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INDUCTION VERSUS EXPECTANT MANAGEMENT BETWEEN 34 TO 37 WEEKS GESTATION WITH PRETERM PRELABOUR RUPTURES OF MEMBRANE: A PROSPECTIVE RANDOMISED CONTROLLED STUDY IN A PERIPHERAL MEDICAL COLLEGE, INDIA.

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ABSTRACT

Aims & Objective: To compare Feto-maternal outcome in induction versus expectant management in women with singleton pregnancy without any complication with preterm prelabour rupture of membranes between 34 to 37 weeks gestation.

Materials & Methods: It was a hospital based prospective clinical observational study.100 women with singleton pregnancy between 34 to 37 weeks of gestation was selected. Randomization was done 1: 1 ratio for induction or expectant management. Women with odd numbers (1,2,3 etc) was allocated for induction of labour. Labour was induced according to the local protocol within 12 hours after randomization. Women with even numbers (2,4,6 etc) were allocated for expected management and was monitored according to standard local protocol until delivery started spontaneously.

Result: There was no significant difference in mean age, parity, booking status in both group but rate of caesarean section was lower in induction group (28%) than expectant group (32%), mean randomization to delivery interval was more in expectant group (42 hours) compare to induction group (20 hours). Chorioamnionitis was 10% versus 34% and statistically significant (p value 0.0251). Foetal distress seen in 22% versus 24% in induction vs expectant group. Incidence of postpartum fever was more in expectant group than induction group (32% versus 5%) and statistically significant (p value 0.0141). Better Apgar scores at 1 minute (p value 0.0141) and 5 minutes (p value 0.0007) was in induction group as compared to expectant group. Rate of neonatal intensive care unit admission in induction group (40%) was lower than expectant group (64%) and p value 0.0277. No significant difference seen in incidence of low birth weight in both groups. Rate of neonatal death was lower in induction group (2%) than expectant group (8%).

Conclusion: In this study it was observed that induction of labour in case of preterm prelabour rupture of membrane between 34 to 37 weeks leads to better Feto-maternal outcomes in terms of better Apgar scores, lesser neonatal intensive care unit admission, lower randomization to delivery interval , reduced chance of developing chorioamnionitis along with decreased incidence of postpartum fever as compared to expectant management. Hence active management by induction of labour in preterm prelabour rupture of membrane is better line of management & recommended as per our study result.

KEYWORDS : Preterm prelabour rupture of membranes. Induction of labour. Expectant management.

INTRODUCTION:

Preterm premature rupture of membrane is a leading cause of preterm birth, perinatal morbidity with tremendous socio-economic impact in society. It complicates 1-5% of all pregnancies & account for 40% of all preterm deliveries (1). It also associated with increased foetal & maternal morbidity, mortality (2).

Generally, two option for managing preterm prelabour rupture of membrane
– expectant and planed early birth. While waiting for spontaneous onset of labour increases chance of infection of both mother & babies, induction of labour leads to preterm birth, increases neonatal morbidity & mortalities. Expectant management results prolonged antenatal hospitalization while planed early delivery may leads increase caesarean delivery, need of intensive care of neonate. Though there was significant benefit in expectant management for gestation < 34weeks but management of preterm prelabour rupture of membrane between 34 to 37 weeks gestation is the most controversial period (3). There is no such guideline on management of women with preterm prelabour rupture of membrane between 34+0 weeks and 37+0 weeks gestation. American congress of Obstetricians & Gynaecologist recommended induction of labour if preterm prelabour rupture of membrane occurs at or beyond 34+0 weeks of gestation (4). Royal College of Obstetrician and Gynaecologist guideline state that delivery should be considered at 34+0 weeks of gestation and women with preterm prelabour rupture of membrane beyond 34 weeks gestation be counselled about the increased risk of chorioamnionitis and presumed decreased risk of neonatal respiratory problems, admission in neonatal intensive care unit and caesarean section (5). A recent Cochrane review on the management of preterm prelabour rupture of membrane prior to 37 weeks concluded that there is insufficient evidence to guide clinical practice in the management of preterm prelabour rupture of membrane (6).Due to this lack of evidence to justify the induction of labour or expectant management, a hospital based observational study performed by us to evaluate the Feto-maternal outcome in induction of labour versus expectant management in women of gestational age between 34 to 37 weeks with preterm premature rupture of membrane.

MATERIAL AND METHODS:

This prospective study was done at Rampurhat Government Medical college, India from April 2018 to March 2019. Total 100 women who was admitted in labour was selected for study after taking proper consent. 50 was of induction group and 50 in expectant group. Women with conformed gestation of 34 to 37 weeks, singleton pregnancy, cephalic presentation and preterm prelabour rupture of membrane more than 12 hours was selected as study group. Women with multiple pregnancy, non -vertex presentation, known medical disorder, pregnancy with congenital anomalies, any features of infection of both mother or baby was excluded from study. Randomization was done 1: 1 ratio for induction or expectant management. Women with odd numbers (1,2,3 etc) was allocated for induction of labour. Women with even numbers (2,4,6 etc) were allocated for expected management and was monitored according to standard local protocol until delivery started spontaneously. Labour was induced according to the local protocol within 12 hours after randomization. Induction group

was induced according to local procedure by Dinoprostone gel 0.5 mg intracervicaly or augmented by oxytocin with ringer lacted solution. Maternal age, parity, booked and unbooked status, duration of rupture of membranes, randomisation to delivery interval, mode of delivery, presence of foetal distress, incidence of chorioamnionitis, occurrence of post- partum fever were compared as maternal parameters in both groups, For neonatal outcome of both groups- Apgar score at 1 minute and 5 minutes, neonatal intensive care unit admission, incidence of occurrence of low birth weight, chorioamnionitis, asphyxia, respiratory distress syndrome, neonatal sepsis and neonatal death were compared. For statistical analysis Student t test and Chi-square test was used. P value <0.05 was taken as significant.

RESULTS:

Table 1 showed mean age of induction group was 24.2±2.4 years while that of expectant group was 24.6±2.6 years, slightly higher but p value was non-significant.

Table 1: Mean age in years (based on Student-t test)

Age in years	Induction group (n=50)	Expectant group (n=50)	P value
Mean age	24.2±2.4	24.6±2.6	0.4286

Figure 1 showed 40% cases in induction group and 36% in expectant group were booked cases. P value comes out 0.836 which was statistically insignificant. Unbooked cases were found in 60% of induction group and 64% in expectant group. P value again 0.836, means the difference was not significant.

In table 2 two groups were compared on the basis of parity. In induction group 68% were primipara where in expectant group it was 60%. 32% and 40% were multipara in induction group and expectant group respectively. P value were 0.532 in both groups which was statistically insignificant.

Table 2: Distribution according to parity (Based on Chi-square test).

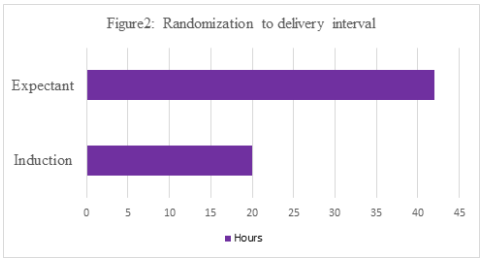
Parity	Induction group(n=50)	Expectant group(n=50)	P value
Primipara	34(68%)	30(60%)	0.532
Multipara	16(32%)	20(40%)	0.532

Table 3 showed 80% and 76% women showed rupture of membrane between 24 to 72 hours in induction and expectant group respectively. Only 20% women in induction and 24% in expectant group had duration > 72 hours. P value (0.809) was statistically insignificant in both groups.

Table 3: Duration of rupture of membrane (Based on chi-square test).

Duration	Induction group(n=50)	Expectant group(n=50)	P value
24-72 hours	40(80%)	38(76%)	0.809
>72 hours	10(20%)	12(24%)	0.809

In figure 2 randomisation to delivery interval in both groups was compared. Mean interval was 20 hours in induction group and 42 hours in expectant group. P value was <0.0001- which is statistically significant.



In figure 3 two groups were compared regarding their mode of delivery. 72% women in induction group and 68% in expectant group were delivered by vaginal route. Rate of caesarean section was 28% and 32% in induction and expectant group respectively. P value was 0.827 in both groups which is not significant.

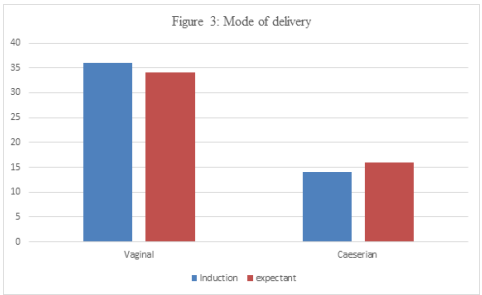


Table3 showed that foetal distress was seen in 22% and 24% women in induction versus expectant group respectively. P value was statistically insignificant.

Table 3: Presence of foetal distress.

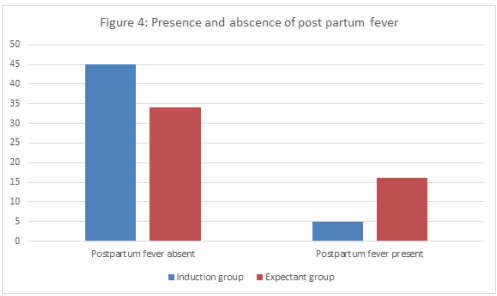
Foetal distress	Induction group(n=50)	Expectant group(n=50)	P value
Present	11(22%)	12(24%)	1
Absent	34(78%)	38(76%)	1

Table 4 showed maternal outcome in term of development of chorioamnionitis clinically was compared 10% of women in induction group and 34% in expectant group developed features of chorioamnionitis. P value was 0.0251 which was statistically significant. 90% women in induction group and 66% in expectant group had no chorioamnionitis. P value was 0.0079 and statistically significant.

Table 4: Incidence of chorioamnionitis.

Chorioamnionitis	Induction group(n=50)	Expectant group(n=50)	P value
Present	5(10%)	17(34%)	0.0251
Absent	45(90%)	33(66%)	0.0079

Figure 4 showed postpartum fever developed in 10% women of induction group and 32% in expectant group. P value 0.0141 which was statistically significant.



Neonatal outcomes.

Table 5 showed Apgar score at 1 minute and 5 minutes was calculated in babies born in both groups. Mean Apgar score at 1 minute were 7.2±2 in induction group and 6.2±2 in expectant group. P value 0.0141 was statistically significant.

At 5 minutes the mean Apgar score was 8.2±2.1 in induction group and 6.8±2.2 in expectant, p value was 0.0007 which was statistically significant.

Table 5: Apgar score at 1 minute & 5 minutes.

Mean Apgar score	Induction group(n=50)	Expectant group(n=50)	P value
At 1 minute	7.2± 2	6.2± 2	0.0141
At 5 minutes	8.2± 2.1	6.8± 2.2	0.0007

In figure 5 neonates of both groups were compared based on neonatal intensive care admission. It was 40% and 64% in induction group and expectant groups. P value 0.277, which was statistically significant

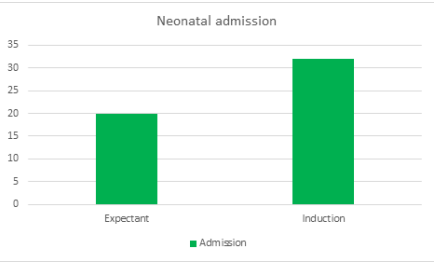
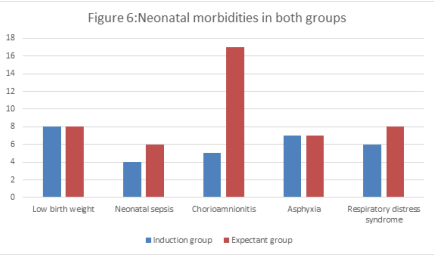


Figure 5: Neonatal intensive care admission:

In figure 6 neonates were evaluated for their morbidities. 16% of each group showed low birth weight. P value is insignificant. 10% neonates of induction group and 34% of that of expectant group developed chorioamnionitis, P value 0.0005 was statistically significant. Asphyxia was found in 14% of neonates of each group and statistically insignificant.



In table 6 fate of baby in term of death and discharge was compared among two groups 2% neonates from induction group and 8% from expectant group were dead or stillborn. P value (0.3588) was statistically significant.

Table 6: Neonatal discharged and mortality (Based on chi-square test).

	Induction group(n=50)	Expectant group (n=500	P value
Death	1(2%)	4(8%)	0.3588
Discharge	49(98%)	46(92%)	0.35858

DISCUSSION:

In our study majority of women were of mean age of 24.2 years in induction group and 24.6 years in the expectant group. In the PPROMEXIL trail by David P Vander Ham, Jan G Nijhuis et al (7) showed mean age for induction group was 29.5 years and 29.6 years in the expectant group. In the PPROMEXIL-2 trail by Vander Ham, DP et al (8) age group was 19-44 years with mean age 30.5 years ln induction group and 29.4 years in the expectant group. Robert W. Naef et al (9) elected women in age group 17 to 29 years with mean maternal age of 22.8 years and 23 years in expectant group respectively. Result of these studies were overall similar to our studies. In our study 60% & 64% women were unbooked in induction versus expectant group. No similar study had taken this factor in their trail.

Majority of women were primiparous. 68% of the women in the induction group and 60% in expectant group were found primiparous. Study by T Biswas, S.K. Das, et al.(10) in India reported that 58% and 52% were primipara in induction group and expectant group respectively. In PPROMEXIL trial by Vander Ham DP et al (7) found 56% were nulliparous. In the study of Naef et al.(9) 47% in induction group and 44% in expectant group were nulliparous, rest in both groups were multigravida

In our study women were distributed according to duration of rupture of membrane. It showed that in 80% women of induction group and 76% in expectant group had rupture of membrane within 24-72 hours of randomisation. Rest 20% and 24% of both groups had rupture > 72 hours. Study by Jonathan M. Moris, C.L.Robert et al.(11) reported 36% in induction group versus 33% women had rupture of membrane within 24-72 hours.

We analysed the mode of delivery in the two group in our study. Most of the women delivered vaginally in two groups (72% in induction group and 68% in expectant group). A study by Joveria Sadaf et al.(12) showed that 72% and 78% women delivered vaginally in induction group and expectant group respectively. Sasaf Maqbool, Afsan Saeed et al. (13) showed that 67% and 39% women delivered vaginaly in induction and expectant group respectively. Our study result was almost supported by this result. A retrospective study in a tertiary care centre in France done by G. Kayem, A. Bernier-Dupreelie,et al.(14) 86.1% delivered vaginaly in active management group and 90.5% in expectant group which was reveres of our study.
Clinical chorioamnionitis seen in 10% in induction group and 34% in expectant group in our study. It signified that expectant group were more prone to develop clinical features of chorioamnionitis. Our result was supported by study by T. Biswas, S. K. Das et al. (10) reported 0% versus12% and Maqbool, A. Saeed et al. (13) showed 5% versus 25%, Robert W. Naef et al. (9) also reported 2% versus 16% in induction group and expectant group.

In our study randomisation to delivery interval 14-26 hours in induction group and 32 -52 hours in expectant group. Study by A. Gupta, S. Gautam et al. (15) showed it was 17.21 hours versus 23.34 hours in induction and expectant group respectively. Vander Ham DP et al. showed 38.4 hours versus 117 hours in PPROMXIL trail (7) and 39 hours versus 110 hours in PPROMXIL-2 trail (8).

Joveria Sadaf et al. (12) analysed foetal distress and found 10% women of induction group and 14% of expectant group had foetal distress. As per S. Maqbool, A. Saeed et al. (13) foetal distress was 23% versus 36% in induction and expectant group. In our study we found it 22% versus 24% in induction group and expectant group, little bit more and may be due to busy labour room with heavy patient load and minimal resources.

In our study rate of postpartum fever was low (5%) in induction group as compare to expectant group (32%), no comparable study found.

Mean Apgar score at 1 minute and 5 minutes was found 7.2 and 8.2 respectively in induction group as compare to 6.2 and 6.8 in expectant group respectively. In PPROMXIL trail (7), Apgar score at 1 minute was < 7 in 4.5% cases in induction group and 6.4% in expectant group. In the study of Naef et al. (9) the mean Apgar score at 1minutes and 5 minutes was 8.3 and 9.1 respectively in the induction group and both 9.1 in expectant group.

Of all neonates delivered ,40% from induction group and 64% from expectant group were admitted in intensive neonatal unit. T. Biswas, S.K. Das et al. (10) showed neonatal intensive

care unit admission was 30% versus 38% in induction versus expectant group. Naef et al. (9)) found it 19% versus 24%. In PPROMEXIL-2 trail Vander Ham DP et al. (8) neonatal intensive care unit admission was seen in 7% in induction group and 8.2% in expectant group respectively. Our result was much greater than these studies and because of poor antenatal check-up, poor nutritional status of mother leading to poor neonatal outcome. Baby of induction group stayed shorter period in neonatal intensive care unit compare to the expectant group.

Among the causes of neonatal morbidity low birth weight, birth asphyxia, respiratory distress syndrome, neonatal sepsis was analysed by us in our study. Low birth weight, birth asphyxia had no difference between the two group, low birth 16% and birth asphyxia 14% in both groups. In our study respiratory distress syndrome was seen in 6% in induction group and that of 8% in expectant group, neonatal sepsis was of 4% and 6% in induction versus expectant group. Study by E. Baras, M. Rodriguez et al. (16) showed respiratory distress syndrome 6.84% versus 3.7%, neonatal sepsis 6.4% versus 3.86% in induction versus expectant group. T. Biswas, S.K. Das, et al. (10) in their study showed respiratory distress syndrome in 4% versus 8%, neonatal sepsis 2% versus 12% in induction versus expectant group respectively. PPROMXIL-2(8) trail reported respiratory distress syndrome 6% versus 5.1% in induction versus expectant group. Study by J. Morries (11) showed 8% versus 5% baby of induction and expectant group developed respiratory distress syndrome. Brain M, Mercer. MD et al. (17) reported neonatal sepsis 4.4% and 6.8% in induction group and expectant group respectively. J. Morries et al. (11) showed 2% in induction group and 3% in expectant group.

In our study one neonate (2%) of induction group and 4 (8%) of expectant group were died, one baby of induction group died after 48 hours due to sever birth asphyxia. Neonatal death was less in induction group than expectant group. T. Biswas, S.K. Das et al. (10).in India found 0% versus 2% neonatal death in their study. PPROMXIL-2(8) trail had 1% neonatal death in induction group and no deaths in expectant group.

Conclusion: It is observed that during our study time the induction of labour in case of preterm prelabour rupture of membrane between 34 to 37 weeks leads to better Feto-maternal outcomes in terms of better Apgar scores, lesser neonatal intensive care unit admission, lower neonatal sepsis, lower randomization to delivery interval, reduced chance of developing chorioamnionitis along with decreased incidence of postpartum fever as compared to the expectant management. There was reduced neonatal as well as maternal morbidity and mortality. We emphasised that active management by induction of labour in preterm prelabour rupture of membrane has better outcomes as well as better line of management but since it is a single centre study and of short time period hence multicentre study will be required for more effective result.

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