

A COMPARATIVE STUDY OF LABOUR INDUCTION WITH INTRAVAGINAL MISOPROSTOL VERSUS INTRAVENOUS OXYTOCIN IN PREMATURE RUPTURE OF MEMBRANES BEYOND 36 WEEKS GESTATION

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DOI: 10.5455/ijmsph.2013.210420133

Received Date: 22.03.2013

Accepted Date: 21.04.2013

ABSTRACT

Background: The recommended strategies for a woman with PROM at term have changed considerably during the last several decades. PROM occurs in about 10% of patients beyond 36 weeks of gestation. IV oxytocin infusion has stood the test of time as labor inducing agent but associated with high perinatal and maternal morbidity. Misoprostol is gaining increasing interest as an alternative induction agent.

Aims & Objective: (1) To study the efficacy and safety of labor induction with Intravaginal misoprostol and i.v. oxytocin in women with premature rupture of membranes beyond 36 weeks of gestation. (2) To evaluate & compare the efficacy between vaginally administered misoprostol with i.v. oxytocin.

Material and Methods: A prospective randomized study was carried out where 200 women admitted to department of obstetrics & gynaecology, 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. No significant association was found between prevalence of PROM with parity. It was seen that lesser the pre induction bishop's score, more was the time required for a patient to go into active labor. The induction-delivery interval was significantly higher in oxytocin group compared to misoprostol group.

Conclusion: Misoprostol is a better inducing agent than oxytocin in low bishop's score & unfavourable cervix. Misoprostol is an effective & safe agent for induction of labor in women with PROM.

KEY-WORDS: Premature Rupture of Membranes; Oxytocin; Misoprostol; Bishop's Score; Induction Delivery Interval; Parity

Introduction

The recommended management strategy for a woman with PROM at term has changed considerably during the last several decades, partly because of concomitant improvements in the identification and treatment of maternal and neonatal infections and partly because of an improved understanding of the impact of various interventions on maternal and neonatal outcome. Premature rupture of membranes (PROM) occurs in about 10% of patients beyond 36 weeks of gestation.^[1-3]

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. It appears to be an effective method of labour induction with term PROM.^[4] Advantages of misoprostol include effectiveness, low cost and ease of administration because it is given intravaginally rather than in the endocervix. This study was therefore taken up to compare the outcomes of misoprostol versus Oxytocin infusion for labour induction in women with pregnancy beyond 36 weeks of gestation with premature rupture of membranes.

Aims and Objectives

1. To study the efficacy & safety of labour induction with intravaginal misoprostol and intravenous oxytocin in women with

premature rupture of membranes beyond 36 weeks gestation.

- To evaluate and compare the efficacy between vaginally administered misoprostol with intravenous oxytocin.

Materials and Methods

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:

- Vaginal misoprostol group
- Oxytocin infusion group

Selection Criteria

- 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.
- 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.

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 effectiveness of 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): Fifty micrograms of misoprostol was placed in the

posterior vaginal fornix and repeated every four hourly till effective uterine contractions were achieved. A maximum dose of 150 µg was given.

Group-B (Intravenous Oxytocin Group): 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.

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 X² test.

Results

The table-1 shows the incidence of PROM in different age groups. There were 58% cases in 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 child-bearing age of most women in our country.

Table-1: Age Wise Distribution of the Subjects with PROM (N=200)

Age in Years	Group A Misoprostol No. (%)	Group B Oxytocin No. (%)	Total (N=200) No. (%)
15-20	34 (17%)	32 (16%)	66 (33%)
21-25	60 (30%)	56 (28%)	116 (58%)
25 above	06 (03%)	12 (06%)	18 (09%)
Total	100 (50%)	100 (50%)	200(100%)

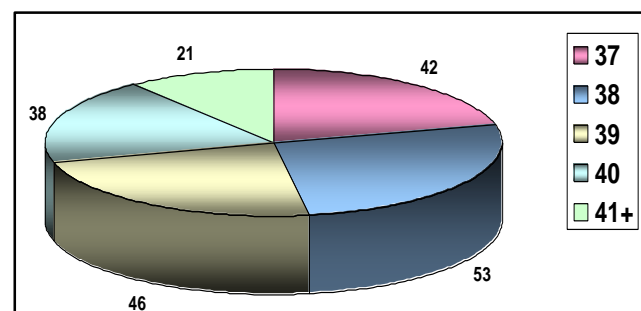


Figure-1: Gestational Age Wise Distribution of Subjects (Weeks) (n=200)

The figure-1 reflects the incidence of PROM in different gestational age groups. There is not much difference of PROM cases in different age groups. The figure-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 statically significant association found (Value of $\chi^2 = 1.5$, d. f. =1, $p > 0.05$)

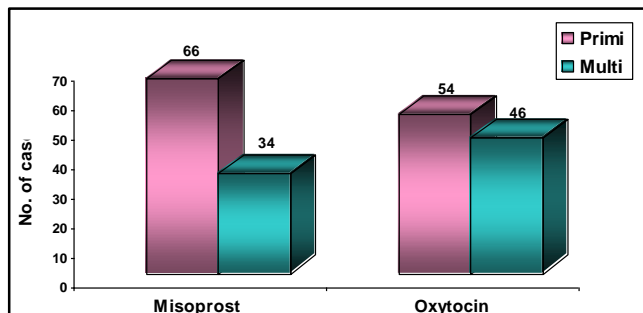


Figure-2: Parity Wise Distribution of the Subjects (Weeks) (n=200)

The table-2 reveals distribution of cases under both drugs according to pre induction Bishop’s score. Less than 4 Bishop’s Score (0-3) was found in 58% of the cases in misoprostol group and 48% in oxytocin group. Whereas 38% and 50% cases of misoprostol and oxytocin group respectively were having 4-6 Bishop’s Score.

Table-2: Pre Induction Bishop’s Score wise Distribution of Cases in Both Groups (Misoprostol Vs Oxytocin)

Score	Group A: Misoprostol (n=100)		Group B: Oxytocin (n=100)	
	Primi No. (%)	Multi No. (%)	Primi No. (%)	Multi No. (%)
0-3	40 (20%)	18 (09%)	20 (10%)	24 (12%)
4-6	22 (11%)	16 (08%)	34 (17%)	16 (08%)
7-9	02 (01%)	02 (01%)	04 (02%)	02 (01%)
10-13	00 (00%)	00 (00%)	00 (00%)	00 (00%)
Total	64 (32%)	36 (18%)	58 (29%)	42 (21%)

The table-3 reveals that lesser the pre induction Bishop’s Score, more is the time required for the patient to go into active labour, irrespective of the drug used. It was noted, that with Bishop’s Score of 0-3, average time required for patient to go in active labour with misoprostol was 4.30 hours and with oxytocin was 6.30 hours. With Bishop’s Score of 4-6, average time required for patient to go in active labour with misoprostol was 4.00 hours and with oxytocin was 6.00 hours. The above findings also suggest that the time required is lesser when patient is induced with misoprostol (Std. error of difference= 4.63, $p < 0.0001$).

It was observed, that the mean induction delivery interval with misoprostol was 8.5 hours and with oxytocin was 9.3 hours and this difference is

statistically significant using std error of difference between two means (std. error of difference= 4.637, $p < 0.0001$). (Table 4)

When the means induction delivery time interval was compared between the groups, it showed that the induction to delivery interval was longer in oxytocin group 7.17 ± 1.20 hours in primigravida and 6.06 ± 1.09 hours in multigravida. Whereas, in misoprostol group 6.61 ± 1.06 hours in primigravida and 5.27 ± 1.11 hours in multigravida. This difference between the 2 groups was found to be ($p < 0.05$) statistically significant (using t test). (Table 5)

Table-3: Relationship of Pre Induction Bishop’s Score and Onset of Active Labour in Both Groups (Misoprostol Vs Oxytocin)

Bishop’s score	Group A (hours) Misoprostol (n=100)	Group B (hours) Oxytocin (n=100)
0-3	4.30	6.30
4-6	4.00	6.00
7 and above	3	5
Mean	3.87	5.77

Table-4: Relationship of Bishop’s Score to Induction Delivery Interval in Both Groups (Misoprostol Vs Oxytocin)

Bishop’s score	Group A (hours) Misoprostol (n=100)	Group B (hours) Oxytocin (n=100)
0-3	09.45	10.45
4-6	9.00	9.45
7 and above	7.15	8.00
Mean	8.5	9.3

Table-5: Average Induction - Delivery Time Interval in Both Groups (Misoprostol Vs Oxytocin)

Parity	Group A Misoprostol Mean \pm SD	Group B Oxytocin Mean \pm SD	t value	p value	Result
Primi	6.61 \pm 1.06	7.17 \pm 1.20	1.99	$p < 0.05$	Significant
Multi	5.27 \pm 1.11	6.06 \pm 1.09	2.24	$p < 0.05$	Significant

Discussion

Numerous prospective trials have sought to compare the effects of immediate induction with those of expectant management in women with PROM at term and an unfavorable cervix. These studies may seem conflicting but are however consistent with one another when similar protocols for expectant management are compared. Specifically, some studies have prospectively compared early induction to expectant management until the point of either delivery or infection.[2,4-7]

Purpose of the present study was to compare vaginally administered misoprostol (Cytotec) with intravenous oxytocin for labor induction in women with premature rupture of membranes beyond 36 weeks' gestation in two hundred women who presented to Pravara Rural hospital. Wing D A et al in a similar study 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%, $P < 0.001$) and intraamniotic infections (12% vs. 4%, $P < 0.01$) in the group of women managed expectantly. Several studies found that the majority of women managed expectantly began spontaneous labor within 24 to 48 hours following prelabor amniorrhexis.^[2]

The present study showed that the average time interval to the onset of labor and also to the occurrence of vaginal delivery was longer in oxytocin group as compared to misoprostol group (6.61 ± 1.06 hours and 7.17 ± 1.20 hours) and (5.27 ± 1.11 hours and 6.06 ± 1.09 hours in primigravida and multigravida respectively (the difference was significant). These same results have also been found by many other authors like Morgan Ortiz F et al where average induction delivery interval in misoprostol was 11 hours and in oxytocin was 18 hours. These findings are consistent with our results.^[8]

In present study, it was observed that the induction delivery interval in multigravida was lesser than primigravida with unfavourable cervix in both the groups. With misoprostol it is 54.54% and 67.67%, and with oxytocin 43.45% and 52.33% in primigravida and multigravida respectively. Reason may be, because in primigravida cervix is tubular and unfavourable with less bishop score. As, we have seen misoprostol is known to cause ripening of unfavourable cervix by increasing activity of collagenase and increasing proportion of low affinity glycosaminoglycans compared to high affinity glycosaminoglycans. So increase success rate in prostaglandin group is due to changing unfavourable cervix to more favourable cervix for induction of labour. Other study like AA Sobande et al carried out in Soudi Arabia, is consistent with

present study. Where mean \pm SD in primigravida was (01.21 ± 0.47), and multigravida was (3.47 ± 0.125) and which was significant and consistent with our study.^[9]

Conclusion

Misoprostol is better inducing agent than oxytocin in low Bishop's Score and unfavourable cervix. Misoprostol is an effective and safe agent for induction of labor in women with term premature rupture of membranes. Misoprostol is an alternative agent for induction of labour at term in viable pregnancy. Vaginal application of 50 μ g every 4 hours results in more vaginal deliveries within 24 hours and a faster induction to delivery time than oxytocin infusion

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Cite this article as: Shah B, Nagar N, Nagar S. A comparative study of labour induction with intravaginal misoprostol versus intravenous oxytocin in premature rupture of membranes beyond 36 weeks gestation. *Int J Med Sci Public Health* 2013; 2:632-635.

Source of Support: Nil

Conflict of interest: None declared