

Comparison of Efficacy of Foley's Catheter and Intracervical Prostaglandin E2 Gel for Improving Induction of Labour in Tertiary Care Hospital

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Abstract: **Background:** Induction of labor is a crucial and customary clinical procedure in obstetrics. It is arguably one of the most abused procedures. Cervical ripening determines the success of delivery. The availability of newer oxytocics and induction techniques which are simpler and also more predictable has significantly modified our traditionally conservative attitude toward induction of labor. **Aims and Objectives:** The objective of this study was to determine the effectiveness of Foleys catheter against prostaglandin E2 (PGE2) gel for pre-induction cervical ripening. **Materials and Methods:** Women attending hospital for induction of labor, with a Bishop's score <6, were allocated randomly to Foley's group (Group F) and PGE2 gel group (Group P). Fifty women were allocated to Foley's group (Group F) and 50 were allocated to gel group (Group P). **Results:** Improvement in Bishop score was more in the PGE2 gel group when compared with the Foley's balloon dilatation group P value <0.05. Mean induction to labour interval was shorter in the PGE2 gel when compared to the Foley's balloon dilatation group P value <0.05. Mean induction to delivery interval was also shorter in the PGE2 gel group when compared with Foley's balloon dilatation. P value <0.05. **Conclusion:** Cervical ripening more effective with prostaglandin E2 gel application. Mean induction to active labour interval and mean induction to delivery interval were shorter with prostaglandin E2 gel instillation.

Keywords: Foley's catheter; Induction of labour; Prostaglandin E2 gel

1. Introduction

Induction of labour is the use of mechanical or pharmacologic means to stimulate regular uterine contractions before the commencement of labour, resulting in progressive cervical dilatation and subsequent delivery.¹ The emergence of newer, more effective, and more predictable oxytocics and induction procedures has drastically altered our previously conservative stance regarding induction of labour. Cervical ripening and induction of labour are aimed at achieving the vaginal birth rather than resorting to cesarean section.¹ Preinduction cervical Bishop's score determines the success of induction.² The correlation between the presence of a favorable cervix and subsequent vaginal delivery was first described by Bishop. The presence of a ripened cervix correlated closely with successful induction of labour.³ The methods for cervical ripening, that are safe to both the mother and fetus, cause minimal discomfort to mother, not requiring extensive monitoring, with low cost is the ideal.⁴ These include (a) stripping the membranes, (b) intravaginal or intracervical application of prostaglandins (PGs), (c) intracervical placement of osmotic dilators, (d) oxytocin, and (e) amniotomy.⁵ Krause in 1853 first described the use of the Foley's catheter for the induction of labour.⁶ In 1967, Embrey and Mollison found a success rate of 94% with use of Foleys catheter for cervical ripening in 100 women.⁷ Mechanical or pharmacological ripening is required for women with an unfavorable cervix. The mechanical methods of cervical ripening cause stretching and dilatation of lower uterine segment and cervix. Use of extra-amniotic balloon catheter for cervical ripening has the advantages of reversibility, lack of side effects, low cost, and simplicity.⁸ PGE2 gel has been approved by the Food and Drug Administration for cervical ripening and induction of labour for more than a decade. The Foley's catheter and intracervical dinoprostone PGE2 gel are compared for safety and efficacy for induction of labour in this study.

Aims and objectives

To compare efficacy of Foley's catheter and intracervical prostaglandin E2 gel for improving induction of labour in tertiary care hospital.

2. Materials and Methods

This is a prospective comparative clinical study. A total of 100 patients fulfilling the inclusion criteria were enrolled in this study. They were randomly distributed into two groups after a written informed consent.

I) Inclusion criteria

- Singleton pregnancies
- Cephalic presentation
- Term or post term pregnancies
- Bishop score <5
- Intact fetal membranes
- Absence of infection

II) Exclusion criteria

- Malpresentation
- Multiple pregnancy
- Ruptured membranes
- Active Genital Infections
- Heart Disease
- Contracted Pelvis
- Previous scarred uterus

The patients were randomly assigned to either Foley catheter group (n=50) and PGE2 gel group (n=50). History was taken in detail and clinical examination done. Bishop's score determined. NST taken for 20 min before beginning induction.

Foley's group (Group F)

Patient is placed in 'lithotomy position', perineum and vagina are cleansed with betadine solution. No.16 foley's catheter is

introduced into the endocervix by direct visualization or blindly by locating the cervix with the examining fingers and guiding the catheter over the hand and fingers through the endocervix and into the potential space between the amniotic membrane and lower uterine segment. The balloon reservoir is inflated with 30 – 40 ml of distilled water.

The balloon is retracted so that it rests on the internal os. The patient examined for the progress of labour. Bishop score reassessed after six hours, after removing the Foley’s catheter. Cerviprime instillation required or low amniotomy followed by oxytocin augmentation are noted. All patients received prophylactic antibiotics. Two doses of injection

ampicillin 1 gm after test dose eight hours apart given.

PGE2 gel group (Group P)

PGE₂ gel – Cerviprime gel which contains 0.5 mg of PGE₂ per 3 gm present in 2.5 ml prefilled syringe is used. Bring gel to room temperature before application. Monitor fetal heart rate and uterine activity continuously starting 15to 30 minutes before gel introduction.

3. Observation

Indication for Induction

Indication	Foley's Balloon dilatation		PGE2gel		Total
	Number	Percent (%)	Number	Percent (%)	
Postdated	38	76	33	66	71
Preeclampsia	7	14	9	18	16
IUGR	3	6	4	8	7
Oligohydramnios	2	4	4	8	6
Total	50	100	50	100	100

Postdatism was the commonest indication in both study groups. Both groups had similar indication for induction of labour.

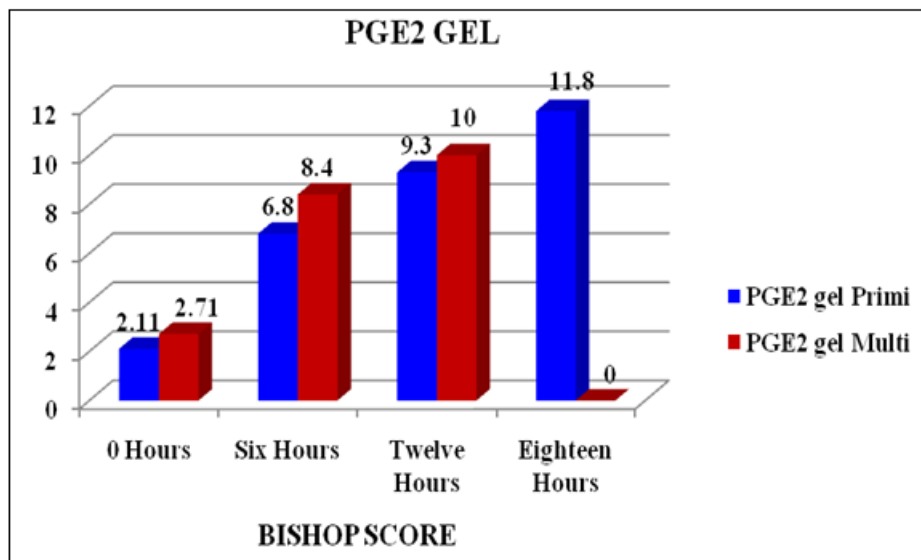
Mean Bishop Score

Bishop Score	Foley's Balloon dilatation		PGE2 gel	
	Primi	Multi	Primi	Multi
0 Hours	2.1	2.4	2.11	2.71
Six hours	5.7	6.7	6.8	8.4
Twelve hours	8.2	9.8	9.3	10
Eighteen Hours	11	10.8	11.8	0

P<0.05

Table shows the Mean Bishop Score at 0,6,12,18 hours in both groups. The mean Bishop Score at ‘0’ hours is

statistically not significant. The mean Bishop score at 6 hours was 5.7 hours in primis in the Foley’s group when compared to the PGE₂ gel group where the mean Bishop score was 6.8 hours. Similarly, the mean Bishop Score at 12 hours was 8.2 in primis in the Foley’s group when compared to the PGE₂ gel group where the mean Bishop score was 9.3. There is a statistically significant difference in the mean Bishop score at 6 and 12 hours in the PGE₂ compared to the Foley’s group. The mean change in the score also significant in both nullipara and multipara in the PGE₂ gel group compared to the Foley’s balloon dilatation.



Mode of Delivery

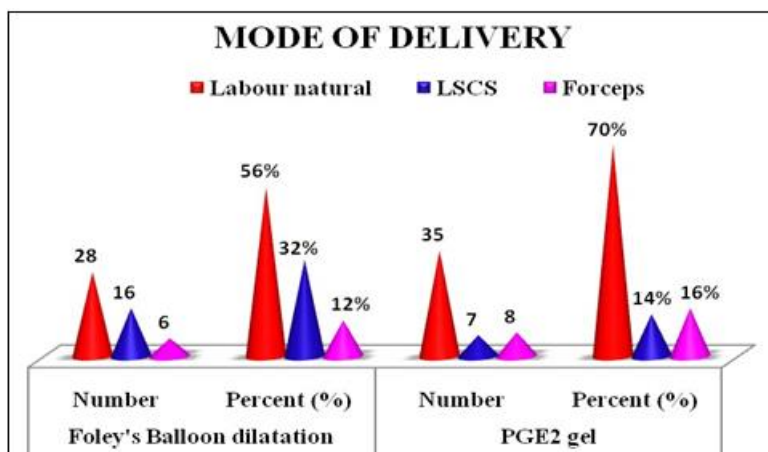
Mode of Delivery	Foley's Balloon dilatation		PGE2 gel		Total
	Number	Percent (%)	Number	Percent (%)	
Labour natural	28	56	35	70	63
LSCS	16	32	7	14	23
Forceps	6	12	8	16	14
Total	50	100	50	100	100

P<0.05

70% delivered by labour natural in PGE₂ gel group, only 56% delivered labour natural in Foley's balloon dilatation. 32% LSCS rate in Foley's balloon dilatation, whereas only 14% in PGE₂ gel regimen. There is statistically significant difference in the mode of delivery between the two groups using chi-square test.

Indications for Caesarean Section

Indications	Foley's Balloon dilatation		PGE ₂ gel		Total
	Number	Percent (%)	Number	Percent (%)	
Fetal Distress	6	37.50	4	57.10	10
Failed Induction	7	43.75	2	28.52	9
CPD	3	18.75	1	14.38	4
Others	-	-	-	-	-
Total	16	100	7	100	23



Caesarean section rate being higher in Foley's group, the most common indication being failed induction, next comes the fetal distress.

4. Result

- Both PGE₂ gel group and Foley's balloon dilatation, induction was started with the same Bishop score of <5.
- Both groups had majority of the women being primigravida.
- Age group commonest in both groups being 20 – 24 years.
- Improvement in Bishop score was more in the PGE₂ gel group when compared with the Foley's balloon dilatation group P value <0.05.
- Mean induction to labour interval was shorter in the PGE₂ gel when compared to the Foley's balloon dilatation group P value <0.05.
- 6) Mean induction to delivery interval was also shorter in the PGE₂ gel group when compared with Foley's balloon dilatation. P value <0.05.
- Mean induction to labour interval and mean induction to delivery interval were shorter in multigravida compared to primigravida in both groups of PGE₂ gel and Foley's balloon dilatation.
- Oxytocin for augmentation was higher in the Foley's balloon dilatation around 78% whereas the rate of usage of oxytocin for augmentation in the PGE₂ gel group was 36%.
- Mode of delivery being labour natural 76% for patients in the PGE₂ gel group where it was only 56% in the Foley's balloon dilatation group.
- Including the forceps deliveries, most patients in the PGE₂ gel group delivered vaginally.

- Caesarean section rate in Foley's balloon dilatation was higher 32% whereas it was only 14% in the PGE₂ gel group.
- Incidence of caesarean for the indication of failed induction was higher in the Foley's balloon dilatation group.
- Neonates admitted in neonatal intensive care unit were more in the Foley's balloon dilatation group.
- Hyper stimulation was more in the PGE₂ gel group whereas intrapartum and puerperal pyrexia were higher in the Foley's balloon dilatation group.
- PGE₂ gel was found to be more effective method of cervical ripening and induction of labour.

5. Discussion

The study has been conducted to assess the efficacy of Foley's intracervical balloon dilatation compared to prostaglandin E₂ gel for cervical ripening and induction of labour. The study was carried out in 100 patients. Fifty patients being assigned randomly to the balloon dilatation and 50 patients to PGE₂ gel. In this study, both Foley's balloon dilatation and PGE₂ gel group had patients of almost similar age group, parity and gestational age. Maximum number of patients induced belonged to the 20 – 25 years age group. Studies by Janet B et al Feb 1999 showed the maximum number of patients belonged to 20 – 30 years of age group. Another study by Anderson et al in 1965 also showed that maximum number of cases belonged to the above age group. Maximum number of patients in the study group were primigravida. Studies by Debra^a Guinn 2000 and DivyaRouben et al 1993 also had maximum number of women as primigravida. In this study maximum number of patients induced between 37 – 40 weeks of gestation by

PGE2gel. In Foley's group equal distribution between 37 – 40 weeks and >40 weeks gestation. The study of Divya Rouben¹⁰ et al 1993 showing maximum patients induced at 40 – 42 weeks. In this study, postdatism was the commonest indication for induction in both groups. According to Janet et al and DivyaRouben, the commonest indication was postdatism, whereas according to Debra and Guinn¹¹, preeclampsia was the commonest indication. Change in Bishop Score -Induction was started in both groups with similar Bishop Score. The mean Bishop Score at '0' hours in PGE2 was in primis 2.11 when compared to the Foley's balloon dilatation group where it was 2.1. The mean Bishop score at '0' hours in PGE2 gel group in multigravida was 2.71 when compared to the Foley's balloon dilatation group where it was 2.4. The mean Bishop score at 6 hours in primigravida was 6.8 hrs in PGE2 gel group when compared to the Foley's balloon dilatation where the mean Bishop score at 6 hours was 5.7 hours. Similarly, the mean Bishop score at 12 hours was 9.33 hrs in primigravida in the PGE2 group when compared to the Foley's balloon dilatation where the mean Bishop score at 12 hours was 8.2 hours. The mean Bishop score at 6 hours in multigravida was 8.3 hrs in the PGE2 gel group when compared to the Foley's balloon dilatation where the mean Bishop score at 6 hrs was 6.7 hrs. Similarly, the mean Bishop score at 12 hrs in multigravida was 10 hrs in the PGE2 gel group when compared to the Foley's balloon dilatation where the mean Bishop score was 9.8 hrs. Mean improvement in Bishop score was higher in the PGE2 gel group when compared to the Foley's balloon dilatation. According to a study by Taani et al¹² Royal Medical Services, change in mean Bishop score was significantly higher in the PGE2 gel group 3.09 versus catheter group 3.1, p value <0.01. Induction to Active Labour interval In PGE2 gel group, 41% of primigravida established labour within 6 hours and 55% within 12 hours. Also 28% of multigravida within 6 hours and 71% of multigravida within 6 – 12 hours. In Foley's balloon dilatation, 39% of primigravida established labour within 6 hours and 50% within 12 hours. Also 25% of multigravida established labour within 6 hours and 75% within 12 hours. In PGE2 group, only 2% crossed 12 hours to establish labour, whereas in the Foley's balloon dilatation, 10% crossed 12 hours to establish labour. All were primigravida. The mean induction labour interval in primigravida in the PGE2 gel group was 6.5 hours. The mean induction to active labour interval in primigravida with Foley's balloon dilatation group was 7.5 hours. The mean induction labour interval in multipara with PGE2 gel was 5.2 hours. The mean induction labour interval in multipara in the Foley's balloon dilatation group was 6.6 hours. The difference between the two groups is statistically significant. PGE2 gel was found to be more effective in inducing labour when compared to Foley's balloon dilatation. Induction to Delivery Interval In PGE2 gel group, 61% of primigravida and 85% of multigravida delivered within 12 hours. In Foley's balloon dilatation, 47% of primigravida and 50% of multigravida delivered within 12 hours. The mean induction delivery interval in primigravida with PGE2 gel was 11.7 hours. The mean induction delivery interval in primigravida with Foley's balloon dilatation was 13 hours. The mean induction to delivery interval in multipara with PGE2 gel was 9.9 hours. The mean induction delivery interval in multipara with Foley's balloon dilatation was 13.4 hours. The difference between the two groups is statistically significant. According to Taani et al¹² time from induction to delivery interval shorter in PGE2 gel compared to catheter group 42%

delivered within 16 hours in catheter group and 61% delivered within 16 hours in PGE2 gel group. Oxytocin augmentation-The need for oxytocin augmentation to deliver was higher with Foley's balloon dilatation when compared to the PGE2 gel group. 78% of women in the Foley's balloon dilatation required oxytocin whereas only 36% of the PGE2 gel required oxytocin. According to studies by Taani et al¹², S.Chua et al, 49% required oxytocin in catheter group, whereas only 20% required oxytocin in the PGE2 gel group. Mode of Delivery-Delivery by labour natural was higher in the PGE2 gel group when compared to the Foley's balloon dilatation group. Caesarean section rate was higher in the Foley's balloon dilatation group when compared with the PGE2 gel group. 70% delivered by labour natural in PGE2 gel group, 16% had forceps deliveries whereas in the Foley's balloon dilatation group only 56% had labour natural and 12% had forceps deliveries. LSCS rate in Foley's balloon dilatation group was 32% when compared to the PGE2 gel group where it was only 14%. The difference in the mode of delivery is statistically significant. Indication for Caesarean Delivery-Fetal distress was the commonest indication for caesarean section in PGE2 group whereas failed induction was the major indication for caesarean section in Foley's balloon dilatation group. According to studies by Taani et al¹², fetal distress was more frequent in the catheter group. Fetal Outcome -In the Foley's balloon dilatation group, 20% of neonates were admitted. The most common reason being respiratory distress. In the PGE2 gel group, 10% of neonates got admitted in neonatal intensive care unit due to birth asphyxia or meconium aspiration mainly due to the hyper stimulation which occurred in some women induced. Maternal Complications-Intrapartum pyrexia and puerperal pyrexia were observed more in the Foley's balloon dilatation group due to prolonged labour whereas these complications were less in the PGE2 gel group due to faster response to induction. The incidence of postpartum hemorrhage was equal in both groups. Few were atonic which settled with uterotonic agents, other few were traumatic due to forceps deliveries which settled with suturing. Hyperstimulation noted in 5 women who were induced with PGE2 gel. They settled with changing them to left lateral position, plain fluids and nasal O₂. These delivered labour natural with babies in good condition and good maternal Outcome.

6. Conclusion

- 1) Cervical ripening more effective with prostaglandin E2 gel application.
- 2) Mean induction to active labour interval and mean induction to delivery interval were shorter with prostaglandin E2 gel instillation.
- 3) Oxytocin augmentation was less with prostaglandin E2 gel instillation.
- 4) Response of multigravida in both groups better than primigravida.
- 5) Fetal and maternal outcome were better with prostaglandin E2 gel.
- 6) From this study, it is known that prostaglandin E2 gel is a better and more effective agent than Foley's balloon dilatation in cervical ripening and induction of labour.

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