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Original Research Article.

To Assess the Safety and Efficacy of Misoprostol Administered Vaginally For Induction of Labour in Patient with PROM with Poor Bishop's Score

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ABSTRACT

Background: The management of PROM has often been a dilemma in obstetrics. This study is aimed to assess the safety and efficacy of misoprostol administered vaginally for induction of labour in patient with PROM with poor Bishop's Score.

Materials & Methods: A randomised observational study done on 90 Patients of PROM admitted in labour room of Mahila Chikitsalaya, SMS Medical College, Jaipur as per inclusion and exclusion criteria. Augmentation with oxytocin was done in patients with favourable bishop score (>5) with mild uterine contraction or patients with poor bishops score (<5) even after 3 doses of misoprostol. If leaking of more than 24 hours and unfavourable cervix (bishop <5) or any evidence of foetal distress then further management was at the discretion of attending obstetrician.

Results: Our study showed that the mean induction delivery interval was 7.67±4.86hours & 78 patients (86.7%) delivered within 12 hours after induction in patient of PROM. Apgar score of new born babies at 1 min in majority was 8 – 10 min. (81.1%) and at 5 min in majority was 8-10 (98.9%).

Conclusion: Misoprostol maximum of 75µg is an effective method of improving the inducibility score and induction of labour in properly selected cases. Misoprostol in above doses is without any untoward effect on maternal and foetal outcome and hence, safe.

Keywords: Misoprostol, PROM, Apgar Score, Induction , Vaginal, Labour, Foetus.

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INTRODUCTION

Premature rupture of membranes (PROM) is a syndrome characterized by rupture of foetal membranes (chorion and amnion) before the onset of labour. Membrane rupture that occurs before 37 weeks of gestation is referred to as preterm premature rupture of membranes (PPROM). Although term PROM results from the normal physiological process of progressive weakening, preterm PROM can result from an array of pathological mechanisms acting individually or in consert.[1] Most Indian studies report an incidence of PROM between 7 to 12 percent of which 60-70% occurs at term.[2]

Management of PROM generally includes induction of labour, if contractions did not begin within 6-12 hours. Such interventions evolved approximately 60 years ago because of maternal and foetal complications due to chorioamnionitis Calkins (1952).[3] Several investigators have reported a significant increase in perinatal loss and maternal morbidity associated with PROM.

The management of PROM has often been a dilemma in obstetrics. Despite a relative explosion of studies on the subject in recent obstetric literature, only a few controversies surrounding the subject have been resolved. Different regimens are followed in different centres all over the world for management of PROM. Stimulation with oxytocin is more likely successful if cervix is favourable (Bishop's Score >6). In unfavourable cervix it takes time for establishment of labour, renders patient non-ambulatory and requires careful titration. Prostaglandins have been shown to induce cervical ripening and stimulate uterine contractions and have been found to be effective in numerous clinical trials at a variety of doses and routes of administration.[4]

Misoprostol is a methyl ester of prostaglandin E_1 additionally methylated at C-16 and is marketed for use in the prevention and treatment of peptic ulcer disease caused by prostaglandin synthetase inhibitors. It is inexpensive, easily stored at room temperature and has fewer systemic side effects.

Misoprostol has been shown in several studies to be an effective myometrial stimulant of the pregnant uterus, selectively binding to EP-2/EP-3 prostanoid receptors.[5] Because of its uterotonic and cervical ripening actions, misoprostol has been used for induction in the third trimester.

The WHO manual 'Managing Complications in Pregnancy and Childbirth'[6] recommends the use of misoprostol for induction of

labour and places it in its list of 'Essential Drugs' and also present in the official WHO list of essential drugs.[7]

This study is aimed to assess the safety and efficacy of misoprostol administered vaginally for induction of labour in patient with PROM with poor Bishop's Score.

MATERIALS & METHODS

A randomised observational study done on 90 Patients of PROM admitted in labour room of Mahila Chikitsalaya, SMS Medical College, Jaipur as per inclusion and exclusion criteria.

Inclusion Criteria

1. All pregnant women with spontaneous rupture of membranes confirmed by demonstrating vaginal pooling of amniotic fluid at initial p/s examination and with positive litmus paper test.
2. Primigravida
3. Gestational age at or more than 37 weeks to 40 weeks
4. Singleton pregnancy
5. Cephalic presentation
6. No regular uterine contraction (less than 6 contractions/hour)
7. No evidence of fetal distress
8. Maternal oral temperature less than 37.5 degree C.
9. Bishop's score (less than 5)

Exclusion Criteria

1. Less than 37 completed weeks of gestation (Preterm)
2. Foetal congenital malformations
3. Intra uterine growth restriction (IUGR)
4. Symptoms and signs suggestive of chorioamnionitis with maternal temperature more than 37.5 degree C.
5. Meconium stained liquor at the time of admission
6. Cord prolapsed at the time of admission
7. Prior uterine surgery(myomectomy)
8. Bad obstetric history.
9. Antepartum hemorrhage
10. Cephalopelvic disproportion.
11. Dai handled patients
12. Medical disorder of pregnancy Hypertension/ Diabetes Mellitus/ Asthma/ Cardiac disease / ICP Etc.

Methods: Detailed history of past medical and present pregnancy was taken of all admitted patients and detailed general, systemic including per abdomen examination to know fundal height, lie, presentation, and foetal heart sound was done. Per speculum examination was done to confirm vaginal leakage either by frank passage of amniotic fluid through the cervical os or by demonstrating leak on coughing or by performing valsalva manoeuvre. Litmus paper test to test the change of vaginal pH due to leakage of amniotic fluid in PROM was done. Litmus paper soaked in fluid collected on speculum blade and if there is change red to blue colour it was PROM. Per vaginal examination for presence or absence of membranes, dilatation, effacement and position of cervix and station of presenting part, adequacy of pelvis and bishop score was noted.

The next dose of misoprostol was withheld if:

1. Bishop score >8.
2. Adequate uterine contractions i.e. 3 per 10 minutes.
3. Cervical dilatation> 3 cm with regular uterine contractions.
4. Presence of hyper stimulation, as evident by tachysystole or hyper tonus associated with foetal tachycardia, late decelerations and beat to beat variability.

a. Tachysystole:- 6 contractions in 10 min for 2 consecutive 10 min periods.

b. Hyper tonus: - Single uterine contraction lasting > 2 minutes

Augmentation with oxytocin was done in patients with favourable bishop score (>5) with mild uterine contraction or patients with poor bishops score (<5) even after 3 doses of misoprostol. If leaking of more than 24 hours and unfavourable cervix (bishop <5) or any evidence of foetal distress then further management was at the discretion of attending obstetrician.

Table -1: Distribution of Women According To Age

Age groups	n	%
<=20	10	11.1%
21-25	55	61.1%
26-30	17	18.9%
>30	8	8.9%
Total	90	100%

Table-2: Distribution of Women According To Induction –Delivery Interval

Induction Del Interval time	n	%
≤12 hrs	78	86.7%
12-24 hrs	12	13.3%
Total	90	100%

Table-3: Distribution of Women According To Outcome of Labour

Mode of delivery	n	%
Instrumental delivery	1	1.1%
LSCS	13	14.4%
NVD	76	84.4
Total	90	100%

Table-4: Distribution of Women According To Maternal Side Effects

Maternal S/E	n	%
Fever	2	2.2%
Nausea	1	1.1%
Vomiting	1	1.1
Nil	86	95.4%
Total	90	100%

Table-5: Analysis of APGAR Score

At min	APGAR Score	n	%
1 min.	≤7	17	18.9%
	>7	73	81.1%
Total		90	100%
5 min.	≤7	1	1.11%
	>7	89	98.9%
Total		90	100%

RESULTS

Our study showed that the mean age in was 24.33±3.535 years and maximum patients were between 21-25 years (61.1%) (table 1). Mean induction delivery interval was 7.67±4.86hours & 78 patients (86.7%) delivered within 12 hours after induction in patient of PROM (table 2).

Majority of women was delivered vaginally; 76 patients (84.4%). One patient required Ventouse (indication: inadequate maternal effort) & LSCS was done in 13 patients (14.4%) (table 3).

Gastrointestinal side effects were noticed in two patients (2.22%) & fever was observed in two patients (2.22%) in table no. 4.

Apgar score of new born babies at 1 min in majority was 8 – 10 min. (81.1%) and at 5 min in majority was 8-10 (98.9%) (table 5).

DISCUSSION

PROM complicates about 10% of all pregnancies (Gunn et al 1970) and result in loss of natural protection of foetus and intrauterine contents from bacterial invasion.[8] As such, PROM turn pregnancy into high risk situation which warrants induction of labour with or without pre induction cervical ripening to reduce maternal and foetal morbidity and mortality. To tide over such situation common regimens employed universally for induction are oxytocin and prostaglandin analogue like misoprostol.

In our study the mean induction delivery interval was 7.67±4.86 hours, 85.5% patients delivered vaginally and 14.4% by caesarean section. similar results found in study done by Chaudhuri S, Mitra SN et al (2011)[9] in a study in women with PROM at term were received an intravaginal 25 µg misoprostol tablet, 4-hourly with a maximum of five doses, induction-to-delivery interval was 10.75 hours, 92.3% patients delivered vaginally and 7.6% by caesarean section.

Gastrointestinal side effects in the form of vomiting was seen in 2 (2.22%) women. However, no antiemetics were required. Nausea and vomiting was seen more frequently in the study by Feitosa et al.[10], 8% and 3% in vaginal group. In our study Fever was seen in 2.22%, which was comparable with Feitosa et al. Bartusevicious et al.[11], makes no mention of these side effects.

In our study 85.5% participants delivered vaginally and 14.4% required LSCS. In the study by Bartusevicious et al.[11], 77% delivered vaginally.

CONCLUSION

Misoprostol maximum of 75µg is an effective method of improving the inducibility score and induction of labour in properly selected cases. Misoprostol in above doses is without any untoward effect on maternal and foetal outcome and hence, safe.

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