

Dinoprostone Vaginal Insert vs Intracervical Foley Catheter for Preinduction Cervical Ripening in Women with Previous Cesarean Section

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ABSTRACT

Aim: To determine the efficacy of Foley catheter compared to dinoprostone insert for preinduction cervical ripening in women with a previous cesarean delivery.

Background: Labor induction is a common intervention in obstetric practice. Both intracervical Foley catheter and dinoprostone insert have been used for the ripening of the cervix and labor induction. Foley catheter has been used for cervical ripening and labor induction in women with previous cesarean section. Recently dinoprostone insert has been approved for preinduction cervical ripening in women having unfavorable cervix.

Method: A prospective clinical observational study was conducted in Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh from October 2019 to December 2021.

Results: Group I included women who were induced with dinoprostone insert while group II had women induced with transcervical Foley catheter. Most of the women in both groups were induced for hypertensive disorders and gestational age >40 weeks. Successful vaginal birth was significantly higher in the Foley catheter group as compared to the dinoprostone group. Significant uterine hyperstimulation was seen in women induced with dinoprostone while there was negligible maternal and neonatal complications in group II.

Conclusion: Our study showed that transcervical Foley catheter was more effective, safe, and acceptable method for labor induction in women with previous cesarean sections without increasing maternal and neonatal morbidity. There was an increased rate of uterine hyperstimulation and scar tenderness in women who were induced with dinoprostone insert.

Clinical significance: Intracervical Foley catheter is a better preinduction cervical ripening agent in women with previous cesarean section.

Keywords: Cervical ripening, Dinoprostone, Induction of labor, Insert, Previous cesarean section, Trial of labor after cesarean, Vaginal birth after cesarean.

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INTRODUCTION

Induction of labor is the artificial initiation of uterine contractions in a relaxed uterus.¹ Induction starts the process of labor comprising of cervical dilatation, effacement, and uterine contractions which ultimately leads to the birth of the baby.

A trial of labor after cesarean (TOLAC) is a planned attempt to achieve a successful vaginal delivery in a woman with a previous history of cesarean delivery. This vaginal birth after cesarean section (VBAC) leads to decreased maternal complications immediately and in the future.² According to ACOG, pregnant women with previous cesarean delivery with low-transverse incision are eligible for TOLAC, they can be counseled for the trial of labor.

Various mechanical and pharmacological methods are in use for induction of labor, although no single method is suitable and universal for every clinical situation.

Balloon catheters have been used for decades for the purpose of labor induction. Foley catheter is inserted above the level of internal os and filled with 60 cc of normal saline to cause mechanical dilatation of the cervix. Cervical ripening occurs due to direct pressure and overstretching of the lower uterine segment, causing release of prostaglandins. It has a good safety profile, is inexpensive, and has got higher reliability for inducing the ripening of the

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cervix and hence labor induction. This mechanical method has a decreased risk of uterine tachysystole and fetal distress but poses a higher risk of accidental membrane rupture, prolapse of cord, and chorioamnionitis because of ascending infections.³

A dinoprostone vaginal insert is a thin, flat, polymeric rectangular slab that contains 10 mg of dinoprostone. The controlled-release formulation releases dinoprostone at a sustained rate of 0.3 mg per hour. Many studies have evaluated the ripening of the cervix with prostaglandin E₂ (PGE₂) and have reported different results. Leftwich did a retrospective cohort study to conclude that there was significantly higher incidence of uterine rupture in women with previous cesarean section who were induced with dinoprostone insert when compared with those induced with Foley catheter with oxytocin.⁴

In view of the gap in the knowledge on the subject, we conducted this study comparing the effectiveness and safety profile of dinoprostone vaginal insert with transcervical Foley catheter for ripening of cervix and induction of labor.

MATERIALS AND METHODS

The prospective clinical observational study was conducted in the Department of Obstetrics and Gynaecology in collaboration with the Department of Paediatrics at Jawaharlal Nehru Medical College and Hospital, Aligarh Muslim University, Aligarh from October 2019 to December 2021.

The purpose of the study was to determine the efficacy of transcervical Foley catheter vs dinoprostone insert for preinduction cervical ripening in women with previous cesarean section at term. Our study comprised 85 women who had a history of previous cesarean delivery and required labor induction.

Pregnant women with a history of previous cesarean section with a singleton gestation, gestational age more than 34 weeks, cephalic presentation, Bishop score of ≤ 6 , reactive non-stress test with intact membranes, and with an indication for induction were included in the study.

Exclusion criteria were any condition precluding vaginal delivery, any contraindication to prostaglandins such as a history of bronchial asthma, previous uterine surgery other than lower segment cesarean section, abnormal placental location, active genital tract infection, abnormal fetal heart rate pattern (FHR), and allergy to latex or ruptured membranes. Women were divided into two groups:

1. Group I – thirty-five women who received a dinoprostone insert.
2. Group II – fifty women who received intracervical Foley catheter.

The dinoprostone insert was placed transversely in the posterior vaginal fornix. Insert was left *in situ* for 24 hours. Intracervical Foley catheter was instilled with 60 cc saline followed by 30 cc after 8 hours. Women in both the groups were monitored with regular

FHR monitoring and assessment of uterine contractions. All the women were monitored carefully, and if they went into labor with cervical dilatation >3 cm or moderate uterine contractions or in case of any adverse event like uterine tachysystole, scar tenderness, and fetal distress or if more than 24 hours elapsed since placement, the insert and Foley catheter were removed. Reassessment of Bishop's score was done following the removal of the insert or catheter in both the groups. The statistical analysis was carried out using computer-based software SPSS 25.0.

RESULTS

The mean age of women in group I was 27.49 ± 3.18 years, while that of women in group II was 28.29 ± 3.69 years. The mean gestational age in group I was 39.69 ± 1.25 weeks and that in group II was 39.27 ± 1.43 weeks. Both the groups were comparable in terms of age and gestational age. Group I had 62.86% of primiparas, while group II had 62.0% of primiparous women, which was not statistically significant. Majority of the women in both the groups belonged to rural areas, i.e., 57.14% in group I and 62.0% in group II (Table 1).

The most common indication for induction in group I was hypertensive disorders (31.43%), while in group II, 20.0% of women had hypertensive disorders. Induction for gestational age >40 weeks was done in 22.86% in group I and 24.0% in group II (Table 2).

The mean preinduction Bishop score in group I was 3.23 ± 0.43 compared with 3.41 ± 0.62 in group II. The improvement in Bishop's score postinduction was better in group II. Mean postinduction Bishop score in group I was 5.20 ± 1.13 , while in group II, it was 8.33 ± 2.60 . Women induced with Foley catheter had a significantly better postinduction Bishop score as compared with those induced with dinoprostone insert (Table 3).

The mean duration of induction to active labor in group I was 9.04 ± 5.04 hours, while that in group II was 13.14 ± 5.15 hours which was statistically significant.

The mean induction to delivery time in group I was 16.43 ± 11.17 hours as compared with 21.00 ± 7.59 hours in group II.

When the mode of delivery was compared, only 8.57% of women in group I had a successful VBAC as compared with 62.0% of women in group II. Women induced with dinoprostone insert had a significantly higher rate of cesarean section as compared to those induced with Foley catheter (91.43% in group I vs 38.0% in group II) (Table 4).

The most common indication for cesarean delivery in both the groups was fetal distress (65.63% in group I vs 86.36% in group II) (Table 5).

Table 1: Baseline characteristics

Baseline characteristics	Group I	Group II	p-value
Age (mean \pm SD)	27.49 ± 3.18	28.29 ± 3.69	>0.05
Gestational age (mean \pm SD)	39.69 ± 1.25	39.27 ± 1.43	>0.05
Area of residency			
Rural (n, %)	20, 57.14%	31, 62.0%	>0.05
Urban (n, %)	15, 42.86%	19, 38.0%	>0.05
Parity (n, %)			
1	22, 62.86%	31, 62.0%	>0.05
≥ 2	13, 37.14%	19, 38.0%	>0.05

Table 2: Indication for induction

Indication for induction	Group I n (%)	Group II n (%)
Hypertensive disorders	11 (31.43)	10 (20.0)
Gestational age >40 weeks	8 (22.86)	12 (24.0)
Oligohydramnios	6 (17.14)	5 (10.0)
Fetal growth restriction	3 (8.57)	6 (12.0)

Table 3: Comparison of Bishop score

	Preinduction Bishop score (mean \pm SD)	Postinduction Bishop score (mean \pm SD)
Group I	3.23 \pm 0.43	5.20 \pm 1.13
Group II	3.41 \pm 0.62	8.33 \pm 2.60
p-value	>0.05	<0.01

Table 4: Mode of delivery

Mode of delivery	Group I n (%)	Group II n (%)
Vaginal	3 (8.57)	31 (62.0)
LSCS	32 (91.43)	19 (38.0)

Table 5: Indication for cesarean section

Indication for cesarean section	Group I n (%)	Group II n (%)
Fetal distress	21 (65.63)	19 (86.36)
NPOL	2 (6.25)	1 (4.55)
Scar tenderness	9 (28.13)	2 (9.09)

Table 6: Maternal complications

Maternal complications	Group I n (%)	Group II n (%)
Uterine tachysystole	21 (60.0)	1 (2.0)
Uterine rupture	1 (2.86)	0 (0)

Table 7: APGAR score

APGAR score	Group I	Group II	p-value
At 1 minute (mean \pm SD)	5.14 \pm 0.69	5.96 \pm 0.87	<0.01
At 5 minutes (mean \pm SD)	6.54 \pm 0.78	7.39 \pm 0.79	<0.01

While in group II, 60.0% of women in group I experienced tachysystole as compared to only 2.0% of women in group II, which was highly significant. There was one case of uterine rupture in group I, while no such event occurred in group II (Table 6).

Mean birth weight of neonates born to women in both the groups was comparable. In group I, it was 2.87 \pm 0.37 kg, while in group II, it was 2.79 \pm 0.33 kg ($p > 0.05$). Neonates born to women in group II had a significantly better Apgar score at 1 and 5 minutes as compared to the neonates in group I, however, both the groups were comparable as regards to neonatal complications (Table 7).

DISCUSSION

Repeat cesarean section exposes women to multiple risks like blood loss, injury to the urinary tract, infections, adherent placenta, and cesarean hysterectomy. Vaginal birth after cesarean section is a procedure that can be offered to women who have had a prior cesarean section.

Induction of labor is often taken up in the interest of the mother and the fetus. Labor induction in the presence of an unfavorable cervix is associated with labor dystocia and a higher incidence of repeat cesarean section. Hence, the use of cervical ripening agents is beneficial. Induction with Foley catheter is a safe, inexpensive, and reliable method of cervical ripening, with a low risk of uterine tachysystole and fetal distress but poses a potential danger of accidental rupture of membranes, cord prolapse, chorioamnionitis, and pyrexia because of infection.⁵ While dinoprostone insert has also been proven to be effective for cervical ripening agents with a gradual onset of labor through a controlled release of 0.3 mg of dinoprostone per hour with the advantage of single application. Many studies that have evaluated cervical ripening with prostaglandin E₂ (PGE₂) insert have shown conflicting results and in the absence of conclusive studies, many countries continue to use PGE₂ for induction of labor.

In our study, the majority of women were induced for hypertensive disorders and gestational age >40 weeks followed by oligohydramnios, fetal growth restriction, IHCP, etc.

Our findings were in coherence with the study conducted by Jozwiak et al.,⁶ Ghanaie et al.,⁷ and Huisman et al.⁸ In our study, women induced with dinoprostone insert had a shorter induction to active labor duration but a higher rate of cesarean section. The mean preinduction Bishop score in our study was comparable to those of Cromi et al.,⁹ Jozwiak et al.,⁶ and Ghanaie et al.⁷ who also did not find any difference in preinduction Bishop score of their study groups.

Our study showed that postinduction Bishop score was better with transcervical Foley catheter ($p < 0.01$). López-Jiménez et al.¹⁰ reported a comparable postinduction Bishop score in their study.

In our study, vaginal delivery was significantly more in the Foley catheter group as compared to the dinoprostone group (62.0% vs 8.57%; $p < 0.01$), and women undergoing cesarean section were significantly higher in the dinoprostone group as compared to the Foley catheter group (91.43% vs 38.0%; $p < 0.01$). Our study was in coherence with Ghanaie et al.⁷ and Huisman et al.⁸⁻¹¹

The induction to delivery interval was significantly shorter in the dinoprostone group as compared to the Foley catheter group (16.43 \pm 11.17 hours vs 21.00 \pm 7.59 hours; $p < 0.01$). Our findings were consistent with the study conducted by Jozwiak et al.⁶

Various prospective studies suggest that local PGE₂ therapy has fewer maternal side effects and favorable neonatal outcomes, but in our study, uterine tachysystole was significantly higher. Neonatal outcomes were comparable among the two groups. However, the APGAR score was significantly better in Foley group.

CONCLUSION

Our study suggests that intracervical Foley catheter is efficient in achieving cervical ripening and successful labor with reduction in latent phase of labor and total delivery time without increasing the rate of cesarean section, uterine tachysystole, and uterine rupture. Dinoprostone vaginal insert had a shorter induction to active labor as well as induction to delivery interval but had an

increased risk of uterine tachysystole and scar tenderness which eventually led to more fetal distress and an increased rate of cesarean sections. Considering the good performance of maternal and neonatal outcomes, the intracervical Foley catheter can be used as a better choice for preinduction cervical ripening and induction of labor in women with previous cesarean sections in resource-limited settings.

However, in our study, the sample was small and hence a proper recommendation regarding preinduction cervical ripening cannot be made, and further studies with larger sample sizes are needed to assess the significant efficacy, labor complications, labor outcomes, and adverse maternal and neonatal complications.

AUTHORS' CONTRIBUTIONS

UK: Designing, planning, conducting, data analysis, manuscript writing, and editing. SP: Designing, planning, conducting, manuscript writing, proof reading, and editing. NN: Conducting, manuscript editing, and proof reading. UF: Designing, planning, and conducting.

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