Research Article

Induced Labour in Cases of Premature Rupture of Membranes

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Abstract

Background: Expectant management of Premature Rupture of Membranes (PROM) is a routine in most of the centres usually associated with fetal and maternal complications. Active management by inducing labour will decrease the time between PROM and delivery resulting in lower rates of infections.

Objective: To evaluate the clinical effectiveness and safety of the available means of labour induction in cases of pre-labour-rupture of membranes using combination of Misoprostol and intracervical Foley's or Misoprostol alone.

Methods: A Quasi-experimental study, performed in a teaching hospital affiliated with King Edward Medical University Lahore. Women more than 34 weeks of gestation with PROM, singleton, viable foetus with cephalic presentation and no previous caesarean section. After initial evaluation, Subjects included in the study were assessed for Bishop score and those with unfavourable cervix were induced labour with endocervical catheter plus 50 micro grams of intravaginal Misoprostol. The ones with favourable cervix, 50 mcg of Misoprostol was given by oral route. After expulsion of the catheter and in the 2nd group, further augmentation was continued with repeated 4 hourly dose of oral Misoprostol (50 mcg) till the labour was established and after that if required, intra venous Oxytocin infusion was given. Induction to delivery interval, maternal infections like chorioamnionitis, complications noticed during the process like tachysystole and fetal outcome. Aim was to achieve vaginal deliveries within 24 hours and number of C-sections.

Results: A study on 113 patients. Out of these 113, vaginal delivery was achieved in 92.9%. Patients were divided into cervical catheter group (n=46) and Misoprostol group (n=67). Vaginal delivery was achieved in 41(89.1%) in the cervical catheter group and 64 (95.5%) in the Misoprostol only group. Out of the total, 8(7.1%) patients had caesarean sections due to fetal distress and failed progress. There were only minor adverse effects and no case of chorioamnionitis recorded. Fetal outcome was satisfactory.

Conclusion: Induction of labour in cases of PROM is a better option. Oral Misoprostol in a lower dose or transcervical Catheter combined with intravaginal Misoprostol in poor Bishop score, followed by sequential use of oral Misoprostol is relatively safe and there is a greater probability of vaginal delivery < 24 hours.

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Key Words: Induction of labour, low dose Misoprostol, ruptured membranes, transcervical catheter.

Introduction

Premature rupture of membranes PROM is the rupture of membranes before onset of labour. It occurs in 8-10% of pregnancies and its most common complication is chorioamnionitis[1]. So to avoid this complication, labour induction has an important role in this situation.

In about 85-90% of cases with PROM approaching term, labour starts within 24 hours but in about 10-15% of the cases, it takes longer (prolonged rupture of membranes) specially in lesser gestational age[2]. Waiting for spontaneous onset of labour with required feto maternal monitoring is called Expectant management. The risk of intrauterine infection increases

with the duration of ROM. Evidence supports the idea that induction of labour as opposed to expectant management, decreases the risk of chorioamnionitis and there is no increase in the caesarean delivery rate [3].

Active management is needed to enable delivery within 24 hours of PROM. It is associated with better maternal and neonatal outcome[4]. American college of Obstetricians and Gynaecologists suggest that all women with PROM if they have no contraindication to vaginal delivery should have induced labour instead of expectant management. Whether we use Foley's bulb or Oxytocin for this purpose, the induction to delivery interval is always decreased[5].

About 15% of all gravid women have a very poor BISHOP Score, they need cervical ripening before labour induction. There are different methods used for it, including mechanical methods like Foley's catheter and non-mechanical like Prostaglandins. Foley's trans- cervical catheter has been in use successfully for years for this purpose specially in long, firm and tubular cervices[6]. Several trials have presented evidence of the efficacy of intracervical Foley's catheter balloon in comparison to prostaglandins for pre -induction cervical ripening[7].

Misoprostol, a prostaglandin E1 analogue is an alternative induction agent to vaginal Dinoprostone, it is cheap and stable at room temperature and results in fewer Caesarean sections than Oxytocin alone. A dose of 25 mcg 2 hourly or 50 microgram 4 hourly orally has been demonstrated to be effective for induction of labour. When used carefully in such low doses, it appears to have a lower incidence of adverse side effects[8]. Higher or more frequent doses of Misoprostol appear to be less safe both for the mother and for the baby due to higher incidence of tac-hysystole and hyperstimulation[9]. In a recent study carried out to determine the efficacy of induction of labour using a balloon catheter and sequential oral Misoprostol, found a significantly more number of vaginal deliveries as compared to Misoprostol alone[10]. Expulsion of the catheter and effacement of the cervix takes a longer time when used alone as compared to when it is combined with intra vaginal Misoprostol at the time of insertion of Foleys' balloon. A recent study concluded that the most effective cervical ripening agent is vaginal Misoprostol but it has the highest incidence of uterine hyperstimulation with fetal heart rate changes. The use of a Foley's catheter for this purpose has the lowest incidence of such adverse effects[11]. Thus, the use of cervical catheter lowers the number of doses of Misoprostol required for ripening the cervix and results in decreasing the incidence of hyperstimulation syndrome and increasing the rate of vaginal delivery[12].

In our study, we used trans-cervical catheter in uneffaced, long tubular cervix and to further reduce the time taken for cervical ripening, we added 50 mcg intravaginal Misoprostol at the time of Foleys insertion, whereas in favourable cervix, we used only Misoprostol.

Methods:

The study took place in Government Kot Khawaja Saeed teaching Hospital Lahore affiliated with King Edward Medical University from Feb 2015 to Jan 2016 for a period of 1 year. Non probability purposeive sampling technique was used. The sample size was calculated using WHO software taking proportion of vaginal deliveries equal to 75%, confidence level equal to 95% and margin of error equal to 8%[13]. One hundred and thirteen (113) women who came with pre- labour rupture of amniotic membranes during this period with singleton pregnancy of more than 34 weeks, cephalic presentation and normal fetal cardiotocography with no signs of labour. The patients with previous caesarean or uterine scar were excluded from the study.

In each case, detailed evaluation was carried out by complete history, general physical and systemic examination. Diagnosis of ruptured membranes was confirmed by a sterile speculum examination. Vaginal examination was performed under sterile conditions to assess the Bishop score. Fetal well-being was assessed by cardiotocography (CTG).

The informed consent was taken from all the patients included in the study for active management of their condition (PROM) instead of expectant management and only those who agreed were included. Antibiotics and Dexamethasone were given to the patients as per routine according to their requirements. All the women were counselled for induction of labour and depending upon the parity (primiparous or multiparous) and modified Bishop score, mode of induction was decided.

For firm, non-taken up cervices, we passed Foley's catheter in the cervix and the balloon filled with 60 ml of water. Once the leaking of liquor was stopped with the Foley's balloon, 50 micro gram of Misoprostol tab was placed in the posterior fornix in the same sitting.

The patients with the cervical catheter were kept under supervision till the catheter was expelled. Thereafter these patients and all others with Bishop score 6 0r more were given 50 microgram Misoprostol orally with a sip of water (A 200 microgram tablet cut into 4 equal pieces). This dose of 50 microgram was planned to be repeated after 4 hours till the patient developed regular uterine contractions. Further doses of Misoprostol were not given. Instead, they were maintained on oxytocin infusion as required.

Routine intra-partum fetal monitoring was maintained by a sonicaid. Tachysystole (> 5 contractions in 10 minutes) and hypersystole (a contraction lasting for 2 minutes or more) were diagnosed by abdominal palpation and confirmed by CTG. These conditions were managed conservatively by putting the women in left lateral position and continuous CTG. Hyperstimulation syndrome (tachysystole and hypersystole with fetal heart abnormality) was managed by either tocolysis (A nitroderm patch was given for this purpose). If there was no improvement after 30 minutes, patient was planned to proceed for caesarean section.

The primary outcome was the time between the start of induction and delivery (induction delivery interval). The secondary outcomes were number of vaginal deliveries within 24 hours and caesarean sections. The time taken for balloon expulsion and further till complete delivery, intra-partum events like uterine activity, maternal adverse effects like chorioamnionitis. Fetal outcome was assessed by birth weight, APGAR Score < 7 at 5 min and rate of intensive care unit admissions.

The Data analysis was done by using SPSS 23. Frequency and percentage were given for vaginal deliveries, maternal infections like chorioamnionitis, complications and fetal outcome. Chi square and Fisher's exact test was used to compare the proportion of intrapartum vaginal bleeding, uterine hyperstimulation, hyper stimulation syndrome and vaginal deliveries between both groups. A P-value < 0.05 was taken as significant

Results:

Total 113 cases were included in the study in a period from 1st Feb 2015 to 31st Jan, 2016. Age ranged from 20 to 35 years. They were from primigravida to gravid -4.

Bishop score was poor in 46 patients and 6 or more in 67.

Routine side effects of Misoprostol like nausea, vomiting and diarrhoea, were negligible. Pyrexia with shivering was noticed in 1-2 patients but no suspicion of chorioamnionitis was found in any of the case. Tachysystole and hyperstimulation syndrome was found in 13(11.4%) patients in both groups.

Table 1: *Labour and Delivery*

Variables	Catheter + Misoprostol Group (n=46) Frequency (%)	Misoprostol Group (n=67) Frequency (%)	p-value
Intrapartum vaginal bleeding	8 (17.4%)	6 (10.4%)	0.285
Uterine Hyperstimulation	4 (8.7%)	4 (6.0%)	0.714
Hyperstimulation syndrome	2 (4.3%)	3 (4.5%)	0.999
Vaginal deliveries	41 (89.1%)	64 (95.5%)	0.267

As shown in labour profile, induction to delivery interval is upto 16 hours in 69.6% of cervical catheter group. And in 19.6% is within 18-20 hours.

After expulsion of the catheter in catheter group and in Misoprostol only group, delivery process was complete within 6-10 hours in all vaginally delivered cases and rest of the 4 (4.2%) cases had C-Section due to fetal distress 3(7.14%) and 1(2.3%) due to failed progress.

In the Misoprostol only group ,45(67.1%) had delivery within 6-8 hours. 22(32.8%) cases were deli-

vered within 8-12 hours. The delivery process in patients with poor A/S was completed within 20 hours (< 24 hours) and the ones with A/S > 5, it was completed within 6-12 hours.

Table 2: *Labour Profile of Cervical Catheter Group*

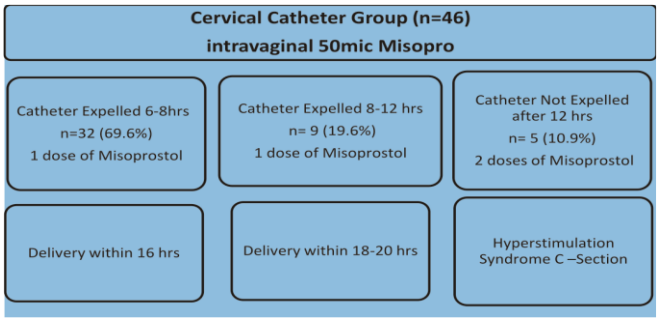
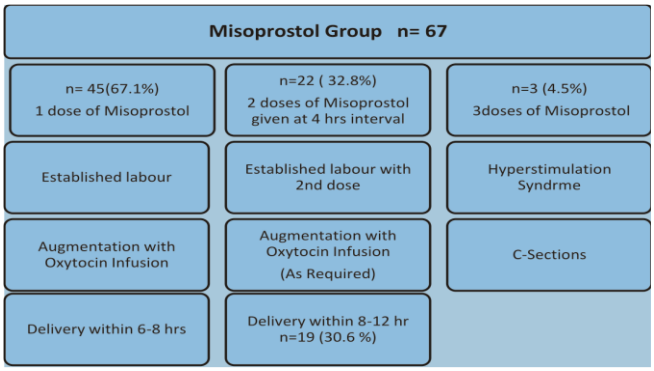


Table 3: *Labour Profile of Misoprostol Group*



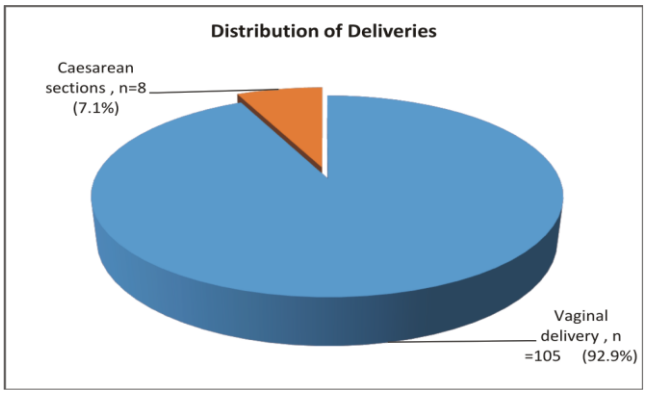


Figure 1: *Distribution of Deliveries*

Table 4: Neonatal Outcomes:

1	Birth weight.	1.8 -3.6 Kg.
2	Apgar score at 5 min (< 7)	8 (7.2%)
3	Referral to neonatal unit.	16 (7.2%)
4	Admission to neonatal unit > 24 hrs.	6 (8.5%)
5	Sepsis.	0
6	Seizures & neonatal deaths.	0

Discussion:

All the patients were managed within 24 hours ending up in vaginal deliveries or caesarean sections as given in the results. Maternal and fetal outcomes were satisfactory. Only minor adverse effects were noticed in the mothers. Neonates had a lower morbidity rate, easily manageable as no neonatal complications were recorded and there was no neonatal death. As a result, overall stay in the hospital was shortened and took quite a load off from the hospitals overfilled beds and overworked staff.

The results given in the labour profile shows that the patients with good BISHOP score required only one to two doses of Misoprostol to establish labour and further augmentation was done with Oxytocin infusion. As a result, 64 patients out of 67 were delivered safely within 6-12 hours of induction. Three patients had c-sections due to hyperstimulation syndrome. Similar results are shown in a systematic review of literature of different clinical trials where vaginal delivery was achieved in < 12 hours using 50 micro grams of Misoprostol[14].

In our study, for ripening of the firm and uneffaced cervix, (n = 46), Foley's catheter was used along with 50 micro grams Misoprostol in the posterior fornix to potentiate mechanical effect of the catheter. The same combination of intracervical catheter and intra vaginal Misoprostol was used in a study, they declared decreased induction time by 2.71 hours (95% CI-4.33 to 1.08, p = 0.001) and at the same time, no evidence of uterine tachysystole and meconium staining was found with this first dose of intravaginal Misoprostol[15]. After expulsion of the Foley 's, further augmentation required only one dose of oral Misoprostol before oxytocin infusion in all 41 patients hence a lower incidence of adverse effects was recorded as the effects are dose related[16]. In 5 patients where catheter was not expelled, it was pulled out through the partially dilated cervix and 2 doses of Misoprostol were given. one patient had a 3rd dose but due to adverse effects, all these five patients had caesarean sections.

There are studies which have a lower incidence of adverse effects but they used an even smaller dose like 25 micrograms of Misoprostol at 4 hourly intervals. They had a 31- 33% incidence of multiparous to primiparous patients who did not achieve delivery

in 24 hours[17]. While in our case, although we used a relatively higher dose i.e. 50 micrograms of Misoprostol 4 hourly, all the cases were delivered (vaginal or operative) within 24 hours.

Our study can be seen in the background of a Meta-analysis of Foleys catheter plus Misoprostol versus Misoprostol alone which showed the similar results i.e reduced time to delivery, reduced frequency of tachysystole with Foetal heart rate changes but they found an increased incidence of chorioamnionitis[18]. We recorded no case of chorioamnionitis. A study by McMaster K performed specially to evaluate if Foley's catheter is a source of infection or not, got the similar results and no case of chorioamnionitis was found[19].

The use of a double balloon catheter for priming the cervix followed by Oxytocin, 6 hours later in a similar population as ours, supports the use of catheter in reducing the induction delivery interval and thus the chance of chorioamnionitis. At the end of the study, they recommended the cervical catheter as a valid method of cervical ripening agent in cases of PROM [20]. Instead of double balloon catheter we used single balloon Foley's bulb but there are studies which prove that single balloon is equally effective for this purpose[21,22].

Although we found pyrexia in 21.3% of the cases during labour but no specific points indicating chorioamnionitis were recorded. Similarly, in a randomized control trial in 2016 comparing the Foleys catheter with misoprostol in term women with PROM found no significant evidence of intrapartum maternal infections with the use of Foley's bulb compared to Misoprostol 2.2% vs 2%[23].

Uterine hyperstimulation and its syndrome was found in 5 patients. Although there was no case of uterine rupture and neonatal outcome was also satisfactory still, we recommend that we should remain vigilant regarding the safety of Misoprostol. Rest of the adverse effects like nausea, vomiting, diarrhoea, shivering and pyrexia were as found in other studies. They were not severe and were self-limiting.

Conclusion:

Active management of PROM by labour induction using any of the safe available inducing agent seems to be a good option. Our experience suggests that oral Misoprostol is acceptable, easy to administer, cheap and easily available but we have to be more careful in its use as compared to the earlier Prostaglandins. Its combination with cervical catheter reduces the required doses of Misoprostol and results in further shortening of the induction delivery interval. Addition of the catheter does not increase the risk of chorioamnionitis.

Ethical Approval: Given
Conflict of Interest: The authors declare no conflict of interest
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