FETOMATERNAL OUTCOME IN PATIENTS WITH PRELABOUR RUPTURE OF MEMBRANE IN CIVIL HOSPITAL KARACHI

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ABSTRACT

Objectives: *To compare the fetal and maternal outcomes in interventional (induction of labor) verses expectant management of prelabour rupture of membranes at term.*

Materials and Methods: *This Randomized control trial was conducted from December 2014 to June 2015 in obstetrics and gynecology department civil hospital Karachi.. A total of 284 patients were recruited via non probability consecutive sampling technique. Women were randomized into group A (intervention group) & Group B (expectant group). Randomization was blinded and was done by opening of the closed envelopes. Women in group A induced with tablet prostaglandin E2 placed in posterior vaginal fornix (2 doses 6 hours apart) group B expectant group patient monitored for 24 hours for spontaneous initiation of labour, under strict fetomaternal monitoring. (Fetal heart rate (<160bmp) was monitored one hourly and maternal vital signs (pulse <100bmp) four hourly, If patients in group B did not go into labor till 24 hours, they were induced. Labour management was according to normal labour protocols. The management outcomes were measured and recorded on approved Performa.*

Results: *Average ages was 27.6 ± 6.1 in interventional group and 27.7 + 6.2 years in expectant group with mean duration of labor was 9.4 ± 4.9 and 13.6 ± 5.7 respectively and mean duration of PROM was 3.1 ± 1.9 and 2.9 ± 2.0. When APGAR score were compared, 9(6.3%) had APGAR score < 7 in interventional group and 13(9%) had APGAR score < 7 in expectant group, showed no significant difference but when Chorioamnionitis were compared, 8(5.9%) had positive in interventional group and 28(19.7%) had positive in expectant group and showed significant difference.*

Conclusion: *This trial concluded that the interventional management leads to reduced Chorioamnionitis as compared to expectant management but did not find the differences in the rates of fetal outcome.*

Key words: *Prelabour rupture of membrane, Interventional management, Expectant management, Fetomaternal outcome*

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INTRODUCTION

A PROM called prelaboour repture of the membrane is a frequent issue observed in gynaeoclogy. About 60 percent of pregnancies with it reach as term pregenencies (5–10 percent of all pregnancies).[1-2] Within 24 hours, 80 percent of patients with PROM

at term go into spontaneous labour.[3] Low socio-economic status, low body mass index, smoking, PROM or previous preterm labour, infections like urinary tract infections, STDs, Chorioamnionitis, vaginal bleeding at any stage of pregnancy, cervical insufficiency, Polyhydramnios, multiple gestations, and invasive procedures like amniocentesis are risk factors for PROM.[4]

Both the mother and the foetus are at danger with PROM. Chorioamnionitis, endomyometritis, placental abruption, dysfunctional labour, a higher caesarean rate, pelvic abscess, septicemia, and postpartum haemorrhage are all maternal problems related to PROM[5,6].

A chorioamnionitis-related infection complicates 25% of PROM cases. Postnatal sepsis happens in 10% of instances, while serious maternal infections happen up to 1% or less of the time. Fetal risks include neonatal sepsis which occurs in 2- 4% cases. Due to the increased likelihood of cord prolapse, cord compression, and placental abruption associated with PROM, foetal hypoxia is also more likely to develop.[1] The mechanical difficulties of delivery, higher likelihood of malpresentations, and decreased alcohol consumption all contribute to an increase in neonatal morbidity.The management of term prelabor membrane rupture is either immediate inducement of labour or spontaneous commencement of labour. While postponing labour puts both mother and baby at danger, inducing labour has its own difficulties, including failed inductions, foetal discomfort, and a higher rate of caesarean sections[7].

At term, PROM is controlled either proactively or by inductionWhen induction is delayed for longer than 24 hours, expectant management runs the danger of infection. If induction is started too soon, however, there is also a chance of failure and operative delivery.[4] Recent research on term using PROM has produced promising induction of labour outcomes[1-8] Despite the fact that certain research support the term expectant management of PROM.[9] In their article, Khan B. and Rasheed B. arrive to the conclusion that rapid labour induction in cases with term PROM reduces the overall length of labour and the period of maternal hospitalisation without causing any negative effects on maternal and perinatal outcomes. Although within 24 hours, 44 percent of women had given birth vaginally in the expectant group compared to 73.3% in the interventional group, Caesarean section rates were reported to be 20 percent in the interventional group and 30.7 percent in the expectant group. Regarding the health of the foetus, difficulties with labour and delivery, and neonatal or postpartum mother morbidity, there were no differences between them.[1] Induction of labour is more advantageous than expectant management, with more spontaneous deliveries, fewer caesarean sections, less chorioamnionitis, and less neonatal sepsis, according to a study from

As PROM is a common distressing problem in Pakistan with poor fetomaternal outcomes, data regarding its management varies widely. As above mentioned, studies[1-5] favours induction of labour and on the other hand some studies favours expectant management. This research was carried out to find out the better and superior management option for PROM and its application to the community, so that to avoid unnecessary delay for waiting spontaneous labour (if induction of labour proves to have better outcome in terms of lesser caesarean deliveries, lesser chorioamnionitis, better APGAR score in neonates and lesser cases of neonatal sepsis,) and if expectant management proves to be better outcome, it would decrease financial burden caused by induction and hospitalization of patients.

MATERIALS AND METHODS

This Randomized control trial (RCT) was conducted in Obstetrics & Gynecology Unit III Civil Hospital Karachi. From December 2014 to June 2015. Sample size was calculated by using WHO sample size calculator taking prevalence of APGAR score of 96% in interventional group, and 88% in expectant group.7Confidence interval 95%, Power of test: 80%, Level of significance: 5%. Estimated sample size was n = 142 in each group. So the Total sample size = 284 sampling technique used was non-Probability consecutive sampling. That included all women of reproductive age i.e. 20-35 yr, Parity 1-5, patients having PROM at 37 to 40 weeks of gestation (as mentioned in operational definition), Singleton with cephalic presentation (By ultrasound scan), Previous normal delivery, Normal Cardiotocogram. Patients excluded from the study were patients with Signs of established labour, PROM before 37 or beyond 40weeks of gestation, Twin pregnancy or malpresentation ,Previous caesarean

section, Abnormal cardiotocogram, Fetal distress (meconium stained liquor),Signs and symptoms suggestive of chorioamnionitis (maternal fever (temp > 38'C), maternal tachycardia(pulse >100bmp), purulent vaginal discharge, fetal tachycardia (FHS >160bmp)),Postdate pregnancy, Substantial foetal or maternal problems, such as pregnancy-related vaginal bleeding, significant proteinuria, hypertension, intrauterine growth restriction, intrauterine mortality, polyhydrominas, or diabetic mellitus. After taking ethical approval, Patients fulfilling the inclusion criteria were enrolled as my study subjects. Biasness was controlled by following inclusion & exclusion criteria strictly. Detailed history was taken regarding rupture of membranes. General physical examination (temperature, pulse, BP) and abdominal examination was done. Abdominal examination supported the presence of a fixed presenting portion. Any uterine contractility was observed. A fetal cardiotocographic trace to confirm fetal well-being. Digital examination was avoided. Diagnosis of PROM was confirmed by examining amniotic fluid on sterile speculum examination. Samples for base line investigations including complete blood count, urine detailed examination, blood grouping and Rh factor was sent to Central Laboratory CHK. All eligible women were counseled and provided full detail subscription of the detailed protocol. Patients provided informed consent after being informed of the study's goals and methods. Randomly assigned groups A (the intervention group) and B included consenting women (expectant group). The closed envelopes containing the cards that identify the type of management were opened blindly during the randomization process. After randomization, neither the patients nor the staff was blinded to the mode of management as one of the aims was to assess patient preference. Fetal heart rate was monitored one hourly and maternal vital signs six hourly. Women in group A induced with tablet prostaglandin E2 placed in posterior vaginal fornix (2 doses 6 hours apart) group B expectant group patient monitored for 24 hours for spontaneous initiation of labour, under strict fetomaternal monitoring. (Fetal heart rate (<160bmp) was monitored one hourly and maternal vital signs (pulse <100bmp) four hourly, If patients in group B did not go into labor till 24 hours, they were induced. Labour management was according to normal labour protocols. The management outcomes were measured (as defined in operational definitions) in terms of mode of delivery (spontaneous vaginal, or caesarean section) at the time of delivery, development of Chorioamnionitis were accessed at 3rd post-natal day, good or poor APGAR score at time of birth and after 5 minutes. At the end all demographic outcomes were entered in pre designed Performa.

The data was entered and analyzed using SPSS version 17. Mean and standard deviation (SD) was calculated for quantitative variables (age, parity, duration of PROM, duration of labour) while frequency and percentage was calculated for qualitative variables (mode of delivery, Chorioamnionitis, APGAR score). Chi Square test was applied to compare Chorioamnionitis and APGAR score in both groups. Confounders/ effect modifiers were controlled by stratification with age, parity, mode of delivery duration of PROM, duration of labor to see the effect on these on outcome. Post stratification applying Chi square test was applied, taken p-value <=0.05 as significant.

RESULT

Total number of patients was 284, both groups had 142 patients. Average ages was 27.6 ± 6.1 in interventional group and 27.7 + 6.2 years in expectant group with mean duration of labor was 9.4 ± 4.9 and 13.6 ± 5.7 respectively and mean duration of PROM was 3.1 ± 1.9 and 2.9 ± 2.0 shown in table#01,02&03.

In interventional group 24(17%) and in expectant group 41(29%) delivered through cesarean section shown in table no 04.

When APGAR score were compared, 9(6.3%) had APGAR score < 7 in interventional group and 13(9%) had APGAR score < 7 in expectant group, showed no significant difference but when Chorioamnionitis were compared, 8(5.9%) had positive in interventional group and 28(19.7%) had positive in expectant group and showed significant difference shown in table no 05.

When APGAR score was stratified with respect to age, parity, duration of PROM and duration of labor no significant difference was observed and when Chorioamnionitis was stratified with respect to age, parity, duration of PROM and duration of labor significant difference was observed expect when it was stratified with women with parity (3-5), having duration of PROM < 3hours and duration of labor >12 hours showed no significant difference shown

in table no 6-14.

DISCUSSION

A common obstetrical scenario called PROM refers to the rupture of the foetal membranes prior to the onset of labour, which causes amniotic fluid

Table 1: Mean Age of the Patients

Groups	Mean	SD
A- interventional	27.6	6.1
B- expectant	27.7	6.2

Table 2: Mean duration of the labor

Groups	Mean	SD
A	9.4	4.9
B	13.6	5.7

Table 3: Mean duration PROM

Mean duration of PROM	Mean	SD
Group A	3.1	1.9
Group B	2.9	2.0

Table 4: Distribution of women according to the mode of delivery

Mode of delivery	Group A (n=142)	Group B (n=142)
Vaginal delivery	118 (83%)	101 (71%)
C/section	24 (17%)	41 (29%)

Table 5: Comparison of fetal and maternal outcome in interventional versus expectant management of prelabor rupture of membrane at term

Fetal and maternal outcome	Group A	Group B	P-value
APGAR Score ≤7 **APGAR Score >7**	**9 (6.3%)** **133 (93.6%)**	**13 (9%)** **129 (91%)**	**0.375**
Chorioamnionitis Yes No	 08 (5.9%) 134 (94.1%)	 28 (19.7%) 114 (80.2%)	0.000

Table 6: Stratification of fetal and maternal outcome in both groups with respect to age group (20-28)

Fetal and maternal outcome	Group A	Group B	P-value
APGAR Score ≤7	**06**	**08**	**0.610**
APGAR Score >7	**73**	**73**	
Chorioamionitis Yes	05	17	0.010
No	74	64	

Table 7: Stratification of fetal and maternal outcome in both groups with respect to age group (<28-35)

Fetal and maternal outcome	Group A	Group B	P-value
APGAR Score ≤7	**03**	**05**	**0.488**
APGAR Score >7	**60**	**56**	
Chorioamionitis Yes	03	11	0.024
No	60	50	

Table 8: Stratification of fetal and maternal outcome in both groups in women with parity (1-2)

Fetomaternal outcome	Group A	Group B	P-value
APGAR Score ≤7	**08**	**11**	**0.620**
APGAR Score >7	**98**	**106**	
Chorioamionitis Yes	06	25	0.001
No	100	92	

Table 9: Stratification of fetomaternal outcome in both groups in women with parity (3-5)

Fetomaternal outcome	Group A	Group B	P-value
APGAR Score ≤7	**01**	**02**	**0.562**
APGAR Score >7	**35**	**23**	
Chromoamionitis Yes	02	03	0.392
No	34	22	

Table 10: Stratification of fetomaternal outcome in both groups in women having during of pre-labor rupture of membrane ≤ 3hrs

Fetomaternal outcome	Group A	Group B	P-value
APGAR Score ≤7	**02**	**04**	**0.682**
APGAR Score >7	**74**	**75**	
Chorioamnionitis Yes	02	09	0.057
No	74	70	

Table 11: Stratification of fetomaternal outcome in both groups in women having duration of pre-labor rupture of membrane > 3hrs

Fetomaternal outcome	Group A	Group B	P-value
APGAR Score ≤7	**07**	**09**	**0.599**
APGAR Score >7	**59**	**54**	
Chorioamnionitis Yes	06	19	0.002
No	60	44	

Table 12: Stratification of fetomaternal outcome in both groups in women having duration of labor ≤ 6hrs

Fetomaternal outcome	Group A	Group B	P-value
APGAR Score ≤7	**03**	**03**	**1**
APGAR Score >7	**52**	**47**	
Chorioamnionitis Yes	03	11	0.020
No	52	39	

Table 13: Stratification of fetomaternal outcome in both groups in women having duration of labor >6hrs and ≤12hrs

Fetomaternal outcome	Group A	Group B	P-value
APGAR Score ≤7	**05**	**08**	**0.563**
APGAR Score >7	**62**	**62**	
Chorioamnionitis Yes	04	14	0.021
No	63	56	

Table 14: Stratification of feto- - maternal outcome in both groups in women having duration of labor >12hrs

Feto-maternal outcome	Group A	Group B	P-value
APGAR Score ≤7	**01**	**02**	**1**
APGAR Score >7	**19**	**20**	
Chorioamnionitis Yes	01	03	0.608
No	19	19	

to spontaneously leak[10]. This situation turns a low-risk pregnancy into a high-risk pregnancy.About 95 percent of patients deliver within 28 hours, while 5% of women give birth within five hours of membrane rupture.[11] Approximately 8% of pregnancies experience it. Normally fetal membranes rupture during active phase of labour, if it ruptures it can causes preterm labour, prolonged labour, dry labour, chorioamnionitis (CAM), congenital pneumonia, neonatal infections and even death.[10].

Management of pre labour rupture is effected principally by gestational age, any other complicating factor as non-reassuring fetal status, abruption placentae clinical infection of membranes etc. ACOG JAN 2018[11]

In our study 223 women had parity 1 to 2 and 61 patients had parity 3-5. Age ranged from 20 years to 35 years. The mean age in interventional group was 27.6 + 6.1 years and in expectant group was 27.7 + 6.2 years, as compared to 24.6 years range 16-41yearsand 69.7%were primigravida.[10] In our study maternal outcome i.e. chorioamnionitis was in 08(5.9%) cases in interventional group and in expectant group it was in 28(19,7%) its P value was significant. It was more significant in women with parity 1-2. As compared to a study by Arpita et al maternal morbidity was 26%, causes 11.9%, Chorioamnionitis, 10.5% febrile illness. 30% neonatal infection. No Perinatal mortality was observed in our study as compare to 1.43% ARPITA.[12]

It is observed in our study that 71% went into spontaneous labour and delivered normally, and 83% delivered normally in interventional group,29% delivered by c/s in expectant group and 17% byc/s. AS compared to 27.05% went into spontaneous labour and delivered vaginally . 56.50% delivered by induction and 20% delivered by c/s. AMULYA[13]

In our study fetal outcome i.e. APGAR score < 7 was in 09(6, 3%) cases in interventional group and in expectant group it was in 13(9%) cases.

Future study designs should try to blind outcomes like neonatal and maternal infection and to report these outcomes in a consistent manner. Similrly research studies must incorporate outcomes including maternal satisfaction, maternal and newborn infectious morbidity, other neonatal morbidities, and longer-term child development/disability.

CONCLUSION

Randomized controlled trials have concluded that the interventional management leads to reduced chorioamnionitis as compared to expectant management but did not find the differences in the rates of fetal outcome. Since the differences in outcomes.

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