International Journal of Medical and Health Research
ISSN: 2454-9142
Received: 26-11-2018; Accepted: 28-12-2018
www.medicalsciencejournal.com
Volume 5; Issue 1; January 2019; Page No. 210-212

A prospective study to assess effectiveness of oral misoprostol in active management of prelabour rupture of membrane at or after 36 weeks of pregnancy

Dr. Snehil[1], Dr. Pallawi Singh[2*], Dr. Amrita Pritam[3]

[1, 3] Senior Resident, Department of Obstetrics & gynaecology, Sri Krishna Medical College & Hospital, Muzaffarpur, Bihar, India
[2] Associate Professor, Department of Obstetrics & gynaecology, Sri Krishna Medical College & Hospital, Muzaffarpur, Bihar, India
[*] Corresponding Author: Dr. Pallawi Singh

Abstract
Approximately 80% of PROM at term begins labour within 24 hrs and 95% within 72 hours. PROM is often associated with significant maternal and perinatal infections. As the exact aetiology of PROM is not known, it cannot be predicted or prevented. The present study was conducted to assess effectiveness of oral misoprostol in active management of term prelabour rupture of membrane. The present prospective randomized study was carried out in the department of obstetrics & gynaecology at Sri Krishna Medical College and Hospital, Muzaffarpur from May 2016 to April 2017. The study was carried out on 100 patients at term with prelabour rupture of membrane at or more than 36 weeks of gestation and who have no other contraindication for induction of labour and vaginal delivery. Labour induction with oral Misoprostol is effective and has resulted in significant reduction in PROM – delivery interval, Induction Delivery interval and reduction in duration first stage of labour. Oral Misoprostol has not resulted in increased rate of cesarean delivery and the rate of maternal side effects.

Keywords: PROM, pregnancy

Introduction
Prelabour rupture of membranes is defined as rupture of membranes prior to the onset of labour. PROM occurs in approximately 5-10% of all pregnancies, of which approximately 60% occur at term (Term PROM) [2, 3]. Approximately 80% of PROM at term begins labour within 24 hrs and 95% within 72 hours [4]. PROM is often associated with significant maternal and perinatal infections. As the exact aetiology of PROM is not known, it cannot be predicted or prevented. A prolonged interval from rupture of membranes to delivery is associated with an increase in the incidence of chorioamnionitis and neonatal sepsis [4]. So, Prostaglandins are the widely used agent. Prostaglandins are used as cervical ripening agent for labour induction. Misoprostol is extensively used because it is effective, inexpensive, easily stored (shelf life 2 yrs), not affected by ambient temperature and needs no refrigeration for its storage and no needles or syringes for administration. It has, in comparison to the other prostaglandins, minimal effects on cardiovascular system and bronchial tree smooth muscles and so can be safely used in hypertension and asthmatics [5].

Aims and Objectives
The present study was conducted to assess effectiveness of oral misoprostol in active management of term prelabour rupture of membrane.

Materials and Method
The present prospective randomized study was carried out in the department of obstetrics & gynaecology at Sri Krishna Medical College and Hospital, Muzaffarpur from May 2016 to April 2017. The study was carried out on 100 patients at term with prelabour rupture of membrane at or more than 36 weeks of gestation and who have no other contraindication for induction of labour and vaginal delivery. Necessary approval was obtained from the ethical committee of the hospital prior to commencement of study.

Inclusion Criteria
1. It is on voluntary basis
2. Patients presenting with prelabour rupture of membrane diagnosed by sterile speculum examination showing passage of fluid.
3. Singleton pregnancy
4. Cephalic presentation
5. Gestation ≥36 weeks
6. Patient not in active labour (bishop score ≤ 5)
7. Reactive NST at the time of admission
8. Informed consent was taken from all the subjects involved

Exclusion Criteria
1. Any contraindication to vaginal birth
2. Patient with prior uterine surgery
3. Patient in active labour
4. Oligohydramnios – AFI < 5
5. Active maternal bleeding
6. Patient with features of chorioamnionitis
7. Any contraindication to prostaglandin use
8. Major fetal anomalies

Detail history, A thorough general examination, A thorough systemic examination, Obstetric examination and Sterile speculum examination was done.
100 patients were given 50µgm of oral Misoprostol at 4 hourly intervals till onset of contraction and full dilatation of cervix or a maximum of 5 doses were given. A CTG was done before each dose of Misoprostol. Women who went into active labour, had vaginal examinations at 4-6 hour intervals.

If after 5 doses woman did not go into active labour, the induction was considered as failed.

- All patients received prophylactic antibiotics.
- All patients were monitored by intermittent auscultation and CTG as required.
- Any adverse events including tachysystole (at least 06 contractions in 10 min for 2 consecutive 10 min periods), hypertonus (a single contraction lasting 2 min), hyperstimulation syndrome (tachysystole or hypertonus with FHR deceleration or tachycardia) were recorded
- A vigilant watch was maintained to detect signs of chorioamnionitis.
- Labour was monitored in each patient with a partograph.

Observations and Results

In our study we used Oral Misoprostol 50 µg every 4 hourly to a maximum of 5 doses. Mean dose of oral Misoprostol required was 2.94. 50% of the cases required 3 doses of 50 µgm Misoprostol. 3% of the cases delivered in only 1 dose of oral Misoprostol whereas 5% of the cases delivered in 5 dose of oral Misoprostol which was the maximum dose given in this study. PROM – Delivery interval in the Misoprostol group was 861.18 min (14.35hrs) with a std. deviation of 189.30 min (3.15hrs) Induction Delivery Interval of 650.40 min (10.84 hrs) in the Misoprostol group with std. deviation of 202.44 min (3.37 hrs) Analysis of data from our study showing significant reduction in Induction Delivery Interval showed that there was significant reduction in the duration of 1st of first stage of labour only. Our study found that mean 1st stage duration was 543.07 min (9.05 hrs) with std deviation of 154.7 min (2.58 hrs) However there was no significant reduction duration of 2nd and 3rd stages of labour. Hence reduction in IDI was contributed solely by reduction in duration of 1st stage. Our study showed that 76 % of patients delivered vaginally. Rate of forceps delivery in Misoprostol was 5%. Cesarean section rates were 19 %. These findings are significant since Misoprostol has not been found to increase the rate of cesarean deliveries. Incidence of maternal side effects was 15%. Majority of side effects were gastro intestinal other than hypertonus, tachysystole, and perineal trauma.

Discussion

PROM – Delivery interval in the Misoprostol group was 861.18 min (14.35hrs) with a std. deviation of 189.30 min (3.15hrs) This significant decrease in PROM – Delivery interval has also been supported by many studies. In the study conducted by R.A.M. Hoffmann *et al.* PROM – Delivery interval was significantly reduced from 2670 min (45 hrs) in the placebo group to 1787 min (30 hrs) in the Misoprostol group ($P < 0.0001$) [6].

Table 1

Study	Route and Dose	PROM– Delivery Interval
R.A.M. Hoffmann *et al.* [6]	100µgm PO 6 hrly x 2 doses	30 hrs
Shetty *et al.* [7]	50µgm PO 4 hrly x 5 doses	20.5 hrs
Ozden *et al.* [8]	50 µgm vaginal	19.37 ± 7.20hrs
Roni Levy *et al.* [9]	50 µgm PO 4 hrly x 2 doses	13.8 ± 5.9 hrs

Induction Delivery Interval

The Induction Delivery Interval was 650.40 min (10.84 hrs) in the Misoprostol group with std. deviation of 202.44 min (3.37 hrs) Analysis of data from our study showing significant reduction in Induction Delivery Interval showed that there was significant reduction in the duration of 1st of first stage of labour only.

Table 2

Study	Route and Dose	IDI	Remarks
R.A.M.Hoffmann *et al.* [6]	100 µgm PO,6hrly x 2 doses	7.5hrs (median)	Reduction in IDI
Hussaini *et al.* [10]	100 µgm PO, 6 hrly x 2 doses	5.5 ± 2.9 hrs	Reduction in IDI

In a prospective study done by Monika B. Nagpal *et al.* [11] IDI was significantly reduced with the use of misoprostol. Similar observations were found in the studies where Misoprostol was used intravaginally. IDI was significantly reduced in Misoprostol group than control group. Kimberly D. Butt *et al.* [12], Ngai *et al* [60], Mozurkewich *et al* [65], and Mamta Rath Datt *et al.* [5] found no significant reduction in Induction Delivery Interval with the use of oral Misoprostol. These findings were contrary to the outcome of our study.

Mode of Delivery

Our study showed that 76 % of patients delivered vaginally. Rate of forceps delivery with Misoprostol was 5%. Caesarean section rates in Misoprostol group were 19%. Ngai *et al* in his study also reported no significant difference in the mode of deliveries between Misoprostol and Oxytocin group [13]. He reported caesarean section rate of 5% in Misoprostol group and 7.5 % in Oxytocin group. Forceps delivery rate was similar i.e. 5% in both groups. Findings of this study also support the outcome of caesarean delivery rate reported by Mozurkewich *et al.* [14]. Caesarean rate reported by Mozurkewich *et al* 20.1% in Misoprostol and 19.9% in the Oxytocin group. Rate of caesarean delivery was not statistically different.

Maternal Side Effects

In the present study the most common side effect seen was gastrointestinal with Misoprostol. Maternal side effects were Hypertonus 1%, Tachysystole 3% and perineal trauma 2%. Incidence of PPH was nil with Misoprostol g. None of the maternal side effects were statistically significant. Over all incidence of side effects with Misoprostol was 15%. Kimberly D Butt *et al*, Mozurkewich *et al.* Crane *et al.* had reported similar profile of side effects mainly GI side effects, hypertonus and tachysystole. Although none had reported significant difference in Misoprostol and Oxytocin group [15].

Neonatal Outcome

In present study neonatal outcome studied in terms of Apgar < 7, Meconium Stained Liquor (MSL) and NICU stay. We

found that 5% neonates had Apgar <7 with Misoprostol. Incidence of MSL and NICU stay were 9% & 10%. Overall outcome of neonatal complication in terms of reference were 18%. None of these findings were statistically significant. Kimberly D Butt *et al.* that neonatal outcome in reference with mean cord pH, Apgar score, birth asphyxia and admission to NICU. Incidence rate were similar in both groups and with statistical significance. Ngai *et al.* reported that neonatal outcome in both groups were comparable. He reported nil incidence of Apgar <5. There was no significant difference of NICU admission [13]

Conclusions

Labour induction with oral Misoprostol is effective and has resulted in significant reduction in PROM – delivery interval, Induction Delivery interval and reduction in duration first stage of labour. Oral Misoprostol has not resulted in increased rate of cesarean delivery and the rate of maternal side effects and neonatal outcomes are not increased. Dose and frequency of Misoprostol administration for induction of labour at term PROM varies considerably and needs to be studied further by multicentric RCTs to establish a treatment protocol.

References

1. Fernando Arias, Shirish N Daftary, Amarnath G Bhide. Practical guide to high risk Pregnancy and Delivery, 3rd edn. 2008, 240-258.
2. Ellen Mozurkewich. Management of Premature Rupture of Membranes at Term: An Evidence - Based Approach. Clinic Obstet. & Gynecol. 1999; 42(4):749-756.
3. Duff P. Premature Rupture of Membranes in term patients: Induction of labor versus expectant management. Clinic. Obs. & Gynecol. 1998; 41(4):883-891.
4. Tan BP, Hannah ME. Prostaglandin versus oxytocin for PROM at term (Cochrane Review) Cochrane Database Syst. Review 2000; (2):CD000158.
5. Mamta Rath Datta, Kabiraj Manas. Induction of labour with oral misoprostol in women with prelabor rupture of membranes at term. J. Obstet Gynecol India. 2007; 57(6):505-508.
6. Hoffmann RAM, Anthony J *et al*. Oral Misoprostol vs. Placebo in the management of prelabour rupture of membranes at term. Int J Gynecol Obstet. 2001; 72:215-221.
7. Shetty A, Stewart K, Stewart G *et al.* Active management of term prelabour rupture of membranes with oral Misoprostol. Br J Obs Gynecol. 2002; 109:1354-1358.
8. Ozden S, Delikara MN *et al*. Intravaginal Misoprostol vs. Expectant management in premature rupture of membranes with low bishop scores at term. Int. J Gynecol Obstet. 2002; 77(2):109-115.
9. Levy R, Vaisbuch E, Furman B *et al*. Prospective randomized clinical trial of immediate induction of labor with oral Misoprostol for prelabour rupture of the membranes in women with unfavourable cervix at term. Am J Obstet Gynecol. 2005; 193(6):S44
10. Al Hussaini TK, Abdel-Aal SA *et al*. Oral Misoprostol vs. Intravenous Oxytocin for labor induction in women with prelabour rupture of membranes at term. Int J Gynecol Obstet. 2003; 82:73-75.
11. Monika B, Nagpal *et al*. Oral Misoprostol versus intracervical prostaglandin E_2 gel for active management of premature rupture of membranes at term. Int J Gynecol Obstet. 2009; 106:23-26.
12. Butt KD, Bennett KA *et al*. Randomized comparison of oral Misoprostol and Oxytocin for labor induction in term prelabor rupture membrane. Obstet Gynecol. 1999; 94:994-999.
13. Ngai SW, Chan YM, Lam SW *et al*. Labour characteristics and uterine activity: Misoprostol compared with Oxytocin in women at term with prelabour rupture of the membranes. Br J Obs Gynecol. 2000; 107(2):222-227.
14. Mozurkewich E, Horrocks J, Daley S. *et al*. The MisoPROM study: A multicentre randomized comparison of oral Misoprostol and Oxytocin for premature rupture of membranes at term. Am J Obstet Gynecol. 2003; 189(4):1026-1031.
15. Crane JMG, Delaney T *et al*. Oral Misoprostol for premature rupture of membranes at term. Am J Obstet Gynecol. 2003; 189(3):720-724.