

# Contrastive Analysis of Vaginal Misoprostol and Foley Catheter in Cervical Ripening and Labor Induction

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## ABSTRACT

**Background&Objective:** The induction of labor is needed to terminate pregnancy in pregnant women lacking labor pain. Common indications of labor induction include rapture of membranes without labor pain, hypertension, fetus' unreassuring conditions and post-term pregnancies. The purpose of this study is to compare and contrast vaginal misoprostol with Foley catheter in cervical ripening and the induction of labor.

**Materials & Methods:** This study was done on pregnant women who showed pregnancy termination indication for any cause, using randomized clinical trial method. Inclusion criteria in this study included gestational age equal to or greater than 37 weeks and ultrasonography of the first trimester, unfit cervix Bishop Score 1 equal to or less than 4, single-shot pregnancies, vertex display, intact membrane and the subject's consent to participate in the research. Patients were divided into two equal groups of 60. Oxytocin was used for the induction of labor if the patient did not enter the active phase.

**Results:** In this study, the average age of women in Foley catheter group and misoprostol group were  $27.03 \pm 4.04$  and  $26.85 \pm 3.49$  respectively in which there was no meaningful difference statistically. However, the average age of women with cesarean delivery was statistically more than the average age of women with NVD. Bishop score 2 has demonstrated more increase in comparison to Bishop score 1 among Foley catheter group rather than misoprostol group. The average of labor speed, the number of women with NVD and the failure of induction in Foley catheter group exceeded those in misoprostol group.

**Conclusion:** According to the results gained in this study, Foley catheter application for induction of labor had better outcomes in comparison to vaginal misoprostol. It can even be a better alternative for vaginal misoprostol; hereby the side effects of misoprostol such as possible tachysystol and fetus distress can be prevented.

**Keywords:** Cervix ripening, Foley catheter, Induction of labor, Misoprostol



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## Introduction

Whenever the benefits of ending pregnancy before the automatic beginning of labor excel the benefits of pregnancy continuation that is the time for labor induction (1). Labor induction is a common necessity to induce labor in the absence of labor pain (2).

Common indications of labor induction include rapture of membranes without labor pain, hypertension, fetus' unreassuring conditions and post-term pregnancies (3). Nowadays, using active labor induction is continuously increasing and labor induction is used in more than 15% of pregnancies (1). Amniotomy and induction using

oxytocin are among common methods of labor induction, at the moment (4,5).

The rate of success in these methods depends on the degree of cervical ripening before induction. Cervix condition and its desirability is hugely essential for labor induction and it is not desirable enough in most of the situations where labor induction is needed. Bishop is one of the scoring methods for cervix in which the less the score, the less cervical ripening and consequently the less the possibility of successful labor induction. This also doubles the demand of cervical ripening (1).

In previous researches the Bishop score for undesirable cervix equals 4 or less which is the cervical ripening indication. Therefore, special attention has been paid to cervical ripening before the induction of labor (6).

Various methods are being used for cervical ripening which can be categorized into two general groups of medical techniques and mechanical techniques (7).

There is a risk of uterine rupture following uterine tachysystole in medical methods, therefore, there is a particular focus on mechanical methods for cervical ripening and extensive studies has been done in this area and on comparing the effects of different methods (8).

Mechanical methods are generally classified in three categories: cervical trans catheter, hygroscopic dilators including Laminaria and stripping membranes (9).

Cervical trans catheter with or without Salin infusion, causes immediate improvement of Bishop score and decreasing labor speed. Laminaria is a type of seaweed which functions as a cervical dilator in the way that it thickens gradually through absorbing moisture and dilates cervix (1).

Synthetic misoprostol is prostaglandin E1 which is used to prevent ulcer peptic in 100 and 200 microgram tablets. This product is utilized for cervical ripening and labor induction and it can be prescribed oral or vaginal (2). Its vaginal application is more effective and it has less maternal complications. It is also more economical considering the fact that one 100 microgram misoprostol tablet costs less than \$1 while the cost for a dose of 0.5 milligram dinoprostol vaginal jelly is \$75. Side effects such as nausea, vomit, diarrhea, fever and cramp is also less seen while using misoprostol (3,10,11).

Prostaglandin E2 physiologically improves cervical ripening by increasing membrane mucus under the cervix and fluctuating collagen bands. It also increases uterine myometrial sensitivity to oxytocin (12).

In lots of studies, Foley catheter and prostaglandin effects have been compared in cervical ripening before labor induction. In Dalui study, Foley catheter has been more effective than prostaglandin E2 in cervical ripening before the induction of labor utilizing oxytocin (13), whereas in Saleem study prostaglandin E2 and Foley catheter were contrasted in cervical ripening before labor induction with oxytocin and no discrepancy was seen in induction duration and cesarean rate (14). In Cromi study, as well, which was a descriptive one, utilizing Foley catheter inside cervix before labor induction was found safe and effective (15). In previous clinical

trials, gestational age and the number of delivery have been widely diverse and different results have been gained. Cervical stretching by Foley catheter is one of the mechanical methods and utilizing misoprostol prostaglandin E2 a medical one, by the combination of which cervical ripening and labor induction is possible (16).

In a study by Jozwiak *et al.* vaginal misoprostol and Foley catheter placed in cervix and the combination of both methods were examined. In this study there was no difference among the three groups in terms of vaginal delivery rate and labor induction duration, delivery active phase duration and the interval between induction and the beginning of active phase. They also concluded that combining both methods is necessarily more effective on cervical ripening (17).

Studies done by other researchers also indicated similar results. Since no study has been done in Iran in this matter so far, and since it is of great importance to prevent taking medications which are not easily provided, more practical methods are required. Therefore, it was decided to do a contrasting analysis on using vaginal misoprostol on its own and cervical stretching through Foley catheter and the combination of these two methods for cervical ripening and labor induction. If the same results of the above-mentioned studies are gained, it suffices to stretch the cervix in such cases (15).

Particular attention has been paid to mechanical methods for cervical ripening since there are the risks of uterine rupture following possible tachysystole, fetal distress and mother and fetus death in medical methods for cervical dilatation. Therefore, this study was designed.

## Materials and Methods

This was a Randomized clinical trial which was performed between December 2016 and September 2019. Women visiting delivery block in Besat Hospital and had the indication of labor induction were examined. Inclusion criteria in the study were: gestational age equaling or greater than 37 weeks (based on first trimester sonography and certain LMP), unfit cervix (Bishop score 1 equaling or less than 4), single-shot pregnancy, vertex display, intact membrane and patient's consent to participate in the study. Patients were also homogenized in term of gravid distribution. Criteria for exiting the study were cesarean background, previous uterine surgery, vaginal bleeding, placenta previa, the possibility of placenta abruption, regular uterine contractions, potential susceptibility to contra-indication of prostaglandins and IUGR fetuses and severe preeclampsia, problem in controlling the fetal heart rate and fetal distress. Patients were distributed in random 4-part

blocks and the methods were randomly attributed to each.

This study was done on pregnant women who showed pregnancy termination indication for any cause (delivery date, post-term pregnancy, hypertension), using a randomized clinical trial. Based on the formula for determining the sample size of patients who had inclusion criteria, the minimum number of patients in each group was 60, and 120 patients were enrolled in the study. The study was approved by the Ethics Committee of the Faculty of Medicine and the procedure was fully explained to the patients, who, in case of written consent, were included in the study. In the first group (misoprostol group), misoprostol at 25 µg (200mg Samisaz tablets divided by divaidier) was placed in the posterior fornix of the vagina and was repeated almost every 6 hours to a maximum of 3 doses (75 µg total).

If the patient did not enter the delivery phase (regular uterine contractions accompanied by progressive changes in the cervix), after 12 hours of induction, oxytocin was used to terminate the pregnancy.

In the second group (Foley catheter), including 60 patients, Foley catheter 16 was injected through the cervix under sterile condition (vaginal rinse with iodine) and then a balloon filled with 30 mL of distilled water, was placed behind the interior hole. Then, the other end of the catheter was attached to the patient's bed to a 500 mL serum to create stretching. If, after 6 hours, the patient did not enter the active phase on her own, labor induction began using oxytocin.

The fetal heart rate and maternal uterine contractions were monitored every 15 minutes. The age of the mother, the gestational age, the initial bishop scores (before the onset of induction), the interval between the start of the procedure and the beginning of the active phase, the interval between the onset of the method and the delivery, active phase duration, the mode of delivery, the baby's Apgar score in both groups were recorded and compared with each other. Descriptive statistics has been used to summarize and report the results of the effects of Foley catheter and vaginal misoprostol in terms of their variables. In order to compare these two methods, in terms of induction rate and Bishop Score, independent t test was used. To compare the two methods from the point of view induction security, the X<sup>2</sup> test was used.

## Results

In this study, the average age of women in Foley catheter group and misoprostol group were  $27.03 \pm 4.04$  and  $26.85 \pm 3.49$  respectively in which there was no meaningful difference statistically. However, the average age of women with

cesarean delivery was statistically more than the average age of women with NVD. Bishop score 2 has demonstrated more increase in comparison to Bishop score 1 among Foley catheter group rather than misoprostol group. The average of labor speed, the number of women with NVD and the failure of induction in Foley catheter group exceeded those in misoprostol group. Fetal distress and meconium excretion occurred more in vaginal misoprostol group rather than Foley catheter group. There was no significant difference in Apgar scores in the two approaches of labor.

## Discussion

Labor induction can be problematic when cervical condition is undesirable; this can even lead to cesarean or maternal and neonatal consequences. For this reason, the present study was done with the purpose of contrasting vaginal misoprostol and Foley catheter in cervical ripening for labor induction. In this study, the average age of women in Foley catheter group was greater than the average age in misoprostol group and it was also higher in women with cesarean delivery in comparison to those who had NVD, however no cases of cord prolapse was recorded in either group.

The mean of labor speed was significantly higher in Foley catheter group than the vaginal misoprostol group. In a study by Cunningham *et al.*, Foley catheter 80 mL was found faster and more effective for dilatation than Foley catheter 30 mL (3). Additionally, in other studies, the use of Foley catheter has been suggested for rapid progression of delivery even in patients with a history of cesarean delivery to whom NVD has been suggested (2,10,11).

The induction safety in the Foley catheter group was greater than the vaginal misoprostol group, but this difference was not statistically significant. The number of secure inductions in women with normal delivery was higher than those with cesarean delivery, but this difference was not statistically significant.

To justify this, it can be noted that the Foley Catheter method is safer compared to Misoprostol, which has been mentioned in numerous studies. It is because in the Foley method, dilatation usage and prostaglandin release result in a proportional relationship in the delivery stages. In this way misoprostol treatment mostly considers the effects of contractions, therefore tachysystol causes significant complications. The lack of difference can be due to the small number of samples. Incompatibility in the results of the studies is also due to the dose of misoprostol, the application intervals, application specifications such as the size of the catheter, and the rate of cuff inflammation.

The number of NVD women was higher in Foley catheter group than in vaginal misoprostol group. This was in contrast with the study done by Vahid Roudsari *et al.* in which it was demonstrated that natural delivery rate was higher in vaginal misoprostol group in comparison to Foley catheter group. It was also in contrast with the studies done by Noor *et al.* and Chen *et al.* in which there was no difference in the type of delivery in the two groups (18,19). One of the differences of this study to the previous ones can be the fact that in the study done by Noor *et al.* amniotomy and indication with additive oxytocin dosage was done after cervical ripening and it might be the early amniotomy in this stage which can justify the reason for difference (18,19).

A positive and significant relationship was observed between labor speed and Bishop score. This means that labor speed increased with increase in Bishop score. This is also in accordance with the current study (1).

The mean of Bishop 1 and Bishop 2 was higher in Foley catheter group than in vaginal misoprostol group, however the difference was not statistically significant. The mean of Bishop 1 and Bishop 2 was significantly higher in NVD women than cesarean women.

As mentioned above, the use of Foley catheter increases the effective indicators in delivery. The minor difference can be caused by the higher Bishop score, since patients with higher scores are more prepared for delivery and its progress. Therefore, it is suggested to adjust and control patients in all terms in future researches.

Induction failure was significantly higher in Foley catheter group than in vaginal misoprostol group. This finding is similar to that of a study done by Owlabi in which 49 cases out of 60 versus 10 cases out of 60 led to failure (2).

In a study done by Martin and another by Mallah, the possibility of success was mentioned as higher in vaginal misoprostol compared to Foley catheter (2,20).

Meconium excretion was higher in vaginal misoprostol group than in Foley catheter group, however this difference was not statistically significant and this was in agreement with a study done by Martin *et al.* (2). In the current study, meconium excretion was significantly higher in cesarean women than NVD women.

Fetus distress was observed more in vaginal misoprostol group than in Foley catheter group, however this was not statistically significant. Fetus distress was significantly more observed in cesarean women than in NVD women.

Heart rate drop and meconium excretion occur in fetus distress cases. Fetus distress and uneasy

blood supply happens due to misoprostol mechanism in increasing uterine counteractions while in Foley catheter method, delivery procedure is accelerated for fetus transfer via dilatation (4).

The reasons for not being significant, in contrast to some studies, can be the sample size, the dosage of the medicine, Foley catheter size, and the amount the catheter is inflated. The above reasons mostly are true for cesarean patients because of the pathology which leads to cesarean. That is because neonates with fetus distress are more likely to have cesarean (5).

Baby's Apgar score in women with NVD was higher than in women with cesarean; however, the difference was not statistically significant. This happens because patients requiring cesarean usually have indications such as respiratory distress and hard delivery etc. or women with background causes like mothers who have preeclampsia in their background pathology which results in Apgar score decrease.

The mean of labor speed was higher in women for whom vaginal misoprostol was applied more times, but the difference was not statistically significant. In a study done by Kariane *et al.* it was indicated that the usage of vaginal misoprostol improves the labor induction (6).

By comparing the number of vaginal misoprostol with Bishop1 score, the results indicated that the need for misoprostol was more in the lower limbs, and this difference was statistically significant.

## Conclusion

According to the results of the study, as it can be seen, in general, the use of Foley's catheter for induction of vaginal delivery is better than that of vaginal misoprostol, and can even be a good alternative to it, and the side effects of misoprostol such as the increase in the likelihood of tachycardia and hypertonia can be prevented, although more research is needed in this area with a larger sample size. It should be noted that the effect of Foley's catheter in comparison to vaginal misoprostol has been proven in numerous studies.

## Limitations

To justify and persuade women to be tested, due to the novelty of the method, deploying experienced midwives to apply both methods of induction, physical condition such as age, cervical position at the time of labor, the size of the embryo, the size of the delivery canal, and physical health of the mother, mother's mental-psychological factors such as stress and anxiety.

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## Conflict of Interest

Authors declared no conflict of interest.

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