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# Original Article

## Observational study comparing cervical ripening and induction of labour with intravaginal Misoprostol against transcervical Foley's catheter

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***ABSTRACT*:**
**Background:** In the recent decade, there has been a considerable increase in the rate of labour induction. Achievement of a vaginal delivery for a woman who requires induction of labour may be among the greatest challenges facing obstetricians today. Aim of the study: To compare cervical ripening and induction of labour with intravaginal Misoprostol and transcervical Foley's catheter as their safety and efficacy in clinical practice as an induction agent is concerned. **Materials and methods:** In the study, 100 patients were observed, who had undergone induction of labour. Out of 100 patients, 50 patients were induced with intravaginal misoprostol and 50 with transcervical Foley/s catheter. The decision of induction was taken by the concerned obstetrician, depending on the indication and Bishop score and the assessment of pelvic adequacy and excluding the patient for home vaginal delivery was contraindicated. **Results:** The study showed that there was no difference in the demographic characteristics of the two groups. The age distribution being in the same among two groups. One patient induced with vaginal Misoprostol, G2MTP1, 39. 2 weeks of gestation included in view of cholestasis in pregnancy develop uterine hyperstimulation (>6 contractions in 10 minutes associated with non-reassuring fetal heart pattern) with one dose of vaginal Misoprostol and required Cesarean Section. Baby had one-minute APGAR score of 9. Out of 100 babies born, 92 had one-minute Apgar score as >7 and only 8 had Apgar score <7 at 1 min. Severe birth asphyxia with very low Apgar scores less than 3 was not seen in the study does. **Conclusion:** Thus, when used rationally and with a good quality of intrapartum monitoring, bith Foley's catheter and Misoprostol are equally efficacious and safe for labor induction.
**Keywords:** Misoprostol, Foley's catheter, C-section

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**INTRODUCTION:**
In the recent decade, there has been a considerable increase in the rate of labour induction. Achievement of a vaginal delivery for a woman who requires induction of labour may be among the greatest challenges facing obstetricians today.[1] Labour induction is usually performed when the risks of continuing a pregnancy are more than the benefits of delivery. Indications for induction of labour include immediate conditions such as severe preeclampsia or ruptured membranes with chorioamnionitis.[2] The other common medical and obstetric indications include membrane rupture without labour, gestational hypertension, postdated pregnancy, oligohydramnios, non-reassuring fetal status, intrauterine growth restriction, chronic hypertension, and diabetes. Currently, Foley catheter balloon is the most commonly used mechanical device for labor induction, which acts not only as a mechanical dilator of the cervix but also a stimulator of endogenous prostaglandins release from the fetal membranes.[3, 4] Double-balloon catheter has been designed and introduced recently for labor induction. However, two studies showed that double-balloon catheter could not improve outcomes and might be associated with

more operative deliveries compared with Foley catheter balloon. there remains some controversy concerning the dosage, the mode, and interval of administration of misoprostol.[5] Although perhaps more effective, use of a high dose could be associated with an increased risk for hyperstimulation of the uterus; however, there are ongoing trials regarding optimal dose, dosing regimen, and route of administration. In the case of women who have previously undergone a caesarean section and thereby run an increased risk for uterine rupture in connection with vaginal delivery, induction of labour with misoprostol may further enhance this risk and is not recommended.[6] Hence, the present study was conducted to compare cervical ripening and induction of labour with intravaginal Misoprostol and transcervical Foley's catheter as their safety and efficacy in clinical practice as an induction agent is concerned.

**MATERIALS AND METHODS:**

In the study, 100 patients were observed, who had undergone induction of labour. Out of 100 patients, 50 patients were induced with intravaginal misoprostol and 50 with transcervical Foley/s catheter. A valid consent was taken from the patients and relatives for observing the labour and post-delivery status and evaluation of case papers for the same. History was taken from the patient and antenatal records were checked to look for any high-risk factor, the gestational age was noted, the demographic information was obtained like age, the obstetric history noted. The decision of induction was taken by the concerned obstetrician, depending on the indication and Bishop score and the assessment of pelvic adequacy and excluding the patient for home vaginal delivery was contraindicated. Informed consent was taken by us to observe the labour and its outcome. For the patients whose labour was induced with vaginal Misoprostol, dose of 25 mcg was inserted per vaginum, after assuring that non-stress test was reactive. Fetal heart rate monitoring was done with intermittent auscultation every 30 minutes in first stage and every 5 minutes in 2nd Stage and intrapartum monitoring with cardiotocogram at interval of 2 hours or whenever necessary as decided by obstetricians. The patient was monitored for vital parameters, per proportion which was entered the pelvis, the presentation and the altitude of the presenting part and measuring the uterine contractions in term of number, duration, frequency and intensity in 10 minutes interval. Pelvic exam is repeated after 4 hours or depending on the uterine activity and fetal heart rate pattern. If labour has not been established then dose of 25 mcg per vaginum was repeated and similar procedure followed. If labour was established, patient was reassessed after 2 hours for the same parameters, if needed, augmentation with injection Oxytocin was done depending on uterine activity and fetal heart rate pattern. The dose of Misoprostol was repeated again with 4 hours of second dose, if labour not established. For the second group, under all aseptic precautions 18 F Foley's catheter placed through the cervix with the help of artery forceps. The balloon will be inflated with 50cc sterile solution. It pulled against internal os and with the help of tape tied to inner side of thigh for traction. Continuous monitoring for vital parameters, FHS and uterine activity done. In case spontaneous expansion of Foley's catheter does not take place after 6 hours, balloon will be deflated patient reassessment depending on the clinical situation decision regarding starting of Oxytocin augmentation made. The end point of study will be achieved by delivery of baby after induction other vaginally or by C section until patient and baby discharged from the hospital

The groups were compared by Chi square or Fisher's exact test for categorical variables and Student's T- test or the Mann Whitney U test for continuous variables where appropriate. All p values are reported on two sides. P value $\leq$0. 05 was considered statistically significant.

**RESULTS:**

Table 1 and 2 shows demographic variables of two groups. The study showed that there was no difference in the demographic characteristics of the two groups. The age distribution being in the same among two groups. [Fig 1] Table 3 shows maternal complications. One patient induced with vaginal Misoprostol, G2MTP1, 39. 2 weeks of gestation included in view of cholestasis in pregnancy develop uterine hyperstimulation ($\geq$6 contractions in 10 minutes associated with non reassuring fetal heart pattern) with one dose of vaginal Misoprostol and required Cesarean Section. Baby had one minute APGAR score of 9. Another patient induced with vaginal Misoprostol primigravida induced in view of postdatism who had normal vaginal delivery after two doses of Misoprostol had Postpartum pyrexia. Patient treated with intravenous antibiotics and antipyretics patient had no more fever spikes and rest of Postpartum period was uneventful. There were no maternal complications observed associated with cervical Foley's catheter. Table 4 shows neonatal outcome in two study groups. Out of 100 babies born, 92 had one-minute Apgar score as $\geq$7 and only 8 had Apgar score $\leq$7 at 1 min. Severe birth asphyxia with very low Apgar scores less than 3 was not seen in the study does. Thus, there was no statistical difference between the two groups as far as neonatal outcome in terms of 1-minute Apgar score is concerned.

**Table 1:** Demographic characteristics of two groups- Age

| Demographic character | Vaginal Misoprostol | Transcervical Foley's | p-value |
|---|---|---|---|
| Age (mean $\pm$ SD) | 26.98 $\pm$ 4.023 | 25.74 $\pm$ 3.641 | 0.109 |

**Table 2:** Demographic characteristics of two groups- Parity

| | Method of induction | | Total | p-value |
|---|---|---|---|---|
| | Misoprostol | Foley | | |
| Nullipara | 39 | 36 | 75 | 0.488 |
| Multipara | 11 | 14 | 25 | 0.644 |
| Total | 50 | 50 | 100 | |

**Figure 1:**

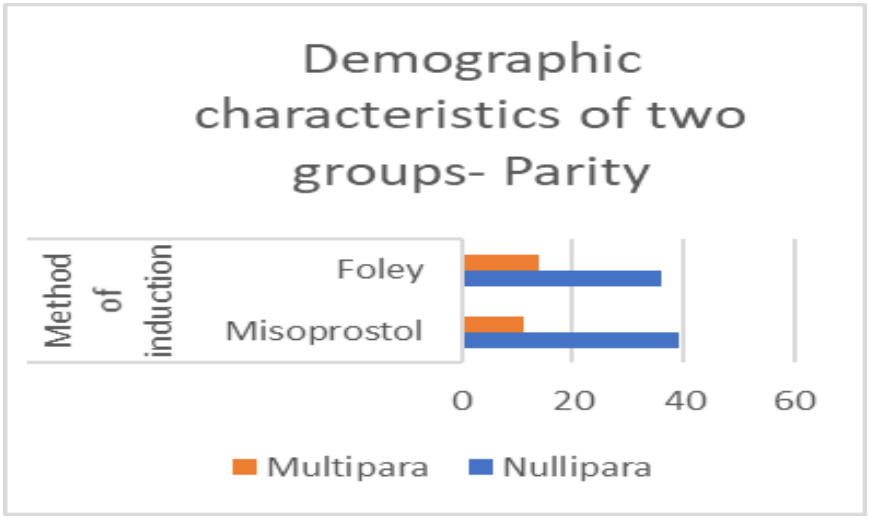


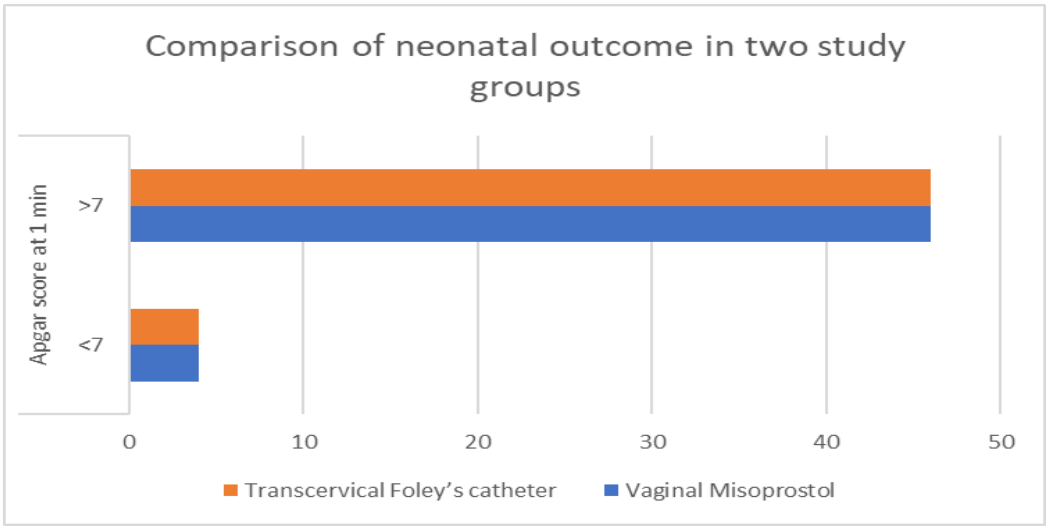

**Table 3:** Maternal complications

| Maternal complications | Vaginal Misoprostol | Transcervical Foley's catheter |
|---|---|---|
| Uterine hyperstimulation | 1 | 0 |
| Post-partum pyrexia | 1 | 0 |

**Table 4:** Neonatal outcome in two study groups

| Mode of delivery | Apgar score at 1 min | | Total | p-value |
|---|---|---|---|---|
| | ≤7 | ≥7 | | |
| Vaginal Misoprostol | 4 | 46 | 50 | 1.000 |
| Transcervical Foley's catheter | 4 | 46 | 50 | 1.000 |
| Total | 8 | 92 | 100 | |

**Figure 2:**



**DISCUSSION:**

In the present study, it was observed that there was no difference in the demographic characteristics of the two groups. The age distribution being in the same among two groups. One patient induced with vaginal Misoprostol, G2MTP1, 39. 2 weeks of gestation included in view of cholestasis in pregnancy develop uterine hyperstimulation (≥6 contractions in 10 minutes associated with non-reassuring fetal heart pattern) with one dose of vaginal Misoprostol and required Cesarean Section. Baby had one-minute APGAR score of 9. Another patient induced with vaginal Misoprostol primigravida induced in view of postdatism who had normal vaginal delivery after two doses of Misoprostol had Postpartum pyrexia. Garba I et al compared the induction delivery intervals using transcervical Foley catheter plus oxytocin and vaginal misoprostol, and to identify the factors associated with successful induction among postdate singleton multiparae. The study was a prospective randomized controlled trial of singleton multiparous pregnant women. They were randomized into two groups, one group for intravaginal misoprostol and the other group for transcervical Foley catheter insertion as a method of cervical ripening and IOL. The incidence of postdatism was found to be 136 (13.1%). The mean induction delivery time interval was shorter in the misoprostol group 70 (5.54 ± 1.8 h) than in the Foley catheter oxytocin infusion group 66 (6.65 ± 1.7 h) (P = 0.035). There was, however, no statistically significant difference in the maternal and neonatal outcomes when these two agents were used for cervical ripening and IOL. Higher parity and higher Bishop's score were the factors found to be associated with high success rate of IOL. They concluded that vaginal misoprostol resulted in shorter induction delivery time interval as compared to transcervical Foley catheter. High parity and high Bishop's scores were the factors found to be associated with the success of IOL. Adeniji OA et al compared the effectiveness of the intravaginal Misoprostol and transcervical Foley catheters as pre-induction cervical ripening agents, to estimate the proportion of patients achieving vaginal delivery and to compare the complications of labour and foetal outcome between the two groups. The study was a prospective, randomised study of pregnant women, with singleton pregnancies who presented for antenatal care and delivery at the University College Hospital (UCH), Ibadan, Nigeria. Ninety-nine patients were invited to participate and ninety-six (96) agreed. No patient withdrew from the study. The patients were assigned by means of computer-generated random numbers to receive transcervical Foley catheters (Size 16F, with 30 ml balloon capacity) or 50 microg intravaginal Misoprostol (Cytotec tablet, Searle & Co., Chicago). Fifty (50) patients received intravaginal Misoprostol and Forty-six (46) received Transcervical Foley catheters. The proportions of nulliparous, primiparous and multiparous patients were 52, 20 and 28% in the misoprostol group and 43.5, 26.1 and 30.4%, respectively, in the Foley catheter group. The time to achieve a favourable cervical status was significantly shorter in the Misoprostol group, with 98.0% of the subjects attaining Bishop score > or = 6 within 6-12 hours of insertion of the study agent, in contrast to 69.0% of the subjects in the Foley catheters group. Thirteen (26.6%) and three (6.5%) patients in the Misoprostol and Foley catheters groups, respectively, went into labour while undergoing cervical ripening and all had uneventful vaginal deliveries. The induction-delivery interval did not differ significantly between the groups. They concluded that intravaginal Misoprostol is as effective a pre-induction cervical ripening agent as transcervical Foley catheters, with added advantages of shorter duration of cervical ripening, reduced oxytocin requirement for induction of labour and greater , acceptability to patients. [7, 8]

Ugwu EO et al conducted a randomised controlled trial carried out over a 14-month period in a tertiary health institution in Nigeria, to determine the effectiveness of Foley catheter and synchronous low dose misoprostol for pre-labour cervical ripening. Term pregnant women with unfavourable cervices (Bishop's score < 6) requiring cervical ripening/induction of labour were assigned randomly into three groups: Group A, transcervical Foley catheter was used synchronously with low dose intravaginal misoprostol; Group B, transcervical Foley catheter alon,e was used and Group C, low dose intravaginal misoprostol alone was used. The time to achieve a favourable cervical status as well as vaginal delivery was significantly shorter in the synchronous group than in the control groups. The synchronous use of Foley catheter and misoprostol is very effective in cervical ripening and should be considered in clinical situations where there is need to hasten vaginal delivery in the presence of an unripe cervix. Vahid Roudsari F et al compared vaginal misoprostol with Foley catheter for cervical ripening and induction of labor. This randomized clinical trial was performed on 108 pregnant women who had referred to the teaching hospitals of Mashhad University of Medical Sciences during a time period of September 2007 to March 2008. These women were randomly divided into two groups: Misoprostol (including 49 patients) and Foley catheter (including 59 patients). For the first group, 25 microgram vaginal misoprostol was administered every 4 h up to maximum 6 doses. For the second group, Foley catheter 18 F, inflated with 50 cc of sterile water, was placed through the internal os of the cervix. Two groups were similar in the view of demographic characteristics, cesarean indications, maternal and fetal outcomes and neonatal outcomes. Vaginal delivery was significantly higher in misoprostol group. The mean of delivery time was significantly shorter in misoprostol group. In the cases of pregnancy termination and unripe cervix, two methods of misoprostol and Foley catheter were considered suitable, but it seemed that misoprostol decreases the delivery time and was needed for the cesarean section.[9, 10]

## CONCLUSION:

Thus, when used rationally and with a good quality of intrapartum monitoring, bith Foley's catheter and Misoprostol are equally efficacious and safe for labor induction.

## REFERENCES:


1. Mozurkewich E., Chilimigras J., Koepke E., Keeton K., King V. J. Indications for induction of labour: a best-evidence review. BJOG: An International Journal of Obstetrics and Gynaecology. 2009;116(5):626–636.
2. Promila J., Kaur G. B., Bala T. A comparison of vaginal misoprostol versus Foley's catheter with oxytocin for induction of labor. The Journal of Obstetrics and Gynecology of India. 2007;57(1):42–47.
3. Jozwiak M, Rengerink KO, Benthem M, van Beek E, Dijksterhuis MG, de Graaf IM, et al. Foley catheter versus vaginal prostaglandin E2 gel for induction of labour at term (PROBAAT trial): an open-label, randomised controlled trial. Lancet. 2011; 378: 9809: 2095–2103.
4. van Baaren G, Jozwiak M, Opmeer B, Oude Rengerink K, Benthem M, Dijksterhuis M, et al. Cost-effectiveness of induction of labour at term with a Foley catheter compared to vaginal prostaglandin E2 gel (PROBAAT trial). BJOG. 2013; 120:987–995.
5. Dewan F, Ara AM, Begum A. Foley's catheter versus prostaeglandin for induction of labour. Singap J Obstet Gynaecol. 2001;32:56–63.
6. Anthony C, Sciscione DO, Helen M, et al. A prospective, randomized comparison of Foley catheter insertion vs. intracervical $PGE_2$ gel for preinduction cervical ripening. Am J Obstet Gynecol. 1999;180:55–59. doi: 10.1016/S0002-937t8(99)70149-3.
7. Garba I, Muhammed AS, Muhammad Z, Galadanci HS, Ayyuba R, Abubakar IS. Induction to delivery interval using transcervical Foley catheter plus oxytocin and vaginal misoprostol: A comparative study at Aminu Kano Teaching Hospital, Kano, Nigeria. Annals of African Medicine. 2016;15(3):114-119. doi:10.4103/1596-3519.188890.
8. Adeniji OA, Oladokun A, Olayemi O, Adeniji OI, Odukogbe AA, Ogunbode O, Aimakhu CO, Omigbodun AO, Ilesanmi AO. Pre-induction cervical ripening: transcervical foley catheter versus intravaginal misoprostol. J Obstet Gynaecol. 2005 Feb;25(2):134-9.
9. Ugwu EO, Onah HE, Obi SN, Dim CC, Okezie OA, Chigbu CO, Okoro OS. Effect of the Foley catheter and synchronous low dose misoprostol administration on cervical ripening: a randomised controlled trial. J Obstet Gynaecol. 2013 Aug;33(6):572-7. doi: 10.3109/01443615.2013.786030.
10. Vahid Roudsari F, Ayati S, Ghasemi M, et al. Comparison of Vaginal Misoprostol with Foley Catheter for Cervical Ripening and Induction of Labor. Iranian Journal of Pharmaceutical Research : IJPR. 2011;10(1):149-154.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