

Expectant Vs Active Management of Prelabour Rupture of Membranes at Term

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ABSTRACT

Background: Despite multiple study trials, the management of Term PROM is still controversial. The current study was carried out in our population to compare the results of both active and expectant management that will be applicable for management of such patients in future.

Aim: To compare the outcomes of active versus expectant management in patients with term PROM in terms of cesarean section rate, mean latency period & chorioamnionitis.

Study design: Randomized controlled trial

Settings: Department of Obs.&Gynae, Allama Iqbal Medical College, Jinnah Hospital Lahore.

Duration: Six months period (1st January 2013 to 30th June 2013).

Methods: Two hundred women with rupture membranes at or >37 weeks gestation fulfilling the inclusion criteria were enrolled in this study. The cases selected were allocated randomly through lottery method into two groups i.e. Group A (actively managed group) was induced with tablet misoprostol and Group B (expectantly managed group) watched for spontaneous occurrence of labour within 24 hrs after PROM. Data was compiled, transferred and analyzed through SPSS (version 10). Means and standard deviations were calculated for quantitative data e.g., age, latency period. Chi square was applied for comparison of outcome variables i.e., C-section & chorioamnionitis and t test was used to compare the mean latency period in both groups.

Results: The induction to labour interval was significantly shorter in induced group. Delivery within 12 hours occurred in 97(97%) cases of group A and 83(83%) cases in group B while within 24 hours occurred in all 100(100%) and 97(97%) cases respectively. There was no statistically significant difference in the duration of labour and also in the mode of delivery. There was also no statistically significant difference in Apgar score at 5 minutes and admission of neonates to intensive care unit (87% and 80%) in group A and group B respectively.

Conclusion: There was no difference in the active and expectant management in patients with prelabour rupture of membranes at term.

Keywords: Prelabour rupture of membranes (PROM), induction of labour, Prostaglandins,

INTRODUCTION

Spontaneous or premature rupture of the membranes (PROM) refers to amniorrhexis prior to onset of labour or regular uterine contractions. It can occur at term or prior to term, in which case it is designated as preterm premature rupture of the membranes (PPROM). The frequencies of term, preterm and midtrimester PROM are 8, 1-3 and less than 1 percent of pregnancies, respectively¹. Prelabour rupture of membranes (PROM) is an obstetric conundrum; it has been poorly defined with an obscure etiology, difficult to diagnose and associated with significant maternal, fetal and neonatal risks and management strategies that are often diverse and controversial. The management strategies used are waiting for spontaneous onset of labour (expectant)

and induction of labour with prostaglandins/oxytocin (active). The demand of women so called natural childbirth means that, in many cases expectant management is still adopted, but a recent study has confirmed that such a policy increases the subsequent need for maternal antibiotic therapy, delivery by caesarean section and neonatal sepsis². There is much to commend a policy of induction of labour 6-12 hours after PROM³. A recent prospective study of over 5000 women in six countries confirmed that women treated expectantly were more likely to feel negative about their subsequent labour, presumably because of its perceived protracted duration and increased need for intervention with antibiotics. In PROM, induction of labour has advantages over expectant management as it decreases the risk of maternal and neonatal infections and increases maternal satisfaction⁴.

The rate of induction is on rise⁵. In United Kingdom it is of order of 15-25 percent. It is one of the most commonly performed obstetrical procedures in the United States. Between 1990 and 1998, the

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frequency of labour induction doubled from approximately 10 to 21 percent^{6,7}. Reasons for this increase include the availability of better cervical ripening agents, the desire to arrange a convenient time of delivery, and more relaxed attitudes towards marginal indications for induction⁸. Induction of labour is performed when prolongation of pregnancy is considered in advisable for fetal and / or maternal well being⁽⁹⁾. There are mechanical and medical methods of induction of labour¹⁰. However, in case of PROM medical methods are considered because of the risk of increased sepsis rate. Medical methods include oxytocin, prostaglandins and combinations of both¹¹. Most women with term PROM will go into labour spontaneously if followed expectantly. In one review of these pregnancies delivery within 24 and 48 hours occurred in 70% and 85% of women respectively^{2,12}. Studies comparing immediate induction with oxytocin to expectant management found that immediate induction resulted in lower rates of chorioamnionitis, endometritis, neonatal intensive care unit admissions and neonatal infection. The rate of caesarean delivery was similar in both groups, and there was a trend toward fewer perinatal deaths among women induced immediately¹³. Induction of labour with prostaglandins (with or without subsequent oxytocin) compared to oxytocin alone for induction of labour in term PROM showed increased risk of chorioamnionitis and neonatal infections in first group, but the frequency of caesarean delivery, endometritis and perinatal mortality did not differ between the groups¹⁴. Study of oral misoprostol (100 microgram for up to two doses six hours apart) for induction of labour in women with term PROM did not find any advantage compared to use of oxytocin¹⁵. Traditional management of labour induction with oxytocin alone has been showing an increase in maternal as well as perinatal morbidity whereas studies with prostaglandins have reported good success with the induction of labour in patients with PROM with an unfavorable cervix⁽¹⁶⁾. The maternal and fetal or neonatal hazards from induction of labour include, failed induction, uterine hyperstimulation, fetal distress, abruptio placentae, uterine rupture, inadvertent preterm delivery, hyponatremia, hyperbilirubinemia, hypotonic uterus and postpartum haemorrhage¹⁷.

Despite multiple study trials, the management of Term PROM is still controversial. The current study was carried out in our population to compare the results of both active and expectant management that we could apply it on general population in future. In this study we have compared the efficacy of prostaglandin E₁ (misoprostol) in terms of induction to labour interval, duration of labour, mode of delivery, neonatal Apgar score and need for neonatal intensive

care unit admission in this group of patients and expectant management.

MATERIALS & METHODS

Two hundred women with rupture membranes at or >37 weeks gestation fulfilling the inclusion criteria were enrolled in this study and they were admitted in labour room either throughout or emergency. The cases were selected on random allocation basis, using random number table, and divided into two groups i.e. Group A (actively managed group) and Group B (expectantly managed group) with 100 patients in each group. Informed consent was taken from all the patients. Patients were excluded on the basis of previous LSCS and not willing to become part of the study.

Detailed history, general physical, obstetrical and sterile speculum examination was carried out on all the patients. On speculum examination cervical dilatation vaginal pooling and colour of liquor was assessed. High vaginal swab was taken at the time of speculum examination. Bishop score was assessed once with sterile gloves, at the time of admission and was restricted until the establishment of active labour. Group A patients (actively managed group), were induced immediately at presentation with tablet misoprostol. Group B which was being expectantly managed, was watched for spontaneous occurrence of labour within 24 hrs after PROM and if not in labour after 24 hrs then was managed as per departmental protocol. By exclusion criteria bias and confounding factors like gravidity was controlled by stratifying data for primigravida and multigravida at the end. Both the groups were watched for establishment and then progress of active labour. Caesarean section rate, development of chorioamnionitis, latency period and other variables like maternal satisfaction were recorded and compared in both groups. All the information was collected through specially designed proforma and entered into SPSS version 10 for analysis. The quantitative data including demographic (age, parity), induction to labour interval and duration of labour was presented as means and standard deviation.

Qualitative variables like mode of delivery, development of chorioamnionitis, neonatal Apgar Score and need for neonatal intensive care unit admissions was presented as frequency and percentages. The comparative efficacy of two procedures was assessed by indicators like mode of delivery and avoidance of complications. Any association found in the two methods was subjected to chi-square test at P value of 0.05 or less.

RESULTS

Out of the two hundred, 100 subjects were induced with misoprostol (Group A) and 100 were managed expectantly randomly. The subjects were similar with respect to mean age, parity and estimated gestational age at entry. At the time of induction the mean bishop score of Group A was 3.5±4.9 and mean value of group-B was 3±5.4.

The induction to labour interval was significantly shorter in the misoprostol group with P-value = 7.81 (Table-I). Percentage of cases delivered within 12 hours in group-A was 96.67% while in group-B, it was 83.33%. However, percentage of cases delivered between 12 to 24 hours of induction in group-A was 3.33% while in group-B, it was 13.33%. Only one case of Expectant management was delivered after 24 hours i.e., 3.34%. There was no statistically significant difference in the duration of labour of both groups (Table-II).

In group-A, rate of normal vaginal delivery was found to be 86.67%, while in group-B, it was 73.33%. Instrumental delivery rate was 3.33% in group-A and 10% in group-B. In group-A, rate of Cesarean section was 10% and in group-B 16.67%. The chi-square test indicates that there is no significant difference in mode of delivery between two groups (Table III).

Regarding indications for caesarean sections, there were 3 patients with indication of fetal distress in group A while 2 patients in group B. No case of non-progress of labour in group A and 2 cases in group B. There was one case of failed induction in group-A.

No case of prolonged labour, hyperstimulation of uterus and antepartum haemorrhage (APH) was noted in either group. Fever was noted in 3.33% cases of Group A and in 10% of Group B. Tachycardia was noted in 6.67% of Group A and in 10% of Group B. No Case of postpartum haemorrhage (PPH) was found in Group A while it occurred in 3.33% cases of Group B. No complication observed in 90% cases of Group A and 76.66% of Group B so there was a significant difference regarding maternal complications between two groups.

Passage of meconium was 10% in Group A and 16.66% in Group B. There was no significant difference in passage of meconium in both groups.

Out of 100 babies of mothers induced with misoprostol, 6/ 30 x 100 had Apgar Score of 6-7 after 5 minutes and 24/30 x 100 had Apgar Score of 8-9, while 4/30x100 babies of mothers with expectant management, had Apgar Score of 6-7 and 26/30 x 100 had 8-9 (Fig.I). There was no significant difference between two groups as far as Apgar Score at 5 minutes is concerned.

In group A 13.37% neonates were admitted to ICU and in group-B ,the rate was 20%. The chi-

square test indicates no significant difference in both groups with respect to admission to ICU at 5% level of significance (Table-IV). There was no statistically significant difference in fetal and neonatal complications between two groups (Table-V). Out of 100 cases induced with misoprostol tablet, 27(27%) needed augmentation with syntocinon, where as 2nd dose of misoprostol tablet was needed after 6 hours in 23 patients.

Table I: Induction to Labour Interval (n=200)

Duration (hrs)	Group A	Group B
≤ 5	97(97%)	67(66%)
6-10	3(3%)	27(26%)
11-15	0	3(3%)
> 15	0	3(3%)

Chi Square = 60

P-value = 7.81

Table II: Duration of labour (n=200)

Duration of labour (hrs)	Group A	Group B
1-12	97(97%)	83(83%)
13-24	3(3%)	13(13%)
> 24	0	4(4%)

Chi Square = 3.96

P-Value = 5.99

Table III Mode of Delivery between Two Groups (n=200)

Mode of Induction	Mode of Delivery		
	Normal Vaginal delivery	Instrument al delivery	C-Section
Group A	87(87%)	3(3%)	10(10%)
Group B	73(73%)	10(10%)	17(17%)

Chi Square = 2.20

P-value 5.99

Fig. 1: Distribution of cases b ApgarScore at 5 times (n=200)

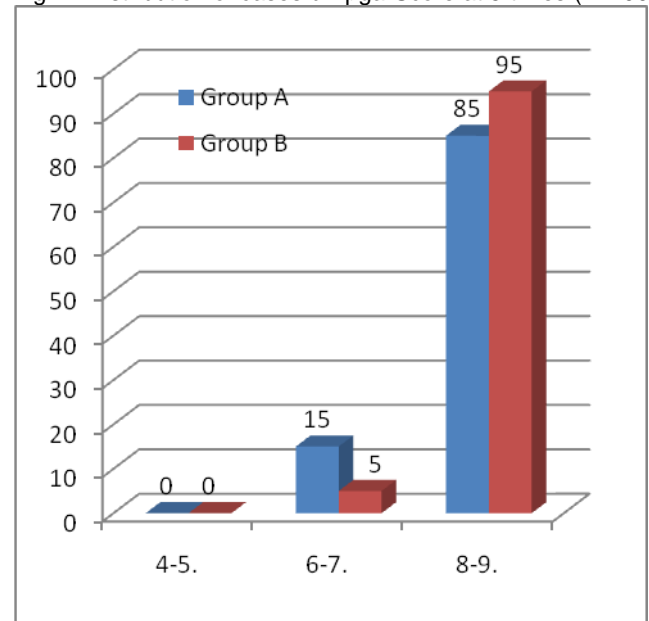


Fig. 2: Distribution of cases b ApgarScore at 10 times (n=200)

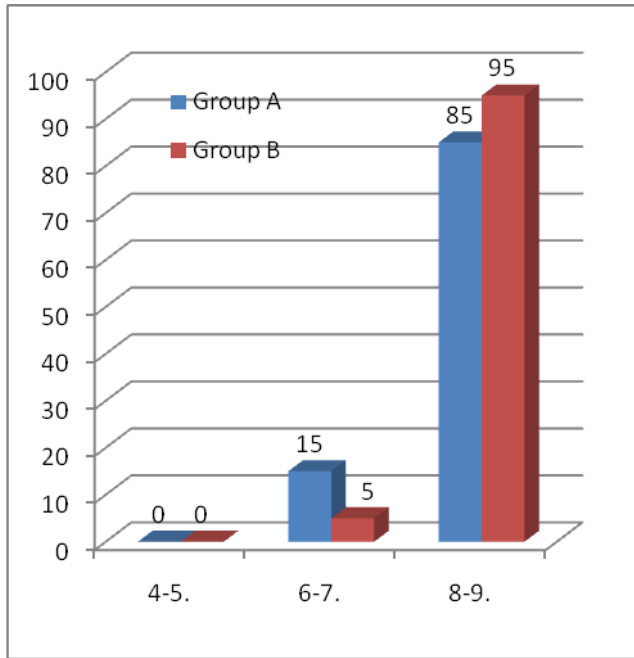


Table IV Admission of Neonate to ICU

Mode of Induction	Admission to ICU	
	Yes	No
Group A	13(13%)	87(87%)
Group B	20(20%)	80(80%)

Ch square = 0.48

P-value = 3.84

Table V: Fetal and Neonatal complications observed in two groups(n=200)

Mode of induction n	Fetal and neonatal complications			
	Fetal distress	Neonatal Jaundice	Neonatal sepsis	None
Group A	10(10%)	7(7%)	3(3%)	80(80%)
Group B	7(7%)	3(3%)	10(10%)	80(80%)

Ch square = 1.534

P-value = 7.81

DISCUSSION

Spontaneous rupture of membranes at term occurs in approximately 10% of pregnancies. Most women with term PROM go into labour spontaneously if followed expectantly and delivery within 24 and 48 hours occurs in 70 and 85 percent of women respectively⁸. The major issue in managing a woman with PROM at term is whether to follow her expectantly or proceed with delivery⁽²⁾. There was no significant difference in age of patient between two groups. Highest number of patients who presented with PROM between 37-41 weeks gestation were primigravidas, 113(63% and 70%) in group-A and group-B respectively. The results are comparable with the meta-analysis conducted by Tan BP, Hannah ME who after a quasi randomized trial of early stimulation of uterine contractions with prostaglandins (with or without oxytocin) versus with oxytocin alone in women with

spontaneous rupture of membranes at term (37 weeks or more gestation) concluded that women with prelabour rupture of membranes at term having their labour induced with prostaglandins appear to have a lower risk of epidural analgesia and fetal heart rate monitoring⁽⁹⁶⁾. However there appears to be an increased risk of chorioamnionitis and neonatal infectious after prostaglandin induction compared to oxytocin.

Similar results were obtained by Wing et al⁽⁸⁶⁾ in a meta-analysis of three management schemes followed in cases of term PROM which showed that a policy of routine induction of labour with oxytocin in women with term PROM appeared to be associated with small reduction in maternal and neonatal infection, lower treatment costs and no increase in caesarean delivery. The benefits were highest in women with favorable cervixes. However the optional management of term pregnancies complicated by PROM remains controversial.

The results are also comparable with the study carried out by JahanAra who compared the maternal and fetal outcomes in pregnancies with PROM at term with early induction of labour with misoprostol or expectant management. The author concluded that immediate induction of labour with misoprostol does not increase the risk of caesarean section. Women at term with prelabour rupture of membranes should therefore be reassured that immediate induction with misoprostol currently appears to be the best policy with respect to maternal and neonatal morbidity. In a study conducted by ShaziaAftab, Khurshheed J Noorani⁽¹⁰⁹⁾, in which patients were randomized to receive either PGE₁ tablet or immediate induction by oxytocin, it was shown that there was not statistically significant difference in maternal infection rate. The two groups were comparable with respect to age and parity. There was no significant difference in duration of labour and neonatal outcome regarding Apgar Score.

The results in the present study also seem to suggest that there is no significant difference in the efficacy between prostaglandin E₁ (misoprostol) tablet and expectant management in patients with PROM at term. The number of patients delivered within 12 hours and 12 to 24 hours and mode of delivery were not statistically different in two group. The parameters evaluated for safety, including uterine hyperstimulation rates, passage of meconium observed and interventions for fetal concerns were again similar in the two groups, MisbahKausarJavaid et al⁽¹¹⁰⁾, in their review concluded that caesarean section rate was about 12% following induction of labour with prostaglandin E₂ for PROM at term and it was also note worthy that oxytocin augmentation was carried out in 22.3% cases. These results are

comparable to the current study in which caesarean section rate was 16.67% and augmentation with syntocinon needed in 26.67% in group of patients induced with prostaglandin E₁ tablet.

CONCLUSION

It is concluded from the current study that there is no difference in the active and expectant management in patients with prelabour rupture of membranes at term. However induction of labour (6 hours after PROM) is not associated with increased rate of instrumental vaginal delivery or caesarean section. It is recommended that early induction of labour should be considered in patients with term PROM. Misoprostol tablet can be used effectively to prevent the complications which usually occur after PROM.

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