Original Article

Indian Journal of Maternal-Fetal and Neonatal Medicine
Volume 8 Number 1, January – June 2021
DOI: http://dx.doi.org/10.21088/ijcd.2395.6631.8121.3

One-Year Comparative Study on Immediate Versus Delayed Induction of Labour in Premature Rupture of Membranes at term Gestation

[1]Deepashree, [2]Basangouda Patil, [3]Neeta P N

How to cite this article:
Deepashree, Basangouda Patil, Neeta P N, One-Year Comparative Study on Immediate Versus Delayed Induction of Labour in Premature Rupture of Membranes at term Gestation. Indian J Matern Fetal Neonatal Med. 2021;8(1):23–27.

Author's Affiliations: [1-3]Assistant Professor, Raichur Institute of Medical Sciences, Raichur, Karnataka 584102, India.

Corresponding Author: Neeta P N, Assistant Professor, Raichur Institute of Medical Sciences, Raichur, Karnataka 584102, India.

E-mail: drnita10@gmail.com

Abstract

Background: Premature rupture of membranes (PROM) has an incidence of about 5-10% of all pregnancies and is a significant event as it can cause maternal complications, neonatal morbidity and mortality. Some believe that the expectant management of PROM at term reduces the perinatal and maternal morbidity, and immediate induction of labour leads to high rate of caesarean section. Some authors reported a significant increase in the rates of neonatal, maternal infection and foetal distress if delivery occurs over 24 hours after PROM. Thus, a data is required to manage the cases of PROM to effect safe delivery for both mother and baby. The objective of the study was to compare the neonatal and maternal outcomes between immediate and delayed induction with tab misoprostol in term PROM. **Methods:** This study was conducted in Department of Obstetrics and Gynaecology, Command Hospital Air Force, Bangalore as a randomized comparative interventional study on 60 patients with confirmed PROM at term 37 to 40 weeks gestation. These patients were randomly divided into two groups by using computer generated random system of allocation after fulfilling the inclusion and exclusion criteria. Group A (immediate) received misoprostol within 6 hours of PROM and Group B (delayed) received misoprostol after 6 hours of PROM. history was elicited regarding age, menstrual and obstetric history with enquiry regarding the time of rupture of membranes, duration and amount of leaking with general, systemic and detailed obstetric examination. Augmentation of labour if required was done with oxytocin infusion. **Results:** The number of misoprostol tablets needed for induction varied between the two groups. There was difference in maternal and neonatal morbidity and which was statistically significant (p value <0.05). Among delayed group, 6 (20%) subjects had maternal morbidity (intrapartum fever, GIT symptoms, PPH, LSCS) and 6 (20%) neonatal morbidity (foetal distress, meconium aspiration syndrome, neonatal sepsis, NICU admission) was recorded. No maternal complication among immediate induction group whereas one case of respiratory distress observed in neonates.

Keywords: Labour Induction; Oral Misoprostol; Premature Rupture of Membranes; Immediate and Delayed.

Introduction

Premature rupture of membranes (PROM) at term is defined as rupture of the membranes prior to the onset of labor in women at or over 37 weeks gestation.[1] It continues to be an obstetric enigma in terms of cause and management despite modern perinatal care.

PROM occurs in approximately 5-10% of all pregnancies, of which approximately 80 % occur at term (Term PROM).[2] The interval between rupture of membranes and onset of labour is called latent period of leaking, which is the key factor for determining maternal and fetal outcome. Several reports have been published that demonstrated a markedly increased risk, at all gestations, of both maternal and fetal morbidity and mortality with a prolonged latent period.[3,4]

Few researchers believe in the conservative or expectant management, in which an expectant period of

12–24 hours after the incident is observed to allow a good number of women to go into spontaneous labour with high vaginal delivery rate. [5-6] Others believe in immediate induction of labour, in which labour is induced immediately after admission irrespective of the duration of rupture of membranes. [5,6]

Oral Misoprostol (prostaglandin) E1 which is cheap, heat stable and easy to store, with better acceptability has been found in many studies to be efficient and safe in ripening the cervix and inducing labour in a dose of 50µg tablets every 4–6 hours. [7-9] Its efficacy in ripening the cervix and inducing labour, with high vaginal delivery rate and favourable feto-maternal outcome, has brought the return of 'day light obstetrics' with all its conveniences.[7] Misoprostol synthetic analogue is rapidly absorbed when given orally and becomes extensively bound to plasma proteins. When administered vaginally peak plasma levels are reached more slowly (80+/-27 min) than with oral administration (37+/-17 min) and are sustained up to 4 hours, probably because of the obligatory hepatic pass that occurs with oral, but not with vaginal administration.[10]

The ultimate goal of obstetrics is a pregnancy that results in healthy infant and minimally traumatized mother. The art of good obstetric care involves balance of avoiding caesarean section with its attendant complications & yet ensuring optimal neonatal outcome.

The aim and purpose of this study was to compare the maternal and neonatal outcomes between immediate and delayed induction (after 6 hours) with oral misoprostol in women with term premature rupture of membranes (PROM).

Methodology

This prospective study was conducted on 60 pregnant women with premature rupture of membranes at term (37-40 weeks) in Department of Obstetrics and Gynaecology, Command Hospital Air Force, Bangalore. All eligible patients who gave consent, were allotted into test group and control group through a computer-generated random system of allocation of group on patients' admission, and will be administered with the tab Misoprostol 25micrograms 2hourly till the patient goes into active labour or till maximum of 24 doses till 48 hrs whichever is earlier. As per random allocation, 30 patients with immediate (within 6 hours) tab misoprostol administration (Test / Immediate Group A) and rest 30 patients with delayed (after 6 hours) administration (Control / Delayed Group B) was successful. Oral Tab Misoprostol will not be administered in case of onset of active Labour, tachysystole, hyperstimulation, foetal distress. Augmentation of labour if required will be done with oxytocin infusion.

PROM was confirmed by history (i.e., sudden gush or trickling of watery fluid per vagina) and clinical examination by sterile speculum if not immediately obvious (i.e., pooling of fluid in the posterior fornix of vagina or leakage of fluid from the cervical os). Inclusion criteria included term pregnancy ≥ 37 weeks confirmed by LMP and/or early sonography; singleton live pregnancy; vertex presentation; no contraindications for vaginal delivery; not in active labour, admission CTG shows no abnormality. Exclusion criteria included Abnormal NST, Antenatal patients with contra-indications to vaginal delivery/induction of labour, PPROM/ EROM, PROM in > 40 weeks POG, Post LSCS pregnancy, Meconium-stained liquor, Malpresentations, Multiple gestations, Heart disease, Bronchial asthma, Allergies to Prostaglandins, Antepartum haemorrhage with placental previa, Patient unwilling for induction.

If study subjects came to hospital after 6 hours of PROM, they were started with antibiotic after sensitivity test and were continued for 3 doses after delivery unless evidence of sepsis was seen, where it was given for a longer time along with a broader cover. Induction to delivery interval and PROM to delivery interval were noted. Maternal pulse, blood pressure, foetal heart rate and its variations were checked frequently. The onset of any complications like foetal distress, foetal heart rate variations, and chorioamnionitis (clinical) were looked for. Progress of labour was monitored. If there was any evidence of foetal jeopardy or any other obstetrical complications, labour was cut short by instrumental delivery or caesarean section as required.

The maternal outcomes included duration from ROM to the onset of labour pain; duration from ROM to delivery; number of doses used for induction, vaginal delivery rates; operative delivery rates (C.S); maternal morbidity and mortality (e.g., postpartum haemorrhage, vaginal or cervical tears and chorioamnionitis).

The delivery was attended by paediatrician. Initial resuscitation was done in the labour room; Apgar score was calculated and recorded. Any baby requiring NICU care was shifted to NICU and treated under care of neonatologist. Oxygen support in the form of oxygen by hood, ventilator was given depending upon requirement of neonate. The babies were followed up in the postnatal period. Neonatal morbidity and mortality were noted.

Mothers were watched during intrapartum period for side effects of misoprostol, third stage complications like PPH and retained placenta. They were followed up in puerperal period till discharge from hospital. In puerperal period, vital parameters like temperature, pulse, blood pressure of mother, foul smelling vaginal discharge, febrile morbidity, urinary symptoms, and episiotomy or caesarean wound infection were looked for in both mother and the baby were followed up till their stay in the hospital

Statistical analysis:

Data were entered in MS Excel sheet and tabulated. It was processed using statistical package for science and society (SPSS 20.0) for windows. Qualitative data were expressed in the form of frequency, rates and percentages, proportion were compared with Chi-square or Fischer's exact test. Quantitative data were expressed in the form of mean and standard deviation. P value was considered significant when < 0.05 and considered highly significant when < 0.01.

Results and Discussion

Sixty women participated in the study. Thirty women had immediate (within 6 hours) induction of labour with oral misoprostol, and the same number of women had delayed (after 6 hours) induction with oxytocin infusion after an expectant period of 24hours. of the total deliveries of induced patients in both groups there was only one patient in the delayed group who underwent LSCS accounting for 3.3% and rest all patients in both the immediate and delayed group had induced vaginal delivery without any instrumental delivery.

The general characteristics of the women did not show any statistically significant difference (p > 0.05) between the two groups. (Table 1) the duration of induction to delivery among two groups was statistically significant (p <0.05).

Table 1: General characteristics of the study subjects.

variables	Immediate Group (30)	Delayed Group (30)	chi square test p value
Age (Years)	No. (%)	No. (%)	
21 - <26	15 (50)	16 (53.3)	4.39
26 - <30	11 (36.7)	14 (46.7)	0.11
30 - 35	4 (13.3)	0 (0)	-
Gravida			
Primi	17 (56.7)	18 (60)	0.07
Multi	13 (43.3)	12 (40)	0.79
Gestational age (in weeks)			
37 -≤ 38	5 (16.7)	11 (36.7)	3.32
38 – ≤39	12 (40)	12 (40)	0.132
39 - 40	13 (43.3)	7 (23.3)	
Bishop's score			
2 – 3	10 (33.3)	12(40)	0.77
4 – 5	19 (63.3)	17(56.7)	
6	1(3.3)	1(3.3)	
Misoprostol doses			
2-4	13(43.3)	8(26.7)	0.1
4-8	17(56.7)	19 (63.3)	
8-24	0 (0)	3(10)	
Pitocin			
Required	0 (0)	3(10)	0.163
Not required	30 (100)	27(90)	

Maternal complications reported as intrapartum (fever, GIT symptoms) and past partum (PPH) accounted for 20% of cases among delayed group, which was statistically significant (p <0.05) compared to nil cases among immediate group. (Table 2)

Table 2: Maternal complication.

Maternal complications	Immediate Group	Delayed Group	chi square p value
	No (%)	No (%)	
Intrapartum			
Fever	-	2 (6.7)	
Hyperstimulation	-	-	
GIT symptoms	-	2 (6.7)	-
Chorioamnitis	-	-	
LSCS	-	1 (3.3)	
Post-Partum			
Febrile Mortality	-	-	
Puerperal sepsis	-	-	
Wound infection	-	-	P = 0.02
PPH	-	1 (3.3)	
Total	0 (0%)	6 (20%)	

As regard foetal weight, the mean of 2.88±0.34 in the immediate group, while in delayed group, the mean of 2.99±0.34 and there was statistically not significant difference between groups. As regard neonatal morbidities, it was in the form of respiratory distress syndrome (3.3%) in immediate group in comparison to foetal distress (3.3%), Meconium aspiration syndrome (MAS) (3.3%), neonatal sepsis (6.6%) and NICU admission (6.6%) in expectant group with statistically significant difference between both groups (p <0.05) (table 3).

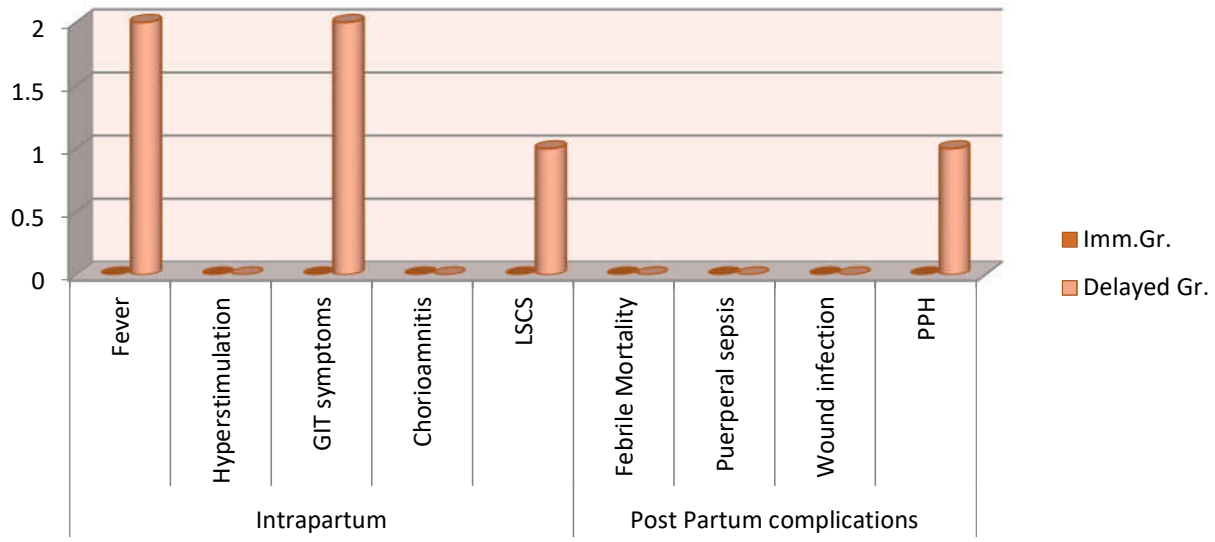

Table 3: Neonatal complication

Neonatal complications	Immediate Group	Delayed Group	chi square p value
	No (%)	No (%)	
Intrapartum			
IUD	-	-	
Neonatal			
Birth Asphyxia	-	-	
RDS	1 (3.3)	-	
MAS	-	1 (3.3)	
Neonatal Sepsis	-	2 (6.7)	
NICU admission	-	2 (6.7)	
Total	1 (3.3%)	6 (20%)	P = 0.04

Discussion

Immediate induction was compared with that of delayed induction after 24 hours of PROM in term PROM cases. Both study groups were comparable with regard to age, parity, bishop's score and gestational age.

In the present study, the rate of caesarean section was 1.6%, which is much less when compared to the studies done by Kodkany T [11], Gautam[12], and Kamala J.[13] which was 14 %. However, Rate of caesarean section was higher in the studies by Anjana Devi.[14]

The rate of instrumental delivery in present study was zero which is in contrast to 4% in the study done by Sita Ram Shrestha et al. [13], and is lower than 6% reported by Gautam.[12]

Foetal weight ranged from 2.6-3.5kg in the present study and this is same as that of observation made by Hannah et al [15] showing 78% of term PROM delivered newborn weighing between 2.6 kg to 3.5 kg. Similar results were obtained by Ngai et al. [16] and were supported by Crane et al. [17] and Lee and co-workers.[18]

The most significant maternal risk of term PROM is intrauterine infection, which is a risk that increases with the duration of membrane rupture. Unlike in studies by Obi[19], there were no recorded cases of clinical evidence of chorioamnionitis in the present study. The reason could be that majority of patients in this hospital are booked cases ensuring proper antenatal care. Digital examination was done only if indicated and later too restricted once patient was in labour.

The rate of maternal morbidity in the present study was 10% of the total study group. The commonest cause was febrile morbidity (3.3%) and GIT symptoms (3.3%) This is much lower than in the study done by Kamala J [20] Fabiana da Graca [21] in her study regarding maternal post-partum follow up in patients with PROM found favourable results in study groups with minimal rates of puerperal infection (4%), requirement of antibiotic therapy and other complications. In the present study, prophylactic antibiotic was given to all the mothers. These factors may have contributed to the absence of chorioamnionitis, still birth and early neonatal deaths recorded in present study. Also, there was not a single case of any maternal complication in the immediate group of induction of labour in our study. These findings are difficult to explain except for because of use of antibiotics, adherence to protocol and follow up was done strictly.

The relationship of PROM to consequent fetal complications is a matter of concern. With rupture of membranes the clock of infection starts to tick. Perinatal mortality rate has also been observed to be higher in association with PROM.

In the present study, the major causes of neonatal morbidity were neonatal sepsis accounting to 3.3% of total study group. Meconium Aspiration Syndrome and fetal distress had equal incidence of 1.6% in total study group of 60 in this study. The rate of neonatal sepsis in the present study was 3.3%, but similar to the study carried out by Aqueela Ayaz [22] in 2008 and the studies done by Hannah et al.[15]

Conclusion

In short, this study showed that immediate induction of labour for women with term PROM had relatively better maternal and neonatal outcome as compared with delayed induction after 24 hours of conservative management. However, larger scales, multicentric randomizes studies are needed before drawing a final conclusion.

Limitations

Numbers of study participants were less; further studies are required with a greater number of subjects for better statistical correlation.

Conflicts of interest: NIL

References

1. NICE clinical guideline: Induction of labour. 2008.
2. Gunn G C; Mishell D R ; Morton D G- premature rupture of the Fetal membranes : a review. Am J Obst Gynec1970;106:469-73.
3. Lanier L, Scarbrough R.,Fillingim D. Prudence of maternal and fetal complication associated with rupture of membrane before onset of labour. Am J ObstetGynecol 1965;93:398.
4. Kappy K, Cetrulo C, Knuppel R, Ingardia C, Sbarra A, Scerbo J, et al. Premature rupture of the membranes at term: a comparison of induced and spontaneous labours. J Repro Med 1982;27(1):29.
5. Jazayeri A, Galan H, Suzanne T. Premature rupture of membranes. emedicine. 2006. http://www.emedicine.com/med/topic3246.htm.
6. Kongnyuy EJ, Chiabi A, Nkele N, Doh AS. Premature rupture of membranes: many questions still unanswered. Clinics in mother and child. 2004; 1: 115–24
7. Wagner M. Misoprostol (cytotec) for labour induction. A cautionary tale. Midwifery today. 2003; 67: 1–6.
8. Kwawukume EY, Ayertey RP. The use of misoprostol for induction of labour in a low-resource setting. Trop J Obstet Gynaecol. 2002; 19: 78–81.

9. Soni N, Rayput P. Comparative study between tablet misoprostol (Prostaglandin E1) and Dinoprostone GEL for the induction of labour. J Obstet Gynaecol Ind. 2004; 54: 554–555.
10. Clinical Obstetrics and Gynaecology "cervical ripening and labour induction". Sept 2000;43(3):427-468,524-536.
11. Kodkany, Telang. Premature rupture of membranes, a study of 100 cases. Journal of Obstet and Gynecol of india (1991);41:492.
12. Gautam Jageswor. Fetal outcome of premature rupture of membranes. A thesis submitted in partial fulfillment of the requirement for the degree of medicine in obstetrics and gynaecology, T.U. Kathmandu;1997.
13. Sita Ram Shrestha, Paban Sharma: Fetal outcome of pre-labour rupture of Membranes. N. J. Obstet. Gynaecol Vol. 1, No. 2, p. 19 -24 Nov-Dec 2006.
14. Anjana Devi and Reddi Rani- Premature rupture of membrane. A clinical study J of Obst. Gynec, India 1996;46:63.
15. Hannah M, Ohlsson A,Farine D, Hewson S, Hodnett E, Mohr T. Induction of labour compared with expected management for prelabor rupture of the membranes at term. N Engle J Med 1996; 334:1005–10.
16. Ngai SW, Chan YM and Lam SW (2000): Labour characteristics and uterine activity: misoprostol compared with oxytocin in women at term with premature rupture of the fetal membranes. Br J Obstet Gynecol; 107(2): 222- 7.
17. Crane J, Delaney T and Hutchens D (2003): Oral misoprostol for premature rupture of the membranes at term. Am J Obstet Gynecol; 189(3):720-4.
18. Lee M, Park W and Yoon H (2009): Early rupture of membranes after the spontaneous onset of labour as a risk factor for caesarian delivery. Eur J Obstet Gynecol and Rep Bio; 148:152-57.
19. Obi SN, Ozumba BC. Pre-term Premature Rupture of Fetal Membranes: The Dilemma of Management in a Developing Nation. J Obstet Gynaecol. 2007 Jan; 27(1):37-40.
20. Jayaram VK, Sudha S. A study of PROM – Management and outcome. Journal of Obstet and Gynecol of India 2001;51: 58-60.
21. Fabiana da Graca Krupa, Jose Guilherme Cecatti et al, Misoprostol versus expectant management in premature rupture of membranes at term. BJOG: An International Journal of Obstetrics and Gynaecology. 2005; 112:.1284-1290.
22. AqueelaAyaz, Shazia Seed et al. Pre-labour rupture of membranes at term in patients with an unfavorable cervix: active versus conservative management. Taiwan J Obstet Gynecol.June 2008; 47:.2.
23. Marco Cascella, Michael Rajnik, Arturo Cuomo, Scott C. Dulebohn,Raffaela Di Napoli. Features, Evaluation, and Treatment of Coronavirus (COVID-19).StatPearls Publishing; 2020.Available from: https://www.ncbi.nlm.nih.gov/books/NBK554776/. [Last Accessed on 20 December 2020].