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ORIGINAL RESEARCH OBSTETRIC ANESTHESIA

Comparison of induction of labor versus conservative management in premature rupture of membranes on fetal outcome

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ABSTRACT

Background & Objective: Premature rupture of the membranes (PROM) is defined as rupture of the membranes (amniotic sac) before the commencement of the labor and after 37 weeks gestation. Opinions differ whether to induce labor in these parturients or continue to manage conservatively. The purpose of this research was to compare the incidence of unfavorable fetal outcomes in cases of early rupture of the membranes and expectant treatment in the induction of labor.

Methodology: This randomized controlled trial was conducted at the Department of Obstetrics & Gynaecology, Lady Reading Hospital, Peshawar, from 1st August 2022 to 31st January 2023. A total of 610 pregnant women with PROM were included in the study. In total, 305 patients were in the expectant management group or Group A, while 305 patients were in induction of labor or Group B. After delivery, fetal outcomes (birth asphyxia, low Apgar score, and sepsis) were noted and compared in both groups.

Results: Birth Asphyxia was observed in 69 (22.6%) patients in Group A as compared to 44 (14.4%) patients in Group B (P = 0.009). A low Apgar Score was observed in 27 (8.9%) patients in Group A compared to 10 (3.3%) patients in Group B (P = 0.004). Sepsis was observed in 8 (2.6%) patients in Group A as compared to 1 (0.3%) patient in Group B (P = 0.019).

Conclusion: It is concluded that all patients presenting with premature rupture of membranes at term should be actively managed with induction of labor.

Keywords: Pregnancy; Premature rupture of membranes; Labor induction; Expectant management; Adverse fetal outcomes

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1. INTRODUCTION

A crucial point in any pregnancy is known as premature rupture of the membranes (PROM), which happens when the membranes burst before labor begins, generally after the 37th week of gestation.[1] PROM is caused by a variety of factors, ranging from extrinsic factors like tobacco use and low socioeconomic level to physiological alterations like programmed cell death.[2,3] Premature rupture is linked to 30–40% of premature births, which accounts for a high morbidity and death of newborns.[4,5]

Preterm premature rupture of membranes (PPROM) complicates around 3% of pregnancies in the US each

year; thus, managing and treating this condition is still critical.[6,7] In times of uncertainty, novel diagnostic methods utilizing biochemical markers such as placental alpha-microglobulin-1 have demonstrated encouraging sensitivity and specificity, assisting in accurate diagnosis and subsequent treatment choices.[8]

Emerging data points to a move away from expectant management and toward labor induction in the context of divergent methods of controlling postpartum hemorrhage.[9] Research comparing expectant management versus induction of labor in women with PROM, such as done by Hannah et al., showed that induction techniques decreased the risk of maternal infections but showed equal rates of cesarean deliveries.[10] Furthermore, it has been documented that women have more positive opinions of induction than expectant management.[10]

The decision between expectant management and induction, however, impacts the fetal health.[11] Nath et al. discovered significant variations in unfavorable fetal outcomes in patients with PROM between expectant care and induction of labor, highlighting different rates of birth hypoxia, poor Apgar scores, and infection; underscoring the necessity for a thorough comparison.[12]

The need to quickly determine the best course of action for controlling postpartum hemorrhage (PPH), considering the possible hazards connected to both expectant management and labor induction, was the driving force behind this investigation. Careful consideration must be given to the possibility of poor fetal outcomes because of induction failure or hyperstimulation. Therefore, we assessed the incidence of poor fetal outcomes between expectant management and labor induction for patients who had PROM.

2. METHODOLOGY

2.1. Study particulars

It was a randomized controlled trial conducted at the Lady Reading Hospital, Peshawar, from August 1, 2022, to January 31, 2023. It involved 610 pregnant women with PROM. Randomization and double blinding were achieved using computer-generated random numbers, which helped in minimizing selection bias and achieving comparable groups. Participants were randomly assigned to either the expectant management group (Group A, n = 305) or the induction of labor group (Group B, n = 305). Data on fetal outcomes, including birth asphyxia, low Apgar score and sepsis, were collected post-delivery.

2.2. Sample size / sampling technique

The predicted sample size of 617 patients—305 in each group—was calculated using 80% test power and a 5% significance threshold to guarantee statistical significance. Non-probability sequential sampling was used to choose participants.

The calculation utilized a formula commonly employed for comparing two independent proportions in clinical trials. This formula incorporates factors such as the desired significance level (α), power (β), and estimated proportion of the population with the characteristic of interest. Raosoft online calculator was used for such calculations. Additionally, non-probability sequential sampling was employed to select participants based on convenience or availability when random selection was impractical or impossible. The calculation was based on the following formula;

$$n = \frac{2\times(Z_{\alpha/2}+Z_{\beta})^2\times p\times(1-p)}{(p_1-p_2)^2}$$

n is the required sample size,

Z-score (for 95%, ≈1.96 Z≈1.96).

p is the estimated population.

E = standard error (0.5).

$$n = \frac{3.8416 \times 0.25}{0.0025}$$

$$n = \frac{0.9604}{0.0025}$$

$$n = 384.16$$

The sample calculated was 384 and after removing the participants with missing data, the end sample size for each group was 305 for each group.

2.3. Study population

The women included in the study were 18-35 y of age, had ultrasound proof of a singleton pregnancy, had a gestational age of more than 36 weeks according to LMP, had a parity between 0 and 4, and met the operational criteria for preterm rupture of the membranes. Cases of meconium aspiration syndrome, cephalopelvic disproportion, intrauterine fetal mortality on ultrasonography, malpresentation, and moms with PROM who had previously taken antibiotics before delivery as documented in medical records, were excluded. The 610 eligible patients or their guardians gave their informed consent. The institutional ethics committee granted approval for the study.

2.4. Data collection procedure

Age, gestational age, and parity were among the documented demographic data. Group A patients were observed for twenty-four hours using a sterile vulval pad to wait for spontaneous labor to begin. Limited vaginal exams were performed until absolutely required to evaluate the state of labor. If contractions did not start within 24 h, labor induction took place. LSCS was used in an emergency based on specific indications including fetal distress, failed induction of labor, maternal complications such as hemorrhage or hypertensive disorders, or other clinical factors necessitating urgent delivery to ensure the safety and well-being of both the mother and the baby.

Induction of labor patients (Group B) were inducted based on Bishop's pre-induction score. Intravenous oxytocin or PGE1 tablets were used, with dose adjustments made until effective uterine contractions were obtained. Fetal outcomes, including birth hypoxia, low Apgar scores, and sepsis, were documented on a specified proforma and annotated using predetermined criteria after delivery.

2.5. Data analysis

IBM SPSS version 22 (IBM Corporation. New York, USA) was used for data analysis; mean ± SD for quantitative variables and frequency/percentage for qualitative variables are presented. The results were compared between groups using the Chi-square test ($P \leq 0.05$ deemed significant). Age, parity, and gestational age stratification were used to evaluate their effect on outcomes using post-stratification chi-square testing for significance ($P < 0.05$).

3. RESULTS

The demographic profile of the two participant groups, A and B, each with 305 individuals, is shown in Table 1. Group B has a slightly higher mean age. In terms of gestational age. Group B has a slightly higher mean gestational age ($P = 0.353$). Both groups have similar sample sizes, and only minor age and gestational age differences are displayed.

Table 1 also shows the distribution of parity in Group A and Group B. Parity, determined by the number of prior pregnancies, shows interesting variations between the groups. The results show significant differences in the groups' parity distributions: Group B is more represented in higher parities, especially parity 3, whereas Group A has a higher percentage of nulliparous people (parity 0).

Table 1: Comparison of age, gestational age (weeks) and parity of the participants

Parameters	Group A (n = 305)	Group B (n = 305)	P-value
Age (y)	27.800 ± 2.39	28.531 ± 2.34	0.000
Gestational age (weeks)	38.429 ± 1.12	38.511 ± 1.16	0.353
Parity			
0	80 (26.2)	47 (15.4)	0.000
1	91 (29.8)	83 (27.2)	
2	83 (27.2)	84 (27.5)	
3	34 (11.1)	72 (23.6)	
4	17 (5.6)	19 (6.2)	

Data presented as mean ± SD or n (%)

Total birth-related complications including the frequency of birth asphyxia, low apgar score, and sepsis in Groups A and B in relation to age group, parity and gestational age are compared in groups in Table 2, 3 and

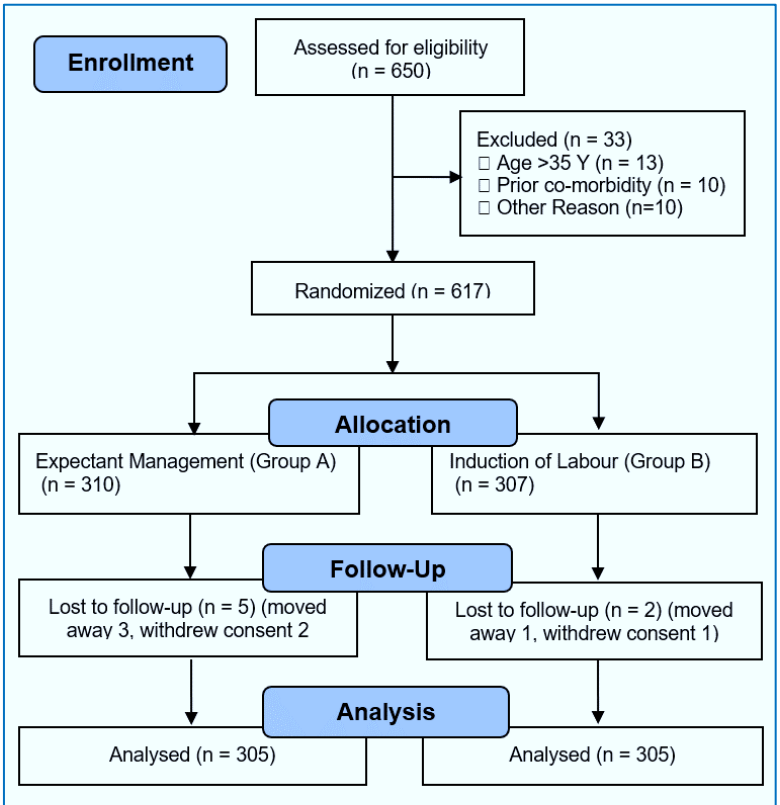

Figure 1: The CONSORT flow chart

Table 2: Comparative birth asphyxia complication in Groups A and B; [n (%)]

Variable		Group A (n = 305)	Group B (n = 305)	P-value
Total birth asphyxia		69 (22.6)	44 (14.4)	0.009
Age group	18-30 (y)	55 (21.4)	28 (12.6)	0.010
	> 30 (y)	14 (29.2)	16 (19.5)	0.207
Parity	0-2	52 (20.5)	26 (12.1)	0.016
	3-4	17 (33.3)	18 (19.8)	0.072
Gestational age	36-39 weeks	58 (22.9)	39 (15.3)	0.029
	> 39 weeks	11 (21.2)	5 (10)	0.122

Table 3: Comparative low Apgar score in Groups A and B; [n (%)]

Variable	Detail	Group A (n = 305)	Group B (n = 305)	P-value
Low Apgar score (total)		27 (8.9)	10 (3.3)	0.004
Age group	18-30 y	22 (8.6)	9 (4)	0.044
	> 30 y	5 (10.4)	1 (1.2)	0.016
parity	0-2	20 (7.9)	9 (4.2)	0.101
	3-4	7 (13.7)	1 (1.1)	0.001
Gestational age	36-39 weeks	21 (8.3)	6 (2.4)	0.002
	> 39 weeks	6 (11.5)	4 (8)	0.548

Table 4: Comparative sepsis complications in Groups A and B; [n (%)]

Variable	Detail	Group A (n = 305)	Group B (n = 305)	P-value
Sepsis (Total)		8 (2.6)	1 (0.3)	0.019
Age group	18-30 y	7 (2.7)	0 (0)	0.013
	> 30 y	1 (2.1)	1 (1.2)	0.699
parity	0-2	7 (2.8)	0 (0)	0.014
	3-4	1 (2)	1 (1.1)	0.675
Gestational age	36-39 weeks	7 (2.8)	1 (0.4)	0.031
	> 39 weeks	1 (1.9)	0 (0)	0.324

4. In comparison to Group B, Group A showed significantly greater incidence of sepsis (P = 0.019), low Apgar score (P = 0.004), and birth asphyxia (P = 0.009).

When birth asphyxia is broken down by maternal age, significantly low Apgar scores were found in the >30 age group (P = 0.016), and for ages 18–30 (P = 0.010) and >30 (P = 0.207). Birth Asphyxia varies across parities 0–2 (P = 0.016), and there is a difference in birth asphyxia between gestational ages 36–39 weeks (P = 0.029) as shown in Table 2.

Low Apgar scores were observed significantly more in Group A compared to Group B regarding age group, parity as well as in mothers with gestational age of 36-39 weeks (P = 0.002) (Table 3).

Regarding sepsis the frequency was significantly higher in Group A in 18-30 (y) age group (P = 0.013), Para 0-2 (P = 0.014), and gestational age 36-39 weeks (P = 0.031) (Table 4).

4. DISCUSSION

The mean maternal age, gestational age, and parity of the women in Group A (the expectant management group) and Group B (the induced group) were similar in our

research. Given the similarity of their socio-demographic profiles, variations in management techniques rather than demographic disparities were the primary cause of any observed differences in outcomes between these two groups. Significant findings from the study indicate a notable reduction in adverse fetal outcomes, including lower rates of birth asphyxia, low Apgar scores, and sepsis, among patients managed with induction of labor compared to those undergoing expectant management for premature rupture of membranes (PROM). In our investigation, we found that 44 patients in Group B experienced birth asphyxia (14.4%), whereas 69 patients in Group A (22.6%) experienced it (P = 0.009). Compared to 10 (3.3%) patients in Group B, 27 (8.9%) patients in Group A had low Apgar scores (P = 0.004). Compared to 1 (0.3%) patient in Group B, sepsis was seen in 8 (2.6%) patients in Group A (P = 0.019). The findings of my research are consistent with a study by Nath et al., which found that poor Apgar scores were 8% vs 4%, sepsis was 2% against 0%, and the frequency of birth asphyxia was 28% in expectant management compared to 16% with induction of labor in PROM patients.[12]

According to research by Shanti et al., the predicted group's LSCS rate was 5.7%, whereas the active group's rate was 12%.[13] Another research by Suneela et al., found that 88.3% of expecting women had birth vaginally, compared to 85.0% of active management women. This means that the expectant group had an LSCS rate of 11.7%, whereas the induced group had a rate of 15%.[14]

In a study by Suneela et al. 3.3% and 5%, of the induced and expectant groups respectively, developed pyrexia. In another study, Sumaira et al., (Peshawar) reported 2.4% fever, but in the expectant group, it was 16.0%.[14] According to Suneela et al., 108's study, 6.6% of the expecting group experienced severe delivery hypoxia that required ventilation, while 11.7% of the expectant group experienced neonatal sepsis.[14]

Reducing the latent period and improved mother satisfaction are just two of the many advantages of active therapy in cases with PROM at term.[15] In these situations, inducing labor not only shortens the PROM-delivery time but also lowers the risk of sepsis in both the mother and the newborn without significantly increasing the LSCS rate.[16] It is evident that within 24 h, around 70% of term PROM patients experience spontaneous labor without an intervention.[14] Based on the cervical findings or Bishop's pre-induction score, either oxytocin or PGE1 (misoprostol) is used during induction.[17]

The key end measures of the current study showed that the induction group had considerably shorter time to delivery, a significantly greater rate of cesarean sections, and equivalent rates of maternal and newborn morbidity.[18] The expecting group's secondary result is that their need for oxytocin augmentation is not considerably raised, and their PGE1 pill dosage is significantly lower. The expectant group's hospital stay was longer than that of the early induction group.

5. LIMITATIONS

Our study was limited to one hospital only, with limited age range and specific medical conditions, which limited its wider applicability. There could be potential observer bias in clinical assessments like Apgar scores and sepsis. The study was restricted to short-term outcomes, overlooking long-term maternal and fetal impacts.

Reliance on medical records risks inaccuracies due to documentation related variabilities.

6. CONCLUSION

This study concluded that inducing labor in parturients with premature rupture of the membranes (PROM) at term resulted in a shorter PROM delivery interval, dramatically improved mother satisfaction, and improved fetomaternal outcomes. Patients felt worry and anguish due to the increased rates of maternal and fetal morbidity and sepsis in the expecting group that received conservative care. We recommend that to lower the risk of maternal and fetal morbidity, all patients who present with premature rupture of the membranes at term should be actively handled with induction of labor following cervical status assessment using Bishop's Pre-Induction score.

7. Data availability

The numerical data generated during this research is available with the authors.

8. Acknowledgement

We gratefully thank faculty and staff of the Department of Obstetrics & Gynecology, Medical Teaching Institution, Lady Reading Hospital, Peshawar, Pakistan for their full cooperation during the conduct of this study.

9. Conflict of interest

The study utilized the hospital resources only, and no external or industry funding was involved.

10. Ethical considerations

The ethics committee of Lady Reading Hospital, Peshawar granted approval for the study. Written informed consent was obtained from every participant.

Authors' contribution

Both authors took equal part in th, conduct of the study, data collection, statistical analysis, and manuscript preparation.

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