

**INDUCTION OF LABOUR BY FOLEYS CATHETER Vs PROSTAGLANDIN E2GEL**

**\*<sup>1</sup>Amirtha Devarajan, <sup>2</sup>Dr.M.Sangeeranai. and <sup>3</sup>Dr.S.Viswanathan**

<sup>1</sup>Post Graduate, Department of Obstetrics & Gynaecology, Rajah Muthiah Medical College & Hospital, Annamalai University, Chidambaram-608002, Tamil Nadu, India.

<sup>2</sup>Assistant Professor, Department of Obstetrics & Gynaecology, Rajah Muthiah Medical College & Hospital, Annamalai University, Chidambaram-608002, Tamil Nadu, India.

<sup>3</sup>Professor, Department of Obstetrics & Gynaecology, Rajah Muthiah Medical College & Hospital, Annamalai University, Chidambaram-608002, Tamil Nadu, India.

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**ABSTRACT**

**BACKGROUND AND OBJECTIVES :**

**OBJECTIVE(S):** We aimed to evaluate the predictive value of effect on cervical ripening in terms of bishops score, induction - labour interval, Mode of delivery and maternal & fetal outcome. **DESIGN:** A prospective randomized controlled study. **SETTING:** In a single hospital. **METHOD(S):** This was a prospective study of 100 antenatal women booked at Rajah Muthiah Medical College & Hospital during the year 2012 -2014 with gestational age between 37wks – 42wks. The womens history, clinical examination recorded and bishops score were measured and the outcome of labour was compared between two groups i.e., Induction using Prostaglandin E2 gel & Foleys catheter. **STATISTICAL ANALYSIS:** Determined by Chi – square test and student ‘ t ‘ test used in appropriate places **RESULT(S):** The mean bishops score, the mean induction – active labour interval, the mean induction – delivery interval, Apgar score at 5 mins showed statistically significant difference (p <0.05, p <0.05, p <0.05, p <0.01). **CONCLUSION:**, From this study prostaglandin E2 gel is a better and more effective agent than Foley’s catheter in reducing the induction – active labour interval by improving the bishops score.

**Keywords:** Foleys catheter, Prostaglandin E2 gel, Bishops score, induction – active labour interval, Mode of delivery.

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**1.INTRODUCTION**

Labour refers to onset of effective uterine contractions leading to progressive effacement and dilatation of the cervix resulting in expulsion of fetus, placenta and the membranes. About 20% of all deliveries are preceded by labour induction. Techniques for inducing labour have been achieved by cervical stretching, amniotomy and more recently to pharmacologic manipulation using oxytocin and prostaglandins. Post term pregnancy is the most commonest indication for induction.

‘Cervical Ripening’ is a process by which the cervix becomes soft, compliant and partially dilated. Structurally, the cervix is composed of collagen, glycosaminoglycans (dermatan sulphate, chondroitin sulphate) which repel water and are responsible for firmness of the cervix. Towards term, the glycosaminoglycan concentration of the cervix alters and the dermatan sulphate and chondroitin sulphate are replaced by hyaluronic acid which imbibes water and destabilizes the collagen fibrils contributing to cervical ripening. Leucocyte elastase is another enzyme are found to increase with gestational age and decrease concentration of collagen

Cervical ripening agents are used to make an unfavourable cervix to a favourable cervix. Methods of cervical dilators are as follows - laminaria tents, membrane stripping, mechanical dilatation – Foleys catheter, mifepristone, prostaglandins (PGE2, PGE1).

Prostaglandins are derivatives of prostanoid acid and act as local hormones. They have direct effect on the production of procollagenase which is a precursor of collagenase, decreases collagen & increases hyaluronic acid which inturn softens the cervix and helps in cervical effacement and dilatation. Hence administration of intracervical prostaglandins (PGE2 & PGF2) produces cervical changes in women. They have become the standard method of ripening and induction of labour.

Intracervical Foleys catheter induction produces a mechanical distension of the lower uterine segment. This may lead to activation of phospholipase-A leading to formation of arachidonic acid which later converted to prostaglandins.

Bishops scoring system used which is very much sensitive in predicting success of labour.

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\*Corresponding author: Dr Amirtha Devarajan, Post Graduate, Department of Obstetrics and Gynaecology, RMMCH, Chidambaram, India

## LITERATURE SURVEY

The need to time delivery has been recognized and practised for centuries. Artificial rupture of the membranes being first used by Denman in 1756 and known as the English method. Pitocin extracted from the posterior pituitary gland in 1906. Blair Bell described its application in the pregnant uterus in 1909. Its use for induction of labour was first reported by Theobald in 1952. In 1968, Turnbull and Anderson introduced the titration method for oxytocin administration. Prostaglandin first isolated from seminal fluid of monkeys, sheep and goat by Ulf Von Ehler. Elias corey synthesized dinoprostone in 1970. In 1971, Karim and Sharma reported the results of labour at term with the use of oral PGE<sub>2</sub>. In 1975, Alder and Embrey gave PGE<sub>2</sub> extra amniotically.

**Table 1 Bishops Score**

Factors	0	1	2	3
Effacement (%)	0 – 30%	40 – 50%	60 – 70%	80%
Dilatation (in cm)	Closed	1 – 2	3 – 4	5+
Consistency	Firm	Medium	Soft	-
Position	Posterior	Midline	Anterior	-
Station	-3	-2	-1,0	+1,+2

In 1977, Mellour et al, Wilson gave PGE<sub>2</sub> intravaginally. In 1980, Hefni and Louis gave PGE<sub>2</sub> intracervically. Buccellato, in 2000, compared 50µg misoprostol with extra amniotic saline and gave similar outcomes. Karim and his colleagues in Uganda, noted that PGF<sub>2α</sub> appeared in amniotic fluid during labour. An interesting observation noted by Howiewashat women receiving intravenous prostaglandin E<sub>2</sub> or F<sub>2α</sub> for induction of labour exhibited oxytocin levels in the plasma similar to women in the late first stage of spontaneous labour.

## 2. MATERIALS AND METHODS

The study was a prospective study carried out at Rajah Muthiah Medical College, Chidambaram. The study participants included 100 booked antenatal women registered at RMMCH with gestational age between 37wks – 42wks, over a period of 2yrs 2012 – 2014. Inclusion criteria were antenatal women with singleton, term or post term pregnancies, cephalic presentation, bishops score < 5, intact fetal membranes, absence of infection. Women with malpresentation, multiple pregnancy, ruptured membranes, active genital infections, contracted pelvis, previous scarred uterus were excluded from study. The indications for induction taken in the study were post - dated pregnancies, pre-eclampsia, fetal growth restriction, oligohydramnios. On admission, a detailed history was taken and a clinical examination was performed, gestational age assessed and their bishops score was assessed by pelvic examination. After getting informed and written consent, women were divided into 2 groups based on mode of induction:

G1: With Intracervical Foleys catheter, in which No.16 foleys catheter is introduced into the endocervix under direct visualisation of cervix into the potential space between amniotic membrane and lower uterine segment and balloon inflated with 30 – 40ml of distilled water.

G2: With cerviprime gel containing 0.5mg of PGE<sub>2</sub> per 3gm in 2.5ml prefilled syringe, the gel is introduced into the endocervix just below the level of the internal os. Maximum recommended dosage is 1.5mg(3 doses) in 24hrs.

Bishops score was reassessed after 6, 12, 18hrs in both groups, need for oxytocin augmentation is noted. Fetal heart rate, maternal pulse rate, blood pressure, temperature, frequency and duration of uterine contractions were monitored, also, induction – labour interval & induction – delivery interval were noted. Determined by statistical analysis done using chi-square test and student ‘t’ test which were used in appropriate places.

## 3. RESULTS

Out of 200 patients, the mean bishops score at 6 hrs was 5.86 in primis and 6.61 multi in group 1, 6.82 in primis and 7.36 in multi in group 2, and for 12 hrs it is 8.15 in primis and 9.54 in multi in group 1, 10.00 in primis & 9.64 in multi in group 2. There is statistically significant difference in the mean bishops score at 6 & 12 hrs in both groups (p < 0.05). The mean induction – active labour interval in primis & multi in group 1 were 6.27 & 7.25 hrs, and in group 2 were 6.23 & 6.04 hrs respectively. The difference between the two groups is statistically significant (p < 0.05). The mean induction – delivery interval for primis & multi in group 1 were 12.43 & 13.88 hrs, and in group 2 were 11.43 & 11.36 hrs respectively. The difference between two groups using student ‘t’ test is statistically significant (p < 0.05). Caesarean section was performed in 16 (32%) in group 1 and 5 (10%) in group 2. There is statistically significant difference between the two groups using chi – square test (p < 0.05). Apgar score at 5 mins showed a statistically significant difference in both groups using chi – square test (p < 0.01). Out of 50, only 2 patients showed hypotension when induced with Foleys catheter.

**Table 2. cerviprime gel tretement**

		FOLEYS CATHETER		PGE2 GEL		P value
		Primi	Multi	Primi	Multi	
Mean Bishops score (hrs)	6	5.86	6.61	6.82	7.36	<0.05
	12	8.15	9.54	10.00	9.64	
	18	10.50	11.20	13.00	11.00	
Mean induction - active labour interval (hrs)		6.27	7.25	6.23	6.04	<0.05
		12.43	13.88	11.43	11.36	
Mean induction - delivery (hrs)		Number	Percent %	Number	Percent %	<0.05
	Mode of delivery	V	34	68	45	
apgar <7 at 5min		D	16	32	5	10
		C	46	92	41	82

## 4. DISCUSSION

In present study, Induction was started in both groups with similar Bishop Score. the mean bishops score at 6 hrs was 5.86 in primis and 6.61 multi in group 1, 6.82 in primis and 7.36 in multi in group 2, and for 12 hrs it is 8.15 in primis and 9.54 in multi in group 1, 10.00 in primis & 9.64 in multi in group 2. There is statistically significant difference in the mean bishops score at 6 & 12 hrs in both groups (p < 0.05). According to a study by Taani et al<sup>6</sup> 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. According to current study The mean induction – active labour interval in primi & multi in group 1 were 6.27 & 7.25 hrs, and in group 2 were 6.23 & 6.04 hrs respectively. The difference between the two groups is statistically significant (p < 0.05). According to donnez et al time from induction to active labour interval is shorter in gel group 50% in 8 hrs and 32% in 12 hrs in catheter group. In present study The mean induction – delivery interval for primi & multi in group 1 were 12.43 & 13.88 hrs, and in group 2 were 11.43 & 11.36 respectively. The difference between two groups is statistically significant (p < 0.05 ). According to Taani et al 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. In present study mode of delivery vaginal delivery was higher in group 2 when compared to group1. Caesarean section was performed in 16 (32%) in group 1 and 5 (10%) in group 2. there is statistically significant difference between the two groups using chi – square test (p < 0.05 ). According to studies by Taani et al, fetal distress was more frequent in the catheter group. In current study apgar score < 7 at 5mins was noted in 46(92%) in group 1 and 41 (82%) in group 2 ( p < 0.01), the difference is significant, according to Chauhan et al reported in their meta-analysis that induction using Foleys catheter was associated with a 5-min APGAR score <7 (pooled RR -1.8, 95% CI 1.1-2.6). In present study maternal complications like PPH and pyrexia incidence is equal between two groups, 6 patients had hypotension in group 2 and sepsis was slightly higher in group1.

## 5. CONCLUSION

In present study, Cervical ripening more effective with group 2 induction. Mean induction to active labour interval and mean induction to delivery interval were shorter with group 2. Fetal and maternal outcome were better with group 2. From this study, it is known that prostaglandin E2 gel is a better and more effective agent than Foley's catheter in cervical ripening and induction of labour

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