



Outcome of Term Pregnancies with Premature Rupture of Membranes in Whom Labour was Induced with Oral Misoprostol

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Abstract

Aims and Objectives: To study pregnancy outcome in term patients with premature rupture of membranes (PROM) in whom labour was induced with oral misoprostol.

Study Design: The study was a randomized prospective study of 150 cases of pregnant women with singleton pregnancies at and beyond 37 weeks of gestation with induction of labor with oral misoprostol in PROM. Informed consent was taken.

Materials and Methods: The study was carried out in the department of Obstetrics and Gynaecology at a Tertiary care health institute. The study was a prospective study of 150 cases of pregnant women with singleton pregnancies with induction of labor with oral misoprostol in PROM. 150 cases of pregnant women with singleton pregnancies with PROM for induction of labor with oral misoprostol at and beyond 37 weeks of gestation were approached for the study. Study was approved by the ethics committee of the hospital. Informed consent was taken. The outcome was decided into primary and secondary outcome. Primary outcome was measured as PROM-induction interval, PROM-delivery interval and induction to delivery interval. Secondary outcome was measured in terms of mode of delivery, number of doses of drug used, indication of cesarean section, maternal and neonatal complications, adverse effects of drugs like fever, diarrhoea, nausea and others, APGAR score of the neonate at 5 minute, NICU admission and neonatal infection.

Results: Out of the studied patients 8% were in between age group of 18-20 years, 60% were between 21-25 years, 28% were in between 26-30 years and 4% were more than 30 years. Booked cases were 84% and unbooked cases were 16%. Out of these 60% cases were prima and 40% cases were multigravida. Gestational age wise 52% were in between gestational age of 37-39 weeks, 28% were in between 39-40 weeks and 20% cases were having a gestational age of more than 40%. Out of these 1, 2, 3 and 4 doses of misoprostol were required in 20%, 48%, 20% and 12% respectively. Distribution of cases depending upon the doses of misoprostol required and mode of delivery and need for instrumentation revealed that out of 102 cases requiring 1 or 2 doses of misoprostol only 2 patients required instrumentation while out of 39 cases requiring 3 or 4 doses of misoprostol 10 cases needed instrumentation. This was statistically significant. Analysis of misoprostol doses required in relation with maternal complications revealed that

Nausea, vomitings, diarrhea and fever was not statistically significant in relation to the number of misoprostol given while incidence of Post partum hemorrhage was statistically significant in those cases receiving more doses of misoprosolt. Analysis of distribution of cases according to PROM-induction interval revealed that 64% cases took 0-6 hours,24% cases were in between 6-12 hours and 12 % cases required more than 12 hours. The distribution of cases from PROM-Delivery revealed that time required was 0-12hours,12-24 hours and more than 24 hours in 60%,30% and 10% respectively while the time required from induction to delivery was 0-12 hours,12-24 hours and more than 24 hours in 68%,28% and 4% respectively. Amongst the cases studied 69.33% delivered vaginally while instrumentation and LSCS was required in 22.66% and 5.33%respectively. The analysis of distribution of cases of PROM delivery interval in relation to mode of delivery revealed that in cases requiring more than 24 hours from PROM to delivery majority (80%) were those who delivered vaginally. Most common indication of LSCS amongst studied cases was Fetal distress (61.76%). Most common maternal complications were Nausea and vomitings (12%) followed by Fever (6%), Post partumhemorrhage (5.33%) and diarrhoea (2.66%). The duration of PROM delivery and maternal complications were studied where it was found that incidence of PPH was significantly higher (P value < 0.01) if this duration was more than 24 hours. The analysis of delivered babies showed that 8% babies had weight of 2kg or less while thebabies weighing 2.1-2.5 kg and more than 2.5 kg were 52% and 40% respectively. Mostcommon neonatal complications observed were need of antibiotics (32.66%) followed by meconium stained amniotic fluid (19.33%), APGAR score of less than 7 at 5minutes(6%), NICU admissions (6%), Hyperbillirubinemia (4.66%), Neonatalencephalopathy (3.33%) and respiratory distress syndrome(2%). And finally the analysis of cases on the basis of PROM-Delivery Interval in relation with Neonatal complications revealed that the Meconium stained amniotic fluid (23 cases) was most complication if this duration was less than 12 hrs while in cases where this duration was 12-24 hours and more than 24 hours the most common complications seen were need for prophylactic antibiotics (24 cases) and sepsis (11 cases) respectively.

Conclusion: The incidence of Maternal and Neonatal complications increase as the duration of PROM increases in pregnancies with full term gestation in whom labour was induced by misoprostol.

Keywords: *Premature Rupture of membranes, Misoprostol, Primary and secondary Outcome.*

Introduction

Pre-mature rupture of membrane (PROM) at term is one of the most common complications of pregnancy It is defined as rupture of fetal membranes before the onset of labor irrespective of the gestational age ^[1]. In 2013, ACOG published an updated practice guideline for PROM based on the 2007 guideline, recommending the induction of labour immediately after a term PROM diagnosis to reduce maternal and neonatal infections. Even with unfavourable cervix, spontaneous labour starts within 12 hours in most of cases, 50% of women will go in labour after 12 hours, 86% within 24 hours, 94% within 48-95 hours and 6% will not go in labour even within 96 hours of prelabour rupture of membranes ^[2,3,4]. Management of PROM is still controversial and involves a balance between expectant management and intervention. However induction of labour

with prostaglandins compared with expectant management reduces the risk of maternal sepsis and neonatal complications. Active management leads to a shorter interval from PROM to delivery, reducing the risk of maternal and neonatal infection. While it is possible to induce labour in cases of PROM where the gestational age is more than 37 weeks (term) in cases or preterm PROM induction of labour is fraught with complications of prematurity in the newborn babies like hyaline membrane disease, intracranial hemorrhage and necrotizing enterocolitis ^[5,6]. Various agents are available for induction of labour, mainly prostaglandins and oxytocin. They can be used in combination or individually, according to Bishop score. Although oxytocin infusion is accepted widely as a safe and effective labor induction method, its success is highly dependent on the condition of the cervix at the beginning of the induction ^[7]. Prostaglandins are the agents to

soften the unripe cervix independent of uterine activity. Particularly women with poor cervical score can benefit from such approach ^[8]. Misoprostol is a unique prostaglandin E1 analogue, which is rapidly absorbed orally. Its effect on myometrium is mediated by binding to prostanoid receptors in the myometrium. The ease of multiple routes of administration (oral, vaginal, sublingual and rectal) and rapid onset of action make it a better option for induction of labour ^[9]. The advantage of oral misoprostol with particular reference to prelabour rupture of membranes is the avoidance of repeated vaginal examinations to minimize the risk of maternal and fetal sepsis ^[10]. In this prospective study, we have studied pregnancy outcome in term PROM patients induced with oral misoprost.

Material and Methods

This study was a randomized prospective study of 150 cases of pregnant women with singleton pregnancies at and beyond 37 weeks of gestation admitted Obstetrics and gynaecology department of our institute in whom induction of labor was done with oral misoprostol in PROM. The duration of study was 2 years. The sample size of 150 was calculated on the basis of a power of 0.90 and a significance level of 0.05 ^[11].

The study was approved by the Institutional ethical committee. Informed consent was taken before enrolling the patient in the study. 150 cases of pregnant women meeting the criterion of the study were approached for the study. In all patients the cervical score was assessed by Bishop score prior to induction. Detailed obstetrics history and examination was carried out. Abdominal and per speculum examination was done. Vaginal examination to determine bishop score was done. A maximum of six doses of 25 ug of misoprostol were given at 4 hourly intervals. Labor progress was monitored with the help of partograph. If after 6 doses the woman did not go into active labour, the induction was considered as failed induction. Once active labour set in, oxytocin was added for acceleration, if necessary.

They were given antibiotics like amoxicillin, cefotaxime. After establishment of uterine activity augmentation with oxytocin infusion was started if required. Labour was monitored every half hourly by recording uterine activity. Fetal surveillance was done by observing color of liquor and intermittent auscultation of fetal heart. Primary outcome was measured as PROM-induction interval, PROM-delivery interval and induction to delivery interval. Secondary outcome was measured in terms of mode of delivery, number of doses of drug used, indication of cesarean section, maternal and neonatal complications, adverse effects of drugs like fever, diarrhoea, nausea and others, APGAR score of the neonate at 5 minute, NICU admission and neonatal infection. Observations were recorded and descriptive statistics were used for data presentation. Quantitative data was expressed in Mean \pm Standard Deviation and ranges were specified. Chi square/ Fishers' exact test were used to observe the difference between proportions. $P < 0.05$ was considered significant.

Inclusion Criteria: (1) 37 weeks or more gestation. (2) Singleton gestation. (3) Absence of uterine contraction. (4) Cephalic presentation (5) Bishop score less than (6) Live foetus (7) Uncomplicated pregnancy (8) Unscarred uterus (9) Volunteering to participate in the trial.

Exclusion Criteria: (1) Previous cesarean section (2) Scarred uterus (3) Multiple pregnancy (4) Nonreassuring fetal heart tracings (5) Co-existent medical conditions. (6) Known hypersensitivity to prostaglandins (7) Cephalo-pelvic disproportion (8) Abruption placentae or placenta previa (9) Grand multipara (10) Chorioamnionitis

Observations and Results

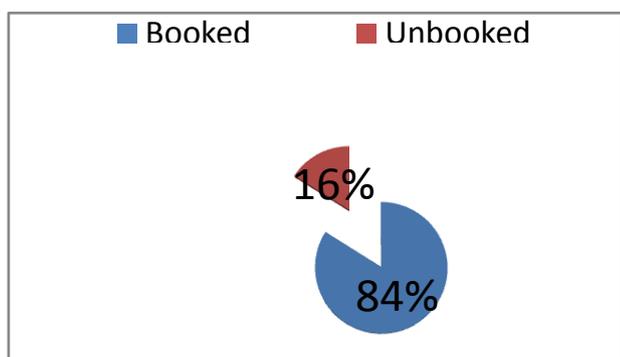
The study was performed on 150 cases of pregnant women with singleton pregnancies at and beyond 37 weeks of gestation with induction of labor with oral misoprostol in PROM, who fulfilled the before mentioned inclusion criteria admitted in Tertiary health care hospital.

Table 1 : Age Wise Distribution of Cases

| Age In Years | No. | Percentage (%) |
|--------------|-----|----------------|
| 18-20 yrs | 12 | 8 |
| 21-25 yrs | 90 | 60 |
| 26-30 yrs | 42 | 28 |
| >30 yrs | 06 | 4 |

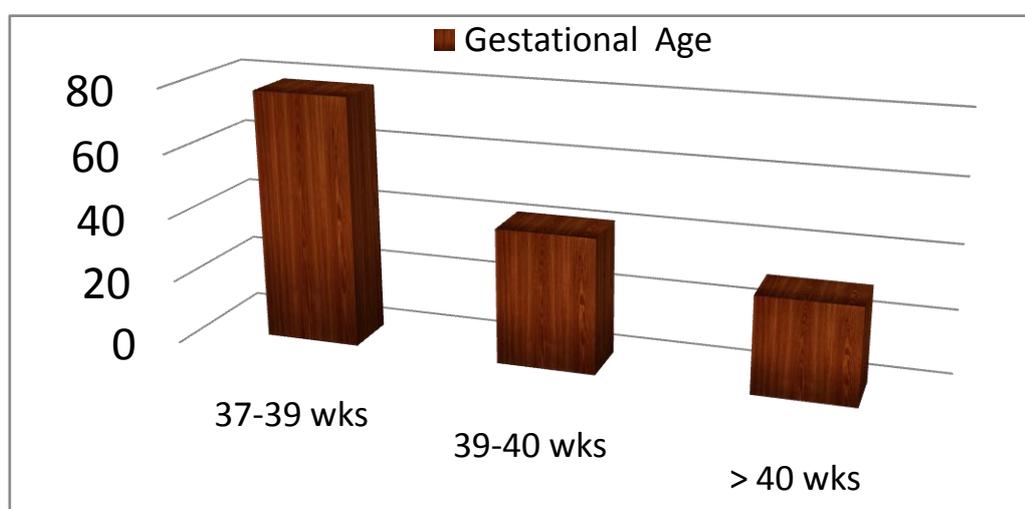
Above table shows age-wise distribution of patients, of which 60% are in age group of 21-25 yrs, 42% are in age group of 26-30 yrs, while 8% in age group of 18-20 yrs, no patient were of less than 18 yrs, >30 yrs of age patient contributed to 4%.

Graph 1: Distribution of Cases According To Anc Visits



Graph 2 : Distribution of patient according to gestational age

This table shows distribution of patients according to gestational age, 52% belongs to 37-39 wks, 28% belongs to 39-40 wks, 20% belongs to above 40 wks and below 42 wks.



Above table shows distribution of patients based on their anc visits, majority of them about (84%) were booked, 16% were unbooked, referral cases contributed to 16% of which all were booked cases.

Table No.2: Distribution of Cases According To Parity

| Parity | No. | Percentage (%) |
|-----------------------|-----|----------------|
| Primigravida | 90 | 60 |
| Multigravida | 60 | 40 |
| • previous abortion | 29 | 19.33% |
| • previous live birth | 31 | 20.66% |

The above table, shows distribution of patients according to parity, 60% were primigravida and 40% were multigravida.

Table No.3: Distribution of Cases According To Number of Doses of Misoprostol

| No. of Doses | No. | Percentage (%) |
|--------------|-----|----------------|
| 1 | 30 | 20 |
| 2 | 72 | 48 |
| 3 | 30 | 20 |
| >4 | 18 | 12 |

Above table shows 48% of patient ,majority of them required 2 doses of misoprostol, 20% required single dose and another 20% required 3 doses, while >4 doses were required by 12%.

Table No.4: Distribution of Cases According To Doses of Misoprostol Required With Mode of Delivery

| Mode Of Delivery | Dosage | | | | | | P VALUE |
|------------------|--------------|-------|--------------|-------|-------------|-------|----------|
| | 1 & 2(N=102) | | 3 & 4 (N=39) | | 5 & 6 (N=9) | | |
| | No. | % | No. | % | No. | % | |
| Vaginal | 92 | 90.19 | 10 | 25.64 | 2 | 22.22 | <0.01,HS |
| Instrumental | 2 | 1.96 | 10 | 25.64 | - | - | <0.01,HS |
| LSCS | 8 | 7.84 | 19 | 48.71 | 7 | 77.77 | <0.01,HS |

p.value= <0.05 -significant (S), p value = <0.01- Highly significant (HS);

p value >0.05= NS- Not significant

This table shows relation of mode of delivery with number of doses of misoprostol. **1&2** doses were required by 102 cases, of which 92 cases(90.19%) delivered vaginally of them 7 cases required augmentation with oxytocin. 1.96% undergone instrumental delivery. 7.84%(8) cases require LSCS of which one required augmentation with oxytocin. **3&4** doses were required by 39 cases, of which 25.64%(10 cases) delivered vaginally of them 2 required augmentation with oxytocin, 25.64% (10 cases) underwent instrumental

delivery, 4 of them required augmentation with oxytocin, 48.71%(19 cases) required LSCS and one of them had augmentation with oxytocin. **5 & 6** doses were required only by 9 cases, of which 22.22% (2 cases) delivered vaginally and they required augmentation with oxytocin, 77.77%(7 cases) had undergone LSCS, in one case augmentation with oxytocin was required.

P value=<0.01,HS, which is statistically highly significant. Thus, it shows that as number of doses increases, there are higher chances of intervention.

Table No.5: Distribution of Cases According To Doses of Misoprostol Required In Relation With Maternal Complications

| MATERNAL COMPLICATIONS | DOSAGE | | | P VALUE |
|------------------------|---------------|--------------|-------------|-----------|
| | 1 & 2 (N=102) | 3 & 4 (N=39) | 5 & 6 (N=9) | |
| NAUSEA,VOMITING | 10 | 5 | 3 | 0.1125,NS |
| DIARRHOEA | 3 | 1 | 0 | 0.8703,NS |
| FEVER | 4 | 3 | 2 | 0.07,NS |
| PPH | 0 | 6 | 2 | <0.01,HS |

p.value= <0.05- significant (S), p value = <0.01- Highly significant (HS); p value >0.05=NS- Not significant

This table shows relation of maternal complications with number of doses of misoprostol. Though they had complications like nausea, vomiting, diarrhoea and fever it is not-significant. This shows that these complications has no relation with number of doses and may be purely due to pharmacological related. Out of 150

cases, 8 cases had pph. Augmentation of labor with oxytocin was done in all these cases. Out of 8 cases, 6 cases required lscs and 2 delivered vaginally. While in case of PPH p value is highly significant which interpret that as number of doses increases there are more chances of pph.

Table No.6: Distribution Of Cases According To Doses Of Misoprostol Required In Relation With Neonatal Complications

| Neonatal Complications | Dosage | | | P VALUE |
|-----------------------------|------------------|-----------------|-------------|-----------|
| | 1 & 2 (N=102) | 3 & 4 (N=39) | 5 & 6 (N=9) | |
| Prophylactic Antibiotic | 8 | 17 | 3 | <0.01,HS |
| Sepsis | 4 | 12 | 5 | <0.01,HS |
| Meconium Staining Of Liquor | 25 | 3 | 1 | 0.06,NS |
| Apgar<7 At 5 Min | 5 | 2 | 2 | 0.1070,NS |
| NICU Admission | 2 | 4 | 3 | <0.01,HS |
| Hyperbilirubinemia | 1 | 3 | 3 | <0.01,HS |
| Neonatal Encephalopathy | 0 | 4 | 1 | <0.01,HS |
| RDS | 3 | 0 | 0 | 0.48,NS |

p.value = <0.05 -significant (S), p value = <0.01 HS- Highly significant ; p value >0.05=NS- Not significant

This table shows relationship between number of doses and neonatal complications. It shows that as the number of doses increases neonatal complications increases which may also be attributed to more duration of PROM. Complications like need of prophylactic antibiotics, sepsis, NICU admission, hyperbilirubinemia and neonatal encephalopathy have p value <0.01 which is highly significant.

Table No.7: Distribution of Cases According To Prom-Induction Interval

| Prom- Induction (Hours) | No. | Percentage (%) |
|-------------------------|-----|----------------|
| 0-6 hour | 96 | 64 |
| 6-12 hour | 36 | 24 |
| >12 hour | 18 | 12 |

Above table shows distribution of patients based on interval between PROM and induction of labour, 64% had PROM-induction interval from 0-6 hrs, 24% of them had PROM-induction interval of 6-12 hrs, 132 cases had PROM-induction interval upto 12 hrs, of which 68.18% (90 cases) delivered within 12 hrs of PROM. 12% cases had PROM-induction interval >12hrs.

Table No.8: Distribution Of Cases According To Prom-Delivery Interval

| Prom-Delivery Interval | No. | Percentage (%) |
|------------------------|-----|----------------|
| 0-12 hrs | 90 | 60 |
| 12-24 hrs | 45 | 30 |
| >24 hrs | 15 | 10 |

Table shows distribution according to PROM-delivery interval, 60% (90 cases) of patient delivered with 12 hrs after onset of PROM, 30% delivered in 12-24 hrs, >24 hrs were taken by 10% of patients, almost 90% of cases delivered within 24 hrs of PROM.

Table No.9: Distribution of Cases According to Induction -Delivery Interval

| Induction-Delivery (Hrs) | No. | Percentage (%) |
|--------------------------|-----|----------------|
| 0-12 hrs | 102 | 68 |
| 12-24 hrs | 42 | 28 |
| >24 hrs | 6 | 4 |

In the above table, 68% of patient delivered within 12 hrs of induction, between 12-24 hrs, 28% of

Table 11 : Distribution of Cases on the Basis of Prom Delivery Interval In Relation With Mode of Delivery

| Mode Of Delivery | 0- 12 Hrs (90) | 12-24hrs (45) | >24 Hrs (15) | P.Value |
|------------------|----------------|---------------|--------------|------------|
| Vaginal | 80 | 21 | 3 | <0.001, HS |
| Instrumental | 3 | 6 | 3 | 0.02, S |
| LSCS | 7 | 18 | 9 | <0.01, HS |

p.value= <0.05 significant (S), p value = <0.01 HS- Highly significant
p value >0.05=NS- Not significant

The above table shows that relationship between mode of delivery and PROM – delivery interval. As seen from above table, p value <0.05 which is significant, so as PROM-delivery interval increases, there are high chances of operative interference, high incidence of instrumental delivery and LSCS are seen in cases of PROM-delivery interval >24 hrs

Table No.12: Distribution of Cases According to Maternal Complications

| Maternal Complications | No. | Percentage(%) |
|------------------------|-----|---------------|
| Nausea and vomiting | 18 | 12 |
| Fever >38° C | 9 | 6 |
| Postpartum hemorrhage | 8 | 5.33 |

patient delivered and 4% patient required >24 hrs for delivery. Majority of them (96%) delivered within 24 hrs of induction.

Table No.10: Distribution of Cases According To Mode Of Delivery

| Mode Of Delivery | No. | Percentage (%) |
|------------------|-----|----------------|
| Vaginal | 104 | 69.33 |
| Cesarean | 34 | 22.66 |
| Instrumental | 12 | 5.33 |

Of total 150 patients in study, above table shows mode of delivery-69.33% delivered vaginally and 22.66% required cesarean section and 5.33 % underwent instrumental delivery.

| | | |
|--------------------------|---|------|
| Diarrhoea | 4 | 2.66 |
| Uterine hyperstimulation | 0 | 0 |
| Uterine rupture | 0 | 0 |
| Chorioaminonitis | 0 | 0 |

Above table shows maternal complications, out of 150 cases, total 39 patient had complications, of which 18 (12%) cases had nausea and vomiting, 9 cases (6%) had fever, 8 cases (5.33%) had postpartum hemorrhage and 4 (2.66%) cases had diarrhoea. No cases of uterine hyperstimulation, uterine rupture and chorioaminonitis were reported.

Table No.13: Distribution of Cases on The Basis Of Prom-Delivery Interval In Relation With Maternal Complications

| Maternal Complicationss | 0- 12 hrs (90) | 12-24hrs (45) | >24 hrs (15) | P VALUE |
|-------------------------|----------------|---------------|--------------|-----------|
| Nausea, vomiting | 8 | 8 | 2 | 0.3210,NS |
| Diarrhea | 4 | 0 | 0 | 0.5630,NS |
| Fever | 4 | 3 | 2 | 0.3962,NS |
| PPH | 0 | 2 | 6 | <0.01,HS |

**p value = <0.05(S)-significant, p value = <0.01 HS-highly significant ,
p value >0.05=NS-not significant**

The above table shows relationship between maternal complications and PROM-delivery interval, incidence of PPH is significantly increased with PROM-delivery interval >24 hrs and that is statistically highly significant.

Table No.14: Distribution of Cases According To Neonatal Complications

| NEONATAL COMPLICATIONS | No. | PERCENTAGE(%) |
|-------------------------------|-----|---------------|
| Need of antibiotic | 49 | 32.66 |
| Prophylactic | 28 | 18.66 |
| Sepsis | 21 | 14 |
| Meconium staining of liquor | 29 | 19.33 |
| APGAR<7 at 5 min | 9 | 6 |
| NICU admission | 9 | 6 |
| Hyperbilirunemia | 7 | 4.66 |
| Neonatal encephalopathy | 5 | 3.33 |
| Respiratory Distress Syndrome | 3 | 2 |
| Neonatal Death | 0 | 0 |
| Stillbirth | 0 | 0 |

Table No.15: Distribution Of Cases On The Basis Of Prom-Delivery Interval In Relation With Neonatal Complications

| NEONATAL COMPLICATIONS | 0- 12 HRS (90) | 12-24 HRS (45) | >24 HRS (15) | P VALUE |
|-----------------------------|----------------|----------------|--------------|-----------|
| Prophylactic antibiotic | - | 24 | 4 | <0.01,HS |
| Sepsis | - | 10 | 11 | <0.01,HS |
| Meconium staining of liquor | 23 | 5 | 1 | 0.02,S |
| APGAR<7 at 5 min | 3 | 3 | 3 | 0.04,S |
| NICU admission | - | 3 | 6 | <0.01,HS |
| Hyperbilirubinemia | - | 2 | 5 | <0.01,HS |
| Neonatal encephalopathy | - | - | 5 | <0.01,HS |
| RDS | 3 | - | - | 0.3604,NS |

p value = <0.05(S)-significant, p value = <0.01 HS-highly significant , p value >0.05=NS-not significant

The above table shows relationship between neonatal complications and PROM-delivery interval, complications like prophylactic antibiotic, sepsis (culture proven), NICU admission, hyperbilirubinemia and neonatal encephalopathy have a highly significant p value, which shows that as PROM-delivery interval increases, incidence of this complication increases, while RDS has p value not significant, it has no association with PROM-delivery interval.

Babies of mother who had PROM-delivery interval more than 24 hrs required antibiotics prophylactically and sepsis which is highly significant. Babies of mother who had PROM-delivery interval more than 24 hrs had rate of NICU admission 40 % which is highly significant as compared to PROM-delivery interval less than 24 hrs. Babies of mother who had PROM-delivery interval more than 24 hrs also had neonatal encephalopathy which is highly significant.

Hence, it is our observation that neonatal complications are more to the babies of mother who had PROM-delivery interval > 24 hrs.

Discussion

Present study was aimed at establishing efficacy of oral misoprostol in patients with pre-mature rupture of membranes at term. Study includes active management of labor in PROM using misoprostol as a drug for inducing labor. Recent trials show that maternal and neonatal infectious morbidity is significantly reduced by induction of labor, compared with expectant management^[11]. Using oral misoprostol for labor induction reduces the frequency of vaginal examinations and allows use of intravenous line only later in labor and therefore the patients may not have felt restricted in early stage of labor. This may partly explain the increased satisfaction in this study. For this study, the cases were selected from all groups. Maternal age related with PROM ranged from 18-35 years. The most common age group was 21-25 years. The mean age of our study was 24.34±3.41. Ezechi et al in their study, mean age was 26.4±

5.3 and the mean age in Maskey S et al^[12] was 25.32±3.82, which were comparable.

In our study 90 cases of primigravida (60%) and 60 cases of multigravida (40%) were present with PROM. BUTT et al^[13] had 65.45% cases of primigravida and 34.55% cases of multigravida. FATIMA A, NAZ M, et al.^[14] showed similar figure, with 61% cases belonging to primigravida and 39% cases to multigravida.

In our study 150 cases were during the gestational age 37-42 weeks. Majority of cases, 78 cases were of gestational age between 37-39 weeks. The mean gestational age was 38.82±1.26. BUTT et al^[13] had mean GA of 39.4±1.4, Ezechi et al in their study, mean GA was 38.7±2.73, the mean GA in Maskey S et al^[12] was 39.2±1.26. FATIMA A, NAZ M, et al^[14] had mean GA of 39±1.72 which were comparable.

In our study the average dose of misoprostol required was 2.3, comparable to Datta Mamta Rath et al^[15] it was 3. In the present study, 20% required one dose of misoprostol, 48% required 2 doses. Humaira Zaman Malik^[16] one dose was required by 32% and 68% required two doses, but here each oral dose consisted of 100 microgram. FATIMA A, NAZ M, et al^[14] -one dose was required by 35%, 2 doses were by 39% and >3 doses were by 26%, here each dose was of 50 microgram. In the study conducted by Gupta et al^[17] 25 microgram vaginally upto 3 maximum doses were given, in this study, one dose was required by 42%, 2 doses by 30%, 3 doses by 28%. In other studies majority of patient required low no of doses, because dose was higher than present study. While in Gupta^[17] same dose as that of this study was used, but route was different. This can be explained by the fact that misoprostol given vaginally takes longer to start working, has a lower peak concentration after 60 min, but a more sustained effect. Thus, smaller doses are needed when misoprostol is inserted vaginally. This also explains the incidence of tachysystole 26% and uterine hyperstimulation 4% in Gupta while no cases are found of

tachysystole and uterine hyperstimulation in the present study.

In the present study, PROM-induction interval mean was 5.46 ± 3.58 , comparable to Maskey S et al ^[12] where mean was 6.15 ± 2.83 . In this study, delivery was achieved within 12 hours in 90 patients (60%). The results of the present study are 15.5 ± 6.8 , the mean PROM-delivery interval. The results of the present study are comparable with the study done by Mamta et al ^[15], wherein it was noted that the mean time interval for PROM to delivery was 18.10 hours in induction group. The results of the present study are also similar to the study conducted by Maskey S et al ^[12], where in it was noted that the mean time interval for PROM to delivery was 14.23 ± 4.84 hours in induction group. Cheng ^[18], the mean time interval was 14.5 ± 6.2 , Shanthi ^[19] had the mean time interval between 11.46 ± 6.01 , Yazdani ^[20] showed the mean interval of 14.3 ± 3.4 hrs.

Comparable to Gupta ^[17] in which mean birth weight was 2.67 ± 0.358 kg. and Maskey S et al ^[13] in which mean birth weight was 2.9 ± 0.42 . The meconium staining of liquor was seen in 19.33% in our study, comparable to FATIMA A, NAZ M, et al ^[14] in which meconium staining of liquor seen in 19%. The increased incidence of meconium staining of liquor with misoprostol does not seem to affect the newborn adversely. In Datta Mamta Rath et al ^[15] APGAR < 7 at 5 min was seen in 6.6%, in agreement to our study in which APGAR < 7 at 5 min seen in 6%. NICU admission was seen in 6% of our study, in agreement with Gupta ^[17] it is seen in 6%.

We did not have any stillbirth and neonatal mortality, but 5 babies had neonatal encephalopathy, but in all these 5 cases, there was PROM-delivery interval > 24 hrs.

Conclusion

In this prospective study, we have studied pregnancy outcome in term PROM patients induced with oral misoprostol. The incidence of Maternal and Neonatal complications increase as the duration of PROM increases in pregnancies

with full term gestation in whom labour was induced by misoprostol. PROM of more than 24 hours was found to be adversely affecting neonatal outcome in our study.

Conflict of interest: None

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