

# Combination of Misoprostol with Transcervical Foley's Catheter Compared to Misoprostol Alone for Cervical Ripening at Term and Labour Induction in Tertiary Care Hospital: A Randomized Trial

Minal Kalambe (Akare)<sup>1</sup>, Mugdha L. Jungari<sup>2</sup>, Priya Pratapan Nair<sup>2</sup>, Dipti Shrivastava<sup>3</sup>

<sup>1</sup>Senior Resident, Dept. of Obst and Gyne Datta Meghe Medical College, Shalinitai Meghe Hospital and Research Centre, Hingana, Nagpur-441110, <sup>2</sup>Assistant Professor, Department of Obstetrics and Gynecology, Datta Meghe Medical College, Shalinitai Meghe Hospital and Research Centre, (DMIMS) Nagpur-441110, <sup>4</sup>Professor and HOD, Dept. of Obstetrics and Gynecology, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi, Wardha-442001

## Abstract

**Background:** Induction of labour is a very common in obstetrics, for that both mechanical and pharmacological method used for induction. Mechanical Foley's with misoprostol is an effective method to cut out course of labour in safe timely manner, for safe neonatal and maternal outcome.

**Aims and Objective:** The aim of this study was to compare combination of transcervical Misoprostol with Foley's catheter balloon to misoprostol alone for induction of labour and cervical ripening in uncomplicated pregnancy, with regards to safety and effectiveness.

**Result:** A prospective, randomized controlled study was conducted on 220 term singleton women admitted in our hospital for induction of labour were randomly allocated to Group 1 (combination of Foley's and misoprostol) and Group 2 means (misoprostol) each 110. Combination of Foley's and vaginal misoprostol was much more effective in nulliparous female than multiparous women. Induction delivery interval was shorter in combination group; 14.4±5.70 hours than misoprostol group; 17.1±5.62 hours; p value is 0.007.

**Conclusion:** This study showed that the use of misoprostol with a trans cervical Foley's is an effective method to shorten the course of labour compared with misoprostol alone. This study suggest that combination may be useful to achieve safe and timely delivery in unripe cervix.

**Keywords:** *Transcervical Foley's, Misoprostol, LSCS, Induction.*

## Introduction

The incidence of labour induction has continued to rise over the past decades. The World Health Organization Global Survey on Maternal and Perinatal

Health, conducted in 24 countries which included nearly 3, 00,000 observations, showed that 9.6% of them were delivered by labour induction.<sup>(1)</sup> Mostly labour starts spontaneously near term, but in high risk antenatal cases, labour induction is often required. There are many method of IOL such as mechanical, surgical, pharmacological (prostaglandins (PG) E1 and E2, oxytocin, relaxin) and combined method. Previously for induction of labour, mechanical method were used for dilatation of cervix as well as cervical ripening in women with unfavourable cervix. At term, Osmotic dilators are effective, but they are associated with an increase in maternal infection.<sup>(2,3)</sup>

---

### Corresponding Author:

**Dr. Minal Kalambe (Akare)**

Senior Resident Dept. of Obst and Gyne, Datta Meghe Medical College, Shalinitai Meghe Hospital and Research Centre, Hingana, Nagpur-441110

Induction of labour is a common obstetric procedure; it is defined as the stimulation of uterine contractions during pregnancy before initiation of labour before its spontaneous onset for the purpose of delivery of the foeto-placental, which ultimately aims at achieving vaginal delivery depends on the Bishop's score at the time of induction.<sup>(4)</sup> The patients with a poor Bishop's score have unacceptably higher rates of failure of induction.<sup>(5)</sup>

Mechanical cervical dilatation is an old method that was used routinely.<sup>(6)</sup> Transcervical Foley's catheter balloon found to be effective and a safe method for unripe cervix. Mechanical method leads to separation of membrane from lower uterine segment, leads to release of lytic enzymes which stimulating the production of prostaglandins.<sup>(7)</sup> Misoprostol is a prostaglandin E1 analogue (methyl- 11a 16 - dihydroxy- 16 methyl- 9-oxoprost- 13 enoate), it has uterotonic and cervical ripening action. It is widely used for termination of pregnancy, management of incomplete abortions, induction and augmentation of labour and treatment of postpartum haemorrhage.<sup>(8)</sup> It is used by sublingual, oral, buccal, vaginal and rectal route. Oral route of misoprostol has several publications been shown to be effective method for induction of labour comparable to oxytocin.<sup>(9,10)</sup> The main disadvantage of prostaglandins is uterine hyperstimulation contributing to a risk for foetal hypoxia and may lead to operative intervention. As mechanical Foley's leads to dilation of the cervix and misoprostol result in soften and efface the cervix.<sup>(11)</sup>

**Aims and Objective:** The aim of this study is to assess effectiveness and safety of transcervical Foley's catheter with vaginal misoprostol combination for cervical ripening and induction of labour in term as compare to misoprostol alone.

### Material and Method

A prospective, randomized controlled study was conducted on 220 women admitted to labour room for induction of labour with term singleton pregnancy, cephalic presentation, viable gestation, intact membranes, and having poor bishops score were included in this study for cervical ripening and induction of labour over a period of one year. Informed consent was taken from Patients who were admitted to hospital for induction of labour. The women with History of prior uterine surgery (LSCS or myomectomy), multiple gestations, malpresentation, heart disease in mother,

contraindication to prostaglandins, vaginal bleeding (placenta previa, active herpes infection), anomalous foetus, foetal demise, patients not giving consent were excluded from the study.

Patients were select randomly in to group 1 (misoprostol alone) and group 2 (cervical ripening using misoprostol with Foley's bulb). Simple Randomization with one to one was achieved through a computer-generated assignment with 110 patients in each group. A detail history was taken of all admitted patients along with detailed general and systemic examination was done. In group 1, women were received with F16 Foley's catheter with balloon filled with 50 ml normal saline inserted intra-cervical. The catheter was taped to the patient's inner thigh under gentle traction. Simultaneously they received 25 micrograms of misoprostol per vaginum in posterior vaginal fornix which was repeated every 4 hours for a maximum of 6 doses. Catheter was removed after 24 hours if women didn't go into labour. In group 2 women who were received, misoprostol (prostaglandin E1) 25 micrograms inserted vaginally into the posterior fornix every 4 hours, up to maximum of six doses under all aseptic precautions as per our standard hospital protocol. If cervix became favourable or patients goes in active labour then oxytocin was started after titrating dose, Partograph was maintained throughout the labour. If the cervix was not favourable for artificial rupture of membranes after the stipulated six doses, the induction was considered to have failed. A further dose was withheld in case of tachysystole, hypertonus or hyperstimulation or if patient was in progressive active labour and spontaneous rupture of membranes. Patients were monitored till patient delivered vaginally or by Caesarean section. The two groups were then compared with respect to indication of induction, induction to delivery interval, mode of delivery, maternal side-effects and foetal outcome.

**Statistical Analysis:** The data collected was organised in a separate sheet programme (MS Excel) and analysed with the help of Statistical Package for Social Science for testing. At the end of the study, the data was collected and analysed by using Student t-test and Chisquare test. A p value of < 0.05 was considered significant.

### Result and Observations:

**Total cases of 220 patients were taken for studied 110 were divided to each group and result as follows:**

As shown in this study, maximum numbers of patients were in the age group of 26 to 30 years in both the groups, in (Foley’s plus Misoprostol) group 1 26.4±3.80 and in (Misoprostol) group 2, 25.9±3.81. In this study, maximum primigravida were 81.9% women in Group 1

and 71% in Group 2 (Table 1) In our study most common indication for induction of labor were 26.8% postdated pregnancy, 22.7% GDM, 20.9% oligohydramnios and 19.1% preeclampsia. (Table 2)

**Table 1: Demographic data:**

Variables	Group 1	Group 2	P value	Significance
Age	25.9±3.81	26.4±3.80	0.90	Not significant
Primigravida	81.9%	71%	0.056	Not significant
Bishop score	3.0700±.76877	3.5600±.68638	0.124	Not significant

**Table 2: Indications of induction of labor.**

Indications of induction	Group 1	Group 2	Total
Postdate	35.5%	18.1%	26.8%
PIH	10%	28.2%	19.1%
Oligohydramnios	14.5%	27.3%	20.9%
GDM	29.1%	16.4%	22.7%
IUGR	10.9%	10%	10.45%

In group 1, 78.1% delivered vaginally, 21.9% underwent caesarean section due to meconium stain liquor and foetal distress, tachysystole. In Group 2, 76.4% delivered vaginally, 23.6% women underwent caesarean section due to foetal distress and meconium stain liquor.

came out to be 14.4± 5.70 which was shorter than Group 2 duration 17.1±5.62.

In our study, women were delivered in 6-12 hours in Group 1 55.8%, whereas 33.1% in Group 2. In Group 1 majority of the cases (93%) delivered within 24 hours and only 7% of the women needed > 24 hours to deliver whereas in other group, 16.7% delivered in >24 hours. The mean induction delivery interval (IDI) in Group 1

**Table 3: Indications of LSCS.**

Indications of LSCS	Group 1	Group 2
Meconium stain liquor	37.5%	38.4%
Fetal distress	21%	19.3%
Tachysystole	21%	26.9%
Failure of Induction	16.6%	11.5%
Abruption	4.1%	3.9%
Total	100%	100%

**Table 4: Duration of induction to delivery interval.**

Time in hours	Group 1		Group 2	
6-12 hours	48	55.8%	28	33.4%
>12-24 hours	32	37.2%	42	50%
>24 hours	6	7%	14	16.7%
Total	86		84	
Mean ± S.D.	14.4± 5.70		17.1±5.62	
P value	P-value 0.007			
Significance	Not significant			

Neonatal complications in the form of mild birth asphyxia were seen in 8.1% of the neonates in Group 1 and 12.7% of the neonates in Group 2. Neonatal jaundice occurred in 5.45% of the newborn in Group 1 and 7.27% in Group 2. Around 1% of the newborn in both groups had hypoglycemia. In maternal side-effects, hypertonic uterine action was observed in 5.45% of the cases in Group 1 and 6.36% of the cases in Group 2. The other less common side-effects were postpartum hemorrhage, shivering, nausea and vomiting. No case of chorioamnionitis was seen in our study (Table 5).

**Table 5: Maternal and neonatal outcomes**

Variables		Group 1	Group 2
Neonatal complications	Birth Asphyxia	8.1%	12.7%
	Neonatal jaundice	5.45%	7.27%
	Hypoglycaemia	1.1%	1%
	Uterine hypertonic action	5.45%	6.36%
Maternal outcome	PPH	1%	2.7%
	Nausea & Vomiting	6.3%	4.54%
	Shivering	2.7%	1.1%
	Rupture uterus	0	0
	Chorioamnionitis	0	0

### Discussion

In this study, showed that in misoprostol group 56.3% and in Foley’s plus Misoprostol group 54.5% in the age group of 26 to 30 years. The mean age group were 25.9±3.81 and 26 ±3.80 and in combination group and misoprostol alone respectively. Others study was similar to our study, in Agrawal M et al.<sup>[12]</sup> the mean age group of the participants was 24.72 and 24.12 in group 1 and group 2 respectively. In Noor et al, in misoprostol mean age were 25.1 ± 2.8 and in Foley’s catheter mean age were 25.6 ± 4.1<sup>[13]</sup>.

In this study, 76.4% women were primigravida and 23.6% were multigravida. Other study which was comparable to our study were Agrawal M et al.<sup>[12]</sup> In our showed that vaginal delivery was 78.1% and 76.4% while 21.9% and 23.6% delivered by caesarean section in group 1 and group 2 respectively. Others study which was comparable our study were Charaya E at el<sup>[14]</sup> and Baron B at el<sup>[15]</sup> whereas Chung JH et al<sup>[16]</sup> and Carbone JF et al<sup>[7]</sup> studies have shown higher caesarean rates. The studies by Kehl S at al<sup>[17]</sup> and Ande AB at al<sup>[18]</sup> showed lesser LSCS rate in combination group.

In this study showed that rate of success means induction to delivery interval was shorter in (14.4±5.70) Foley’s catheter plus misoprostol than misoprostol alone (17.1±5.62). Others study which were similar to our study that Carbone et al.<sup>[7]</sup> Hussein et al<sup>[14]</sup> Ande et al, showed that combination of Foley’s with vaginal misoprostol for induction takes significantly shorter duration of time in cervical ripening and induction to delivery time. In Charaya E at el Induction to delivery interval was 11.76±5.89 hours in combination group and 14.54±7.32 hours in misoprostol group with difference of 2.78 hours. The study by Levine et al showed that shortening in the induction to delivery time by 4 hours 30 minutes with the combination group as compared with the misoprostol-alone group. In Hill JB et.al, the time from induction to delivery in group Foley’s catheter and oral misoprostol (12.9 hours) was significantly shorter than that in group vaginal misoprostol (17.8 hours). Maternal and neonatal outcome were maximum in misoprostol group than combination group.

### Conclusion

The results of this prospective, comparative study showed that the combination of Foley’s with vaginal misoprostol results in a shorter duration of labour as well as induction to delivery interval compared with vaginal misoprostol alone. These results also suggest that the combination of Foley’s with vaginal misoprostol may be useful to achieve timely and safe delivery in the presence of unripe cervix mainly with nulliparous. So, all nulliparous women with poor bishop should be offered induction with combination of Foley’s bulb with vaginal misoprostol.

**Ethical Clearance:** Taken from institutional ethics committee.

**Source of Funding:** Self.

**Conflict of Interest:** Nil.

### References

1. Induction of labor. ACOG Practice Bulletin No. 107. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2009;114;386–97.
2. Jozwiak M et al. Mechanical method for induction of labour. *Cochrane Database Syst Rev*. 2012; 14: 3: CD001233.
3. Induction of labor. ACOG Practice Bulletin No. 107. American College of Obstetricians and

- Gynecologists. *Obstet Gynecol* 2009;114:386–97.
4. Sanchez- Ramos Let al. Misoprostol for cervical ripening and labor induction: A meta-analysis. *Obstet Gynaecol*. 1997;89:633-42
  5. Delaney Set al. Labor induction with a Foley balloon inflated to 30 MI compared with 60 mL: a randomized controlled trial. *Obstet Gynecol* 2010;115:1239–45.
  6. Carbone Jet al. Combination of Foley bulb and vaginal misoprostol compared with vaginal misoprostol alone for cervical ripening and labor induction: a randomized controlled trial. *Obstet Gynecol* 2013; 121:247–52.
  7. J. Tang, Net al, WHO recommendations for misoprostol use for obstetric and gynecologic indications, *International Journal of Gynecology & Obstetrics*, vol. 121, no. 2, pp. 186–189, 2013.
  8. G. J. Hofmeyr, Oral misoprostol is as safe as Foley catheter for labour induction...or is it?" *The Lancet*,2016; 387(10028): 1593-1594.
  9. Aronsson A et al. Effects of misoprostol on uterine contractility following different routes of administration, *Human Reproduction*, 2004; 19(1): 81–84.
  10. Agarwal M, Kose V. Comparative study of vaginal misoprostol and intra cervical Foley’s catheter for pre-induction cervical ripening at term. *Int J Reprod Contracept Obstet Gynecol* 2017;6:1283-7.
  11. Hussein M. 307: A comparison between vaginal misoprostol and a combination of misoprostol and Foley catheter for cervical ripening and labour induction in early third trimester pregnancy. *American Journal of Obstetrics and Gynecology*. 2012; 206(1):S147.
  12. Chung J et al. A prospective randomized controlled trial that compared misoprostol, foley catheter, and combination misoprostol-foley catheter for labor induction, *American Journal of Obstetrics and Gynecology*, 2003; 189(4):1031–1035.
  13. Kehl Set al. Sequential use of double balloon catheter and oral misoprostol versus oral misoprostol alone for induction of labour at term (CRB trial): a multicentre, open label randomized control trial. *BJOG* 2015;122:129-36
  14. Ande Aet al. Induction of labor in prolonged pregnancy with unfavorable cervix: comparison of sequential intracervical Foley’s catheter-intravaginal misoprostol and intravaginal misoprostol alone. *Arch Gynaecol Obstet* 2012; 285(4):967-71.
  15. Charaya E, Dahiya K. Comparative study of combined Foley Bulb and Vaginal Misoprostol with Vaginal Misoprostol alone for cervical ripening and Induction Labour Research Article *Br J Med Health Res*. 2016; 3(5) ISSN: 2394-967.
  16. Levine Let al. Mechanical and pharmacologic method of labor induction: a randomized controlled trial. *Obstet Gynecol* 2016; 128:1357–64]
  17. Hill Jet al. A randomized clinical trial comparing vaginal misoprostol versus cervical Foley plus oral misoprostol for cervical ripening and labor induction. *American journal of perinatology*. 2009 Jan; 26(01):033-8.