

A Comparison of Oral Misoprostol and Extra-amniotic Foley's Catheter with Oxytocin for Induction of Labour at Term

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ABSTRACT

Objective: To compare the efficacy and safety of misoprostol with a Foley's catheter and oxytocin for induction of labor at or beyond term.

Study Design: Quasi experimental study.

Place and Duration of Study: This study was carried out in the Department of Obstetrics and Gynaecology, Railway Hospital Rawalpindi from January 2008 December 2008.

Materials and Methods: Hundred patients requiring induction of labor at or beyond term with bishop less than 5 were randomized by lottery method to receive oral misoprostol or a cervical Foley's plus oxytocin. Patients in the misoprostol group (Group A) received 50 microgram misoprostol at 6 hourly interval for a maximum of 4 doses or until an adequate contraction pattern developed. Those in the Foley's group (Group B) had a Foley's catheter inserted in the cervix. Whereas oxytocin was administered intravenously by a standard incremental infusion protocol to a maximum dose of 36 milliunits/min.

Results: The mean induction delivery interval is 9.8 hours in group A while in Group B the mean induction delivery interval was 17 hours. Although all patients delivered in both groups within 24 hours but the mean induction delivery interval was prolonged in Foley's group as compared to misoprostol group. The neonatal outcome was comparable in both the groups.

Conclusion: Oral misoprostol at the dose 50 microgram is better than Foley's group for induction of labor at term.

Key Word: Term, Primigravida, Induction of Labour, Misoprostol, Induction Delivery Interval.

Introduction

Labour is commonly induced in response to a number of fetal and maternal situations, including post term pregnancy, Pre-eclampsia and rupture of the membranes without the onset of spontaneous contractions within the next 24 hours.¹ Different methods are used for induction of labor depending upon the bishop score. If bishop score is less than 5 then different methods of induction of labour are misoprostol,^{2,3} dinoprostone, sweeping of membrane and many other mechanical methods. Results of different methods of induction of labor differ widely at different centers regarding their success rate, failure

rate, complications and cost. Prostaglandin are used to under labour in about 23% of all confinement.⁴ The prostaglandin E2 (PGE₂) dinoprostone, which is unstable at room temperature and requires refrigeration, is most commonly used.

Misoprostol a prostaglandin E-1 analogue manufactured for the prevention and treatment of gastric ulcer has also been evaluated as a cervical ripening agent. Costs of misoprostol is approximately 300 times less per dose than PGE₂, stable at room temperature, easy to administer and may be given as an oral medication. There have been several meta-analysis and systemic reviews of randomized controlled trials evaluating the use of misoprostol for cervical ripening and labor induction. These reports are suggesting that misoprostol is effective ; but there is concern that

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misoprostol may increase the rate of tachysystole and hyperstimulation.⁵ Oral misoprostol reduces the need for oxytocin infusion from 51% to 13% and shortens delivery time by 8.7 hours.⁶ Induction of labour with this analogue does not affect the frequency at which caesarean section is required. There is an increase in the rate of uterine hyperstimulation resulting in changes in fetal heart rate (FHR) pattern and staining of the amniotic fluid with meconium but without any apparent deleterious effect on the outcome.⁷

Inflated Foley's catheter has been used successfully as a mechanical device for ripening of unfavorable cervix because it is simple, in-expensive, reversible and has no systemic serious side effects⁸ compared to medical modes of cervical ripening. It has some association with an increase in caesarean section rate as compared to spontaneously laboring women.⁹ In the case of women who have previously undergone a caesarean section and thereby run an elevated risk for uterine rupture in connection with vaginal delivery, induction of labour with misoprostol may further enhance this risk and is not recommended.¹⁰

In a systemic review of 45 randomized trials, mechanical methods of labour induction were found to be less effective than prostaglandins and reduced the risk of uterine hyperstimulation; compared with oxytocin, there were fewer caesarean sections with mechanical methods.¹¹ The purpose of this study was to evaluate the efficacy and safety of misoprostol versus extra amniotic Foley's catheter and Oxytocin for induction of labour at term.

Materials and Methods

This Quasi experimental study comparing oral Misoprostol and Foley's catheter and oxytocin for induction of labour at term was carried out in the Department of Obstetrics and Gynaecology, Railway Hospital Rawalpindi from January 2008 December 2008. All women requiring induction of labour at or beyond term (> 37 weeks gestation) and Bishop score <5 were included in the study. Patients with previous Caesarean section or any other uterine scars, multiple pregnancies, Bishop score > 5, placenta previa, mal-presentations, ruptured membranes were excluded from the trial. After informed consent, women were randomized by lottery method and assigned to receive oral Misoprostol tablet in group A and Foley's catheter in group B. After complete history and examination, a reassuring fetal heart tracing was confirmed with a cardiotocograph. Vaginal examination was performed to assess the Bishop's score. Misoprostol (50 micrograms) was given orally to patients in group A and repeated after six hours if required. A maximum of 4 doses were given. The use of oxytocin was according to the labour ward protocol and was not started less than 4 hours after the last dose of Misoprostol. If cervix was not favourable for artificial rupture of membrane after 4 doses of Misoprostol tablets, the induction was considered to have failed and the woman was offered caesarean section. A partogram was maintained for progress of labour. In Group B; after Bishop score, pre-packed sterile Foley's catheter 20 F balloon was introduced and catheter balloon was inflated with 30 ml of sterile normal saline. Patients were observed for 10-15 min for any

leakage of amniotic fluid or deflation of balloon. After 12 hours if it was not expelled then oxytocin infusion was also started along with it. All information collected was recorded in a pre-designed Proforma.

The data was entered on SPSS Version 18 for statistical analysis. Student's t test was applied to compare induction delivery interval between oral Misoprostol and Foley's catheter with oxytocin groups. Statistical significance was assigned to P-value < 0.05. Percentage of indication of induction of labour, Use of oxytocin, mode of delivery, maternal outcome such as hyperstimulation syndrome, tachysystole, hypertonus, nausea and vomiting, pyrexia of 38 c, antepartum hemorrhage, uterine rupture and neonatal outcome such as assessment of 1 min and 5 min APGAR score, need for intubation and NICU

Table I: Mean age and birth weight

	Oral misoprostol (n=50)	FOLEY'S CATHETER (n = 50)
Maternal age (years)	27.1	29.7
Gestational age (weeks)	39.6	40.2
Induction indication		
• Postdate	25 (50%)	33 (66%)
• Hypertension/ PIH/ Preeclampsia	13(26%)	7(14%)
• GDM	10(20%)	10 (20%)
• Oligohydramnios	2 (4%)	0
Neonatal birth weight (Kilograms)	3.2 kg	3.4 kg

Table II: Induction delivery interval

Route	Mean	St. Deviation	St. Error (Mean)
Misoprostol n=50	9.8	2.74	0.5487
Foley's Catheter n=50	17.0	3.09	0.6921

admission were calculated.

Results

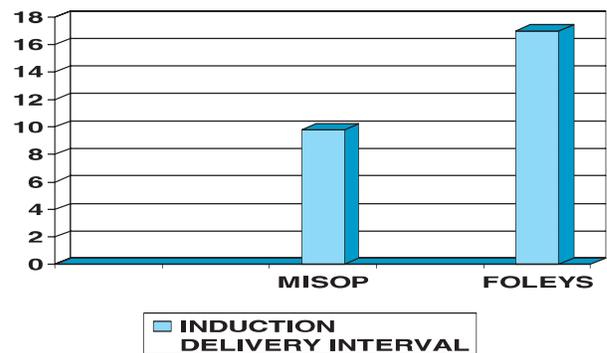


Figure 1: Induction Delivery Interval in both Groups

Table III: Maternal outcome

	Oral misoprostol (n=50)	Foley's Catheter (n = 50)
1 min Apgar	12 (24%)	12 (24%)
5 min Apgar	15(30%)	15(30%)
Need for intubation	2(4%)	2 (4%)
NICU admission	7 (14%)	5 (10%)

Table IV: Neonatal outcome

	Oral misoprostol (n=50)	Foley's Catheter (n=50)
Mode of delivery		
• Caesarean section	8 (16%)	17 (34%)
• SVD	42 (84%)	33 (66%)
Tachysystole	7(14%)	0
Hypertonus	0	0
Hyperstimulation	2 (4%)	2 (4%)
PPH	3 (6)	3 (6%)
Uterine rupture	0	0
Nausea, vomiting, fever	3 (6%)	2(4%)
Failed induction	3(6%)	17 (34%)

The patients characteristics like age and parity were comparable in both the groups. The mean age in misoprostol group was 27 years and in the Foley's group it was 29.7 years. The mean gestational age in group A was 39.6 weeks and in group B was 40.2 weeks. Different indications for induction of

labor were summarized in Table I .The commonest indication was postdated pregnancy in both the groups. Table II showed induction delivery interval. Induction delivery interval was prolonged in Foleys group as compared to misoprostol group. The mean induction delivery interval was 9.8 hours in group A and 17 hours in Foley's group which statistically was not significant (p value=0.654) .Need of Oxytocin infusion was more in group B (100%) than in group A (21%). Although all patients delivered within 24 hours but delivery occurred earlier in misoprostol group than Foley's group. Labour was interrupted by caesarean section in 8 (16%) women in group A and 17 (34%) in group B. The commonest indication of caesarean section in group A was fetal distress and in group B was failure to progress in active phase of labor.The incidence of failed induction was higher that is 17 (34%) in group B than group A, in which it was 3 (6%) .There was increased incidence of tachysystole in group A i.e., 7 (14%), while none in the Foley's group. The incidence of PPH was 3 (6%) each in both groups. Three (6%) patients developed fever in misoprostol group (Table III). For the neonates the mean birth weight, the incidence of 5 minute APGAR score were similar. One baby developed meconium aspiration in misoprostol group and none in the Foley's group (Table IV). The incidence of N.I.C.U admission is almost similar in both groups

Discussion

Misoprostol has been shown to be effective when given orally or vaginally for induction of labour. With vaginal administration doses of 50 µgm and more have been associated

with a higher incidence of excessive uterine contractility.¹² The oral route may have advantages in terms of easier administration and lack of restriction of mobility. Also, in keeping with the pharmacokinetics of drug, it may be associated with lower uterine hyperstimulation rate.¹³ There is attractive possibility of administering the drug without repeated vaginal examinations which would be of particular benefit in patients with prelabor spontaneous rupture of membranes. Another study in which induction of labor using a Foley's balloon with or without extra-amniotic saline infusion was compared. Results showed shorter induction to vaginal delivery time in Foley's with extra- amniotic saline infusion than with Foley's alone, without affecting cesarean delivery rates.¹³ Cormi et al recently conducted a study for cervical ripening with Foley's catheter concluded that transcervical use of Foley's catheter is safe for pre-induction cervical ripening , and the associated risk of maternal and perinatal infections are negligible.¹³

Shetty et al concluded that with most of the parameters of efficacy there was no statistical difference in the 50µg and 100 µg misoprostol groups. However, there were significantly more failed inductions in low dose groups with more doses of misoprostol required. In that study there was failed induction with misoprostol in 100 µg group is 6% while in our study there is 10% incidence of failed induction with misoprostol using 50 µg dose.¹⁴

A large number of randomized trials suggest that vaginally administered misoprostol is an effective agent for cervical ripening and labor induction. The main concern with this technique is the incidence of excessive

uterine contractions, which appears to be dose related. The higher the misoprostol dose, the shorter the induction to delivery time but the higher rate of uterine hyperstimulation.¹⁵ Tachysystole with or without fetal heart rate changes continues to be the most common complication of misoprostol for cervical ripening and induction of labor. In the current study where patients received serial 50µg doses of misoprostol six hourly; 13.3% of women were noted to have at least one episode of tachysystole.

In our study, more oxytocin is required in Foley's catheter group as compared to misoprostol group. In a study conducted in 2008, in which comparison between supracervical Foley's catheter, intravaginal dinoprostone gel, supracervical Foley's catheter and 100 µg oral doses of misoprostol or serial 100 µg oral doses of misoprostol showed that women in the balloon plus misoprostol group were treated with lower doses of oxytocin.¹⁶

In our study the induction delivery interval is prolonged in the Foley's group as compared to misoprostol group, but it is not statistically significant. While, the previously mentioned study showed that the median induction to delivery time was longer with misoprostol. The relevant neonatal outcomes were comparable to both groups in our study as well as in the previously mentioned study.¹⁷

Oral misoprostol has all the properties that constitute a viable technique for labor induction. It is effective, inexpensive, easily administered, and stable at room temperature and well tolerated by the mother and fetus. In contrast to oxytocin, misoprostol does not require to be mixed as

solution and there is no requirement of an infusion pump thus reducing the possibility of drug errors.

Extra amniotic saline infusion (EASI) with concomitant oxytocin administration was associated with a shorter interval from induction to delivery and a higher rate of successful vaginal delivery within 24 hours compared with intravaginal misoprostol with unfavorable cervix. In a study, EASI with concomitant oxytocin administration appears more effective and is associated with fewer FHR tracing abnormalities than vaginally administered misoprostol for cervical ripening and labor induction. EASI however, had more rapid cervical ripening and shorter induction delivery interval.¹⁸

In a local study in which trial of extra amniotic saline infusion with oxytocin versus prostaglandin E2 pessary for induction of labor, showed that both modes of induction were equally effective in terms of mode of delivery and APGAR scores.¹⁹

Another study showed that Induction of labour using mechanical methods results in similar caesarean section rates as prostaglandins, with a lower risk of hyperstimulation. Mechanical methods do not increase the overall number of women not delivered within 24 hours. However, the proportion of multiparous women who did not achieve vaginal delivery within 24 hours was higher when compared with vaginal PGE2 and mechanical methods for induction of labour.²⁰

According to Olimpio et al., Vaginal misoprostol is more effective than and as safe as Foley's catheter and oxytocin for induction of labor in term and post-term pregnancy.²¹ Another study conducted in 2011 showed that induction with

intravaginal misoprostol and transcervical Foley's catheter have similar effectiveness and similar risk of caesarean section; but, with a reduced risk of tachysystole with transcervical Foley's catheter.²²

Conclusion

A transcervical balloon catheter can be used to achieve effective and safe induction of labour. Induction with misoprostol is equally effective and safe. Its cost effectiveness and easy storage due to its stability at room temperature favours its use especially where resources are limited.

References

1. Prager M, Grimfors EE, Edlund M, Marions L. A randomized controlled trial of intravaginal dinoprostone, intravaginal misoprostol and transcervical balloon catheter for labour induction. *Br J Obstet Gynaecol* 2008;115:1443-50.
2. Hofmeyr GJ, Gulmezoglu AM. Vaginal misoprostol for cervical ripening and induction of labour. *Cochrane Database System Rev* 2003; 1: CD000941.
3. Rehman K, Nadira S. Vaginal misoprostol: The revolutionary start switch in induction of labor. *Pak Armed forces Med J* 2004; 54: 20-4.
4. Dodal JM, Crowther CA, Robson JS. Oral Misoprostol for induction of labour at term: randomized controlled trial, *BMJ* 2006; 332:509-13.
5. Hofmyer GJ. Induction of labor with an unfavorable cervix. *Best Pract Res Clin Obstet Gynecol* 2003;17: 777-94.
6. Alfirevic Z. Oral misoprostol for induction of labour. *Cochrane Database System Rev* 2003; 1: CD001338.
7. Crane JM, Butler B, Young DC, Hannah ME. Misoprostol compared with prostaglandin E2 for labour induction in women at term with intact membranes and unfavourable cervix: a systematic review. *Br J Obstet Gynecol* 2006; 113:1366-76.
8. Hemtin J, Moller B. Extra-amniotic saline infusion is promising in preparing the cervix for induction of labor at term in multiparous women. *Obstet Gynecol* 1998;77:45-9.
9. Seyb ST, Berka RJ, Scol ML, Dooley SL. Risk of cesarean delivery with elective induction of labor at term in multiparous women. *Obstet Gynecol* 1999;94:600-7.
10. Bouvain M, Kelly A, Lohse C, Stan C, Irion O. Mechanical methods for induction of labour (Cochrane Review). In: *The Cochrane Library*, Issue 2, 2002. Oxford: Update Software.
11. Rust O, Greybush M, Atlas R, Balducci J. Does combination pharmacologic and mechanical pre-induction cervical ripening improve ripening to delivery interval? *Am J Obstet Gynecol* 2000;182: 136.
12. Crane JMG, Butter B, Young DC, Hannah ME. Misoprostol compared with prostaglandin E2 for labour induction at term with intact membranes and an unfavorable cervix Systemic review. *Br J Obstet Gynecol* 2006.
13. Cromi A, Ghezzi F, Tomea S, Ucella S, Lische H, Bolis PF. Cervical ripening with Foley Catheter *Int J Obstet Gynecol* 2007; 97:105-9.
14. Shetty A, Martin M, Danielian P, Templeton A. A comparison of two dosage regimens of oral misoprostol for labour induction at term. *Acta Obstet Gynecol Scand* 2002;81: 337-42.
15. Godinjak Z, Imsirija L, Imsirija N. Vaginal application of misoprostol for labor induction after 36 weeks of pregnancy. *Med Arh* 2007 ; 61: 218-20.
16. Cheng SY, Ming H, Lee JC. Titrated oral compared with vaginal misoprostol for labor induction. Randomized controlled trial. *Obstet Gynecol* 2008;111:119-25.
17. Hofmeyr GJ. Misoprostol administered vaginally for cervical ripening and labour induction in the third trimester Oxford, England: *Cochrane Library Update Software*, 1998, issue 3.
18. Saleem S. efficacy of dinoprostone, intracervical Foleys and misoprostol in labour induction. *J Coll Physicians Surg Pak* 2006; 16:276-9.
19. Mazher SB, Alam K. Induced labour: Indications and outcome. PIMS experience. *J Surgical* 2001; 23:31-3.
20. Jozwiak M, Bloemenkamp KW, Kelly AJ. Mechanical methods for induction of labour. *Cochrane Database Syst Rev* 2012;3:CD001233.
21. Olimpio B, Moraes F, Rivaldo M. A randomized controlled trial comparing vaginal misoprostol

versus Foley catheter plus oxytocin for labor induction. Acta Obstet Gynecol Scand 2010; 89: 1045-52.

22. Fox NS, Saltzman DH, Roman AS. Intravaginal misoprostol versus Foley catheter for labour

induction: a meta- analysis .Br J Obstet Gynecol 2011;118:647-54.

