

## A comparative study of intra-cervical foleys catheter and PGE2 gel for pre-induction cervical ripening in primigravida

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### Abstract

The goal of obstetrics is a pregnancy that results in a healthy infant and a healthy minimally traumatized mother. Much of the art of good obstetric care involves the delicate balance of avoiding cesarean delivery with all its attendant complications. Planned pre-induction cervical ripening and induction of labor has become an established part of modern obstetric practice. Different methods used for the induction of labor in women with an unfavorable bishops score are, mechanical methods such as trans cervical extra-amniotic Foley's catheter(FC)insertion, intra cervical balloon catheter and medical methods like vaginal prostaglandin(PGE2) and misoprostol(PGE1)are used for IOL in women with an unfavorable cervix for pre-induction cervical priming. The present prospective study was conducted in a tertiary care hospital after obtaining clearance from institutional ethical committee with no GMC/IEC/140/2019 to compare the efficacy of intracervical Foleys catheter with Dinoprostone gel (PGE2) in cervical ripening and induction of labor, maternal and neonatal outcome. Maternal outcome compared in terms of pre-induction bishop score and change in bishop score after induction, need for reinstallation and augmentation of labor, the interval between intervention and delivery, mode of delivery, indication for cesareansection, induction delivery interval. Neonatal outcome compared in terms of apgar score at 1min and 5min, perinatal morbidity and mortality. Two hundred antenatal mothers with bishop score<5were randomly allocated to be induced with intracervical foleys catheter (group A) and PGE2 gel (group B). In this study, both Foley's balloon dilatation and PGE2 gel group had patients of almost similar age group, parity, and gestational age. In the present study, in both the groups (foleys and PGE2 gel groups), post-datism was the commonest indication for induction- 52% and 45%, respectively, followed by pre-eclampsia-19%and 32%. The mean improvement in Bishop score was higher in the PGE2 gel group when compared to the Foley's. The need for oxytocin augmentation to deliver was higher with Foley's balloon dilatation when compared to the PGE2gel group. The mean induction delivery interval in Foley's group was 13.17hours. The mean induction delivery interval in the PGE2 gel group was 11.43hours. In both the groups, the maternal and fetal outcomes are found to be similar. In both the groups, the rate of normal vaginal and cesarean section delivery was also

found to be equal. This study shows that prostaglandin E2 gel is a better and more effective agent than foley's balloon dilatation in cervical ripening and induction of labour.

**Keywords:** Prostaglandin E2, Dinoprostone, Pregnancy, delivery, Labor, Mechanical methods of induction, Obstetrics.

### Introduction

The goal of obstetrics is a pregnancy that results in a healthy infant and a healthy minimally traumatized mother. Much of the art of good obstetric care involves the delicate balance of avoiding cesarean delivery with all its attendant complications. Planned pre-induction cervical ripening and induction of labor has become an established part of modern obstetric practice. The main intention of induction is to perform a safe vaginal delivery. Induction of labor is indicated when the risks of continuation of pregnancy either to the mother or to the fetus is more<sup>[1, 2, 3]</sup>. Commonly accepted medical reasons for induction include post-term, preeclampsia, intrauterine fetal growth restriction, oligohydramnios, gestational diabetes mellitus (GDM), premature rupture of membranes (PROM), premature termination of pregnancy (abortion), fetal death in utero or any anomalous baby. The induction rate varies significantly between different countries, population groups and hospitals. The frequency of induction varies by location and institution<sup>[4]</sup>. The induction of labor (IOL) has become more frequent in recent years, occurring in about 20% of almost all settings<sup>[5, 6]</sup>. The success of induction depends on the state of the cervix before commencement, with the most favorable outcomes occurring in cervixes, which are soft and effaced. A cervix that is closed, firm, and difficult to distend increases the likelihood of failed induction, longer duration of labor, and cesarean section<sup>[7, 8, 9]</sup>. Different methods used for the induction of labor in women with an unfavorable bishops score are, mechanical methods such as trans cervical extra-amniotic Foley's catheter (FC) insertion, intra cervical balloon catheter and medical methods like vaginal prostaglandin (PGE2) and misoprostol (PGE1) are used for IOL in women with an unfavorable cervix for pre-induction cervical priming<sup>[10, 11]</sup>. Mechanical methods are the oldest methods to initiate labor. Recently these mechanical methods have been replaced by pharmacological methods<sup>[12]</sup>. The obstetric outcome is generally good with spontaneous onset of labor compared to IOL, which may result in instrumental deliveries or cesarean sections. Also, the fetus is affected, which can develop distress, birth asphyxia, etc<sup>[13, 14]</sup>.

### Background

Induction by foleys catheter is a mechanical method of cervical ripening, which was used by Dr. Kraux in 1853. Inflated Foleys catheter placed extra amniotically has been used to improve cervical inducibility. It brings about cervical ripening through the local release of tissue prostaglandin since the cervix and lower uterine segment. The mechanical action of the Foleys catheter strips the fetal membranes from the lower uterine segment and causes the rupture of liposomes in the decidual cells. The lytic enzymes, thus released, include phospholipase A, which acts on the phospholipids and form arachidonic acid, which in turn converted to prostaglandins. (gustavill1973) This view is supported by the demonstration of elevated maternal plasma levels of <sup>[13, 14]</sup> dihydro 15 keto prostaglandin (a metabolite of Prostaglandin F)

Local release of prostaglandin (PGF2) alpha cytokines Interleukin - 1 (5 and Interleukin-6 directly in to the vagina<sup>[15]</sup>. Decidua produces Prostaglandin E2 and PGF2 alpha. Prostaglandin produced in the decidual tissue lining the fore bag has no direct access to maternal vasculature, thus favoring transfer into the vagina, associated with cervical dilatation. Foleys catheter allows a successful induction of labor and reduces the induction delivery interval from what it would have been in an unripe cervix<sup>[16]</sup>. Advantages of Foleys catheter are easy availability, cheap, it reduces the induction delivery interval and hence lesser hospital stay, causes gradual cervical dilatation so associated with minimal patient discomfort, oxytocin can be started immediately after Foley's catheter extrusion rather than waiting, so expenses of stay decreases, it can be used were prostaglandin's are contraindicated

like bronchial asthma, it can be safely used in patients with previous lower segment cesarean section. Whereas disadvantages are risk of premature rupture of membranes, bleeding, fever, infections but these all occur very infrequently.

Prostaglandins are a family of polyunsaturated -fatty acids, 20 carbon compounds, and subdivided into groups (A-I), according to differences in the structure of five-membered cyclopentane ring. Chemically they are derivatives of hypothetical prostanoic acid. Prostaglandins of the one series (PGE<sub>1</sub>), two series (PGE<sub>2</sub>), and three series (PGE<sub>3</sub>) are formed respectively from precursor fatty acids Dihomo-γ-linolenic acid, Arachidonic acid, and Eicosapentaenoic acid. Thromboxane and Leukotrienes are also derived from Arachidonic acid. After the release of Arachidonic acid from membrane Phospholipids, it is metabolized by two types of enzymes Cyclooxygenase and Lipoxygenase. All the prostaglandins are hydroxylated in 15 positions and possess 13 trans double bonds in the lower side chain. The main classes are divided according to the degree of unsaturation of side chain, and suffix denotes the number of double bonds (PGE<sub>1</sub>, PGE<sub>2</sub>, PGE<sub>3</sub>). They are classified into E and F series. PGE series contain a Keto group at the C-9 position and an OH group at C-15. PGF series OH group both positions. Prostaglandin E<sub>2</sub> has molecular Formula: C<sub>20</sub>H<sub>32</sub>O<sub>5</sub>. Exogenous local application of prostaglandin E<sub>2</sub> results in cervical ripening, softening of the cervix by altering the extra cellular ground substance of the cervix<sup>[17]</sup>. It increases the activity of collagenase, which reaches maximum activity at 2hr after application in a multipara and 4hr in nulliparous, It affects the smooth muscle of the cervix and uterus. It relaxes the smooth muscle of the cervix and this causing cervical dilatation. Then it causes uterine contractions<sup>[18]</sup>. Prostaglandins increase the synthesis of collagenases and induce transformation of the latent form of collagenases into active form<sup>[19, 20]</sup>. Optimal intracervical dose is 0.5mg; lower doses are less effective; the higher dose decreases the need for oxytocin but the rate of hyper stimulation increases. Its advantages include induction in less time, can be administered easily, decrease induction delivery interval and decreases the incidence of prolonged labor. Whereas disadvantages are its very expensive, augmentation with oxytocin cannot be started immediately; a minimum of 6hr is required after the last dose of PGE<sub>2</sub> gel, causes hyperstimulation, fever, vomiting, and diarrhea.

Contraindications include bronchial asthma, glaucoma, renal impairment, hepatic impairment, cardiac problems, hypersensitivity to prostaglandins. A major safety concern for PGE<sub>2</sub> use in cervical ripening is the production of hyperstimulation when compared with low dose oxytocin defined as < 4 mu/min, the rate of hyperstimulation with PGE<sub>2</sub> either intra vaginally or intra cervical is equal with a rate of 4.8%<sup>[21]</sup>.

## Material and Methods

The present prospective study was conducted in a tertiary care hospital after obtaining clearance from institutional ethical committee with no GMC/IEC/140/2019 to compare the efficacy of intra cervical Foleys catheter with Dinoprostone gel (PGE<sub>2</sub>) in cervical ripening and induction of labor, maternal and neonatal outcome. Maternal outcome compared in terms of pre-induction bishop score and change in bishop score after induction, need for reinstatement and augmentation of labor, the interval between intervention and delivery, mode of delivery, indication for cesarean section, induction delivery interval. Neonatal outcome compared in terms of apgar score at 1min and 5min, perinatal morbidity and mortality. Two hundred antenatal mothers with bishop score < 5 were randomly allocated to be induced with intracervical foleys catheter (group A) and PGE<sub>2</sub> gel (group B). Induction labor interval, induction delivery interval, rate of cesarean deliveries, maternal and fetal outcomes were compared to both groups. Before inducing, expected date of delivery was confirmed with regard to last menstrual period, the regularity of menstrual cycles, early ultrasound.

Inclusion criteria includes singleton pregnancy, cephalic presentation, absence of infection, Bishop's score < 5, post-term pregnancies, intact fetal membranes whereas exclusion criteria taken were low lying placenta, malpresentation, maternal infection, rupture of membranes, maternal comorbid illnesses like heart diseases, chronic kidney disease. Patients needed for

induction of labor were categorized into two groups of 100 cases each. Group I: Cervical ripening by intra cervical foley's catheter and group II: Cervical ripening by PGE2 gel. After meeting the inclusion and exclusion criteria, informed and written consent was taken for each patient. Detailed general physical, per abdominal, per vaginal examination was conducted to each antenatal women. Pre and post-induction non stress test was taken. Pre induction Bishop Score is assessed and improvement in bishop score is assessed at 6hrs, 12hrs, and 18hrs of induction.

### **Group-A**

Under strict aseptic precautions, a 16F trans cervical Foley's catheter balloon is advanced into the cervical canal or up to the internal OS, and the balloon is inflated with 50ml of sterile water. The catheter is then placed on gentle traction by taping the distal tip to the medial thigh. To maintain the gentle traction, periodic repositioning of the distal tip on the thigh is necessary. This is supported by a recent comparison of simple taping to the thigh versus keeping the balloon on tension, which found that total time to delivery did not differ for the 2 methods; time to spontaneous catheter expulsion was significantly shorter in the traction group. Bishop score is assessed at 6hrs and 12hrs if there is no spontaneous expulsion within 12hrs, Foleys catheter is reapplied for next 12 hrs. In all, Foley's should not be retained for >24 hrs. Patients were monitored for signs of labour, maternal vitals, fetal heart rate, and progress of labour. If spontaneous expulsion occurs, augmentation of labour should be done by artificial rupture of membranes (ARM) or oxytocin augmentation.

### **Group-B**

Under strict aseptic precautions, after exposing the cervix by a Cusco's speculum, 0.5mg of PGE2 gel is instilled intra cervically from a preloaded syringe. Following installation, close monitoring is done for hyperstimulation of the uterus. Bishop's score is reassessed after 6 hours. If the bishop score remains still poor, the same dose is repeated and reassessed after 6 hours with a maximum of 3 doses in 24 hours. Continuous fetal heart rate monitoring and maternal vitals to be monitored until delivery. The neonate was assessed using APGAR Score at 5 minutes, birth weight to be assessed, and neonates who were admitted followed until discharge.

### **Statistical Methods**

The Statistical analysis was performed by STATA 11.2 (College Station TX USA). Shapiro Wilk test has been used to check the normality; students t-test were used to find the significant difference between the age, gestational age, Bishop score, induction to labor interval, Induction to delivery interval, Birth weight (Kg) with treatment groups (Intra cervical Foleys catheter and Cerviprime gel) and these expressed as mean and standard deviation. Chi-square or Fisher exact test has been used to measure the association between the age groups, gravida, Complications, Reinstallation, Augmentation, mode of delivery, Indication of LSCS, NICU Admission, PPH, Intra partum pyrexia with treatment groups and these expressed as frequency and percentage.  $p < 0.05$  considered as statistically significance.

### **Results and Discussion**

The study has been conducted at the Government General hospital Guntur 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 on 200 patients. Hundred patients being assigned randomly to the Foley's balloon group and hundred patient's 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. Patients in both groups were primigravida.

In the present study, the maternal age in Foleys Group  $23.12 \pm 3.198$  years and prostaglandin E2 Gel group is  $22.68 \pm 2.957$  years. Maximum number of patients induced belonged to the 21-25 years age group.

**Table 1:** Mean age distribution of study groups

	Foleys	Cerviprime	p-value
	Mean±S.D.	Mean±S.D.	
Age	23.12±3.198	22.68±2.957	0.314
Range	18-32	18-31	

Table 1 shows in group A, the patients' age falls between 18 to 32 years, and in group B, in between 18 to 31 years. Since the p-value is greater than the significance level of 0.05, hence there is no significant difference in mean age between two groups of the population.

**Table 2:** Age distribution of study groups

Age group	Foleys	Cerviprime	Total	p-value
18-20	27	32	59	0.822
21-25	53	51	104	
26-30	18	16	34	
>30	2	1	3	
Total	100	100	200	

Table 2 shows the distribution of age in both groups. Most of the patients in both the groups fall in between 21-25 years, i.e., in group A, there are 52% of the patients, and in group B, there are 51% of the patients in this age group. Since the p-value is greater than the significance level of 0.05, hence there is no significant difference between two groups in age distribution. The study of Alama, *et al.*, Dileep *et al.* show a maximum number of patients induced belong to 23-27 age group<sup>[21, 22]</sup>.

**Table 3:** Gestational age at time of induction

	Foleys	Cerviprime	p-value
	Mean±S.D.	Mean±S.D.	
Gestational Age	39.63±1.593	39.95±1.914	0.2
Range	37-43	37-42	

Table 3 shows in group-A, patients are in between 37-43 weeks of gestation whereas, in group-B, patients are in between 37-42 weeks of gestation. The majority of patients are around 40 weeks gestation post-dated, being the most common indication. The study of Dileep *et al.* shows maximum patients induced between 37-40 weeks whereas the study of Alama, *et al.* (2016), showing maximum patients induced at 40-42 weeks which is comparable to the present study<sup>[21, 22]</sup>.

**Table 4:** Indications for induction

Indication of Induction	Foleys	Cerviprime	Total	p-value
GDM	0	1	1	0.042
IUGR	11	2	13	
Oligohydrominos	18	18	36	
Post-dated	52	45	97	
Pre-eclampsia	19	32	51	
Antepartumeclampsia	0	1	1	
Imminenteclampsia	0	1	1	
Total	100	100	200	

Table 4 shows in this study, post datism, is the commonest indication in both the groups accounting for 45% in the PGE2 gel group and 52% in the foleys group, followed by

preeclampsia, oligohydramnios, IUGR, GDM, Antepartum Eclampsia, and Imminent Eclampsia. In the present study, in both the groups (foleys and PGE2 gel groups), post-datism was the commonest indication for induction- 52% and 45%, respectively, followed by pre-eclampsia-19% and 32%. In Dileep *et al.* study, Richa jha *et al.*, post-datism is the common indication for induction followed by PIH, which is compatible with my study [22, 23]. According to Alma A and *et al.*, and Rajeswari *et al.*, the commonest indication was preeclampsia followedby post-dates [21, 24].

**Table 5:** Bishop Score

Bishop Score	Foleys	Cerviprime	p-value
	Mean±S.D.	Mean±S.D.	
0Hours	2.10 ±0.678	2.2±0.78	0.496
6Hours	5.86 ±1.52	6.70 ±1.82	0.014
12Hours	8.91 ±2.12	9.89 ±1.34	0.035
18Hours	10.80±0.45	11.67±1.53	0.26

Table 5 shows that there is no significant difference in the Bishop score at '0' hours between the two groups. In the present study both groups, induction started with a similar Bishop Score <3. The mean Bishop Score at '0' hours in the foleys group was 2.11 when compared to the PGE2 group, where it was 2.2. The mean Bishop score at 6 hours in Foley's group was 6.1 hours compared to thePGE2 group, where the mean Bishop score at 6 hours was 6.6 hours. Similarly, the mean Bishop score at 12 hours was 8.91 hrs in Foley's group compared to the PGE2 group, where the mean Bishop score at 12 hours was 9.89 hours. The mean improvement in Bishop score was higher in the PGE2 gel group when compared to the Foley's. In the study of Dileep *et al.*, there is a statistically significant difference in bishops score at 6hrs and 12 hrs in the PGE2gel group when compared to Foley's group<sup>[22]</sup>. In the study of Almaa *et al.*, Rajeswari *et al.*, Richa jha *et al.*, there is no statistically significant difference in bishops score at6hrs and 12hrs in both groups. Both are equally effective in cervical ripening<sup>[21, 23, 24]</sup>.

**Table6:** Reinstallation

Re-Instillation	Foleys	Cerviprime	Total	P-Value
Yes	27	46	73	0.008
No	73	54	127	
Total	100	100	200	

Table 6 shows the need for re-installation in both groups. There is a statistically significant difference between both groups.

**Table7:** Oxytocin augmentation

Augmentation	Foleys	Cerviprime	Total	P-Value
Yes	84	38	122	<0.001
No	16	62	78	
Total	100	100	200	

The table7 shows the need for augmentation in both groups. In Foley's group, 84% need augmentation with oxytocin when compared to the PGE2gel group, which required only 38%. There is a statistically significant difference being PGE2 gel requires less augmentation than Foley's group. The need for oxytocin augmentation to deliver was higher with Foley's balloon dilatation when compared to the PGE2 gel group. According to a study by Dileep *et al.* and Richa Jha *et al.* need for oxytocin augmentation is higher in Foley's group compared to the PGE2gel group<sup>[22, 23]</sup>. In the study of Alma a *et al.*, Rajeswari *et al.*, there is no statistically significant difference in the need for augmentation in both groups<sup>[24]</sup>.

**Table 8:** Induction to active labour interval

	Foleys	Cerviprime	p-value
	Mean±S.D.	Mean±S.D.	
Induction to active Labour Interval (inHrs)	6.23±1.995	5.61±1.511	0.013

Table 8 shows the mean induction active labour interval in Foley's group was 6.23 hours. The mean induction to active labour interval in the PGE2 gel group was 5.61 hours. The difference between the two groups using the t-test is statistically significant. Active labour starts earlier in the PGE2 gel group when compared to Foley's group. PGE2 gel was found to be more effective in inducing labour when compared to Foley's group. According to Dileep *et al.*, induction to labour interval is shorter in the PGE2 gel group than Foleys which is comparable to the present study<sup>[22]</sup>.

**Table9:**Induction delivery interval

	Foleys	Cerviprime	p-value
	Mean±S.D.	Mean±S.D.	
Induction Delivery Interval (inHrs)	13.17±2.754	11.43±3.076	<0.001

Table 9 shows the mean induction delivery interval in Foley's group was 13.17 hours. The mean induction delivery interval in the PGE2 gel group was 11.43 hours. The difference between the two groups using the t-test is highly statistically significant. Induction to delivery interval is shorter in the PGE2 group when compared to Foley's group. According to Dileep *et al.*, the time from induction to delivery interval is shorter in PGE2 gel than in the catheter group<sup>[22]</sup>. In the study of Alma *a et al.*, Rajeswari *et al.*, Richa Jha *et al.*, there is no statistically significant difference in induction delivery interval between both groups<sup>[21, 23, 24]</sup>. Metaanalysis done by Hongye Wang *et al.* concluded that induction of labor with controlled-release dinoprostone insert seems to be more effective than Foley catheter which is in consistant with the present study<sup>[25]</sup>. In Vallikkannu N *et al.* 2022 study induction to vaginal delivery intervals was mean ± standard deviation 22.5 ± 10.4 vs. 35.1 ± 14.9 h, P = < 0.001 for Foley catheter-controlled-release dinoprostone and Foley catheter alone arms, respectively<sup>[26]</sup>.

**Table 10:** Mode of delivery

Mode of Delivery	Foleys	Cerviprime	Total	p-value
Forceps	7	2	9	0.289
LSCS	37	33	70	
Normal	56	65	121	
Total	100	100	200	

Table 10 shows out of 100%, 65% delivered by normal labour in the PGE2 gel group, 56% delivered by normal labour in Foley's balloon dilatation. 37% LSCS rate in Foley's balloon dilatation, with 33% in PGE2 gel regimen. There is statistically no significant difference in the mode of delivery between the two groups. This study is compared to Dileep p. Javadekar *et al.*, Anjuman Alam *et al.* studies, comparable to the present study<sup>[21, 22, 23]</sup>. In contrast, in Rajeswari *et al.* and Richa Jha *et al.*, there is no statistically significant difference between the mode of delivery in both groups<sup>[23, 24]</sup>.

**Table 11:** Mode of delivery in each group

	Foleys	Cerviprime	Total
<b>GDM</b>	<b>0</b>	<b>1</b>	<b>1</b>
Forceps	0	0	0
LSCS	0	0	0
Normal	0	1	1
IUGR	11	2	13
Forceps	1	0	1
LSCS	3	1	4

Normal	7	1	8
Oligohydramnios	18	18	36
Forceps	0	0	0
LSCS	9	4	13
Normal	9	14	23
PostDated	52	45	97
Forceps	3	2	5
LSCS	19	14	33
Normal	30	29	59
AntepartumEclampsia	0	1	1
Forceps	0	0	0
LSCS	0	1	1
Normal	0	0	0
ImminentEclampsia	0	1	1
Forceps	0	0	0
LSCS	0	1	1
Normal	0	0	0
Pre Eclampsia	19	32	51
Forceps	3	0	3
LSCS	6	12	18
Normal	10	20	30

**Table12:** Indications for LSCS

Indications forLSCS	Foleys	Cerviprime	Total	P-Value
FailedIOL	14	13	27	0.813
Fetal Distress	11	8	19	
MSL	7	5	12	
NonReassuringCTG	5	7	12	
Total	37	33	70	

Table 12 shows caesarean section rate is same in both the groups, the most common indication being failed induction next comes fetal distress. In Foley's group, cesarean section is due to failed IOL in 14 cases, 11 due to fetal distress, five due to non-reassuring CTG out to 37 Cesarean. In the PGE2group, cesarean section due to failed IOL is 13 patients and due to fetal distress is 8 out of 33 cesarean deliveries. According to a study by Dileep *et al.*, the commonest indication for cesarean section is fetal distress<sup>[22]</sup>. In Alma *et al.*, fetal distress (7 in Foleys group and 11 in Prostaglandin group) followed by failed induction is the indication for cesarean section<sup>[21]</sup>. In the study of Richa Jha *et al.*, fetal distress (9 in Foleys group and 9 in Prostaglandin group) followed by failed induction is the indication for cesarean section<sup>[23]</sup>. Rajeswari *et al.* fetal distress (9 in Foleysgroup and 11 in Prostaglandin group) indicate cesarean section<sup>[24]</sup>.

### Fetal Outcome

In Foley's group mean birth weight is 2.91, comparable to the PGE2group, which was 2.99 with no statistical significant difference. In the Foley balloon dilatation group, 15% of neonates were admitted. The Most common reason being respiratory distress. In the PGE2 gel group, 16% of neonates got admitted to neonatal intensive care unit due to birth asphyxia or meconium aspiration mainly due to the hyper stimulation. The difference between the two groups is not statistically significant. In the study of Dileep *et al.*, Alma *et al.*, Rajeswari *et al.*, Richa Jha, there is no statistically significant difference in fetal outcome in both groups<sup>[21, 22, 23, 24]</sup>.

### Maternal Complications

Intra partum pyrexia and puerperal pyrexia observed in the Foley's balloon dilatation group is 3% due to prolonged labour, whereas in the PGE2 gel group was 1%. The incidence of postpartum hemorrhage was equal in both groups. One woman had developed traumatic PPH due to forceps deliveries, which settled with suturing. Hyper stimulation was noted in 2 women who were induced with PGE2 gel. They had settled by changing them to the left lateral



position, plain fluids, and nasal O<sub>2</sub> who delivered by normal labour with babies in good condition and good maternal outcome.

### Conclusion

Cervical ripening is more effective with dinoprostone gel application, Mean induction to active labour interval and mean induction to delivery interval were shorter with dinoprostone gel. Oxytocin augmentation was less with prostaglandin E<sub>2</sub> gel instillation. In both the groups, the maternal and fetal outcomes are found to be similar. In both the groups, the rate of normal vaginal and cesarean section delivery was also found to be equal. This study shows that prostaglandin E<sub>2</sub> gel is a better and more effective agent than foley's balloon dilatation in cervical ripening and induction of labour. Induction of labour should be done when indicated, that is, when maternal and fetal complications outweigh the risks of continuing pregnancy and to prevent unnecessary fetal distress and increasing cesarean section rate. Proper history, clinical examination, and necessary investigations like ultrasound, Doppler, routine blood investigations should be done before induction of labour. Bishop score is a simple measure to assess the favourability of the cervix and used as a scale to assess the progress of labour. Mode of delivery may be individualized based on factors such as parity, cervical ripeness, maternal and fetal status, patients' preferences, cost-effectiveness. Informed consent should be taken before induction, explaining the advantages and risks. Induction of labour should always be conducted in a hospital for intra partum maternal and fetal surveillance. Obstetricians, Paediatricians, and anesthetists should be available at any time. Optimum delivery time should be personalized based on maternal and fetal conditions for effective induction and good maternal and neonatal outcomes.

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