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Original research article

Pre-induction Cervical Ripening - A Comparative Study Between Transcervical Foley's Catheter Versus Intracervical Prostaglandin E_2 Gel

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Abstract

Background: The cervical condition at the time of induction determines whether or not labor induction is successful. Patients with low Bishop scores are expected to experience an unacceptably high rate of induction failure. The solution is cervical ripening using any approach to reduce induction failure. The objective of the study is to analyze the safety and efficacy of Transcervical Foley's catheter for cervical ripening in pregnant women with term gestation.

Methods: The study included n=200 patients after 38 completed weeks of gestation with a Bishop's score <4 with various indications for induction were randomly allocated to receive n=100 patients with transcervical Foley's catheter and n=100 patients to receive intracervical prostaglandin E_2. In the Foley group, 12 hours after insertion of the catheter, it was deflated and removed, and rescoring of the cervix was carried out for improvement in the bishop's score. In the Dinoprostone group, Bishop's score was reassessed after 6 hours. If the bishop score was poor, the same dose of PGE_2 was repeated and reassessed after 6 hours for a maximum of 3 doses in 24 hours.

Results: The bishop score is assessed at 0 hrs in both the groups. The majority of patients had Bishop scores of 0- 2. In Foley's group, n=62 cases and the PGE_2 gel group to n=56 cases had Bishop scores in the range 0-2. There was no statistical significance between the two groups. At 6 hrs only Dinoprostone group patients were reassessed according to protocol. The majority of patients in the Dinoprostone group show Bishop scores of 5-7 at 6hrs. The bishop score is

assessed at 12hrs in both groups. In Foley's group n=42 cases and in Dinoprostone group, n=31 cases had delivered within 12 hrs and hence were not assessed. Majority of patients in both the groups showed bishop's scores of 5 – 7 at 12 hours.
Conclusion: Foley's catheter is an equally effective method for pre-induction cervical ripening as Prostaglandin E_2 gel in terms of initial cervical score, improvement in cervical score, the success of induction, and the induction delivery intervals. The use of a Foley catheter was equally acceptable to the patients as the prostaglandin gel.

Keywords: Cervical Ripening, Transcervical Foley's Catheter, Intracervical Prostaglandin E_2 Gel, Induction, Labor

Introduction

In obstetric practice, induction of labor is a common procedure that accounts for 20% of all deliveries. [1] It usually averts the necessity for a cesarean section and aids in achieving vaginal delivery when the pregnancy is not prolonged in a way that is healthy for the expectant mother and the fetus. In 15% of cases, a poor cervix is a key factor contributing to unsuccessful labor induction. The cervix's unfavorable condition during labor is fixed via ripening. According to the available research, annual rates of induction range from 9.5% to 33.7% of all pregnancies. At least 20% of pregnant women require medical help to start their labor. The overall incidence of labor induction tripled in the United States between 1990 and 2019, going from 9.5 percent in 1990 to 29.4 percent in 2019. [2] A post-date pregnancy, maternal issues (such as diabetes mellitus, renal disease, hypertension), oligohydramnios, pre-labor membrane rupture, intrauterine fetal death, logistical considerations, and other medical or obstetric concerns are among the signs that labor should be induced. Women who are somewhat hypertensive after 37 weeks of pregnancy should be advised to undergo labor induction because it is linked to better maternal outcomes. An elective birth can reduce the likelihood of problems, severe hypertension, and the requirement for antihypertensive medication therapy in women who have preeclampsia or gestational hypertension after 34 weeks of pregnancy. [3-5] In women with gestational diabetes, without other maternal or fetal conditions, no difference was detected in birth outcomes regardless of the approach used (i.e., induction between 38 and 39 weeks versus expectant management) [6-8] Foley's catheter, posterior fornix prostaglandin E_2 and oral or vaginal PGE_1 are in common use for induction of labor. The use of transcervical foley catheter is the main non-pharmacological method of cervical ripening and induction of labor. A Transcervical Foley catheter is better at improving the cervical OS dilatation score at pre-induction cervical ripening. Salim, et al. found that women who spontaneously expelled their catheter demonstrated favorable outcomes with regards to shorter times from induction to delivery and a significantly lower proportion of operative deliveries. [9] The prostaglandins mainly act through fibroblast activity and also as chemotactic agents promoting the infiltration of leukocytes and macrophages into the cervical stroma. The cells thus infiltrated are the source of specific degradative enzymes and changes in the extracellular matrix associated with ripening. PGE_2 is successful in increasing vaginal deliveries within 24 hours with no increase in operative delivery rates. [10] It is the most common prostaglandin drug used in recent days. But, the systemic absorption of PGE_2 results in side effects including nausea, and vomiting. Initiation of uterine contractions may lead to uterine hyperactivity, especially in women with an unfavorable cervix. However, no clear data is available in this part of the country to compare the efficacy of transcervical foley catheter with intracervical PGE_2 as a pre-induction cervical

ripening agent in recent times. Hence this study was taken up to compare the efficacy of these two.

Material and methods

This prospective comparative study was done in the Department of Obstetrics and Gynecology, Government Maternity Hospital, Hanamkonda, Telangana State from June 2021- June 2022. Institutional Ethical approval was obtained for the study. Written consent was obtained from all the participants of the study after explaining the nature of the study in the local language.

Inclusion Criteria:

1. Women with Gestational age between 38 to 42 weeks
2. Age of pregnant women between 18 to 30 years
3. Singleton fetus
4. Cephalic presentation
5. Intact membranes
6. Bishop scores less than 6
7. Reactive non-stress test

Exclusion Criteria:

1. Intrauterine foetal death
2. Women with a Previous history of LSCS
3. Prelabour rupture of membranes
4. Malpresentation
5. Antepartum hemorrhage (Placenta previa, vasa previa)
6. Any contradiction to vaginal delivery
7. Hysterotomy/myomectomy scar, Classical Scar
8. Co-morbid conditions like heart disease etc

Based on the inclusion and exclusion criteria a total of n=200 pregnant women cases were included in the study they were randomly allotted into two groups the n=100 (Foley's catheter) and n=100 (Dinoprostone; Prostaglandin E_2 gel). At the time of entry into the study, a detailed history was collected regarding medical, surgical, and obstetrical information. A vaginal examination was performed to rule out cephalopelvic disproportion and to assess the bishop's score. The gestational period was evaluated by eliciting information on the last menstrual period. The ultrasound examination was conducted for the gestational age, liquor volume, maturity, and fetal wellbeing. The fetal condition was assessed by using non-stress test tracings. Baseline laboratory investigations were conducted by collecting the blood samples.

Foley's group: Under all aseptic precautions no. 16 foley's catheter was introduced through the cervix past the internal OS and inflated with 30 ml of distilled water. After 12 hours the catheter was deflated and removed and rescoring of the cervix was carried out to improvement of Bishop's score. If there was no improvement in Bishop's score after 12 hours reassessments were carried out. If there was a spontaneous expulsion of the catheter, spontaneous rupture of membranes & if the patient went into inactive labor cervical assessment was conducted after 12 hours. Failure of induction was considered when there was no improvement in the bishop's score after 24 hours.

PGE_2 group: N=100 patients received 0.5 mg of PGE_2 (Dinoprostone) instilled with the help of a loaded syringe after exposing the cervix. Close monitoring was conducted for hyperstimulation of the uterus. Bishop's score was reassessed after 6 hours. If the bishop score was poor, the same dose of PGE_2 was repeated and reassessed after 6 hours for a maximum of

3 doses in 24 hours. Fetal and maternal monitoring was performed with the help of a partogram on all the patients. Bishop's score was assessed every 6 hours in the PGE_2 group. Artificial rupture of membranes was conducted in active labor to hasten the process of delivery and to note down the color of the liquor. If the contractions were inadequate in the active phase of labor, oxytocin drip was started with 5 U in 500 ml ringer lactate with 2 mu/min and increased geometrically every 30 min till 3 contractions were observed in 10 min period lasting for 45 seconds up to a maximum of 40 mu/min. Labour and delivery parameters including the interval from the start of induction to delivery, number of patients requiring oxytocin augmentation, and mode of the delivery were collected in a proforma. The occurrence of fever, gastrointestinal symptoms, hyperstimulation, and postpartum hemorrhage was also evaluated. The fetal criteria included the presence of thick meconium in the amniotic fluid, fetal distress as defined by abnormal cardiotocography prompting emergency delivery, APGAR scores at one and five minutes, meconium aspiration, and transfer to NICU were also evaluated.
Statistical analyses: were performed using IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp. Results on continuous measurements were presented on Mean ± SD & categorical as Frequency (Percentage). The normality of the data was assessed using the Shapiro Wilk test. Inferential statistics like Chi-square/Fishers Exact test and independent t-test were used to compare variables between the groups.

Results
Based on the distribution of cases in various age groups 20% of cases were below 20 years age group 50% were in the age group 21 – 25 which was the most common age group of patients included in this study and 30% of cases were aged between 26 – 30 years. The mean age group of Foley catheter patients was 23.67± 3.11 years and the mean age in the Dinoprostone group was 23.57±2.90 years the p values were 0.814 hence not significant the details depicted in table 1.

Table 1: Demographic profile of the cases included in the study

Age In Years	*Foley's*	*Dinoprostone*	*Total*
< 20	20	20	40
21 – 25	50	50	100
26 – 30	30	30	60
Total	100	100	200
Mean ± SD	23.67±3.11	23.57±2.90	

It has been observed in this study the majority of cases 55% in both groups were between 40.1 – 42.0 weeks those below 45 weeks were 45% cases. The mean gestational age in weeks of Foley's group was 39.85±0.57 weeks and those in the Dinoprostone group were 40.00±0.00 weeks.

Table 2: Distribution of cases based on Gestational age

Gestational Age (weeks)	Foley's	Dinoprostone	Total
38.0 – 40.0	45	45	90
40.1 – 42.0	55	55	110
Total	100	100	200
Mean ± SD	39.85±0.57	40.00±0.00	

It has been observed from this study that the majority of patients in both groups were primigravida i.e., 74% in each group depicted in figure 1.

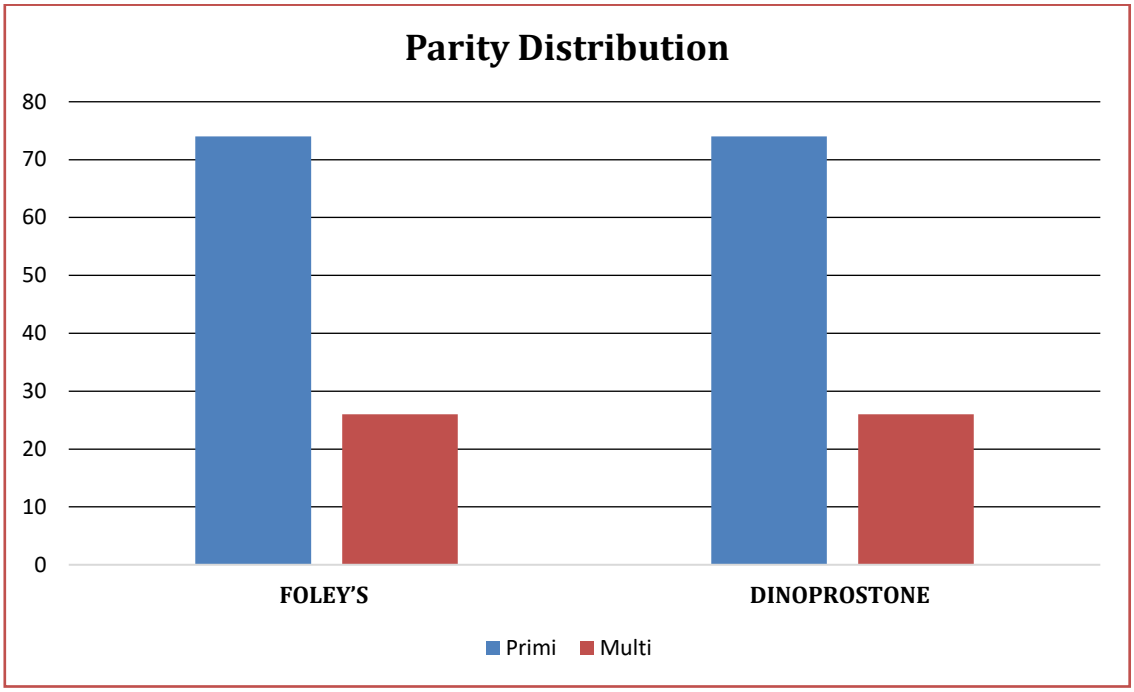

Figure 1: Parity distribution among patients of the study

The various indications for induction in the study are depicted in table 3. It is observed in this study that the majority of cases in both groups were induced because of post-dated pregnancy and gestational hypertension i.e.,68% for postdates, 13% for gestational hypertension, and 10% were oligohydramnios.

Table 3. Indication for Induction in the cases of study

Indication	*Foley's*	*Dinoprostone*	*Total*
Post Dates	65	71	136
Oligohydramnios	12	08	20
Gestational Hypertension	14	12	26
Intra Uterine Growth Restriction	04	04	08
Rh-Negative pregnancy	03	03	06
Pre-Eclampsia	02	02	04

The bishop score at 0 hrs is assessed in both the groups. The majority of patients had Bishop scores of 0- 2. In Foley's group, n=62 cases and the PGE_2 gel group to n=56 cases had Bishop scores in the range 0-2. There was no statistical significance between the two groups. At 6 hrs only Dinoprostone group patients were reassessed according to protocol. The majority of patients in the Dinoprostone group show Bishop scores of 5-7 at 6 hrs. The Bishop's scores is reassessed in both the groups at 12 hrs. In Foley's group n=42 cases and in Dinoprostone group, n=31 cases had delivered within 12 hrs and hence were not assessed. The majority of patients in both groups had a bishop score of 5-7. Maximum cases in the Dinoprostone group are 7 with Bishop Score n=7 whereas in Foley's group it is 1 with Bishop Score 10 as shown in Table 4

Table 4: Showing Bishop's score at various intervals in both groups

Bishop's Score	*Foley's*	*Dinoprostone*	*p-value*
Bishop's Score at 0 hours			
0 – 2	62	56	0.875
3	27	36	
4	11	08	
Bishop's Score at 6 hours			
Delivered	0	9	0.550
≤ 4	48	40	
5 - 7	32	43	
≥ 8	20	8	
Bishop's Score at 12 hours			
Delivered	42	31	0.037*
≤ 4	2	6	
5 - 7	30	37	
≥ 8	26	26	
Bishop's Score at 24 hours			
Delivered	99	87	0.016*
≤ 4	0	0	
5 - 7	0	13	
≥ 8	1	0	

* Significant

The Foley's group had n=69 vaginal deliveries whereas in the Dinoprostone group n=61 vaginal deliveries were recorded. The need for operative intervention (LSCS) was not significant between the two groups. N=31 underwent LSCS in Foley's group and n=39 underwent LSCS in Dinoprostone group. There was no statistical significance between the two groups. LSCS was done for fetal distress in n=18 cases in Foley's group and n=19 cases in the Dinoprostone group. The other indications for LSCS were failure to progress n=9 cases in Foley's group and6 cases in Dinoprostone group and for a non-reactive non-Stress test, n=3 cases in Foley's group and n=12 cases in Dinoprostone group depicted in figure 2.

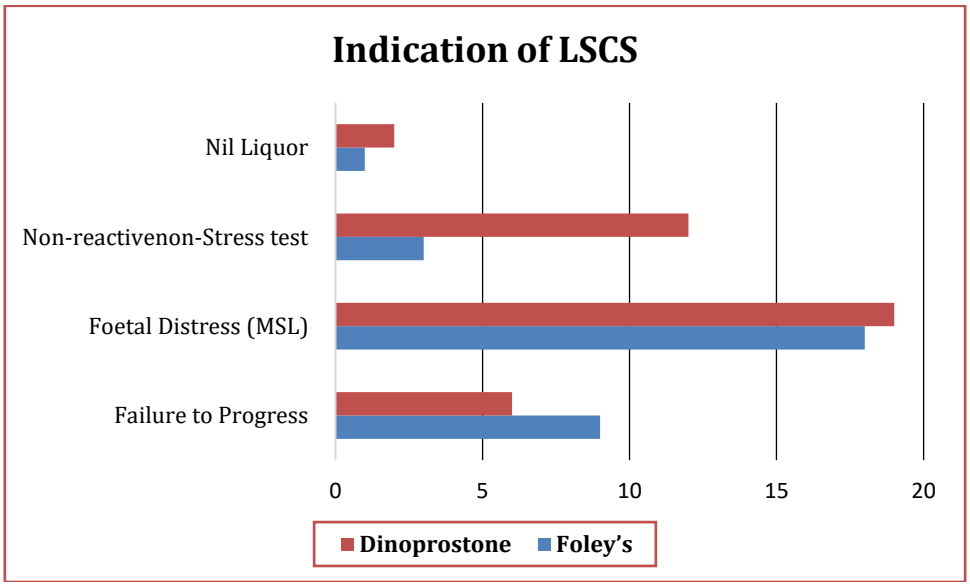

Figure 2: Indication of LSCS in both group cases of the study

Table 5 shows that there was a statistical significance (p=0.027) in the induction delivery interval between the two groups. The majority of cases in both groups had an induction delivery interval of 7-12 hrs. In Foley's group, it is n=51 cases and in the Dinoprostone group, it is n=40 cases.

Table 5: Induction to Delivery Interval the cases of study

Induction Delivery Interval (hours)	*Foley's*	*Dinoprostone*	*Total*
0 – 6	8	14	22
7 – 12	51	40	91
13 – 18	35	16	51
19 – 24	6	30	36
Total	100	100	200
Mean ± SD	13.72 ± 6.53	12.01 ± 3.99	

N=17 babies required NICU admission in the Foley group and n=19 babies in the Dinoprostone group. no statistical significance in the neonatal morbidity in both the groups. Hyperbilirubinemia was the cause in 8% of babies in both groups followed by birth asphyxia in 4% of Foley's group and 5% of the Dinoprostone group. Meconium aspiration was observed in 3% of Foley's group and 4% of the Dinoprostone group. 2% of babies in both groups were admitted for observation. Post-Patrum hemorrhage was observed in 2% of cases in the Dinoprostone group and in Foley's group 4% had a postpartum hemorrhage and 2% had puerperal pyrexia.

Discussion

In the present study n=200, women between 18-30 years of age were randomly subjected to pre-induction cervical ripening between 38-42 weeks of gestation by Prostaglandin E_2 gel and Foley catheter. The mean age of cases in the Foley group was 23.67 ± 3.11 years and in the PGE_2 (Dinoprostone) group it was 23.57 ± 2.90. Similar observations were done by M Ezimokhai et al., [11] with the mean age of the two groups as 22.9 ± 4.1 and 23.5 ± 5.6 years respectively. In a similar study Ghezzi F et al., [12] found the mean age of Foley's group 26.1 ± 2.8 years and PGE_2 26.2 ± 3.3 years. The Gestational age of the majority of the patients in the present study was 40.1 weeks - 42.0 wks. constituting 55% in both the Foley's group and PGE_2 gel group. M Ezimokhai et al., [11] also found the gestational age of 40.0 ± 1.9 weeks and 40.6 ± 1.1 weeks in both groups respectively. Deshmukh et al., [13] found the mean gestational age of 38.7 ± 1.73 weeks in the Foley's group and 38.6 ± 1.68 weeks in the PGE_2 group. the majority of cases in both groups were induced because of post-dated pregnancy and gestational hypertension i.e., 68% for postdates, 13% for gestational hypertension, and 10% were oligohydramnios (Table 3). In this study, post-dated pregnancy was the primary cause of induction of labor in 65% of Foley's group patients and 71% of PGE_2 group patients, respectively. The next most frequent indication was oligohydramnios 12% and 8% respectively. Only 3% of patients in the foley's group and 4% of patients in the PGE_2 group met the definition of a prolonged pregnancy (>42 weeks) out of the total patients, who were patients with gestational ages of 40.1-42 weeks and 42.1-43 weeks, respectively. Due to our hospital's protocol, all patients who are pregnant for longer than 40 weeks must be induced. Pregnancy-induced hypertension was the cause in 14% and 12% of cases respectively. St. Onge RD et al., [14] found the majority of the indications for induction were pregnancy-induced hypertension (47%) in the catheter group and oligohydramnios (42%) in the PGE_2 group. The mean pre-induction Bishop's score in the current study was 2.39 ± 0.88 in the Foley group and 2.37 ± 0.91 in the PGE_2 group. Sciscione, et al., [15] in a similar study found the mean pre-

induction bishop's score of 2.8 ± 1.7 and 2.4 ± 1.3 in agreement with the observations of the current study. In the present study mean post-induction score at 12 hrs was 6.32 ± 1.75 in the Foley group and 6.91 ± 1.21 in the PGE_2 gel group. The post-induction Bishop score is statistically significant with a p-value of 0.037. In the present study, the findings correlate with the study by M Ezimokhai et al., [11] Ghezzi F et al., [12] and Deshmukh et al., [13]. The change in the bishop's score was found to be significant after 12 hours and 24 hours. However, the comparison between the groups did not show that one method has an advantage over the other group. Similar changes in bishop's scores were reported in the studies conducted by Dahiya K et al., [16] also showed that the change in bishop score after 6 hours was comparable to this study (in PGE_2 group 4.6 ± 1.48 and foley's group 4.18 ± 1.81), comparable were the results of St. Onge RD et al., [14] and Deshmukh et al., [13]. The majority of women had vaginal delivery 65%.69% in Foley's group and in PGE_2 gel group is 61%. The overall rate of cesarean section was 35%.31% in the foleys group and in the PGE_2 gel group, it is 39%. The p-value comes to 0.299 which is statistically insignificant. The results of this study were similar to Deshmukh et al., [13] and Ghezzi F et al., [12]. The mean birth weight was 2.91 ± 0.35 in the Foley group and 2.88 ± 0.26 in the PGE_2 gel group. Similar observations were made by Deshmukh, et al (2011) [3]and Ghezzi F et al., [12]. The induction delivery interval is (13.72 ± 6.53) in the foley group, and in the PGE_2 gel group, it is 12.01 ± 3.99 with a P value of 0.027. There is a statistical significance between these two groups in induction delivery interval with a p-value <0.05 (0.027) though there is not much difference between the two groups. Similar observations were made by Ghezzi F et al., [12] and Deshmukh et al., [13].

Conclusion

Within the limitation of the current study, it can be concluded that;

1. Foley's catheter is an equally effective method for pre-induction cervical ripening as Prostaglandin E_2 gel in terms of initial cervical score, improvement in cervical score, the success of induction, and the induction delivery intervals.
2. The use of a Foley's catheter was equally acceptable to the patients as the prostaglandin gel.
3. The main argument against the use of Foley catheters has been the risk ofthe introduction of infection and accidental rupture of membranes. These risks are reduced by aseptic precautions and active management of labor.
4. None of the patients in this study had accidental rupture of membranes. Dinoprostone needs refrigeration at 6-8 degrees Celsius.
5. Foley's catheter can be safely used in women with asthma where PGE_2 is contraindicated

Because of the similar effectiveness of Foley's catheter and Prostaglandin E_2 gel, the catheter has an adequate place in a developing country due to the lower economy incurred and no special storage requirements.

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