PROM;
EXPECTANT VS ACTIVE MANAGEMENT

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ABSTRACT…..INTRODUCTION: PROM is not uncommon in pregnancy. It occurs in 10% of term pregnancies. At term about 75% of women will go into labour within 24 hours of rupture of membranes. At term there are two options, either wait for spontaneous onset of labour or immediate induction to establish labour. For induction of labour different kinds of drugs are used according to Bishop score. If Bishop score is favorable ($\geqslant 6$), oxytocin can be used. It decreases the risk of chorioamnionitis and is more satisfying for mother. **OBJECTIVE:** To compare the immediate induction with expectant management in PROM at term with favorable cervix in terms of frequency of caesarean section. **MATERIALS & METHODS:** This prospective randomized controlled trial was conducted in the department of obstetrics & gynaecology, Punjab Medical College and affiliated hospitals, Faisalabad from 1st June to 30th November 2010. One hundred and twenty pregnant ladies were randomly divided into two equal groups. Odd numbers were placed in group 1 who were given expectant management for 24 hours for spontaneous onset of labour. Even numbers were placed in group 2, who were started immediate induction with oxytocin infusion. **RESULTS:** In my study overall age was 25.64±2.98. In expectant group mean age was 25.18±3.21 and in induction group mean age was 26.10±2.69. The rate of c-section in immediate induction group was 8.3% while in expectant group it was 11.6%. In my study there was no significant difference regarding rate of c-section in both groups (p= 0.543). **CONCLUSION:** Both expectant & immediate inductions are common management options in women with PROM, but immediate induction was favorable approach for both mother and fetus. The later was more satisfying for mother and decreased risk of maternal and neonatal infection.

Key words: PROM, prelabour rupture of membranes, oxytocin in PROM, induction of labour, favorable cervix, Fetal distress, Cardiotocography.

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INTRODUCTION

Pre labor rupture of the fetal membranes (PROM) refers to rupture of membranes (ROM) beyond 37 weeks' gestation prior to the onset of labor[1]. It affects approximately 10% of women at term[2]. Its etiology is multifactorial. At term, programmed cell death and activation of catabolic enzymes, such as collagenase and mechanical forces, result in ruptured membranes[3].

Main risks relating to PROM at term are maternal and neonatal infection, prolapsed cord, placental abruption, fetal compromise resulting in operative delivery or low five minute Apgar score of baby[2]. Management options are expectant management or immediate induction of labour. Inspite of many studies available in the literature, the clinical management is surprisingly controversial. Disagreement exists among maternal health care providers on the optimal management of women with PROM, particularly the need for and timing of induction[4]. The concern with conservative management is the risk of infection to the mother and the fetus whereas immediate induction can increase cesarean (CS) rate[5].

Immediate induction of labour (IOL) in cases of PROM used to be a strongly advocated standard practice to avoid potential complications of intrauterine infection and oligohydramnios. The rationale for this type of managemen called (active management) stems from research that was done in 1960s (shubeck,1966; Rusell & Anderson,1962) which found that longer the women with ruptured membranes, greater the chances of infections, chorioamnionitis, maternal & fetal infections[6,7]. However induced labour is likely to be prolonged with increased risks of fetal and maternal complications due to oligohydramnios like cord compression and high rate of operative delivery.

Therefore, the most appropriate choice of management of PROM is still controversial[8]. There is conflicting evidence regarding the frequency of caesarean section (CS) with expectant and active management. Although studies show lower rate of CS with immediate induction[5] and a difference in CS rate of 5% Vs 24% in immediate induction and expectant management group respectively has been noted[9]. Evidence to the contrary is also available in literature[2]. At the same time literature is full of studies that show no difference in cesarean delivery and neonatal infection[5]. Many practitioners have adopted a policy of active management, as it decreases the risk of infection, PROM to delivery interval and LSCS rate.

SUBJECTS AND METHODS

This prospective randomized controlled trial was conducted on 120 patients. The patients were taken from labour and maternity wards and admitted either through out-patient department or emergency. On admission a detailed history was taken and gestational age was confirmed by LMP & ultrasound and the time of PROM was noted. Abdominal examination was done for fetal heart sound and for palpable uterine contractions. Diagnosis was based on: (1) history of gush of fluid, (2) pooling of fluid in posterior fornix on sterile speculum examination (prolapsed cord was excluded) (3) absence of membranes on palpation through cervical canal. No other tests of PROM e.g. nitrazine test or presence of fern pattern on microscopy were made Bishop scoring was also done. Admission CTG was done to assess fetal status. The women were eligible for entry into the trial if they had ruptured membranes at $\geqslant$ 37 weeks of gestation, had single live fetus with cephalic presentation, were not in labor and had Bishop score (BS) $\geqslant$ 6 and reactive CTG. Whereas the patients who were in labor, had cephal-opelvic disproportion, scarred uterus (e.g. previous hysterotomy, myomectomy), placenta previa, chorioamnionitis or contraindication to IOL and expectant management e.g. fetal distress were excluded fom the study. Woman and her partner were counseled about the management options, its risks and benefits and written informed consent was taken. Women were then randomly allotted to either expectant or immediate induction group by lottery method. Odds numbers were placed in group1 (expectant) and even numbers were placed in group 2 for immediate induction. Prophylactic antibiotic cover with penicillin or a cephalosporin group was given.

In immediate induction group, labor was immediately induced with oxytocin infusion. Infusion was started as 5 units of oxytocin in 500 ml of Ringer's solution at 2mI.U/minute. Infusion rate was doubled every 15 minutes until three contractions of 40-45 seconds were obtained in 10 minutes or until a maximum infusion rate of 32mI.U/minute was achieved. Fetal heart rate was monitored every 15 minutes in first stage and every 5 minutes in second stage of labour. Vaginal examination was done 4 hourly in latent phase and 2 hourly in active phase of labor to assess the progress of labor. Partogram was maintained.

Women in group 1 were expectantly managed for spontaneous onset of labor. Women were closely monitored by trained medical staff for 24 hours for the signs of chorioamnionitis No digital vaginal examination was done until patient was clinically in active labor. IOL was started in case of chorioamnionitis. If labor did not supervene in 24 hours of PROM, IOL with oxytocin infusion was done in the same way as in the immediate induction group.

Mode of delivery was noted. CS was decided when indicated either due to abnormal labour or due to fetal distress (meconium on sanitary pads and/or abnormal CTG pattern) The data was collected through Proforma.

The main outcome was measured in terms of frequency of caesarean section. Data was analysed by using SPSS version 10.0. Mean and standard deviation was calculated for quantitative variables e.g

age, parity, gestational age(in weeks), duration of prelabor rupture of membranes(in hours). Frequency of c-section in both groups was calculated by using Chi-square test. P value < 0.05 was considered significant.

RESULTS

Out of 120 patients, 60 patients were given immediate induction with oxytocin infusion and 60 were offered expectant management. No patient fulfilling the criteria refused to be part of the study and none opted out once enrolled. The protocol was strictly followed. Baseline characteristics were almost same in both groups.

Out of 120 women, 68 were booked patients (56.7%) and 52 were unbooked (43.3%). Maternal demographics like age and parity (Table-I) in both the groups were same. The age range of women was 19-33 years. The mean maternal age was 25.642.98(Table-I). The mean maternal age in expectant group were 25.183.21 and immediate induction group was 26.102.69(Table-IV). Mean parity was 1.211.40(Table-I). Range of parity was 0-7. In expectant group, 34 patients were primipara (56.7%) and 26 were multipara (43.3%). While in immediate induction group, 27 were primipara (45%) and 33 were multipara (55%) (Table-II). Average gestational age at which women presented with PROM at term was 38.771.04(Table-I). Gestational age in expectant group was 38.570.95 and in immediate induction group was 38.971.10(Table-IV). The range of gestational age in my study was 37-41 weeks.

Mean duration of PROM was 7.042.95(Table-I). It was7.732.90 in expectant and 6.352.85 in immediate induction group. The range was 1-13 hours (Table-III). A total of 12 ladies (10%) had emergency cesarean sections due to obstetric indications out of which 07 (11.6%) were in the expectant group and 05 (8.3%) were in the immediate induction group (Table-IV).

According to my study, there was no significant difference in frequency of CS in both expectant and immediate induction groups (P value=0.543), (Table-IV). The frequency of CS was high in primipara 8(13.1%) than multipara (6.8%) (Table-V).

Characteristics	N	Minimum	Maximum	Mean	S.D
Age	120	19	33	25.64	2.98
Gravidity	120	1	8	2.38	1.54
Parity	120	0	7	1.21	1.40
Duration of PROM in (hrs).	120	1	14	7.04	2.95
Gestational age in weeks.	120	37	41	38.77	1.04
Valid N (list wise)	120				

Table-I. Baseline characteristics of women.

Group of management		Frequency	Percent	Valid percent	Cumulative percent
Expectant management Valid	Primipara	34	56.7	56.7	56.7
	Multipara	26	43.3	43.3	100.0
	Total	60	100.0	100.0	
Immediate induction Valid with oxytocin	Primipara	27	45.0	45.0	45.0
	Multipara	33	55.0	55.0	100.0
	Total	60	100.0	100.0	

Table-II. Distribution of women in both groups according to parity.

Descriptive Statistics

Group for managen		N	Minimum	Maximum	Mean	Std. Deviation
Expectant managen	Age	60	19	33	25.18	3.21
	duration of PROM at of admission (hours)	60	2	14	7.73	2.90
	gestational age in we	60	37	41	38.57	.95
	Valid N (listwise)	60				
Immediate induction with oxytocin	Age	60	20	33	26.10	2.69
	duration of PROM at of admission (hours)	60	1	13	6.35	2.85
	gestational age in we	60	37	41	38.97	1.10
	Valid N (listwise)	60				

Table-III. Baseline characteristics of women in each groups.

Group for management * cesarean section Crosstabulation

		Cesarean section		Total
		Cesarean section	Vaginal delivery	
Group for management	Expectant management	7	53	60
	immediate induction with oxytocin	5	55	60
Total		12	108	120

Table-IV. Mode of delivery in both groups.
Chi square value=0.370, df=1, p-value (1-sided)=0.543

Cesarean Section

Parity		Frequency	Percent	Valid Percent	Cumulative Percent
Nullipara Valid	Cesarean section	8	13.1	13.1	13.1
	vaginal delivery	53	86.9	86.9	100.0
	Total	61	100.0	100.0	
Multipara Valid	Cesarean section	4	6.8	6.8	6.8
	vaginal delivery	55	93.2	93.2	100.0
	Total	59	100.0	100.0	

Table-V. Frequency of c-section according to parity.

DISCUSSION

Prelabor rupture of membranes is a common clinical problem and the assessment of women with possible membrane rupture is a management issue faced in everyday practice. When PROM occurs, the fetus loses the relative isolation and protection afforded within the amniotic cavity. There is no standard protocol for management. Management strategy is divided into four groups, immediate induction with oxytocin, expectant management followed by oxytocin, immediate induction with prostaglandins and expectant management followed by prostaglandins.

The management of the term patients with PROM, especially those with an unfavorable cervix, remains controversial. Several reports have detailed an increase in maternal and neonatal morbidity with expectant management whereas active management leads to a shorter interval from PROM to delivery,

reducing the risk of postnatal infection. In addition, active management is preferred by patients.

In a study by Seema Tariq and colleagues similar CS rate was seen in immediate induction and expectantly managed groups, 9.3% and 10.7% respectively and was similar to my study[10]. Similarly the definitive Term PROM study found no difference in neonatal infections between immediate and delayed induction with oxytocin and PGE2. However, neither PGE2 nor delayed induction resulted in fewer cesarean sections than immediate oxytocin[11].

A review was identified in literature that compared the effects on fetal, infant and maternal wellbeing of planned early birth versus expectant management (waiting) for women with PROM. The review included 12 trials with 5000 women who had PROM at 37 or more weeks of gestation with no specific maternal or fetal contraindications to either type of management strategy. The review found no statistically significant differences in the risk of Caesarean section, operative vaginal birth, postpartum fever, use of epidural anaesthesia, uterine rupture, cord prolapse, neonatal infection, fetal or perinatal mortality, Apgar score < 7 at 5 minutes, mechanical ventilation, length of stay in the neonatal intensive care unit and breastfeeding duration. The authors concluded that planned management reduces the risk of infection-related maternal morbidity without increasing the rates of CS and operative vaginal birth. Also, with planned management, fewer infants need intensive neonatal care, although neonatal infection rates remain unchanged[12].

However there are studies showing lower rate of CS with immediate IOL in patients with PROM[13]. In a study by Chaudhuri Snehamay and colleagues on 223 patients noted significantly lower CS rate 17.8% Vs 28.5% in Immediate Vs expectant group respectively. The CS rate was higher than that seen in my study. The reason could be higher number of nullipara in the former study that was 75%5. In a study by Talaat and colleagues CS rate in immediate induction group was 8% and was comparable to my study. However CS rate in the expectantly managed group was 24% compared to 11.6% in my study despite the fact that demographics and parity were similar in both the studies[14]. Larger scale studies are required to draw definitive conclusions.

In contrast, a study by Tansupasiri showed a higher rate of CS in the immediate induction group[15]. In another study by Farhat Karim and Mamoona Mushtaq, CS rate was significantly higher in the IOL compared to the expectantly managed group 17.95% and 7.04% respectively. The CS rate in the immediate induction group was very high compared to my study[2]. A plausible explanation could be that 84.6% of patients were with unfavourable Bishop score (< 5) while my study included patients with favourable score only ($BS \geqslant 6$). Deliveries by the vaginal route were 89.2% and CS rate was 10.90%, higher in those induced and primigravidas as compared to multigravidas. This is similar to my results where CS rate was high among primigravida (13.1% in nullipara vs 6.8% in multipara). In my study, 67% women in group 1 had spontaneous onset of labour similar to the observation of Farhat Karim that was 64.54% and only 35.45% required active intervention[2].

Available research does not associate early induction of labour for women with PROM with an increased risk of operative delivery or caesarean section, but these women are more likely to require pain medication and continuous fetal monitoring. Therefore, an expectant management approach is more likely to result in a normal, less interventive childbirth. Ultimately women who experience PROM are best suited to make the final decision by weighing the risks and benefits within the context of their own values and interests.

The ladies with PROM $> 37+0$ weeks' gestation

should be offered the option of induction or expectant management. In the absence of abnormal fndings expectant management is as appropriate as induction of labour. Women should be explained that they can revisit their management plan and may choose induction of labour if they no longer desire expectant management. In order to reduce the risk of maternal and neonatal infection, avoid digital vaginal exams for women with PROM until active labour or upon induction of labour[4].

CONCLUSION

Both expectant & immediate inductions are common management options in women with PROM, but immediate induction was favorable approach for both mother and fetus. It was more satisfying for mother, and decreased risk of maternal and neonatal infection. However, there was no significant difference in cesarean section rate in both management groups.

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PREVIOUS RELATED STUDIES

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The graveyards are full of indispensable men.

Charles de Gaulle (1890-1970)