Title of abstract: PRETERM PRELABOUR RUPTURE OF MEMBRANES AFTER 34 WEEKS – EXPECTANT MANAGEMENT TILL 37 WEEKS VERSUS IMMEDIATE DELIVERY- A NON INFERIORITY RANDOMISED CONTROL TRAIL COMPARING MATERNAL AND NEONATAL OUTCOMES.

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Objectives:

1. To determine whether rates of neonatal sepsis were similar in babies born to women presenting with preterm prelabour rupture of membranes with two types of treatment-namely – immediate delivery versus expectant management until completed weeks of gestation.

2. To determine whether these two approaches will cause significant differences in neonatal and maternal morbidities and mortality.

Methods: This was a prospective, non inferiority randomised control trial to ascertain whether conservative management of preterm prelabour rupture of membranes had similar neonatal and maternal outcomes in comparison to immediate delivery, in pregnant women after 34 weeks of gestation till 37 completed weeks.

All pregnant women reporting to labour room with preterm prelabour rupture of membranes (leaking per vaginum from 34 to 36+6 weeks of gestation) were eligible. All consenting and eligible women were randomized to either the immediate delivery or conservative management group. In the immediate delivery group, induction of labour/caesarean section was carried out as per protocol. If randomized to expectant management group, pregnancy was allowed to continue till 36 completed weeks, in the absence of any maternal/ fetal complications, and induction of labour /LSCS was carried out as per protocol at 37 weeks.
Results: Our study screened 157 patients with preterm prelabour rupture of membranes for eligibility, and 39 patients were recruited into the trial. Of these, 20 patients were randomised to the Immediate Delivery arm and 19 patients were randomised to the Expectant Management arm.

Primary outcome looked at was neonatal sepsis and the difference between the two groups was not statistically significant.

Of the Nineteen patients in the Expectant Management arm, we were able to continue five pregnancies to term, at which time they were induced. Others had to be delivered earlier for various reasons. The mean time gained in utero in the Expectant Management group compared to Immediate delivery was statistically significant (p value 0.04).

The incidence of Chorioamnionitis in the two groups was not statistically significant.

Neonatal outcomes

More babies in the Immediate delivery arm required intensive care, had more morbidity and ultimately higher hospital bills than their counterparts in the Expectant Management arm. There was a statistically significant difference in the rates of neonatal ICU admissions in the Immediate Delivery arm compared to the Expectant Management arm (8 versus 2 babies, p value of 0.03).

Although the mean cost of hospital stay in immediate delivery group is more than thrice in the expectant management group, this was not found to be statistically significant. This could be explained by the small sample size of our study.

Conclusion: In pregnant women presenting with Preterm Prelabour Rupture of Membranes between 34 and 36+6 weeks, the risk of Neonatal sepsis does not increase with Expectant Management upto 37 weeks compared to Immediate Delivery in carefully selected patients. Maternal morbidity/ mortality is not affected by either Immediate Delivery or Expectant Management. Mode of delivery does not differ with either line of management.

Immediate delivery may lead to higher rates of admission to Neonatal ICU, greater morbidity to the baby and higher hospital costs and emotional anxiety for the parents.