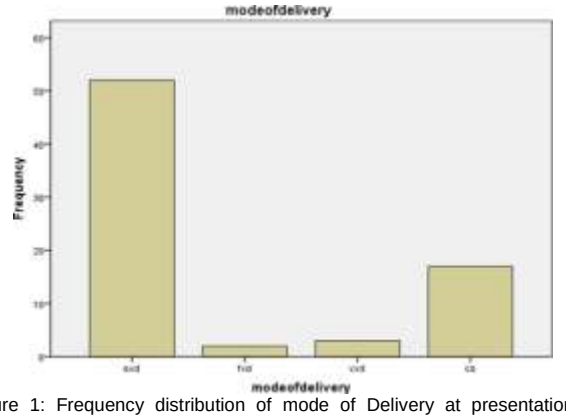


Figure 1: Frequency distribution of mode of Delivery at presentation in patients presenting with PROM.

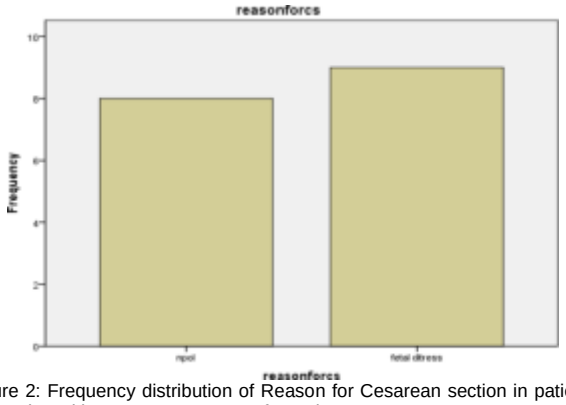


Figure 2: Frequency distribution of Reason for Cesarean section in patients presenting with Premature rupture of Membranes.

## DISCUSSION

This research was focused on benefit vs. risks of medical management in patients with term pregnancy and rupture membranes without labour pains.

Regarding the risk of higher rate of caesarian section in test group this was unequivocal and same in both groups as shown by meta-analysis published in 2017. [12] Although some studies have shown increased risks of early intervention in terms of prolonged labour and increased instrumental deliveries our study did not agree with this evidence [13].Research has shown that patients managed conservatively had higher rates of infection [14]but in our study this increased infectious morbidity was not observed. Systemic Review shows that women who deliver earlier through medical intervention have fewer risks of sepsis, and decreased ICU admission for both mother and baby[12]

Our study population included women who were not in active labour, whether to induce or not is a big dilemma here in these women, our study tried to resolve this paradox. The usual assumption here is no intervention is the best policy but recent literature and our study contradicted this wait and see policy as the intervention group did not show increased morbidity or higher caesarian section rates[15].Hence in agreement with different evidence, the type of delivery was equivocal in both groups and intervention group carried the added advantage of shorter labour duration from rupture membranes to normal delivery. Our results were comparable to the studies of Cheung et al [16], Snehamay et al [17], and Levy et al [18].

Amongst the various agents used for initiation of labour different studies report diverse outcomes, some studies favour oxytocin. [19] In our study we found prostaglandin E2 as medical induction agent to be safer, and more effective then oxytocin. Prostaglandin E2 was better in induction and reducing surgical morbidity in our intervention arm, this has been validated by others. [20] However majority the literature reviewed supports the idea of using prostaglandin as an agent of choice for inducing labour which we used in our population.[8][21]

Although there is some research supporting intervention like our study but still in order to have an undebatable firm policy in favour of intervention there is a need for multicenter large trials.

**Strengths and limitations:** The strength of our study was a Randomized control trial which is a strong study design as it minimizes the risk for data bias and confounding because of randomization. It was conducted in a tertiary care hospital. A small sample size of our research piece was a limitation.

## CONCLUSION

The results of our study showed that there are no differences in outcomes of conservative management of PROM with that of active management. However, patients managed by immediate induction of labor were delivered earlier as compared to patients with spontaneous management.

**Recommendations:** More prospectively conducted randomized control trials are expected to further clarify our results. Meanwhile obstetricians and other health care providers are advised to use their best judgments in the light of our existing knowledge on this subject.

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