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STUDY TO EVALUATE THE EFFICACY OF OXYTOCIN AND VAGINAL MISOPROSTOL FOR LABOUR INDUCTION IN PREMATURE RUPTURE OF MEMBRANES (PROM)

Obstetrics & Gynaecology

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ABSTRACT

Background: Pre-labour rupture of fetal membrane (PROM) is a common obstetric condition complicating about 3-18% of pregnancies. Some reports favor early induction of labour based upon the fact that the risk of maternal and neonatal infection increases the longer the duration of rupture of membrane. It reduces perinatal mortality rate and number of mature unexplained still birth. Present study was carried out to study the maternal and fetal outcomes in induces labour with Pitocin and misoprostol in PROM patients.**Methodology:** Study was conducted on 292 patients presented with PROM. Patients who have PROM, are routinely given Vaginal misoprostol (25 µg at 4-hour interval) (Group I) or IV oxytocin (5IU in 500 ml NS starting at a dose of 4 drops/min) (Group II). The primary study outcome is time from onset of induction to vaginal delivery (IDI). Also, onset of labour, induction method, modes of delivery, Maternal outcome, neonatal outcome were assessed.**Results:** Average duration of induction to delivery of group II was significantly more (9.12±1.59 hours) than that of group II (13.7±2.51 hours). Average Duration of active phase of labour of group II was more (5.11±1.40 hours) than that of group II (5.19±1.99 hours). Birth asphyxia was more in group I (61.11%) and MSL was more common in group II (27.77%) had MSL. Most common maternal complication was PPH both in group I was (13.71%) and in group II (8.8%). Occurrence of complications was significantly more in group I. Duration of different stages labour was also significantly more in group I. **Conclusion:** The present study emphasizes that with better method of induction labour can progress uneventfully in most patients resulting in more normal vaginal deliveries and lesser incidence of caesarean sections and instrumental deliveries than as previously reported. Our study demonstrates that intravaginal misoprostol results in a lesser interval from induction of labor to delivery when compared to IV oxytocin in patients of Pre-labour rupture of membranes.

KEYWORDS

Ectopic pregnancy, Methotrexate, β-hCG levels.

INTRODUCTION:

Pre-labour rupture of fetal membrane (PROM) is a common obstetric condition complicating about 3-18% of all pregnancies. [1] Some reports favor early induction of labour based upon the fact that the risk of maternal and neonatal infection increases the longer the duration of rupture of membrane (ROM), others have shown that expectant management is safer and more successful in achieving vaginal delivery.[2,3] Now a days the hopeful expectancy is replaced by an active management of labour. Partogram can be used as a useful aid for this purpose. [1] Data from the National Centre for Health Statistics for the last decade indicate that the rate of labour induction has increased many folds. Reasons for this jump in the induction rate are better planning of birth by the physician, patient and her family. [1]

Usually, the risk of perinatal morbidity and mortality increases progressively with increase in the gestational period i.e., beyond 37 weeks. Induction between 37 to 41 weeks' gestation gives good neonatal outcome. [2] Timely induction can reduce the vital events i.e., maternal mortality or morbidity and ensure a healthy baby. Elective induction of labour might contribute not only to reduction in perinatal mortality rate but also in number of mature unexplained still birth. Induction of labour helps to reduce the number of fetal deaths due to placental insufficiency caused by the prolongation of pregnancy beyond 40 weeks.[3]

WHO defines normal birth as: spontaneous in onset, low risk at the start of labour and remaining so throughout labour and delivery.[4] To be successful, induction of labour must result in labour namely adequate uterine contractions and progressive dilatation of cervix, labour should result in vaginal delivery, as there is little purpose in bringing about labour as a mere preparation for caesarean section and in viable pregnancies, these aims must be achieved with minimum discomfort and risk to both mother and foetus.[5,6]

Present study was carried out to study the maternal and fetal outcomes in induces labour with Pitocin and misoprostol in PROM patients.

OBJECTIVES:

1. To evaluate the effectiveness of vaginal misoprostol versus intravenous oxytocin in women with PROM
2. To assess the rate of risks, include fetal hypoxia and asphyxia, uterine rupture, fluid retention, PPH and amniotic fluid embolism associated with the use of vaginal misoprostol and oxytocin infusion.

MATERIAL AND METHODS:

The present observational study was conducted on 292 patients aged between 18 to 60 years presenting with PROM in OPD of Department of Obstetrics and Gynaecology at a tertiary care hospital at district place in central India. Between July to January 2022. Patient information like sociodemographic factors, clinical findings, fetal hypoxia and asphyxia, uterine rupture, fluid retention, PPH and related information was collected.

Written informed consent was taken before start of the study. Predesigned, pre-tested, structured proforma was used. In our hospital, patients who have PROM, are routinely given Vaginal misoprostol (25 µg at 4-hour interval) (Group I) or IV oxytocin (5IU in 500 ml NS starting at a dose of 4 drops/min) (Group II), the efficacy of both were observed. Local examination (P/V) to confirm diagnosis of PROM, presentation, position station, and assessment of the Bishop's Score was carried out. The primary study outcome is time from onset of induction to vaginal delivery (IDI). Also, onset of labour, induction method, modes of delivery, Maternal outcome, neonatal outcome were assessed. The collected data was compiled in Microsoft Excel 2010 and analyzed using SPSS software. Appropriate statistical tests were used.

RESULTS

In the present study, the average age of group I and II was 23.11±2.35 and 23.65±2.61 years respectively, average height of group I and II was 155.19±4.92 and 156.06±4.36 meter respectively. Average weight of group I and II was 63.17±3.76 and 62.64±3.61 Kg respectively and average gestational age of group I and II was 38.80±0.96 and 40.03±0.26 weeks respectively. The difference in above characteristics was not statistically significant and groups were comparable. (Table 1)

Table 1. Baseline Characteristics Of The Study Population:

Baseline Characteristics		Group I	Group II
Age (Years)	≤20 Years	25 (17.12%)	19 (13.02%)
	21 to 25 Years	98 (67.13%)	92 (63.01%)
	>25 Years	23 (15.75%)	35 (23.97%)
	Mean Age	23.11±2.35	23.65±2.61
Height (Meter)	≤150 m	34(23.29%)	24 (16.43%)
	151 to 155 m	41(28.08%)	37 (25.34%)
	>155 m	71(48.63%)	85 (58.21%)

	Mean Height	155.19±4.92	156.06±4.36
Weight (Kg)	50 to 55 Kg	00(00%)	01 (0.68%)
	56 to 60 Kg	47(32.19%)	52 (35.61%)
	>60 Kg	99(67.81%)	93 (63.69%)
	Mean Weight	63.17±3.76	62.64±3.61
Gestational Age (weeks)	≤40 weeks	139(95.21%)	79 (54.11%)
	>40 weeks	7(4.79%)	67 (45.89%)
	Mean Gestational Age	38.80±0.96	40.03±0.26
Total		146(100%)	146 (100%)

Table 2 shows that average Duration of Induction to delivery of group II was significantly more (9.12±1.59 hours) than that of group II (13.7±2.51 hours). Average Duration of active phase of labour of group II was more (5.11±1.40 hours) than that of group II (5.19±1.99 hours). Mode of delivery of was vaginal delivery was more common in both groups. LSCS in group I was significantly less (15.76%) than that of group II (32.88%). Instrumental delivery of was similar in group I (6.51%) as well as in group II (8.16%) (p value =0.31) (Table 2)

Table 2. Details Of Delivery Of The Patients:

Details of delivery of the patients		Group I	Group II
Duration of Induction to delivery in hours	≤10	102 (69.86%)	28 (19.18%)
	>10	44(30.14%)	118(80.82%)
	Mean	9.12±1.59	13.7±2.51
Duration of active phase of labour (hours)	≤5	109(74.66%)	81(55.48%)
	>5	33(22.60%)	51(34.93%)
	Didn't achieve active phase of labour	4(2.74%)	14(9.59%)
	Mean	5.11±1.40	5.19±1.99
Mode of delivery	Vaginal	123(84.24%)	98(67.12%)
	LSCS	23(15.76%)	48(32.88%)
Method used in Vaginal delivery	Normal	115(93.49%)	90(91.84%)
	Instrumental	8(6.51%)	8(8.16%)
Reason for LSCS	Foetal distress	11(47.82%)	11(22.92%)
	Failure of induction	4(17.39%)	14(29.16%)
	Maternal request	1(4.34%)	11(22.92%)
	Non progress of labour	6(26.08%)	11(22.92%)
	Persistent occipito-posterior position	1(4.34%)	1(2.08%)
Total		146(100%)	146(100%)

Most common reason for LSCS in group I was Foetal distress (47.82%) followed by failure of induction (17.39%). Also, common reason for LSCS in group II was Foetal distress (22.92%) followed by failure of induction (29.16%). The difference between groups was statistically significant. (p value=0.0003)

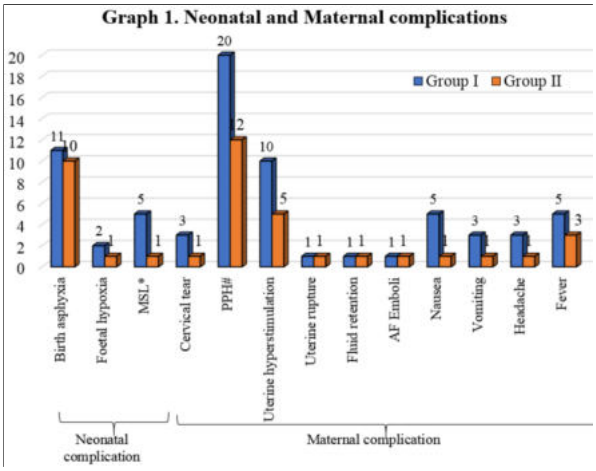
Table 3. APGAR Score And NICU Admission:

APGAR Score And NICU Admission		Group I	Group II
Average APGAR score at 1 min	<4	3(2.06%)	10(6.85%)
	4 to 7	19(13.01%)	8(5.48%)
	>7	124(84.93%)	128(87.67%)
	Mean APGAR Score	6.58±1.01	6.61±1.08
Average APGAR score at 5 min	4 to 8	18(12.33%)	12(8.22%)
	>9	128(87.67%)	134(91.78%)
	Mean APGAR Score	8.77±0.64	8.75±0.86
NICU admission	Yes	18(12.33%)	12(8.22%)
	No	128(87.67%)	134(91.78%)
Total		146(100%)	146(100%)

Average APGAR score at 1 min and 5 min of group II (6.58±1.01 and 8.77±0.64) was similar to that of group II (6.61±1.08 and 8.75±0.86). NICU admission were also similar in group I (12.33%) and group I (8.22%) (Table 3).

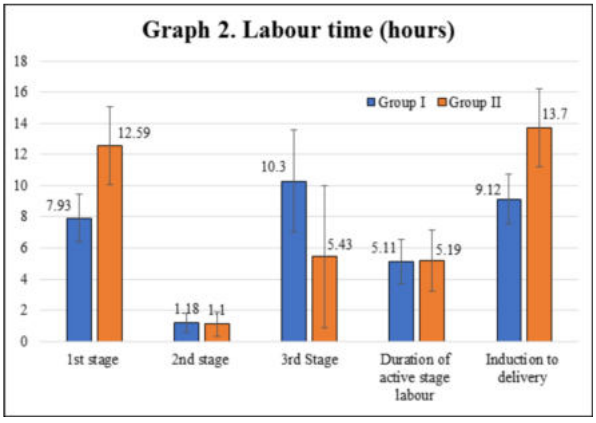
Graph 1 shows that in group I, most common neonatal complication was birth asphyxia seen in 61.11% neonates, 11.11% had foetal hypoxia, 27.77% had MSL. In group II, 83.33% neonates had birth asphyxia, 8.33% had foetal hypoxia and 8.33% had MSL. The difference between groups was not significant (p value =0.39)

In group I, most common maternal complication was post-partum haemorrhage seen in 20(13.71%) followed by Uterine hyper stimulation in 10(6.85%)patients. In group II also, most common maternal complication was post-partum haemorrhage seen in 12(8.8%) followed by Uterine hyper stimulation in 5(3.42%) patients. Other complications were cervical tear, uterine rupture, fluid retention , amniotic fluid emboli, nausea, vomiting, headache and fever. Occurrence of complications was more in group I, compared to group II and the difference was statistically significant (p value <0.05).



*MSL – Meconium Stained Liquor,
#PPH – Post Partum Hemorrhage

Duration of different stages labour was also more in group I compared to group II and the difference was significant (p value <0.05) (Graph 2)



DISCUSSION

In the present study, we had two groups, each group contain 146 pregnant patients. Group I was given vaginal misoprostol and group II was given I.V. oxytocin.

We had maximum patients from 21 to 25 Years. **Acharya T et al** [61] showed that majority 44.4% were in age group of 20 to 24 years. Most of the patients had gestational age ≤40 weeks. **Acharya T et al** [61] showed that majority 45.9% had gestational age 41 weeks. Average Duration of Induction to delivery of group II was significantly more (9.12±1.59 hours) than that of group II (13.7±2.51 hours). Similar study by **Singh A et al** [6] showed that average duration was 6.08±2.3 hours. In study by **Şahin Zeteroğlu et al** [47], the mean interval from induction to delivery was 10.61 ± 2.45 hours in the misoprostol group and 11.57 ± 1.91 hours in the oxytocin group (p = 0.063).

Vaginal delivery was more common in both groups. Mode of delivery of was LSCS in group I was significantly less (15.76%) than that of group II (32.88%). Study by **Chaubey S et al** [3] showed that majority had vaginal delivery in both groups. Similar results were seen in present study. Study by **Yadav P et al** [5] showed that majority had vaginal delivery among both the groups. (P=0.02), shows statistical significance. Similar study by **Singh A et al** [6] showed that majority delivered vaginal among both the groups. (p=0.00) Study by **Abisowo OY et al** [45] showed that among both groups' majority delivered vaginally. P<0.0001, shows significance. In study by **Şahin Zeteroğlu et al** [47] and **Datta Mamta et al** [48] showed similar findings.

Present study shows that, among those who delivered vaginally in both groups, majority had normal vaginal delivery but some needed instrumental delivery (5.47% in both groups respectively). Study by **Yadav P et al** [5] showed that only 6.7% needed instrumental delivery. In present study between group I and II it was seen that foetal distress was the common reason for LSCS. Similar study by **Singh A et al** [6] showed that indication for LSCS were cephalopelvic disproportion, fetal distress and failure to progress. (p=0.00) shows significance. Study by **Abisowo OY et al** [45] showed that main reason for LSCS was cephalopelvic disproportion followed by fetal distress among both groups. P=0.03. Similar findings were seen in present study.

Average APGAR score at 1 min and 5 min of group II (6.58±1.01 and 8.77±0.64) was similar to that of group II (6.61±1.08 and 8.75±0.86). NICU admission were also similar in group I (12.33%) and group I (8.22%) (Table 3). Study by **Abisowo OY et al** [45] showed that mean APGAR at 1 min of control group was 6.3±1.4 and induced group 6.2±1.4. **Wing DA et al** [49] showed that mean APGAR at 5 min of control group was 8.4±1.3 and induced group 8.33±1.2.

In in group I, most common neonatal complication was birth asphyxia seen in 61.11% neonates, 11.11% had foetal hypoxia. In group II, 83.33% neonates had birth asphyxia, 8.33% had foetal hypoxia. The difference between groups was not significant (p value =0.39) In study by **Yadav P et al** [5] it was seen that cervical tear was in only induced cases. P=1

Similar to present study, study by **Chaubey S et al** [3] showed that mean duration of 3rd stage among induced females was 4.78±1.34 min and among non-induced was 8.79±3.59 min. Study by **Lin M et al**[45] did a systematical review and found that Misoprostol was similar to oxytocin with respect to vaginal delivery less than 24 hours.

The duration of induction to delivery time in present study, in patients induced with vaginal misoprostol was less in comparison to patients induced with IV oxytocin. **Leila Pourali et al** [51] showed that first group underwent Oxytocin infusion according to low-dose standard protocol and the second group received 25 μg sublingual Misoprostol every 4 h. Time interval from induction to the beginning of active phase of labour was similar in both groups. Second stage of labour was significantly shorter in misoprostol group ($p < .05$).

CONCLUSION:

The present study emphasizes that with better method of induction labour can progress uneventfully in most patients resulting in more normal vaginal deliveries and lesser incidence of caesarean sections and instrumental deliveries than as previously reported. Our study demonstrates that intravaginal misoprostol results in a lesser interval from induction of labor to delivery when compared to IV oxytocin in patients of Pre-labour rupture of membranes.

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