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Original 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

Anuradha Kumari[1], Alpna Bansal[2]

[1]PG-Student, Department of Obstetrics and Gynaecology, Government Medical College & Maharani Hospital, Jagdalpur (C.G.), India

[2]Professor and HOD, Department of Obstetrics and Gynaecology, Government Medical College & Maharani Hospital, Jagdalpur (C.G.), India

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Corresponding author: Dr. Alpna Bansal
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Abstract

Aim: The aim of the present study was to compare the outcomes of misoprostol versus oxytocin with respect to the maternal and neonatal outcomes and patient satisfaction.

Methods: The Prospective, randomized study was conducted in the Department of Obstetrics and Gynaecology, Government Medical College & Maharani Hospital, Jagdalpur (C.G.), India for two years. 100 women which were admitted in the Department of Obstetrics and Gynecology, Government Medical College & Maharani Hospital, Jagdalpur (C.G.), India with prelabour rupture of membranes beyond 36 weeks of gestation enrolled for the study out of which 50 cases allotted to 2 groups.

Results: There was not much difference of PROM cases in different age groups. Maximum cases were primigravida (62%) others were 38%. There was no statistically significant association found. 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. There was one and five minutes APGAR score between two drugs under study. Incidence of hyperbilirubinemia with oxytocin was 10% as compared to misoprostol (4%).

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.

Keywords: PROM, Oxytocin, Misoprostol, Patient satisfaction

Introduction

It is common practice to induce labour in an effort to enhance maternal and infant health outcomes and lower incidence of caesarean births, prolonged labour, gestational hypertension, and postpartum haemorrhage. [1] Prelabor rupture of the membranes (PROM) occurs when the fetal membranes rupture before the onset of labor. About 8% of term pregnancies are complicated by this, and the most serious maternal consequence is intrauterine infection, the risk of which rises with the duration of the membrane rupture. [2] A 2017 Cochrane systematic review comparing expectant care for PROM at term vs planned early delivery (with induction of labour) found that planned early birth reduced the risk of maternal infectious morbidity without appearing to increase the chance of caesarean section. [3]

In comparison to other widely used techniques (oxytocin, Foley catheter, amniotomy), the use of prostaglandin for cervical ripening in women with low Bishop scores has been shown to be more effective. [4] Nevertheless, uterine tachysystole, hyperstimulation syndrome, alterations in foetal heart rate (FHR), and uterine rupture are all more common. [5] Despite that, prostaglandins, including misoprostol, are still recommended for induction of labour (IOL), and result in fewer cesarean sections than oxytocin alone, as concluded by the Cochrane systematic review. [6] This conclusion was reached by Pourali et al. in their study, which found that

sublingua l misoprostol for IOL in PROM cases is more efficient than oxytocin and has superior neonatal outcomes. [7] Misoprostol taken orally or sublingually is an appealing option for IOL since it is affordable, heat stable, and simple to use. [6,7]

On the other hand, oxytocin, the most widely used induction agent globally, is the agent of preference suggested in cases of PROM by the American College of Obstetricians and Gynecologists [2], likely due to its higher safety profile. Moreover, the study by Kulhan found that oxytocin was more efficient than vaginal dinoprostone in achieving vaginal birth within 24 h of induction in term pregnancies with PROM. [8] Oxytocin and prostaglandins are most frequently used pharmacological agents for induction of labor. [9] Although oxytocin infusion is widely accepted 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.

The aim of the present study was to compare the outcomes of misoprostol versus oxytocin with respect to the maternal and neonatal outcomes and patient satisfaction.

Materials and Methods

The Prospective, randomized study was conducted in the Department of Obstetrics and Gynaecology, Government Medical College & Maharani Hospital, Jagdalpur (C.G.), India. 100 women which were admitted in the Department of Obstetrics and Gynecology, Government Medical College & Maharani Hospital, Jagdalpur (C.G.), India with prelabour rupture of membranes beyond 36 weeks of gestation enrolled for the study out of which 50 cases allotted to 2 groups:

1. Vaginal misoprostol group

2. Oxytocin infusion group

Methodology of the study

Women who presented to 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 □g 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.

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.
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 $\chi 2$ test.

Results

Table 1: Gestational age wise distribution (Weeks)

Gestational Age (Weeks)	No. (%)
37	22 (22%)
38	25 (25%)
39	24 (24%)
40	18 (18%)
41+	11 (11%)

There was not much difference of PROM cases in different age groups.

Table 2: Parity wise distribution

Parity	Group A Misoprostol (n=50)		Group B Oxytocin (n=50)		Total (100)	
	No.	(%)	No.	(%)	No.	(%)
Primi	34	34	28	28	62	62
Multi	16	16	22	22	38	38
Total	50	50	50	50	100	100

Maximum cases were primigravida (62%) others were 38%. There was no statistically significant association found.

Table 3: Mode of delivery in both groups (Misoprostol Vs Oxytocin)

Mode of delivery	Group A Misoprostol (n=50)		Group B Oxytocin (n=50)		Total (100)	
	No.	(%)	No.	(%)	No.	(%)
Vaginal	42	42	44	44	86	86
Instrument	1	1	1	1	2	2
LSCS	7	7	5	5	12	12
Total	50	50	50	50	100	100

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.

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

APGAR Score	Group A Misoprostol (n=50)		Group B Oxytocin (n=50)	
	1 min	5 min	1 min	5 min
0-3	00	00	00	00
4-6	2	00	2	00
7-10	21	25	25	25

There was one and five minutes APGAR score between two drugs under study.

Table 5: Neonatal complications in both groups

Neonatal complications	Group A Misoprostol		Group B Oxytocin	
	Cases	(%)	Cases	(%)
Hyperbilirubinemia	2	4	5	10
Respiratory Distress	2	4	2	4
Neonatal Infection	1	2	1	2
Mortality	00	00	00	00

Incidence of hyperbilirubinemia with oxytocin was 10% as compared to misoprostol (4%).

Discussion

Premature rupture of membranes (PROM) occurs in about 10% of patients beyond 36 weeks of gestation. [10-12] 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. [13] Advantages of misoprostol include effectiveness, low cost and ease of administration because it is given intravaginally rather than in the endocervix.

Sanchez-Ramos L et al [14] found that there were no much cases of puerperal sepsis were seen. 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. [11,15] There was not much difference of PROM cases in different age groups. Maximum cases were primigravida (62%) others were 38%. There was no statistically significant association found. 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. There was one and five minutes APGAR score between two drugs under study. Incidence of hyperbilirubinemia with oxytocin was 10% as compared to misoprostol (4%). Sanchez-Ramos L et al [14] also there was slightly higher incidence of respiratory distress in misoprostol group 12% as compared to oxytocin group 10%.

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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