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Original Research Article

## Foley catheter with vaginal prostaglandin E2 gel versus vaginal prostaglandin E2 gel alone for induction of labour: a randomized controlled trial

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### ABSTRACT

**Background:** Induction of labour is significant when continuing pregnancy possess adverse effect on health of mother and her unborn baby. Different methods have been used for induction of labour. At present there is very less literature regarding simultaneous use of Foleys catheter and PGs. The present study was done to compare the efficacy of using intracervical Foleys catheter and PGE2 gel simultaneously versus PGE2 gel alone for induction of labour.

**Methods:** Prospective study, conducted in department of obstetrics and gynaecology for duration of 6 months. 100 women requiring induction of labour were included in the study and were randomly divided into two groups. 50 women were included in group A (simultaneous use of intracervical Foley catheter with PGE2 gel) and 50 women were included in Group B (intravaginal insertion of PGE2 gel only).

**Results:** Maternal age, gestation age, parity, indication of induction and primary Bishops score were comparable in both the groups. Mean induction to active phase interval in both groups which was  $5.8 \pm 0.80$  hours in Group A and  $6.23 \pm 0.40$  hours in Group B. Also mean time taken from induction to delivery in Group A was  $10.08 \pm 5.6$  hours and in Group B was  $14.6 \pm 6.9$  hours which was significantly less in Group A. The rate of vaginal delivery in group A and Group B was 66% and 58% respectively which was slightly more in Group A but was not significant.

**Conclusions:** In the present study we conclude that simultaneous use of mechanical method with Foleys catheter and PGE2 gel is better and more effective method for induction of labour than PGE2 alone. However, large sample size is required to reach more confirmatory results.

**Keywords:** Cervical ripening, Foley's catheter, PGE2 gel

### INTRODUCTION

Induction of labour is the artificial initiation of labour prior to its spontaneous onset for the purpose of accomplishing delivery of feto-placental unit.<sup>1</sup> Cervical ripening is a process of preparing the cervix by cervical effacement and dilatation (as measured by Bishop's score) for labour induction.<sup>2</sup> The success of induction of labour depends upon the consistency, compliance and configuration of cervix.<sup>3</sup> Induction of labour is significant when continuing pregnancy possess adverse effect on

both mother and neonatal health where induction of labour has been shown to reduce both perinatal and maternal mortality and morbidity. About 20% of all deliveries are proceeded by induction of labour.<sup>4</sup> Different method has been used for induction of labour including mechanical as well as pharmacological ripening agents. Mechanical agents such as transcervical insertion of Foley's catheter and pharmacological agents such as prostaglandins, antiprogestins, or NO donors. Each agent has its own merits and demerits but till date no ideal agent has been found. However, mechanical methods are

among the oldest and most important approaches used for induction of labour.<sup>5,6</sup>

Intracervical Foley's catheter induction produces a mechanical distension of the lower uterine segment. This may lead to activation of Phospholipase-A leading to formation of arachidonic acid which later converted to prostaglandins.

Prostaglandins are derivatives of prostanoid acid and act as local hormones. They have direct effect on the production of procollagenases which is precursor of collagenase, decreases collagen and increases hyaluronic acid which in turn softens the cervix and helps in cervical effacement and dilatation. At present literature is scarce regarding simultaneous use of prostaglandins and mechanical methods to induce labour so the present study aims to compare the efficacy of introducing both transcervical Foleys catheter and prostaglandin E2 gel together with prostaglandin E2 gel alone.

**METHODS**

This was a prospective comparative study done in department of obstetrics and gynaecology S. N Medical college, Agra for a duration of 6 months.

**Inclusion Criteria**

- Singleton pregnancy with live fetus
- Gestational age >36 weeks
- Cephalic presentation
- Intact membranes
- No signs of infections
- Bishops score <5

**Exclusion Criteria**

- Multiple pregnancy
- Hypersensitivity to prostaglandin
- Malpresentation
- Absent membranes
- APH
- Medical disorders like heart diseases, renal disease

Any other contraindication to vaginal delivery such as cephalopelvic disproportion, severe oligohydramnios, IUGR and any other.

A written informed consent was obtained from all subjects prior to the performance of any study related procedure. In this study we recruited 100 antenatal women and were randomly divided into Group A (Foleys catheter and prostaglandin E2 gel) and Group B (prostaglandin E2 gel)

Group A- In 50 women under aseptic condition and after giving prophylactic antibiotic Foley's catheter of 18 F size (which comes in pre-sterilized pack) was introduced

through cervix in extra-amniotic space with an aid of speculum and sponge holding forceps and 30 ml distilled water was instilled into the balloon. Then balloon is pulled up to the internal os. Catheter was tapped with thigh with simultaneous insertion of 0.5 mg of prostaglandin E2 gel (dinoprostone gel) in prefilled syringe in the posterior fornix of the vagina.

Group B- In 50 women only insertion of 0.5 mg of prostaglandin E2 gel (dinoprostone gel) in prefilled syringe in the posterior fornix of the vagina for up to 2 doses if effective uterine contraction didn't begin (6 hours) apart under aseptic precaution.

All patients were monitored clinically for progress of labour and fetal wellbeing. Bishops score was recorded pre induction and post induction after 6 hours of induction, doses required for induction, induction to active phase time duration, induction to delivery time duration, length of active phase, mode of delivery, Intrauterine infection was recorded if there was any febrile morbidity during study period, Uterine tachysystole (defined as >6 contraction every 10 minutes), and uterine hyperstimulation (continuing contraction more than 2 minutes) or any other associated obstetric and intrapartum complications.

**RESULTS**

In the present study total of 100 antenatal women with indication of pregnancy termination were evaluated. Both the groups were similar in the view of demographic profile including age, parity, and Bishop score. The mean and standard deviation of age in both groups was 24.3±4.0 and 24.2±5.0 (p>0.1) respectively. Gestational age in group A was 40±0.9 weeks and in group B was 39.8±1.4 weeks (p>0.1).

**Table 1: Comparison according to pre and post induction bishops score.**

	Group A N=50	Group B N=50	p- value
Mean Primary bishops score	1.80±0.40	1.64±0.48	0.0001
Mean Post induction bishops score	7.16±0.37	6.80±0.50	0.0001

The primary bishop score in group A was 1.80±0.40 and in group B was 1.64±0.48. post induction bishop score in group A and group B was 7.16±0.37 and 6.80±0.50 respectively as shown in Table 1.

Table 2 shows mean induction to active phase interval in both groups which was 5.8±0.80 hours in Group A and 6.23±0.40 hours in Group B which is not significant (p>0.1), also mean time taken from induction to delivery in Group A was 10.08±5.6 hours and in Group B was 14.6±6.9 hours which was significantly less in Group A

because of combined mechanism of action of both mechanical and pharmacological agent used in Group A as compared to Group B ( $p < 0.5$ ).

**Table 2: Comparison of mean of phases of labour in both groups.**

	Group A N= 50	Group B N=50	p value
Mean Induction to active phase interval (in hours)	5.80±0.80	6.23±0.40	>0.1
Mean Induction to delivery interval (in hours)	10.08±5.6	14.6±6.9	<0.05

Table 3 shows number of prostaglandin E2 gel doses required in Group A only 20% women required second dose of PGE2 gel whereas in Group B 70% women required second dose. Also, more women in Group B required oxytocin augmentation than Group B.

**Table 3: Number if doses required for induction.**

No. of doses	Group - A	Group - B
1	40(80%)	15(30%)
2	10(20%)	35(70%)

Table 4 shows mode of delivery in both groups, the rate of vaginal delivery in group A and Group B was 66% and 58% respectively which was slightly more in Group A but was not significant.

**Table 4: Mode of Delivery in both groups.**

Mode of delivery	Group A N=50	Group B N=50
Caesarean section	15(30%)	18(36%)
Instrumental vaginal	2(4%)	3(6%)
Spontaneous vaginal	33(66%)	29(58%)

Table 5 shows indication of caesarean section in both groups, in Group A chances of cord prolapse is slightly higher seen in 3 women whereas failed induction was more in group B as seen in 10 women which leads to caesarean section delivery in both groups.

**Table 5: Caesarean section indications in both groups.**

Indications	Group A N=50	Group B N=50	Total
Fetal distress	8	6	14
Non-progression of labour	2	10	12
Meconium stained liquor	2	2	4
Cord prolapse	3	0	3
Total	15	18	33

Regarding the result shown in Table 6 tachysystole was observed in 2 women in group A and no one in the group B. 1 women in Group A and 1 women in Group B was complicated by uterine atony after delivery but the observation was not statistically significant ( $p > 0.1$ ).

**Table 6: Pregnancy outcomes in both groups.**

Outcomes	Group A	Group B
Uterine hypertonicity	1	0
Uterine tachysystole	2	0
Uterine atony	1	1

## DISCUSSION

This study was conducted to compare the effectiveness of using simultaneous insertion of intracervical foley catheter and intravaginal prostaglandin E2 gel with only placement of intravaginal prostaglandin E2 gel.

Ideally a cervical ripening agent include cervical remodelling without stimulating uterine activity. It should be effective, convenient, safe, reversible and inexpensive.

The use of Foleys catheter to effect cervical ripening was first described by Embrey and Mollison in 1967.<sup>7</sup> The advantage of such mechanical methods of induction are simplicity of use, potential of reversibility, reduction in certain side effects like excessive uterine activity and low cost.<sup>8</sup>

Prostaglandin especially PGE2 are extensively used for cervical ripening. They reduce the likelihood of not being delivered in 24 hours and decrease in use of oxytocin for augmentation but with higher rate of uterine stimulation.<sup>9</sup>

Multiple studies have been done comparing effectiveness and safety between prostaglandin and Foleys catheter. Sciscione et al., compared the two methods and showed that Foleys catheter group had a shorter induction delivery interval.<sup>10</sup> St Onge and Connors found that both Foleys catheter and PGE2 gel methods led to similar improvement in Bishop's score.<sup>11</sup>

## CONCLUSION

In the present study Cervical ripening is more effective with Group A induction. Mean induction to active phase and mean induction to delivery interval were shorter in Group A.

From this study we conclude that simultaneous use of mechanical method with Foleys catheter and PGE2 gel is better and more effective method for induction of labour than PGE2 alone. However, large sample size is required to reach more confirmatory results.

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