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Comparative Study On Induction Of Labour: Foley's Catheter Vs Prostaglandin E2 Gel.

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ABSTRACT

Labour refers to the onset of effective uterine contractions leading to progressive effacement and dilatation of the cervix resulting in expulsion of the fetus, placenta and the membranes. Around 20% of all deliveries are preceded by labour induction, a proportion that has not varied dramatically over recent years. Fetal death was the only indication for labour induction centuries ago. While this is now a very rare indication with prolonged pregnancy and maternal hypertensive disorders being the major indications for the last 50 – 60 years. Techniques for inducing labour have also changed from dietary delicacies and verbal threats giving way to physical stimulation mainly achieved by cervical stretching and amniotomy and more recently to pharmacologic manipulation using oxytocin and prostaglandins. Relaxin, antiprogestins, nitric oxide have also been explored in recent years. To assess the effectiveness of intracervical Foley's balloon catheter versus prostaglandin E2 gel for ripening of the cervix and inducing labour. This prospective study was conducted in 2020 at Division Of Obstetrics & Gynaecology Government Tiruvanamalai Medical College, Tiruvanamalai, Tamil Nadu, India. 100 patients, 50 Patients were included in the study in each group. History taking from the patient included the last menstrual period, menstrual cycle regularity, past obstetric and medical history. Clinical examination of the patient done. Vitals are examined. Anemia, pedal edema noted. Obstetric examination of the abdomen done. After correlating the history, clinical findings and previous ultrasound findings, according to the indication, patient selection for induction is done. After selecting the patients for study, their Bishop score was assessed by pelvic examination by evaluating the cervical consistency, effacement, position, dilatation and station of the presenting part. Major degrees of cephalopelvic disproportion ruled out. Most of the patients age group fall between 20 – 24 years. There is no significant difference in the age group between the two groups. gravida distribution for Foley's balloon dilatation and prostaglandin E2 gel. In both Foley's dilatation and PGE₂ regimen. 72% were primigravida. 28% multigravida in both Foley's and PGE₂ regimen. There is no difference in the gravida distribution between the two groups. Bishop score of <5 taken as indication for induction. In both groups, maximum patients had a Bishop score of 2 or 3. In Foley's balloon dilatation, 50% had a Bishop score of 2. In PGE₂ gel regimen, 46% had Bishop score 2. In Foley's balloon dilatation, 30% had a Bishop score of 3 and in PGE₂ gel regimen, 32% had a Bishop score of 3. No significant difference in the Bishop score at '0' hours between the two groups. Hence, both the groups started the induction with similar Bishop score. Bishop Score at 6 hours for both groups. 76% of pregnant women in PGE₂ gel regimen had favourable Bishop score within 6 hrs. Only 56% of pregnant women in Foley's balloon dilatation had favourable Bishop score within 6 hours. There is a statistically significant difference in the Bishop score between both groups. 52% of patients in the PGE₂ gel delivered within 12 hours. 62% of patients in Foley's balloon dilatation had a favourable Bishop score at 12 hours. There is a statistically significant difference in the Bishop score in the PGE₂ gel compared to Foley's balloon dilatation. In Foley's balloon dilatation, 35% of primi and 21% of multi established labour within 6 hours. 54% of primi and 78% of multi within 12 hours 9% crossed 12 hours. In PGE₂ gel regimen. 41% of primi and 28% of multi established labour within 6 hours. 55% of primi and 71% of multi established labour within 12 hours. Only 2% crossed 12 hours. In PGE₂ gel regimen, 61% of primi and 85% of multi delivered with 12 hours. In Foley's balloon dilatation, 47% of primi and 50% of multi delivered within 12 hours. The mean induction delivery interval in multigravida with Foley's balloon dilatation was 11.7 hours. The mean induction delivery interval in multi with PGE₂ gel group was 9.9 hours. The difference between the two groups using the 't' test is statistically significant. 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. 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. Oxytocin augmentation was less with prostaglandin E2 gel instillation. Response of multis in both groups better than primis. Fetal and maternal outcome were better with prostaglandin E2 gel. 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.

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

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INTRODUCTION

Labour refers to the onset of effective uterine contractions leading to progressive effacement and dilatation of the cervix resulting in expulsion of the fetus, placenta and the membranes. Around 20% of all deliveries are preceded by labour induction, a proportion that has not varied dramatically over recent years [1]. Fetal death was the only indication for labour induction centuries ago. While this is now a very rare indication with prolonged pregnancy and maternal hypertensive disorders being the major indications for the last 50 – 60 years [2]. Techniques for inducing labour have also changed from dietary delicacies and verbal threats giving way to physical stimulation mainly achieved by cervical stretching and amniotomy and more recently to pharmacologic manipulation using oxytocin and prostaglandins. Relaxin, antiprogesterins, nitric oxide have also been explored in recent years [3]. Measurement of fetal fibronectin in cervical mucus, maternal serum nitrite/ nitrate concentrations, ultrasound delineation of cervical form and electrical impedance measurements across the cervix are all being investigated [4]. Most methods of inducing labour before the last half century involved mechanical manipulations including Galvanism, repeated pressurized douches, extra amniotic aqua piece, tents, bougies and catheters [5]. A number of folkloric or old wife’s tales are still used today by women to encourage their labour to start [6]. Hypertensive states constitute the second most common indication for labour induction because of anticipated maternal or fetal problems. Nowadays, oligohydramnios, GDM, PROM and anomalous fetus are other indications. Obstetricians consider that cervical state should determine the timing of delivery. [7]. Labour induction is not without its risks for the mother and particularly for the fetus. Inadvertent delivery of a pre term baby has been largely eliminated by the widespread use of ultrasound assessment of gestation [8].

METHODS

This prospective study was conducted in 2020 at Division Of Obstetrics & Gynaecology Government Tiruvanamalai Medical College, Tiruvanamalai, Tamil Nadu, India. 100 patients, 50 Patients were included in the study in each group. History taking from the patient included the last menstrual period, menstrual cycle regularity, past obstetric and medical history. Clinical examination of the patient done. Vitals are examined. Anemia, pedal edema noted. Obstetric examination of the abdomen done. After correlating the history, clinical findings and previous ultrasound findings, according to the indication, patient selection for induction is done. After selecting the patients for study, their Bishop score was assessed by pelvic examination by evaluating the cervical consistency, effacement, position, dilatation and station of the presenting part. Major degrees of cephalopelvic disproportion ruled out. 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 a part given. 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 15 to 30 minutes before gel introduction.

RESULTS

Table 1: Age Distribution

Age in years	Foley's Balloondilatation		PGE2 gel		Total
	Number	Percent(%)	Number	Percent(%)	
<20	3	6	6	12	9
20 - 24	34	68	26	52	60
25 - 29	10	20	15	30	25
30 - 34	3	6	3	6	6
Total	50	100	50	100	100

Table shows the distribution of patients for age. Most of the patients age group fall between 20 – 24 years. There is no significant difference in the age group between the two groups.

Table 2: Gravida

Gravida	Foley's Balloondilatation		PGE2 gel		Total
	Number	Percent (%)	Number	Percent (%)	
1	36	72	36	72	72
2	9	18	8	16	17
3	5	10	4	8	9
4	-	-	1	2	1
5	-	-	1	2	1
Total	50	100	50	100	100

This is the table showing gravida distribution for Foley's balloon dilatation and prostaglandin E₂ gel. In both Foley's dilatation and PGE₂ regimen, 72% were primigravida, 28% multigravida in both Foley's and PGE₂ regimen. There is no difference in the gravida distribution between the two groups.

Table 3: Gestational Age

Gestational age in weeks	Foley's Balloondilatation		PGE2 gel		Total
	Number	Percent (%)	Number	Percent (%)	
37 - 40	24	48	36	72	60
>40	26	52	14	28	40
Total	50	100	50	100	100

Majority of patients in PGE₂ gel → 37 – 40 weeks of gestation (72%).

In Foley's balloon dilatation → equal distribution between 37 – 40 and >40 weeks 28%.

Table 4: Indication For Induction

Indication	Foley's Balloondilatation		PGE2 gel		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.

Table 5: Bishop Score At '0' Hour

BishopScore	Foley's Balloondilatation		PGE2 gel		Total
	Number	Percent (%)	Number	Percent (%)	
0	1	2	-	-	1
1	8	16	8	16	16
2	25	50	23	46	48
3	15	30	16	32	31
4	1	2	3	6	4
Total	50	100	50	100	100

Both the groups were started with same Bishop score. Bishop score of <5 taken as indication for induction. In both groups, maximum patients had a Bishop score of 2 or 3. In Foley's balloon dilatation, 50% had a Bishop score of 2. In PGE₂ gel regimen, 46% had Bishop score 2. In Foley's balloon dilatation, 30% had a Bishop score of 3 and in PGE₂ gel regimen, 32% had a Bishop score of 3. No significant

difference in the Bishop score at '0' hours between the two groups. Hence, both the groups started the induction with similar Bishop score.

Table 6: Bishop Score At '6' Hours

BishopScore	Foley's Balloondilatation		PGE2 gel		Total
	Number	Percent (%)	Number	Percent (%)	
<5	22	44	12	24	34
6 - 10	28	56	38	76	66
>10	-	-	-	-	-
Total	50	100	50	100	100
Mean	6		7.3		P<0.05

Table showing Bishop Score at 6 hours for both groups. 76% of pregnant women in PGE₂ gel regimen had favourable Bishop score within 6 hrs. Only 56% of pregnant women in Foley's balloon dilatation had favourable Bishop score within 6 hours. There is a statistically significant difference in the Bishop score between both groups.

Table 7: Bishop Score At '12' Hours

BishopScore	Foley's Balloondilatation		PGE2 gel		Total
	Number	Percent (%)	Number	Percent (%)	
Delivered	4	8	26	52	30
≤5	6	12	-	-	6
6 - 10	31	62	15	30	46
>10	9	18	9	18	18
Total	50	100	50	100	100
Mean	8.6		9.42		P<0.05

52% of patients in the PGE₂ gel delivered within 12 hours. 62% of patients in Foley's balloon dilatation had a favourable Bishop score at 12 hours. There is a statistically significant difference in the Bishop score in the PGE₂ gel compared to Foley's balloon dilatation.

Table 8: 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

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.

Table 9: Induction To Active Labour Interval

Duration in hours	Foley's Balloon dilatation				PGE2 gel			
	Primi		Multi		Primi		Multi	
	Number	(%)	Number	(%)	Number	%	Number	%
<6	11	35.4	3	21.4	15	41.66	10	28.58
6 - 12	17	54.2	11	78.5	20	55.55	4	71.42
>12	3	9.4	-	-	1	2.67	-	-
Total	31	100	14	100	36	100	14	100

Table showing the induction to active labour interval. In Foley's balloon dilatation, 35% of primi and 21% of multi established labour within 6 hours. 54% of primi and 78% of multi within 12 hours. 9% crossed 12 hours. In PGE₂ gel regimen. 41% of primi and 28% of multi established labour within 6 hours. 55% of primi and 71% of multi established labour within 12 hours. Only 2% crossed 12 hours.

Table 10: Mean Induction To Active Labour Interval

	Foley's Balloon dilatation		PGE2 gel	
	Primi	Multi	Primi	Multi
Induction labour interval	7.5	6.6	6.5	5.2

The mean induction active labour interval in primigravida with Foley's balloon dilatation was 7.5 hours. The mean induction to active labour interval in primigravida with PGE₂ gel group was 6.6 hours. The mean induction active labour interval in multipara with Foley's balloon dilatation was 6.5 hours. The mean induction active labour interval in multipara with PGE₂ gel group was 5.2 hours. The difference between the two groups using the 't' test is statistically significant.

Table 11: Induction Delivery Interval

Duration in hours	Foley's Balloon dilatation				PGE2 gel			
	Primi		Multi		Primi		Multi	
	No	(%)	No	(%)	No	%	No	%
6 - 12	17	47.22	7	50	22	61.11	12	85.72
12 - 24	19	52.78	7	50	14	38.89	2	14.28
Total	36	100	14	100	36	100	14	100

Table showing the Induction Delivery interval in both groups. In PGE₂ gel regimen, 61% of primi and 85% of multi delivered with 12 hours. In Foley's balloon dilatation, 47% of primi and 50% of multi delivered within 12 hours.

Table 12 Mean Induction Delivery Interval

	Foley's Balloon dilatation		PGE2 gel	
	Primi	Multi	Primi	Multi
Induction Delivery interval in hours	13	13.4	11.7	9.9

P<0.05

The mean induction delivery interval in primigravida with Foley's balloon dilatation was 13 hours. The mean induction delivery interval in primigravida with PGE₂ gel group was 13.4 hours.

The mean induction delivery interval in multigravida with Foley's balloon dilatation was 11.7

hours. The mean induction delivery interval in multi with PGE2 gel group was 9.9 hours. The difference between the two groups using the 't' test is statistically significant.

Table 13: Patients Requiring Reinstillation With PGE2

PGE ₂ gel	Foley's Balloondilatation		PGE2 gel		Total
	Number	Percent (%)	Number	Percent (%)	
Not used	31	62	37	74	68
Used	19	38	13	26	32
Total	50	100	50	100	100

Table showing higher use of 2nd method of induction by PGE2 in Foley's balloon dilatation than PGE₂ gel group.

Table 14: Patients Requiring Oxytocin For Augmentation

Oxytocin	Foley's Balloondilatation		PGE2 gel		Total
	Number	Percent (%)	Number	Percent (%)	
Not used	11	22	32	64	43
Used	39	78	18	36	57
Total	50	100	50	100	100

Table shows that Oxytocin augmentation requirement is more 78% in Foley's balloon dilatation than PGE₂ gel regimen where it is only 36%. The difference is statistically significant using chi-square test.

Table 15: Mode Of Delivery

Mode of Delivery	Foley's Balloondilatation		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

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.

Table 16: Indications For Caesarean Section

Indications	Foley's Balloondilatation		PGE2 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.

Table 17: Maternal Complications

	Foley's Balloon dilatation	PGE2 gel
	Number	Number
Hyper stimulation	-	5
Postpartum hemorrhage	3	3
Intrapartum Pyrexia	5	4
Puerperal pyrexia	4	2
Total	12	14

5 patients had hyper stimulation in the PGE₂ gel group. PPH incidence equal between two groups. Intrapartum and puerperal pyrexia slightly higher in Foley's group.

DISCUSSION

The study was carried out in 100 patients. Fifty patients being assigned randomly to the balloon dilatation and 50 patients to PGE₂gel. 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 [9]. 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. 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 [10]. 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 [11]. 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 [12]. 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. 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 [13]. 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. Delivery by labour natural was higher in the PGE₂ gel group when compared to the Foley's balloon dilatation group [14]. 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. 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. In the Foley's balloon dilatation group, 20% of

neonates were admitted [15]. 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. 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 [16]. 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 [17]. 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 [18].

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. Oxytocin augmentation was less with prostaglandin E₂ gel instillation. Response of multigravida in both groups better than primigravida. Fetal and maternal outcome were better with prostaglandin E₂ gel. 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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