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RESEARCH ARTICLE

Expectant versus active management in term prelabor rupture of membranes (PROM) - a prospective study in a tertiary care hospital

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ABSTRACT

Objectives: This study was done with the main objectives of assessing the prevalence, identifying the associated factors and comparing feto-maternal outcomes in expectant versus active management in term PROM. **Methods:** This was a prospective cohort study where two convenience groups were categorized as expectant and active management with feto-maternal morbidities and mode of delivery as outcomes of interest. Further, the active group was categorized into two groups one of which received oxytocin and the other received a combination of prostaglandins and oxytocin. Here the main outcome of interest was the mode of delivery. The statistical software "R" was used to calculate the odds-ratios, 95% C.I. and p-values. **Results:** Prevalence of PROM was 16.7% and apart from multiparity (p=0.0467) none of the other factors were significantly associated with term PROM. Maternal infective morbidity was significantly more in the expectant management group (p=0.001) with no significant difference in the C-Section rates (p= 0.906) and neonatal morbidity (p=0.4). Active management with oxytocin and prostaglandins resulted in a significantly higher number of vaginal deliveries (p< 0.001) when compared to the only oxytocin group. **Conclusion:** Expectant management did not result in significantly higher operative deliveries or increased neonatal morbidity. Using prostaglandin with oxytocin gave a better result than oxytocin alone in terms of vaginal delivery.

Keywords: Pre-labor rupture of membranes (PROM), expectant, active, fetal, maternal.

The normal development, structural integrity and function of the fetal membranes are essential for the normal progress and outcome of pregnancy. One of the most important functions of the membranes is to remain intact until the onset of labor in order to maintain the protective intrauterine fluid environment. In most pregnancies labor begins at term in the presence of intact fetal membranes [1, 2]. Without any intervention their spontaneous rupture usually occurs near the end of the first stage of labor. In 8- 10% of pregnancies they fail to maintain their structural integrity, resulting in pre-labor rupture [1, 3]. This can be either at term pre-labor rupture of membranes (PROM) or preterm pre-labor rupture of membranes (PPROM). Both are to some extent separate entities as in the latter "prematurity" become the main issue [1, 2].

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Term PROM is an obstetric conundrum which is poorly defined with a multitude of obscure etiologies associated with significant maternal and fetal morbidity and has diverse and controversial management strategies [1, 4-7]. Expectant management entails the increased risk of chorioamnionitis and its consequences and active interference brings with it the risk of C-Section [4 - 7]. The strategies for active intervention are also not clearly defined particularly when the cervix is unfavorable [5 - 10]. The treating obstetrician often needs to decide whether to manage conservatively or go for active management and if active management is the choice he needs to decide which methods would optimize results [8-10].

We did this study with the following objectives: 1) Assess the incidence of PROM in our hospital delivery group; 2) Identify the associated factors; 3) Compare feto-maternal outcomes in expectant versus active management in term PROM; 4) Compare the outcome in terms of mode of delivery in two different modalities of active management.

Methods

This was a prospective cohort study conducted in the department of Obstetrics and Gynecology, Durgapur Steel Plant (DSP) Main Hospital, Durgapur, West Bengal from 1st December 2012 to 30th November 2013. Ethical approval for the study was obtained from the institutional ethical committee. With an acceptable margin of error of 5% and a confidence level of 95% (for our annual delivery population of 1200) and taking the worldwide average incidence of PROM as 8-10% from previous established studies [1, 3], the recommended sample size was 125 using the formula $p(1-p)Z^2/ME^2$ where p is the prevalence of the disease, 5% alpha level and 80% power through "R software". The present study included 200 cases by consecutive sampling.

The study population consisted of pregnant women at term (≥ 37 weeks of gestation) with leaking per vagina, who reported to the Gynecology OPD or Emergency admission room of the hospital

Following were the inclusion and exclusion criteria -

Inclusion criterias:

-Gestational age of ≥37wks (confirmed by dates and first trimester ultrasound),

-Singleton pregnancy,

-Fetus in vertex presentation,

-PROM established by sterile speculum examination to demonstrate leakage of amniotic fluid from external os. Patients were asked to cough in order to see liquor coming out and litmus (nitrazine) paper was used for confirmation.

Exclusion criterias:

-Gestational age <37wks,

-Mal-presentations,

-Multiple gestations,

-Medical disorders in pregnancy,

-Intrauterine Fetal Death (IUFD).

An informed consent was taken from the included participants. History, examination and investigations (before and after delivery) for both mother and neonate were recorded as per a pre-tested proforma. After confirming PROM the patients were consecutively divided into two groups one for expectant management (n=120) and the other for active management (n=80). Expectant management was taken as absence of any intervention, intended to expedite delivery, within 24 hrs after admission whereas active management was taken as intervention done to expedite delivery within 24 hrs of admission. Expectant management was only done when there was no evidence of clinical chorioamnionitis. Clinical chorioamnionitis was taken as a maternal fever > 100.4^0 F plus any two of: maternal tachycardia >100\min, fetal tachycardia >160\min, foul smelling liquor and uterine tenderness. If clinical chorioamnionitis was diagnosed the lady was included in the study but was allocated to the active management group. Further, the active management was done in two groups as follows: 1) If the Bishop's score was >6, Oxytocin drip was started as soon as admission formalities were complete and consent had been taken (n=33); 2) If the Bishop's score was <6 intracervical PGE_2 gel was instilled, followed by oxytocin drip after 6hrs of instillation (n=47). A partograph was maintained for both groups. Both groups were given antibiotic prophylaxis. The outcomes of interest were 1) Maternal: Mode of delivery (Vaginal delivery or C-Section) and infectious morbidity (puerperial pyrexia, scar dehiscence, mastitis and urinary tract infection); 2) Fetal: Neonatal mortality and neonatal intensive care unit (NICU) admissions and their indications.

Results

A total of two hundred cases of term PROM were taken for the study. Majority of women were between 20-25 years and the overall mean age was 24.1 years (Table1). Of the 200 women who had term PROM 37% (n=74) were primiparous and the rest 63% (n=126) were multiparous [P1: 34% (n=68); P2: 20% (n= 40); P3 and 1% (n=2)] (Table 1). When considering all the multiparous women together: PROM was present in 63% (n=126) of multiparous women as compared to 37% (n=74) of primiparous women denoting a significantly higher (p=0.0467) incidence of PROM in multiparous women (Table 2). Urinary tract infection (UTI) and vaginitis were the two most common factors associated with PROM in both multiparous and primiparous women. However there was no significant difference between the two as regards the presence of these associated factors. It is also important to note that in 11% of cases included in our study had no associated risk factor (Table 3). When all factors contributing to infection were combined, and compared with the non – infective factors we found a significant association ($p < 0.001$) of the infective factors with PROM in both multiparous and primiparous women (Table 4). An Odds Ratio of 1.3 (95% Confidence Interval 0.53-2.47) suggests there is 13% risk of LSCS in the Expectant group when compared to the active group. This however is not statistically significant (p=0.906)(Table-5). We compared the active management subgroup separately for the mode of delivery in the oxytocin alone versus the intra-cervical prostaglandin E_2 gel + oxytocin group. An odds ratio of 9.783 suggests that there is a 97% risk of C-Section in the only oxytocin group when compared to the intra-cervical prostaglandin plus oxytocin group. This was statistically significant (p=.001) (Table 6). Fifty babies were admitted to NICU of which 20 were from the expectant group and 30 were from the active management group. Among babies in the expectant group 30% had birth asphyxia, 30% physiological jaundice and 10% neonatal infection as compared to 33.33%, 16.67% and 16.67% respectively in active group. There are no significant differences in the neonatal outcomes between the expectant and active groups (Table -7).

Out of the 200 women who had PROM 63% (n= 129) women developed some form of infective morbidity. The infective morbidity was significantly more ($p< 0.001$) in the expectant management group (98.7%, n=73) as

Table 1: Age and Parity distribution

Categories		Number (%)
Age in years	<20	16(8%)
	20 - < 25	106(53%)
	25 - < 30	64(32%)
	≥ 30	14(7%)
Parity	P_0	74(37%)
	P_1	68(34%)
	P_2	40(20%)
	P_3	16(8%)
	P_4	2(1%)

Table 2: Comparing Term PROM in primiparous and multiparous women

Parity	Number (%)
Primi	74 (37%)
Multipara	126 (63%)
P=0.0467*	

*p-value calculated using one sample proportions test

Table 3: PROM and associated factors

Categories	Primi No. (%)	Multi No. (%)	P-value
H/o coitus	8(10.81%)	20(15.87%)	0.286
P/v exam	2(2.70%)	10(7.94%)	0.167
Fever	5(6.76%)	15(11.90%)	0.25
Vaginitis	20(27.03%)	25(19.84%)	0.443
Urinary Tract Infection	25(33.78%)	30(23.81%)	0.455
Polyhydramnios	4(5.41%)	12(9.52%)	0.221
No risk factor	10(13.51%)	14(11.11%)	0.417
Total	74	126	

Table 4: Infective versus Non infective factors in PROM

Categories	Infective factors (p/v exam + fever + UTI vaginitis + +h/o coitus)		Non infective factors (Polyhydramnios + No associated factors)		P value
	No	%	No	%	
Primi	60	81%	14	19%	<0.001
Multi	100	79.4%	26	20.6%	<0.001

Table 5: Comparing vaginal deliveries and C - Sections in expectant versus active management

Categories	C-Section	VD	Total
Active	12	68	80
Expectant	20	100	120
Total	32	168	200
P value = 0.906			

Table 6: Comparing vaginal deliveries and C-Sections in only oxytocin versus the PGE_2 + oxytocin groups.

Categories	VD	LSCS	Total
Oxytocin	23	10	33
PGE_2 + Oxytocin	45	2	47
Total	68	12	80
P value = 0.001			

compared to the active group (46.7% n=56). The causes of maternal morbidity were urinary tract infections (UTI),

Table 7: Comparing neonatal outcomes in expectant and active management groups

Neonatal outcomes	Expectant No. (%)	Active No. (%)	P value
Asphyxia	6(30%)	10(33.3%)	0.375
Infection	2(20%)	5(16.7%)	NA*
Respiratory distress	2(10%)	4(13.3%)	NA*
Jaundice	6(30%)	5(16.7%)	0.545
Others	4(20%)	6(20%)	NA*
Total	20	30	0.4

*NA –Denotes not applicable due to few numbers

Table 8: Causes of maternal morbidity in the expectant and active management groups

Condition	Expectant N (%)	Active N (%)	Total N (%)	P value
P Pyrexia	20 (27.3%)	16(28.6%)	36(27.9%)	0.556
Scar dehiscence	8 (10.9%)	4 (7.1%)	12(9.3%)	0.667
UTI	10 (13.7%)	8(14.3%)	18(13.9%)	0.556
Mastitis	35(47.9%)	28(50%)	63(48.8%)	0.556
Total	73	56	129	

mastitis, puerperal pyrexia and scar dehiscence however there was no significant difference in the numbers between the two groups (Table - 8).

Discussion

At term the incidence of PROM was found to be 16.7% in the present study. The overall incidence of term PROM is approximately 8% [3, 10, 11]. Several studies most of which have been conducted at tertiary care centers have quoted the incidence to have ranged from 5% -19% [12 - 18]. In our study multiparity was found to be significantly associated with term PROM. This has been corroborated by other such studies [12 – 15]. Besides multiparity many other factors have been found to be associated with PROM, but what actually causes the membranes to rupture before the onset of labor is not known [18-20]. Ascending infection is thought to play a definite role and has been found to be associated with at least a third of the cases of PROM [19-23]. The present study shows UTI, vaginitis, history of coitus or per-vaginal examination, fever and polyhydramnios to be associated with term PROM. Individually none of the associations were found to be significant but if vaginitis, UTI, history of coitus and PV examination are thought to contribute to ascending infection and taken together, they are associated with more than two thirds of the cases of term PROM (N=140,70%). This was statistically significant as well. It is also important to note that that there were no associated factors in 12% of the cases.

Rupture of membranes has been taken as one of the signs of labor and waiting for labor pains to commence can be justified. However rupture of membranes before actual onset of labor pains carries with it the risks of maternal and neonatal morbidity and mortality. The clinician therefore has to decide whether to wait for spontaneous onset of labor pains or to expedite labor by interventions which could themselves contribute to maternal and fetal morbidity. Studies have given conflicting results [5 - 10]. Induction of labor has been advocated by some as having lesser infectious morbidity for the mother and baby while others have found an increased C-Section rate. A recent cochrane review which has included 23 trials has stated that there is evidence to suggest that there was no significant difference in the C-Section rates and neonatal infectious morbidity in planned early births (active management) versus expectant management groups [11]. However there appeared to be a significantly lesser incidence of maternal infectious morbidity in the early planned birth group (active management) when compared to the expectant group. Both the above findings of the review were echoed in our study.

While opting for expectant management the combined interventions of prostaglandin and oxytocin has a significantly lesser risk of C-section when compared to oxytocin alone in our study. Evidence as regards this comparison is singularly lacking and guidelines have expressed that there is need for more trials to see whether the combined intervention is better and in which cases. Also are there any adverse effects of this combined intervention in terms of maternal and neonatal morbidity needs to be assessed [10]. Although this study showed that there is a better chance of a vaginal delivery when intra-cervical prostaglandins are used with oxytocin rather than oxytocin alone the number of participants were less. More studies with a larger sample sizes are needed to establish the efficacy of the combined intervention over oxytocin alone when assessed in achieving vaginal delivery.

Conclusion

This hospital based prospective study showed a 16.7% prevalence of PROM, comparable to other studies with multiparity being significantly associated with term PROM. Apart from multiparity none of the other individual factors had any significant association with term PROM. Combining factors into two groups of infectious versus non infectious, there was a significant association of PROM with the infectious factors. This could be taken to reinforce the fact that infection plays a major role in prelabor rupture of membranes. Expectant management did not have significantly greater operative delivery or neonatal infectious morbidities rates but was associated with greater maternal infectious morbidity. In the active management group intracervical prostaglandin combined with oxytocin showed lesser C-section rates than oxytocin alone. However participant numbers were less and this needs to be addressed in forthcoming studies.

Conflict of interest: None. **Disclaimer:** Nil.

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