ABSTRACT

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Title Of study: A randomized controlled unmasked trial comparing safety and efficacy of oral misoprostol with intravenous oxytocin for induction in prelabour rupture of membranes at term

Objective

The aim of this randomised controlled trial is to compare the safety and efficacy of oral misoprostol with intravenous oxytocin for induction in prelabour rupture of membranes at term (PROM).

Background: Different methods exists for active management of PROM. Traditional method of induction with oxytocin needs continuous intravenous access and titration of dose which restricts patient mobility even in early labour. More recently induction with oral misoprostol, followed by infusion with oxytocin if required has been used.

Methods: This prospective randomized study included 134 women admitted to the department of Obstetrics and Gynaecology department at Christian Medical College Hospital, vellore with PROM at term. Women are randomly assigned to one of the two groups (groups A or B): Group A received 50μg of oral misoprostol every 4 hours for a maximum of three doses in nulliparous and maximum of two doses in multiparous. Group B received intravenous oxytocin starting with a dose of 2 mU/min with incremental increase of 2-4mU/min till adequate contractions occur. Primary outcome was induction to delivery interval, vaginal delivery within 24 hours and
caesarean section rate. Secondary outcomes were measures of effectiveness, maternal and neonatal complications, measures of satisfaction.

**Results:** This study showed clinically lesser incidence in caesarean section rate in oral misoprostol group compared to oxytocin group (9(13.43%) and 17(25.37%) respectively; p<0.081) with no significant difference in induction to delivery time interval (Group A 12.77±7.14h and Group B 11.73±5.52h; p value 0.6774). There was no difference in maternal and neonatal morbidity in both the groups.

**Conclusion:** Oral misoprostol for induction of labour with women with PROM results in a significant decrease in caesarean section rate without any difference in induction to delivery interval. It is the preferred method to traditional intravenous oxytocin for induction of labour as it does not need IV access which restricts ambulation in early labour.

(key words: Term premature rupture of membranes, active management, oral misoprostol, oxytocin intravenous)