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Research Article

A comparative study of maternal & neonatal outcome and patient satisfaction with intravaginal misoprostol versus intravenous oxytocin in patients with premature rupture of membranes beyond 36 weeks gestation

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ABSTRACT

Background: Premature rupture of membranes (PROM) occurs in about 10% of patients beyond 36 weeks of gestation. In this situation, labor induction with prostaglandins, has been proved to be beneficial and results in decreased chorioamnionitis, neonatal antibiotic therapy, neonatal intensive care (NICU) admission, and increased maternal satisfaction. Many techniques for induction of labor are available. This prospective randomized comparative study was thus taken up to compare the outcomes of misoprostol versus oxytocin with respect to the maternal and neonatal outcomes and patient satisfaction.
Methods: A prospective randomized study was carried out where 200 women admitted to department of obstetrics & gynecology, Pravara Rural Hospital, PMT, Loni with PROM beyond 36 weeks of gestation were included where 100 each were included in two groups- vaginal misoprostol group & oxytocin infusion group.
Results: Nearly 58% of the cases of PROM were in the age group 21-25 yrs. Vaginal deliveries were 42% in misoprostol group, where as 44% in oxytocin group; whereas LSCS were 7% in misoprostol group and 5% in oxytocin group. Maximum number of cases had APGAR score between 7-10 in both the groups. Patients with misoprostol induction were more satisfied as compared to patients with oxytocin induction.
Conclusions: Labor induction with oxytocin infusion for PROM beyond 36 weeks in an unfavorable cervix is associated with longer duration of the second stage and a higher risk of cesarean delivery for failure to progress in comparison to those with transvaginal misoprostol. Patients with misoprostol induction were more satisfied as compared to patients with oxytocin induction.

Keywords: PROM, Oxytocin, Misoprostol, Patient satisfaction

INTRODUCTION

Premature rupture of membranes (PROM) occurs in about 10% of patients beyond 36 weeks of gestation.[1-3] In this situation, labour induction with prostaglandins, has been proved to be beneficial and results in decreased chorioamnionitis, neonatal antibiotic therapy, neonatal intensive care (NICU) admission, and increased maternal satisfaction.

Induction of labour is indicated when it is agreed that the fetus or mother will benefit from a higher probability of a healthy outcome than if birth is delayed.

Many techniques for induction of labour are available. Intravenous oxytocin infusion has stood the test of time as labour inducing agent but associated with increased risk of perinatal & maternal morbidity. More recently misoprostol is gaining increasing interest as an alternative induction agent.[4] Advantages of misoprostol include effectiveness, low cost and ease of administration because it is given intravaginally rather than in the endocervix.

Studies suggest that vaginal misoprostol is effective as a cervical ripening and labour induction agent. Compared with intravenous oxytocin, labour induction using vaginal

prostaglandins in women with PROM results in a higher rate of vaginal delivery within 24 hours, a significant reduction of induction-to-delivery intervals and an increased maternal satisfaction.[5-8]

Further research is needed to identify the preferred dosage, route and interval of administration, and to assess uncommon maternal and neonatal outcomes. There has been limited research on the use of prostaglandins, including misoprostol, for induction of labour with an unfavourable cervix and ruptured membranes.

This prospective randomized comparative study was thus taken up to compare the outcomes of misoprostol versus oxytocin with respect to the maternal and neonatal outcomes and patient satisfaction.

Aims and Objectives

1. To find out and compare the maternal and neonatal outcome between two groups of patients- One with intravaginal misoprostol and other with intravenous oxytocin.
2. To assess and compare the maternal (patient) satisfaction in them.

METHODS

The purpose was to compare maternal & neonatal outcome and to assess & compare the patient satisfaction in 2 groups of patients viz. vaginally administered misoprostol with intravenous oxytocin in women with premature rupture of membranes beyond 36 weeks gestation.

Study Design: Prospective, randomized study.

Study Group: 200 women which were admitted in the Department of Obstetrics and Gynecology, Pravara Rural Hospital, PMT, Loni with prelabour rupture of membranes beyond 36 weeks of gestation enrolled for the study out of which 100 cases allotted to 2 groups:

1. Vaginal misoprostol group
2. Oxytocin infusion group

Methodology of the study

Women who presented to Pravara Rural Hospital during a period of 2 years with spontaneous rupture of the membranes beyond 36 weeks' gestation were enrolled for a comparative study of the maternal and neonatal outcome and patient satisfaction between vaginally administered misoprostol and oxytocin infusion.

Patients were randomly assigned to group A [Intravaginal misoprostol] and group B (IV oxytocin) at random using computer generated randomized tables for the purpose of study, keeping in mind the inclusion and exclusion criteria.

Written informed consent was taken for induction of labour in all cases.

Group A: Intravaginal Misoprostol Group

Treatment Protocol with Misoprostol

50 micrograms of misoprostol was placed in the posterior vaginal fornix and repeated every four hourly till effective uterine contractions are achieved. A maximum dose of 150 μg was given.

Group B: Intravenous Oxytocin Group

Treatment Protocol with IV Oxytocin

Oxytocin was administered intravenously by a standardized incremental infusion protocol. Starting with a small dose of 2 units in 500 ml of RL at 8 drops per minute and accelerated till adequate contractions were achieved. A maximum dose of 22 mU per minute for multigravida and 40 mU per minute for primigravida were given.

Selection Criteria

A. Inclusion Criteria

1) Premature rupture of membrane as defined.
2) Absence of active labour or fetal distress.
3) Singleton pregnancy with vertex presentation and no known hypersensitivity to prostaglandins.
4) No contraindication to vaginal delivery.

B. Exclusion Criteria

1) Hypersensitivity to prostaglandins.
2) Previous caesarean section.
3) Previous major uterine surgery.
4) CPD.
5) Patient with fetal distress.
6) Medical conditions like heart disease, asthma and glaucoma.
7) Patients not giving consent.

The data was analyzed using SPSS for windows and the variables were compared and associated using Z test (for difference between means and proportions) and χ^2 test.

RESULTS

A total of 200 subjects were included in the study, 100 in each group treated with misoprostol and oxytocin. The Figure 1 shows the incidence of PROM in different age groups. Nearly 58% of cases were in the age group of 21-25 years. The distribution of subjects in both groups A and B in the above age group was similar. This reflects the average child-bearing age of most women in our country.

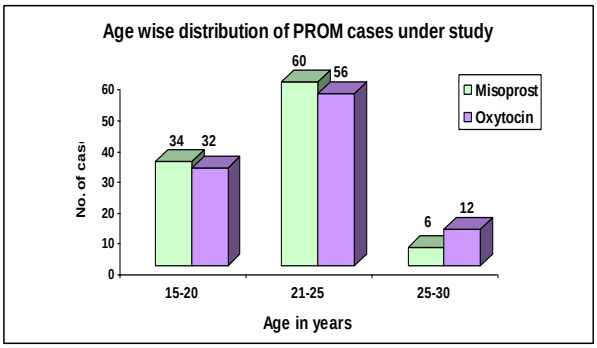

Figure 1: Age wise distribution (Years).

Table 1: Gestational age wise distribution (Weeks) (n=200).

Gestational Age (Weeks)	No. (%)
37	42 (21%)
38	53 (26.5%)
39	46 (23%)
40	38 (19%)
41+	21 (10.5%)

The Table 1 shows the incidence of PROM in different gestational age groups. There is not much difference of PROM cases in different age groups.

Table 2: Parity wise distribution.

Parity	Group A Misoprostol (n=100)		Group B Oxytocin (n=100)		Total (200)	
	No.	(%)	No.	(%)	No.	(%)
Primi	66	(33%)	54	(27%)	120	(60%)
Multi	34	(17%)	46	(23%)	80	(39%)
Total	100	(50%)	100	(50%)	200	(100%)

Value of χ^2 = 1.5, d. f. =1, p>0.05

The Table 2 shows PROM prevalence in different parity. Maximum cases were primigravida (60%) others were 40%. When the chi squared test was applied to find out association between the variables, there was no statistically significant association found (Value of χ^2 = 1.5, d. f. =1, p>0.05).

Vaginal deliveries were 42% in misoprostol group, where as 44% in oxytocin group. Whereas LSCS were 7% in misoprostol group and 5% in oxytocin group. Instrumental deliveries were 1% in both groups. So it can be said that mode of deliveries was almost similar in both the groups.

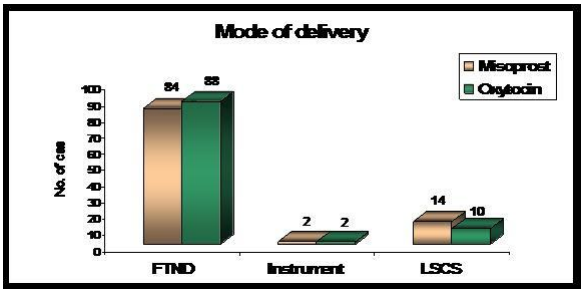

Figure 2: Mode of delivery in both groups (Misoprostol Vs Oxytocin).

When an association was tested between vaginal delivery, operative inference and drug, no significant association was found using chi squared test (Value of χ^2 = 0.374, d.f. = 1, p>0.05).

Table 3: Relationship of parity to success rate in both groups (Misoprostol Vs Oxytocin).

Parity	Group A Misoprostol (n=100)	Group B Oxytocin (n=100)
Primi	81.09%	83.04%
Multi	88.03%	93.05%

Out of 66 primigravida in misoprostol group 54 delivered vaginally, and out of 34 multigravida, 30 delivered vaginally; whereas in oxytocin group 45 primigravida delivered vaginally out of 54, and 43 multigravida delivered out of 46. The difference between the 2 groups was not found to be statistically significant using Z test (standard error of difference between 2 proportions).

Table 4: APGAR score wise distribution of cases in both groups (Misoprostol Vs Oxytocin).

APGAR Score	Group A Misoprostol (n=100)		Group B Oxytocin (n=100)	
	1 min	5 min	1 min	5 min
0-3	00	00	00	00
4-6	03	00	05	00
7-10	42	50	50	50

The above table reveals one and five minutes APGAR score between two drugs under study**.**

There was no case of APGAR score between 0-3 in both the groups. Maximum number of cases had APGAR score between 7-10 in both the groups.

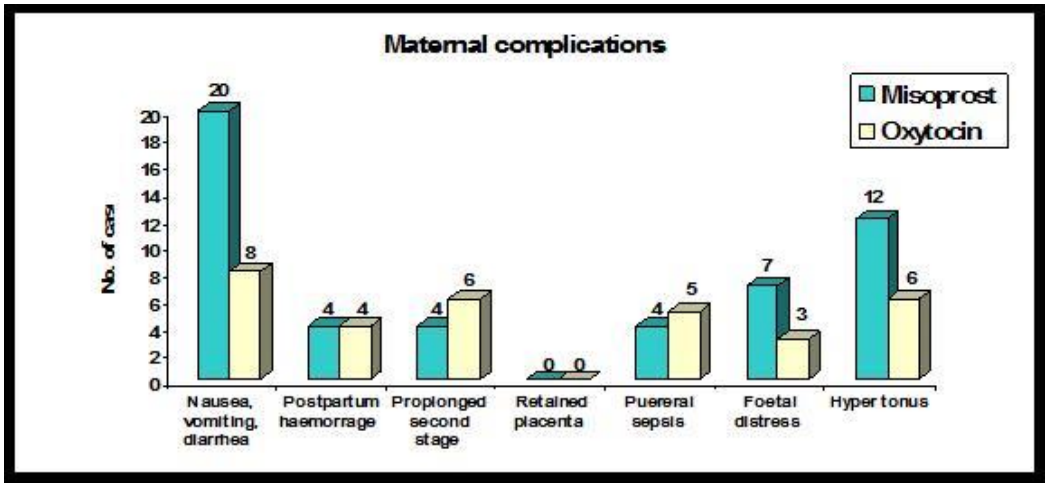

Figure 3: Maternal complications wise distribution of cases in both groups (Misoprostol Vs Oxytocin).

Nearly 20 misoprostol treated patients had GI symptoms where as in oxytocin group it was only in 8 (Figure 3).

Incidence of hypertonicity was more with misoprostol (6%) as compared to oxytocin (3%). Incidence of puerperal sepsis/ PPH/ retained placenta was almost same in both groups.

The Table 5 shows neonatal complications while using both groups. Incidence of hyperbilirubinemia with oxytocin was 10% as compared to misoprostol (4.5%).

Table 5: Neonatal complications in both groups (Misoprostol Vs Oxytocin).

	Group A Misoprostol		Group B Oxytocin	
	Cases	(%)	Cases	(%)
Hyperbilirubinemia	09	(4.5%)	20	(10%)
Respiratory Distress	06	(3%)	08	(4%)
Neonatal Infection	04	(2%)	05	(2.5%)
Mortality	00	00	00	00

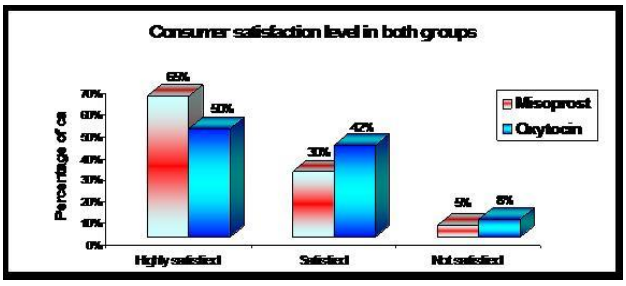

Figure 4: Consumer satisfaction level in both groups (Misoprostol Vs Oxytocin).

The Figure 4 shows that there was difference in consumer satisfaction level in both groups. Patients with misoprostol induction were more satisfied as compared to patients with oxytocin induction. This may be because of restricted mobility in case of oxytocin induction groups.

DISCUSSION

Several prospective randomized trials of women with PROM at a gestational age of 36 weeks or more and an unfavorable cervix have been carried out in the past. Patients were randomized either to induction with oxytocin infusions within 12 hours after amniorrhexis or to hospitalization for expectant management until spontaneous labor occurred or until there was evidence of intraamniotic infection. Women undergoing immediate induction were more likely to require cesarean delivery (20% vs. 8%) and developed intraamniotic infections (16% vs. 4%) than women managed expectantly. The majority of cesarean deliveries in the induction group were performed for failed induction with no change in cervical status after 12 hours of oxytocin infusion.[9,10]

Wing DA et al similarly compared immediate induction to expectant management for an indefinite period in women with PROM at 36 weeks or more of gestation & found a statistically significant reduction in cesarean deliveries (21% vs. 7%) and intraamniotic infections (12% vs. 4%) in the group of women managed expectantly.[2] In the same study it was noted that there were no significant differences between treatment groups in terms of tachysystole or hypertonus incidence or in the frequency of abnormal fetal heart rate tracings. Zeteroğlu S et al revealed uterine contraction abnormalities as 8.3% in the misoprostol group and 8.2% in the oxytocin group.[11]

Some authors have observed that the incidence of uterine tachysystole or hypertonus in the frequency of abnormal fetal heart rate tracing were different between the groups;

it was more prevalent in the misoprostol group. Our findings also confirm the same.

Compare to other study like Wing DA et al in which caesarean section in misoprostol group was 13.03% as compared to oxytocin group 14.1% and it was not consistent with present study. The difference may be due to different dosage regimen.

In present study incidence of puerperal sepsis is almost same for both groups, there were 5.00% cases in misoprostol group and 4.00% cases in oxytocin group. Sanchez-Ramos L et al and other studies carried out in other part of world, there were no much cases of puerperal sepsis were seen.[8] There study was not consistent with present study, as present study was carried out with rural area. Because of pre existing general condition and hygiene status of patients, prevalence of anemia in this part of world there were more incidence of puerperal sepsis in our study in spite of broad spectrum antibiotics.

Our study showed no differences between the groups regarding Apgar score at the fifth minute of life and perinatal results. The majority of studies have shown that when perinatal results are evaluated by means of Apgar score, cord pH, admission to intensive care unit, number of days of hospitalization, meconium passage syndrome or hyperbilirubinemia, there are no differences between the groups, which confirms the findings of the present study.[2,5]

In present study there was a higher incidence of hyperbilirubinaemia in oxytocin group 20 cases, as compared to misoprostol group i.e. 9 cases.

The present study revealed that respiratory distress in oxytocin group was found in 8 (4%) cases & that in misoprostol group was 6 (3%). In a series by Sanchez-Ramos L et al also there was slightly higher incidence of respiratory distress in misoprostol group 12% as compared to oxytocin group 10%.[7]

CONCLUSION

Labor induction with oxytocin infusion for PROM beyond 36 weeks in an unfavorable cervix is associated with longer duration of the second stage and a higher risk of cesarean delivery for failure to progress in comparison to those with transvaginal misoprostol. Misoprostol is an effective and safe agent for induction of labor in women with term premature rupture of membranes. When compared with oxytocin, the risk of contraction abnormalities and the rate of maternal and neonatal complications were similar among the 2 groups. Patients with misoprostol induction were more satisfied as compared to patients with oxytocin induction.

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Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

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